

Should Australia Export Corneas?

*Eye Banks, Exports and Australian
Opinion: Exploring national
utility of human corneal
tissue donation.*

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ABSTRACT

There are 12.7 million people, globally, waiting for a corneal transplant. Most reside in low-middle-income nations or locations without sufficient local access to corneal tissue (CT) from an eye bank (EB). As such they are unable to access donated end-of-life CT, necessary to perform a sight restoring or enhancing corneal transplant. They are reliant on CT importation from EBs in other nations that are in a position to export. Despite export and import services commencing in 1961, and the practice now responsible for around 23% of all annual corneal transplantations, there has never been a review of the practice. There is no information to indicate if donors are aware or consented, how the practice impacts the export nation's own access, or how it impacts the import nation's ability to build their own EB service. There is no indication if the current approach is effective and equitable in allocating the CT, or if nations, in a position to export, should routinely do so. Therefore, through the example of my own nation, Australia – a nation with a history of *ad hoc* exportation, but reported to be in a position to potentially export routinely, I examined if Australia should export CT? Importation was examined through this research however its primary focus was examination from the perspective of the exporter.

Method: I use a mixed methods approach to determine if Australia should export CT. Firstly, data was captured from all n=5 Australian Eye Banks (AUEBs) regarding their collection and non-collection of CT (Aim 1). This provided information on the potential export level and ascertained if Australia was meeting domestic demand and in a position to export. Secondly, grounded theory semi-structured interviews were conducted with n=92 purposively selected eye care and eye tissue experts (Aim 2). I interviewed until themed saturation was met. Their responses were sentiment analysed to determine their opinion on Australia's export potential and unearth foundation information about the practice. Finally, e-surveys were conducted with a sample of the Australian public (n=1044) (Aim 3). The e-survey determined their willingness to export their CT on their death. Correlation coefficients were used to examine association between categorical variables, and determine their willingness and opinion on how the practice should occur.

Results: Aim 1 indicated that there were sufficient donations collected to meet domestic demand, and that excess CT could potentially be exported. Importantly, it also highlighted that AUEBs were not meeting domestic demand all of the time and steps to improve domestic allocation were required prior to or simultaneously to examining routine exportation. Aim 2 indicated that sector professionals supported the notion of Australia routinely exporting CT (n=84/92, 67%), on the proviso that a nationally coordinated system was implemented, and donors were consented, or at the least informed, that their donation may be moved to another location, though day-to-day decisions on allocation, they believed, should be left to the professionals. They favoured exportation to Western Pacific Nations, neighbouring nations, and low-middle-income nations. Aim 2 also provided foundation information about the export and import practice. For example, there is no indication that donors are uniformly aware or consented for exportation of their donation, and current practice does not provide equitable access to CT - with the primary decision to export to another nation based on the importers ability to pay. This meant that those in low-to-middle-income nations were least likely to access CT. Finally, Aim 3 indicated that there were Australians willing to export their corneas (n=397/1044, 38%). It also indicated that there were Australians who would not (n=248/1044, 23.8%), and others who required further information before deciding (n=399/1044, 38.2%). Collectively, they indicated that donors must be consented or, at the least, informed that their donation may be moved to another location for use. They also indicated that the sector professionals should decide on the allocation location, on the proviso that a nationally coordinated system was in place that clearly explained their decision making.

Discussion: This research highlighted that there is a paucity of information available to describe the practice of exportation and importation of CT. It indicated that the practice is not conducted in a structured or planned manner by the exporters nor the importers. It proposed that Australia could potentially export CT to other nations, with low-middle-income, neighbouring, or Western Pacific nations prioritised. It also recommended that additional steps be implemented to ensure that domestic demand was routinely being met, and that CT donors were consented, or at the least, informed that their donation may be moved outside their local EB location.

Furthermore, the development of public and point-of-donation information and/or consent-to-export steps are necessary. The eye tissue and eye care sectors must work with a range of stakeholders to develop a nationally coordinated system that allocates, distributes, and monitors CT that is exported. This should be developed within a structured national program, describing how and why exporters should export and how import locations and partners are selected. Through development of a national system for exportation, domestic allocation could also be enhanced, with similar steps extended to the movement of CT intra-nationally for domestic transplantation or research use.

This is the first study to map the collection, use and potential use of CT, excess to domestic demand, and it is the first study to examine the CT export and import process. While this research provides valuable information about the export and import practice, predominantly from the perspective of the exporter, it highlights that further examination from both exporters and importer perspectives are required.

DECLARATION

This is to certify that:

- I. the Thesis comprises only my original work towards the degree of Doctor of Philosophy, except where indicated in the Preface;
- II. due acknowledgement has been made in the text to all other material used;
- III. the Thesis is less than 80,000 words in length, exclusive of tables, references, appendices and footnotes

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PREFACE

The exportation of corneal tissue (CT) from one nation to another for the treatment of sight-saving or enhancing transplantation, has previously been an unexplored area of enquiry, globally, until the commencement of this original research project. I have pioneered the development and exploration of this topic through a series of individual peer reviewed papers that address the shortfall in existing literature, through the example of one nation – Australia. By using the example nation as a potential routine exporter, the research has allowed the examination and extraction of a wide range of sub-themes resulting in a series of proposed recommendations. These findings impact and influence both exporter and importer who are interconnected by their action. Thus, exportation does not exist independently of importation, and exportation does not exist without the involvement of the export nation.

Through this research I have inspired global interest, within the eye tissue and eye care sector, to examine existing practice with the intent to improve transparency, planning, and CT access in the future. The papers presented in this thesis have examined a range of sub-themes, including defining need, demand, wait lists, surplus and waste, and how CT exportation and importation, collectively referred to as transnational activity (TNA), tissue movement, allocation, or provision, currently takes place or perhaps could or should take place. I have interviewed, consulted, and collaborated widely, with a broad range of stakeholders, to ensure this research has local, national, and global relevance. My hope is that this research will be adopted, adapted, and used by a range of local, national and global stakeholders, decision makers and policy makers to enact real, lasting and impactful change for the future management of the end-of-life gift of corneal donation and provision of sight-restoring corneal transplant surgery for those seeking treatment in Australia and elsewhere.

The opportunity to examine Australia, my home country, also offered essential insights into my nations CT domestic recovery and allocation. Australia was a suitable choice as there had recently been a report¹ indicating that Australia was meeting need and should export routinely. This research offered the opportunity to explore if this was the case and if it was indeed a viable option for Australia and Australian donors and recipients. It became apparent when designing this project that there were no prior foundation publications to describe the Australian situation nor the definitions and options in Australia or elsewhere. Therefore, in order to contextualise our export conversation, the thesis includes an overview of Australia, and definitions, and an examination of Australia's export potential, alongside the conversation specific to exportation and allocation.

Finally, to assist exporters and importers in Australia and elsewhere, the individual papers weave in vignettes and examples from other nations. While the outcomes will assist Australia when considering exportation, it may simultaneously offer opportunity for examination on the global stage.

Global Pandemic Impact

The global COVID-19 pandemic occurred during the final year of my PhD, after the research collection phase of this project had been completed and several papers published. As a qualified registered nurse, I was compelled to put-my-hand-up to assist the response efforts in my city and took on a role within a telehealth service team, assisting Melbournians who tested positive to COVID-19. I also trained in readiness to administer the covid-vaccination in 2021. Additionally, journals started to prioritise COVID-19 content, and co-authors and other affiliates were delayed in their availabilities. Grant opportunities evaporated and conferences were cancelled. This reduced the opportunity to present the outcomes of my research to my peers.

The content of my PhD was also impacted. For example, the export and import of corneas is reliant on access to freight and logistic services and health service, therefore, as flights were cancelled and curtailed, and health resources redirected to the COVID-19 response efforts, so too was the movement of CT – this in turn impacted wait lists in each location. While COVID-19 highlighted some of the key issues with exportation, they also posed a challenge for the PhD write-up. To tackle this change, I integrated, where possible, for ongoing published and non-published material, information on how the research, conducted pre-COVID-19, could be interpreted or used in a post-pandemic era, and how we could use the COVID-19 challenges constructively to redefine future CT movement practice.

PhD by Paper and Thesis Structure

This thesis has been completed largely via publication of papers. In total it contains 12 published papers and 1 submitted paper (under review), and 2 non-published sections. Each paper and section is referred to as a ‘sub-chapter’ within this thesis. Published material appeared in a range of peer reviewed journals, each with their own editorial manuscript requirements and under different peer reviewers. Therefore, each published paper takes on its own unique shape in order to be presented in a journal as a standalone paper and, as per that journal’s publication specifications. Each paper includes a series of recommendations, which I have consolidated in the final concluding chapter (Chapter 5), to announce whether Australia should or should not routinely export CT.

In order to integrate the papers into this manuscript in a logical and consistent style for the reader, I highlight the following modifications, and retained aspects.

1. The numbers of heading, tables, figures, boxes, and supplemental material have been changed to indicate the sub-chapter placement within the thesis and to retain a consistent thesis style.
2. Supplemental materials are located within Appendix 1.0, rather than within each sub-chapter.
3. Structure and acronym use in each paper, has been retained as per that journals requirements.
4. References and acknowledgements remain with the published paper, rather than as a stand-alone collated list at the end of the thesis. In turn, references for non-papers are retained with their sub-chapter for stylistic consistency. Lastly, reference style was adjusted within each sub-chapter, for thesis consistency.
5. The text in the supplemental materials (excluding tables, boxes, and figures) is added into the PhD word count as they contain key information on the methodology that was removed from the publication, to accommodate the journal publication word limit and content style requirements. They were difficult to place in the flow of the sub-chapter text, because of the decision to publish by paper, and therefore are provided in the Appendix.

Of note: The thesis has been prepared for digital viewing and downloading. Therefore page numbering are positioned on the lower right of each page. The page size is set to A4, however 2 tables in the appendix are set to A3 ‘fold-out’ size.

Firsts

This thesis contains world first and internationally leading research, including:

1. World first interview of sector professionals involved in CT export and import, that:
 - a. captured key definitions such as ‘need’, ‘demand’, ‘surplus’, and ‘wait lists’;
 - b. documented how export and import of corneas occurs; and
 - c. captured sector sentiment and belief on current practice and potential areas of change;
2. A comprehensive and critical review of the Australian public’s opinion of CT exportation and their willingness to engage; and
3. A critical evaluation of Australia’s actual allocation, surplus potential, and responsibilities toward research allocation.

Publications

All published (and in-press papers) have been peer reviewed and placed into corresponding themed chapters within the thesis. These being chapters 1-4. Permissions for inclusion have been obtained from all co-authors ready to submit to the University of Melbourne. The published papers are set out as follows:

Chapter 1

1. Machin H, Arslan J, Baird PN. Examining the impact of corneal tissue transnational activity, and transplantation, on import and export nations: a review of the literature. *Cornea*. 2020;39:795-800.
2. Machin HM. Documenting the evolution of contemporary eye bank and corneal tissue services in Australia. *Int J Eye Bank*. 2019;2:7.

3. Machin H, Philipppy B, Ross C, Sutton G, Baird PN. Part One: Understanding the impact of COVID-19 on corneal transplant need and demand through the example of Australia. *Int J Eye Bank*. 2020;8:2.
4. Machin, Philipppy B, Ross, C, Sutton G, Baird PN. Part 2: Defining surplus and waste in the pre- and post-COVID-19 era via Australian and USA examples. *Int J Eye Bank*. 2020;8:3.
5. Machin H, Brown K, Sutton G, Baird P. Ocular tissue for research in Australia: Strategies for potential research utility of surplus and transplant-ineligible deceased donations. *TVST*. 2020;9(4).

Chapter 2

6. Machin H, Buckland L, Georges P, Ghabcha M, Golding-Holbrook T, Leighton C, Mackey A, Weinel L, Whiting V, Sutton G, Baird PN. Supply and demand of domestic corneal tissue and its implications on export potential - using Australia as an example. *Cornea*. 2020.Dec. Online ahead of print.

Chapter 3

7. Machin H, Sutton G, Baird PN. Should nations with surplus donated corneal tissue, export to those without? A review of sector opinion via the example of one nation – Australia. *Cornea*. 2020;39(10):1334-1340.
8. Machin H, Sutton G, Baird PN. Sector opinion, on how corneal tissue should be exported, and to whom – using the example of Australia as an export nation. *Int J Eye Bank*. 2021;9:2.
9. Machin H, Sutton G, Baird PN. Should donors' consent to export their corneas? Examination of eye tissue and eye care sector opinion. *Cornea*. 2021;40(3):398-403.
10. Machin H, Sutton G, Baird PN. Do eye bank models and competitive practice impact international cornea allocation? *Cornea*. 2021;1(40):936-941.
11. Machin H, Sutton G, Baird PN. Examining the corneal tissue exportation fee and its impact on equitable allocation. *Cornea*. In-print.

Chapter 4

12. Machin H, Buckland L, Critchley C, Sutton G, Wiffen S, Baird PN. Determining the Willingness of Australians to export their corneas on death. *PlosOne*. 2021;<https://doi.org/10.1371/journal.pone.0246622>
13. Machin H, Buckland L, Critchley C, Sutton G, Wiffen S, Baird PN. Australian Public opinion on national and international allocation of donated corneal tissue. *PlosOne*. Under-review.

Formal conference abstract

- I. Machin H, Buckland L, Critchley C, Wiffen S, Sutton G, Baird PN. Alleviating global blindness through strengthening equitable access to end-of-life eye donations: A population survey of Australia's willingness to share donations across national-borders. Consortium of Universities for Global Health, Washington, DC. April 2020. Cancelled due to global COVID-19 Pandemic and rescheduled as a virtual event in March 2021.

External Out-Put

During the period of my PhD (February 2018 – February 2021) I continued to contribute to the wider eye bank and ophthalmology communities through various mediums. This included opportunities directly affiliated with my PhD and those not affiliated. These were:

Affiliated:

Professional appointments:

1. WHO: Global Action Framework on Tissue Transplantation - Working Group Member.
2. Lions Clubs International: Eye Bank Working Group Member.

3. International Agency for the Prevention of Blindness: Global Nurse and Eye Bank Member Representative.
4. Lions Eye Donation Service at the Centre for Eye Research Australia: Project Officer.
5. Lions Eye Donation Service at the Centre for Eye Research Australia: Biobank 13-1151H: Principal Investigator.
6. Australian Commonwealth Government's Organ and Tissue Authorities: Eye and Tissue Advisory Committee – Member.
7. Global Alliance of Eye Bank Associations: Developer.
8. Eye Bank Association of Australia and New Zealand: Project Officer.

Key guiding frameworks/seminal work:

1. WHO. Global Action Framework on Tissue Transplantation. Working Group Draft Co-Contributor - Under development.
2. The Global Alliance of Eye Bank Associations. The Barcelona Principles: An Agreement on the Use of Human Donated Tissue for Ocular Transplantation, Research, and Future Technologies. *Cornea*. 2018;37:1213-1217. On behalf of the Global Alliance of Eye Bank Associations and other Stakeholders. Lead Developer and launch manager (event and communications) in Barcelona in 2018.

Conferences/Roadmaps:

1. Lions Clubs International Virtual Meeting 2020. Invited Presenter: Global eye banking and PhD project up-date.
2. Eye Bank Association of Australia and New Zealand. Annual Conference. Invited Presenter: Sector opinion on exporting corneas. 2020. Auckland.
3. Canadian Blood Services/Canadian Ophthalmology Society. National workshop to develop a roadmap for Canadian eye banking. Invited Presenter and the only non-Canadian workshop member. Toronto. 2020.
4. Eye Bank Association of India. National workshop to develop roadmap for India eye banking – and conference Chair. Invited Guest and Chair. Bangalore 2019, and Pune 2018.
5. King Khalid Eye Specialist Hospital, Invited Presenter: Grand Rounds – PhD project up-Date. Riyadh. 2020.
6. Australian Ophthalmic Nurses Association VIC. Invited Presenter - PhD project up-date. Melbourne. 2019.
7. Eye Bank Association of Australia and New Zealand. Annual Conference. Invited Presenter: PhD project up-date. 2019. Adelaide.
8. Global Alliance of Eye Bank Association. World Eye Bank Symposium. Event Convenor. Barcelona. 2018.
9. International Council of Ophthalmology. World Ophthalmology Congress, Global Eye Bank Session. Session Convenor. Barcelona. 2018.

Other publications:

1. Machin H, Ross C. Accessing human corneal tissue. A new chapter in the second edition. In Vajpayee R, Sharma N, Tabin G and Taylor H, Corneal Transplantation. Under review.
2. Hodge C, Pollock GA, Sutton G, Machin H. Human material for research: Eye banking, biobanking and ethical access. In Prakash G, Iwata T. *Advances in Vision Research*, Volume III. Springer. 2021.
3. Machin H (on behalf of the Global Alliance of Eye Bank Associations). Contested organ-obtainment methods in published transplant-research: A timely reminder to those in the affiliated ocular field. *BMJOpen*. May 7th, 2019.

Non-affiliated:

Professional appointments:

1. Australian Ophthalmic Nurses Associations National Council (AONANC). Representative (and Victorian President 2018/Victoria Treasurer 2019-2020).

2. Coalition of National Nursing and Midwifery Organisations. AONANC Representative at National Meeting. 2019.
3. Fred Hollows Foundation NZ. Consultancy support as required.
4. cohealth. (COVID-19) Positive Pathway Project Care Connector Team Leader (August-October 2020).

Key guiding frameworks/seminal work:

1. Australian Ophthalmic Nurses Association National Council. *Practice Standards for Ophthalmic Nurses in Australia*. Oct 2018. Role: Co-Lead-Developer.

Conferences:

1. American Academy of Ophthalmology Annual Congress. Invited Presenter: Human Resources in Health in ophthalmic nursing. Chicago. 2018.
2. International Council of Ophthalmology. World Ophthalmology Congress. Invited Presenter: Human Resources in Health in ophthalmic nursing. Barcelona. 2018.
3. International Agency for the Prevention of Blindness. Members Meeting. Invited Presenter: Workforce engagement of nurses. Hyderabad. 2018.
4. Soroptimist International Conference. Invited Presenter - Younger Inspiring and Innovative Women Session. Melbourne. 2018.
5. Australian Ophthalmic Nurses Association-VIC, annual conferences. Convenor. Melbourne 2019.
6. Australian Ophthalmic Nurses Association-VIC held in conjunction with the Royal Australian and New Zealand College of Ophthalmology, Annual Conference. Convenor. Adelaide 2018. *Other publications:*

1. Machin H, Antwi-Boasiako S. Ophthalmic nurses: vital team members in the push for better eye health. *Community Eye Health Journal*. London School of Hygiene and Tropical Medicine. 2021.33(10);42-44.
2. Machin H, Vazquez Barrero A, Cosme E, Lansingh V, Marsden J, Raynel S, Vola L. Keeping trained ophthalmic nurses in eye care improves services: Lifting the lid on the importance of effective sub-specialty nurse rostering. *Insight*. 2019. 44(3)15-20.
3. Machin H. 2020 but what now? A global ophthalmic nursing call to action. *ASORN'S Insight*. 2020.42(2);4 & 26.

Media:

1. Vision Australia: PodCast Topic: *Eye banking and experience as a CERA PhD Student*. 2020.
2. CERA: Social Media. Blog: *From saving sight to fighting COVID-19*. 2020.
3. CERA: PodCast. Topic: *The Barcelona Principles*. Co-presented with Graeme Pollock. 2018.

Invited peer reviewer for papers submitted to affiliated journals:

1. *Progress in Transplantation*. 2020.
2. *Cornea*. 2019; 2021.
3. *WHO Bulletin*. 2018.

Grants/Scholarships:

1. Australian Ophthalmic Nurses Association Grant: First workforce survey of Australian nurse engagement in eye care. Awarded in 2020. Commenced January 2021.
2. Royal Collage of Nursing Scholarship: The Leader's Mindset Masterclasses Series. 2020.
3. Australian Commonwealth Government and Royal Collage of Nursing Scholarship: Government Funded Refresher Program - 803G (to be COVID Ready). 2020.

Professional practice:

1. Registered Nursing License. APHRA. Renewed annually.
2. Code of Good Manufacturing Practice Certificate. Seer Pharma. 2019.

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I wish to acknowledge and thank the Australian National Health and Medical Research Council (NHMRC) for awarding me a Postgraduate Scholarship (IDAPP1150637), and Lions Eye Institute, Perth Western Australia, for a research grant to conduct the Aim 3 (Chapter 4) public survey.

ETHICS

The project in full was approved by the *Royal Victorian Eye and Ear Hospital (RVEEH) Human Research Ethics Committee (HREC)* and identified in their system as *18-1374H*. As Aim 1 (Chapter 2) required multi-site engagement to conduct the data collection, it received additional national HREC approval, via the: *South Eastern Sydney Health District (SESHD)*, in their capacity as a Certified NMA approver, and is identified in their system as *18/139(HREC/18/POWH/292)*. After NMA approval, individual *Site-Specific Assessment* (governance) approvals and data transfers were obtained from the Australian Eye Banks, being: New South Wales Eye and Tissue Bank, Sydney; South Australian Eye Bank, Adelaide; Lions Eye Bank of Western Australia, Perth; and Queensland Tissue and Eye Bank. Note: The Melbourne eye bank – Lions Eye Donation Service is part of the Centre for Eye Research Australia (CERA) and affiliated with the RVEEH and was automatically covered under the original *18-1374H RVEEH HREC* internal approval. *For copies of approvals, please see Appendix 03*. I obtained all human ethics for the work presented in this thesis.

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Individuals: This body of work is testament to the support I received from friends, family, and colleagues across Australia and beyond. I acknowledge the contribution of Kelly Mikunda, Rachel Lee and Helen Zhang for administrative support, Carly Parfett for assisting with the lengthy and multiple ethics approvals; the RVEEH's HREC; the staff and executives at CERA; the Lions Eye Donation Service Team; Myra McGuinness and Nicole Tindell for their software and statistical guidance; and Mark McDonald for national DonateLife statistics support.

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I make special mention of: CERA past PhD graduates Sandra Staffieri for her eternal guidance and Gillian Cochrane for her research design support; CERA current PhD and Masters students who shared the experience with me; the national and global sector members who allowed me to survey and interview them and entrust me with their stories and opinions; the 1044 members of the public who participated in my public survey; my PhD panel advisors Marisa Herson, Graeme Pollock and Ian Trounce for their advice in bringing the body of work to fruition – and spurring me on; my co-supervisors Professor Gerard Sutton and Professor Anne-Maree Farrell for their expertise, support and enthusiasm which kept me on track and give me new ideas; and my principal supervisor Professor Paul N Baird for his constant check-ins, endless editing, persistence, and for pushing me to reach new heights. I could not have done this without Paul.

I send my appreciation and thanks to the late Professor Christine Critchley. Christine passed away in late 2020. She was instrumental in the design and analysis of Chapter 4, and I believe she would be proud to see our papers published. I also wish to acknowledge my mentor and friend, the late Professor Janet Marsden, who encouraged me to “just get on with it and get it done.” Unfortunately, Janet passed away in 2018, but I am confident that she would be pleased with my professional progress and the outcome.

Finally, I thank my family, in particular Mum Adele, Dad Ken and Stepdad Steve, and my friends around the world for supporting me and allowing me to spread my wings, fly high and soar above the clouds. And last but not least, I thank my feathered friends who entertained me endlessly as I tapped away at my keyboard.

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ABBREVIATIONS

ABS	Australian Bureau of Statistics	NoK	Next-of-Kin
ACGR	Australian Corneal Graft Registry	NZ	New Zealand
ANZ	Australia and New Zealand	LEDS	Lions Eye Donation Service (Melbourne)
ANZCS	Australia and New Zealand Corneal Society	OECD	Organisation for Economic Co-operation and Development
AU	Australia	OTA	Organ and Tissue Authority (Australian Commonwealth Government)
AUEB	Australian Eye Bank/s	OTR	Ocular Tissue for Research
CERA	Centre for Eye Research Australia	PICF	Participant Informed Consent Form
CSEP	Comprehensive Strategic and Economic Partnership	PK	Penetrating Keratoplasty
CT	Corneal Tissue	PTT	Preservation-to-Transplant-Time
DFAT	Department of Foreign Affairs and Trade	PWC	Price Waterhouse Cooper
DSAEK	Descemet's Scraping Automated Endothelial Keratoplasty	PWCR	Price Waterhouse Cooper Report: Analysis of the Australian Tissue Sector, 2016
DPT	Death-to-Preservation-Time	R&D	Research and Development
EB	Eye Bank s/ers	RANZCO	Royal Australian and New Zealand College of Ophthalmologists
ECD	Endothelial Cell Density	RVEEH	Royal Victorian Eye and Ear Hospital
EBAA	Eye Bank Association of America	SDG	Sustainable Development Goals
EBAANZ	Eye Bank Association of Australia and New Zealand	SWAp	Sector Wide Approach
GAEBA	Global Alliance of Eye Bank Associations	TGA	Therapeutic Goods Administration
NHD	Have not decided	TNA	Transnational Activity
HREC	Human Research Ethics Committee	WHA	World Health Assembly
IAPB	International Agency for the Prevention of Blindness	WBCLG	World Bank Country and Lending Group
MD	Medical Director	WHO	World Health Organization
MD	Medical Doctor		
NGO	Non-Government Organisation/civil societies/non-state actors		

i. PHD OVERVIEW

A corneal transplant is performed to assist corneal blindness conditions that result in corneal opacification. These conditions account for 4% of the world's 45 million blind.² The procedure is the most commonly performed ocular transplant type, and the most frequently performed human transplant type worldwide with an estimated 184,576 transplants performed per year globally.³ It is reliant on access to end-of-life human donated corneas (corneal tissue – CT) that are recovered, processed, and distributed by an eye bank (EB). Preferably the EB allocates the donation to local recipients first.

The have-nots

There are an estimated 12.7 million recipients globally³ awaiting a corneal transplant who are unable to undergo a transplant because they do not have routine access to CT. This is because an estimated 53% of the world resides in a location without their own EB³— most of whom are in low-middle income nations where need is the greatest.^{3,4} To assist, CT can be imported legally, from another nation able to export. This practice is referred to as Transnational Activity (TNA), comprising movement, allocation, or export and import. The practice, that dates back to 1961,⁵ is predominantly provided by routine exporting nations including the USA, Sri Lanka and Italy,³ however, other nations like Australia also participate albeit minimally in an ad-hoc manner.⁶ Today, this practice is responsible for 23% of all global transplants.³ Despite its prominence, there remains a huge number of recipients globally awaiting a transplant and in urgent need of access to CT.

The haves – Australia as a country case study / example

Simultaneous to global need, there are nations - like Australia, where their EBs are at a unique juncture, with the public willing to donate CT for sight-restoring corneal transplantation domestically suggested as surpassing the scheduled known surgical domestic demand.¹ As CT expires after 7-30 days (depending on the storage technology), and due to the bio-psychosocial connotation surrounding tissue donation,⁷ the Australian Eye Banks (AUEBs) and the donor sector seek solutions to manage what has been termed 'surplus CT' management⁸ with exportation as its leading management option. An assumption therefore would be for Australian 'surplus' CT to be routinely recovered and allocated to those nations seeking assistance to support citizens in their nation. It would seem to be an appropriate match – but is it, and how would Australia determine which country to allocate to when global need was so great? Additionally, how would Australia confirm that they were indeed meeting domestic need and that routine rather than *ad hoc* exportation would not undermine domestic services. How would exportation be arranged and how would Australians feel about their donation being exported? How could Australia explain their decisions to allocate to one location over another? The ability to export routinely therefore requires evaluation if Australia is to become a routine export nation. This kind of information would not only be invaluable for Australia but for any other country reaching such a juncture in their CT collection recovery and allocation system.

Matching the haves with the have-nots: the thesis

Given the knowledge about the significant global need for CT (the have-nots), and suggestion of emerging routine export nations - like Australia (the haves) to export, then the aim of this thesis, is to examine, through the example of Australia, if nations should export, and if so, how and to whom? I show that despite the existence of the practice dating back to 1961⁵ and accounting for 23% of current global provision,³ that there has been no prior review of this subject.⁹ This thesis therefore provides the first research in this field, placing it as the pre-eminent opinion piece on CT TNA – though predominantly exportation. The thesis commences with setting the scene in Australia. It considers alternative uses for CT (e.g. for domestic research), and calculates Australia's current position in terms of meeting domestic need and demand and export potential, to determine if it is indeed in a position to consider routine exportation. The thesis then presents research outcomes specific to TNA and concludes by determining if Australia should export. As part of this examination, consideration is given to key conceptual key themes such as 'need', 'demand' and 'wait lists' in order to define and discuss 'surplus' and contextualise the discussion on Australia's export engagement.

I have uncovered information on how the practice of exportation occurs, through identifying the views of Australian and global sector experts via semi-structured interviews. I then examined public willingness to export through an e-survey. The thesis research unearthed key themes that were previously uncaptured, offering powerful insight into how the current practice occurs globally and within Australia, and how it could be further reviewed and improved. It offers necessary detail to guide nations like Australia when considering their position as a potential routine exporter and proposes a way forward in terms of developing a national export program. In making this proposal, the aim is to inform, and guide sector decision making in the eye tissue and eye care sectors, with the objective of preventing the undermining of other aspects of domestic and international eye and human biological sectors, and retaining respectful and transparent engagement with Australian eye tissue donors.

Throughout the thesis, EB practice, and CT TNA – though predominantly exportation, will be described and discussed. It will present explanations previously un-described in the literature and intertwine these explanations with the concept of exportation and more precisely, Australia's export potential. It uses a mixed methods approach to investigate quantities of potential surplus volume, alternative use, and how and where Australia could export based on my findings from both eye tissue and eye care sector stakeholder interviews as well as a public willingness e-survey to determine public willingness to export CT on death.

a. Key research question

If, in the event that corneal donations are not needed in Australia at the time of a donation, should Australia export the donation? (abbreviated as: Should Australia export corneas?)

b. Hypotheses

AUEB could export surplus CT without hindrance to current Australian services:

1. AUEBs currently unknowingly turn away donations that could be recovered and exported;
2. Australians would be accepting of exporting their donation to recipients of other countries if domestic need had been met; and
3. AUEBs could export CT within the boundaries of bioethics, legal and financial obligations, without reducing access for Australian recipients.

c. Aims

Ascertain if Australia is in a position to routinely export surplus CT, and if so, could it ensure that domestic EB services and waiting recipients are not disadvantaged? The thesis also seeks to understand how this may impact how and where Australia may wish to export to. Specific sub-aims are:

1. Quantify the potential surplus levels within Australia;
2. Undertake a qualitative study of the views of stakeholders in the eye tissue and eye care sectors, on the issues surrounding surplus management and export potential; and
3. Use population survey methods, to ascertain the willingness of Australians to export donated CT when domestic use has been met.

d. Methodological approaches

As no single method can completely provide an answer¹⁰⁻¹² to Australia's export potential, then a blended-discipline, triangulation (mixed methods) research approach was applied. Triangulation was first proposed by Campbell and Fiske in 1959¹³ as a method that could be applied to multiple disciplines but has gained most acceptance in the health and social science disciplines.^{11,14} This approach is necessary when a complex research question is presented,^{11,15} there is little existing information available upon which to draw from, and one research method on its own is inadequate. It prevents the weakness of research bias that may appear when only one method is used, strengthening data outcome validity through multiple approaches.^{14,15} As proposed by Östlund et al.¹⁶ it also 'facilitate[s] the integration of qualitative and quantitative findings, help[s] researchers to clarify their theoretical propositions and the basis of their results ... [and] challenge[s] theoretical assumptions and develop[s] new theory'.

There is no set process for triangulation modelling, perhaps in part because the approach must be designed based on the complexity and need of the research questions. Therefore, for this research, three independent research pieces were performed to address Aims 1-3. (Figure i) They were accompanied by information about Australia, as the chosen country case study, definitions about ‘need, demand, wait lists, surplus and waste’, and a literature review regarding CT TNA. Aim 1 specifically explored Australia’s quantitative potential, while Aims 2 and 3 examined the overall premise of Australia’s export potential from the perspective of the eye tissue and eye care sector experts and the Australian public, via a qualitative method (being: grounded theory interviews of sector experts and an e-survey of a sample population group).

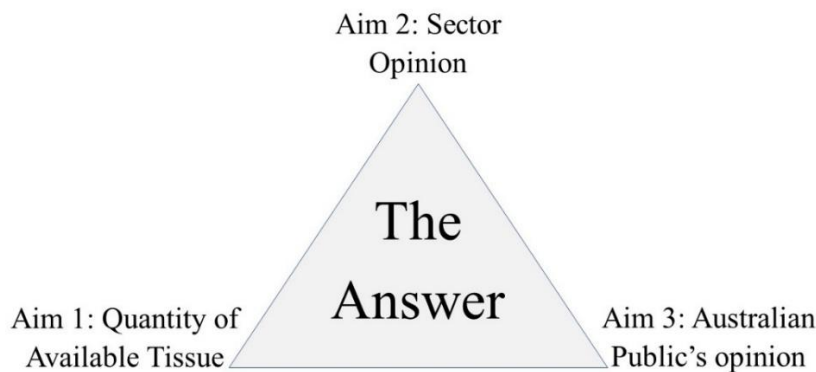


Figure i: Mixed methods approach

As the examination of CT TNA is in essence the examination of a practice or a system, then a ‘system thinking’ approach has been applied. What this means is that while each published research piece was independent, they intertwine as part of a wider analysis of exportation. While independence may appear to be a weakness due to potential incompatibility,¹⁴ because each piece informed the next, then in the current context, independence should not be viewed as a weakness in the circumstance. This reflected that each research piece supported the development and commencement of the following piece, by offering rich data to contextualise, devise and construct the next part of the investigation. (Figure ii) It also highlighted that the subject matter was multi-perspective, context-dependent but at the same time also inter-dependent.¹⁷ The approach also ensured different aspects of never-before-documented multi-dimensional empirical information and realities were captured and analysed.^{10,14} This naturalistic inquiry approach was essential when little was known about the particular practice or when seeking to understand the experience and possibilities – that could also be influenced from independent variables (e.g. economic status, existence of EBs in an import nation or degree of need), and be important to the conversation.¹⁸ It provided an understanding of the impact of the practice on those involved (being the AUEB, eye tissue and eye care sector and the Australian public).^{10,17} Collectively, they converged to answer the question ‘Should Australia export corneas?’ (Figure ii)

A mixed methods approach also ensured the research question was examined from a variety of perspectives and practice points, which ultimately strengthened the outcome and depth of the discoveries, discussion, and recommendations. This also reduced the likelihood of investigator bias (reflexology) by ensuring the premise was examined in multiple ways. This enhanced the credibility of the research. To further enhance the quality, researcher credibility, and prevent investigator bias, the required University of Melbourne research integrity course work, for a PhD thesis, was completed (RIOT – Certificate, available in ADM02, page 257).

As all three research pieces are independent and this thesis is by publication, the individual research methods are described within each thesis Chapter: being Chapters 2, 3 and 4.

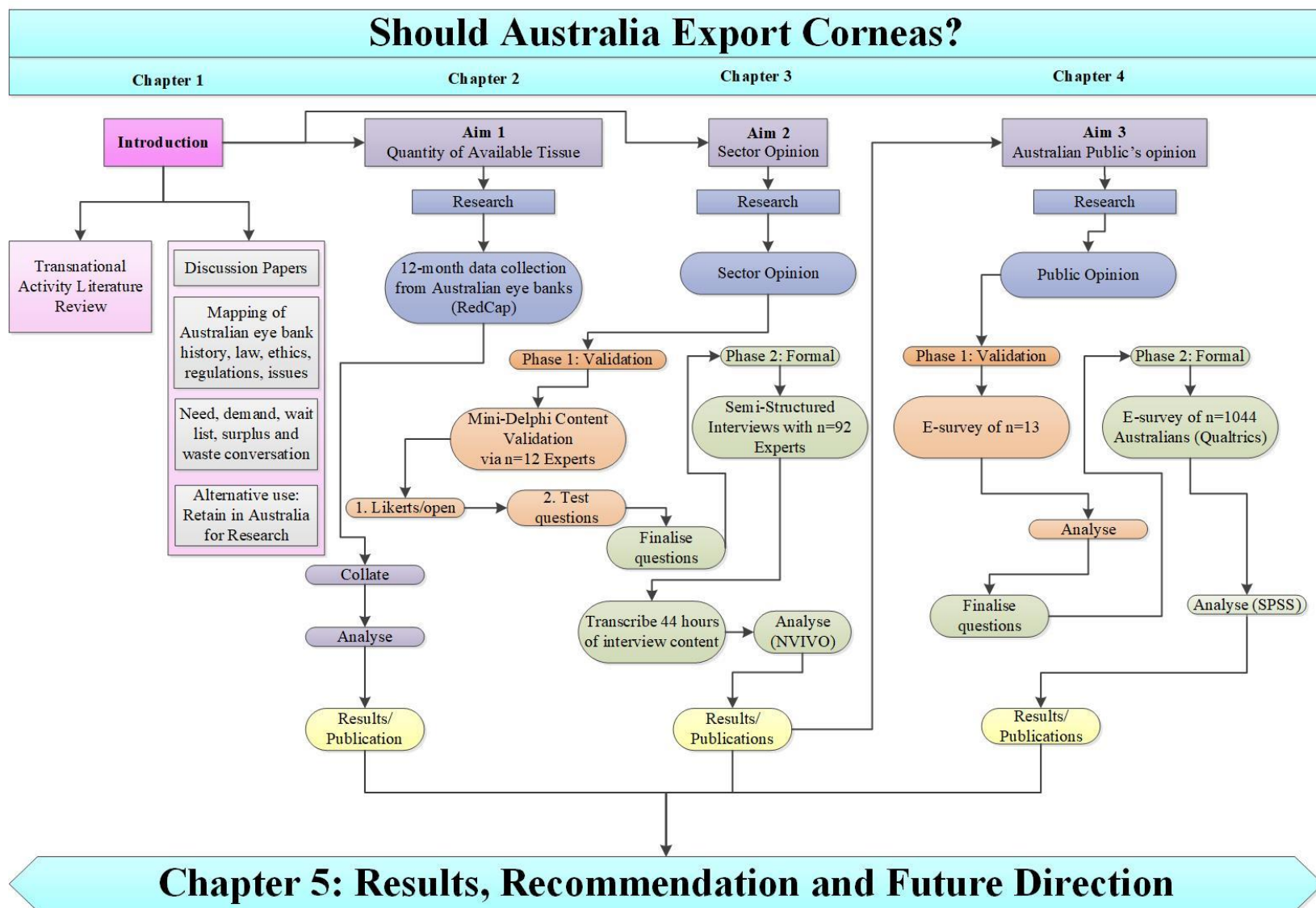


Figure ii: PhD Project Pathway. The pathway outlines the research process, and its placement within each chapter of the thesis.

ii. CHAPTER, SUB-CHAPTER OVERVIEW

After presenting information about TNA, obtained through a literature review (Chapter 1), the thesis explores the Australian system and presents definitions and options previously undescribed in the literature. It then presents an overview of Australia's surplus corneal export quantity potential (Chapter 2-Aim 1) before presenting the sector interviews (Chapter 3-Aim 2) and public survey results (Chapter 4-Aim 3). Collectively, the thesis answers the question, 'Should Australia export corneas?' And presents recommendations and opportunities for future direction (Chapter 5).

Chapter 1: Introduction: Setting the scene in Australia.

Chapter 1 provides the first global literature review of CT exportation and importation. It indicates that despite the practice occurring since 1961 – globally, to-date there has been insufficient review of the practice. It highlights, that non-clinical aspects, e.g. consent-for-export, and transparency on where CT is exported to and under what arrangements, has been significantly under reported in the literature. It indicates there has been no nationwide examination in Australia or anywhere regarding the practice and no attempts to define how tissue is moved or how alternative avenues for domestic use could be applied.

To address gaps in the literature and assist with contextualising the research presented in Chapters 2-4, Chapter 1 introduces and maps the AUEB sector, from inception in the 1940's until present day where TNA in the Australian context is presented. It then explores and defines the concepts of 'need', 'demand', 'wait lists', 'surplus', and 'waste', and explores other allocation options, e.g. retention of donations in Australia for domestic research either in a simultaneous manner or as an alternative to exportation.

Sections:

- 1.1 Introduction.
- 1.2 * Examining the impact of corneal tissue transnational activity, and transplantation, on import and export nations: a review of the literature.
- 1.3 * Documenting the evolution of contemporary eye banks and corneal tissue services in Australia.
- 1.4 * Understanding the impact of COVID-19 on corneal transplant need and demand through the example of Australia.
- 1.5 * Defining surplus and waste in the pre- and post-COVID-19 era via Australian and USA examples.
- 1.6 * Ocular Tissue for Research in Australia: Strategies for potential research utility of surplus and transplant-ineligible deceased donations.
- 1.7 Chapter conclusion.

Chapter 2 (Aim 1): Quantify the potential surplus levels within Australia.

In collaboration with all five consenting AUEBs, Chapter 2 presents data collected between October 2018 and September 2019. It examines the quantity of potential eligible CT, surplus to current domestic demand, that could alternatively be recovered for export, per year. In addition, this approach identified the variances in the AUEB data capturing and referral systems. Understanding such differences may assist in opening-up new conversations between the AUEB and their partners, by evaluating and improving referral pathways at the state/territory jurisdictional level. While prior reports have indicated that Australia always meets domestic demand, this chapter shows that this is not always the case. However, there are sufficient donors to not only meet domestic demand but also increase its use. This could also be extended in the ability to recover further donations for allocation toward research. Chapter 2 indicates that there are potential donations for exportation in Australia, and therefore the exportation practice warrants examination.

Sections:

- 2.1 Introduction.
- 2.2 *Supply and demand of domestic corneal tissue and its implications on export potential - using Australia as an example.
- 2.3 Chapter conclusion.

Chapter 3 (Aim 2): Expert opinion on export and import engagement.

Chapter 3 presents key findings from global eye tissue and eye care sector experts (n=92), drawn from semi-structured interviews in line with a grounded theory approach. The approach ascertained the sector's opinion regarding the overall export concept and specifically if Australia should export, and under what arrangements. Through saturation and sentiment analysis methods, it captured for the first time, global opinion on CT TNA - though primarily exportation. It demonstrated that interviewees supported the concept of Australia exporting CT, however they wished to see several safeguards in place to protect both import and export nations. Principally, they recommended the practice be transparent with donors, nationally coordinated, non-profit, part of a wider humanitarian program, short-term for the importing nation as they moved towards self-sufficiency, and that Australia must define and confirm domestic need, as well as ensure demand is met before routine exportation. Their interviews offered over 44 hours of commentary, and led to further papers and non-published data that explored how and where to export to, if consent-for-export was appropriate and their opinion on key aspects of the EB business modelling, e.g. organisational structure, governance, funding and if, in essence, CT TNA is good, bad or somewhere in between.

Sections:

- 3.1 Introduction.
- 3.2 * Should nations with surplus donated corneal tissue, export to those without? A review of sector opinion via the example of one nation – Australia.
- 3.3 *Sector opinion, on how corneal tissue should be exported, and to whom – using the example of Australia as an export nation.
- 3.4 *Should donors' consent to export their corneas? Examination of eye tissue and eye care sector opinion.
- 3.5 *Do eye bank models and competitive practice impact international cornea allocation?
- 3.6 *Examining corneal tissue exportation fee and its impact on equitable allocation.
- 3.7 Is corneal tissue transnational activity good, bad or somewhere in between?
- 3.8 Other aspects for consideration
- 3.9 Chapter conclusion.

Chapter 4 (Aim 3): Willingness of Australians to export their corneas on death.

Chapter 4 presents the findings from an e-survey regarding the public's willingness to export their corneas on their death. The e-survey included Australians (n=1044) who were asked, if they would be willing to export their corneas, how they would prefer the process to occur, how the allocation should be decided, and how they expected the donation and extended eye tissue and eye care sectors to manage the process on their behalf? The research indicated that there were Australians who would be willing to see export take place. Conversely there were others who would not and, therefore, Australia would need to review its pre-donation information and consent process, to ensure declining donor wishes could be honoured, prior to implementation of a routine export program. Finally, a good number of participants were undecided. This led me to make a series of recommendations for Australia to introduce clear information on the process and consent options, to assist this undecided group to decide, one way or another, if they would like to participate in the exportation of their donation, on their death.

Sections:

- 4.1 Introduction.
- 4.2 * Determining the willingness of Australians to export their corneas on death.
- 4.3 * Australian Public opinion on national and international allocation of donated corneal tissue.
- 4.4 Chapter conclusion.

Chapter 5: Conclusion: Should Australia Export?

Chapter 5 draws on findings from Chapters 1-4 to answer the key research question of the thesis, 'Should Australia export corneas?' Based on such findings, the answer to this question is that Australia could export corneas. The eye tissue and eye care sectors and the public support the notion, so long as there is sufficient quantity to ensure domestic recovery and demand is met, and there can be simultaneous allocation to domestic research while undertaking export. However, it does highlight that simply because Australia can export does not automatically mean it necessarily should undertake this role. It is therefore recommended that a national export program be developed, to determine the guidelines of how such a system could be developed and to where Australian corneas are exported. This would ensure that export practices are transparent and monitored, and that the eye tissue and eye care sectors, the public, donor families and recipients are all kept informed.

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CHAPTER 1.0

Introduction: Setting the scene in Australia.

1.1 INTRODUCTION

In order to contextualise the research in this thesis, Chapter 1 provides important information about exportation and importation, the AUEB system, and defines key terms such as: ‘need’, ‘demand’, ‘allocation’, ‘surplus’ and ‘wait lists’. In providing this overview, I am able to situate CT TNA in Australia.

Sub-chapter 1.2 provides a comprehensive literature review covering both Australian and global CT TNA. This was undertaken via a desk-based review of published material via key search engines, pre-determined selection criteria, and a search date period of 1991-2018. The review highlights the paucity of information to describe the practice of exportation and importation of corneas, and limited information to guide best practice and adoption by Australia. It highlights that the research conducted in this thesis is original.

Sub-chapter 1.3 maps AUEBs from inception in the 1940’s until present day. It describes how the sector has evolved, how it is governed and regulated, and current TNA arrangements already undertaken. Sub-chapters 1.4 and 1.5 collectively define and debate ‘need’, ‘demand’, ‘allocation’, ‘surplus’ and ‘wait lists’. The definitions contextualise the use of the terms throughout the thesis. Additionally, they explore these terms in the era of COVID-19, with 1.5 providing a review of the terms ‘surplus’ and ‘waste’ in contrast to another nation that routinely exports (the USA) to contextualise differences in recovery and allocation practice. Finally, sub-chapter 1.6 presents an alternative or simultaneous utility option for Australian corneal donations not required for domestic transplantation. In particular it examines the allocation to domestic research, by describing and mapping research allocation.

Collectively, Chapter 1 sets the scene for the thesis, highlighting the gaps in existing knowledge and research. This outlines the originality and necessity for the research presented in this thesis.

All sub-chapter in this chapter have been published by peer reviewed journals.

1.2 Examining the impact of corneal tissue transnational activity, and transplantation, on import and export nations: A review of the literature.

ABSTRACT

Background: Globally, an estimated 12.7 million people await a corneal transplant. Of these, 53% are without routine access to a domestic supply and are reliant on transnational activity (importation) of corneal tissue for transplantation. While corneal tissue transnational activity commenced in 1961, there has been no evaluation of its impact on import and export nations. **Method:** We wished to examine the impact of clinical and non-clinical corneal tissue transnational activity on export and import nations, with non-clinical aspects our primary focus, to help guide future practice. We conducted a review of the academic literature, via various search engines. We prefix and place our review in the relevant historical, practice and global context. **Results:** Despite commencement in 1961, we only located 14 papers (11 clinical and 3 non-clinical) pertaining to corneal tissue transnational activity. These were published between 1991-2018. Clinical papers reported death-to-preservation-time, preservation-to-transplantation-time, logistics, donor and recipient selection, and quality as relevant. Non-clinical papers identified emerging themes pertaining to financial, ethical, and sustainability aspects of transnational activity. **Conclusion:** All aspects of corneal tissue transnational activity are grossly under-reported, resulting in our inability to effectively analyse the overall impact to export and import nations. The few clinical papers in our review concluded that despite endothelial cell loss and other risk factors, imported corneal tissue appears comparable to domestic corneal tissue, and remains an option in the absence of domestic supply. Non-clinical aspects (e.g. ethical, equitable and economic) have also not been adequately addressed.

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Appendix material related to this paper.

- SUP 01: Chapter 1 - Inclusion and exclusion criteria
- SUP 02: Chapter 1 - Review papers capturing clinical aspects of transnational activity
- SUP 03: Chapter 1 - Review papers capturing non-clinical aspects of transnational activity
- PER 01: Chapter 1 - EBAANZ Executive

1.0 INTRODUCTION

Corneal Tissue (CT) is recovered from deceased donors, to treat waiting corneal transplant recipients living with limited or no vision. They are typically needed to treat corneal opacification or damage, accounting for 4% of the world's 45 million blind.¹ Globally, an estimated 12.7 million people await a corneal transplant.² While 47% reside in areas with domestic Eye Banks (EBs) able to supply CT, the majority (53%) reside in locations without a local EB, or without routine supply from their domestic EBs. This results in dependence on imported CT across jurisdictional and national borders. This paper focuses on the Transnational Activity (TNA) rather than the dearth of CT at the domestic level, and the multiple medical, social and political reasons preventing domestic development.

1.1 Transnational Activity Introduction

The transfer of human biological material, such as a CT, from one country to another, is referred to as Transnational Activity (TNA), cross-border/jurisdictional movement, or exportation and importation. This terminology refers to the movement of human biologicals across recognised national or geographic regions.

Human biological TNA originated in World War II,⁴ commencing with blood. During that time, small blood collection networks were established in the United Kingdom and Algeria. Military and civilian donors from the USA and parts of Europe donated blood, symbolising their contribution to the war effort, by improving morale and expressing solidarity and nationalism. Donations were transferred to collection centres for processing and later to military hospitals and the frontline, where wounded soldiers awaited a blood transfusion.

Today, TNA is widely used within global civilian healthcare sectors. Other human biologicals such as plasma, cord blood, organs, tissues, cells, breast milk, and reproductive materials routinely move across-borders within a variety of government, benevolent, and private organisation supply-chains and health systems. Some also move within illegal systems (e.g. black market) and lucrative but legally, socially and ethically contested enclosed and for-profit markets (e.g. commercialisation).⁵⁻⁸

CT is an ideal human biological for TNA if stored and handled as directed and managed within the ethical norms outlined within Principle 8 of *The Barcelona Principles: An Agreement on the use of human donated tissue for ocular transplantation, research and future technologies*.⁸ Principle 8 addresses the potential ethical, legal and clinical implications of TNA, providing recommendations for engagement. The size of CT and preservation mediums allow its movement, prior to expiration, with relative ease. Generally, the expiration period provides time for testing, allocation, distribution, air/land transfer, and border control (Customs) processing at origin and destination. As CT does not require a genetic, ethnic, gender or age match between donor and recipient, then in theory, it can be allocated relatively easily amongst varied populations. Collectively, this has resulted in CT being moved internationally.

CT TNA commenced in 1961,⁹ when the International Eye Bank in Washington DC, dispatched gifted-humanitarian CT, to waiting recipients in over 45 countries or states. CT was provided fresh (requiring relatively quick use) as well as preserved. Since that time, CT TNA has increased exponentially, with countries such as the USA, Sri Lanka and Italy, playing dominant roles in the routine exportation of CT.² Gain et al.² estimated that CT TNA provided 22.8% of global corneal transplants (42,251 of 184,576 corneal transplants) within their 12 months (August 2012 - August 2013) of data collection. While it would appear that TNA is common, there is no publicly available data, other than the Gain et al.² paper, to examine TNA trends over time.

We conducted a review to understand the impact of CT TNA on both import and export nations, and EBs and health services.

2.0 METHOD

We searched Web-of-Science, PubMed, Scopus, Embase (OVID), AustLii, PLoS, Cochrane, NCBI and Google Scholar for documents. An inclusion and exclusion process was used to narrow our search (Tables 1.2.1 and 1.2.2, Figure 1.2.1).^{10,11} The inclusion and exclusion criteria is outlined in detail in Appendix SUP01 on page 189. The review is exempt from ethics approval.

Primary criteria included: export, import, trade, market, surplus, human tissue for ocular application, HTO, human cornea*, cornea, “corneal tissue”, “eye tissue”, ocular, “eye transplant*”, transfer, distribution, surgeon*, “eye bank*”, need, surplus, sustainabl*, “third world” “lower resource”, “capacity development”, international, global, “cornea* blind*”, “transnational” “cross-border”, “tissue econom*”, supply, and demand.

Additional secondary criteria: bone*, “heart valve”, skin, tendon, teeth, milk, sperm, gametes, oocytes, sclera, amnion, “cord blood”, “blood bank*”, “tissue bank*”, “milk bank”, and “sperm bank”.

Table 1.2.1: Inclusion Criteria used for capturing transnational activity regarding corneal tissue
* identifies words ending in either/or: y, e, s, ation, ies, ity, or ness.

Search words excluded: “transplant tourism”, “medical tourism” “human traffic*”, xeno, “stem cell*”, “biobank*”, cosmetic, “tissue bank*”, bone*, “heart valve”, skin, tendons, teeth, milk, sperm, gametes, oocytes, “cord blood” “blood bank” “milk bank” “sperm bank” “artificial reproductive technology”, “cross-border reproductive care”, “saving sight”, “sight-saving”.

Table 1.2.2: Exclusion Criteria used for capturing transnational activity regarding corneal tissue. * identifies words ending in either/or: y, e, s, ation, ies, ity, or ness.

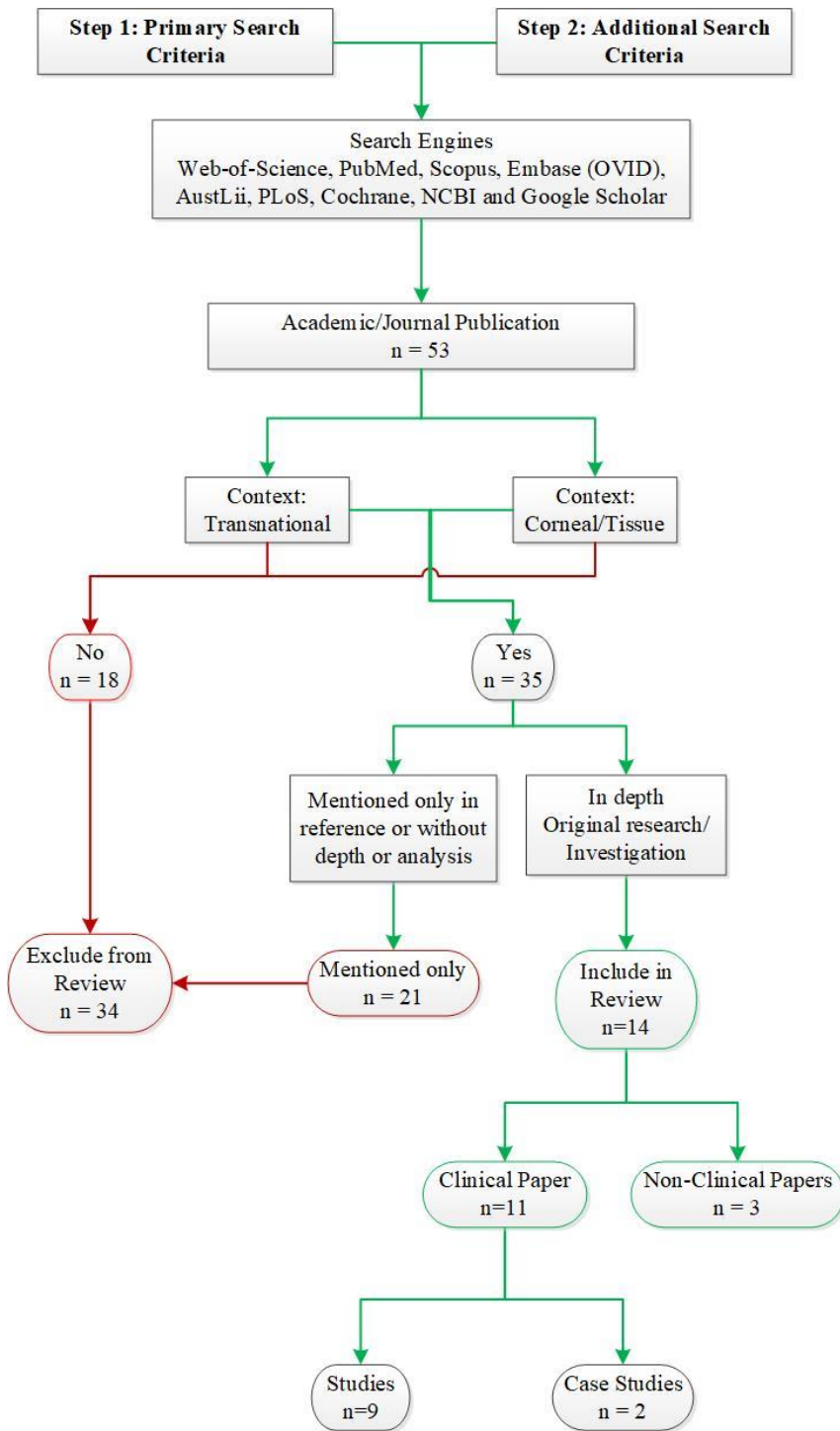


Figure 1.2.1: Review Inclusion and Exclusion Pathway

3.0 RESULTS

Our search resulted in 53 papers (Figure 1.2.1). We discarded 18 due to contextual irrelevance (e.g. they discussed milk or artificial reproductive material), and 21 that only briefly mentioned CT TNA. Therefore, a total of 14 papers dating from 1991 to 2018 remained. Of those, 11 were clinically related (9 studies and 2 case studies), and 3 were non-clinical. As the information in the clinical/non-clinical publications were not interchangeable, we analysed them independently.

3.1 Clinical Papers

All 11 clinical papers (available in Appendix SUP02 page 190) were published over a 27-year period (1991–2018), with 50% in the last 10 years (2008–2018). Two papers were case studies^{12, 13} and 9 provided small retrospective single-centre studies.¹⁴⁻²²

The 9 studies all involved exporting EBs. In terms of recipient medical records, 8 of the 9 studies examined the efficacy of CT movement and transplantation across-borders^{1,4-21} while 1 study simply examined the integrity of CT between the export and import destinations, prior to transplantation.²²

3.1.1 Export nation

A majority of the donor corneas originated in the USA via various accredited EBs of the Eye Bank Association of America. One study identified Australia, alongside USA, as a nation involved,¹⁸ however, there were no details indicating which Australian EB, or how many of their 188 CT originated from Australia compared to the USA.

3.1.2 Import nation

CT import nations and import quantities included: Israel with 95²⁰, Japan with a total of 376 via 3 studies (being 134¹⁷, 118¹⁸, and 124²²), Jordan with 75¹⁴, Taiwan 68¹⁵, Thailand 102¹⁶, Turkey 100¹⁹, and Saudi Arabia 885²². Surgeon training and expertise level were not confirmed in all the studies, however Lekhanont et al.¹⁶ indicated novice surgeons involved in their study, while Varssano et al.²⁰ and Shimazaki et al.¹⁸ confirmed recruitment of experienced surgeons. While all 8 studies analysed imported tissue, only 4^{14, 18-20} (Japan, Turkey, Jordan and Israel) compared imported CT to domestic CT, with the domestic CT provided by their affiliated EB.

3.1.3 Preservation medium

Hypothermic preservation medium, Optisol-GS (Bausch & Lomb Inc/USA), was predominantly identified as the preservation medium for imported CT. Shimazaki et al.¹⁸ did not provide detail of their storage medium, however, we conclude that their use of USA CT indicates hypothermic storage usage, as this was the favoured preservation method in the USA at that time. As Shimazaki et al.¹⁸ also listed Australia as a provider, the CT may have been provided in hypothermic or normothermic storage mediums. However, as normothermic preservation did not become commonplace in Australia until after 2005, we conclude that Australian CT was most likely hypothermically stored. Domestic tissue from Japan, Jordan and Israel also used Optisol-GC (Bausch & Lomb Inc/USA), while Turkey used Eusol-C (ALCHIMIA/Italy).¹⁹

3.1.4 Surgical technique and tissue preparation

Six studies examined the TNA of CT involved in Penetrating Keratoplasty (PKP) surgeries.^{14, 15, 18-21} The remaining 3 studies examined Descemet Stripping Automated Endothelial keratoplasty (DSAEK) Surgery.^{16, 17, 22} Yamazoe et al.²² opted to examine the viability and Endothelial Cell Density (ECD) of imported CT, without reporting on the surgical and recipient outcome phase. In Yamazoe et al.'s study,²² the CT had been pre-cut in the USA EB for DSAEK, and air and land transferred to Tokyo over an undisclosed duration. The CT was evaluated pre-cut, post-cut and post-transfer to Tokyo for its viability. Similarly, Nakagawa et al.¹⁷ pre-cut all CT in the USA prior to export, and they continued their analysis until 36 months post-transplant. Lekhanont et al.¹⁶ also examined pre-cut CT for DSAEK, where 69 of 102 CT were pre-cut in the USA prior to their transfer to Thailand. The remaining 33 were pre-cut by two novice surgeons prior to transplantation, with a follow-up of 5 years post-transplant.

3.1.5 Key themes

There were 4 overarching themes within the 9 clinical studies, being: time, freight, donor section, and recipient outcome. Collectively, they examined how these factors influenced CT viability and post-operative outcomes.

3.1.5.1. Time: Within all but one study, Death-to-Preservation Time (DPT) for imported CT ranged from 6-12 hours (mean 7.8 hours). Comparatively, domestic CT DPT ranged from 2.5 – 11 hours (mean 5.9 hours) within those papers involving domestic CT. We did not include the remaining study from Ababneh and Al Omari¹⁴ in our DPT range, as they stated, ‘less than 24 hours’. Variances in DPT time were not described.

Preservation-to-Transplant-Time (PTT) was also significant, with imported tissue influenced by air freight, customs release, and overland transfer time. Imported CT experiencing transfer durations of 10-20 hours, with the longest at 48 hours.¹⁶ As a result, imported CT PTT was 7-9 days, compared to 3.7 days for domestic CT PTT.

3.1.5.2. Freight: While land and air transfers occurred in all studies, they were not routinely described. All studies reported greater ECD loss in imported CT, alluding to the process of air and land transfer as the route cause. Unfortunately, limited pre-export information within some studies, multiple selection and longitudinal monitoring variables made summarising the ECD loss difficult for our review. Varssano et al.²⁰ and Ababneh and Al Omari¹⁴ discussed the impact of freight on ECD loss, referencing prior work from Wang and Hu²³ who investigated the impact of shaking on endothelial preservation. Their animal studies simulated shaking, by placing CT in an incubator, programmed at the speed of 5 rpm at 4° for 10 hours, vs. a control group that was not subjected to these conditions. This replicated unavoidable shaking caused during transportation. They examined ECD loss at days 1 through to 9. Their results indicated that ECD loss did not alter significantly until day 9 for the control group, in comparison to day 3 for the primary group. Varssano et al.²⁰ summarised that the dangers of acceleration, vibration and shaking could occur during prolonged transnational flights and land transfers. They indicated that this may explain why imported CT, that arrived for transplantation at days 7-9 post-PTT had greater ECD loss compared to domestic CT that was not moved great distances and transplanted within the 4-5 PTT period. Nakagawa et al.¹⁷ indicated 2.3% ECD loss of post-pre-cut CT for TNA. Additionally, Hu et al.¹⁵ further outlined that 5 CT, deemed unsuitable for PKP on arrival, were diverted to waiting lamellar recipients.

3.1.5.3. Donor selection: Selection methods for CT involved in TNA were not routinely outlined. We identified several methods, such as: consecutive selection based on next available CT,¹⁶ pre-transfer cell count^{14, 19}; and random non-selected.²⁰ Ababneh and Al Omari¹⁴, provided the most comprehensive donor selection method, inclusive of: cause of death, no cataract and intraoperative lens surgery, a minimum ECD of 2500 and an estimated arrival to the import nation of no more than 10 days from death. All studies lacked information regarding donor consent for recovery and exportation.

Donor characteristics such as gender, ethnicity, medical and surgical history, and CT integrity (e.g. endothelial cell count pre-export and absence of guttae) were not routinely reported. Age was the only characteristic routinely included across all studies, with a mean of 52 for imported, and 54 for domestic. While studies were inconclusive as to the impact of older CT involved in TNA, Ababneh and Al Omari¹⁴ commented that despite the older age of some imported CT, there was no significant difference in graft outcomes to domestic CT.

3.1.5.4. Recipient outcomes: Recipient selection varied however Fuch’s dystrophy, keratoconus and corneal opacification were the primary requirements for corneal transplantation, with some requiring additional surgical intervention, such as a secondary cataract and intraocular lens procedure. All studies implemented different recipient selection methods. Shimazaki et al.¹⁸ was the only group to document a patient-centred approach by offering recipients the choice between domestic and imported tissue. All studies described the surgical techniques as standard and routine, with outcomes measured in terms of post-operative best-corrected-visual-acuity, intraoperative pressure, ECD loss, and evidence of no complications, such as infection and graft rejection, with graft clarity as the final outcome measure. Studies indicated that imported CT ECD loss occurred regardless of provided it intact or as pre-cut. One study also suggested that imported CT had a comparable graft survival rate with Western countries who used fresher, domestic CT.²¹

3.1.6 Case studies:

2-remaining clinical papers^{12,13} were historical post-PKP case studies from Saudi Arabia¹² and Hong Kong¹³. They described independent instances of post-operative infection, from procedures involving imported CT, from Sri Lanka and the USA. Both pointed to the donor cornea and the original EB preparation techniques, rather than the TNA, as the root cause of the infection. While foreign EB techniques and practices were not central to our review, they raised other questions regarding the risk of importing from a country (or population group), that may or may not implement the same preparation and risk prevention standards expected by the importing nation.

3.2 Non-Clinical Papers

Published data on non-clinical aspects of CT TNA was limited. We were only able to locate 3 papers that met our criteria (available Appendix SUP03 page 193). Martin et al.³ were the most prominent in the conversation. Through their principle-based normative analysis, Martin et al. highlighted common dilemmas in the EB and eye care sector regarding the complexity of TNA when tackling supply and demand. Discussing jurisdictional self-sufficiency as the optimum goal, they outlined four key recommendations, being: promoting self-sufficiency; promoting autonomy; assuring quality and safety; and assisting organisational and professional decision making. The sector has subsequently published *The Barcelona Principles*⁸ which now provides direct recommendations including several points proposed by Martin et al.

In the broader context of performance metrics, for a variety of human biologicals, the second non-clinical paper²⁴ discussed the need for economic reform within Canada – which imported, and still imports, CT to meet the shortfalls from their domestic EB. They outlined that importation should be a short-term mechanism. During an era of declining domestic donors, they commented with concern, that “*ready access to USA CT means there is no pressure from clinicians or for Canadian banks to provide.*”

Only one paper² attempted to map CT TNA, within the context of global corneal transplantation data capturing. Gain et al.² reported one year of data (August 2012 - August 2013), from 742 voluntary participating EBs, from across the globe. From 148 countries surveyed, 116 recovered CT for transplant. They collectively supported 184,576 corneal transplants worldwide in that year. Of the 116 countries, 107 indicated the origin of the CT. Of those 107, 37 countries (77% of transplants, being 142 325 CT) used only nationally recovered CT, meaning they were self-sufficient; 27 countries (1.2% of transplants, being 2183) used only imported CT, indicating they had no national EB; and 43 countries (21.7% of transplants, being 40 068 CT) used a combination of national and imported CT, indicating imports were used to top-up national shortfalls. Gain et al. also indicated that 8% of the 107 respondent transplants (23 247) used imported CT provided by 9 exporting nations, with the USA (85%), Sri Lanka (9%) and Italy (3%) the largest.

4.0 DISCUSSION

Despite our extensive search, we determine that there is a dearth of literature pertaining to CT TNA. Those available did not provide consistent information to perform a comprehensive review of the impact of CT TNA. While we feel 9 clinical papers is inadequate to validate CT TNA, we note that collectively, all 9 clinical studies concluded that despite receiving CT with greater DPT and PTT and higher ECD loss, that the recipient outcomes were adequate and comparative to domestic CT. Some studies concluded that CT TNA remained a safe, effective, and viable source of CT, in the absence of adequate domestic EB services.^{18,22} Unfortunately, due to the significance of variables (e.g. different EB, packaging methods, surgeon experience level, differences in reporting on donor selection and CT assessment and condition pre-export, or a uniformed post-operative review period) within these studies, we were unable to comment further on the clinical aspects of CT TNA.

We were also unable to determine why some nations engaged in TNA, or how this was economically and practically supported by either party. Based on the papers in our review, it would appear that high-income nations (namely, the USA) were the primary exporters of CT, with mid-income nations (e.g. Sri Lanka) engaged to a lesser extent. They supplied CT to a range of low-middle income nations, with no clear explanation of how they allocated for export. Exportation in these papers, may have been possible

because the export nation was routinely meeting known need. How they defined and determined that need was met, prior to exportation, was also not clear. If the exporters were indeed meeting need, then such a scenario may indicate that exportation was used as a method of managing surplus donations. Conversely, exportation may have been provided as a form of humanitarian assistance or to prevent waste, or to recover some or all costs incurred during the recovery and processing phase, by the EB. In this process, domestic and international need may have been managed simultaneously, within the same distribution system, with one service dependent on the existence of the other.

As several clinical papers were published prior to the development of guiding documents such as *The Barcelona Principles*,⁸ then non-clinical aspects which we hoped to find, were not routinely included in the papers, e.g. donor consent to export, legalities around national permissions to export or import. We feel further clinical papers regarding CT TNA, need to state/list:

1. Why and how export and import nations were selected.
2. How TNA models were structured (e.g. within capacity development programs, short-term supply with clear exit strategies or permanent business plans and long-term supply).
3. Those involved (e.g. EBs and distributors).
4. Donor export consent and selection methods.
5. If domestic need was met, prior to export.
6. If recipients were informed on import use.
7. Cost mechanisms (e.g. gratis, cost recovery, sliding scale or for-profit), commoditisation and supply chain lines involved in the movement of the CT.
8. The positive or negative impacts on export and/or import nations.
9. Adherence to the WHO Principles of Donation, and The Barcelona Principles.

In closing, despite CT TNA dating back to 1961, and the existence of a flourishing export/import sector (indicated by the 42,251 CT involved in TNA, as reported by Gain et al.² for a 12-month period), it is of concern that we were only able to find 9 clinical studies within the last 27-year period (which collectively examined just 1701 singular imported CT), and 2 case studies and 3 non-clinical papers. Thus, our review highlights that there is a gross under-reporting and investigation in this area, with few efforts within the EB and eye care sectors to examine the appropriateness of current practice, and associated supply and demand decision-making. This does not necessarily imply that TNA is conducted poorly or ineffectively, simply that there are no reference points to examine and guide practice, or allow for transparency, safeguards and appropriate practice development (or withdraw) in the future.

Finally, we note that all 3 non-clinical papers were published in the past 5 years. We propose that this may indicate a new era of global interest regarding how CT TNA is conducted. This emerging area of enquiry corresponds with the development and subsequent ratification of The Barcelona Principles⁸ in 2018 - which provides guidance on CT TNA. We call on those engaged in CT TNA, EB and corneal service providers to support further research into CT TNA, promote the transparency of clinical, but predominantly non-clinical, engagement and appropriateness.

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1.3 Documenting the Evolution of Contemporary Eye Bank and Corneal Tissue Services in Australia

ABSTRACT

This paper documents the continued evolution of Eye Banking in Australia and the role of Eye Banks in advancing corneal transplantation through corneal tissue provision. While outlining known historical dates and key contemporary practice demarcation points, this paper simultaneously identifies a paucity of historical documentation regarding the evolution of eye banking practice in Australia. While the paper aims to document and preserve known historical and contemporary Australian Eye Banking practice for future generations, it also hopes to encourage other nations, professional groups and service providers to document their own evolution and practice before it is lost to time.

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Appendix material related to this paper.

- PER 01: Chapter 1 - EBAANZ Executive

1.0 INTRODUCTION

Australian Eye Banks (AUEBs) are the Custodians of altruistic voluntarily donated human eye tissue. They recover, prepare and transfer donations, primarily to waiting Australian recipients who require sight preserving or restoring transplant surgery. Commencing services in Australia around 70 years ago, today, AUEB are predominantly recognised for Custodianship of Corneal Tissue (CT).

Very little has been documented about eye banking history in Australia, or the significant role AUEBs have played in increasing access to corneal transplantation services across their nation. As such, there are only a handful of publicly available documents showcasing their evolutionary steps, and very few data sets dating back to the nation's first corneal transplant. As such, a majority of this paper will describe contemporary practice and present only known and available data. It simultaneously acknowledges key historical gaps within Australia's EB story. In presenting this paper, recognising Australia's historical deficits and documenting current practice, within the context of the broader eye care and human biological fields, it is hoped that some of Australia's EB practice will be preserved for future generations. In turn, it will encourage others to chart their own evolution and practice before, like AUEBs, historical facts and knowledge are lost to time.

1.1 Emergence of Australian Eye Banks

The first recorded corneal transplant occurred in Australia in 1941 in Brisbane.¹ The donor had died 12 hours prior. The whole eye was not enucleated. Only the cornea-scleral rim was removed. It was not placed in a transfer medium like it would be today. Instead, it was taken straight to a recipient awaiting a penetrating keratoplasty transplant.

Very little is known about the early days of EB practice in Australia. It has been suggested that the first informal AUEB opened, again in Brisbane, at the Mater Hospital, in the late 1940s² however the exact date is difficult to pin down. The period between the late 1940 and 1980s remains relatively unmapped and early AUEBs shared little resemblance to today's dedicated organised providers. The service was *ad hoc*, and often a *fridge in a room* was described as an EB. Service was dependant on the availability of unit registrars to locate and follow-up potential donors in public hospitals.³ While the world's first dedicated EB opened in New York in 1944,⁴ Australia did not catch-up with its international contemporaries, until 1981 when the Flinders Medical Centre, Adelaide² opened Australia's first dedicated organised EB under the leadership of Dr Doug Coster.

It was around that time, when the Australian Federal Government introduced greater control and regulation of human biologicals, inclusive of eye tissue. This resulted in the AUEBs and the corneal sector joining as one *common voice*² to provide a sector response to the regulatory changes. With the additional inclusion of New Zealand (NZ) (as Australian and New Zealand medical professional societies routinely collaborate), this group later evolved to become, what we know today as the Australian and New Zealand Corneal Society (ANZCS). Dedicated contemporary AUEBs were then established in Perth in 1986,⁵ Sydney in 1989,⁶ Melbourne in 1991,⁷ and Brisbane in 1992.⁸

2.0 CONTEMPORARY PRACTICE

2.1 Donor recovery

Operating within an opt-in donation system, the donation recovery model of AUEBs differ from other countries. AUEBs consent and recover tissue to match known surgical scheduled requests, rather than recovering all tissue and then searching for a recipient. The process is designed to ensure need is met, without waste, however we note there are no formal definitions to describe *need*, how meeting need is determined or how this differs across the various jurisdictions. Generally, tissue is recovered from donors in major public hospitals or from the coronial office. Some AUEBs may also occasionally recover from nursing homes or funeral homes, if their State's Tissue Act permits recovery in those locations.

2.2 Allocation

Through the Eye Bank Association of Australia and New Zealand (EBAANZ), a communitarian model of allocation is favoured. In their model, each AUEB recovers from their jurisdiction and allocates in their jurisdiction. Jurisdictions without an AUEB (Tasmania, Northern Territory and the Australian Capital Territory) are co-managed by the local medical staff or DonateLife retrieval teams (DonateLife is the donation agency of the Australian Commonwealth Government's Organ and Tissue Authority) and transferred to the closest AUEB. Similarly, those AUEBs allocate the next available tissue back into those jurisdictions when requests for tissue are made.

Surgeons in Australia obtain tissue by placing their request with their local AUEB. That AUEB is responsible for recovering locally or arranging tissue from another Australian jurisdiction, to assist local shortfalls. Most jurisdictions participate in a two-way tissue sharing system. The tissue sharing system is designed to retain the relationship between the surgeon and the EB and ensure tissue need is examined at the local level first. Occasionally, individual AUEBs do allocate directly to a surgeon, however this is reserved for specific instances such as provision of a particular cut-type over an agreed duration and is conducted in consultation with the local EB. The communitarian method also ensures a cooperative relationship is in place, and it removes competition for tissue placement, resource waste, and the development of a marketplace.

A majority of corneal transplant surgery takes place in public eye-only-urban hospitals, general metropolitan hospitals and standalone ambulatory surgery centres. They are predominantly private facilities. This reflects the distribution of ophthalmologists in Australia within urban centres, and the nature of the Australian health system which encourages individuals of a certain financial status to participate in the private health insurance scheme. Additionally, most corneal transplant surgery in Australia is provided as a day-surgery procedure.

Post-operatively, Australian Surgeons and AUEBs have voluntarily participated in the world's longest longitudinal co-operative analysis of corneal transplant outcomes, known as the *Australian Corneal Graft Registry* (ACGR). In operation since 1985, the ACGR, housed at Flinders Medical Centre Adelaide, collates information, volunteered by surgeons, on some 33,000 transplants since inception. The Registry quantifies outcomes via descriptive, univariate and multivariate sectorial analysis of the donor, AUEB, recipient, surgeon, graft type and the operative procedure.⁹ This remains the most comprehensive record of corneal transplant numbers in Australia. Of note, transplant (and donor) numbers prior to the commencement of the ACGR were not collated by any governing agency or health department. Data capturing has improved somewhat in recent times, particularly over the past 5-7 years, with both the EBAANZ and the Australia and New Zealand Eye and Tissue Donation Agency¹⁰ (who receive data from EBAANZ and individual AUEB) continually increasing their data collection sets.

While Australian recipients may be required to fund some aspects of their hospital stay and the procedure (depending on their level of public or private health cover), they do not pay for the provision of the CT. The CT is funded by the Government's Medicare system or the recipient's private health insurance company, who reimburse the AUEB directly. CT costs are determined by the individual AUEB. They are based on a cost-recovery price structure. They outline their prices, publicly, on the Australian Prosthesis Register.¹¹

2.3 Technology and innovation

2.3.1 Preservation:

Over the years, the AUEBs have ensured that donation and corneal services remain on par with other high-resource industrialised nations. AUEBs supported the introduction of hypothermic cold preservation storage medium. Today, Adelaide and Brisbane continue to use hypothermic storage as their primary preservation medium. In the early part of the 21st century, AUEBs started to explore normothermic organ culture medium, and by 2005 this became, and remains, the dominant preservation medium for Melbourne, Perth and Sydney.

2.3.2 Database and tracking:

AUEBs are amongst the first EB group (and the first of any tissue-type in Australia) to commence implementation of a nationwide Electric Donor Record (EDR) system. This system provides tracking standardisation across the country, and network interaction with the EDR primary partner - the National Organ Donation Agency. The EDR Eye Module, developed and based on the iTransplant software system, originally devised for USA EB's, *went live* in Australia in 2018, with each AUEB responsible for the implementation. To date, Adelaide and Perth have completed the implementation phase. Preparation for the Australian module required significant alterations from the original USA module, in order to reflect the diverse practices (e.g. different preservation methods) of the AUEB, and the Government's requirement for future integration with their broader national organ and tissue tracking system. In this process, Australia also commenced a nationwide implementation of the international tracking and surveillance nomenclature system ISBT128, a system developed during the Persian Gulf War to solve blood labelling issues.¹² Such tracking systems allow for full traceability and recognised labelling.¹² This is especially important when tissue can be transferred across local and national borders, when knowledge of the full life cycle is required.

2.3.3 Surgical techniques:

While Penetrating Keratoplasty (PKP) and lamella grafting was widely debated during the 18th to early 20th century,¹³ PKP reigned supreme for decades,¹⁴ and continues to be favoured within lower resource locations,¹⁵ as a treatment choice for corneal opacification.¹⁶ In recent times however, lamella grafting has experienced a global renaissance, as the treatment option for specific diseased layers of the cornea.¹⁶ The lamella grafting technique, *Descemet's Scraping Automated Endothelial Keratoplasty (DSAEK)*, was first performed in Melbourne, by Australian Surgeon Dr Rasik B Vajpayee, at the Royal Victorian Eye and Ear Hospital in the 2008¹⁷ but the technique required careful tissue preparation at the operating table by the surgeon. To combat the time required to cut the tissue, and to improve services, Melbourne moved towards a pre-cut tissue service, providing Australia's first pre-cut tissue to a Vajpayee patient in 2009. Perth were next to follow. In the late 2000, *Descemet's Membrane Endothelial Keratoplasty (DMEK)* started to gather global interest, and Brisbane's Dr Andrew Apel becoming the first Australian surgeon to perform the procedure. The Melbourne EB followed by adding additional pre-cut DMEK services in 2014.¹⁸ AUEBs that provide pre-cut services also offer pre-cut training to their local surgeons, and today all but one AUEB provides a pre-cut DSAEK service.

2.4 Institutional arrangements and EBAANZ

Despite the establishment of the ANZCS in the 1990s, it was not until 2003 that EBAANZ formed,¹⁹ under the leadership of Drs Grant Snibson and founding Chairperson Doug Coster.²⁰ EBAANZ and ANZCS continued to remain as partners, ensuring an open feedback loop between the AUEB and surgeon. Established to support the ANZ EB in the delivery of their services, through representation, cooperation and education,²¹ EBAANZ membership is per the EB. All 5 AUEB and the Auckland EB at the Department of Ophthalmology, University of Auckland, New Zealand are founding and remaining members.

Today, EBAANZ is recognised within the national and global sector. It is a founding partner of the Global Alliance of Eye Bank Associations (GAEB), established in 2014,²² and is actively engaged by DonateLife, and their Medical Standards are also recognised by their regulator, the Therapeutic Goods Administration (TGA). Within the eye care sector, EBAANZ partners with groups such as the Royal Australian and New Zealand College of Ophthalmologists and the Australian Ophthalmic Nurses Association National Council's state-based independent partners, on a variety of projects relating to eye tissue. For example, in 2016, EBAANZ were the first eye bank association to work with Stakeholders to develop a resource for operating theatre facilities, on safe care and handling of tissue, titled *National Guidelines: A Resource for Australian Hospitals, Operating Theatres and day surgery staff regarding the care and handling of human tissue for ocular transplantation*.²³

Inspired by their interaction with the GAEB, and influenced by the World Health Organization's human cell, tissue and organ transplant recommendations, EBAANZ became the first EB Association

to establish a regional *Bioethical Framework for Policy and Procedure* in 2015.²⁴ This was followed in 2018 by the global equivalent, *The Barcelona Principles: An agreement on the use of human donated tissue for ocular transplantation, research, and future technologies*,²⁵ for which EBAANZ played a leading development role.

2.5 Organisation models

Despite governing attempts in the late-2000 to amalgamate all tissue types into one multi-bank within each State,²⁶ AUEBs have remained predominantly standalone facilities, with their facilities predominantly staffed by post-graduate level medical-science and nursing professionals. They remain affiliated with benevolent organisations, such as Lions Clubs, and hospital and/or university ophthalmology departments. Sydney (New South Wales), and Brisbane (Queensland) are the only State Health Department managed AUEB. They are both multi-tissue banks.

Due to the transition towards biotherapeutics and greater requests for research tissue, all AUEBs provide consented research tissue to human ethics approved research projects. While all AUEBs provide some form of biobanking service, it was not until 2017,^{6,27} in Sydney, that Australia formed the country's first formal Biobank, *The Australian Ocular Biobank*, under the leadership of Dr Gerard Sutton and Jane Treloggon, and in collaboration with the Sydney University Save Sight Institute, and under the governance of the New South Wales Organ and Tissue Donation Service.²⁷

All AUEBs, and all but one Australian tissue bank, are not-for-profit organisations. They do not split their recovery, processing and allocation services or transfer altruistic donations from their (or their affiliates) not-for-profit (NFP) recovery arm into a for-profit (FP) shareholder incentivised arm. While such models do not occur in the AUEB sector, they are familiar with such models as similar versions operate within the Australian musculoskeletal tissue sector.²⁸ To date, AUEBs have remained critical of such a split or FP model, and have been active participants in their national governance, and the global conversation, regarding the retention of NFP bioethical norms and standards within the sector. AUEBs have, at this stage, sort to retain their communitarian approach, whereby tissue is treated and retained as a public resource for the shared benefit of all within a NFP supply-line.

2.6 Governance and regulations

Each state and territory has in place their own Tissue Act. This provides the parameters of donation and use within that jurisdiction. The Acts, limited in their scope, only deal with consent and removal of tissue.²⁹ While there is no uniformed approach across the Australian human biologicals sector,²⁶ biologicals such as CT, are mostly governed by a health or medical-science department within the Australian Government and regulated by the TGA. All biologicals are managed and licensed by the TGA in accordance with the *Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products* (cGMP).³⁰ The code provides guidance on the collection, processing, testing, storage, release for supply, and quality management within Australia. While complying with the code, each biological requires different regulatory treatment and oversight.

The TGA maintains a range of biological frameworks, such as the *Australian Regulatory Guidelines for Biologicals*,³¹ that provide information to the manufacturer, sponsor (those who process and manage the biological, such as an EB), healthcare professional and the public, on the legal arrangements in Australia. The biological framework uses a 4-stage categorisation system that approves or does-not-approve the inclusion of a biological (that are otherwise exempt, approved or authorised) and their restrictions. CT is categorised as a Stage 3 biological. Biologicals are then registered on the *Australian Register of Therapeutic Goods* (ARTG), prior to use in Australia or internationally. Imports must also be listed on the ARTG and may only enter the country if demonstrated that domestic supply cannot meet domestic need. A permit, under a strict special access scheme is then granted to allow the import, for instance, if emergency CT from New Zealand (NZ) is required.

2.7 Guidelines and frameworks

As mentioned previously, EBAANZ developed their bioethical framework in 2015. EBAANZ then participated in the development of a global framework, *The Barcelona Principles*, alongside other countries and numerous sector stakeholders. Both frameworks adhere to the *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, 2010. AUEBs also adhere to the *National Health and Medical Research Council* guidelines, titled: *Ethics and the exchange and commercialisation of products derived from human tissue – background and issues*³² to guide practice, however, these guidelines are currently under review, and the sector eagerly await the release of the next edition.

2.8 Governing recommendations

Australia has had several key sectorial reviews of the human tissue sector. Notably, 2008 when the *Council of Australian Governments* agreed to implement a world's best practice approach to organ and tissue donation and transplantation. This led to the development of *the Organ and Tissue Authority* in 2009,²⁶ with the gift relationship as the central underlying ethical principle. More recently, *Price Waterhouse Cooper* (PWC) were commissioned by the Government to complete a sectoral analysis of the Australian Eye and Tissue Sector.²⁸ Their report reviewed the demand, supply and use of eye, bone, skin and heart valve services across the country, comparing service models, professionalism and outcomes. The Report was significantly critical of the general tissue sector, offering caution in terms of importation, the for-profitization and the bundling of tissues as one sector without recognition of the unique management, use, wait lists and needs of the individual tissue type. While recommending some national oversight, PWC outlined the need for some specific tissues to be overhauled. Within the report, CT fared well, being the only tissue type identified to be entering a potential surplus to surgical need phase, however we note that the definition regarding meeting need and surplus-to-need, was not clearly described. The report also outlined that while some national oversight is necessary, AUEBs should retain their national communitarian approach, and their feedback loop with the surgeons. In addition, the report also proposed any surplus CT currently not recovered, could be recovered and exported. To date, there has been no formal analysis of Australia's exportation potential or other domestic surplus use options (e.g. retention for research, training or future therapies) or how such service would be provided and funded.

2.9 Transnational allocation

Through EBAANZ, AUEBs engage in a Trans-Tasman agreement with the Auckland based NZ EB.³³ In this cooperative, if either nation is unable to provide for a recipient, they contact the cooperative members, who then transfer the CT to the requesting EB. The receiving EB then dispatches the tissue to the surgeon. This method reduces confusion and the need for surgeons to contact or work with multiple CT providers. This also ensures tissue movement between Australia and New Zealand is tracked and recorded, and wait lists are monitored. Additionally, it ensures that cross-border sharing does not undermine local services or support the creation of a tissue marketplace. The Trans-Tasman arrangement is also based on a cost-recovery model. Through examining the EBAANZ data over the past 5 years, Australia indicated that they transferred n=94 CT to NZ between 2014-2018 (Table 1.3.1 on page 26). While Australia, during the same period, did not import from NZ, their Trans-Tasman sharing arrangement remains in place. This supports Australia, should they need to request emergency CT from NZ.³⁴

Historical affiliation between Australian surgeons and their peers in lower-resource locations has resulted in AUEBs providing some humanitarian CT to the Western Pacific Region, primarily being Myanmar and New Caledonia, as identified during the EBAANZ 2014-2018 recording period. One publication in 2004 also indicated that Australia exported to Japan, however the degree of engagement, and terms of the arrangement are unclear.³⁵ In the instance of humanitarian provision, AUEB and/or their philanthropic partners (e.g. the organisations managing the development program) have predominantly covered the costs for such efforts. EBAANZ commenced collection of their non-ANZ allocation data in 2014. Their data indicates that n=63 CT have been exported for humanitarian use during that 5 year-period.³⁴ Exportation engagement, at this stage, remains ad-hoc.

While CT has been exported from Australia, AUEBs are not routine exporters. This is primarily due to the AUEB model of recovering CT to meet scheduled booked surgeries only. This means that AUEBs do not have quantities of recovered CT readily available to export. AUEBs could recover more tissue and formally participate in transnational activity, as a response to the global need, but to do so, they would need to evaluate their own capacity to provide internationally, while ensuring domestic services are not disadvantaged. Their review would also require examination of the Australian public's willingness to routinely export, and additional revision of the donation education and consent process, as exportation is not a routine component of the donation conversation in Australia.

3.0 CONCLUSION

AUEBs have played a significant role in the advancement and accessibility of corneal transplant services in Australia, especially post 1980 (Figure 1.3.2). Unfortunately, very little has been recorded, and several key historical facts remain unknown (e.g. there is no data base going back to 1941 outlining the total donor or recipient numbers in Australia). In providing this overview, it is hoped that some aspects of historical and current practice can be preserved for future generations. In turn, it is hoped that the paucity of historical details will encourage other nations, professional groups and sectors to follow suit by capturing their own evolutionary steps and historical milestones before they too are lost to time.

4.0 ACKNOWLEDGEMENT

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	2014	2015	2016	2017	2018	Total
Donors	1139	1415	1272	1361	1387	6574
Corneal transplants	1894	2124	2074	2155	2231	10478
Exported CT to NZ	7	2	6	37	42	94
Imported CT from NZ	0	0	0	0	0	0
Exported CT outside of ANZ	22	0	15	17	9	63

Table 1.3.1: Donor and corneal tissue recovery and allocation rates within Australia, including transnational allocation through a formal arrangement with New Zealand (a Trans-Tasman Agreement) and *ad hoc*. humanitarian purposes outside of Australian and New Zealand (ANZ) Region. (EBAANZ internal data recording from 2014 – 2018).

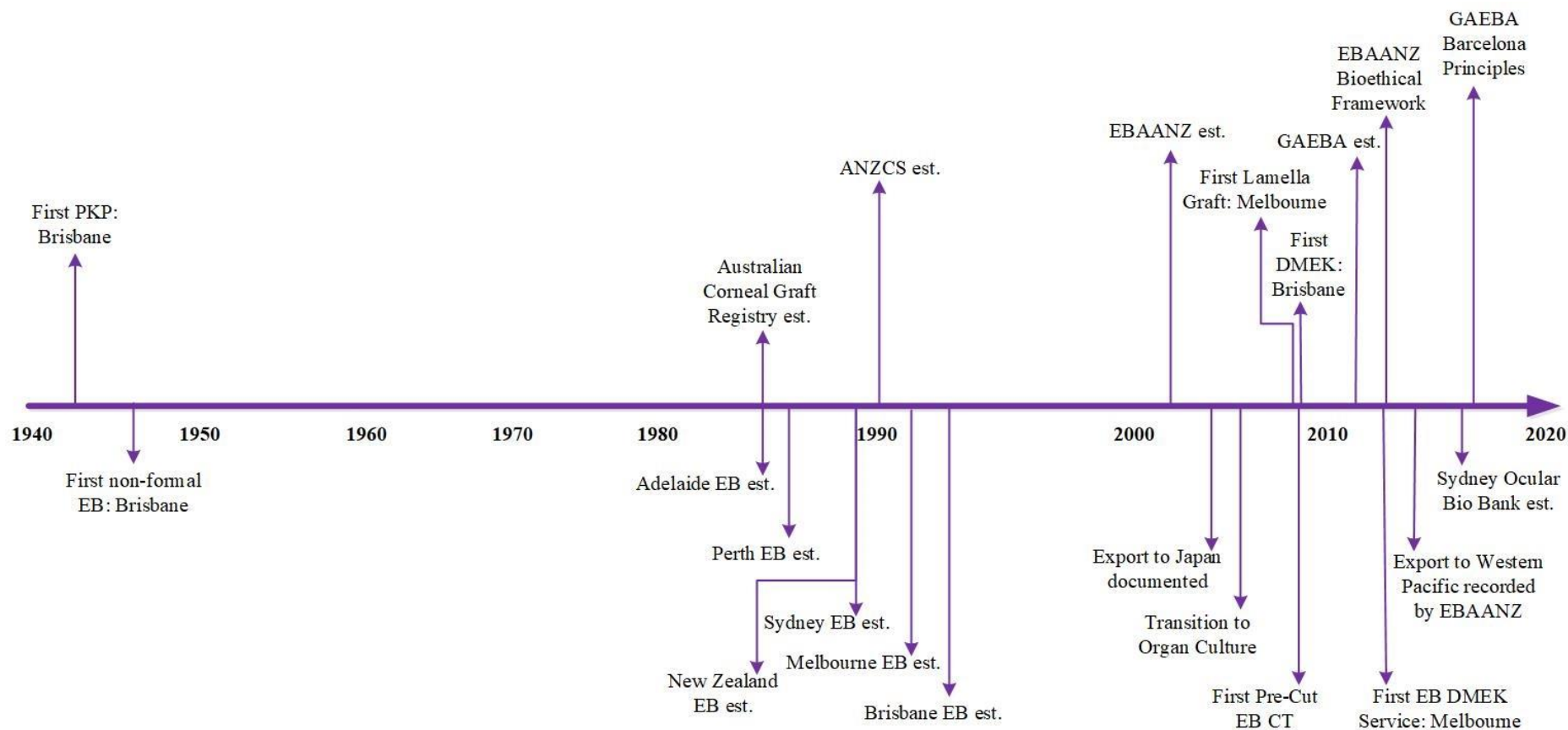


Figure 1.3.2: Timeline of Eye Bank evolution in Australia (ANZCS: Australian and New Zealand Corneal Society; CT: Corneal Tissue; DMEK: Descemet's Membrane Endothelial Keratoplasty; EB: Eye Bank; EBAANZ: Eye Bank Association of Australia and New Zealand; GAEBA: Global Alliance of Eye Bank Associations; PKP: Penetrating Keratoplasty).

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1.4 Understanding the impact of COVID-19 on corneal transplant need and demand through the example of Australia.

ABSTRACT

COVID-19 has changed corneal tissue supply and demand cycles. Inevitably, wait lists and wait times will increase globally, and eye banks and surgeons alike will be challenged to retain or re-instate services. Now, more than ever before, definitions and strategies to assist in understanding the delicate nuances between supply and demand, are essential. Our Two Part Series uses real-world nation examples and scenarios to discuss and propose strategies on this delicate balance. In Part One we examine need, demand, allocation, wait times and wait lists via the example of Australia, a nation pre-COVID-19, described to be routinely meeting demand. In Part Two we examine surplus and waste concepts through the comparison of Australian and USA recovery and allocation models.

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1.0 INTRODUCTION

Due to the COVID-19 pandemic, the global balance between corneal tissue (CT) supply and demand has shifted, for the first time in history. In a matter of weeks, the balance has tipped in some parts of the world, from over-demand and under-supply to over-supply and under-demand. The long-term impacts will not be understood for some time, but inevitably wait times will increase, allocation will be challenged, and need may not be met, where previously it had. This will invariably impact eye banks (EB) around the world as they witness unimaginable global shifts in service. During uncertain times, the sector needs now, more than ever before, definitions and strategies to assist in understanding the nuances between supply and demand, and its tipping points.

To conceptualise this delicate balance, we present a two part series. In this part, via the examination of Australia which, pre-COVID-19, was described as potentially meeting CT need,¹ we examine the concept of need, demand, allocation, wait lists and how these aspects impact real-world tipping points, such as access to operating theatres. We include definitions and propose subsequent management strategies to guide EBs, during and post the COVID-19 era. We exclude examination of other biologicals and nations, but recognise these concepts are adaptable and applicable elsewhere. We defer discussion of associated themes, surplus and waste, to Part Two of our perspective piece.

1.0 DEFINING TERMS

1.1 Need

It is necessary to be clear about terminology used in our paper. Our concept of ‘need’ refers to the overall need for a service or object. It remains central to the non-market allocation of many public resources,² and can be theoretically discussed as subjective and objective, relative and absolute, and based on prioritisation, societal and individual interpretation, expectations and particular states of technical possibility.^{2,3} In this context, ‘need’ is subject to the availability and ability of an object or action to satisfy or reduce *perceived* need.

1.2 Demand (required)

‘Demand’ is often confused with need, with the terms used interchangeably. In our scenario, demand refers to the ability to meet specific requests, within the confines of a systems resource level. For example, a location may have 1000 people on a wait list, but only one surgeon able to perform 10 surgeries a week. In this example, while the need is 1000, the demand (requirement) of the EB, per week, is to provide CT for 10 surgeries a week. Therefore, while need may not be met in this example, demand can be met.

1.3 Want

‘Want’ differs from need, being reflected in changing societal and technological values, and the ability to identify, respond, meet, reject or challenge the notion of an object being considered as needed or wanted.^{2,3} While wants may not always be needed, basic human need underlies all aspects of want. For example, a recipient may need a lamellar transplant. That is a need, alleviated by the surgeon inserting the CT manually. The advent of injectable corneas, while advantageous, ultimately provides the same end result – of the CT being inserted, and could be perceived as a current on-trend *want*. In other words, wants can be limitless, satisfied only by access to limitless resources, while needs can be satisfied relatively easily.

Wants experience a greater transient status than need. For example, injectables are the trend of the day, desired by EB and surgeons, but when they are superseded by future technology, they will be redundant and unwanted. The constantly moving technological goalposts, coupled with strategic marketing strategies, manipulation of recipient hope, and surgeon and EB desire to remain innovative, the first, or wishing to provide better options to recipients, influence perception. This impacts the degree of uptake of new and emerging wants (or a desire for an object or service) by presenting them as a need, regardless of the reality of the need.

In the current COVID-19 context, CT itself has become a temporarily redundant resource, as national health systems prioritise COVID-19 treatment and pandemic planning. While this will change in time, it reaffirms that want is subject to, and influenced by, external factors, regardless of need or demand.

1.4 Allocation

‘Allocation’ defines *how* a resource is utilised within a specifically defined criteria, or agreement/contract. Need and demand impact the decision making of allocation in relation to fairness of resource allocation and equitable access, particularly with regards to healthcare and public/common resources. Need and demand are also reliant on allocation, or at the least, appropriate allocation, to maximise and alleviate need and maximise the CT donation. Wants can influence allocation, depending on the resource level of those in need or those making the demand.

In healthcare, national and global frameworks can influence how and where CT is recovered and allocated. These include but are not limited to, a country’s regulatory authority/s roadmaps, the Social Determinants of Health, Sustainable Development Goals, World Health Organisation targets (human tissue and eye care fields), and specific to the CT context, e.g. *The Barcelona Principles: An Agreement on the Use of Human Donated Tissue for Ocular Transplantation, Research, and Future Technologies*. These soft tools assist in understanding what is universally considered as a basic need that must be met. They also provide recommendations for resource allocation.

1.5 Indirect influences

As evidenced by the global spread of COVID-19, need, demand, want and allocation are all influenced by external indirect factors. For example, service disruption in one location could be resolved by the importation of manpower, funding or supplies from another location. During the global pandemic however, where multiple locations are simultaneously impacted, services are limited without resolve. For example, COVID-19 has resulted in a reduction in operating theatres and air transport options to export CT to other locations in a timely manner. This means services are significantly impacted at multiple locations and by multiple factors, at the same time.

2.0 DEFINING “MEETING NEED” *via AUSTRALIAN pre-and-current-COVID-19 Example*

We will now examine these concepts within our example nation, Australia.

Corneal transplantation is the dominant root cause of Australian CT need. It presents itself to Australian Eye Banks (AUEBs) as CT *demand*, with the AUEB responsible for CT recovery and allocation. It can be defined by the ability of the AUEB to recover and allocate consented, donated CT to booked known operating theatre scheduled recipients, as determined by the transplant facility and surgeon.

2.1 Wait list

Recipients who are scheduled for surgery are placed on individual AUEB CT wait lists for their jurisdiction. The list provides the AUEB with a forecast of CT requests they must fill in the coming weeks and months. It is not an entire list of potential recipients in Australia but provides a useful guide to AUEB. For example, it may not necessarily include all regional and remote potential recipients (inclusive of Australian Indigenous or Torres Straight Islanders) as referrals to a corneal surgeon, by regional physicians may not have occurred. In this instance, physicians might not place patients on the list for a corneal transplant due to anticipated post-operative logistical issues. This indicates there may be pockets of potential recipients outside of the AUEB wait list.

There is no national framework regarding the management of Australian CT wait lists, and the wait times vary depending on the state/territory. Variables include availability of operating theatres, nurses and surgeons, a surgeon’s own wait list, jurisdictional resource limitations, location, manpower of AUEB, CT type requested, allocation for emergency CT requests, recipient reimbursement category (e.g. public, private) and the bundling of re-graft recipients with first graft waiting recipients.

There is no database indicating if and how AUEB wait lists reference re-graft recipients, or how often recipients are rescheduled due to unavailability of CT. It does not indicate if some recipients have been

waiting a week or a month and does not indicate if recipients have been rescheduled and have re-appeared on the wait list. Therefore, AUEB wait lists, while useful to AUEBs to determine their demand, do not effectively describe the overall Australian wait list system nor if need, or demand, is being met. This is because other elements we describe that are outside the scope of the AUEBs also influence need, demand and wait lists. Finally, there is no information indicating the duration that Australian recipients are on the AUEB wait list, nor how this may compare across the states/territories, individual surgeons, or to other eye care (e.g. cataract surgery) or transplant services (e.g. heart transplant). For example, is one week, one month, or one year an acceptable wait time and do these times alter the definition of a nation meeting need or demand?

2.2 Fluctuations in demand

While AUEBs are routinely providing CT to meet scheduled requests, there may be periods where recipients are rescheduled or delayed due to no, or not enough, eligible donations at that point in time in a jurisdiction. Conversely, as experienced pre-COVID-19 but significantly so during the COVID-19 breakout, the situation can switch, with more donations than scheduled surgeries, resulting in AUEB declining donations, as additional surgeries cannot be quickly scheduled to facilitate the CT availability. Additionally, AUEBs may decline donations, regardless of surgeon or operating theatre availability, if they have met their service's routine allocation quota/cap. Caps (e.g. an AUEB plans to provide 20 CT a week) are determined based on their available funds and staffing levels. While caps are practical management solutions, they require routine review to ensure they adjust and reflect changing demands e.g. population shifts, entrance of more surgeons, changes in operating theatre capacity, or cancellations due to external influences. This prevents AUEBs from knowingly (or unknowingly) underserving (or overserving) their jurisdiction at any given time.

2.3 Wait vs. need

Here we ask, what is an appropriate wait time for an Australian recipient? This is an essential concept to discuss as invariably wait times will increase in Australia due to COVID-19. Consider a scenario where a recipient in one location waits 7-8 weeks from the time their surgeon informs them that they need a transplant, until they undergo the procedure. In isolation, this wait time is either unremarkable, meaningless, excellent or disappointing. Meaning it could be considered a desired or dream target in locations without routine access, where wait lists stretch into the years; conversely those experiencing similar access times may consider it normal. Finally, those who experience ready access may see this as under-performance. While there are no publications describing wait times or allocation mechanisms, to indicate whether 7-8 weeks is typical or atypical for Australia (or any nation), we wonder are we comparing apples with apples or apples with oranges? Meaning, what does the sector or the public deem a suitable wait time for a corneal transplant – and in turn access to CT, within the practical confines of the health system resource level? Surely there are situations rendering allocation patterns incomparable. Additionally, COVID-19 has demonstrated that wait times can change instantaneously despite the best efforts of sector stakeholders. Finally, we are left wondering, are wait times influenced by single or multiple factors, and what can nations do to equalise and reduce wait times? Do jurisdictional differences influence wait times? The premise that one jurisdiction has a different wait time to another, within the same nation, may indicate that citizens of a nation may not receive equitable access to the same service.

To extend this scenario, we wonder if a wait of 1 or 2 weeks is vastly or significantly different from a wait of 7 to 8 weeks. With the exception of emergencies, is 8 weeks a long time or unreasonable? Where is the cut-off or comparison point? Where is the tipping point from the wait time moving from reasonable to unreasonable and vice versa? Is it based on: government-targeted expectations, individual EB or surgeon expectations through comparison to other providers, the degree of backlog, surgeon peer competition, operating theatre or clinic scheduling, impact of external factors, or based on the surgical needs of the individual recipient? While ultimately 'as soon as possible' is the desired wait time, we are unclear if 8 weeks is reasonable or practical, or not.

Lastly, we propose that wait times are independent of need and demand. For example, it could be argued that those waiting 8 weeks had the same surgery as those who waited 2 weeks, and therefore the end

goal of meeting need was ultimately met regardless of the wait time – thus it could be argued that need is met eventually. Therefore, does a few weeks matter for non-urgent cases? While this argument fares reasonably well for shorter time periods, perhaps if ‘under 3 months’ was the agreed target, it might not work in scenarios where supply of CT was scarce or operating theatres were unavailable, and wait times were already stretching into *years*. The margins (tipping points) from reasonable to unreasonable may have more weight when applied to longer periods of time, rather than shorter periods, though again, we come back to our premise that nations need to examine what is a reasonable or achievable wait time within the confines of their health system and resource level, at a specific moment in time. For example, a pre-COVID-19 wait time for 8 weeks may have appeared lengthy in the Australian context, but in the post-COVID-19 era, this may become a desired wait time, indicating that the demarcation points of acceptable and unacceptable are transient.

2.4 Technology

Changes in technology and techniques also impact services. For example, the uptake of posterior lamella transplantation in Australia in the 2000s⁴ opened new pools of recipients. In other words, new and emerging treatable recipient population groups change need, demand, wait lists and allocation. Technological advancements will continue to arise and continue to move the goal posts.

2.5 Finding the balance

The ability to meet need and demand is influenced by four key components: 1. Donors, 2. Surgeons, 3. Recipients, and 4. Transplant Facilities (Figure 1.4.1), with resources and funding the overarching theme for all components. When all four components move in unison, demand will most likely be met, and need could potentially be met. If one component or another steps out of sequence, and change does not occur in unison, then neither need nor demand will be met, as one component or another will be over- or undersupplied. As demonstrated by the COVID-19 pandemic, CT and surgeons were available in Australia, but there were no available operating theatres, as health resources and workforces were freed-up to battle COVID-19.

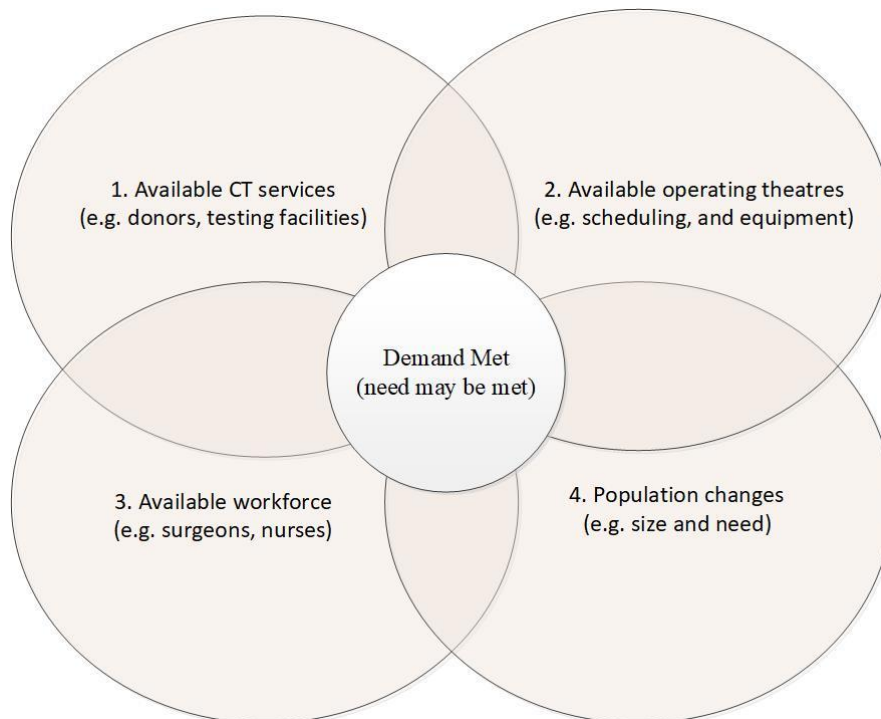


Figure 1.4.1: Finding the balance. When all four components move in unison, corneal tissue (CT) demand will most likely be met, and need could potentially be met. If one component or another, steps out of sequence, and change does not occur in unison, then neither need nor demand will be met, as one component or another will be over or undersupplied. Access to Funding underpins all for components.

3.0 CONCLUSION

The idea of *meeting need* is, we believe, an ever-changing construct. It is a difficult achievement for many nations and organisations to claim or sustain and can never be absolute. We propose, instead of using the *meeting need* construct as an absolute definition or status, to instead split the construct into 1. Meeting need, and 2. Meeting demand. This approach allows nations to strive towards meeting demand first, but clearly identifies barriers to meeting need that must be addressed. Meeting demand rather than meeting need seems to be a more realistic and achievable status for the EB, as other aspects, e.g. surgeon, and operating theatre availability, are outside of their scope of control. It also provides a mechanism to buffer service disruption, e.g. COVID-19 derailment of corneal transplantation services. This allows EBs to alter their business model to meet the scale-back and scale-up requirements over time.

This approach allows for flexibility, ensuring that nations like Australia can equitably allocate donations across their population. For example, the wait list may be high in one location, but if there are no surgeons or operating theatres available, then the AUEB have no demand in which to meet. As such it may be prudent to allocate to another jurisdiction that, at the same time, does have surgeons and operating theatres available and is not meeting demand, or vice versa (if services such as air freight are available). Therefore, we propose that meeting demand, and subsequent decisions to share donations with other locations (or nations), needs to be examined via a national sharing arrangement, with incremental demand stages met, as opposed to an overall premise of meeting an absolute need before sharing.

3.1 Proposal

We propose 3 incremental allocation steps to be performed by EBs to determine if they are meeting demand, rather than need, at any one time. This approach is essential as CT has an expiration date and if it isn't required locally, the EB must consider alternate utility options, to maximise the donation (Figure 1.4.2). This 3-step approach ensures the efficacy of CT allocation, with local and national transplant allocation prioritised. It also offers allocation flexibility, to adapt and meet changes in demand at any one time and any one location, and considers other aspects in the needs paradigm, beyond the scope of this paper, e.g. research, training and exportation.

In closing, COVID-19 has impacted service. It has overtly highlighted the fragility of the 4 balancing elements we describe, that must move in unison for demand, and potentially need, to be met. We have no way of knowing how significant the COVID-19 events will be on the long-term provision of corneal transplantation and EBs, but we can reasonably predict that wait lists and wait times will increase in Australia, if not globally for a period of time.

Our paper has defined key terms, and through our example of Australia, we have described real-world scenarios and gaps, highlighting that need and demand are not absolute, and will change over time due to controllable and non-controllable factors. Nations must consider these concepts and scenarios and determine what is an appropriate wait time for CT access and transplant services in their situation. They must develop incremental demand, rather than need, assessment tools to assist in evaluating and confirming CT allocation, as well as preparing their organisation for scaling-down and up, over time. Nations must determine if and how CT for research and training could also fit into these paradigms by offering alternative utility options during a downturn in transplantation demand. Finally, while EB are not in control of other elements necessary to meet need, e.g. access to operating theatres, they must work collaboratively, by supporting other stakeholders to examine how the barriers to meeting need can be lifted.

4.0 ACKNOWLEDGEMENT

The authors thank Marisa Herson (AU) for guiding a supply and demand conversation with our lead author, which led to the creation of this perspective series, and the development of diagram 1, refined in collaboration with Collin Ross (USA).

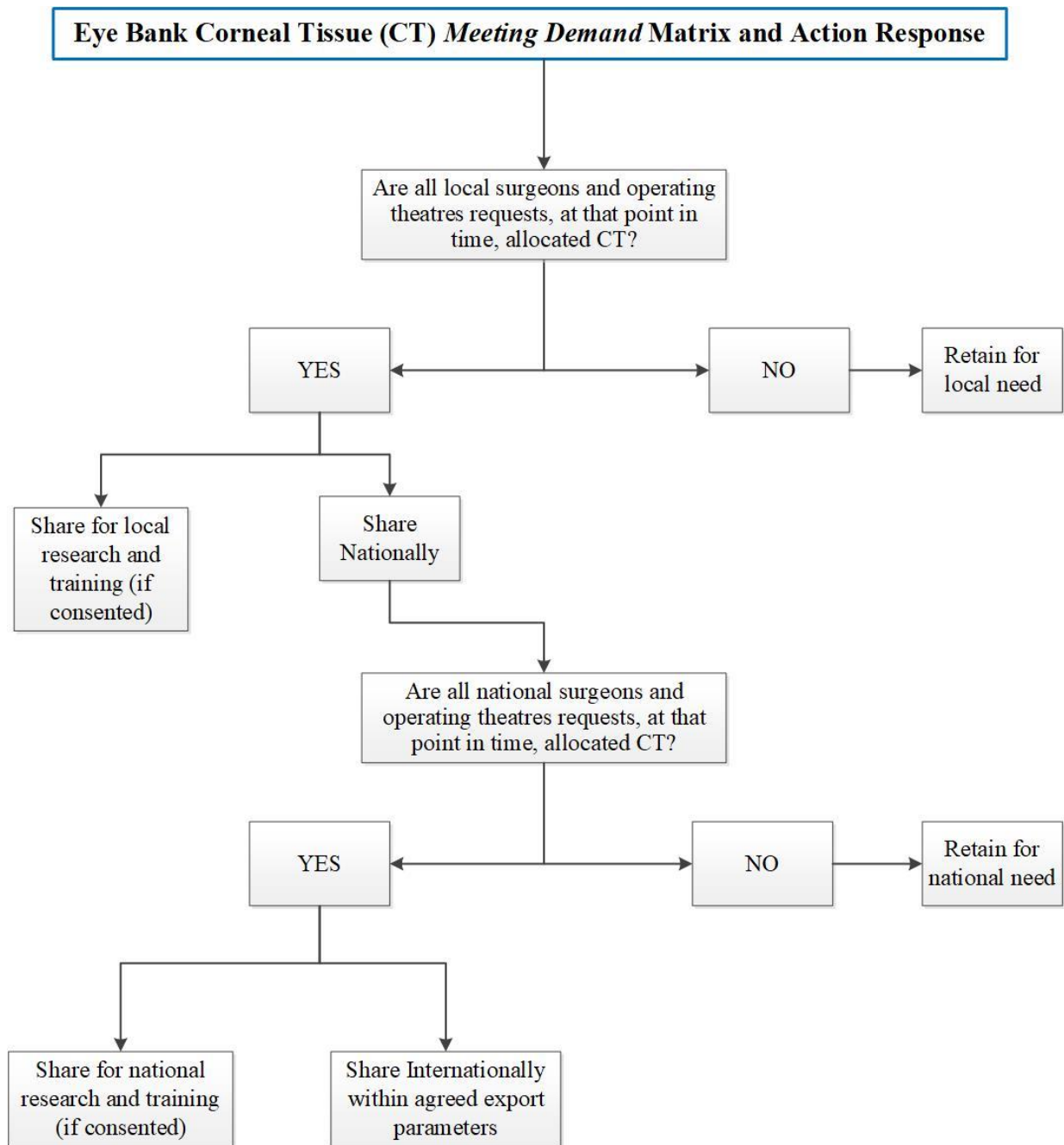


Figure 1.4.2: The 3-Step Allocation approach. The steps assist eye banks to determine if they are meeting surgical demand, at any one time, prior to allocating elsewhere.

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1.5 Defining surplus and waste in the pre- and post-COVID-19 era via Australian and USA examples.

ABSTACT

In Part One of our series we examined need, demand, wait list and allocation aspects of the corneal tissue supply and demand cycles, with an emphasis on the contemporary COVID-19 era. In Part Two we expand upon these concepts by examining surplus and waste constructs. We use real-world examples and scenarios, though predominantly focusing on Australia in comparison to the USA, to demonstrate surplus and waste management differences. Finally, we continue to include the COVID-19 pandemic example to highlight the fragility of the supply and demand cycle.

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1.0 INTRODUCTION

The 2020 COVID-19 pandemic resulted in a temporary global reduction in Corneal Tissue (CT) demand for corneal transplantation. Consequently, eye banks (EBs) globally encountered a radical shift in demand, resulting in increased surplus and wasted CT donations. Unfortunately, terms such as ‘surplus’ and ‘waste’, have not been described in the literature, in relation to CT, nor has there been any examination of how excess CT can be managed. Therefore, there is little information in the literature to prepare EBs that find themselves in the uncharted territory of surplus and waste.

In Part One of our perspective piece, we focused on need, demand, wait lists and allocation.¹ We will now examine the terms surplus and waste, predominantly in the Australian context, and to a lesser extent, the USA context. We selected Australia as it was reported to have been in a surplus and waste phase pre-COVID-19. While the USA did have a robust management system in place, COVID-19 has meant that the USA has now entered a temporary surplus and waste phase, similar to Australia. This means that while both nations are not meeting the need during this period, they are meeting domestic demand. Subsequently both have access to more CT than is requested. For the USA, they have also experienced a reduction in international demand for their exported CT. Collectively these national examples allow examination of the surplus and waste construct, offering different recovery and allocation explanations and valuable insights for future management. Finally, our paper outlines how CT surplus and waste play an important, and at times, co-dependent role, in the global management of CT.

1.1 Focus to-date

Globally, supply, demand and allocation conversations have focused predominantly on strategies to increase CT access within under-served areas, where the promotion of local and national self-sustainability remain the key goal.^{2,3} In contrast, management and experiences of those with oversupply, once demand is routinely met in their location/nation, has not been awarded the same degree of examination and consideration. This may be because few countries or human biologicals had reached this status, with oversupply viewed as an emerging niche issue in a small number of countries (pre-COVID-19). The perception may have been that oversupply only impacted those locations, and therefore it was viewed as an isolated issue not requiring wider address or definition. During the peak of the COVID-19 era, this status changed, with EB around the world experiencing an oversupply regardless of need and demand. Many EB managed the situation by slowing or ceasing operations until elective surgical services could be reinstated.

1.2 USA example

Pre-COVID-19, USA Eye Banks (USAEBs) used an inventory model, where eligible CT was collected regardless of local surgical demand. Recovered CT was then allocated to a recipient. Excess CT was exported outside local jurisdiction and often internationally, with exportation allowing EB to recoup some costs outlaid in collection and processing. This prevented already recovered CT from being discarded. This resulted in the USA becoming the largest global provider of exported CT,⁴ with an export history dating back to 1961.⁵ In 2019, USAEBs contributed CT to 28,402 recipients in 113 nations.⁶ This represented 33.1% of the 85,601 USAEB-sourced CT transplants in 2019. USAEBs also provided CT for training and research, through sharing platforms such as *EyeFind*, resulting in 13,743 ocular tissues used for research and 9,487 for training.^{6,7}

In brief, USAEB ability to export emerged as an indirect result of their practice principle of recovering eligible tissue with a presumption of ‘infinite demand’. As surgical techniques evolved, USAEB adapted to meet and match surgeon niche criteria (e.g. specific medical history or tissue attributes). The niche criteria demand emerged as a result of endothelial keratoplasty (EK) popularity in 2005. To meet requests, USAEB increased their tissue intake. This practice continued, and USAEBs recovered more donations to meet that demand, resulting in surplus CT to USA domestic demand. USAEBs retained domestic service buoyancy through the export allocation of non-domestically allocated CT, meaning they exported surplus CT. Over time, this inadvertently evolved into a co-dependent system, whereby domestic surgical services were financially reliant on both domestic (non-local) and international

demand, and vice versa. Though, notably, the USAEB model also included a mechanism for domestic services to subsidize CT used internationally – where able, and particularly so for low-middle income nations.

While 2020 statistics will not be available until 2021, the careful balance between supply and demand is at a kilter, with both USAEB domestic and international allocation impacted by the COVID-19 pandemic. As an unprecedented and unimaginable situation, USAEBs like many EB around the world, had to immediately cease or significantly slow the rate of CT recovery. The change in the demand cycle occurred in a matter of weeks. International CT outlets suddenly ceased or significantly slowed importation, e.g. due to limitations with air freight availability, their own national rapid-pandemic responses, and the cessation and slow-down of global elective surgeries, which impacted non-urgent corneal transplant treatment. While some USAEBs experienced a decrease in CT services,⁸ resulting in their closure or reduced hours, many commendably helped the pandemic response efforts by donating supplies and volunteering time and expertise in their communities.⁹ While it is too early to determine the long-term impact of COVID-19 on USAEBs, in the short-term, they have entered a likely temporary surplus and waste phase.

1.3 Australia example

Pre-COVID-19, it was already proposed that Australian Eye Banks (AUEBs) were in a surplus and waste phase due, in part, to their recovery and allocation model. In this context, surplus referred to CT both recovered and not transplanted, as well as CT not recovered from a donor.¹⁰ This included eligible transplant donors whose donation was declined (not recovered) because scheduled surgical demand had been met at that time, or because staffing and funding issues prevented recovery. While the term surplus predominantly refers to declined and non-recovered eligible donations in the AUEB scenario, the term could be extended to encompass donations not suitable for transplantation that are recovered for research or training. In this context, ‘surplus’ could also encompass demand for CT for the expressed purpose of research and training use.

In contrast to USAEBs, AUEBs favour a just-in-time model, enhanced by their predominant use of organ culture preservation medium.¹⁰ Their method caters for a pre-determined CT criteria, where AUEBs alter their recovery criteria to meet fluctuations in booked (local) CT requests only. Therefore, AUEBs do not recover CT additional to known demand. They routinely decline donations by altering the criteria, (with the main contrast with the USAEBs being AUEBs cater to local demand only, while USAEB criteria changes applied to local, domestic non-local, and international demand changes). This prevented unnecessary waste of resources, such as staffing costs,¹⁰ which in turn keeps cost down and is generally considered more efficient.¹¹ This means AUEB do not have excess CT and do not need to export CT in order to recoup costs. While they may not have actively supported other nations in need, like the USAEBs, AUEBs remain self-sufficient and are not reliant on exportation to retain their domestic service. During the peak of the COVID-19 pandemic, while services were reduced, no AUEB closed. Notably, skilled workers within AUEB whose EB activity was significantly slowed, provided assistance to Australian pandemic response in a nationally-coordinated effort to provide a coordinated public health program (e.g. nurses providing telehealth services).

2.0 SURPLUS

As some EBs around the world now find themselves routinely declining donations (like in the AUEB example) because of the reduction in elective surgeries, we now ask, is a surplus status a problem, and does it need to be addressed? Does it matter if surplus CT is not recovered? Is donation a right? Finally, could EBs that find themselves in a surplus phase, recover surplus CT to assist other forms of demand or other areas of need, e.g. could surplus CT be recovered for greater allocation to research or training during a period of transplant downturn as experienced during the COVID-19 period or exported, if nations had the capabilities and funding to do so?

There is no mandate stipulating EBs must accept and recover all CT donations, or provide for exportation, training and research. Failure to recover surplus CT may however be viewed as wasteful or against the wishes of those seeking to donate or viewed as anti-economic.¹² Conversely, collection

for pre-determined research or export requests may be viewed as a form of bio-mining. As EBs would intentionally be recovering CT outside of their primary purpose of supplying for domestic transplantation, rather than using these allocation options as an alternative allocation for already recovered CT, as described in the USAEB model.

2.1 Pros of surplus

Surplus CT recovery and allocation could assist domestic research and training, or transplant need in other countries. Therefore, surplus CT possesses positive communal value, contributing constructively to global humanitarian eye care treatment plans. This is an incalculable benefit to many, and it offers a greater chance of donation for those wishing to donate.

2.2 Cons of surplus

As surplus CT does have alternative avenues for use, it possesses speculative asset commoditised value. It holds latent technicity as a human biological, meaning it has the ability to acquire bioeconomic value. This is especially so if deemed as ‘waste’ – rendering it as fair-game and something to freely lay claim and allocate at will. This could result in its reduced ontological value, yet increased economic commoditised value¹² if not managed well.

As highlighted by the COVID-19 period, multiple providers (or nations) could simultaneously have surplus CT. This may then contribute to competitive organisational behaviour, as providers seek to allocate donations.¹³ While we acknowledge the constructive value of healthy competition and disruptive business rationales as constant and central themes within continual change paradigms, if not monitored and managed well, competition could lead to counterintuitive practices. This is characterised by low transparency, accountability and safeguards, the undermining of other health services and providers (domestically and/or internationally), and the skewing of agendas away from collective norms and targets. At times, this may also include enclosure of donations by those with profit-motives^{13,14} who divert health funds away from healthcare or create barriers to sector advancement through the prevention of knowledge-sharing and collaboration due to in-confidence contracts.

Excessive levels of surplus within competitive systems may also drive or erode costing models. While we do not dispute the necessity for health care systems and recipients to access CT that is fairly and equitably priced, it could encourage a range of complex costing models, not necessarily compatible with ethical norms in terms of cost-recovery outlined by The Barcelona Principles¹⁵ and WHO human cells, tissues and organ transplantation guiding principles.³ This may result in donations being viewed for their economic-commoditised value. As COVID-19 has destabilised services, it may also lead to monopolisation, which could have a detrimental effect on the overall system and supply and demand balance.

3.0 WASTE

3.1 CT waste categories

There are three avenues for CT waste:

1. Collected, determined ineligible and not used;
2. Collected, determined eligible and not used; and
3. Not collected.

All three avenues emerge in different EB environments, but all have the same outcome, whereby donations are not used. Regardless, any collected and not used CT indicates stewardship (Custodianship) may not have been effectively applied. We examine these three categories next.

The first, ‘*collected, determined ineligible and not used CT*’, emerges due to donor contrary indications, manufacturing issues, or contamination or damage, rendering CT unsuitable for transplantation. Un-transplantable donations not consented for training and research use, or nations that over-recover to meet a niche surgeon-request criteria, also feature in this category. In the later instance, EB recover

more than they require in order to find niche criteria CT. CT not meeting that criteria becomes waste if it is not allocated to other forms of use (e.g. glaucoma shunt patches).

The second, '*collected, determined eligible and not used CT*' describes a classic definition of waste. Recovered CT in this category, on inspection, is determined to have less-than-ideal endothelial cell quality to meet the niche demands of the most frequently performed surgical types in that location. In the USAEB system, CT in this category are infrequently allocated in the US though some may be allocated internationally if import nations are willing to accept CT of a lower cell-count.

The third, '*not-collected CT*' refers to nations, like Australia, where recovery tends to occur only when there is known booked surgical lists or to a lesser degree, research and training requests.^{10,16} Within the United States, '*not-collected CT*' includes CT that was actively sought to meet infinite demand, but was not recovered for a variety of reasons (e.g. medical examiner did not approve EB recovery, donor consented/family dissented, inability to reach family for authorization, weather-related prevention of recovery, etc.). In these scenarios, uncollected donations are either not counted in the wider donor pool, or conversely, a source of potential collection.

3.2 Complexity of waste

The aporia of the CT waste construct is evident. It is both existent and non-existent. We will now outline several aspects, demonstrating that referring to or managing non-transplanted CT as waste is complex.

The waste concept is influenced by individual perspectives of global need, growing environmental and resource debates of our time, and the impact of external influencers (e.g. global pandemic) on health and societal prioritisation. For example, if there was no global need, e.g. if the sector moved toward genetically engineered treatment options, rendering CT donation obsolete, then it may not be considered wasteful to not collect CT for donation. In other words, the definition of CT waste is not static. It could also be assumed that CT waste has emerged because of the COVID-19 pandemic, but it was in existence pre-COVID-19, e.g. AUEB routinely declined donations, and nations where no EB existed inevitably wasted potential donations.

The grouping of collected and not used, and non-collected CT as wasteful, may also place the donation into a compromised position. Once perceived as waste, it is considered as something that can be freely acquired (taken), because it has been (or would be) surrendered by its original owner (donor) and rejected within the EB service models at that time. It is therefore available for others to lay claim, or in the research, training and export instance, other avenues of need to lay claim.¹⁶ Ideas to lay claim or develop new forms of usefulness, when it was previously valueless and not counted, is relevant to the discussion, because when it transitions toward collection for a new or greater use, its technicity and ontological value may change and its vulnerability as an object of desire, ownership and possession may increase.^{12,17}

Wasting CT could be viewed negatively, and as something to be avoided. This view supports the premise that surplus donations should be recovered for training and research or exported. It may be viewed that wasting CT is both anti-economic, and illogical when globally, an estimated 12.7 million people await a corneal transplant.⁴ However, as demonstrated during the COVID-19 pandemic, waste can be unavoidable due to the global cessation of elective surgery and reduction in air freight carriers.

The term 'waste' in itself suggests something has no value, is worthless, is abject, or holds latent worth; however this is not always the case, as CT does not change. Only demand changes. Additionally, suggestions to recover CT deemed unneeded and unsuitable in one location yet useful in another suggests that the CT was and is not waste and is simply "just matter out of place."¹² Meaning CT recovered and unrecovered has equal value.

3.3 Influences of environmental movement

Recovery and allocation of surplus donations may also be considered as an environmental action, e.g. an act of recycling by preventing waste of the donation. The premise here, we agree with. We wonder, however: How does the concept of environmental recycling influence the decision to recover surplus

CT? For example, do global conversations regarding recycled glassware, tin cans and so on, impact the perception of CT waste? If so, this is a commendable motivation as general global resources are finite, and there are calls from the World Health Organization (WHO) to reduce health-service induced environmental damage and waste.¹⁸

Conversely, and specifically for CT exportation, we wonder: Is recovering CT in one nation to send to another an effective form of recycling and environmental management? Does this contribute to our collective actions toward healthy environments and environmental sustainability? For a nation to recover and air freight CT, it would invariably be increasing their carbon footprint. This weakens the environmental recycling premise, particularly in the scenario that CT is exported to distant nations (rather than closer nations), without some form of carbon footprint neutralisation scheme in place. The recovery and processing aspects may also increase environmental damage and outweigh the benefits of the initial motivation to prevent wasting the donation.

While reducing exportation of CT from organisations without a carbon neutralisation scheme in place may sound desirable, we note that there has been no investigation into the environmental impact of EBs or CT exportation. Finally, as many nations do not have a donation culture or an EB in place, rendering them reliant on international allocation, then CT need, and the desire to prevent CT donation waste, may continue to outweigh environmental efforts in the short term.

4.0 CONCLUSION

A surplus status arises when locations/nations routinely meet their surgical demand for CT, and they are unable to allocate excess supply within their normal patterns. EBs can achieve this status over time (e.g. the AUEB model and USAEB pre-COVID-19 models) or instantly due to external factors (e.g. the COVID-19 pandemic), which may or may not have a short- or long-term impact on services. In all instances, donations are either declined, or recovered and allocated elsewhere. Regardless of the scenario, careful consideration and management of surplus could assist those wishing to donate and those seeking donations, while providing transparency and clarity to all parties. Decisions to not collect could also be managed and framed in a manner not deemed as wasteful or a lesser end-of-life option to a donor. For instance, USAEB may reduce waste by the use of lower quality CT or by improving the algorithms used to prevent recovery of CT not known to be needed locally, domestically, internationally, or for research and medical education.

To date, the terms have not been adequately described in the literature, nor considered within national recovery and allocation plans. Their emergence is dependent on organisational models and degrees of demand within each nation, whereby surplus CT may or may not be recovered and utilised. In our application of the term ‘surplus,’ we outline that surplus CT, recovered or not, possesses equal communal value and requires careful management to ensure its stewardship complies with guiding principles in this field, and is retained as a gift regardless of the changes experienced in the sector. Known global need offers some explanation as to why donations should be recovered (e.g. for exportation), however that cannot, as a stand-alone rationale, validate its collection.

COVID-19 has highlighted that despite the existence of need, and the availability of surgeons and EBs to recover CT, that surplus and waste can be unavoidable and beyond the control of the sector. Exportation specifically may prevent some waste, but aspects of the practice inevitably contradict efforts to improve healthcare-related environmental impact. Therefore, EBs wishing to export CT, based on the premise of preventing CT waste, need to ensure their organisation’s practice, policies and strategies are framed in support of healthcare environmental initiatives.

With no prior publication describing surplus and waste, we propose EBs at the national level define the terms within the context of their EBs and healthcare models. This may require examination of:

1. How a surplus status is defined/achieved, either:
 - a. In addition to domestic need (AUEB pre-COVID-19 model);
 - b. As necessity in order to retain/support domestic services (USAEB pre-COVID-19 model); or
 - c. As temporary (due to changing external influences)

2. Develop information to inform the public and donors, either:
 - a. Options to allocate for export, research or training; and/or
 - b. An explanation on why the donation was declined
3. The scope of services, either:
 - a. Based on a booked request system (AUEB ‘intentional supply’ model); or
 - b. Routinely recovered and then allocated (USAEB ‘infinite demand’ model)
4. Determine if/how it can be retained for domestic training and research, and/or exported
5. Develop a business model to prevent surplus CT inclusion within counterintuitive and contestable practices e.g. prevent:
 - a. Commoditisation; and
 - b. Enclosure in for-profit or monopolised supply lines

In closing, we have presented key complex terms and scenarios relevant for understanding the supply and demand cycle of CT. We have highlighted that the cycle and supply lines are fragile and fluctuate over time, rendering it necessary for all nations to consider how they should or should not manage surplus and wasted CT. This may provide rationale for the ‘infinite demand’ model (USAEB) or the “intentional supply” model by (AUEB), when socioeconomic conditions warrant it, or specific global health crises arise. Finally, other aspects (e.g. allocating surplus transplant eligible CT to research rather than exporting,¹⁶ and the environmental impact of EBs) would benefit from further examination within future CT management discussions.

5.0 ACKNOWLEDGEMENT

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1.6 Ocular Tissue for Research in Australia: Strategies for potential research utility of surplus and transplant-ineligible deceased donations.

ABSTRACT

A 2016 Price Waterhouse Cooper Report, commissioned by the Australian Commonwealth Government's Organ and Tissue Authority, indicated that Australia had been meeting its human ocular tissue for transplant needs. It further suggested that Australia should consider exportation as a management strategy for excess tissue. While we do not seek to discuss how the Price Waterhouse Cooper Report determined that need was being met, nor the potential value of exportation in this paper, we propose that Ocular Tissue for Research and particularly, identification of donors for research, and timely access to fresh domestic tissue, be considered as an alternate or simultaneous surplus management strategy. A robust Ocular Tissue for Research system could provide long-term domestic support and investment into research and development of therapies in Australia. Such a system would also provide a meaningful donation option for those otherwise unable to donate for transplant. This paper attempts to document, for the first time, the current recovery and distribution processes of deceased Ocular Tissue for Research in Australia. It maps the process steps, identifies the stakeholders and needs, discusses the limitations and barriers, and proposes key policy and practice reform strategies that may assist in improving access to Ocular Tissue for Research.

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1.0 INTRODCUTION

The advancement of vision science and the development of most new treatments, techniques, and diagnostics is dependent on access to sufficient quantities of well characterised high quality human ocular tissues. While the 2016 National Research Infrastructure Roadmap¹ includes calls for a national framework regarding access to biological samples, to date, there are no specific Ocular Tissue for Research (OTR) national strategies in place to prepare Australia, as it explores new technologies (e.g. tissue engineering, and stem cells), as well as provide ocular tissue for conventional research needs (e.g. corneal diseases or retinal material for diabetic eye disease, glaucoma and age-related macular degeneration).

While some tissue samples can be obtained from a living human, primarily identified and managed by clinician-scientists and living-donation-programs, the majority of vision science researchers are reliant on deceased donation from consented voluntary and altruistic donors. This in turn has made researchers reliant on the deceased organ and tissue donation sector for donor identification, consent, recovery, processing, and allocation.

As the Australian organ and tissue donation sector has been historically focused, funded, and designed for the purposes of transplant, OTR services were added by way of an *ad-hoc* by-product-service, rather than as a direct and unique area of planned service. However, more recent developments through the emergence of biobanks, and the 2016 National Research Infrastructure Roadmap are changing this paradigm.

This paper highlights the need for a coordinated approach to deceased OTR and prompt collaborative discussions with key stakeholders, to allow planning for OTR use going forward.

1.1 The current process

1.1.1 The researcher:

In Australia, OTR is typically provided to researchers by their closest Australian Eye Bank (AUEB) (Adelaide, Brisbane, Melbourne, Perth, and Sydney) or at times, the Biobank (The Australian Ocular Biobank, Sydney). The researchers must provide evidence of human research ethics approval alongside information about their project, team members, and the type of tissue they require. Depending on the research, they may ask for a certain quantity, tissue type (e.g. the retina or the cornea), and storage preference (fresh or preserved or specific storage condition e.g. liquid nitrogen, -80C, for nuclear material or subsequent derivation of cell lines from the tissue etc). At times, they may also request diseased or non-diseased (control) tissue, or tissue from a donor with certain characteristics (age, smoking status, and so on). The researcher is then notified by the AUEB/Biobank if donated OTR, matching their request, is available.

Due to uneven supply and demand, researchers may go through periods without any OTR, and then be provided with several in quick succession. Researchers are required to plan their experiments around the availability, accordingly, often having little time to collect and utilise the tissue before it expires or before another researcher lays claim to the tissue. While a small minority of researchers do budget for tissue service costs, with pre-planned recovery (removal) processes in place with their local AUEB or biobank, most do not, and rely instead, on tissue provided on a 'no-cost' basis by the AUEB. This may reflect the research process, where additional experiments, changes in protocols, or emergence of new techniques, meaning OTR needs may change after the time of initial research grant application or reflect emerging areas of new research.

1.1.2 The organ and tissue sector:

The process of determining deceased donors for research, varies amongst the Australian States and Territories, though it generally commences with the donor coordinators located in the hospital setting.² They ascertain willingness of an individual to donate for transplant, and/or research and training. Willing donors (via their next-of-kin) indicate their donation wish. The donor coordinators notify the AUEB when potential donors are identified.

As the donation system in Australia is historically designed to support transplantation, only donors who are potential eligible donors for transplantation tend to progress in the system. The donors are then triaged through a donor eligibility criteria pathway before consent and recovery is performed. The eligibility and donation pathway is outlined in Figure 1.6.1, demonstrating the various steps necessary for triage towards donation. Those eligible for transplantation are consented (via their next-of-kin), prior to recovery of their donation. This includes examination of medical, surgical, and social donor history. Blood samples analysed, and ocular tissue integrity and suitability are examined closely. Ocular tissue that continues to meet transplant eligibility criteria becomes transplant ocular tissue. If the donor is eligible, and there are scheduled recipients awaiting a transplant, the AUEB recovers the donation. They transfer the donation to the AUEB for processing, and then allocate to a waiting recipient.

Recovered ocular tissue that, during the examination process, is deemed unsuitable for donation, does not progress as transplant tissue. Instead, it becomes potential tissue for training and/or research, however this can only occur if the donor also consented for research and/or training. Those not consented are discarded.

AUEBs vary in terms of what they recover from a donor, with some collecting just the corneo-scleral-rim for corneal transplant, or occasionally the whole globe for scleral need. Others routinely collect the whole globe. While the cornea and sclera are needed for transplantation, the other parts of the whole globe are discarded, unless there are known researchers with Human Research Ethics Committee (HREC) approval, needing the donation and the donor has consented for research use.

Alternatively, if the AUEB does not need tissue at that time, or if the donor is ineligible for transplant, the donor is not moved ahead in the pathway presented in Figure 1.6.1. This means that potential OTR is not collected, even if the donor may have considered donation for research only. Furthermore, this indicates a potential pool of OTR donors who could otherwise donate for research, if funding allowed for their recovery by the AUEB.

Historically in Australia, ocular tissue was provided to transplant recipients without charge, with cost recovery services philanthropically supported.³ While philanthropic and benevolent support (such as Lions Clubs) remain, each AUEB is reimbursed for the provision of a transplantable graft (e.g. cornea) by Medicare in Australia or a recipient's health insurance company, with costs outlined on the Australian Prosthesis List. In this model, tissue for transplantation is funded, while non-transplant tissue (e.g. OTR) is not funded, resulting in an individual AUEB, or rarely a researcher, incurring the cost.

Each AUEB has established cost recovery systems independently. Some are able to provide the ocular tissue to researchers without a fee, while others require a cost recovery fee up-to AU\$500. Fee structures also take into consideration any preparation (e.g. dissection or provided whole) or preservation cost-recovery needs, to meet the preservation requirements of the researcher.

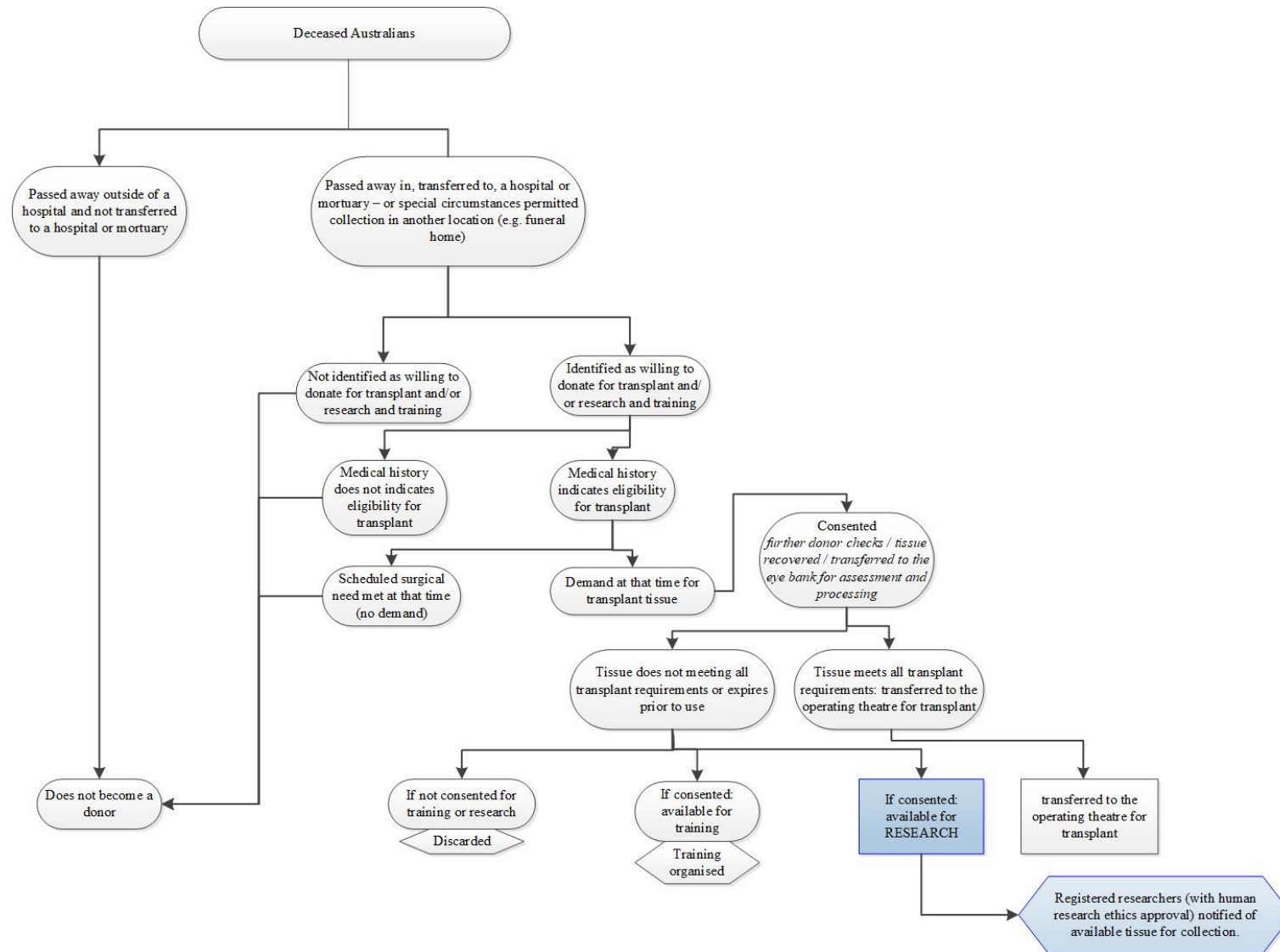


Figure 1.6.1: Current OTR pathway in Australia

1.2 Research needs

To-date, there is no centralised registry in Australia, regarding OTR utility and need. While individual AUEBs do record tissue recovered for transplant, that later becomes OTR, their data does not merge with other AUEBs/biobanks, possible imports, and other non-bank living procurement services. Nor do Australian authorities collect data on any human material required or used for research. Therefore, despite an Australian national research infrastructure scoping review anticipated to commence in 2020¹ to review and plan for access and allocation (e.g. via biobanks), today, there is no clear picture of OTR current or future need within Australia.

As an indicator of potential need, research conducted by Stamer et al.⁴— based in the USA, identified, in a voluntary survey of the Association for Researchers in Vision and Ophthalmology's (ARVO) domestic and international members, that vision-science researchers had a strong interest in using more tissue if it were easier to obtain. While no similar study has been performed in Australia, we suspect the same may also be true of Australian Researchers, with research size and design, adapted (or reduced) to meet OTR availability. As a guide, Stamer et al.⁴ also outlined that their respondents required an estimated (mean) of 4 ± 11 human eyes per month and 31 ± 111 eyes per year, though this may change if researchers had ready and routine access to OTR.

1.2.1 Examining OTR trends:

While OTR demand in Australia may not be documented or tracked, there is an increasing volume of medical research being conducted,⁵ and government policy and research design is increasingly focused on encouraging translational medicine, with concomitant translation of basic science for human medical use. Such translational work often requires greater quantities of human tissue.

For example, the emergence of increasingly sophisticated molecular and cellular methods has created new demands for OTR. These include multiple methods in biological disciplines including genomics, epigenetics, proteomics, as well as immunostaining, cell culture, cell therapy, tissue engineering, and genetic engineering. Similarly, the development of new genetic engineering approaches and single cell RNA sequencing has created a greater requirement for access to fresh tissue to assess expression profiles of individual or cell specific profiles.⁶ These innovations enable 'big data' approaches with concomitant ability to undertake analysis of very large data-sets to discover statistically significant associations through bioinformatic approaches, for example Kuiper et al.⁷; Lin et al.⁸ To fully make use of these scenarios researchers will be reliant on having access to donor tissue from hundreds or even thousands of individuals. Increased access to OTR might prove a catalyst to such advancements in the biomedical space.

As well as investigations to further medical knowledge, some of these techniques are being used in clinical trials. The facilities, networks and the skills of AUEBs, position them to not only provide tissue for pre-clinical experiments and clinical trials but to contribute through assessment of emerging genetic, cellular, tissue engineered therapies and drug response changes in tissue or structural changes (e.g. corneal crosslinking). Alongside delivering these therapies to clinicians, some of these therapies will continue to require ocular tissue, provided by AUEBs/Biobanks, for their process and preparation.⁹

Aside from the potential for new techniques and big data, researchers may have specific requirements, some of which will be different to the requirements for donation or locally available OTR. Some experimental techniques require fresh tissue to avoid artefacts resulting from post-mortem processes,⁶ for example Lukowski et al.⁶ required retinas to be fewer than 15 hours post-mortem. Other techniques require preservation methods not used within AUEB, such as cryopreservation for some immunofluorescence techniques.

1.3 Barriers to OTR

Numerous barriers prevent a steady and robust supply of adequate OTR. We attempt to explore several of these components in this section.

1.3.1 Diverting transplant-surplus to research:

The *Price Waterhouse Cooper Report* (PWCR)¹⁰ comments that Australia is meeting surgical ocular tissue need and is in a surplus state. They suggested that Australia should consider exporting surplus tissue that is not required for transplant in Australia. While they do not explain how they define meeting need, within such a scenario, we propose that a ‘surplus status’ occurs when donor coordinators and/or AUEBs decline eligible donors because scheduled surgical transplant need has been met at that time. As ocular tissue is time sensitive, the AUEBs may not be able to transplant the tissue before it expires. Currently, transplantation is the mainstream use of a donation. Wherever possible, rather than recovering excess tissue, wasting it and incurring the associated recovery costs (e.g. staffing), the AUEBs respectfully declines the donation.

While the PWCR intended to focus on Australia’s transplant need and services, with their export recommendation as a side emerging theme, and a logical first solution, that would provide transplant assistance to waiting recipients of another nation, there remains no examination of domestic OTR use as a surplus management strategy. As an alternative or simultaneous proposal, surplus transplant eligible (and ineligible) ocular tissue could still be utilised in Australia, if cost recovery mechanisms were there to support research. While not reviewed in the PWCR, OTR need, would meet other objectives of the PWCR, such as investment into Australian Research and Development (R&D) and preparing Australia, and the donation sector, for the proposed transition towards tissue engineering and cell therapy. Ironically, such future treatment options are impossible without R&D conducted using human ocular tissue, so retention of some fresh tissue, surplus-to-domestic-transplant need (and recovery of non-transplant grade tissue) could provide greater long-term potential for Australia. Without adequate access to OTR, it is likely that Australian researchers may, either: go without, being unable to complete their research, modify their experiments to meet access needs, or migrate their work, and the development potential, outside of Australia.

1.3.2 Domestic and international obtainment of OTR:

Alternatively, researchers in Australia could import OTR from other countries, such as the USA, who do have surplus tissue, that is suitable and consented for research needs.¹¹ As the USA also has a robust transplant-exportation system,¹² such exportation for research may indeed be viable. This would quickly increase access for laboratory level experimentation. There are no hard laws preventing Australian researchers doing so – assuming adherence to customs and import laws, and ensuring that any human trials using imported, or research-tissue meet the criteria of the Australian regulators.

While importation appears a viable option, Australian vision science researchers do not appear to import OTR. This may be because of logistics, handling costs, and because the researcher may need to navigate and then manage the relationship with the importer or third party distributor. The practicalities of transporting tissues from distant exporting nations in the Northern Hemisphere to Australia, is also a challenge, reducing access to the much needed fresh tissue, resulting in importation of preserved (e.g. hypothermic stored) corneal tissue only. Researchers who import would therefore be restricted to research not requiring fresh tissue (though remaining within an adequate death-to-preservation period).¹³

Within Australia, access to fresh tissue for research may be an issue due to the geographical size of the country. However as most Australian eye researchers are in East Coast cities that house most of the AUEBs/biobanks and recovery allocation practices are based on serving local first, then this access to fresh-tissue may not be an issue for most researchers. Perth is the only exception, due to its isolation on the west coast, with flight times from East-to-West taking 4.5 hours (on top of recovery, processing and land transport logistics). Therefore, fresh OTR needs, in Perth, are reliant on local self-sufficient services from the Eye Bank of Western Australia. For preserved tissue, Australia has similar death-to-preservation time processes as other countries, and shares similar recovery time, freight, cost and

overland transfer times as other larger geographical nations, such as the USA, and as such, domestic preservation methods can be tailored to meet the researchers needs.

Regardless of the nation or the donation recovery systems in place, fresh tissue poses unique logistical and practical challenges, particularly for research protocols requiring fresh tissue within tight timeframes (e.g. within 2 hours of death). Such short time periods are unpractical and unlikely to change as donation services must allow respectful grieving time to donor families, complete all donation consent steps and schedule in the AUEB recovery team, prior to the recovery and delivery to the researcher.

Proposing to import OTR from the Northern Hemisphere, while the PWCR simultaneously proposes to export surplus Australian transplant-grade tissue to other countries for transplantation, may sound absurd and inefficient but is not necessarily so. This scenario draws on elements not discussed in the PWCR, whereby the grade of the tissue may predict its use and destination. This however raises further questions, such as:

- What is research-grade and transplant-grade tissue?
- Do researchers need access to transplant grade tissue as well as non-transplant grade tissue – in order to conduct comparative studies?
- Should transplant-grade tissue be allocated to recipients today or go towards research and future therapies for future generations?
- Could donors, who are not triaged through the eligibility process (as they do not meet transplant criteria) also be recovered for research?
- Does death-to-preservation time influence use for transplantation or research?

The current process implies that Australian researchers typically receive non-diseased relatively healthy tissue with some imperfection or donor ineligibility that rendered the tissue not-suitable for donation.

1.3.3 Non-transplant grade tissue:

As some researchers may specifically seek a diseased eye, or tissue from a donor of a specific characteristic (e.g. keratoconus, that would not normally progress to becoming a donor for transplant), the recovery from non-transplant ineligible donors is essential. Access to such donors, with specific criteria, can be problematic, especially in the instance of a rare disease.¹⁴ The system is currently dependant on the relationships between the AUEB and hospital donor coordinators, to liaise and identify possible consenting donors, who are ineligible for transplantation, that may wish to donate for research specific requests. Unfortunately, identification and willingness to donate do not automatically mean the donation is recovered.² This will depend on funding to the AUEB, which is restricted, due to staffing constraints or processing restrictions or space. Additionally, without funding from the researcher or another avenue, the AUEB's willingness to recover tissue and prepare the tissue, at no cost to the researcher would become a limiting factor for the recovery of OTR.

Development of systems, to allow for ineligible transplant donors to donate, is important for research¹⁴ and may be enhanced through the use of consortia tissue management; assuming multi-AUEB/Biobank-ethical conduct was established. Consortia tissue management occurs when banks of two different natures collaborate to share skills and knowledge, in order to recover from consenting donors of a particular characteristic. For example, the AUEB may be enlisted by the brain bank to recover ocular tissue on behalf of the brain bank. This may occur if researchers are examining the pathway or investigating shared pathology between the brain and the eye, such as in Alzheimer's Disease or between the eye and other tissue such as ocular melanoma and melanoma of the skin or systematic disease within the same consented donor.

In some instances, AUEBs are contacted by researchers regarding known donors who, pre-mortem, arrange for their body to be donated to another research bank (e.g. the brain bank), or to a specific research project they participated in during their life. For example, someone who participated in a research program examining macular degeneration, may consent for their eye to be examined by the same vision-science research team, post-mortem, as the final component of their participation in that research project. In these instances, the AUEB staff are contacted to perform the recovery and

preparation because they have the appropriate recovery skills. The recovered tissue is prepared and transferred to the pre-determined researcher/bank. Such cross-bank consortia, while in occurrence in Australia, are not commonplace within the vision science sector.

1.3.4 Access to OTR type:

Without a national registry for OTR need and utility, we cannot determine the types of OTR that are routinely required by researchers, e.g. the cornea, lens, retina and so on. While Stamer et al.,⁴ survey did not ask respondents to clarify the type of tissue they required, they did collect information on the characteristics and section affiliations of their respondents. This may assist in indicating OTR type need, of the participating ARVO Members, with their main respondents being: Cornea (21%), Glaucoma (17%), Retina cell biology (16%), and Retina (10%).

While Stamer et al.,⁴ did not delve further into why the main respondents were from the cornea and glaucoma sectors, we propose that this may be based on their existing relationship with their local eye bank - whose transplant services provide for cornea and glaucoma surgical management. This means that there is a greater likelihood that tissue recovered for those transplants may become OTR if found ineligible for transplant. This is predominantly so if the AUEB tends to recover the corneo-scleral-rim as routine, as opposed to the whole globe. While this recovery process works for the transplant sector and prevents additional processing time, cost and discard of other ocular parts, it does not necessarily work for non-corneal or glaucoma OTR needs. While we were unable to find evidence, we propose that this may lead to faster and greater R&D success in the cornea and glaucoma sectors as opposed to other areas of ocular enquiry in years to come.

1.3.5 Other access avenues:

Occasionally, consenting non-deceased OTR is recovered from the operating theatre (e.g. the non-transplanted corneo-scleral rim). While the researcher may be known to the AUEB and ethics approved, the recovery is often arranged between the researcher and surgeon for a specific project. Collection practices are outside of the management of the AUEB, with responsibility placed on the transplant facility (hospital, day surgery) and ethics-approved researcher, to ensure donor consent is in place, and safe handling practices are followed prior to handing the OTR to the researcher.¹⁵ Of note: consenting living recipient/patients may also donate excised OTR (e.g. specimens, tissue of unknown aetiology or corneal buttons). While such living donation programs and specimen collections are beyond the scope of this paper, they indicate another source of OTR.

1.3.6 Competing demands for non-transplant tissue:

The increased interest in lamella surgical techniques in recent decades has also impacted OTR access, with excess recovered corneal tissue being fully utilised by physicians as they perfect these new techniques. While we were unable to find any published data pertaining to tissue allocation for training use in Australia,¹⁶ from the Eye Bank Association of America (EBAA), states that the USA, *“experience[d] a slight decline in the number of corneas provided for research from the highs of 2011 and 2012, [and can be] explained by the concurrent increase in tissue allocated to education and training purposes.”* Corcoran recalls *“that this period coincides with the development of more technically challenging endothelial keratoplasty procedures.”*

As new surgical techniques continue to be explored, with subsequent surgeon training essential, and animal tissue remaining the only simulated pre-cut-training option, then we consider the competing demands with tissue-for-training as a permanent tissue utility requirement in Australia (unless virtual reality simulation systems are developed). Therefore, other avenues for OTR access are required, to ensure tissue-for-training is simultaneously maintained.

1.4 Unlocking the barriers to access

While there may be a desire to support greater access to OTR, there are several aspects of current practice in Australia that require address.

1. There is a lack of information available to prospective donors and the next-of-kin, regarding their option to donate to research.³
2. There is no central shared record/registry for OTR, other than via the local AUEB/biobank. This means that researchers may not be aware of tissue available elsewhere, and vice versa.
 - Without a shared record/registry, the national OTR need, utility, or importation numbers remains unclear.
 - As OTR falls outside of the transplant sector's focal area, there appears to be no central body who would be responsible for the collection of the data or management of a researcher registry.
3. Tissue-for-training remains a competing need. Mechanisms to simultaneously support training and OTR are required, though development of virtual reality simulations could be a useful alternative.
4. Researchers themselves do not routinely factor in OTR cost recovery into grant proposals and project budgets. Therefore, they are reliant on sporadic access to no or low-cost domestic tissue, and are unable to afford imports or to pay cost recovery to the AUEB.
5. Researchers with specific donor criteria (e.g. short post-mortem times or specific characteristics such as a female smoker over the age of 50, or a male pacific islander with keratoconus) restrict their access to OTR. This is because OTR is not made-to-order and cannot be promised.
6. The conversation regarding demand in Australia, needs to be expanded to include examination of OTR need. It's absence to-date has resulted in exportation as the only surplus management strategy proposed to the Organ and Tissue Authority in the PWCR.
7. Access to fresh-tissue remains reliant on proximity to local AUEBs, and their collection methods.
8. The role and perception of the AUEB Custodian needs to transition beyond that of a transplant tissue provider, to one where they are the Custodian of the donation¹⁷ servicing a wide range of donor and public and sector needs, be that: transplant, research and/or training (with the potential to lead the development of simulated training options).

The above barriers are not unique to Australia. The USA is the only known nation to address such barriers through a collaborative EBAA and ARVO initiative. Collectively, they have developed a web-portal, *EyeFind*, designed to connect USA eye bankers with researchers.^{4,11,16,18}

Curcio,¹⁸ suggested that those involved in research must also make changes. She highlighted similar strategies outlined in *Principle 9 of The Barcelona Principles* (Box 1.6.1 on page 56)¹⁹ - a bioethical framework developed by the Global Alliance of Eye Bank Associations in conjunction with the global eye care and corneal communities. Curcio,¹⁸ proposed that researchers must describe their human tissue selection methods in their manuscripts; and that organisations providing the tissue must be named as authors or acknowledged partners. This highlights the collaborative partnership and ensures that there is significant demonstration of criteria for ethical and appropriate recovery and allocation.

2.0 REFORM STRATEGIES

The research, transplant, and donation sectors are interconnected – unable to improve, progress or resolve issues without co-operation. Researchers are reliant on OTR to develop new treatment options. The transplant sector is simultaneously reliant on research and development, to provide new treatment options. Finally, the donation sector is also reliant on the discovery of new technologies, to reduce the long-term burden and strain on donation services. This will ultimately lead to a point where there is a reduced need for donations, as other approaches can be used.

Regulation has not kept pace in the ever-changing research and deceased donation sectors,¹⁷ and is unlikely to do so for some time. Therefore, we propose the sector itself take a leadership role and promote change, by engagement of researchers, organ and tissue professionals and transplant professionals, to develop a policy and practice reform strategy that improves access to OTR for Australian researchers, while simultaneously ensuring such access does not compromise donor wishes, hinder transplant needs, nor undermine tissue for training needs, or potential exportation. We believe, if done in a systematic manner, Australia could become a leader in OTR practice and retain a viable vision-science research sector.

We propose a series of policy and practice strategies are developed to unblock the barriers we describe above, via stakeholders, including: The Organ and Tissue Authority, AUEBs/biobanks, vision-science researchers, bioethicists and biological health lawyers, and the professional peer associations of these groups. These strategies could include:

1. A recommendation that all researchers automatically factor in average OTR costs into their grants and budgets,³ or researchers work with their funding bodies to develop new OTR funding avenues.
2. Adherence to *The Barcelona Principles – Principle 9* (Box 1)¹⁹; all published research to include information regarding where and how they obtained OTR and its ethical origin.
3. Placement of an additional ‘Register for Research’ box on the national Medicare donor register page. This will assist in identifying OTR donors and could assist in identifying donors with specific disease characteristics.¹⁴
4. Development of a public information campaign, reemphasising consent for research options to donate non-transplant grade tissue, to research, and/or research-only donations. Information could be made available alongside information on donation for transplantation.
5. Provision of information, via a health provider (e.g. a general practitioner, ophthalmologist, optometrist, nurse) directly to patients, outlining their option to donate for research. This could also assist in increasing rare, diseased or specific demographic donation requests^{20,21} – as otherwise, such donors may not consider donation on their death.
6. Allowance of those ineligible for transplantation, who would otherwise exit the donation pathway pre-consent, to be consented and recovered as OTR-donation-only.
 - a. Funding options will need to be addressed regarding provision of OTR at either a no cost and/or at a fee subsidised by the Australian Government or another avenue as such methods may risk the sustainability of the AUEB/biobank. Our proposal is outlined in Figure 1.6.2.
7. Development of a national co-operatively managed Register, to allow ethics approved researchers to connect directly with their AUEB/biobank to match their OTR need with available donations. This system could allow:
 - a. The AUEB/biobank to arrange for ethics approved imports or cross-state/territory OTR, as required by researchers. This would alleviate navigation issues for the researcher, who would otherwise have to register with multiple-providers, work with distributors, manage the logistics and confirmation of the ethical validity of the donation and involved parties. This ensures Australian research, involving domestic or foreign donors, meet the ethical norms and legal principles that govern Australia, and those outlined within *The Barcelona Principles*, without limiting the potential of Australian Research and Development
 - b. Ensure Australia has an OTR tracking and data monitoring system in place
 - c. Improve relations between AUEB/biobank and researchers
 - d. Open-up opportunities for collaboration with other national and international eye banks, researchers, consortia, and donation agencies
 - e. Ensuing cross-sector transparency to the Australian public and government

3.0 CONCLUSION

While access to human tissue of any quantity and size is an end-of-life donation, rather than a consumable that can be demanded, if there is an unmet need for OTR, and there are donors whose donation wishes have not being met, then steps could be taken to ethically and practically, meet the wishes and needs of all parties.

Barriers to OTR include research budgeting and other cost avenues, limited access to the tissue – and in particular fresh tissue, lack of donor information,³ and a system has historically focused on transplantation. While regulatory change is a primary requirement, it is unlikely to occur in the short-term. As such, we call on sector stakeholders to strengthen their relations as leaders of this field and

work collaboratively to resolve and remove non-regulatory barriers to OTR. In doing so, Australia will retain and build its position as a prominent leader in the vision-sciences.

4.0 ACKNOWLEDGEMENTS

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PRINCIPLE 9: Ensure ethical practice and governance of research (non-therapeutic) requiring Cells Tissue and Organs (CTO). Strategy:

I.	Ensure consent for research				
II.	Provide tissue to research and technical development projects where all parties demonstrate ethically sound practices and processes				
III.	Ensure any intended research for which CTO is requested has been designed, and will be conducted, in accordance with jurisdictional law, and regulations that govern the ethical use of human tissue (inclusive of the Declaration of Helsinki/ International Ethical Guidelines for Health-related Research Involving Humans), and:				
	<table border="0"> <tr> <td style="padding-left: 20px;">a.</td> <td>obtain approval from a qualified human research ethics committee</td> </tr> <tr> <td style="padding-left: 20px;">b.</td> <td>work with scientific journals and peer associations/societies to promulgate scientific standards that honour the ethical consent of CTO for research</td> </tr> </table>	a.	obtain approval from a qualified human research ethics committee	b.	work with scientific journals and peer associations/societies to promulgate scientific standards that honour the ethical consent of CTO for research
a.	obtain approval from a qualified human research ethics committee				
b.	work with scientific journals and peer associations/societies to promulgate scientific standards that honour the ethical consent of CTO for research				
IV.	Researchers should verify that the eye bank providing the tissue has appropriate credentials, policies and practices, and is transparent and open to scrutiny (e.g. demonstrating their ethical consent process for obtaining and allocating CTO for research or further attenuation/commercialisation)				
V.	Scientific journals should establish a mechanism to confirm research is conducted on ethically obtained CTO.				
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Box 1.6.1: *The Barcelona Principles 2018*¹⁹

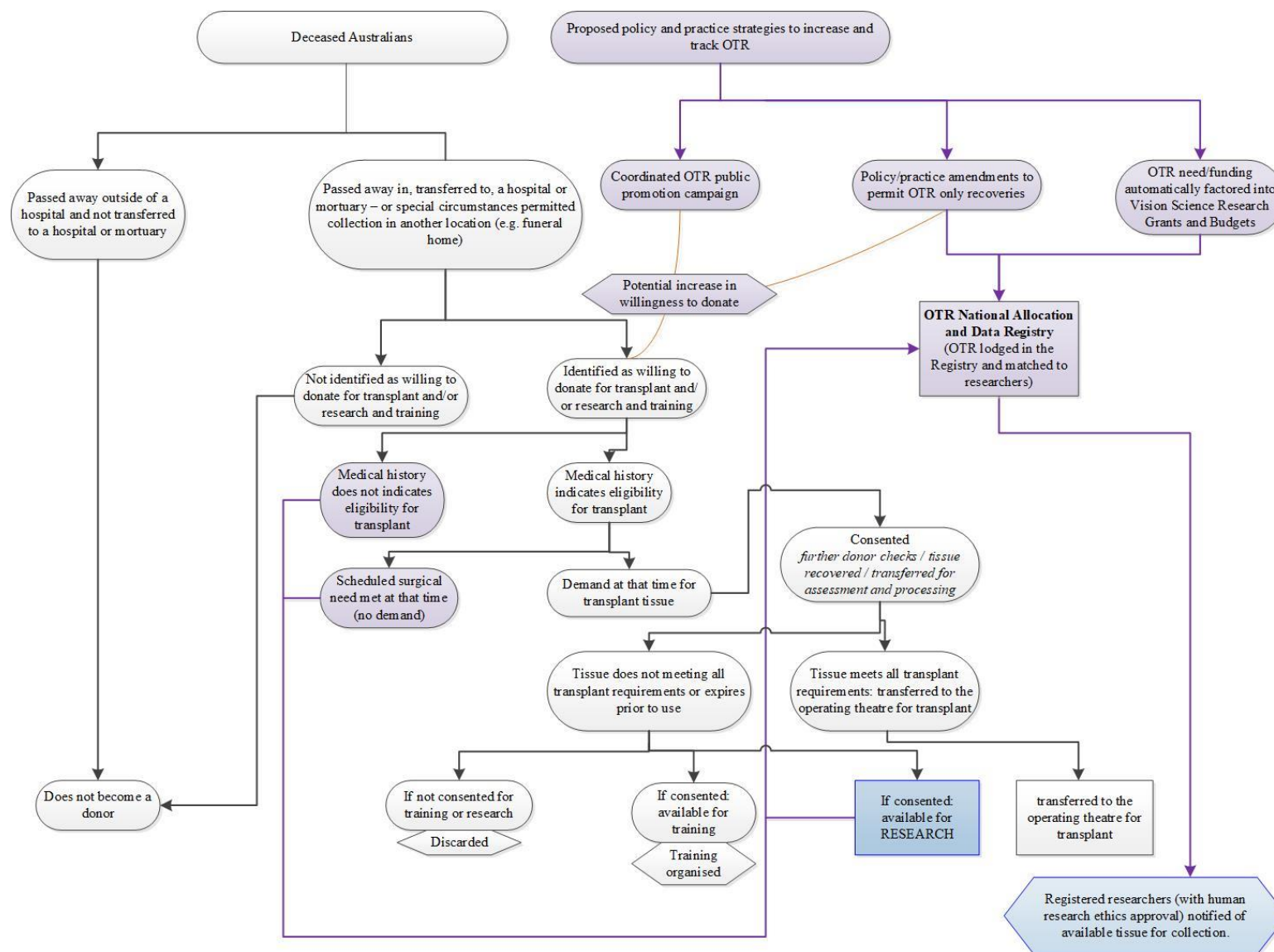


Figure 1.6.2: Proposed reform pathway to improve OTR access in Australia. Purple/filled boxes provide proposed strategy.

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1.7 CONCLUSION

Chapter 1 provided an overview of the transnational movement of CT, the EB system in Australia – and allocation options, and key definitions and terms.

It presented foundational information regarding the history, contemporary practice and levels of TNA, and a baseline for examination of key issues in subsequent chapters. Notably, the Chapter showed that there was a paucity of information to describe and define the practice of TNA both within Australia and elsewhere.

Chapter 1 demonstrated that TNA practice has been in existence since 1961 globally, and on an *ad hoc* basis, since the mid-1990s in Australia. The findings indicated that while there has been some focus on clinical impact regarding the importee recipient, as well as minimal review of non-clinical aspects, exportation practices have not been reviewed by Australia or any other nation in a systematic manner. These findings show the importance of developing a knowledge base that could inform the development of guidance material to nations like Australia when deciding to routinely export. It indicated that there were no prior examples of issues such as logistics, partner decision making, if donors should or should not be consented and how import destinations were determined or influenced by the organisations and individuals involved, nor an understanding of public willingness to support exportation. The risk for Australia, therefore, remains high, as the nation could export without the support of the public and donors, without consideration of domestic need and demand and finally, it could undermine the eye bank activities of other nations or waste the donation.

Therefore, it is proposed that Australia firstly, reconsider its position and approach towards domestic recovery and allocation for research. Secondly, it should determine what it considers to be an acceptable CT wait list and wait time for Australians and how and when Australia could routinely export without adversely impacting/hindering national demand. Finally, AUEBs must work with a wide range of stakeholders to evaluate how demand could be increased domestically in order to match domestic need in the long-term, and work with the general public to determine if Australians would be willing to export. By safeguarding domestic allocation and improving domestic services, any export systems that were implemented would in turn benefit donors, domestic recovery, and domestic allocation (to transplant, research, or training) and recipients awaiting transplantation elsewhere in the world who are without their own local access.

To overcome the deficit in the existing literature and uncover the necessary information required for Australia to be in a position to consider their position as a potential routine exporter, a series of original research was conducted – and presented in this thesis. This research examined existing use and surplus rates (Chapter 2), explored sector opinion, and unearthed information about how the practice currently occurs and the issues involved (Chapter 3), and also explored the willingness of Australians to export (Chapter 4).

CHAPTER 2.0

Quantify the potential surplus corneal tissue for export levels in Australia.

2.1 Introduction

The key research question of this PhD thesis addresses whether Australia should export CT. The findings from Chapter 1 indicated that there was a fundamental lack of information in this area with regard to guiding Australia with its decision making, and there was no information to describe Australia's export quantity capabilities.

In line with this research question, Chapter 2 aims to: (1) examine if Australia is meeting domestic demand; (2) determine whether there is, and if so, how much CT is available in Australia for export on a routine per annum basis; (3) identify similarities and difference in approach by AUEBs and their partners; and (4) consider how quantities could be managed by Australia to ensure exportation does not undermine domestic need and demand. This has been undertaken to provide a baseline for subsequent investigation in the following chapters, so as to address the circumstances in which exportation of CT should take place. It will also assist in identifying and improving state/territory level recovery and allocation pathways, and data management.

Data were collected between October 2018-September 2019, from all the 5 collaborating AUEBs. An agreed data dictionary and collection template was designed and used to collect the information. Data from all 5 AUEBs was collated and tallied as one collective national sum.

Appendix material related to this Chapter.

- SUP 04: Chapter 2 - Data dictionary tool
- SUP 05: Chapter 2 - Monthly data reporting tool
- ETH 04: Chapter 2 – National approval request
- ETH 05: Chapter 2 – National approval confirmation (18/139 HREC/18POWH/292)
- ETH 06: Chapter 2 - Data transfer agreements (template)
- ETH 07: Chapter 2 - Agreement and governance New South Wales Lions Eye Bank
- ETH 08: Chapter 2 - Agreement and governance Eye Bank of South Australia
- ETH 09: Chapter 2 - Agreement and governance Queensland Tissue Bank
- ETH 10: Chapter 2 - Agreement and governance Lions Eye Bank of Western Australia
- PER 02: Chapter 2 – Lions Eye Donation Service

2.2 Supply and demand of domestic corneal tissue and its implications on export potential - using Australia as an example.

ABSTRACT

Background: Corneal tissue importation is only possible if another country is able to export corneas, without impacting its own domestic demand. Currently, there is little evidence to indicate if export nations have such surplus capacity and in a position to export. To explore this concept, we examined our nation, Australia, which is reported to routinely decline donations, due to its ability to meet domestic corneal transplant demand. Our research offers insights and opportunities for Australia and other nations to evaluate their domestic and international supply and allocation of corneal tissue in this space. **Method:** We collated 12-months of data on collected and non-collected donations, through participating Australian Eye Banks. The explanation of why some known donors were declined or not pursued indicated if demand was met, and potential surplus-for-export levels. **Results:** There were 7.5% (n=11889) of deaths in Australia that were notified to Australian Eye Banks during our reporting period. Of those 9.3% (n=1106/11889) were recovered and allocated, 15.7% (n=1863/11889) were known but declined, and 75% (n=8920/11889) were not pursued. Of those that were declined, 64.3% (n=1197/1863) were declined due to limitations with service/manpower at the eye bank, while 35.7% (n=666/1863) were declined because demand was met. **Conclusion:** Australia did not meet demand all the time, during our data period. There were adequate quantities of potential donors to support increasing recovery for domestic allocation, and provide for exportation without hindrance to Australian demand. Further examination of domestic supply and demand cycles, and the export process, is required before routine exportation.

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1.0 INTRODUCTION

The main reason for corneal tissue exportation is to provide tissue to nations that do not have their own eye bank or are under-resourced in this area. The practice is reliant on an export nations ability and willingness to export, without hinderance to their own domestic demand. To date there has been no evaluation of export allocation, from the perspective of the exporter, nor indication that such practice occurs, or could occur, without hindering domestic demand.

To commence examination of the export practice from the perspective of the exporter, we focus on the actual as well as potential donor pathways, rather than the process of exportation. We use our own nation Australia to examine this relationship, as Australia is reported to be routinely meeting demand and declining donations and is therefore in a potential position to export routinely. Findings from the current research could be applied to other nations and other human biological types, and offers recommendations on how domestic and international demand could be managed going forward.

1.1 Australian Eye Banks

In recent years, it had been reported that the willingness of Australians to donate corneal tissue, predominantly for sight-restoring corneal transplantation, routinely surpassed scheduled surgical domestic demand.¹ As a result, Australian Eye Banks (AUEB) were reported as declining or not pursuing all known donations.^{1,2} This led to discussion within the AUEB and donation sector,² to consider recovering surplus donations for routine exportation. To support this discussion, we sought to examine first, if Australia was meeting demand, and secondly, if it indeed had sufficient surplus donations to warrant an export service without hinderance to Australia's domestic demand.

1.1.1 The donation process:

Typically requests for corneal tissue are submitted to AUEB by surgeons.^{2,3} AUEB manage the consent (within an opt-in environment), recovery, preparation, allocation, and transportation of corneal tissue to operating theatres for surgery. AUEB therefore accept and recover donations to meet operating theatre booking demand, with recipients informed that their surgery is subject to the availability of a donation following donor death.² The supply chain management of corneal tissue can be unpredictable, with intermittent demand and supply. For example, there are times when there are more deaths (donations) than scheduled surgeries (surplus to demand) and vice versa. The AUEB services are funded through the Australian Government Medicare system or the patient's health insurance company. All fees are publicly available on the Australian Prosthesis Register.² They are self-sufficient, however they operate in a national corneal tissue sharing arrangement if support is requested from other AUEB, with varied public and benevolent provider models.²

Once recovered and processed, corneal tissue has a short-utilisation window, expiring after 7-30 days (depending on the storage technology – though organ culture is the most prominent in Australia). It cannot be transplanted after expiration⁴ resulting in it being discarded. Therefore, in instances that corneal tissue demand has been met, additional donors are not recovered or pursued. Non-recovery also prevents tissue and resource waste by the AUEB. AUEB and partner hospital donor coordinators and agencies, work together to ensure the next-of-kin understands why the donation could not be recovered. For example, it could have been because: the donor did not meet the medical selection criteria, there were no available staff to recover the tissue, the donor was geographically located too far from trained donor collectors or eye banks, surgical demand was met at that time, they did not consent for alternative allocation of their corneal tissue e.g. for research, or external events prevented the recovery.

We reiterate that the object of our research is not to examine the export process or willingness of donors to consent-for-export, but instead, examine the quantity of potential corneal tissue within our example nation, Australia, that could be exported, by examining Australia's allocation toward domestic transplantation, research and training. This allows our research to determine if, through the example of Australia, a nation's rational for non-recovery or potential recovery for exportation is truly because demand was met, and that such actions would not hinder domestic demand.

2.0 METHOD

This study was approved by the Human Research Ethics Committee (HREC) of the Royal Victorian Eye and Ear Hospital [18-1374H] as part of a wider research project to examine if Australia should export corneal tissue. National approval was provided by the HREC of the South East Sydney Health District [18/139:HREC/18/POWH/292], with Governance Committees of each AUEB approving the project and data transfer agreements.

We designed and conducted a 12-month data collection project, capturing information on collected (recovered) and non-collected (known but declined or not pursued) corneal tissue donation patterns across AUEB between October 2018 – September 2019. This was a period without pandemic, natural disaster or other external influencers in Australia. A full 12-month period allowed for examination of any ebbs and flows or seasonal variations in collection periods, particularly during known periods of reduced service (e.g. Christmas/New Year break). Our design included preparation of an agreed data tool and dictionary (available in supplementary material - Data dictionary tool page and Monthly data reporting tool page) that captured information on the deaths notified to the AUEB, outlining if they were recovered or not. The tool captured how recovered donations were allocated, e.g. transplanted, discarded or allocated to research or training. Those not recovered were categorised based on donor age and why they were not recovered. Characteristics of donors known but not pursued, and those not known, were not tracked because the AUEB did not have details about the donor.

The project involved all 5 National State AUEB, located in: Adelaide, Brisbane, Melbourne, Perth and Sydney. Tasmania, the Australian Capital Territory and the Northern Territory were excluded as they did not have eye banks, but collaborate with other AUEB to arrange recovery and allocation within and between their jurisdictions.

We included information on whole-eye and corneo-scleral-rims as one whole collective sum, for the purpose of corneal transplantation only. Transplantation included first procedures, emergency, and primary and re-graft surgeries. It excluded corneal tissue used for other purposes (e.g. glaucoma shunt patches). Research and training referred to corneal tissue allocated for research and training. Waste related to corneal tissue recovered for transplantation, that was discarded, expired or found unsuitable after collection and was not consented for research and training. Waste excluded non-cornea components of the eye, discarded during the processing phase.

We used the terms ‘notified’ and ‘not-notified’ to indicate if the AUEB was aware of the potential donor, through standard procurement pathways, and if the donor is consented or not. These terms are defined in Table 2.2.1). Notified donors may not have been consented at the point of notification. Procurement pathways included automated death notification systems, and phone and email communication from affiliated donation agencies or hospital coordinators. We indicate the range of various notification systems for each AUEB in Table 2.2.2. While all AUEB were able to provide information on recovered donations, only n=4 AUEB were able to provide some information on most non-recovered donors in their jurisdiction. This is because the donations were not followed through and thus specific information about the donor was not captured. Therefore, we refer to non-recovered donors as potential donors. The remaining AUEB (Western Australia) was only able to provide details on recovered donors due to their donation-notification arrangements with their affiliated agencies.

Donor Pathway	Action	AUEB Informed of the donor	Consent is completed	Definition
Notified				Consent and pathway vary depending on if the donor is collected, or not collected (declined or not pursued)
	Collected	Yes	Yes	Consented, recovered and prepared for transplant, training and research. May be discarded if not used or damaged. Data collected by the AUEB.
	Not collected (declined)	Yes	Possibly	Consent may or may not have occurred, and the donor may have been declined depending on demand and/or the manpower availability at the closest AUEB. Some data is available to AUEB depending on their jurisdictional arrangements.
	Not-collected (not pursued)	Yes	No	This includes either, 1). No demand or manpower at the time, 2). On evaluation by the AUEB, the donor was deemed ineligible for transplantation and was not consented, and/or). If there was no training/research funding or requests for training/research at that time they may also not be pursued. Some data is available to AUEB depending on their jurisdictional arrangements.
Not notified	N/A	No	No	Deceased was not included in the donation pathway due to the death occurring outside of routine recovery facilities or routine recovery jurisdictions, they were not eligible, the donor declined, or donation agency did not inform the AUEB. The deceased would not be consented or connected with the AUEB. Data on not notified is unavailable to AUEB.

Table 2.2.1: Definition on how Australian Eye Banks (AUEB) manage notified and non-notified donors, indicating if they are aware of the deceased and/or they are consented.

The AUEB	New South Wales (Sydney)	Queensland (Brisbane)	South Australia (Adelaide)	Victoria (Melbourne)	Western Australia (Perth)
Type	Multi-tissue bank	Multi-tissue bank	Eye only bank	Eye only bank	Eye only bank
Organisational model	State Health Department / Benevolent / University affiliated	State Health Department / Benevolent / University affiliated	State Health Department/ Benevolent / University affiliated	Benevolent / University affiliated	Benevolent / University affiliated
Main cornea preservation method used	Organ culture	Hypothermic and introducing organ culture	Hypothermic	Organ Culture	Organ Culture
Provided recovered donation data	Yes	Yes	Yes	Yes	Yes
Provided non-recovered data	Mostly	Mostly	Mostly	Mostly	No
Has an automated death notification system in place	Partial: Covering South East Sydney District	Partial: Covering main referral hospitals predominately in South East Queensland	Partial: Covering main referral hospitals in South Australia	No	No
Alters their recovery criteria based on supply and demand cycle changes	Yes	Yes	Yes	Yes	Yes
Affiliated donor agency or referral hospital notify the AUEB of all end-of-life referrals and/or just those based on the criteria at that time	Yes	Yes	Yes	Yes	No

Table 2.2.2: Range of notification systems for Australian Eye Banks. Indicates the different donor notification systems Australian Eye Bank (AUEB) work within, at their jurisdictional level. While recovered donations are trackable, the system differences alter the AUEB ability to provide data on non-recovered donations. Therefore, there may be further donors eligible for exportation, research and training not captured in our study.

2.1 Analysis

The data collection tool was transferred to the *RedCap* platform, which is a secure web-based research electronic data capturing program, powered by Vanderbilt (USA). On a monthly basis, each AUEB collated and up-loaded their corresponding data. Only the Principal Investigators (Machin/Baird) accessed the AUEB data sets. On completion, data were downloaded as an *excel* file (*Microsoft, USA*) and compiled by the Principal Investigators to represent Australia's national data. During our analysis, we used the Australian Bureau of Statistics annual national death indicator report from 2018⁵ to estimate how many total deaths in Australia were notified to AUEB. We used data from the Eye Bank Association of Australia and New Zealand to compare the rate of recovered donations in our data year, to prior years, with chi-square at an alpha of $p=0.05$ used to determine the significance between the years.

3.0 RESULTS

Based on the Australian Bureau of Statistics 2018 data, there were $n=158,493$ deaths in 2018.⁵ Of those, only 7.5% ($n=11,889$) were notified to the AUEB (Figure 2.2.1). The remaining 92.5% ($n=146,604$) may not have been notified because they died in locations inaccessible, or other system factors, donor characteristics or circumstances of their death meant they were automatically excluded. While some Australians in this group would never have been eligible to donate for transplantation, others may have been. Alternatively, they may have been appropriate for donation towards research or training, if offered the opportunity, consented, and it were practically possible.

Of the $n=11,889$ deaths notified to AUEB, 9.3% ($n=1109$ donors, being $n=2212$ singular corneas) were recovered. While figure 2.2.1 represents a slightly lower collection rate compared to prior periods (e.g. Oct 2016-Sep17 $n=1359$ and Oct17-Sep18 $n=1336$ donors⁶) it was not significantly different ($p=.2$). Additionally, we found that 15.7% ($n=1863/11,889$, being $n=3726$ singular corneas) that were potential transplant eligible Australian donors were declined, and finally, 75% ($n=8920/11,889$) were not pursued. Therefore, 90.7% of all notified non-recovered donors, could have been considered and offered the opportunity to donate-for-export, or if determined as ineligible for transplantation, they could have been offered the option to donate for research and training, should the option be routinely available.⁷ Of the singular recovered corneas, 81% ($n=1805/2212$) were transplanted, with training and research receiving some provision (3.7% $n=82/2212$; 5.5% $n=122/2212$ respectively). Only 8% was wasted because it expired (5.4% $n=120/2212$) or was unsuitable (2.6%, $n=58/2212$). The remaining 1.1% ($n=25/2212$) was unaccounted, indicating the corneal tissue was undergoing evaluation and had not been allocated at the end of our data collection period.

The main rationale for not considering and recovering potential eligible donations was predominantly related to service/manpower limitations (64.3%, $n=2,394/3726$ singular corneas). The second reason to decline donations was because demand was being met at the time (35.7%, $n=1332/3726$ singular corneas). This means our finding differed to what was previously reported¹ where it was indicated donors were declined mainly because demand was being met. During our reporting collection period, we found that AUEB would have recovered more corneal tissue to meet demand, if service/manpower limitations were reduced. The remaining 75% of donors ($n=8920/11889$) were not pursued (considered), possibly because AUEB were already declining donors, so they did not need to pursue others.

3.1 Recovered vs. not-recovered corneal tissue, by month

There were periods of fluctuation in the recovery and non-recovery within our 12-month period (Figure 2.2.2). As AUEB generally recover 2-3 weeks in advance of scheduled bookings, then our data indicated that decisions to recover were based on known/forecasted demand in the coming month. For example, a rise in non-recovery in November/December indicated a reduction in transplant service in December/January, which is expected as this is the main annual holiday period for Australia. Conversely, as transplant service increased after the holiday period, more donations were accepted and declines reduced (though some still appear, indicating service levels may differ within each jurisdiction), with the peak use in August. Similar cycles occurred again in October, which anecdotally preceded the annual national ophthalmology conference. The outlier in our data is the April to June period, where we see a stabilisation of recovered donation, yet a continual rise in non-recovery.

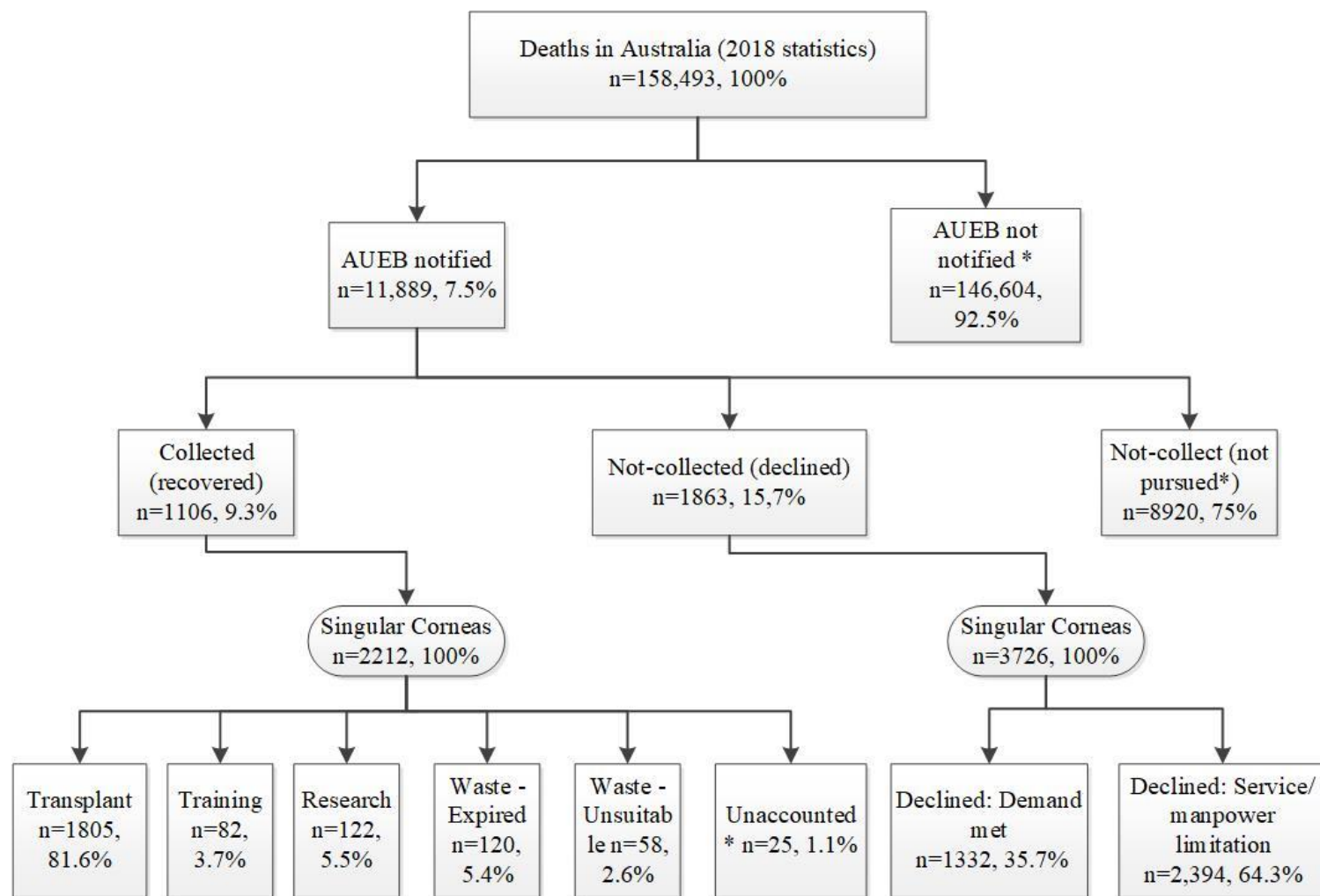


Figure 2.2.1: Results indicate if a donor was recovered or not. (AUEB not notified* = Due to the death occurring outside of routine recovery facilities or routine recovery jurisdictions, not eligible, donor declined, or donation agency did not inform the AUEB. Not pursued* = On evaluation by the AUEB, the donor was deemed ineligible for transplantation, was not consented for training/research, and/or no funding or requests for training/research at that time and therefore not pursued. Unaccounted* = donations recovered and awaiting allocation confirmation.)

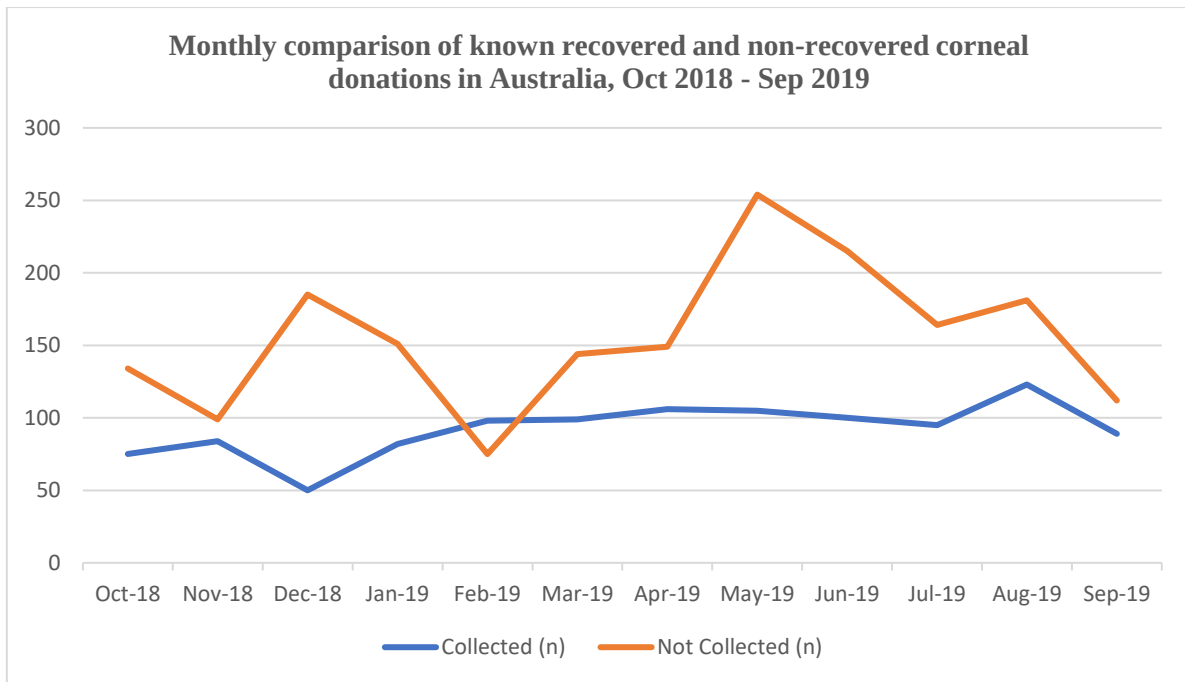


Figure 2.2.2: Monthly data. Monthly comparison of known (notified) collected or declined corneal tissue over a 12-month period by Australian Eye Banks.

4.0 DISCUSSION

This is the first-time data on recovered, in comparison to not-recovered, corneal tissue donation and allocation cycles in our example nation, Australia, have been captured and published. Our data period indicated that there were times when transplant demand ‘was’, and ‘was not’ met during various periods. It indicated that more donors could be recovered for domestic transplantation or alternative use (e.g. research) to meet domestic demand. It also supports the notion that when demand was met, that there were further donors that could have been pursued and recovered for exportation, if a robust export system had been in place at that time.

While Australia was purported to be meeting demand,¹ we found that during our data period, there were times when this was not the case. AUEB declined or did not pursue potential donors predominantly due to resource limitations, rather than because demand was being met. This indicated they would have recovered more if they had resources. While we did not collect data on jurisdictional caps/quotas, wait lists or wait time, or any increases in surgeons, operating theatre availability or requests for specific corneal tissue types, we propose that these factors influence an AUEB ability to meet absolute demand at one location or another, all of the time. Therefore, the concept of meeting absolute demand is not always possible. To counteract this change, AUEB must continually evaluate their services and adapt to continually meet changes in demand, nationally, in the long-term. These continual changes will invariably influence the surplus rates in each location, at different times. In order to capture and examine demand in full, and ensure demand is met routinely across all jurisdictions, before routinely exporting, we propose that AUEB, as a national collective:

1. Define what meeting need and demand means, and how they strive to meet those parameters routinely across all jurisdictions, and:
 - a. Monitor the changes in demand cycle, e.g. wait list length and duration, increased routine access to surgeons and operating theatres in one location may indicate demand has increased in one area, and simultaneously requires an increase in access to corneal tissue.
2. Determine where and when the pockets of under-service are occurring, and seek to prevent them by releasing more resources to increase:
 - a. staffing and quota/cap; and
 - b. inter-state national tissue sharing arrangements;

3. Prepare export programs around Australia's domestic demand cycle to ensure demand is met locally and nationally at that time, before exporting, and:
 - a. examine the notion of informing or consenting donors for export
4. Consider using higher non-demand periods as planned periods to recover and allocate for export, research or training; and
5. Increase biobanking services for non-fresh storage and later allocation, to ensure Australia has access to research tissue.

As previously described, during our reporting period we found that there were greater numbers of potential donations not recovered, than those that were in our example nation, Australia. Therefore, there was sufficient quantities of donations that potentially could have been recovered for greater domestic allocation and/or exportation. We note however that to proceed with exportation, Australia would need to: evaluate donor willingness to export, an import-nation's willingness to accept Australian corneal tissue, and determine how an export system could be tracked and funded. Australia must also review its donation pathways into research and training to determine if this provides an alternative or simultaneous donation option to exportation. This may also offer non-transplant eligible donors a greater chance of becoming a donor.⁷

4.1 Limitations

With no prior examination of non-recovery rates in Australia or elsewhere, we were unable to determine if trends have changed with recovered vs. non-recovered rates over time, or if our calculation of Australia's export potential is an overestimate. Similarly, without prior examples, it is unclear if storage methods influence outcomes, why the April to June period presented a stabilisation of recovered donations, yet a continual rise in non-recovery. We have no explanation for this pattern. Likewise, with no other nation presenting data on their non-recovered rates and therefore their surplus export potential, again we have no way of knowing how comparable our findings are and how they may differ with nations that routinely export, periodically export or never export. Additionally, as the Australian Bureau of Statistics had not published data on the total annual deaths for 2019 at the time of our writing, and nor had they published monthly death indicators for our collection period, we used their 2018 annual data to reflect the possible annual deaths in Australia, despite our collection being October 2018 – September 2019. This may result in some variations on the non-notified donor results; however, it does not alter our notified donor results.

Finally, our project was designed to collect national data on agreed criteria. Unfortunately, each AUEB was subject to jurisdiction-based arrangements with other stakeholders, e.g. State Health Departments, State donation agencies and individual hospitals. Therefore, not all data sets could be completed by all AUEB, in a uniformed manner. With the practice variance between the AUEB noted (Table 2.2.2), we acknowledge that our results do not provide a definitive quantitative answer to our question. They instead, provide a possible indication, with gaps in our data collection due to the systems in each jurisdiction. This may indicate that there could be further sources of potential donors in Australia that are not considered and offered the chance to donate. Conversely, with the inability of all AUEB to confirm for certain, via following through with donor medical-social reviews, to determine actual eligibility, then the potential eligible donor rate may reduce below what we present. That said, non-transplant eligible donors could be offered the opportunity to donate for research and training, and as such should continue to be included as potential donors for non-transplant demand.

The gaps in our data collection highlight the complexity of the eye tissue donation system, where AUEB work with multiple stakeholders. This means system variables impact and prevent their ability to determine absolute non-recovered potential donor numbers. It demonstrates that each AUEB is significantly influenced by their jurisdictional relations and processes, which can either help or hinder their ability to collect and provide effective data. We propose that our research be used constructively to highlight system deficits to prompt decision-makers to examine how data collection and information sharing can be improved at the jurisdictional level. We believe that steps to enhance data collection between the various stakeholders, will assist AUEB to meet domestic demand and coordinate and implement a transparent and effective export system that does not hinder Australian recipient access.

While we have no benchmark to reference Australia's jurisdictional differences to other nations, we feel our jurisdictional experience provides valuable insights, to help other nations or tissue groups who may be examining their demand and surplus cycle, and export potential. We propose:

1. Australia (nations) implements automated death notification systems nationally; or in the absence:
 - a. at the jurisdictional level;
 - b. AUEB and/or stakeholders routinely report information on deceased Australians recovered, and not-recovered (including approached and not-approached donors);
 - c. AUEB and their jurisdictional agencies/hospitals, coordinate and share this data; and
2. Non-recovery due to resource limitation is reviewed, and caps/quota funding and staffing adjusted to keep-up with the changes in the local and national demand cycles and wait list length and duration.

In closing, our example nation Australia needs to review its definition and perimeters of need and demand (inclusive of demand for research and training). It must increase resources to meet the demand cycle within each jurisdiction to ensure national consistency, particularly with regard to the equitable allocation of corneal tissue across the Australian recipient population. We also outline the growth-limiting steps for understanding absolute numbers of donors is due to jurisdictional system differences, which require review. We highlight that Australia may have the capacity to routinely export without hindrance to domestic demand. This warrants developing an export plan, though details such as donor consent-for-export and funding mechanisms, require further address prior to implementation, and assurance that such a system would not undermine the AUEB ability to support Australian demand. Finally, we encourage other nations and tissue groups to examine their own domestic demand cycles and surplus potential and carefully consider their engagement in exportation to ensure domestic requirements are not compromised.

5.0 ACKNOWLEDGEMENT

Eye Bank Association of Australia and New Zealand and their member eye banks.

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2.3 CONCLUSION

While prior reports indicated that Australia always met domestic demand, this Chapter actually indicated that at times, Australia does not always meet demand. It identified that there were sufficient donors available to not only meet such domestic demand but also possibly need. In addition, there are enough donations that could theoretically be recovered and allocated towards research as well as exportation.

Therefore, before considering exportation, it is recommended that Australia reconsiders its recovery and allocation patterns to ensure domestic demand is consistently met and improved across all AUEBs. Donor tracking systems should also be improved (or reconfigured) to ensure that there is a better understanding of the donations that are either recovered or not-recovered on a national basis. Having this type of data would ultimately offer further support to a nationally based domestic recovery system and perhaps to any future export system implemented in Australia.

Given that Chapter 2 results indicated there was scope for potential donations for exportation, the examination of exportation practice was therefore warranted. Chapter 3 will examine and evaluate the practice of exportation through sector interviews, and present sector opinion in a range of areas related to exportation of CT.

CHAPTER 3

Expert opinion on export and import engagement.

3.1 INTRODUCTION

Chapter 3 uses purposeful sampling of semi-structured interviews with global sector experts (n=92). Key themes were identified through the use of a grounded theory approach. The approach ascertained interviewee opinion regarding Australia's export potential and the practice of exportation in general. Through a semi-structured interview tool, participants were asked to consider and comment on various aspects of the export practice, including: who to export to and how, the consenting or informing of donors and how EB modelling and systems impact on export practice (e.g. organisational model, funding, governance, competition, and partnerships). Through the use of a saturation method (where interviews were continually scheduled until no new themes emerged), and sentiment analysis (where commentary was grouped to consolidate and determine key themes and opinion), the research captured for the first time, opinion on CT TNA - though primarily exportation, and identifies key themes regarding the practice.

Collectively, the interviews offered over 44 hours of commentary and a wealth of previously uncaptured data. This is organised and presented as multiple papers (sub-chapter 3.2-3.6) and non-published sub-chapters (sub-chapter 3.7-3.8). Sub-chapter 3.2 introduces the interviewees, the research methods and analysis steps and the overall opinion of the interviewees on Australia becoming a routine exporter. This is followed by several sub-chapters, being: 3.3. exploring how and where to export; 3.4. discussion on informing and consenting donors for export; 3.5. the impact of organisational models and behaviours; 3.6. how fees are structured and how fee structures may impact equitable allocation; 3.7. an examination of TNA to consider if the practice is in general considered good, bad, or somewhere in between, and finally; 3.8. where other aspects are considered, e.g. governance and recipient outcomes when using imported corneal tissue.

The chapter contains a combination of paper and non-paper text, being: 4 papers published in peer reviewed journals, 1 paper submitted and under review, and 2 un-published sections.

Appendix material related to this Chapter.

- SUP 06: Chapter 3 - Formal semi-structured interview tool
- SUP 07: Chapter 3 - Method and validation process
- SUP 08: Chapter 3 - Interviewee commentary
- TEM 01: Chapter 3 - Part 1 pilot PICF
- TEM 02: Chapter 3 - Part 1 pilot invitation
- TEM 03: Chapter 3 - Part 2 formal PICF
- TEM 04: Chapter 3 - Part 2 formal invitation

3.2 Should nations with surplus donated corneal tissue, export to those without? A review of sector opinion via the example of one nation – Australia.

ABSTRACT

PURPOSE: *There is a global demand for corneal tissue for transplantation, with some nations potentially able to export donations to those nations without. Unfortunately, there remains a global paucity of information that explains the process of exportation and importation (transnational activity or TNA), supports or defines practice, or informs those seeking to engage. Without knowledge, inclusive of the pros and cons, participating nations and decision makers are unable to make effective and informed decisions.* **METHODS:** *Through the example of our own nation, Australia, which may be entering a surplus-to-domestic-demand phase, and able to export, we conducted qualitative grounded-theory semi-structured interviews with sector experts. Our approach ascertained if Australia should export, and under what arrangements. Through saturation and sentiment methods, we capture for the first time, global opinion on corneal tissue transnational activity (though primarily exportation), key themes, and finally, determined if Australia should engage.* **RESULTS:** *84 (91%) of 92 participants directly commented on our question “should Australia export corneal tissue?” Of 84, n=67 (80%) stated yes, n=17 (20%) indicated mixed opinion. No participant categorically stated there should be no export.* **CONCLUSION:** *Eye tissue and eye care experts we interviewed, support the concept of Australia exporting corneal tissue, however they advise several safeguards to protect both import and export nations. Principally, they recommend practice be transparent with donors, nationally coordinated, part of a wider humanitarian program, non-profit, short-term for the importing nations as they move towards self-sufficiency, and that Australia must define and confirm domestic need, and ensure demand is met before routine exportation.*

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1.0 INTRODUCTION

Globally, approximately 12.7 million people await a corneal transplant.¹ Of these, 53% reside in locations without routine access to local or nationally recovered corneal tissue (CT).¹ Therefore, importing CT from another nation, might alleviate some pressure on those nations experiencing unmanageable wait lists. To determine if nations should engage as exporters, we used our own nation to examine the concept. Australia, described as possibly reaching a surplus to domestic CT demand level^{2,3} and potentially positioned to export, is an ideal test case. Should Australia wish to routinely export, its nation's Stakeholders must have available a range of information and evidence to examine the viability, and consider their position on transnational activity (TNA) (exportation/importation)^{3,4} and the degree and terms of such arrangements.

Unfortunately, due to a global paucity of information regarding CT TNA^{5,6} decision makers are unable to make effective and informed decisions. As such, and through our example of Australia we conducted grounded-theory semi-structured interviews with sector experts to ascertain opinion and unearth key information regarding CT TNA. We also investigated what current and potential changes nations must make to participate as exporters, and finally asked if Australia should export CT. A qualitative empirical approach was applied, because the subject had not previously been described or evaluated in the literature. Through firsthand experience and vignettes this method provided a starting point for further data mining and knowledge growth in this field.

Our research contributes to a growing calls to examine TNA, safeguard donations, promote transparency, and implement responsible and effective CT recovery and allocation practices domestically and internationally.^{4,7} Additionally, it contributes to conversations related to universal equitable access to health services in the fields of both human tissue, and eye care. Finally, our research may assist other human biological fields (e.g. musculoskeletal, skin etc.) to examine their own position on TNA.

2.0 METHOD

Study approval was obtained from the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC#18-1374H). Participant informed consent was obtained prior to any recruitment into the study, and interview recording.

2.1 Method and validation

With no prior examination available, we designed a semi-structured interview template tool to guide conversation and capture opinion. To determine what questions to include, and validate the process, we used a two-stage design approach. Stage one involved completion of a literature review,⁵ followed by the design and validation of a semi-structured interview tool (this tool is available in Appendix SUP06 page 196), ready for formal use in Stage two. Stage one is outlined in Supplementary two (available in Appendix SUP07 page 198).

2.1.1 Stage 2 formal semi-structured interview process:

Interviews occurred January-April 2019. Transcription and theme coding preparation (the organisation of themes of commentary into groups) occurred the weeks following each interview. Transcript checks, code allocation and final analysis followed.

2.2 Participants

We purposively invited sector experts not engaged in stage one. We invited and interviewed until we met our thematic saturation point – whereby responses were repetitive, and no additional themes emerged. Participants were selected based on their position in a relevant sector. Relevant Sectors included: Eye Banking (EB)ing, corneal ophthalmology, other tissue type/banks, CT allocation and distribution (exporter, importer, brokers), capacity development in the blindness prevention sector (civil societies), and tissue/human biological sectors (law, ethics and peer associations). The participants demonstrated 5 or more years in a relevant sector, awareness of current issues and future developments, and either: publications in a related topic; executive position in a related association/organization; a

review position for a related international journal; educator of related course topics; or had extensive CT cross-border experience. e.g. receiving CT, placement or distribution, and firsthand knowledge.

As the CT and EB Sector is relatively small, then recognising respondents involved via nationality, would be relatively easy. Therefore, respondents were identified via the economic status of their nation, whether their nation imported or exported (or neither), and their profession and gender. Australians were listed separately to allow an insider and outsider perspective. For non-Australian nations, we used the *2018 World Bank Country and Lending Group* (WBCLG)⁸ classification system to define each participant's nation. Participants were further defined by their nation's CT TNA, being importing nation, exporting nation, or neither (which identified the nation as self-sufficient in CT provision and meeting domestic need, or without CT services and therefore potentially not meeting domestic need). Separating national economic resource level and the degree of CT TNA was necessary as national economic levels did not necessarily indicate the degree of CT TNA, e.g. Sri Lanka, an upper-middle income nation exports (Gross National Income (GNI) \$3,996 to \$12,375⁸), while Germany, a high-income nation (GNI \$12,376 or more), imports.¹

2.3 Transcript and code preparation

Interviews were conducted in English by the lead researcher (HM) via teleconference tool Zoom Video Conferencing (USA). The duration ranged from 15-56 minutes (mean 29 minutes). Recordings were transcribed via Amazon Transcribe S3 (Amazon, USA) and manually cross-checked for accuracy. Recordings of poor quality, or where the interviewee was difficult to understand, were manually transcribed. Recordings and transcripts were stored on a secure password protected server at the Centre for Eye Research Australia. No recordings or transcripts were stored on Amazon.

Transcripts received a unique identifier, assigned in the order interviewees agreed to participate. This provided anonymity during the text analysis phase; however, on some occasions our lead researcher, recognised phraseology or vignettes that identified the interviewee, and could have influenced analysis. Therefore, a second independent reviewer (PNB) audited the transcripts to ensure memory bias had not influenced the code allocation and analysis.

Transcripts were transcribed verbatim, however we removed 'stop words' utterances, or sounds commonly used to fill the conversation space (e.g. um, yeh, and like). As Chakrabart and Frye describes these words "were not substantively meaningful and did not contribute to the identification or theme of interest."⁹ While relatively undetected during the interview, once transcribed to text, they became repetitive and distracting. Grammar and phraseology were otherwise left untouched. There was a degree of common *group-think* language which was not necessarily explored, e.g. the use of "W.H.O" universally represented the World Health Organization.

Transcripts were uploaded to qualitative software tool *NVivo 12 QSR* (*QSR International*, Australia) for analysis. Through NVivo's node-index (coding) system, segments of transcript were arranged into key common and emerging themes of commentary. This method reduced data into a form that allowed examination of sentiment, patterns and relationships.¹⁰ Each code then assisted in constructing theoretical and conceptual conclusions on group opinion. The software assisted with bringing attention to the hierarchy (e.g. repetition) of the data, as opposed to a final sentiment or judgement of the individual on one item or another. Instead, this was performed manually, as the automated analysis function was inadequate. Text included deductive content (emerging from the semi-structured tool) and inductive content (derived from the interviewee sharing additional knowledge or vignettes outside of our semi-structured tool). Emotion and comfortability with the interviews were not easy to identify once transcribed. Therefore, our manual approach ensured we picked-up sarcasm, laughter, concern and so on.

2.3.1 Code cohorts:

Our approach resulted in 7 distinct code cohorts within central, peripheral and other themed categories. Each contained sub-themes. These, arranged alphabetically, are presented in Table 3.2.1. On completion of our initial code convergence by the lead researcher (HM), our second reviewer (PNB) audited 10% of the transcripts, checking transcript accuracy, and text code placement. He also conducted a saturation

check by examining interview 1 against interviews at our perceived saturation point (79-81), and the final interview (92). He discussed any identified transcripts and code issues with the lead researcher before a unanimous decision was made to move codes and texts.

We counted the number of interviewees who commented on a theme, rather than the quantity of comments per interviewee. This was because some interviewees repeated the same statements/sentiment in various ways or digressed before returning to the key point. We examined their overall comment on each theme (sentiment). The quantity of interviewees who provided a comment on one point or another, were not used as an indicator of importance of theme hierarchy, as some interviewees provided substantive information while others provided short responses.

2.3.2. Analysis:

Codes were analysed independently. With no previous *priori* saturation threshold (meaning we had no way of knowing), we interviewed until we reached the thematic iterative saturation point for our key themes.

2.3.3 Meeting saturation:

We selected the saturation method as there had been no prior examination of this subject. This method, described by Low,¹¹ was used, because we were “unclear of the extent of various perspectives and ideas, and the number of participants needed to ensure saturation on each key point, was truly achieved.” Without any prior research to guide enquiry, our *priori* was that we might meet saturation between 70-100 interviews, though we had no way of knowing. Therefore, we concurrently invited and interviewed in real-time, until no new themes emerged.

With our question tool used to guide conversation, saturation was not linear. It emerged independently as interviewees took the conversation in one direction or another, shared comment out of sequence to our question tool, or when the scheduling of the interviews took place. For example, most Australians were interviewed first. As Australia does not currently routinely export CT, a majority of Australian interviewees were unfamiliar with the process, so questions pertaining to current export funding systems did not meet saturation until the cohort of international participants were interviewed. This meant that themes met saturation points at different times. Therefore, we did not identify any significant saturation patterns.

Main Code	Sub-Code	Interviewees who commented
Central Themes		
Australia's engagement	Existing Australian TNA practice	13
	Recommendation on how to engage in TNA	69
	Should Australia export?	84
	Where Should Australia Export to?	81
	Would TNA change Australia's Relationship?	85
Donors	Are donors consented for export in your country?	85
	Do donor and NoK have the right to select where the donation is exported to?	71
	Should donors NoK consent for export?	74
CT need	Eye care plans	79
	How is TNA and capacity development determined?	73
	International engagement and capacity development	88
	Recipient domestic vs. imported CT use	67
	Research and development	57
	Where is there need?	91
TNA	Is it good?	18
	Is it Bad?	32
	Is it in between?	78
	When not to engage	62
Peripheral Themes		
Governments, governance, law and geopolitics	Geopolitics	11
	Governing bodies that exist	81
	Governing bodies in the future	52
Business, funding and operational models	Insurance	4
	IT, tracking, data and digital allocation systems	5
	Logistics	17
	Models: NFP, FP, gratis, economics, marketing, commercialisation, commodification.	88
	Quality, standards and risk	83
	Storage mediums	5
	Third parties (distributors, brokers, affiliates)	75
	Tissue costing (fixed price, sliding scale, profit, gratis)	90
	Waste and waste management	20
Other Themes		
Country or region-specific vignettes	Africa and the Middle East	10
	Asia	21
	Europe	6
	General	1
	Pacific (Oceania)	3
	South and Central America	2
	North America	23

Table 3.2.1: Interviewee key themes and sub-theme key points. Key themes emerging from the interviews, and the number (#) of participants who provided comment on each theme. (TNA-Transnational Activity, NoK: Next-of-kin/Carer, CT-Corneal Tissue, IT-Information Technology, NFP-Not for Profit, FP -For Profit)

3.0 RESULTS

3.1 Key question to be answered

While an overwhelming amount of commentary was collected, the key question of ‘should Australia export?’ (Question 10 of the interview template shown in Appendix SUP06 page 196, and the Method and validation process in SUP07 page 198) will be explored in this paper.

3.2 Interviewee response

We recruited our participants in real-time. While we felt our code and meaning saturation points were met at n=79-81 interviews, we conducted a further n=10, totalling n=92 interviews, as several were already consented and scheduled, and we wanted to ensure we had cleared the margins of our saturation points with no additional themes emerging. During the recruitment period we invited n=171 individuals from low, low-middle, upper-middle and high economy nations (as determined by the WBCLG classification system). Of those, n=70 did not respond. A further n=9 declined, stating that they were unfamiliar with the topic or were unavailable. The remaining n=92 participated. The demographic characteristics of the n=92 participating interviewees are outlined in Table 3.2.2.

Medically trained personnel, e.g. ophthalmologists (MD), represented our largest cohort (n=49, 52%). This reflected their position as end-user importers (in the absence of local EBs) and for some, positions as medical directors within EBs and capacity development organisations. EB personnel followed at 27% (n=25). We interviewed more males than females (n=55 (55.8%), n=37 (40.2%) respectively). Australians represented 28.2% (n=26).

3.3 Geographic location of interviewees

High-income nation respondents were the largest economic group, as both exporters (n=21, 22.8%) and importers (n=17, 18.5%) (collectively n=41, 45%). This correlated with how and where CT currently moves internationally, with high resource nations, e.g. the USA recognised as major exporters¹ and regions such as Europe recognised as the location likely to afford imports. Importing low-to-middle income nations were also strongly represented (n=13, 14%), indicating the next tier of economic nations likely to afford importation, though-be-it at a lesser rate than the higher-income nations. Two nations (n=2, 2.17%) neither imported nor exported, and finally, one high income nation (n=1, 1.8%) was classified as ‘unclear’ as we received conflicting information on their TNA status.

Of the 92 interviewees, n=84 (91%) provided direct comment regarding Australia’s CT export potential. Of those, n=67 (80%) stated yes, and n=17 (20%) indicated mixed opinion. No participant categorically stated there should be no TNA. Their responses were distributed relatively equally across all professions (Table 3.2.3). The remaining 8 individuals while not providing a direct answer, offered comment on the mechanics of TNA.

From the n=84, n=26 were Australians. Of the 26 participating Australians, n=24 (92%) directly commented on Australia’s potential TNA engagement. Of the 24, n= 18 (75%) said yes, and n=6 (25%) expressed a mixed opinion. Of the 60 non-Australians, n=49 (81.6%) stated yes and n=11 (18.4%) expressed mixed opinion. Importers and those we could not confirm as engaged in TNA (unclear group) indicated yes, more than exporters (n=32 (86.5%), n=17 (74%) respectively), and low-middle income nations indicated yes more than middle-upper-high income nations (n=16 (89%), n=33 (78.5%) respectively). (Table 3.2.4) Females (x) also expressed more mixed opinion, than males(y) (y 18.36%, to x 22.8% respectively). (Table 3.2.5)

Profession (grouped)	Gender			Economic and transnational activity engagement of the participant's nation														
	Female	Male	Total	Australia	Exporting Nation. High Income Economy	Exporting Nation. Upper-Middle Income Economy	Exporting Nation. Lower-Middle Income Economy	Exporting Nation. Low Income Economy	Importing Nation. High Income Economy	Importing Nation. Upper-Middle Income Economy	Importing Nation. Lower-Middle Income Economy	Importing Nation. Low Income Economy	Neither. High Income Economy	Neither. Lower-Middle Income Economy	Neither. Upper-Middle Income Economy	Unclear	Total	%
Medical-Physician	12	37	49	12	4	1	3	0	7	7	13	0	0	2	0	0	49	53.2
Eye Bankers	14	11	25	7	13	0	0	0	5	0	0	0	0	0	0	0	25	27.1
Distributors	1	2	3	0	1	0	0	0	1	0	1	0	0	0	0	0	3	3.2
Other	10	5	15	7	2	0	0	0	5	0	0	0	0	0	0	1	15	16.3
Total	37	55	92	26	20	1	3	0	18	7	14	0	0	2	0	1	92	
%	40.2	59.8	100	28.2	21.7	1.1	3.2	0	19.5	7.6	15.2	0	0	2.2	0	1.1		100

Table 3.2.2: Demographics of those interviewed in our study. Presented as profession, gender and their nation's economic and transnational status. Professions are determined as: Medical-Physician Trained (ophthalmologists, registrars, global programs, professor, consultants director), Eye Bankers (managers, directors, technicians, coordinators, quality, relationship - domestic and/or with international from either medical science, nursing or eye related backgrounds), Distributors (brokers, partner relations managers not directly associated with a recovery, processing or allocation entity), Other (Medical-Science-Researchers, Government Employees, Regulators, civil society capacity developer, retired expert in related area).

Demographic Data	Medical-Physician Trained (n=45, 53.5%)	Eye Bankers (n=24, 28.5%)	Distributors (n=3, 3.5%)	Other (n=12, 14%)	Total n=84 (%)
Yes	39	18	2	8	67 (80)
Mixed	6	6	1	4	17 (20)
No	0	0	0	0	0(0)

Table 3.2.3: Interviewee response to "Should Australia Export?" as identified by their profession.

(n, %)	Australia (n=24, 28.5)	Exporting Nation. High Income Economy (n=19, 22.6)	Exporting Nation. Upper- Middle Income Economy n=(1, 1.1)	Exporting Nation. Lower- Middle Income Economy (n=3, 3.6)	Importing Nation. High Income Economy (n=15, 17.9)	Importing Nation. Upper- Middle Income Economy (n=6, 7)	Importing Nation. Lower- Middle Income Economy (n=14, 16.6)	Neither. Lower- Middle Income Economy n=(1, 1.1)	Unclear (n=1, 1.1)	Total (n=84, 100)
Mixed	6	5	0	1	4	0	1	0	0	17 (20%)
No	0	0	0	0	0	0	0	0	0	0 (0)
Yes	18	14	1	2	11	6	13	1	1	67 (67%)

Table 3.2.4: Interviewee response to “Should Australia Export?” as identified by their nation’s economic and corneal tissue transnational status.

(n, %)	Gender = Female (n=37, 41.6)	Gender = Male (n=55, 58.3)	Total (n=84, 100)
Yes	27(40.3)	40(59.7)	67(80)
Mixed	8(47.05)	9(52.9)	17(20)
No	0(0)	0(0)	0(0)
Mixed vs. Yes	mixed: 22.85% / yes: 77.14	mixed: 18.36 / yes: 81.63	

Table 3.2.5: Interviewee response to “Should Australia Export?” as identified by gender.

3.4 Yes respondents

The ‘Yes’ group suggested that Australia’s engagement in CT TNA would be acceptable, and that Australia should routinely engage. They proposed that Australia, as a member of the global community, had a responsibility to share and participate in international activities, especially as regional leaders, and particularly as so few countries were in a position to share. Contributing to the international pool was viewed as *“valuable, a game changer for those [import] locations [and it would] open up distribution channels.”* They indicated that such actions would support others, especially those in greater need and those situated in lower-income locations and without local access. It was viewed as honouring the gift of donation, preventing waste, an act of recycling, and a *“logical next step in the evolution,”* for a nation reported to have met domestic need. Some indicated surprise that Australia, were not already routinely exporting CT, with one high-income exporter (EBer) unclear as to *“why Australia would be hesitant.”* Several importers (from low-to-high) indicated they would like to be on the receiving end of Australian CT exportation. There was also a suggestion from a high-income exporter (EBer) and low-income importer (MD) that accessing Australian tissue would be highly desirable.

As regional leaders, it was proposed that such actions would be a *“great starting point for other nations, and might help provoke local ministries of health to see corneal transplantation as a very cost-effective”* intervention. Finally, they viewed it as, unselfishly, an *“unmitigated good and marvellous thing for humanity, with the act of donation and sharing, the greatest service human beings can give to other people”*. A majority of the yes respondents also felt that Australia needed to be meeting need and implement safeguards prior to routinely exporting.

3.5 Mixed opinion respondents

Those with mixed opinion shared similar sentiment to the yes respondents, in terms of services to humanity and preventing resource waste, however they were hesitant to provide a blanket yes response. They required *more information* explaining *how* Australia would do this, and to *whom* they would export, and a clear explanation of the motives and safeguards, indicating how Stewardship would be managed ethically, as advised within *The Barcelona Principles* and those of Australia’s own EB bioethical framework.^{7,12} They indicated further research into donor/family opinion and/or consent was required, and that they *“would need to see clear policy at a national level, and that those engaged in exportation, conducted themselves transparently, and were accountable.”*

Overall, they recommended that CT TNA be short-term for the importer, non-profit, and *“did not compete on price nor undercut the import nations own EB system or ability to build their own system.”* We noted however, that low-middle income nations did not overly describe CT TNA as an act that would wholly undermine their own domestic EB build. They viewed some components as a stepping-stone towards such development. Upper-high income nation commentary proposed the model be flexible, encompassing *“dial back”* mechanisms, to ensure import nations were able to build their own services, with both parties able to adapt to the changes in demand and technology over time. Skill exchange was a key recommendation, with interviewees indicating that engagement needed to go hand-in-hand with training of health professionals, and assistance with EB and/or corneal surgery training and infrastructure.

4.0 DISCUSSION

Our research indicated that Australian and international eye care and eye tissue sector experts engaged in our research, support the notion of our test case, Australia, routinely exporting CT on the proviso additional research and planning aspects are undertaken on several key themes we have described. These ultimately relate to transparency and safeguarding donations and EB systems. They indicate that TNA must go hand-in-hand with wider capacity development projects aimed to support the self-sustainability of import-nations via long-term planning and skill exchange, and must have the flexibility and ability to scale-back, to allow import nations the space necessary to become self-sufficient. They advise that nations who export must work in a nationally coordinated manner, and must examine if donors should be informed and/or consented-for-export. Finally, they believed TNA, while noble, must

not undermine domestic services, with steps to define and determine domestic need and demand necessary planning aspects, before routine engagement.

As the first examination of this subject, we are unable to ascertain how views or processes had changed over time, had adapted, were emerging, or if there were temporal trends that had occurred over time. Without prior examination, we have no way of telling if the interviews we conducted indicate in what direction CT TNA is heading. As original research in this field, we hope our research serves as a useful tool for those practicing today, and provides a starting point to examine the opinion, attitudes, beliefs and practice changes of the eye tissue and eye care sectors in the future.

4.1 Limitations

Due to the sub-specialisation within this sector, those knowledgeable and available to participate effectively in either Stage 1 or Stage 2 were limited. Therefore, the Stage 1 test group was kept to a minimum to ensure greater numbers of participants were available for the formal Stage 2 interview process. While the participant size may not compare with larger studies elsewhere, they indicate the specialisation of the sector and provide the detail necessary to this study.

While we did invite low-income economic nations to participate, they were the only group we were unable to secure as participants. Notably this was the cohort least likely to have EBs and corneal services in place, nor able to afford imports. One invitee, in this cohort, who declined to participate, indicated they were not currently engaged in CT TNA or corneal surgery training/services, and felt they had nothing to contribute to the conversation. We were unclear if and how our findings would have altered if this cohort had participated. Though we suspect their opinion would have mirrored those of low-middle income nations, by supporting the premise.

While 79-81 was our saturation point (though we concluded at 92), we would not like to stipulate on a *priori* threshold for meaning and coding of future studies in this field, as this was the first attempt to gain a theoretical understanding of the opinion and the key themes. More exploration of saturation points for semi-structured interviews in this field may be required to confirm the threshold. From our experience, we have no gold-standard, rubric or key recommendation on determining saturation points in this field. Finally, our research does not examine the opinion of donors in export nations nor recipients and those on wait lists in import nations, who may provide an alternative perspective for consideration.

4.2 Interviewee recommendations

Interviewees provided several recommendations necessary to examine, prior to routine CT TNA engagement. In brief they recommend Australia:

1. Explain how meeting domestic transplant need/demand/supply/surplus is determined, and confirm it is met before exportation. This is essential as some interviewees indicated Australia may not always be meeting need, despite a report suggesting that they were² and raised questions on what a suitable wait time should be in different jurisdictions. They also believed some CT should be retained for domestic research, however how domestic research need interacts with, competes or complements TNA, requires examination.
2. Ascertain potential quantity of export CT.
3. Determine donor opinion, confirming if education and/or a consent-to-export processes are required.
4. Determine and validate appropriate export destinations, partnerships, funds, and terms of arrangement in-line with non-profit, capacity development strategies and *The Barcelona Principles*.
5. Develop a national strategic approach.

In closing, we acknowledge this is the first foray into this subject matter. We do not provide a definitive answer on whether or not nations should export CT, nor Australia's specific engagement. We simply provide an answer, from the perspective of a range of content knowledgeable individuals engaged in contemporary practice. Nor can we say with certainty, if and how nations like Australia will choose to engage, though we hope this research will contribute to the body of evidence necessary for decision making. Finally, we believe our research has reproducibility and transferability, and can be applied to other biologicals, other nation test cases, and from the perspective of importing rather than exporting.

5.0 ACKNOWLEDGEMENT /THANKS

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3.3 Sector opinion, on how corneal tissue should be exported, and to whom – using the example of Australia as an export nation.

ABSTRACT

Purpose: 22.8% of annual global corneal transplants occur through the movement of corneal tissue between nations. While the practice has existed since 1961, unfortunately, there remains a paucity of information describing how export/import occurs, who the key stakeholders are, how this impacts those engaged, and the recommendations and pitfalls. This means eye banks, surgeons and governments, who seek to engage or withdraw from the practice have little information to guide their decision making. **Method:** Through the example of our own nation, Australia, we conducted grounded-theory semi-structured interviews with sector experts, via saturation and sentiment analysis methods. We unearthed previously undescribed information, and captured recommendations influenced by interviewee real-world lived experience. Finally, we asked interviewees if Australia routinely exported, how this should occur, and how they should decide where to export to? **Results:** Interviewees recommended a nationally governed non-profit and transparent collaborative approach, and that domestic demand must be met before exportation. If third parties were to be engaged, clear policy was advised. They proposed low-resource neighbouring nations be prioritised, followed by low-resource nations in Australia's wider geographical region. **Conclusion:** Corneal tissue export/import requires careful planning with national stakeholders, to safeguard both export and import nations, and ensure practice does not undermine either nations self-sustainable directives. Engagement must be transparent and in the best interest of donors, ensuring donations are exported systematically and fairly to those awaiting a transplant in foreign lands.

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1.0 INTRODUCTION

Globally, an estimated 12.7 million people await a corneal transplant,¹ 53% of which are without routine local access to the donated corneal tissue required for surgery, rendering them reliant on transnational activity (export/import). In many instances corneal tissue transnational activity allows surgical intervention for recipients who would otherwise go without treatment.

Current global corneal tissue transnational activity data is unavailable, however Gain et al.¹ indicated approx. 22.8% of total transplants performed globally were conducted using corneal tissue engaged in transnational activity, during their 2012-2013 data period. While 27 nations solely imported, a further 43 imported to assist local shortfall. Only a handful of nations were routine exporters. The USA, Sri Lanka and Italy were most prominent, with Nepal, The Philippines¹ and Australia² participating to a lesser *ad hoc* extent.

Despite corneal tissue transnational activity commencing in 1961,³ there are few publications describing how it is conducted by nations, or how nations decide on their export strategies, and terms of their arrangements.⁴ While The Barcelona Principles provide a recommendation on the Principles of transnational activity⁵ it remains unclear, as to who is involved or indeed how tissue is moved. There is little information to support the evolution of the service, e.g. scaling-up or down, or assisting importing nations to work towards self-sufficiency. This has resulted in corneal tissue transnational activity evolving in a relatively *ad hoc* manner by each eye bank (EB), or cooperative of EBs, and their importing partner ophthalmologists, distributors and transplant centres. Data capturing has been voluntarily provided to peer professional associations where available.

To address the dearth of knowledge in this field, our research used our nation, Australia, as a test case. We conducted grounded theory semi-structured interviews with contemporary international EB and eye care experts to unearth key practical and logistical recommendations. Through our guided conversations, we asked, in the event that Australia was to become a routine exporter, how should this occur? We document for the first time, how corneal tissue transnational activity decision making might be rationalised and planned, addressing critical issues such as where to export (which countries), how that destination can be determined, and by what method. Our research provides an overview of key aspects of corneal tissue transnational activity (e.g. logistics) previously undescribed in the literature.

Our goal was not to dictate where Australia or other nations may or may not export to, but provide an example of how decisions, and engagement frameworks could be developed, to rationalise their decisions. Our hope is that our research encourages greater sharing of knowledge in this field, improves transparency, and provides guidance to those seeking to engage or withdraw, and assist national decision makers when considering corneal tissue transnational activity and their terms of agreement.

2.0 METHOD

Approval for this study was obtained from the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC#18-1374H). Participant informed consent was obtained prior to any recruitment into the study.

As we described in our prior publication (Machin, Sutton, Baird, 2020⁶) we purposively invited Australian and international EB and eye care experts to participate in grounded-theory semi-structured interviews. We used the saturation and sentiment approach to unearth key themes. Responses were arranged into key subjective significant themes, ready for manual sentiment analysis. We describe the methodology, validation, interviewee demographics and the semi-structured interview tool in our prior publication.⁶ Our approach resulted in N=92 consented professionals from a range of nations, national economic statuses, transnational activity perspectives and professional backgrounds (including EBs, ophthalmologists, third party distributors/brokers, capacity development and governance professionals).

While several key themes were captured in our interviews, within this paper, we will only outline conversations and recommendations, pertaining to *how* Australia could export, and to whom, and under what arrangement.

3.0 RESULTS

3.1 Destination practicalities and barriers

Despite knowledge of a global need for corneal tissue, rendering any export activity valuable, interviewees predominantly alluded to practical, political and quantity aspects, as the key rationale for their transnational activity decision making.

Firstly, Australia has a relatively small population compared to other export nations, e.g. the USA, and the practicality of Australia exporting widely or to the same degree was deemed unlikely. A High-Income Exporting EBer stated that Australia's participation "*is probably going to be a drop in the bucket compared to what is needed ... but doing whatever you can is always a good thing.*" This is an essential point, because if Australia has lower quantities to share, then they are unlikely to provide an effective system for either party if they scattered corneal tissue across the globe. Interviewees overwhelmingly recommended that, after Australia, it's nearest geographic neighbours were its priority.

Secondly, Australia is located in the Western Pacific Region, close to South East Asia, playing a dominant regional leadership and political role. The Australian government and eye care sectors focus policy and funding on these regions, prioritising a range of humanitarian and non-medical trade related partnerships. Interviewees indicated that collaborating with, or leveraging from, established programs related to relevant government funded focused schemes (e.g. AusAid) or Australian led capacity development programs, agencies and peer groups, would prevent reinvention of the wheel, prevent EBs working in isolation, help to vet partners and develop a concentrated support program. Focusing on a few neighbouring countries, at first, was also viewed as simultaneously allowing Australia to cement itself as an exemplary export nation, and perfect the process, while helping to pool resources and focus on key regional goals.

Another High-Income Exporting EBer, who did not think Australia should be limited by geography, stated "*I would avoid, if you try to export to places that already have decent access to imports. It's not going to have the [same] kind of public health aspect.*" Though they went on to propose that this may place Australia into an unwanted crowded global and competitive marketplace. In essence Australia's neighbouring countries do fit this description. For example, there are no EBs nor routine exportations (or routine corneal training programs) in neighbouring Papua New Guinea or the Pacific Islands. Indonesia and other regional nations do have EBs and a variety of programs, and do import, but whether or not they need Australia's assistance requires further investigation.

Thirdly, practicality and logistics dominated interviewee recommendations. Commentary suggested singular flight destinations, rather than multi-flight destinations, or arrival within ten hours from departing the Australian EB, though if there was a need to go over 10 hours, it was suggested not to exceed 24 hours. This was suggested to prevent placing the corneal tissue in transit for long periods and prevent possible complications during upload and reload between air and land carriers. Some interviewees described first-hand experience with delays, lost deliveries and other incidences, e.g. road crashes and closures, as real-world events preventing delivery before (or close to) corneal tissue expiry. We note however that there are no global public records indicating how significant or frequent logistical error and delay are within existing global corneal tissue transnational activity, as described by our interviewees. Regardless, shorter flights were believed to facilitate quicker access to re-graft material and emergency material, and improve access to fresher corneal tissue. It was considered more sensible, despite one interviewee feeling that the advancements in modern aviation and sophisticated long-haul freight distribution systems meant it did not (or should not) matter where corneal tissue is exported to. Finally, some interviewees quoted a prior publication that suggested corneal tissue may deteriorate during the transfer phase⁷ as significant to the conversation. The study they referred to demonstrated that shaking or vibrations during transfer contributed to a reduction in the corneal endothelial cell count. We note however that despite the existence of this research and other outcome studies, that this has not curtailed corneal tissue transnational activity to date.⁴

Other aspects identified, included: export and import licence requirements in some nations, increased paperwork from the Ministries of Health, tracking demands, managing airport freight and customs

personnel and rules, ensuring shipping containers were sealed according to policy and handled while in the custody of the courier/freight company, and consideration of additional time required to transfer the corneal tissue prior to expiration. While some controls were identified, e.g. courier tracking number, it was commented by several high-income importing and exporting Ebers, that the process was at the mercy of the transport sector, to ensure it met the connections and arrival expectations (with the exception of weather and disaster disruptions as accepted possible delay explanations). Additionally, while undocumented elsewhere, interviewees alluded to corruption with import Custom Control Officers in some nations, as a significant concern.

Two high-income exporting Ebers shared that they felt a greater degree of stress when managing exports. They described feeling restless until they were confident the donation had cleared customs and reached the surgeon. One indicated they did not sleep well when they knew they had corneal tissue in transit. They confessed to regularly checking the tracking status via the couriers tracking app. when at home and overnight.

Finally, the impact of delays and close-to-expiry-date dispatch practices, on import nations, was reported by multiple low-middle-income importing MD interviewees. They described having to re-arrange operating schedules in order to use the corneal tissue before expiration. This placed pressure on their recipients, some of whom travelled great distances, at short notice to attend. Lastly, pressure on the import health workforce e.g. operating theatre nurses, was also raised. Interviewees recalled that they had to retain staff longer, with some until midnight, to ensure close-to-expired corneal tissue was used before expiration.

3.2 How to export

Interviewees predominantly recommended a comprehensive, well-regulated, coordinated and monitored non-profit approach to Australia's export system, particularly at a national level. In this model, EBs would transfer corneal tissue to the export destination, as determined by the national coordinated system. The system was proposed to manage stakeholder agreements, vet receiving surgeons and transplant centres, ensure domestic need was met prior to exporting, and ensure the system was accountable, evaluated, tracked, and monitored.

While the vehicle or placement for a coordinated approach was not universally determined by interviewees, one Australian Eber did indicate that Australia's own EBing association, the *Eye Bank Association of Australia and New Zealand (EBAANZ)* could manage this system. Conversely, another Australian Eber did not feel EBAANZ, as a peer organisation rather than a service organisation, had the infrastructure to facilitate this process, and the system required engagement with other governing bodies.

As no nationally coordinated export approach (rather than an EB only approach) exists elsewhere in the world (to the best of our knowledge) in which to leverage from, then implementation of a nationalised approach was proposed as a positive, game changing step in how corneal tissue transnational activity could be managed, decided upon and monitored.

While some (n=11) interviewees directly suggested a government-to-government approach, overwhelmingly the remaining interviewees recommended that governments were one stakeholder alongside EBs, surgeons, transplant facilities and donor groups, and that all stakeholders must be engaged collectively. Interviewees indicated that transparency, clear policy, a regulated system, and safeguards were a necessary function of any future system.

When asked how Australia could or should conduct corneal tissue transnational activity, interviewees described 8 key areas that required address, being: 1. Confirm Australia's domestic status, 2. Confirm donor consent-for-export, 3. Identify and engage Stakeholders, 4. Guide dialogue, 5. Implement agreements (between stakeholders), 6. Use capacity development principles, 7. Plan carefully, and 8. Implement processes and systems. We outline the key themes in Table 3.3.1, which are accompanied by selected commentary from the interviewees.

Discussion Area	Common Recommendations	Selected Statements from Interviewees
1. Confirm Australia's domestic status	Define the terms: demand and meeting need within Australia	<i>[You need to] define [the] path for excess tissues, that there is an equitable appropriate avenue for export of tissue, before you go gearing up the donation site. (Australian MD)</i>
	Confirm demand is met at the time of donation, before exporting	
	Simultaneously plan for domestic training and research CT demand	
	Develop a flexible model that can scale-up or down to meet fluctuations in domestic and export demand	
2. Confirm donor consent-for-export	Inform donors and families of export process and options	<i>The public needs to know ... [they need] total transparency. (Australian Other)</i>
	Consent-for-export (or consent to opt-out of export)	<i>Be careful in what we're going to do ... [we don't want] a decrease of donation [because of the] way that the population sees the eye banking work ... they can start [saying] I'm not going to donate because you were making money with that. I think that that's really something that we have to be careful with. (High-Resource Importing MD)</i>
	Retain transparency with the public, donors and families, and healthcare systems	
3. Identify and engage stakeholders	A. Stakeholders identified (listed)	<i>[There is a] lot of stakeholder in the whole process ... I don't think it's just even, eye banks, saying hey, I've got some spare corneas, can I get rid, can I get them used somewhere? I think it has to be discussed at even, at a. It has to be a government level. Governments have to know what's going on. It has to be agreed that this is an acceptable thing to do. (High-Income importing EBer)</i>
	Australian Health Minister's Advisory Group	
	Chief ophthalmologist and surgeons	
	Prevention of blindness representatives	
	Governments (e.g. Departments of Health and/or Foreign Affairs in both countries)	
	Regulatory bodies	
	Eye bankers	
	Transplant centre management (e.g. chief nurse)	
	Eye care non-government organisations	

	Domestic peer group: Eye Bank Association of Australia and New Zealand (EBAANZ)	
	Global peer group: Global Alliance of Eye Bank Associations (GAEBBA)	
	B. Engagement	
	Use existing networks, contacts	
	Work with those you trust and can work with (good partnership)	
	Vet partners (reputable and good track record)	
4. Guide dialogue	Speak openly about transnational activity	<i>I am pleased that you are taking on this difficult subject. It's an important debate to have and it's clearly not going to go away ... it has to start somewhere. (Australian MD)</i>
	Discuss the pros and cons	<i>People don't like to talk about it ... it comes across almost as being like organ trading and things ... If we don't sort these things out for tissue now ... with cell therapy, things now [are] getting more, more complicated (High-Resource, importing MD)</i>
	Open-up communication	<i>If we do not have these conversations or just do not discuss this, and have some legislation planned, then it's just too open to abuse or misinterpretation. And then people are going to get the wrong idea. And then there will be issues moving forward. (High-Resource, importing MD)</i>
	Improve cooperation between stakeholders	<i>Start talking more about all the details of these types of issues, not just the principles and the good will aspects. (High-Income importing EBer)</i>
5. Implement agreements (between stakeholders)	Develop a national (centralised) coordinating body and export system	<i>We don't actually have a united distribution system in Australia. So, at the present moment, how that should be done? I would think individually. Ideally, if all the distribution within Australia was a unified system, then distribution overseas should be part of that unified system. (Australian MD)</i>
	Design the system as a non-profit and non-commercial activity	

Alignment with Australian principles and ethical guiding documents (e.g. EBBANZ, TBP, NHMRC, WHO)	
Implement a formal national export position statement for Australia	
Seek federal funding to support a national approach	
Ensure agreement between import and export Departments of Health	
Ensure agreement between import and export Departments of Foreign Affairs	
Develop core criteria to guide import destination selection	<i>[It is] something that is a diplomatic bonus, and it should be counted, and it shouldn't be just written off from the bottom line of [eye] banks and Australian donors in that way. (Australian Other)</i>
Manage CT exportation independently of other export human biologicals	
Confirm the chain-of-custody (ensure supply-lines can be tracked through Stewardship)	
Allocate in a coordinated national framework (rather than <i>ad hoc</i> provision or to surgeons to take overseas)	
Determine costs fairly, for import and export partners, but not to the detriment of Australians or the EBs	<i>Be very careful because the sector is moving into for-profit. (High-Resource Importing Other)</i>
Collect and report statistical data and outcomes (consider inclusion in the Australian Corneal Graft Registry)	<i>Someone ultimately take legal responsibility for distribution. (Australian Other)</i>
Exported CT are selected and allocated within the same regulatory and quality approach as provided to Australian recipients and surgeons	
Receiving country to meet core criteria	<i>The margin of gains should not be excessive so that it would be out of the reach of the donor agencies and that, the quality of tissue being sold, should be on par with the quality that you're providing locally. (Upper-Middle Resource Importing MD)</i>
Receiving surgeons/hospitals registered in the national body	

	Australian tissue is equitably accessible within agreed import nation, and allocated based on practical surgical intervention priority (e.g. race, creed, colour or religion not considered)
	Agree on how a surgeon or transplant facility charges forward the costs (e.g. does not increase the price to the recipient or change)
	Any gratis tissue matched by gratis surgical and transplant facility provision

Table 3.3.1: Recommendations. The table outlines the 8 key overall recommendations (column 1) from interviewees, relating to how they believe Australia should export corneal tissue (CT). They are accompanied by a consolidated recommendation list (column 2), and selected interviewee comments (column 3). EB = eye bank, MD = medical doctor ophthalmologist, EBAANZ = Eye Bank Association of Australia and New Zealand, TBP = The Barcelona Principles, NHMRC = National Health and Medical Research Council.

3.3 Professional relationships

Export nation interviewees already engaged in corneal tissue transnational activity indicated that existing professional relationships were important in determining partnerships, and where to send to, as trust, reliability, and knowledge of the importing surgeon and affiliated staff and facilities, were key factors to their allocation. Likewise, importers felt they needed to trust exporting EBs before accepting their corneal tissue. In the instance of *ad hoc* volunteer humanitarian programs (occasionally referred to as ‘missions’), some interviewee exporters allocated to destinations, not based on their knowledge of need/demand or the agreements at that destination’s national level, but primarily on their own degree of trust in their own local surgeons who were participating in that program (e.g. as volunteers or mediotourists). Again, this provision was based on trust and relationships rather than via a coordinated national approach by either import or export nation. Traditional and existing relations, while not a systemised approach, were universally deemed important. However for some interviewees, predominantly those managing programmatic and planned capacity development programs, this method was not always deemed as an effective allocation method, as the practice may not be conducted within the key targeted goals as defined by either nation. Meaning, some interviewees were unsure if corneal tissue was distributed to the right location and recipient, when EBs only allocated if their local surgeons were involved at the import destination, or if it was distributed because of personal connection (e.g. a place a key member of the EB/MD Team once lived or retained an affiliation with). They were also unsure if relationships and volunteerism-based allocation undermined import nation EB development.

3.4 Transfer process

Interviewees advised to dispatch corneal tissue to the import EB, or directly to the transplant facility in the absence of an EB. There were some export EB interviewees who used surgeon-couriers, mostly during *ad hoc* volunteer fly-in-fly-out programs. They were recognised as sometimes necessary; however, they were not wholly described as part of the general day-to-day export practice.

Third party engagement, previously undescribed in the literature, was an additional service option that interviewees discussed. These agencies (alternatively referred to as brokers or distributors), both for-profit and not-for-profit, do not recover or process corneal tissue, but engage in the administrative transfer process from EB/processing centres in one nation, to surgeon or transplant facilities in another nation. Opinion was split on their use. Some interviewees indicated that they had no issue with working with third parties, finding them (or the concept) extremely useful and helpful to get the corneal tissue to its destination faster, e.g. third parties may manage the relationship and the administration and export process, which allowed EBs to focus on recovery and processing aspects. Conversely, other interviewees felt the third party sector was an unregulated and ungoverned area of service, which invariably marked-up corneal tissue and provided additional layers of complexity. Interviewees described third party lack of accountability, price mark up, and funds-transfer hording, with evidence of doctoring of the documentation.⁸ We note, however that we could not find any further information describing their role or degree of legal accountability in comparison, or in conjunction with singular or cooperative partner EBs, and nor could we find peer evidence to validate or condemn them. With the exception of South Korea, where there is a legal requirement to import via third parties, our interviewees felt a direct EB-to-EB, or EB-to-transplant facility arrangement (in the absence of an EB at the import destination) were the first options. This ensured a direct communication line was retained between the EB and transplant centre and surgeon. This was deemed important to safeguard donation during transfer and use. They felt third parties were valuable when there were no local EBs to liaise with or the EB was unfamiliar with the import location.

3.4.1 Determining export destination: decision matrix:

Finally, interviewees were asked to recommend where Australia should export to. Each suggested several locations. In summary, n=38 nations and all global regions were proposed as export destinations for Australia (Table 3.3.2). To understand and narrow-down these suggestions and develop a workable framework, we applied several steps to developing a decision matrix.

Firstly, we used the *2018 World Bank Country and Lending Group (WBCLG)*⁹ classification system to describe each proposed destination. Within this modelling, the majority of interviewees recommended a generalist geographical region, rather than a specific nation, however we noted that geographical definition descriptions varied, e.g. Asia or South-Asia were used interchangeably. Overall, all world regions were proposed by all n=92 interviewees. When examining which specific nations they proposed, again under the same classification criteria, our interviewees predominantly suggested low-middle income nations (n=15 nations, via n=45 interviewees), followed by upper-middle income nations (n=8 nations via, n=22 interviewees), and finally high-income nations (n=8 nations via, n=15 interviewees). We were unable to include interviewee recommendations for Nauru and the Cook Islands in this modelling, as they were not listed in the WBCLG, and nor did we pursue a recommendation for Yugoslavia as it is now a dissolved State.

Interviewee Direct Recommendation	Nation total (n)	Region total (n)	WHO Region	WBCLG Economic status
Africa	10	16	Africa	n/a
East African countries	2		Africa	n/a
Northern Africa	1		Africa	n/a
Sub-Saharan Africa	1		Africa	n/a
West Africa	1		Africa	n/a
Eritrea	1		Africa	LM
Far/Middle East	3	6	Eastern Mediterranean	n/a
Djibouti	1		Eastern Mediterranean	LM
Pakistan	1		Eastern Mediterranean	LM
Sudan	1		Eastern Mediterranean	LM
Eastern Europe	1	5	Europe	n/a
Europe	1		Europe	n/a
Croatia	1		Europe	HI
England	1		Europe	HI
Yugoslavia (now dissolved)	1		Europe	n/a
Caribbean	1	10	The Americas	n/a
Latin/South America	3		The Americas	n/a
Argentina	2		The Americas	UM
Brazil	1		The Americas	UM
Colombia	1		The Americas	UM
Peru	1		The Americas	UM
United States of America	1		The Americas	HI
Asia/Asian Countries/Region	14	55	South East Asia	n/a
South Asia	13		South East Asia	n/a
Bangladesh	1		South East Asia	LM
India	5		South East Asia	LM
Indonesia	9		South East Asia	LM
Japan	5		South East Asia	HI
Myanmar (Burma)	4		South East Asia	LM
Thailand	3		South East Asia	UM
Timor Leste	1		South East Asia	LM

your region/backyard first/doorstep/neighbourhood/near Australia/nearer countries	17	75	Western Pacific	n/a
Asia Pacific	2		Western Pacific	n/a
Pacific/Islands/Region/Nations/Indo-Pacific	9		Western Pacific	n/a
Cambodia	4		Western Pacific	LM
China (PRC)	7		Western Pacific	UM
Cook Islands	1		Western Pacific	Not listed
Fiji	2		Western Pacific	UM
Korea (Rep.)	2		Western Pacific	HI
Laos (PDR)	3		Western Pacific	LM
Malaysia	5		Western Pacific	UM
Melanesian	1		Western Pacific	n/a
Micronesia	1		Western Pacific	n/a
Mongolia	1		Western Pacific	LM
Nauru	1		Western Pacific	Not listed
New Caledonia	1		Western Pacific	HI
Papua New Guinea	7		Western Pacific	LM
Polynesians	1		Western Pacific	n/a
Singapore	3		Western Pacific	HI
Taiwan	1		Western Pacific	HI
The Philippines	1		western Pacific	LM
Vietnam	5		Western Pacific	LM
All the world/any country/anyone and everyone, anywhere, don't restrict to any nation/don't necessarily be limited to any geography	9	9	Any	n/a

Table 3.3.2: The regional and national export destinations recommended by our interviewees as export destinations for Australia. Responses are accompanied with their World Health Organization (WHO) geographical regional classification and the 2018 World Bank Country Lending Group Classification (WBCLG) economic status for each destination. *LM* = low-middle Income economies (Gross National Income (GNI) US\$1,025 or less, and US\$1,026 to US\$3,995), *UM* = upper-middle income economies (GNI US\$3,996 to US\$12,375), *HI* = high-income economies (GNI US\$12,376 to MORE), *n/a* = regional groups and dissolved states.

Secondly, we reviewed recommendations based on the *WHO's* 6 regional classification system.¹⁰ In this modelling, interviewees predominately recommended Australia export to the Western Pacific Region (n=75), followed by South East Asia (n=55). Those geographically closest to Australia, e.g. Indonesia (n=9), Papua New Guinea (n=7), and the Pacific Region - as a collective Western Pacific destination (n=32), dominated suggestions. China (PRC) (n=7) while further away, was proposed equally to Papua New Guinea, however as they currently prohibit importation, then for the foreseeable future, this is an unprobeable export destination.

Finally, we analysed recommendations via a common-grouping perspective (Table 3.3.3). In this approach we isolated the top ten frequently mentioned nations and analysed their viability as an export destination based on the interviewees own 3-point recommendations of 1. Western Pacific - determined by the WHO categorisation, 2. Low-Middle Income Nation - determined by the WBCLG categorisation, and 3. immediate neighbour, as described above within section *Destination practicalities and barriers*. In this approach, Papua New Guinea scored highest, with Cambodia, Indonesia and Vietnam equally considered as next appropriate. As our interviewees predominantly bunched Pacific Islands as one collective location, we were unable to un-pack and include each Pacific Island in our 3-point analysis, though we acknowledge that several nations within that region meet the 3-point criteria.

While we have provided a 3-point criteria for determining who Australia could export too, from the perspective of the exporter, we highlight that exporting to any nation requires considerable consultation with import nation stakeholders, based on their current degree of need and demand (wait list), EBing system, existing imports, availability of operating theatres and staff, trained surgeons to facilitate the surgery, and/or corneal training programs, to ensure transnational activity does not undermine their current system and own development. Therefore, the specific named nations, recommended by our interviewees, does not automatically confirm that those nations require assistance or would become export partners with Australia. We provide this as an example only, of how export nations may wish to determine and justify their engagement with one import nation to another.

Ranking		Location and Classification			Interviewee Recommendations			Recommendation Score
Rank order	Frequency Respondents Recommended (n)	Nation	WHO	WBCLG	Western Pacific	LM Income Nation	Immediate Neighbour	Yes, score out of 3
1	9	Indonesia	South East Asia	LM	No	Yes	Yes	2
2	7	China (PRC)	Western Pacific	UM	Yes	No	No	1
	7	Papua New Guinea	Western Pacific	LM	Yes	Yes	Yes	3
3	5	India	South East Asia	LM	No	Yes	No	1
	5	Japan	Western Pacific	HI	Yes	No	No	1
	5	Malaysia	Western Pacific	UM	Yes	No	No	1
	5	Vietnam	Western Pacific	LM	Yes	Yes	No	2
4	4	Burma/Myanmar	South East Asia	LM	No	Yes	No	1
	4	Cambodia	Western Pacific	LM	Yes	Yes	No	2
5	3	Thailand	South East Asia	UM	No	No	No	0
	3	Laos (PDR)	South East Asia	LM	No	Yes	No	1
	3	Singapore	Western Pacific	HI	Yes	No	No	1

Table 3.3.3: 3-Point Criteria Matrix. This matrix demonstrates how the ten most frequently recommended nations (ranked as 1 to 5 alphabetically), meet the interviewees own recommendations, based on three-point criteria of exporting to: 1). low-middle income nations, 2). Western Pacific nations, and 3). neighbouring nations. It indicates that Papua New Guinea meets this criteria (score of 3/3), followed equally by Cambodia, Indonesia and Vietnam (score of 2/3). WHO = World Health Organization, WBCLG = World Bank Country Lending Group, LM = low-middle Income economies (Gross National Income (GNI) US\$1,025 or less, and US\$1,026 to US\$3,995), UM = upper-middle income economies (GNI US\$3,996 to US\$12,375), HI = high-income economies (GNI US\$12,376 to more).

4.0 DISCUSSION

For the first time, we have collected commentary from multiple experts around the world, regarding corneal tissue transnational activity, and specifically asked how nations, like Australia, may routinely engage. Our approach was not to dictate where and how Australia may engage, but provide insights into the process, encourage further evaluation, and demonstrate how foundation matrixes and knowledge sharing may assist those already engaged, those seeking to engage or those seeking to withdraw from the practice. We reiterate that our research indicated the recommendations from our cohort of interviewees only. It does not automatically indicate the destinations they propose would be export destinations for Australia, as nation stakeholders would need to examine a range of additional evidence and practical and logistical aspects. Proposed nations would need to indicate interest in partnering with Australia, with both parties agreeing on the terms of the arrangement and ensuring practice does not undermine either nations effort.

If Australia was in a position to export via a national system, then interviewee recommendations to export to immediate neighbouring nations and then the wider region seems practical and logistically appropriate. Emphasising allocation to low-middle income nations within those regions would also compliment Australia's existing regional relationships and goals.

As low-middle income nations may not be in a position to fund all of the reimbursement costs for the corneal tissue, then gratis or its provision at a lower reimbursement rate could be arranged. Though, if the rate was lower than the rate offered to Australians, then Australia would need to develop a national costing-system to ensure Australian subsidisation was accounted for, and not left to the EBs to self-determine or bear the burden of the cost. For example, nations who already have an Australian Aid agreement in place may be able to receive corneal tissue through that existing arrangement. This would support both nations and the EB sector with funding, traceability and monitoring.

Interviewees described a centralised non-profit national system as appropriate in administering and monitoring Australia's corneal tissue transnational activity, with checks and balances in place to protect the corneal tissue during the partner selection and transfer phase. They suggest that this could develop a new wave of global expectations on how and where corneal tissue is moved. If third parties were to be engaged, then Australia, via the national mechanism, would need to examine the value such service provides, to justify the additional costs, and ensure clear accountability of all parties involved in the chain-of-custody.

Finally, leveraging from existing partnerships and relationships could enhance the process and ensure trust was maintained between all stakeholders. Mechanisms to transition current professional relationships we describe, into nationally agreed framework partnerships, would support those EBs uncomfortable with releasing corneal tissue, to locations they were unfamiliar with, and ensured Australian donations were exported to agreed export destinations within an agreed national framework, rather than based on Australian surgeon and EB familiarity.

We note with concern, the impact that close-to-expired corneal tissue allocation may have on some import nations. We propose Australia automatically exports fresher corneal tissue, thus offering greater time between arrival and expiration. It might alleviate pressure on already strained import health services, offering surgeons and the health workforce a great work-life-balance. It may also offer a safer care environment for recipients, by allowing them time to arrive, and by ensuring the surgeon and workforce caring for them are not fatigued. Finally, it may reduce overtime wage costs incurred by the transplant facility. This is significantly important in low-middle income nations who experience comparatively lower levels of health fund resources.

Other aspects beyond the scope of this paper, such the capacity development (e.g. allocating in conjunction with infrastructure and training provision), defining domestic need/demand, cost-structures, quotas, tracking systems, donor opinion and potential consent-for-export requirements, would also require evaluation before commencement. Specific process details e.g. management of recalls, or provision for re-grafts or emergencies would also need to be unpacked, to prevent practical and legal hitches for all parties.

In closing, we have described key recommendations necessary for nations when determining their degree of corneal tissue transnational activity, or withdraw. The candour and willingness of our interviewees to share their experience and recommendations, provides a foundation understanding of previously undescribed practice and processes. Our approach has unearthed a wide range of themes, that have never been captured, tracked or recorded, that would benefit from further examination. For example, how often do logistic issues occur? Can they be prevented? How stressful is transnational activity on employees tasked to manage the transfer? Is this something employers could examine to ensure employee work-life-balance is maintained? Can the sector develop guidelines and regulations to support engagement of third parties in a transparent manner? Lastly we emphasise that export and import nations must collaborate and determine their own degree of corneal tissue transnational activity or withdraw, and we highlight that they may benefit from developing a decision matrix. The 3-point matrix we describe could be altered to include other scenarios or classification systems, as deemed appropriate by nation stakeholders.

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3.4 Should donors' consent to export their corneas? Examination of eye tissue and eye care sector opinion.

ABSTRACT

Purpose: Corneal tissue international activity is only possible because of the willingness of export populations to donate their corneas on their death. Current pre-donation public education campaigns and at-the-point-of-donation consent practice generally includes consent for transplantation, research and/or training. It is unclear if a consent-for-export step is universally included in the consent process or indeed if it should. We interviewed eye tissue and eye care professionals from around the world, who either exported, imported or did neither, to understand current consent-for-export awareness and determine opinion on future practice. **Method:** During wider qualitative grounded-theory semi-structured interviews with sector experts, to determine if Australia should export, we captured sector opinion on consent-for-export. We used saturation and sentiment methods to determine opinion, and chi-square correlation coefficients to examine association, using an alpha of $p = 0.05$. **RESULTS:** We interviewed $N=92$ individuals, $n=83$ of which discussed consent-for-export. Of those, 51% ($n=42/83$) demonstrated some awareness of the practice, however there were contradictions between interviewees from the same location. Regardless of current awareness, 57% ($n=41/72$) believed donors should be informed or consented for export. Their approval did not extend to donor-directed decisions which would allow donors to decide which nation their donation should be sent, with 62.5% ($n=45/72$) opposing that notion. **CONCLUSION:** Our research indicates the consent-for-export practice is not universally applied by exporting nations, and that eye tissue and eye care professionals have limited awareness of the practice. Universally implementing a consent-for-export step within general consent practice would improve awareness, reduce confusion, and support donor wishes.

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1.0 INTRODUCTION

Corneal tissue international activity is the practice of exporting donated corneal tissue from one nation and importing them into another.¹ It allows waiting corneal transplant recipients, in locations without locally recovered corneal tissue, to undergo surgical treatment. It is estimated that international activity accounts for 22.8% of annual global transplants.² While some aspects have been investigated, e.g. impact of transportation on corneal tissue integrity,³ to date the practice of consenting or informing donors that their donation may be exported (consent-for-export) remains unexplored and unclear.⁴

The principle of general consent is universal yet applied differently between opt-in and opt-out donation systems. It routinely includes consent (or expressed/formal intent to withdraw)⁵ for transplantation, research and training as outlined within human tissue and eye tissue guiding documents and legislation (Tissue Acts) at national and jurisdictional levels. In contrast, and despite global seminal frameworks such as *The Barcelona Principles: An Agreement on the Use of Human Donated Tissue for Ocular Transplantation, Research, and Future Technologies*⁶ and the *WHO guiding principles on human cell, tissue and organ transplantation*⁷ encouraging system review, consent-for-export practice has not been awarded the same national or universal attention. This means, some eye banks (EB)s may be required to consent-for-export based on their jurisdiction, while others may voluntarily participate and some not at all. Regardless, we were unable to find public information to indicate how donors were informed or consented-for-export,³ if at all, nor their degree of willingness to participate. The benefits or barriers of the current approach, on the overall donation and allocation practice, has also not been evaluated, and there has been no debate in the literature to examine if donors should or should not be consented or informed about exportation. The general public and eye tissue and eye care sector's opinion and recommendations have also not been captured and analysed.

With so little attention, there is no way of knowing if current practice is indeed best practice. Nor are there opportunities to consider how practice could be enhanced to meet donor and recipient expectations or the eye tissue and eye care sector's recommendations. While examination of public and sector perspectives are necessary, for this paper, our research focuses on sector perspectives only.

During a broader research project to determine eye tissue and eye care opinion on exportation, and to determine if nations like Australia should export, we unearthed previously uncaptured opinion relating to consent-for-export practice.⁴ Sector interviewees were asked to share their awareness of current practice. They were then asked if they believed donors should be informed/consented-for-export, and finally, if donors had the right to direct where their donation could be sent? While our wider project addressed several key themes, this paper only presents responses pertaining to consent-for-export.

2.0 METHOD

Approval was obtained from the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC#18-1374H). Participant informed consent was obtained prior to conducting the interviews.

During semi-structured interviews with sector professionals,⁴ we captured knowledge and opinion on corneal tissue donor consent-for-export activity. We purposively invited interviewees until we reached the thematic saturation point. We used a semi-structured interview tool to guide rather than define the interview (SUP06 on page 196). This allowed interviewees to take the conversation in one direction or another and ensure a range of themes were unearthed. While we met our thematic saturation point at n=81 interviews we concluded at n=92 interviews to ensure we had cleared the margins of the saturation point, and unearthed all relevant themes and opinion. Interviews were conducted by the same researcher (Machin) recorded via Zoom Video Conferencing (USA), transcribed through Amazon Transcribe S3 (Amazon, USA), then text mined and coded using NVivo 12 QSR (QSR International, Australia) for subjective significance. We used sentiment analysis to interpret opinion. To prevent bias, a second researcher (Baird) audited the transcripts, code allocation and analysis process.

The N=92 interviewees hailed from n=42 nations, including low-middle to high-income economic nations (described based on the World Bank Country Lending Group Classification⁸). Their professions included: eye banker (EBer), medical doctor/director/ophthalmologist (MD), and

distributor/broker/third party (Distributor), with the remaining civil society and government professionals presented as one collective group referred to as 'Other'. Their nation's corneal tissue international activity status was depicted as: exporter, importer, neither, Australian (as we were examining if Australia should export) and finally, an 'Unclear' group which indicated a nation that we received conflicting information regarding their corneal tissue international activity. The methods are outlined in full in Machin, Sutton and Baird, 2020.⁴

In relation to consent-for-export, we guided conversation to address three key questions: 1. Are donors consented-for-export?; 2. Should donors be consented-for-export; and 3. Should donors direct the export destination? The first question gathered information on the sector's current awareness. Questions 2 and 3 indicated how they would like to see the practice conducted, regardless of their current awareness or the current practice.

As our semi-structured interview approach guided, rather than dictated or forced conversation, then interviewees discussed the consent-for-export concept on their own terms. This meant responses were individualised with some commenting on all three aspects, while others commented on one, two or none. Sentiment analysis extracted their awareness and opinion, which we grouped and present as 'yes', 'no', 'don't know', 'unclear response', 'depends', and 'if asked'. We then used chi-square correlation coefficients to examine association between opinion and the interviewee's profession and their nation's international activity status, using an *alpha* of $p = 0.05$.

3.0 RESULTS

3.1 Are donors currently consented-for-export?

To understand current awareness from the perspective of our interviewees, we altered how we framed the question based on their nation's international activity status. For example, those whose nation exported were asked if their nation consented-for-export, while those that imported were asked if the corneal tissue they received was consented-for-export. Finally, those whose nation did neither, were asked if they knew the status in any other nation.

Of $N=92$ interviewees, $n=85$ provided general commentary on the concept of consent, however only $n=83$ (76%) shared their opinion on current practice. Overall, 51% ($n=42/83$) were confident of their awareness of the practice by answering a direct 'yes' or 'no' (Table 3.4.1). Of those 22% ($n=18/83$) indicated donors were consented-for-export (yes) (Table 3.4.1) whereas 29% ($n=24/83$) indicated donors were not (no), and 43% ($n=36/83$) did not know. The remaining 6.0% ($n=5/83$) provided comments that we were unable to interpret (Unclear) because they were either vague or contradictory.

While there was no significant relationship between professional type and awareness ($p = .12$), those that did not know if donors were consented-for-export were predominantly MD (57% $n=25/44$) and Others (50% $n=7/14$) compared to 17.4% ($n=4/23$) of Ebers (Table 3.4.1). Conversely, 78% ($n=18/23$) of Ebers gave a definitive 'yes' or 'no' (43.5% $n=10/23$, 34.8% $n=8/23$ respectively). Finally, both distributors indicated specifically, that the jurisdictions and the partner EBs they engaged, did consent-for-export.

Definitive 'yes' or 'no' responses were not universally reflective of nations per se, but based on local jurisdiction legislation and practice. For example, one *High-Income Exporting Eber* stated, in relation to USA EBs, "Yes. In general, there is. It depends where you're located ... there's a little bit of grey area there." Meaning, exporting interviewees of the same nation while appearing to contradict each other, responded based on which jurisdiction they resided.

When examining awareness based on the international activity status (Table 3.4.2), we found that there was a relationship ($p = .001$), with 77% ($n=17/22$) of exporting interviewees providing a yes or no response depending on their location (59.1% $n=13/22$, 18.2% $n=4/22$ respectively). Conversely, importers (51.5% $n=17/33$) and Others (neither 100% $n=3/3$; and *Unclear* 100% $n=1/1$), predominantly did not know either way. Importers indicated they did not ask for information from their exporter about their consent-for-export practice prior to accepting the donation. Instead, they assumed it must be done if the corneal tissue was being exported or had not thought to find out.

	EB n=23 (28%)	MD n=44 (53%)	Distributor n=2 (2.4%)	Others n=14 (16.86%)	Total n=83 (%)
Yes	10(43.5)	4(9)	2(100)	2(14)	18(22)
No	8(34.8)	11(25)	0(0)	5(36)	24(29)
Don't Know	4(17.4)	25(57)	0(0)	7(50)	36(43)
Unclear	1(4.3)	4(9)	0(0)	0(0)	5(6)

Table 3.4.1: Degree of consent-for-export awareness, by profession. Presents the degree of awareness regarding current consent-for-export practice by our cohort of interviewees, presented based on their profession. EB = eye banker, MD = medical doctor/director/ophthalmologist, Distributor = broker/third party/distributor, Other = civil society and government professionals.

	Australian n=24 (29%)	Exporter n=22 (26.5%)	Importer n=33 (39.7%)	Neither n=3 (3.6%)	TNA Unclear n=1 (1.2%)	Total n=83 (%)
Yes	1(4)	13(59.1)	4(12.1)	0(0)	0(0)	18(22)
No	11(46)	4(18.2)	9(27.3)	0(0)	0(0)	24(29)
Don't Know	10(41.7)	5(22.7)	17(51.5)	3(100)	1(100)	36(43)
Unclear response	2(8.3)	0(0)	3(9.1)	0(0)	0(0)	5(6)

Table 3.4.2: Degree of consent-for-export awareness, by transnational activity status. Presents the degree of awareness regarding current consent-or-export practice by our cohort of interviewees, presented based on their TNA Status. TNA = Transnational Activity.

Lastly, interviewees of the same profession, and in the same jurisdiction, contradicted each other. For example, Australia has a Trans-Tasman arrangement to share corneal tissue on an *ad hoc* basis with New Zealand and to a lesser extent Asia-Pacific for humanitarian purposes.⁹ Despite their arrangements, Australia does not have a national or jurisdictional donor questionnaire that routinely informs or consents donors for export. Out of the Australian Interviewees 46% (n=11/24) were aware that it does not exist (Table 3.4.2). Despite that, one Australian EBER in one jurisdiction indicated that donors were consented-for-export in Australia. To demonstrate that this was not a jurisdictional difference, we also interviewed another EBER and an MD from that same jurisdiction. Both indicated that Australia does not have a process in place. This demonstrates that the practice at the jurisdictional level, as well as the national and global level, is not uniformly understood.

3.2 Should donors be consented-for-export?

Regardless of current consent-for-export practice and our interviewees awareness, we asked interviewees if donors should be consented or informed?

Of our interviewees, 66% (n=72/92) responded. Of those 57% (n=41/72) believed donors should be asked (yes) and 31% (n=22/72) believing they should not (no) (Table 3.4.3). The remaining believed donors should only be informed when they asked (2% n=2/72). Finally, 10% (n=7/72) believed it depended on the situation, e.g. they justified informing the next-of-kin, if it helped their grieving process as opposed to informing them because of curiosity.

When examining the ‘yes’ numbers by profession, then 52.6% (n=10/19) of all EBers, 51.3% (n=20/39) of MDs, 100% (n=2/2) of Distributors and 75% (n=9/12) of Others indicated ‘yes’ to consent-for-export (Table 3.4.3). When examined based on international activity status their responses were distributed fairly evenly across all status types (Table 3.4.4). We did not find a significant relationship between interviewee opinion and their international activity status and profession ($p = .2$; $p = .7$ respectively).

	EB n=19 (26.3%)	MD n=39 (54%)	Distributor n=2 (2.7%)	Others n=12 (16.6%)	Total n=72 (%)
Yes	10(52.6)	20(51.3)	2(100)	9(75)	41(57)
No	6(31.8)	13(33.3)	0(0)	3(25)	22(31)
Depends	3(15.8)	4(10.3)	0(0)	0(0)	7(10)
If Asked	0(0)	2(5.1)	0(0)	0(0)	2(2)

Table 3.4.3: Interviewee opinion on consenting donors for export, by profession. Interviewees opinion on consenting donors for export, presented based on their profession. EB = eye banker, MD = medical doctor/director/ophthalmologist, Distributor = broker/third party/distributor, Other = civil society and government professionals.

	Australian n=24 (%)	Exporter n=16 (%)	Importer n=28 (%)	Neither n=3 (%)	TNA Unclear n=1 (%)	Total n=72 (%)
Yes	14(58.4)	9(56.25)	17(60.7)	1(33.3)	0(0)	41(57)
No	7(29.1)	5(31.25)	8(28.6)	1(33.3)	1(100)	22(30.5)
Depends	3(12.5)	2(12.5)	2(7.1)	0(0)	0(0)	7(9.7)
If Asked	0(0)	0(0)	1(3.6)	1(33.3)	0(0)	2(2)

Table 3.4.4: Interviewee opinion on consenting donors for export, by transnational activity status. Interviewees opinion on consenting donors for export, presented based on their on their TNA Status. TNA = Transnational Activity.

The ‘yes’ response rationale, for supporting the consent-for-export concept, was consistently related to transparency and safeguarding donations, by installing trust in the sector, and preventing population donation withdraw in the future. It was generally considered an act of respecting the donor, and that donors had a right to know how and where their donation would be used, and in turn participated of their own free will. They believed donors would assume allocation nationally but not internationally, with consent-for-export a reasonable step to include. Due to the volume and richness of their responses, we provide a sample of their commentary in supplementary material - Interviewee commentary page.

Opposition to the concept depended on certain factors. The ‘no’, respondents overwhelmingly felt that someone in need, was someone in need, regardless of their geographic location, and that a gift of donation, was a gift. They believed that consent for transplantation (or research and training) was sufficient, pointing out that current practice does not routinely inform, nor consent for use at the town/city, jurisdiction and national levels either. They questioned why international allocation would make a difference to the current consent process. While some did not approve of a formal full consent-

for-export step, they did support transparency in terms of informing donors that their donation may be exported. Opposing interviewee responses are provided in Appendix SUP08 page 206.

3.3 Directed export donation

Our final question asked interviewees if donors had a right to select which export destination/nation their donation should be sent? 62.5% (n=45/72) believed donors should not decide the destination (no) while 19% (n=14/72) believed they should (yes) (Table 3.4.5). This response was consistent across all the professions and types of international activity statuses (Tables 3.4.5 and 3.4.6) and without significance (profession $p = .6$; international activity status $p = .7$).

	EB n=19 (26.3%)	MD n=38 (52.7%)	Distributor n=2 (2.7%)	Others n=13 (18%)	Total n=72 (%)
Yes	5(26.3)	7(18.4)	1(50)	1(7.6)	14(19.4)
No	12(63.2)	23(60.5)	0(0)	10(77)	45(62.5)
Don't know	0(0)	6(15.8)	1(50)	2(15.4)	9(12.5)
Depends	2(10.5)	2(5.3)	0(0)	0(0)	4(5.6)

Table 3.4.5: Interviewee opinion on donor-directed export decision making, by profession. Interviewees opinion on donor-directed decision on where their donation is exported to, presented based on their profession. EB = eye banker, MD = medical doctor/director/ophthalmologist, Distributor = broker/third party/distributor, Other = civil society and government professionals.

	Australian n=21 (29%)	Exporter n=17 (23.6%)	Importer n=30 (41.6%)	Neither n=3 (4.1%)	TNA Unclear n=1 (1.3%)	Total n=72 (%)
Yes	4(19)	2(11.8)	7(23.3)	1(33.3)	0(0)	14(19.4)
No	14(66.7)	13(76.4)	16(53.3)	1(33.3)	1(100)	45(62.5)
Don't know	3(14.3)	2(11.8)	3(10)	1(33.3)	0(0)	9(12.5)
Depends	0(0)	0(0)	4(13.3)	0(0)	0(0)	4(5.5)

Table 3.4.6: Interviewee opinion on donor-directed export decision making, by transnational activity status. Interviewees opinion on donor-directed decision on where their donation is exported to, presented based on their TNA Status. TNA = Transnational Activity.

‘Yes’ respondents believed donors should have the right to decide where their donation goes, because it was their donation. If directing the donation was the caveat for collection, they believed it should be honoured. Conversely, those who indicated ‘no’, primarily had two reasons: 1. practicality, and 2. prevention of xenophobic, racial or geopolitical allocation decision making. They indicated that donors cannot domestically direct the donation and that this premise should be applied internationally, highlighting that this premise is outlined in a range of human tissue soft guiding tools and legislation at various jurisdictional, national and global levels. Finally, this cohort indicated that donors, in general, would not know where there was the greatest need, or which surgeons/hospitals in other nations were vetted to receive donations based on the export nation’s guidelines. They believed that sector members were the experts in this field, who could (or should) navigate where donations are directed internationally, as part of their custodian duty. A selection of interviewee responses are available in SUP08 on page 206 - Interviewee commentary page.

4.0 DISCUSSION

Our research, via our interviewee cohort, highlighted that there is limited awareness of the consent-for-export step amongst eye tissue and eye care professionals. In particular, just over half of our respondents were aware, with the remaining unclear. We identified that there does not appear to be national legislation or a sector wide guiding tool to describe or support the implementation of uniform practice. We also identified that jurisdictional differences within the same nation can create confusion, however professionals in nations that export were more likely to know if such practice occurred. We imagine it would become even more complex and confusing, if the exporting EB entity recovered from multiple jurisdictions all with different degrees of consent-for-export practice. Further complexity and confusion could be added if corneal tissue is moved from multiple locations to a centralised facility (patchwork model) located in yet another jurisdiction, before the corneal tissue is allocated internationally. Therefore, without uniformed and transparent practice or policies in place to cover the range of business models, then understandably, there is confusion.

Communication from exporters regarding their policy on consent-for-export is paramount, however we note that the end user importers (mainly MDs) were not routinely enquiring from their provider EB/distributor, information regarding their consent-for-export policy. Importers tended to assume that the consent was obtained, indicating that it would not have been exported if it was not approved. Though from whom they believed the approval would come (e.g. donor, EB or legislation) was not defined.

In the absence of clarity around consent-for-export, the practice cannot be examined or improved. Additionally, the public and donors have little information available to guide their understanding of what they believe does or does not happen with their end-of-life donation. For example, in 2019 a USA mother of a child-donor took to social media to express anger in the exportation of her child's corneal tissue. This story subsequently went viral, beyond the USA borders.¹⁰ While we cannot claim to know the whole facts in this case, the mother stated that she did not want her child's donation to be exported for-profit. In this case, we identify two independent factors, interpreted as the same activity, by this mother: 1. exportation, and 2. profiting. The confusion here is that exportation occurs in non-profit and for-profit systems, and profit occurs domestically (in her nation) as well as in export scenarios. Unfortunately, there is very little information publicly available, to pre-emptively prevent this confusion amongst the community or to dispel concerns. It would be prudent then, for the sector to consider how it can learn from this example and improve transparency by consenting-for-export and identifying how and where they export, and how these arrangements are determined. Explaining and separating factors such as export, from for-profit, may also assist in alleviating concern. This may allow the sector to ascertain if hesitation is because of exportation or because of profit. For example, could donor reluctance to export be related to the assumption of what they perceive as wrongdoing (e.g. black market or profiting)? Alternatively, is hesitation based on xenophobia, racial or geopolitical/nationalistic bias or simply a lack of awareness of the practice. If these were some of the reasons, then surely steps to alleviate and dispel misconceptions would be beneficial to the donor, recipient and sector.

Regardless of current practice and awareness, our respondents indicated that donors should be consented-for-export, proposing it as a key requirement of transparency and the retention of donor trust in the sector. The majority drew the line at donor-directed decisions, highlighting that donors were not necessarily knowledgeable about where need was, at any given moment. Their proposal that it was the responsibility of the professionals to ensure transparency of practice and to inform donors of how and where they may export their donation, has merit. This approach would ensure respect for the donor while preventing xenophobia and discrimination to those with the greatest need. Additionally, as our interviewees were cognisant of respecting donors and safeguarding access for recipients, we conclude that the gift-relationship is a dominant feature of our interviewees own decision making, alluding to the premise that the gift-relationship continues to hold a dominant central position in contemporary practice. Based on our research, we recommend:

1. Using seminal global guiding principles to reform practice, e.g. *The Barcelona Principles: An Agreement on the Use of Human Donated Tissue for Ocular Transplantation, Research, and Future Technologies*⁶ and the *WHO guiding principles on human cell, tissue and organ transplantation*;⁷

2. National legislation indicating if and how consent-for-export will be managed. This may include information/decision on;
 - a. where export approval rests, e.g. donor, EB and/or legislation;
 - b. outlining if exportation within a nation, across jurisdictional borders, also needs to be clearly defined; and
 - c. determining if donors should or should not be informed and/or consent-for-export
3. In the absence or delay in legislation, exporters voluntarily agree at the peer-based Association or EB/distributor level to implement a standard/policy on its management. This will differ depending on a nations opt-in or opt-out status but could encompass:
 - a. explicit verbal or written information regarding their exportation practices on their websites and at the point of donation, including:
 - i. option to opt-in to export or opt-out of export;
 - ii. an explanation on how/why the sector and/or the EB has determined the export destination, e.g. demonstrates the degree of need and the safeguards at the import locations, and confirms how surgeons/hospitals are vetted; and
 - iii. outlining if for-profit entities are engaged at any point in the supply-line from recovery to delivery at the transplant centre;
4. Importers insisting on corneal tissue only from providers demonstrating transparency in their consent-for-export practice, with the EBs consent-to-export policy made available to importers;
5. EBs/associations/importers sharing data on the exportation and importation of corneal tissue; and
6. EBs/associations collecting consent-to-export data, e.g. for opt-in systems - how many opt-in, and for opt-out systems - how many opt-out.

Our research has provided, for the first time, an indication of the degree of awareness of eye tissue and eye care sector professionals, on consent-for-export practice. Examination, from the public and donor perspective, would enhance research in this field, drawing-out further themes for consideration, e.g. their expectations of the EBs, distributors and eye care sector and their degree of willingness to consent-for-export on their death. A mapping exercise may also capture jurisdictional differences, making navigation easier for all parties. Sector-consensus or national legal reform, for mandatory consent-for-export policy would be valuable but such change is unlikely to occur in the short term and requires more evidence to support the various practice options. Therefore, we propose the eye tissue and eye care sectors proactively and voluntarily, examine and improve their consent-for-export practice, in line with seminal recommendations including *The Barcelona Principles: An Agreement on the Use of Human Donated Tissue for Ocular Transplantation, Research, and Future Technologies*⁶ and the *WHO guiding principles on human cell, tissue and organ transplantation*.⁷ Lastly, we reiterate that clarity from the eye bank and eye care sectors on how the practice is publicly and/or professionally framed, will improve awareness and understanding within the sector and provide transparency to the public in advance of the end-of-life donation moment.

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3.5 Do eye bank models and competitive practice impact international cornea allocation?

ABSTRACT

*International export and import of corneas is dependent on the stakeholders involved in the process and how those organisations engage to move corneas from one point to another. Our paper presents the pathway of corneal donation, from the export nation until its use in the import nation. It presents opinion on how aspects, such as competition and promotional behaviour, the use of online systems and third party engagement may influence allocation. **Method:** We interviewed n=92 eye tissue and eye bank professionals to garner their opinion. We used saturation and sentiment methods to extract and consolidate group opinion. **Results:** Interviewees indicated that competition and promotional behaviours are existent in some eye bank nations – though it is not universal. They indicated that the behavioural approach used by the individual eye bank, rather than the act of information sharing, influenced allocation. They also indicated that organisational models and allocation systems (e.g. online ordering) and engagement with non-state actors are important in allocation practice and decision making. **Discussion:** We mapped, the pathways for corneas involved in export and import, from the point of recovery to their point of transplantation. While generalist in nature and limited by the paucity of existing literature, our paper outlines that the different business models, partnerships and methods applied, influence corneal export and import.*

Key words: corneal transplant, eye banks, export, import

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1.0 INTRODUCTION

Corneal tissue has been exported and imported through permitted channels since 1961.¹ The practice provides corneal transplant options to recipients around the world who would otherwise be unable to receive treatment to restore vision. This practice has rapidly grown, and now accounts for 23% of all global corneal transplants.²

Despite routine corneal exportation dating back decades, the practice has never been mapped. As there is no consistent eye bank (EB) business model there is also no indication of how corneal tissue is moved from source, through the various models, and onwards to the import destination.³ Additionally, there is no way of determining if or how EB business models or behaviours hinder or enhance global access to corneal tissue.

1.1 Contemporary EB business models

Most EBs are affiliated with hospitals, universities or benevolent organisations, with Lions Clubs International, the most prominent global affiliated group.⁴ The structure of EBs varies depending on supply and resource levels, need, demand and the organisational affiliations.⁵ All but one EB organisation in the world functions as a non-profit organization,⁶ however since for-profit emergence in 2016⁶ such profit models have been, and remain, widely contested in the eye tissue and eye care space.^{7,8,9} Additionally, we also note that third party distributors (brokers) and transplant facilities may or may not be for-profit.

In terms of services provided, the majority of EBs around the world provide all service steps, from donor consent, to recovery, preparation, allocation and dispatch, within a comprehensive model (Figure 3.5.1) and may be affiliated with or combined with multi-tissue banks. However, in some cases EBs provide only one or just a few of the necessary steps, and instead engage third party providers (e.g. processing hubs/distributors/brokers) to carry out the remaining step/s in what we term, a patchwork model (Figure 3.5.1). The EB may or may not be directly affiliated with the third parties that they engage. All models can occur within domestic and international allocation pathways, in conjunction with profit and non-profit organizations and third party partners that may or may not also be for-profit.

The international movement of corneas is complex. They can be moved between multiple organisations both within and in different countries from their point of donor recovery to their place of transplantation. They can be retained completely in a non-profit supply line or moved in and out between non-profit and for-profit organisations at several intersecting points until their final use. Figure 3.5.1 highlights the interconnecting pathways for corneas, from their recovery point to their allocation point within the various models, and at both export and import level.

Depending on their relationship and agreements with the providers, and their systems, surgeons who import can self-select corneas for transplantation through tissue exchange programs provided by cooperatives, associations or independent EBs via online ordering or email/phone services. Such considerations may reflect the donor age, expiration date, cell count and cost, e.g. via the Eye Bank Association of America's Ocular Network Exchange.¹⁰ Alternatively, corneas can be ordered as part of a humanitarian program where they are placed in the custody of a non-state actor such as a non-government organisation (NGO) that provides humanitarian or capacity development support to another nation. In this instance the NGO holds the cornea until transfer to the transplant facility. This can also involve the use of surgeon-couriers.

In terms of behavioural aspects, most EBs work collaboratively to share corneas between themselves or their networks both domestically and internationally. While there is limited literature in the field, it is also clear that 'competitive' practices exist, with the USA sector prominently mentioned.^{7,11} In the USA instance, their EBs compete to place corneas both domestically as well as internationally. The literature has also indicated that intriguingly both profit and non-profit EBs can make a profit – depending on their funding structures, and they can deploy a highly aggressive approach to compete and secure access to the donations and to surgeons requiring corneas for their waiting recipients.^{7,11}

The purpose of this paper is to firstly present the various contemporary EB business models – in relation to their export practice, focusing on profit, competitive behaviours, online distribution mechanisms and engagement of NGOs. Secondly, through the use of sector interviews we wished to ascertain if these models positively or negatively impacted international allocation, and ultimately access of corneal tissue to those awaiting corneas in other nations. Our intent is to draw attention to the practice and movement of donated corneas and offer founding concepts to enrich and encourage investigation into the practice.

2.0 METHODS

Approval for this study was provided by the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC#18-1374H). Participant informed consent was completed prior to their commencement in the study.

Our method, validation and interviewee descriptors have been previously described as part of a much broader study into whether Australia should export corneas.¹² To summarise, we interviewed n=92 EB and eye care experts, from n=42 nations, via a grounded-theory semi-structured interview process. Interviewees were purposively selected. They consisted of experts from all 6 WHO defined regions,¹³ and categorised based on their nation's economic status, being from low-middle to high income economic nations. Economic status was determined based on the World Bank Country Lending Group Classification.¹⁴ They were also identified based on their nation's transnational activity status, being export nation, import nation or neither, and their own professional background as EBer, ophthalmologist, third party distributor/broker, capacity development and governance professional. We used saturation and sentiment methods to unearth the key themes relevant to our inquiry from these interviews.

The data presented here was derived from commentary captured in the interviews though predominantly Question 8 within our semi-structured interview tool which explored competitive behaviour, and Question 7 which asked participants about NGOs (SUP06 on page 196). While a wealth of new generalist information was uncovered from the interviews, we present only the aspects relevant to generalist business models in relation to export and import, and what our interviewees knew about the suggestion of competitive and aggressive behaviours, and the inclusion of NGOs, and if/how this may impact on the export and import of corneas for transplantation. We also present captured sub-theme conversation, such as the introduction of online allocation systems and how this may impact practice.

3.0 RESULTS

3.1 Competition and behaviours

Overall, interviewees indicated that competition can propel the sector and the individual, yet it can simultaneously prevent progression. They recognised that it can be healthy, but it can be aggressive and destructive if not checked. Of our interviewees, 45% (n=42) were aware that there was competitive behavioural practice – with the USA the only nation mentioned. There were 13% (n=12) unaware, 4% (n=4) unsure, and 1% (n=1) who indicated it did not exist. The remaining 38% (n=33) did not mention it within the interview. Importers who indicated awareness also reported experience of a 'pushy' approach when seeking corneas from some EBs, finding it to be culturally inappropriate to their setting more so than anything else. As a consequence, they tended to avoid using those EBs wherever possible.

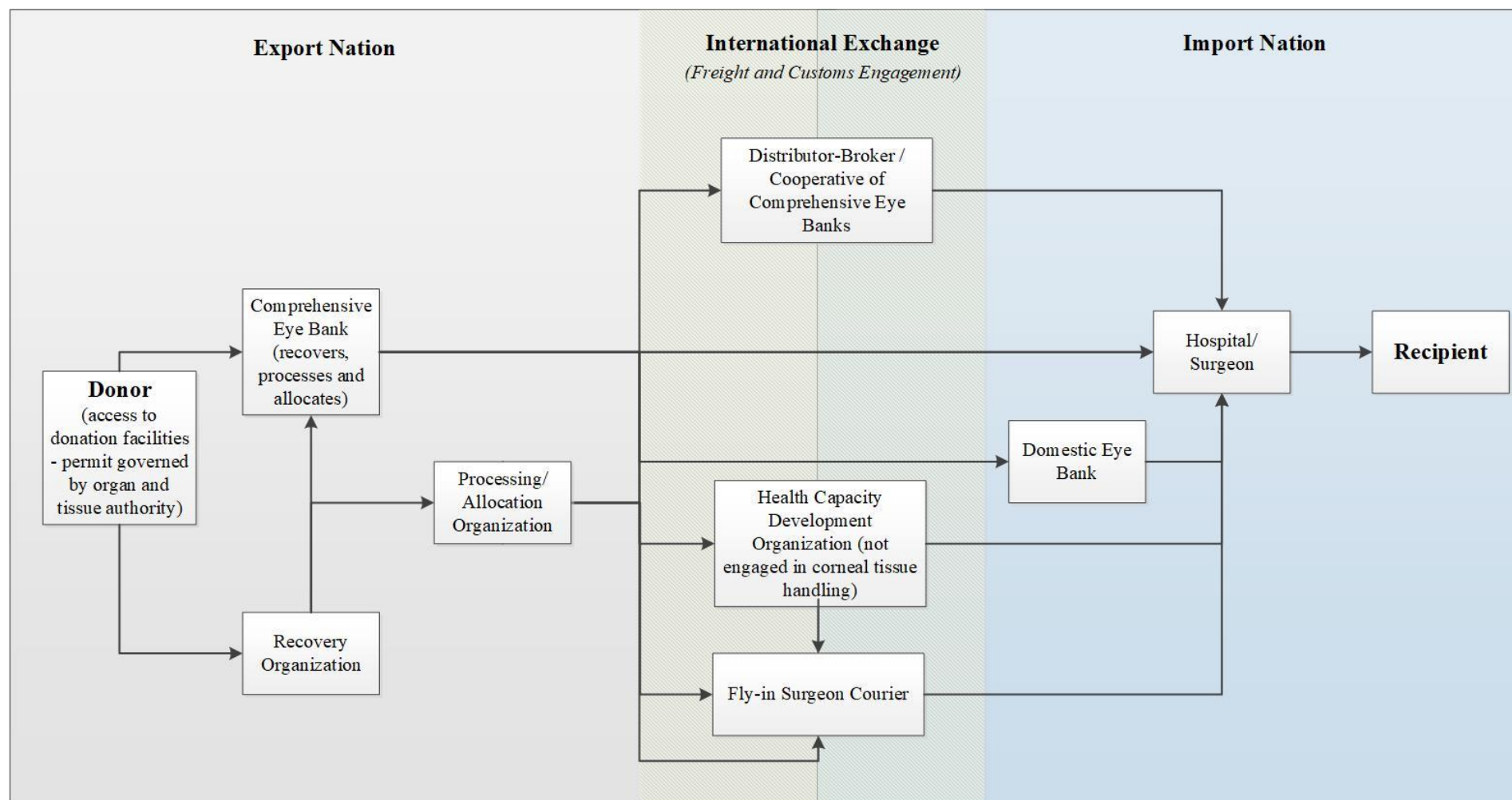


Figure 3.5.1: Export and import pathway matrix. Describes the international movement of corneal tissue from its point of donation to point of transplantation between export and import nations, comprehensive eye banks, and those eye banks with patchwork models whereby they provide some steps but not all. The cornea may be transferred to the transplant facility directly by the eye bank, or via a distributor, development agency or a surgeon courier. Each organisation may or may not be for-profit.

Some USA interviewees attributed the competitive behaviour in their nation as arising from their EB having to cater for niche surgeon requests for only a certain type/quality of corneal tissue. They indicated that surgeon demand in their nation, for the best tissue, had resulted in the creation of an artificial quasi-market, that often sought to place the higher quality tissue first and often at a higher price. Interviewees describe EBs as over-recovering corneas, in order to find and meet the niche demand. In turn this created a self-perpetuating problem, with EBs having to spend more money and time to secure and fill the request for niche tissue. This meant that more corneas were recovered than were demanded domestically. While exportation of corneal tissue from USA EBs offered the opportunity to support other nations, interviewees indicated that it also became a way of recovering their own costs that would otherwise be lost due to their over recovery.

3.2 Competition and promotion

When asked if competitive and aggressive behavioural practice impacted export and import, the response was mixed, with 52% (n=48) saying yes it did, 1% (n=1) saying no, and 14% (n=13) being unsure. The remaining 32.6% (n=30) did not indicate a definitive response during their interview.

Those that were 'unsure', in essence, could not see a correlation between how a business was run and the distribution of corneas. Those who said 'no' held similar responses to those who were 'unsure', primarily basing their response on the belief that competition presents as a normal function of business and interaction. They also did not see how it could impact when demand was high internationally, suggesting that it was an open market with limited competition.

Those who said 'yes', indicated that the competitive practice did influence allocation and could be both negative and positive. They described some EBs as enlisting specialist allocation teams within their organisation for the sole purpose of international allocation. Some had mobile specialists who moved locations. Some engaged in humanitarianism and capacity development practice, and some did not.

Respondents described EBs promoting their services, e.g. at transplant facilities, conferences and other events. Some of the interviewees appreciated this collective level of promotion, as it offered them a chance to discuss new equipment and options face-to-face, and they enjoyed getting to know the Ebers. Conversely, others found it to be a grotesque form of manipulation, primarily targeted to surgeons.

While promotion was viewed as offering some positive opportunities for all parties within the exchange, there was also concern for those EBs located in competitive cultural systems. In these cases, the system had self-created (self-perpetuated) the need to develop, focus and retain a marketing budget for export, rather than using the funds elsewhere. Finally, there was concern that having to focus on marketing and promotion, removed the EB from its principle practice, and commoditised the donation, as well as placing at risk smaller independent EBs who were unable to allocate funds in a similar manner.

Regardless, our interviewees stressed that there was nothing intrinsically or principally wrong with informing end-users of the existence of a range of services and while they could not pin-point how specifically it impacted allocation they acknowledged that it did. Their central points were with regard to the appropriateness and manner of the promotion and/or behaviours, believing it depended on the parties and culture of those involved, rather than the connection and sharing of information itself. Interviewees generally offered both positive and negative comment on competitive and marketing behaviour, rather than being unilateral in their opinion. We present below an overview of comments, as pros and cons, from the n=42 (46%) interviewees who were aware of competitive EB behavioural practice:

- Pros:
 - Sharing of information and options
 - Pushing the boundaries of possibility
 - Creating new opportunities
 - Opening up new conversations and knowledge exchange
- Cons:
 - Creating demand that was not there, or was not needed
 - Closing existing opportunities

- Reducing choice
- Reducing what is possible through enclosed and in-confident-contracts prohibiting collaboration
- May increase conflict of interest for some parties
- Promoting the ‘latest is the greatest’ even if it is not the case
- Profit motive may out-rank the hierarchy of decision making
- Practices may be antagonistic. Aggression may be there but not well defined when referring to cross-border allocation. It is seen more so as ‘inappropriate’
- Compromises public contract of trust and respectability (meaning it is undignified) in the management of the gift of donation.

It was also noted that some interviewees, including both exporters and importers, indicated that kickbacks - and unnecessary pressure to export and secure the best price were occurring or being locked into supply or receival contracts by some organizations. We note that they described kickbacks as providing other opportunities in order to make the connection and get contracts signed and making deals, and that their shared vignettes regarding kickbacks tended to be historical, with no vignette on kickbacks mentioned as occurring within the last few years. This is not necessarily an indication that they are or are not occurring, or how common or rare this maybe, simply that we did not gather sufficient commentary from our interviewee cohort at that time.

3.3 Online ordering systems

One aspect that was mentioned by n=2 (1.8%) interviewees (being n=1 Importing High-Income Ophthalmologist and n=1 Exporting High-Income EBer) was their use of online allocation systems. While the theme was not mentioned by other interviewees, we include their commentary in this paper for two reasons. Firstly, given that e-commerce is rapidly expanding, it is likely that going forward, more e-systems will be implemented in EBs. Secondly, it uncovered two rich schools of thought that potentially have important ramifications in the future for the sector. We consolidate the comments on online ordering below as pros and cons, being:

Pros:

1. It is a 21st century method. It is used in other aspects of life, so EB uptake of online allocation systems is in keeping with current cultural norms and delivery methods of our time
2. Easier for exporter and importer to track and monitor
3. Convenient, especially when engaging others in various time zones and competing schedules
4. Provides a picture of the cornea
5. Easy method to connect those seeking corneas with those who can allocate
6. Allows the importer to consider more than one cornea at a time (allows option)

Cons:

1. It could make the cornea look like a commodity and it could be seen as trading, e.g. an online e-commerce bidding process
2. As a convenience it encourages ‘shopping’ behaviour of surgeons
3. It removes the ‘personhood’ from the donation, e.g.:
 - a. misses the humanistic stories surgeons receive when calling and discussing directly with the EB; and
 - b. it is just a photo on a screen, detached with a few words describing it as an object
4. Removes conversation or relationship building between the surgeon and the EB/distributor. This may erode the system and cooperative relationship (lose of the human touch)
5. Increases competition to ‘secure’ the desirable donation before others do.

3.4 Non-state actors

Our interviewees were asked to comment on the engagement of non-state actors, and significantly health care NGOs that provide humanitarian and/or capacity development work in the eye care space and provide surgery in other nations. NGOs may ask the EBs for corneas to take to one of those nations,

to allow them to conduct their ‘mission’. They may or may not expect the EB to provide the corneas as gratis and may or may not directly involve the EB in the ‘mission’.

Overall, interviewees were enthusiastic to assist such organisations and help provide access to eye care services globally. They believed working with NGOs was essential for connecting and matching supply with locations in need of corneas and capacity development support. They believed such organisations should reimburse EBs, either in part or in total for all of their fees, so that the EB could stay financially viable, or that they should work together to find a provisional and sustainable funding solution. They found that NGOs were not always aware of the complexity involved in providing corneal services as opposed to other services such as cataract surgery – and in particular the post-operative, re-graft and long-term requirements that it committed the surgeon and recipient to maintaining. There was a desire to keep working with NGOs, however, to do so they wanted to see more structure and confirmation from the NGOs on how and where the donations would be used, who the surgeons and hospitals were, how recipients were selected and moreover, to ensure the provision was not undermining EB development in that particular import nation. Finally, they wanted to ensure that the NGO was a *bona-fide* organisation, rather than a fly-in-fly-out group, with a clear plan to improve services in that location (e.g. through surgeon training or infrastructure support or partnership with others), and ensure post-operative services were available for the recipient. Finally, they wanted to ensure that outcome data on procedures involving imported corneas were returned to the EB for their tracking and monitoring requirements as required by their export nation governance and/or laws.

4.0 DISCUSSION

We mapped for the first time the pathways for corneas involved in export and import, from the point of recovery to their point of transplantation. While generalist in nature, our paper outlines a number of business models that have been established in such transfers and how key aspects such as competitive behaviour, online tools and engagement of NGOs may influence placement.

Based on our interviewee responses, we ascertained that competitive behaviour, partnerships and associated mechanisms could influence how corneas are moved internationally. Importantly, the way that exporters and importers interacted (behaved) with each other impacted partnerships and the progression of services. It should also be recognised that it acted as a fundamental influencer in how organisations chose to partner, which in turn leads to where and how corneas were allocated.

Conversely, while aspects such as promotional behaviours gave a louder voice to those larger EBs who promoted their corneas and services, it potentially threatened smaller EBs in locations within competitive cultures. At the same time, this behaviour did not intrinsically change the corneal tissue or the choices available – in a scenario where we assume the EB/providers met standards, regulations and seminal recommendations. It simply vocalised some EB providers more so than others. The concern here is how local cultural aspects are applied by the EB and interpreted by the importer, rather than the act itself. The examination of the behaviour of EBs, to ascertain the appropriateness of their approach, from a cross-cultural strategic point of view, more so than anything else, could overcome these barriers in the future.

As the export and import of corneas is not centrally managed by nations, then their movement is not adequately monitored. Thus, any underhand practices such as kickbacks could potentially occur, though further evidence is required. Perhaps a solution would be to remove individual EB allocation and instead move towards a nationalised, planned and more closely monitored system whereby both sides of the export/import exchange could map and monitor activity – for example through the use of a blockchain system.

We note the contradiction in there being a competitive quasi-market that required EBs to develop marketing strategies when there is an estimated 12.7 million people waiting for a corneal transplant.² If corneas were being equitably allocated there would not be a market in which to compete. This indicated that corneas are not being equitably distributed, and that the marketing or competitive behaviour we describe is because EBs seek reimbursement from those able to pay a higher price – and therefore competition exists only in those locations. This means the concept of a ‘marketplace’ is not universal.

While beyond the scope of this paper, it raises further questions regarding equitable allocation practices, that require investigation.

As a centralised system is unlikely for some time, then aspects such as ‘cornea shopping’ regardless of if being undertaken online or via email will likely remain and grow. The importer has little choice when faced with multiple providers. While it is likely that the growth of the use of e-type systems will continue to flourish in the future, there is a need to examine how the technology can be effectively and ethically used in the corneal tissue space, and ensure it does not exacerbate existing allocation maldistribution patterns. Consideration of how e-systems can be monitored, integrated and data mined, based on nationally determined processes, nomenclature and allocation agendas would also enhance their usefulness. It is important that providers and users readily exchange information on the cornea as well as its cost but at the same time ensure the security and delivery of corneas to the desired location, and ensure human relationships are not undermined. Transparency around the system combined with a national or international approach through a series of guidelines underpinned by The Barcelona Principles,¹⁵ as the seminal framework in this field endorsed by the Global Alliance of Eye Bank Associations, International Council of Ophthalmology, Corneal Society and others, would provide a mechanism to support the appropriate use of such modern e-commerce systems.

4.1 Limitations

Our work, while presenting foundation concepts, is limited by its generalist nature, preventing detail in which to draw out further sub-themes and discussion. Additionally, due to the volume of international allocation engagement from the USA,² our participants invariably presented issues of concern and recalled stories that involved USA EBs more so than EBs of any other nation. While we accept the content of their stories as real-world data, we acknowledge that further investigation of EB exporters elsewhere in the world, and further investigation into the motives and issues experienced by the USA EBers, from an inside rather than an outside perspective, may provide a more balanced and nuanced view and enrich the international allocation conversation. Other aspects of business modelling, e.g. donor consent-for-export, corneal quality, cost, governance and regulations are also relevant but due to the volume and richness of our content we intentionally excluded them from this paper but recognise they also need to be evaluated.

In conclusion, the exportation and importation of corneas is complex. Corneas are moved through several organisations until their point of use. Their international allocation is influenced by competitive behaviour and partnership decisions but not by the act of sharing information about services. Without monitored centralised national export and import systems, it promotes a piecemeal approach as to how organisations interact with each other and invariably determines how and where donations are moved. Our mapping and presentation of the field offers some insight into this complex global system of corneal transplantation and should act as a catalyst to inspire further research and debate not only in this area but also in areas related to other organs, cells and tissues. Future studies should place emphasis on common principles that are underpinned by ethical considerations and a humane understanding of the complex process of moving corneas from the donor to the recipient.

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3.6 Examining corneal tissue exportation fee and its impact on equitable allocation.

ABSTRACT

*While an estimated 23% of all global corneal transplants occur because corneal tissue is moved from one nation to another (export and import), the fee structures, fees charged and the use of reimbursement or profit models, to support this practice, have not been evaluated. This paper describes the fee structures and determines if they support or hinder the equitable allocation of corneal tissue. **Methods:** We conducted grounded theory semi-structured interviews, purposively inviting participants until themed saturation was met. Sentiment analysis was used to determine opinion. **Results:** We interviewed n=92 global eye tissue and eye bank professionals. We determined that corneal tissue, that is exported, costs between US\$100-6000 or is provided as gratis. Collectively, interviewees indicated that globally there were no fixed fee structures in place, and the fee was influenced by multiple factors on both the export and import sides. They indicated that ultimately corneas were allocated based on the importers ability to pay the price determined by the exporting eye bank. **Discussion:** Allocation of corneal tissue that is exported, is influenced by the fees charged by the exporters to meet their bottom line as well as the funds available to importers. Therefore, export allocation is not equitable, with those who can pay a higher fee, prioritised. Steps to guide and support exporters with development of fee structures that promote equitable allocation are essential. This will assist both export and import eye bank development, corneal tissue access development, and assist those awaiting a corneal transplant.*

Key words: corneal tissue, export, import, fee, cost, allocation

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1.0 Introduction

An estimated 23% of all global corneal transplants (being, $n=42,251$ of $n=184,576$ known annual global transplants in 2012)¹ occur because corneal tissue is moved from one nation to another. The practice occurs because of an oversupply in one location, at one point in time, and an undersupply in another location. The practice is referred to as export and import, transnational activity (TNA), or corneal tissue movement or allocation).¹ While human tissue cannot be bought and sold, the practice is reliant on import users being able to pay the fee charged by the exporters, and the exporter being able to stay financially afloat and cover their costs associated with the recovery, processing, and allocation of the corneal tissue. The fees they recoup from importers, alongside their domestic reimbursements cover these costs. In a number of cases gratis (free) provision may occur. At times, profit could be made on the exchange, depending on the cost allocated to the cornea, the services provided, and the exporter organisational business model. For example, the exporter may or may not be a for-profit organisation or they may or may not involve distributors/brokers that are for-profit.²

Despite the cross-border movement of corneas since 1961³ and knowledge that 23% of corneal transplants occur because of TNA, there is no information to describe the fee structures or how these are determined.⁴ There has also been no study to determine if the current approach supports or hinders equitable allocation of corneas. Therefore, there is no information available in which to guide export nations when determining their fee structures and the final fee they should charge to importing users in another nation.

To contribute to this field of enquiry, this paper presents information on how corneas and/or service fees are currently costed when exported and imported. We focus on TNA rather than the domestic (intra-national) fee structures, though we recognise domestic and international activities may be inter-dependent. In order to undertake this study, we canvassed opinion from key leaders of the global eye tissue and eye care sector, who we interviewed as part of a broader study to determine Australia's corneal tissue export potential.⁵ We describe the fee options, the respondent's degree of understanding and awareness of the options, and their opinion. We then determine if the current approaches support equitable allocation.

2.0 Method

This study was approved by the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC#18-1374H). Informed consent was completed by interviewees prior to their participation.

The method, validation and interviewee descriptors have been described previously, as part of a wider study to ascertain if Australia should export corneas.⁵ In summary, we interviewed $n=92$ eye bank and eye care experts via a grounded-theory semi-structured interview approach. Interviewees were purposively selected. They were de-identified, and categorised by three descriptors, being 1). their nation's economic status (from low-middle to high-income economic nations with the status determined based on the World Bank Country Lending Group Classification system,⁶ 2). their nation's TNA status (being an export nation, import nation, neither or both) and 3). their own professional background (as either an eye banker, ophthalmologist, third party distributor/broker, or another profession, which encompassed capacity development and governance professionals). Saturation and sentiment methods were used to unearth key themes relevant to our inquiry. The data presented in this paper has been extracted from commentary provided during the interviews though predominantly from their response to Question 6 within our semi-structured interview tool which explored funding options and their implications. (Available in Supplementary 1.)

3.0 Results

Of the $n=92$ interviewees, $n=90$ (98%) provided commentary on the cost placed on exported corneas. Of those, $n=80/90$ (89%) provided additional commentary on one or more aspects of the funding models used, in general, by eye banks when exporting corneal tissue. Through the saturation interviews, a number of comments were obtained and grouped into key themes. We describe each of the collective themed comments below.

3.1 Corneal tissue fee (cost)

When asked how much corneas cost when exported, n=6/90 (7%) stated that they did not know, n=69/90 (76.5%) did not provide a direct answer, and n=15/90 (16.5%) (being n=13 importers, n=1 exporter, and n=1 neither exporter nor importer) provided details on the cost, which collectively, they described as ranging from gratis (free) to US\$100-US\$6000. Through the commentary, interviewees indicated that there was no fixed cost and that cost depended on several factors, being: 1). who the exporter was, 2). who the importer was, 3). what the import government, health insurance or recipient was willing to pay, and 4). the economic status of the export and import nations involved in the exchange.

3.2 Cost-recovery terminology

The term ‘cost-recovery’ was understood by a majority of the participants, with n=61/90 (67.7%) believing it was the only costing system that should be used. While, collectively, interviewees considered it acceptable, the term itself was not well defined, possibly due to the cost variables within each jurisdiction which may or may not be controlled by the eye bank. Principally, the premise was considered to mean that the cornea itself was without financial value, but the costs were attributed to the overheads of the eye bank e.g. staffing, consumables, electricity, licencing, insurance, equipment, innovation, and development and so on. In terms of exporting, the logistic and freight costs were considered as reasonable additional cost-recovery items. Where costs were recovered from, depended on: 1). the nation (e.g. if the nation had a socialised health system and/or systems in place to manage public government funded payment - such as Medicare in Australia), 2). if the recipient had their own health insurance provider, 3). if it was funded by others (e.g. international aid agencies), and 4). if the recipient had to pay out of pocket in the event they were without health insurance or if they were located in a nation without a socialised health system to cover the cost on their behalf.

3.3 Sliding cost scale

Interviewees were also asked to comment on the changing cost system (cost range) – which we refer to as a ‘sliding cost scale’. While there is no publicly available information describing the sliding cost scale, in essence it is a system that determines the cost, (e.g. fee charged by the eye bank) based on several key and changeable independent elements. These being, 1). expiration date of the cornea, 2). quality/characteristics of the cornea, 3). the ability to pay, and 4). if the cornea required additional preparation for the intended procedural type. Each element decreased or increased the fee for the individual corneal tissue. We present the sliding cost scale elements in Figure 3.6.1.

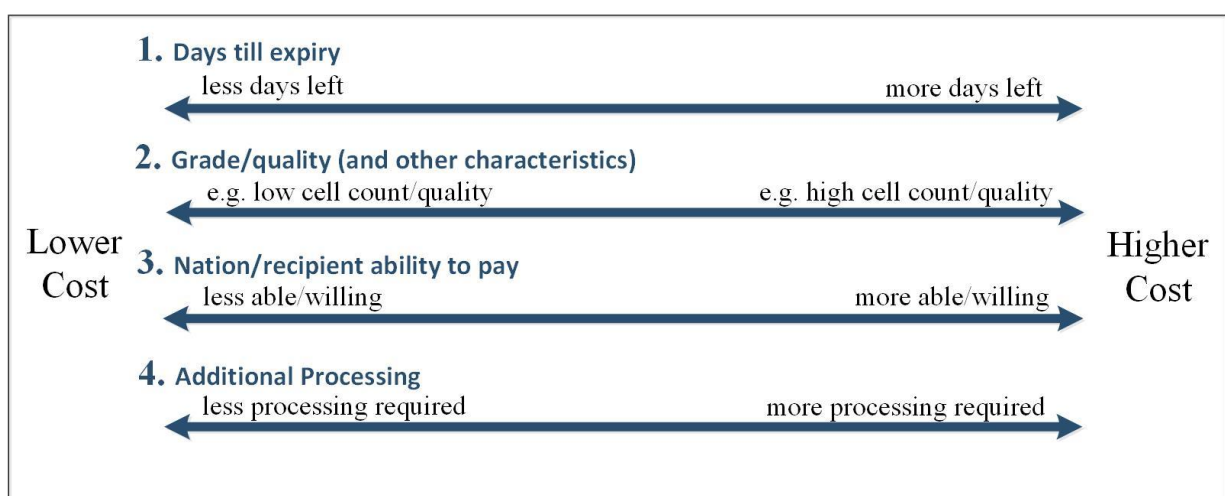


Figure 3.61: Sliding cost scale. Some eye banks implement a sliding cost scale system. In this model, there are four independent elements that independently alter the cost of the corneal tissue charged to the importer by the exporter.

Some interviewees (n=4/90, 4.4%) were firm believers in the value of the sliding cost scale system across all 4 elements. They believed it was a necessary function of the eye bank business model. It ensured that a greater number of corneas were used and not wasted, and it allowed access to recipients/nations with a range of budgets. The system worked by pricing lower quality, less-fresh and less demanded corneal tissue at a lower cost, while pricing higher quality, fresher, in-demand corneal tissue at a higher cost. They believed that allocating lower grade tissue at a lower cost to those with smaller budgets offered them a chance to access corneal tissue that they would otherwise not access, and that despite the quality variance, it was better than nothing for the recipient. Finally, they described that this system allowed eye banks to offset their losses incurred when allocating corneal tissue at a lower cost through the profit made when providing corneal tissue at a higher cost, to those willing and able to pay more. This approach helped the eye bank to equalise their profit and loss and remain financially viable.

Conversely, the n=61/90 (67.7%) interviewees that preferred the cost recovery model, described the sliding cost scale as inappropriate when applied to all 4 elements. They described it as directly creating a corneal allocation hierarchy. They described better quality corneal tissue or those recently recovered, being allocated to the highest bidder (usually a higher-income nation) while those of lesser quality or those least in-demand were the only options available to those with a lower budget (usually a low-middle-income nation). We note that while they disapproved of the sliding cost scale when applied to all 4 elements, that they did support its use for additional tissue preparation (point 4 within Figure 1) which they considered reasonable, due to the additional costs incurred by the eye bank. Lastly, n=3/90 (3.3%) believed sliding cost scales were acceptable for costing and allocating non-optical grade corneal tissue.

3.4 Profiting

The concept of profiting was not on its own considered wholly bad. Interviewees recognised that profits can be used to support eye bank and corneal tissue research, development, and allocation. Some (n=6/90, 6.5%) interviewees considered socialised models that charged a higher cost to those who could pay more as a reasonable profit that helped bridge the gap when other tissue was allocated at a lower cost or as gratis, to those unable to pay at the same level, and ensured the eye banks stayed financially viable. Finally, n=40/90 (44.4%) vocalised their disapproval of profiteering, and of those n=7/90 (7.7%) specifically raised concern at the notion of individuals profiting, e.g. through the diversion of profits to shareholders and investors.

3.5 The gap: governments and health insurance

Of our respondents, n=4/90 (4.4%) commented that export nation health insurance companies, national socialised health systems (funds obtained through taxes) and domestic recipients indirectly filled the gap in the fees lost by the exporter eye bank. This occurred when importers were unable to pay to the same level as the exporter's domestic fee – and they were unable to recoup the fees elsewhere. The fee charged to their domestic recipients was used to cover the shortfalls when the eye banks could not recoup through the export.

3.6 Cornea shopping

In order to secure corneas, some importers we interviewed indicated that they 'cornea-shopped' with multiple export providers. While this was complex for them to navigate, they believed being in touch with multiple providers ensured they secured corneal tissue for their recipient/nation. They considered this their only option when there were multiple providers with different fees and agreement terms, and with different levels of access at any one moment.

3.7 Gratis

Another cost and allocation option explored in the interviews was gratis. This is where the importer does not pay for the corneal tissue based on humanitarian considerations. Interviewees were asked to comment on how useful or viable this option was. Overall, all interviewees believed it was a noble act and ideologically desirable to provide gratis, with n=31 (34.4%) providing commentary on its real-

world application. Of the $n=31/90$, $n=9$ (10%), were in support, $n=2/90$ (2.2%) were against, and $n=21$ (23.3%) expressing mixed opinion. Collectively, interviewees believed it offered access to those who could not otherwise afford access, and it offered the opportunity to help kick-start eye bank and corneal transplant services and training of clinicians in import nations. This in turn demonstrated the importance of accessing corneal tissue within the import nation, with the hope that one day the import nation may allocate resources to pay for more imports or preferably, build their own eye bank.

Those against ($n=2$) believed it was not financially practical for the exporter, and discouraged import nations from developing their own eye bank. They believed that it may undermine an import nation's ability to build their own eye bank, proposing "why would they build their own eye bank when they can get it for free?"

Conversely, those with mixed opinion ($n=21$) stressed that it was a principle aim that should be strived for, but that it could impact negatively on the export eye bank's bottom line if not managed well, and that quantities of gratis were limited – making planning difficult for the importer. Similarly, to those against, they stressed that it could be unsustainable for the export eye bank if not monitored and implemented in a systemised way and that it could undermine development in the import nation. The interviewees described gratis provision as an individual eye bank decision rather than a national export decision, and they were concerned that the use of gratis may indirectly create the perception that the corneal tissue provided were of lesser value, lesser quality, or a commodity to be passed around.

Gratis was automatically considered to be a function offered by high-income nations to low-resource nations, however $n=1/90$ (1.1%) MD from an exporting high-income nation felt that if an eye bank were subsidising gratis to another nation that they needed to examine if they could or should also offer gratis to their own population, who were most likely, through taxes and/or health insurance fees, already paying for it. If that option was not available, they indicated that the allocation may not be fair or equitable to the export nation's own waiting recipients. While they principally supported the gratis option, overall, they advised that gratis be a last resort or only offered for the short-term, in order to prevent undermining export nation domestic access, and eye bank development in the import nation.

4.0 Discussion

Through our interviews we found that the allocation of corneal tissue across national borders is influenced by the fee and fee structure determined by the individual exporting eye bank and based on their individual funding model and bottom line. The practice prioritised those who can pay more. With no other evidence in which to draw upon, then based on our interviews alone, we conclude that corneal tissue export allocation does not appear to be equitable. Allocation is based on economic transactionism rather than on a clear fixed costing system and the requirements of the recipient.

The ability to export may also be indirectly influenced by an export nation's socialised health system, insurance companies and recipients who may buffer financial losses incurred by the eye bank when exporting. We note however that there was no clarity from the interviewees nor publications elsewhere⁴ to indicate if this approach is supported by governments and health insurance companies as a collective agreement to support international humanitarianism efforts. Additionally, how frequently this was used within export nations, or if it was dependent or independent of cost recovery, fixed costs, gratis or sliding cost scales used by the individual eye bank was also not clear. Further work is needed in this area - particularly to ascertain the impact of current fee methods, and their continuation, cessation or adaptation by both export and import nations, and how they may or may not impact service sustainability, corneal access, recovery, allocation, and recipient wait times, and donor willingness to support⁷⁻¹¹

While factors such as currency exchange rates or freight and logistics will change (depending on the physical distance between the exporter and importer and the fees charged by the freight companies for those routes), all other costs incurred by the individual eye bank were determined by that individual eye bank (e.g. what storage method they used and the cost-points on their consumables). This is influenced by the jurisdiction the eye bank is located (e.g. wages will be impacted by the cost of living and wage laws in that jurisdiction), and the impact of inflation. Whether or not the fee is incurred by the recipient

or not, depends on if the nation they reside has in place a socialised health system to pay for it on their behalf or if they have medical insurance. The willingness or ability of the payee to pay the fee presented by the exporter is a key determinant on the ‘if and how’ corneas are exported, and the ‘where and to whom’.

Gratis, while noble and preferable as a humanitarian act, does require further evaluation to ensure that nations providing gratis are not unwittingly doing so without understanding their own population and stakeholder opinion on gratis provision. For example, could exporting eye banks seek national aid-grant support to provide gratis or lower-cost tissue to low-middle-income nations, as part of their nations international humanitarian effort or aid agreements? This would allow allocation to occur in a planned manner and assist exporting eye banks to retain their bottom line without having to use sliding cost scale systems.

It is also essential that those receiving gratis corneal tissue, either through a third party or non-state actor or directly via the eye bank, understands the limitations of the provider when it comes to gratis provision, including the type and quantity they have available and when they are able to schedule the provision – based on their own budgeting ability. Where possible gratis importers must seek to support the provider in order to ensure the eye bank remains sustainable. For example, they could assist the eye bank by finding additional aid-funding supporters and championing eye bank development. Perhaps at the least the importers could commence by funding freight and logistic costs incurred by the eye bank, and work with the provider towards a non-gratis status in time.

Sliding cost scales, while economically understandable and perhaps offering corneas to low-middle-income nations who may not otherwise be able to pay the top cost, and ensuring all recovered donations are used, does create a commoditised situation, and compromises equitable allocation. Our point rests on the premise that allocating corneal tissue based on its quality/characteristics and days until expiration, means recipients in lower socio-economic situations may not have equitable access to the same grade of corneal tissue to those who can pay a higher cost. It is anti-equitable access and further entrenches health inequities in poorer countries. This is of concern when those receiving lower-grade tissue reside in locations with lesser access to post-operative services and may reside in locations with already stretched health systems. The question therefore remains, how does lower grade tissue impact the recipient in that situation? It could be assumed that the post-operative outcomes were lower and therefore the burden on the health system and recipient was greater. If, however the outcomes were comparable to those who were paying a higher cost for higher quality corneas, and residing in higher resource locations, then we ask, why are recipients in those locations paying more for that grade of cornea, when they can get a comparable outcome at a lower fee with lower grade corneas? Either way a fee based on the corneas quality/characteristics appears to be a paradox. While the premise of charging additional fees for additional preparation by the eye bank is reasonable, and a socialised premise of the ‘haves’ subsidising the ‘have nots’ supports equitable access, we are perplexed by the premise of allocating based on quality/characteristics and expiration date, because the tissue is either viable for transplant or not viable for transplant. This therefore means that allocation of corneal tissue of the same quality is therefore viewed as not equitable, with the ‘have-nots’ seemingly at a greater disadvantage.

To examine these export fee options further, we describe the various scenarios in Table 3.6.1 (page 129-130), and examine how one approach or another impacts the exporter, importer, or both.

While this paper is limited by the literature lacuna on corneal tissue export and import costs in which to draw upon, it is hoped that this generalist overview presented from the perspective of those engaged in contemporary practice will alumnate the issues, gaps in knowledge and contradictions. It is hoped that this overview paves the way for further debate in this field. In turn, and based on the evaluation of our interviewee responses, we propose system changes, such as:

1. Standardisation of corneal tissue costs charged by the eye bank or explanations of how costs are determined. This will remove commoditisation and confusion.
2. Modify the sliding cost scale, by:
 - a. removing cost variance based on the cornea’s grade, quality, age, and other characteristics.

- b. retaining aspects associated with additional processing fees (e.g. request to provide as a pre-cut or injectable) and fluctuating freight and overhead costs.
 - c. Introduce a socialised sliding cost scale system based on the nation's economic status, with that status determined by the World Bank Country Lending Group classification system.⁶ In this, high resource nations could pay more than lower resource nations, as per their economic level rather than based on the quality/characteristics and date till expiry of the corneal tissue.
 - d. Consider currency exchange rates in budgeting and planning.
- 3. Encourage surgeons to work with a range of tissue quality levels and dates (within reason and were appropriate to the recipient), otherwise the practice of allocation on quality/characteristics and freshness will continue to distort the demand for corneal tissue by forcing eye banks to create elaborate fee structure solutions based on the individual corneal tissue, in order to recoup costs and stay financially afloat. This invariably commoditizes the tissue and is anti-equitable.
- 4. Exporters undertake further investigation, at the national level, to determine health insurance and/or government willingness to cover the funding gap created by exportation.
 - a. and/or consider working with appropriate aid-agencies, philanthropic or public-private organizations what will help fill the funding gaps to ensure that exporting eye banks remain sustainable without undermining domestic access and the equitable allocation in other nations.

While our recommendations, based on the interviews conducted in our research, offers ways to reimagine how fees are structured and justified, further investigation is needed to examine if and how adaptations may positively or negatively impact the exporter their motivation and sustainability, and the eventual access to import nations and their ability to pay for the export or develop their own domestic service.

In closing, there remains very little in the literature from exporters, importers, or governments to describe the fee structure models used to export and import corneal tissue – and how these support or hinder all parties. The process is not clear and does not appear to support equitable allocation principles. We encourage further examination in this field and encourage both exporters and importers to evaluate, in particular, sliding cost scales, going forward. Further information on how eye bank costing and in turn corneal tissue fees are determined, how engagement of third parties impacts the fee, how prevalent the various options are within practice (e.g., what percentage of exports are provided as gratis), how domestic recovery and allocation impacts exports, and how these differ from one nation to another would greatly enrich this conversation.

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Fee scenarios	Fair to export nation	Fair to import nation	Explanation
Export nation charges users based on a socialised model; whereby high resource nations are charged a higher fee than low-income nations for the same quality tissue.	Yes	Yes	This is the most equitable option, ensuring allocation is based on economic status rather than the individual corneal tissue.
Export nation charges import nation the same fee charged domestically.	Yes	Sometimes	Unless the import nation has a similar economic level to the export nation, then this may be an unobtainable fee to the import nation.
Export nation routinely charges their domestic recipients more in order to subsidise exported corneas provided at gratis or at a lower fee.	No	Yes	While import nations with limited resources will benefit from the lower fee, then depending on the agreements in the export nation, this may reduce access for export nation recipients.
Export nations provide <i>ad hoc</i> , gratis, or lower fee tissue to import nations, based on their bottom line, domestic demand, and supply level at that point in time.	Sometimes	Yes	While planning surgical services will be difficult for the import surgeon and there is no guarantee on supply levels, in terms of funding, this may provide a workable option to both export and import nation.
Export nation charges all import nations more to subsidise their own domestic demand.	Sometimes	Sometimes	This depending on the economic status of the two participating nations. For example, if the exporting nation were a low-middle-income nation, and they charged a high-income nation a higher fee than their domestic rate, then this would replicate socialised modelling. If however the exporter was a high-income nation and the importer a low-income nation then it may be unaffordable for the import.
Costs changed based on the expiration (time since recovery), quality, grade other characteristics (e.g. age), intent for use and/or based on willingness to pay (sliding cost scale system)	Unclear	No	It is unclear if this is fair on the export nation as it depends on if this system is also applied domestically or just applied to exports, or if better quality tissue is exported at the expense of the domestic recipients.
			Depending on the economic level of the import nation, this may mean that those most in need or most vulnerable will not have equitable access to the same quality of corneal tissue as those who can pay more. This may or may not impact recipient access and outcomes.

Additional fees for additional processing (e.g. pre-cut or pre-loaded) are charged by the exporter to the importer	Yes	Yes	Extra processing steps requested by the importer, that result in additional costs to the exporter are reasonable reimbursement costs.
Freight costs paid by the import nation	Yes	Yes	This is an unavoidable standard fee for all corneal tissue movement. It is a reasonable cost for the importer to pay and must be discussed and factored into planning.
Freight costs paid by export nation	Sometimes	Yes	This is an unavoidable standard fee for corneal tissue movement. Depending on the socio-economic status of the exporter this may or may not be fair for them to cover. This must be discussed and factored into planning.
Currency exchange rates fluctuations	Unclear	Unclear	Currency changes are an unavoidable aspect of international funds transfers. Therefore, exporters and importers must factor in currency fluctuations into their planning and budgeting.

Table 3.6.1: Impact of cost options on exporter and importer. Presents the various cost options and determines if they are fair to the exporter and/or importer.

3.7: Is corneal tissue transnational activity good, bad or somewhere in between?

ABSTRACT

Section 3.7 presents un-published data extracted from semi-structured interviews with sector experts. The method and respondent details are described in 3.2. Unlike published sections of the thesis, this section does not include an introduction, methodology and general limitation section, as they are already described elsewhere in the thesis. For style consistency, it retains inclusion of the results, discussion, recommendations and references.

While section 3.2 described sector opinion specifically regarding Australia's TNA engagement, section 3.5 looks more broadly at the overall premise of the practice, to determine if TNA is good, bad or somewhere in between.

1.0 RESULTS

Of the n=92 interviewees, n=9 (9.7%) believed transnational activity was good, n=5 (5.4%) believed it was bad, n=77 (84%) believed it rested somewhere 'in-between', and n=1 (1%) did not respond. Those indicating it was 'good' were mostly high-income responders (n=6, inclusive of n=3 Australians, n=2 upper-middle, and n=1 low-income). In terms of their transnational engagement, n=3 were importers, n=3 exporters, and n=3 Australian. Profession wise n=4 were MDs, n=3 other, and n=2 EBers.

Those who supported TNA believed it was a positive act and was justifiable compared to any negative implications. They indicated exportation was a moral imperative, richly rewarding, very powerful, honoured donor wishes, utilised corneas effectively, prevented waste, and helped alleviate corneal blindness through wait list reduction - especially in low-middle income nations. They believed it was an act of good will as members of a global village, a core tenant of medicine to help others, and finally, in business terms a responsible and practical act.

Those that indicated it was 'good' (n=9) were from a range of economic levels (n=1 low-income nations, n=2 upper-middle nation, n=3 high-income nation and n=3 Australian), professional backgrounds (n=2 EBs, n=4 MDs, and n=3 Other) and TNA backgrounds (n=3 exporters, n= 3 importers, n= 3 Australian). They believed the positives outweighed the negatives, it was an effective use of the donation and provided help to others, especially those in less developed nations.

Those that indicated it was 'bad', were mostly high-income nation respondents (n=4) with the remainder from a low-income nation (n=1). Professionally, they were n=3 MDs and n=2 EB, and engagement wise, n=3 importers, n=1 exporter and n=1 Australian. Their concern centred around where the corneas would be allocated to, believing it created dependence for the importer, e.g. why would they bother developing a local EB system when they can import. They were also concerned that corneas were exported without the export nation's demand being met.

The overwhelming number of respondents believed the practice to be somewhere in-between good and bad, with the pros and cons dependent on the scenario. Of the n=77, n=20 were Australian, n=21 exporters, n=34 importers, n=2 neither. Nation wise, n=35 were high-income, n=5 upper-middle income, n=17 low-middle income, and n=20 Australian. Professionally they were n=43 MDs, n=19 EBers, and n=15 other.

The 'in-between' respondents believed that determining if it was good or bad was too absolute and not realistic. They believed it was a double-edge sword, in terms of supporting the premise of exporting as an act to help others. They believed it was influenced by the policy and the practicality of the process between the various parties, which may compromise equitable access if not managed in a considered manner. They suggested that it depended on several independent factors, e.g.:

1. If need/demand was met in the export nation before exporting;
2. Whether it undermined sustainability efforts of the import nation;
3. If profit was involved;
4. Whether the costs were based on where it was going and to whom - and if those factors altered the cost of the tissue;
5. The distance and duration between the participating nations;
6. How third parties were engaged;
7. How non-EB NGOs were engaged;
8. What the regulations were in either nation;
9. If donors were aware;
10. If it was tracked (for data tracking, surveillance and biovigilance reasons);
11. How the standards were maintained and how the quality was impacted on arrival;
12. Impact of financial markets on currency rates;
13. How reimbursement models were framed;
14. Guarantee of safety in transit;
15. Those with limited choices having to accept poorer quality;
16. If it contributed to the loss of skills within the import nation EB;

17. Behaviour of ministries of health when selecting partners (e.g. ransom themselves to certain companies and getting locked into contracts);
18. How recipients were selected and prioritised;
19. How it impacted the carbon-footprint; and
20. Whether the practice undermined self-sufficiency or dependence of either nation involved in the exchange.

While they recognised the globalisation influences, and benefits of sharing, they also recognised the fear and concern around the idea, as it is a relatively unknown practice outside of the direct sector and it may be perceived negatively within the general public.

2.0 DISCUSSION

Respondents generally believed that cross-border allocation can be both good and bad, but in essence it was dependent on how it was practiced and the terms of the arrangements between the parties. Interviewees believed that the practice could continue but evaluation and reform was necessary to safeguard donation and access, and ensure it was equitable and sustainable to both export and import nations, without either being undermined. They were emboldened for wanting to change the practice.

In agreement with the majority of the respondents, and taking the position that it depended on how it impacted the export nation, import nation or both, then we took select scenario vignettes described by the respondents and examined them from the various perspectives, and in turn considered where the pros and cons were for each perspective. We provide these in Table 3.7.1 on page 135.

2.1 Recommendations

In summary, TNA is neither good nor bad. Its position lies somewhere in between. The decision to engage is complex, in that it may be beneficial to one party however it may not be suitable to another. With that in mind, a series of recommendations are proposed. These are designed to support those seeking to reduce their engagement or those commencing engagement as either an exporter or importer, being:

1. Incorporate cross-border allocation as part of a wider capacity development program;
2. Adhere to the recommendations in this field, e.g. *The Barcelona Principles*;
3. As much as possible, ensure charitable options (e.g. gratis) are fair to both export and import nations;
4. Include exit or scale back strategies so nations can work towards self-sustainability;
5. Allocate tissue for training;
6. Train the whole team (surgeons, nurses, councillors, laboratory technicians and so on), or partner with other organisations who can complete that training;
7. Invest into the wider health system and service;
8. Ensure post-operative follow-up is provided by trained providers before allocating;
9. Track, monitor, and follow-up recipient outcomes;
10. Develop a global response to assist vulnerable populations, e.g. in war zones or displaced by civil unrest (though be aware that they may be moved on from their treating physician or subject to uncontrollable import requirements and post-operative situations. Consider the safety of waiting/postponing treatment vs. treating immediately);
11. Create criterion for vetting surgeons/hospitals of those involved prior to allocation;
12. Develop policy around how importing surgeon/hospital/governing agencies are determined;
13. Audit the practice, e.g. conduct adverse reporting checks at 3- and 6-months post-transplantation; and
14. Insist/confirm post-operative services are available before engaging, inclusive of access to post-operative eye drops. Consider/plan for provision of emergency materials in case of early or primary graft failure.

2.2 Limitations

Since interviewing in 2019, we recognise that our research does not address the impact of Covid-19. We acknowledge we are living through a transformational stage, and we must be prepared to adapt the practice to meet the emerging short- and long-term challenges created by the pandemic.

Finally, the 2019 WHO's Report on Vision¹ was published after our interviews, so we were unable to gather opinion on the report and how it may influence corneal transplant services and in turn demand for corneas. We acknowledge that despite the significance of global corneal tissue need, the report only mentioned access to corneal tissue briefly by stating *“Improved data on donation rates and population needs, coupled with clear policies and legislation and supportive governance oversight on both donation and transplantation, are required for Member States to establish sustainable corneal banking programmes.”* While inadequate to influence practice on its own, its inclusion in a key global eye care report is a positive step forward, and echoes recommendations highlighted in the seminal frameworks within the human tissue, eye tissue and eye care fields²⁻⁴ and the sentiment of our interviewees.

To close, those without local access to corneal tissue, may in the short-term, require imported corneas from other nations able to supply. While the act of sharing is noble and offers many benefits, it is essential that the practice be reviewed and reformed to safeguard allocation for those in need, in the future. Exportation and importation of corneas can be good, bad, or somewhere in-between, depending on the mechanisms, intent, motive, and actions of either the export or import partners. Therefore, EBs, human tissue and eye care sector stakeholders at jurisdiction and national level, must work together to develop workable guidance frameworks to ensure cross-border activity supports, rather than undermines, self-sustainability efforts of either export or import nations.

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EXPORTER	
Pro	Con
Offers donation option to donors who would otherwise be unable to donate. The act promotes the gift relationship	Impacts the organisation by: creating co-dependence on financial return; propping-up domestic services by recovering costs lost in over recovery by recouping some/all costs incurred
Creates jobs for eye bankers	Demand (and/or need) may not be met domestically before exporting
Prevents corneal tissue waste	Can become a competitive commodity
Some/all costs can be recovered	Competition in turn puts pressure on placement before expiry
Allows for allocation during domestic down periods, e.g. holiday periods	Affirms colonial trade power balance
The exporter can contribute directly to global allocation	May defy donor wishes if not consented-for-export
May include knowledge sharing and other global opportunities	In export nations using a sliding cost system, it encourages export nation surgeon pickiness
	Prevents directing transplant eligible donations into domestic research, development, or training
	May perpetuate perception of trading in human body parts and profiting (reaffirming public unease)
IMPORTER	
Pro	Con
Allows surgeons to train in transplant surgery	Distance and cost by: inhibits access to fresher tissue and emergency tissue; commits surgeon to use on arrival even if it has deteriorated during the transfer because it has already been paid for and the time until the next delivery is too long, and they may now always have a slit lamp available to test the cornea on its arrival
Kick-starts services by demonstrating the importance of corneal tissue access to governments for their future investment - particularly if linked to capacity development program or knowledge and skill exchange program	Maldistributed allocation by: giving some surgeons the practice and financial advancement over others; doing so without an equitable allocation system; e.g. only for select recipients or those who can afford the surgery; and in turn, this undermines wait lists and equitable allocation patterns
Provides surgery to those waiting in their nation	May cost more than if recovered locally or a lower fee may undercut the local eye bank service
Helpful in the short-term to those recipients lucky enough to receive the import	Could be a dumping ground for corneal tissue not accepted by export nation surgeons
The cornea may have been prepared in an eye bank that provides services superior to local services, regulations, or ethics	Reaffirms colonial trade power imbalances/partnerships that may be difficult to shake off

	Impedes development of local eye banks and local eye banker skill base and reduces job opportunities
	Creates dependence on imports as a source of access by making it too easy, and therefore governments do not invest locally
	Puts pressure on health systems and workers to use before expiry
	May lock vulnerable populations into contracts and reduced choices
	Creates competition on the corneal tissue costs based on its quality
	May be inferior to local eye bank services, regulations, ethics
KEY POINTS FOR BOTH	
Currency exchange rate can increase and decrease the cost, making budgeting or cost returns difficult for the importer to budget, especially when the recipient may be paying for it directly, and may reduce ability of the exporter to re-coup costs	
Potential to increase global equitable allocation however the current approach is maldistributed due to allocation based on relationships, organisation agendas, ability to pay, and quality cost differences, rather than on national plans or wait lists and wait times in import nation or ability to share from export nations. Without a national system on either side, surgeons 'shop' between eye banks/distributors. This increases the commoditisation of the donation	
An act of humanitarianism and sharing, contributing to a global village approach and solidarity that assists/contributes to wider agreements between nations, as a soft power gift (gesture of sharing), however the current system is without national coordination on either side of the exchange	
Value laden (emotive) yet value adverse (profit)	
No routine global data collection prevents a true understanding of allocation. Therefore, there are variables on both sides of the exchange, e.g. service, training, access levels and the corneal tissue movement and use. This means recipient outcome data is difficult to compare	
Prevents transplant tourism by ensuring the recipient stays in their own nation	
Allocating without Tissue Acts may compromise the practice for all parties	
No clarity on cost points	
Assumptions skew the perception of the practice. For example, it is assumed that: those exporting are high income nations and those importing are low income nations, or the quality of the corneal tissue and services are based on a nations wider geopolitical reputation rather than the decision on which cornea is allocated where and why	
Service is subject to (vulnerability) to key global events and global ethical differences, at various national, regional and global levels e.g. natural disasters, terrorist attacks, pandemics) which impact the process, e.g. cancellation of air freight options.	
National sanctions can impact where to export to. This could be a safeguard for the donation or prevent equitable access to nations without	

Table 3.7.1: presents the pros and cons of transnational activity for exporters and importers.

3.8: Other Aspects for Consideration

ABSTRACT:

Section 3.8 presents un-published data extracted from semi-structured interviews with sector experts. The method and respondent details are described in 3.2. Unlike published sections of the thesis, this section does not include an introduction, methodology and limitations section as these are already described elsewhere in the thesis. For style consistency, it retains inclusion of the results, discussion, recommendations, and references.

This section presents respondent opinion and recommendations on five briefly discussed sub-themes that emerged from the interviews that have not been included elsewhere within sub-chapters 3.2 – 3.7 but contain rich content that requires inclusion and consideration when discussing CT TNA. These are, 1). risk to recipient outcomes, 2). planning, 3). critical events, 4). governance current practice, and 5). governance future practice.

1.0 RESULTS

1.1 Risk to recipient outcomes

While there is very little published on the outcomes of corneal transplants performed using imported CT,¹ interviewees generally believed that in this day-and-age, with the types of storage mediums currently available, and with the sophistication of freight and logistic systems, as previously described in sub-chapter section 3.3, that using imported corneas should not impact the outcome for the recipient. Interviewees believed that the quality of the CT was influenced by how the original EB operated, and the standards and procedures in place to reduce risk, as opposed to the act of cross-border allocation itself. Therefore, they believed overall risk was similar to the export EB's domestic allocation of CT – however they did acknowledge that the additional time from dispatch to transplantation, influenced the CT quality. This was an unavoidable consequence of the freight process itself.

Despite the assumption of 'all services being equal' some (especially low-middle-income MDs) did highlight that importing surgeon's often cannot evaluate the CT on arrival as they do not have a slit lamp to examine it. They indicated that they must use the corneas regardless. They also indicated that variances in fees impacted the quality, though again, that it was not the act of the transfer per say, but the policies of the exporting EB when deciding how to allocate for export. Surgeon's using less optimal corneas (e.g. less fresh or those with a lower cell count), especially in sub-optimal conditions (e.g. an operative environment without hospital air systems or adequate instruments) was also considered a risk, with some indicating that those in compromised operative situations, with limited access to funding, to provide for re-grafts, should receive the best possible CT to prevent post-operative problems for the recipient. Such locations, they believed, simply could not afford the re-graft costs.

The greatest 'risk' our interviewees alluded to was the allocation of CT to locations without adequate post-operative follow-up systems in place, and those allocated to fly-in-fly-out mission programs. They believed this could compromise recipients if conducted without post-operative measures in place, inclusive of access to post-operative eye drops and well trained local medical personnel to manage care and possible re-graft once the mission staff returned to their own countries. If post-operative services could not be guaranteed, they advised not to allocate.

1.2 Planning

Our interviewees believed that the planning and coordination of cross-border allocation was inadequate, and without integration into wider national health and eye health plans. They indicated that the national and global human tissue and eye care sector examination of eye tissue development and allocation was woefully lacking, left off the millennium development goals and that there were no incentives in eye care to support EBs, or if there were, they were peripheral. One High-Resource Exporting EBER stated, *"I honestly think it's an afterthought."* Eye tissue and eye care was described by some interviewees as a small fish in a big pond, playing second fiddle to competing issues such as HIV, tuberculosis, and other major ocular conditions such as cataracts and refractive management.

At the provincial/jurisdictional level, interviewees indicated that there was EB planning taking place but whether or not those plans were reaching national debate was unclear. Interviewees were only able to list 3 nations that had included EBs in their national eye health plans, being: Cambodia, Papua New Guinea and India, however the degree of inclusion specifically to EBs, as opposed to corneal services and corneal transplantation planning was not described. An Australian MD in our cohort highlighted that *"most developed countries, high income countries do not have national plans as such. Most of the national plans that were actually being implemented were in developing countries, and they focused on cataract surgery, maybe on childhood blindness, and I'm not aware of any that will have corneal blindness as a focus [beyond] trachoma and trichiasis, [with the focus on] corneal blindness, not transplantation."* The only guiding document indicated by our interviewees to have come close to addressing CT TNA, was The Barcelona Principles,² which outlined the key principles for capacity development partnerships involved in the exchange.

Conversely, some EB professionals indicated that while eye tissue was not considered in eye care planning, there was movement afoot in the human biological sector, with efforts to collectively work

with other tissues and organ sectors to make legislative change. An Australian interviewee in the ‘Other’ categorised interviewee group stated, *“I think there is a lack of general interest in tissue, because people are unaware or have not heard of it or [if they have, they have] not been involved in discussions around tissue at all.”* They indicated that EB development was determined at the country level and appeared to be on the back burner in terms of political support. One upper-middle income importing MD indicated: *“We’ve tried to launch several sessions to get legislation, at least talked about at the cabinet level, but nothing has been done so far ... our legislation does not exist or it’s very archaic.”* Interviewees indicated that governments and surgeons found it quicker just to *“buy a tissue from abroad,”* and that in some locations, governments were not interested in passing legislation or to push the agenda.

1.3 Critical events

While interviewees supported the notion of working as a global collaborative village, with the best of intent, some acknowledged that politics and world events influenced practice, meaning TNA was subject to a wider health and global system. Interviewees mentioned key influencing events, that disrupted distribution or required additional consideration and planning in order to navigate round these events including the: ‘9/11’ USA terrorist attacks (2001), the Arab Spring (2011), Brexit anticipated changes (2018), and the USA Government shut down (2019). Finally, national level ethical and cultural differences between the exporters and importers, such as conflicting ideology, and practice differences between nations on how tissue was obtained and used, were recognised as significant to allocation and distribution. The COVID-19 pandemic was not mentioned as the interviews took place in early 2019, prior to the commencement of the pandemic.

1.4 Governance current practice

Most interviewees were unsure if there were current laws to govern cross-border allocation, though many identified seminal soft guidance tools e.g. The Barcelona Principles² and WHA Guiding principles on human cell, tissue and organ transplantation (WHA 63.22).³ They identified professional peer associations at global, regional and nation levels as prominent stakeholders most likely to be involved. They recognised that TNA and the access to human eye tissue in general was on the back burner politically as well as within the human tissue and eye care fields. This lack of inclusion was exacerbated by a belief that there was still fear within populations about cross-border allocation, assuming it was perceived by the public as being associated with body theft, profiting, and illegal and ethical violation. Collectively they viewed this as limiting the ability to move the service forward and implement recommendations that they believed were necessary for contemporary practice.

Interviewees described current TNA practice as uncoordinated, hard to control, lacking governance oversight or with weak governance, idolising the practice of industrialised societies without question, and that it created dependence on those that exported. They outlined that it was without international or consistent national agency monitoring or oversight, with an inconsistent use of tracking applications e.g. ISBT128.⁴ Finally, they indicated that politicians and ambassadors were unaware of the process or implications, with some open to persuasion by foreigners they viewed as coming from more trustworthy nations. Interviewees indicated that decisions were made based on the belief that tissue from one nation must be better than tissue from another, because of the nation’s economic level or human rights position in other areas - and vice versa when exporters decided who to send to - rather than on anything clinically or scientifically relevant to the donor, cornea, recipient, corneal transplant, or the individual EB.

Eye banks, eye care non-state actors (NGOs) and public-private partners were seen as important stakeholders, but their involvement was un-controlled and not integrated into national plans, on either side of the arrangement. Finally, investor conflict and competing interests, including surgeons who were EB investors or technology and hospital owners/investors, were viewed as not universally transparent and disrupted the equitable allocation of the corneas, e.g. by diverting to their own contacts or own recipients, rather than, again, working towards a national plan to address wait lists and wait times in a planned and systematic manner.

1.5 Governance future practice

While some interviewees were hesitant to support an increase of regulations, as it may increase bureaucracy, restrictions, and costs, which may hinder the practice by making the process too slow, the majority believed that some steps were needed internationally and nationally to govern the movement of CT. Whether that would be through tracking the movement or an agreement on practice standards, requires further investigation. In essence, their motive to improve practice was related to safeguarding the donation and improving the equitable nature of the allocation. There was also suggestion that those involved (the stakeholder group) needed to be expanded so that cross-border allocation was not left just to surgeons (as this may render allocation to only their recipients) or just to the EB (who may only allocate to the surgeons they know), rather than addressing equitable allocation as a nationally planned approach. National stakeholders were identified as: organ and tissue authorities, healthcare ministries/departments, non-state actors, including: eye care NGOs, EBs, surgeons/researchers, and peer associations. This may in turn increase knowledge sharing and opportunities in other areas of practice too.

Lastly, the interviewees indicated that despite best efforts to implement greater governance, the system would still not capture illegal or counterfeit movement as such activity was unlikely to be reported, and those engaged were unlikely to participate. They had no recommendation on how that could be overcome.

2.0 DISCUSSION

This research indicated that there are a range of issues that required consideration when exporting or importing CT. Unfortunately, as described, there is little EB and CT planning currently taking place, and there is limited information to guide their practice and decision making. It appears uncoordinated and without government engagement.

In terms of recipient risk, as described in sub-chapter 1.2, there has not been sufficient data published by exporters and importers to describe the risks and the outcomes for recipients whose transplantation was performed with an exported/imported cornea. We acknowledge there will always be risks for recipients when using CT that is imported, however this is comparable to the risk posed to domestic recipients who receive CT from the same EB that exported. The risk rested more so with how the exporting EB managed, handled, and prepared the CT before exportation rather than the act of transportation per se – though we do acknowledge that transportation does reduce the cell count of the cornea. A significance variance as we describe in sub-chapter 3.6, may be that the quality of the tissue selected for export in comparison to those retained for domestic use is different – and that the outcomes may be influenced by the selection rather than the act of transporting CT to another nation. We note with concern that importers in some nations were unable to evaluate the CT on arrival. Perhaps higher quality tissue should automatically be allocated in these instances. EBs which currently export and surgeons who currently import, must be encouraged to publish their data in relation to CT export selection and import recipient outcomes, so further information on the risks and outcomes can be extracted.

Our research indicated that CT export and import was unplanned and unstructured, and there was little government engagement. Despite the current situation, interviewees were supportive of developing constructive and progressive stakeholder groups to help guide and plan in the future. Therefore, perhaps through the engagement with governments and a range of stakeholders, an agreement on the movement of CT could be devised and collectively worked forward by both export and import nations. This would prevent the practice from being left to individual surgeons and EBs to self-determine and ensure EBs were not left to fend for themselves, trying to make sense of the narrative, and the validity of the requester.

Agreements must reflect recommendations from the field to ensure they are consistent with contemporary expectations. The key document in this field is The Barcelona Principles,² which promotes a communitarian approach, as part of a planned harmonization of the sector. The WHO Guiding principles on human cell, tissue and organ transplantation,³ alongside other key statements of

the International Council of Ophthalmology⁵ and World Medical Association⁶ collectively encourage self-sufficiency, and promote the equitable allocation of human materials including corneas. Fundamentally, these guiding documents promote eudaimonia (human flourishing) and they are designed to preserve the balance between moral, social and economic order⁷ and retain the reciprocal-nature and intent of the donor's end-of-life donation. In turn this ensures the donation is managed as a common good for the shared benefit of all. This approach is also consistent with the values, beliefs, cultures and expectations of societies, and prevents, as described by Martin,⁸ an '*egocentric pursuit of personal gain of individuals in the profession, possibly at the expense of effective procurement and distribution*'. It may in turn assist in maintaining the public's trust and the legitimacy of the service as a whole.⁹

The critical global and national events highlighted by our interviewees in 2019 remain relevant but have since been dwarfed by the COVID-19 global shut down in 2020. Unfortunately as the interviews took place before the pandemic, the research does not capture their opinion about the pandemic's impact. This is a limitation of my research. As described in sub-chapter 1.4 and 1.5 however, COVID-19 events highlight that despite donor, surgeon, recipient and EB availability, 'need' and 'demand' cannot always be met due to external factors such as closure or reduction of elective surgical scheduling, redirection of hospital workforces or funding diverted to personal protective equipment, and finally the reduction in air and land logistic providers which reduce distribution options between export and import parties.¹⁰ In essence, the pandemic has highlighted the blind spots in the practice, demonstrating that while exportation and importation offers a valuable service, reliance only on TNA, rather than development of domestic services, or the use of a blended domestic and TNA approach, does and will impact access for recipients.

2.1 Recommendations

Steps to reform export and import practice are necessary, and a range of recommendation are provided. While reform is important, how this would be managed, and by whom, in terms of confirming the legitimacy of those involved, needs to be determined. This is essential as donation is a social contract, and if legitimacy is lacking¹¹ then the practice is compromised. Recommendations to develop a structured approach include:

1. Development of nationally planned CT exportation and importation programs; i.e., implementation of a legitimate system, described by Farrell⁹ as:
 - a. "*Constitutional, functional, values-based and democratic in criteria; and*
 - b. "*Policy based, preventing adverse public reaction, as well as litigation, that may arise where families feel aggrieved at the perceived lack of consultation over the donation of a family member's organ after death.*"
2. Transparency of practice when using public monies to support the recovery and distribution; and
3. Improvement of relations between eye tissue, eye care and other human biological stakeholders to strengthen systems and opportunities for inclusion of EBing and tissue exchange within service, security, and capacity development programs.

By implementing a planned approach to exportation, then in turn, EBs and receiving surgeons can improve on the monitoring of outcomes for those donating and those receiving surgery via imported CT. This may provide greater opportunity to unearth further evidence to support EBs when deciding on which CT to export and why.

To close, and as eloquently stated, by Doughman and Rogers,¹² "*For all the progress of the past century, the fact remains that millions of men, women, and children worldwide experience blindness from corneal disease or injury, the largest proportion of whom live in countries without developed economies.*" In part, and through our interviews, we believe that the current approach for allocating CT across-borders has, in some part, contributed to this lack of development, as the current cross-border allocation patterns do not distribute corneas equitably, and it is unstructured. There is a paucity of planning, governance and monitoring of those involved in the TNA. This places donations in a vulnerable position. EBs, human tissue and eye care professionals must work hand-in-hand with

governments to safeguard donation through, at the least, the monitoring of corneal movement in and out of their nation, and ensure such movement supports national eye care and eye tissue targets that aim to improve access to CT and EB services for those awaiting transplantation in both the export and import nation.

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3.9 CONCLUSION

This chapter included a collection of papers describing how CT TNA takes place. Drawing on interviews conducted with key stakeholders from the eye tissue and eye care sectors in Australia and elsewhere, it presented necessary information required to determine how a nation should or should not export. Finally, it determined that there was general sector support both within Australia and elsewhere for Australia to routinely export CT.

Additionally, it highlighted a need for the practice to be planned and monitored; that it is considerate of both the export and the import nation in terms of donor knowledge and formalisation of the program; financially appropriate for the exporter and importer; and that further examination of donor awareness and opinion is paramount. Principally, the interviewees recommended that the practice be transparent with donors, nationally coordinated, non-profit, part of a wider humanitarian program, short-term for the importing nation as they move towards self-sufficiency, and that Australia must define and confirm domestic need, and ensure national demand is met before routine exportation. Finally, it highlighted that while the practice offers access to those in need, it is vulnerable to external factors, especially with the COVID-19 global pandemic emphasising the potential impact of a range of external factors. As a consequence, exportation should be viewed as one possible allocation option for Australia, rather than the only allocation option.

Drawing on such findings, it is proposed that Australia must ensure domestic services are not undermined or compromised by steps taken towards becoming a routine exporter; that exportation be allocated to its regional neighbours (being the Western Pacific); that neighbouring and low-middle-income nations should be prioritised; that donors are consented or at the least informed; and that Australia must consider carefully who it partners with and how they approach and interact with in terms of import nations. Finally, the sector proposes Australia work as a national collective rather than as state based player developing their own export approach and allocation.

Having completed a body of research around sector opinion in this Chapter, Chapter 4 will review Australian public opinion, and in particular, their willingness to export their donation on their death. The wealth of information extracted from the current Chapter contributed to the development of the research design and question set presented in Chapter 4.

CHAPTER 4

Willingness of Australians to export their corneas on death.

4.1 INTRODUCTION

I showed in Chapter 3, the opinion of sector experts with regard to Australia's current export potential and also their opinion on this area in the future. In order to expand on this, it was also essential to assess the opinion of Australians in order to ascertain if they agreed, or had differing views to that of the sector. Therefore, key findings from this chapter will determine if Australians would be willing to allow their donation to be exported if it is not required in Australia at the time of their death. Additionally, this chapter will examine how they believe exportation should be performed in the future.

To evaluate public opinion, this Chapter presents findings from an e-survey conducted with a sample group of the Australian population (n=1044). Based on population demographics, the research uses Chi-Square (Pearson's) and bivariate correlation coefficients to examine associations between categorical variables.

It is divided into 2 sub-chapters. Sub-chapter 4.2 introduces the participants, research and analysis method and overall results on participant willingness and opinion. Sub-chapter 4.3 then delves deeper into how the sample population group believe the sector should conduct export practice.

The chapter contains two papers. The first (4.2) has been published, and the second (4.3) is under review by a peer reviewed journal.

Appendix material related to this Chapter.

- SUP 09: Chapter 4 - E-survey questionnaire
- SUP 10: Chapter 4 - Methodology and validation process
- TEM 05: Chapter 4 - Part 1 pilot PDCF
- TEM 06: Chapter 4 – Part 2 formal e-consent to proceed
- TEM 07: Chapter 4 - Part 2 formal information provided
- PER 03: Chapter 4 – DonateLife

4.2 Determining the willingness of Australians to export their corneas on death

ABSTRACT

Background: 12.7 million people await a corneal transplant, but 53% are without access to corneal tissue. Sharing corneal tissue across nations can provide some access, however the willingness of export populations, like Australians, to export their donation on death, has never been evaluated. Our research samples the Australian population, determining their willingness to export. **Materials and Method:** We conducted e-surveys. N=1044 Australians participated. The sample represented the Australian population, based on population demographics. Chi-Square and bivariate correlation coefficients examined associations between categorical variables, with a sample size of N=1044, power of 0.80, and alpha of $p = 0.05$. Outcome measures were based on population sampling, by exploring willingness export, through the e-survey method. **Results:** 38% (n=397) of respondents said yes to exportation, 23.8% (n=248) said no, and 38.2% (n=399) were undecided. We found no relationship between willingness to export and general demographics, though those registered on the DonateLife Register ($p = < .001$), and those already willing to donate their eyes ($p = < .001$) were significantly more willing to export. **Discussion:** More Australians are willing to export their corneas than not, though a significant portion remain undecided. The DonateLife Register, and donation awareness, are key components of respondent decision making. Therefore, the provision of information about exportation prior to, and at the point-of-donation, is essential for assisting Australian's to decide to export or not. Further examination and development of consent-for-export systems are necessary before routine exportation is undertaken.

Key Words Transnational activity, cornea, transplant, Australia, consent, donation.

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1.0 INTRODUCTION

Nations without routine local access to corneal tissue rely on transnational activity (export/import) as a method of obtaining corneal tissue for corneal transplantation in their nation.^{1,2} The activity can occur legally (e.g. government and/or sector planned or permitted) or illegally (e.g. black market or counterfeit).¹ It is reliant on the export nation's ability to recover and allocate corneal tissue from within their donor pool.

Permitted corneal tissue transnational activity commenced in 1961,³ out of the USA. To this day, the USA remains the most prominent routine exporter followed by Sri Lanka and Italy. Exportation is now credited for the provision for an estimated 23% all global transplants (being, n=42,251 of n=184 576 known annual global transplants in 2012).⁴

In contrast to larger export nations, Australia is not a routine exporter. Australia exports small quantities to New Zealand, and for occasional humanitarian requests within the Western Pacific and South East Asia regions.⁵

With some activity already in existence in Australia, and with the potential to become routine exporters in the future,^{5,6} then examination of the practice is essential for current and future policy development. This is especially important given the potential sensitivities associated with the transfer of human biologicals internationally. Therefore, policy and regulatory reform relating to exportation must examine and incorporate the voice of the public, prior to implementing routine engagement. Therefore, the aim of our exploratory research is to understand the views of Australians and ascertain their willingness toward corneal export, by asking, should Australians export their cornea on their death, if the cornea was not needed in Australia at that time?

While there has been some examination of transnational activity, e.g. recipient outcomes, when using exported corneal tissue² and the opinion of the eye tissue and eye care sectors,⁷ unfortunately, there remains a paucity of information pertaining to donor understanding and knowledge of consent-for-export in Australia and elsewhere. There has been no research conducted to examine how populations feel about the concept of exporting their corneas and/or if they would consent for exportation on their death. Additionally, there is no global information to indicate how this activity functions or is monitored to ensure donor wishes are followed.

Our research, through examination of our own nation, Australia, captures for the first time a sample population's opinion and intent to donate for exportation. It explores how and where Australians would like their donation to be used, and under what arrangements.

It is our intent, that our research would assist nations like Australia to consider if they should or should not export donated corneas. It provides foundation evidence required to build an export framework and implement a plan that matches the expectations of the Australian Public. Of note, our research does not examine if Australia is meeting domestic need or demand, how exportation could occur, or if Australia is ready to routinely do this. Instead, our focus is on unearthing the public's opinion of a potential routine corneal tissue export option.

We acknowledge, that as Australia is not a routine exporter of corneal tissue, the Australian public and donors are not currently informed, consented or aware of the existence of the practice. There has been no discussion about the commencement of this and there are no details on Australian Eye Banks or affiliated government donation webpages or education materials, indicating that this practice of corneal tissue exportation occurs or may occur in the future. This means that for most respondents, our survey is probably the first time they have been asked to consider this concept.

Our null hypothesis was that Australians would be willing to donate corneal tissue for exportation. Additionally, we believed that the willingness of those born overseas – particularly in neighbouring countries, those with a vision impairment uncorrected by glasses, corneal recipients, those awaiting a corneal transplant, or those already registered on the nation's Donatelif e Register (<https://donatelif e.gov.au/register-donor-today>) would support this notion more than other Australians. Lastly, our null hypothesised that those working in a health service would be more supportive of the

concept than others due to familiarity with the health system, awareness of the benefits that can arise from transplantation and the known shortage in other countries. In terms of where they lived, and their age, gender, religion, or if they were Aboriginal or Torres Strait Islander, we had no hypothesis, and simply collected this information as a frequency descriptor only and thus this is exploratory in nature.

2.0 MATERIALS AND METHODS

Approval for this study was obtained from the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC#18-1374H). Funding was provided by the Australian National Health and Medical Research Council and the Lions Eye Bank Western Australia to our lead researcher to conduct the study and manage the data.

Our e-survey was designed to examine a range of scenarios pertaining to the willingness of Australians to donate their corneal tissue to domestic and then international allocation. The scenarios presented in our final questionnaire (Appendix SUP09 on page 210), were devised through examination of transnationalism² and the collection of key themes and recommendations, from Australian and international eye care and corneal sector members.⁷ We described corneal tissue transnational activity as donation sharing within the e-survey, to ensure that the respondents did not associate unethical trading or the black market movement of human body parts and transplant tourism, with our examination of nationally planned and permitted activity. We also excluded words such as “trade” or “export”.

We designed and validated our survey tool (SUP09), via a two-stage approach. During stage one, we devised and piloted our survey, ready for its use in a stage two formal e-survey with the Australian public. We describe our Stage 1 design method and validation in full, in appendix SUP10 on page 224. Once our survey was validated, it was uploaded to the online survey tool, Qualtrics XM (USA)(<https://www.qualtrics.com>). Our formal e-survey took place in July 2019.

We selected Qualtrics because it provided stringent quality control features such as the ability to screen for dishonest, inaccurate, and speedy respondents, use of sophisticated digital fingerprinting to avoid duplication, and compliance with ISO standard and industry standard data protection and security procedures. Qualtrics already had a bank of potential respondents, and we wanted an e-interface that was already familiar to the respondent, so their time was spent considering the questions rather than managing the survey platform. As this was the first time a study of this nature, in this field, had been performed, and with no prior studies to follow or provide suggestions on the groups or types of respondents to engage, we sought a generalist response in order to start the process of long-term examination in this field of research. Therefore, we recruited respondents from an online panel as mentioned below.

2.1 Participant recruitment

Qualtrics identified and recruited participants from their providers' online panel, on the specifications of our selection inclusion criteria of Australian citizen or resident, aged 18 and over. Participants who completed the survey were provided with a small incentive. Our aim was to sample approximately 1000 individuals to achieve a margin of error of 3% at the 95% confidence level. Our intent was to select individuals to ensure that our sample group was representative of the current Australian population, based on the Australian Bureau of Statistics (ABS) 2016 Censuses⁸ population demographics, and were relatively representative in terms of gender, age, state/territory population, Aboriginal and Torres Strait Islanders, and born outside of Australia rates. Through Qualtrics, n=51,136 e-invitations were sent simultaneously to eligible participants. Those who were first to respond were able to participate. When the cohort was met, additional respondents were informed that they were not able to access the survey. The survey was closed at n=1065 respondents.

We used the same consent process described in Stage 1, where participant consent was implied by their decision to click-ahead from the survey home page, to question 1 on the next page. The home page provided information on the survey, the research project and the stakeholders. It contained a pdf. downloadable information sheet explaining the research in full and included contact information.

Finally, as the subject matter discussed death and donation which may be confronting for some, we provided contact details for *LifeLine*, a free counselling service in Australia.

2.2 Analysis and sample size calculation

Responses were downloaded from Qualtrics, stored on a password protected server at the Centre for Eye Research Australia, then uploaded and analysed using IBM SPSS Statistics, version 26, software system (USA). Descriptive statistics determined the level and strength of the responses and confirmed our sample size was comparable to the ABS census data. Chi-Square and bivariate correlation coefficients (Pearson's) examined associations between categorical variables. A sample size of 1000 provided ample statistical power for the analysis to detect an effect of the independent variables on the dependent variable, assuming the power of 0.80, with a small effect size and alpha of $p = 0.05$.

For the qualitative analysis, two open text boxes were included in the survey. The first asked those who had not decided to allow their corneas to be exported, what additional information they would require in order to make a decision (Q22a in SUP09 on page 210). The second provided an opportunity for participants to leave a final comment (Q25 in S1SUP09). Responses were collated, consolidated and key themes identified based on overall frequency of responses.

3.0 RESULTS

3.1 Respondents

A total of $n=1065$ responses were received. We removed those that were incomplete or not completed appropriately (e.g. extensive data or response sets missing). This resulted in a final cohort of $n=1044$ cleared responses.

According to Table 4.2.1, a total of 74.2% ($n=773$) indicated they were born in Australia. The remaining 25.8% ($n=269$) emigrated to Australia between 1949-2019 (with 1990 the mean). A total of $n=56$ nations were represented, with the UK ($n=77$), New Zealand ($n=29$), India ($n=24$), Germany ($n=13$), Malaysia ($n=11$), The Philippines ($n=11$) and Indonesia ($n=9$) dominant. Additionally, 44.4% ($n=464$) of all respondents indicated that they had ties to relatives and friends outside of Australia.

When ocular history was considered, 13.8% ($n=144$), indicated that their vision was not corrected by glasses. Their explanations ranged from old age, macular degeneration, retinal scarring, cataracts, short sightedness, astigmatism and some were unsure, however we identified that not all respondents answered correctly, with some saying they wore glasses for reading and driving – which indicated their vision was corrected with glasses. Only 1% ($n=10$) indicated they had had a corneal transplant, with 0.5% ($n=5$) indicating they awaited a corneal transplant. In comparison 4.4% ($n=46$) had known a relative who had had a corneal transplant, and 2.5% ($n=26$) indicated they knew a relative who awaited a corneal transplant.

Table 4.2.1 also shows that 92% ($n=960$) indicated that they worked in health care. Of those, $n=77/960$ (8%) outlined their profession as: nurse/midwife (33.7%, $n=26$), assistant/orderly (22%, $n=17$), allied health (19.5%, $n=15$), medicine/dental (10.2%, $n=8$), administration/support (9.1%, $n=7$) and medical scientist/pathology (5.25%, $n=4$). The remaining 8% ($n=883/960$) did not state where they worked in healthcare, making it difficult to ascribe a single work category.

Willingness to export based on characteristics (% ,n)	Significance <i>p</i> =.05	Willingness toward export		
		Yes %(n)	No %(n)	HND %(n)
Gender				
Female (49.2, 514)	0.54	38.5(198)	22.1(114)	39.2(202)
Male (50.6, 529)		37.4(198)	25.3(134)	37.2(197)
Other (0.09, 1)		100(1)	0(0)	0(0)
Where they lived (state/territory)				
Australian Capital Territory (2.1, 22)	0.628	45.5(10)	18.2(4)	36.4(8)
Northern Territory (0.9, 9)		33.3(3)	33.3(3)	33.3(3)
New South Wales (30.2, 315)		34.3(108)	25.1(79)	40.6(128)
Queensland (20.6, 215)		42.3(91)	20.5(44)	37.2(80)
South Australia (7.2, 75)		44.0(33)	29.3(22)	26.7(20)
Tasmania (2, 21)		47.6(10)	14.3(3)	38.1(8)
Victoria (25.8, 269)		35.3(95)	24.9(67)	39.8(107)
Western Australia (11.3, 118)		39.8(47)	22(26)	38.1(45)
Religion				
Buddhist (1.8, 19)	0.539	42.1(8)	26.3(5)	31.6(6)
Christian (48.8, 509)		35.4 (180)	26.5(135)	38.1(194)
Hindu (2.6, 27)		51.9(14)	14.8(4)	33.3(9)
Jewish (23, 9)		22.2(2)	33.3(3)	44.4(4)
Muslim (2.3, 23)		43.5(10)	30.4(7)	26.1(6)
No religion (39.4, 411)		40.4(160)	20.2(83)	39.4(162)
Other (4.4, 46)		37.0(17)	23.9(11)	39.1(18)
Age				
15-25 (8.8, 92)	0.275	39.1(36)	15.2(14)	45.7(42)
26-35 (21.6, 226)		44.2(100)	22.1(50)	33.6(76)
36-45 (15.6, 163)		40.5(66)	23.9(39)	35.6(58)
46-55 (13.8, 144)		31.3(45)	25.0(36)	43.8(63)
56-65 (18.3, 191)		34.6(66)	24.1(46)	41.4(79)
66-75 (17.5, 183)		37.7(69)	27.9(51)	34.4(63)
76-85 (4.2, 44)		34.1(15)	27.3(12)	38.6(17)
86-95 (0.1, 1)		0(0)	0(0)	100(1)
Other characteristics				
Aboriginal and Torres Strait Islander (2.3, 24)	0.34	41.7(10)	33.3(8)	25(6)
Not Aboriginal and Torres Strait Islander (97.7, 1019)		37.9(386)	23.6(240)	38.6(393)
Born in Australia (74.2, 773)	0.072	37(286)	25.5(197)	37.5(290)
Not born in Australia (25.8, 269)		40.9(110)	18.6(150)	40.5(109)
Healthcare worker (92, 960)	0.104	37.1(356)	24.1(231)	38.9(373)
Not a healthcare worker (8, 84)		48.8(41)	20.2(17)	31.0(26)
Vision impairment not corrected by glasses (13.8, 144)	0.377	39.6(57)	27.1(39)	33.3(48)

No vision impairment or impairment corrected by glasses (86.2, 898)			37.6(338)	23.3(209)	39.1(351)
Received a corneal transplant (1, 10)		0.087	70(7)	20(2)	10(1)
Has not received a corneal transplant (99, 1034)			37.7(390)	23.8(246)	38.5(398)
Waiting for a corneal transplant (0.5, 5)		0.118	80(4)	20(1)	0(0)
Not waiting for a corneal transplant (99.5, 1039)			37.8(393)	23.8(247)	38.4(399)
Registered on the DonateLife Register (40.5, 422)		< .001	51.2(216)	18.5(78)	30.3(128)
Not registered on the DonateLife Register (59.5, 620)			29(180)	27.3(169)	43.7(271)
Intent to donate eyes (domestically) (35.6, 371)		< .001	58.8(218)	16.2(60)	25.1(93)
No intent to donate eyes (domestically) (18.3, 191)			16.2(31)	51.3(98)	32.5(62)
HND on intent donate eyes (domestically) (46.1, 481)			30.6(147)	18.7(90)	50.7(244)
	Intent to donate cornea for transplantation domestically (91.6, 340/371)	0.612	59.7(203)	15.3(52)	25(85)
	No intent to donate cornea for transplantation domestically (1.9, 7/371)		42.9(3)	28.6(2)	28.6(2)
	HND on donate cornea for transplantation domestically (6.5, 24/371)		50(12)	25(6)	25(6)

Table 4.2.1: Participant demographics. Demographics of the n=1044 participants, including demographic and characteristic significance of their willingness to export their corneas (yes, no and had not decided = HND), analysed through Chi-Square and bivariate correlation coefficients (Pearson's) that examined associations between categorical variables, with a sample size of n=1044, power of 0.80, and alpha of $p = 0.05$. (No minors were involved in this study.)

3.2 Willingness towards general donation and the DonateLife Register

Of our cohort, $n=40.5\%$ ($n=422$) indicated that they were already registered on the DonateLife Register (Q15 in S1 Text). This rate was higher than the 35% recorded registrants listed by the Australian Organ and Tissue Authority.⁹ Despite this, only 35.5% ($n=371$) of respondents indicated a willingness to donate their eyes (Q16 in SUP09). Figure 4.2.1 shows that of those, 91.6% ($n=340/371$) indicated a willingness to donate for transplantation domestically (Q16a in SUP09).

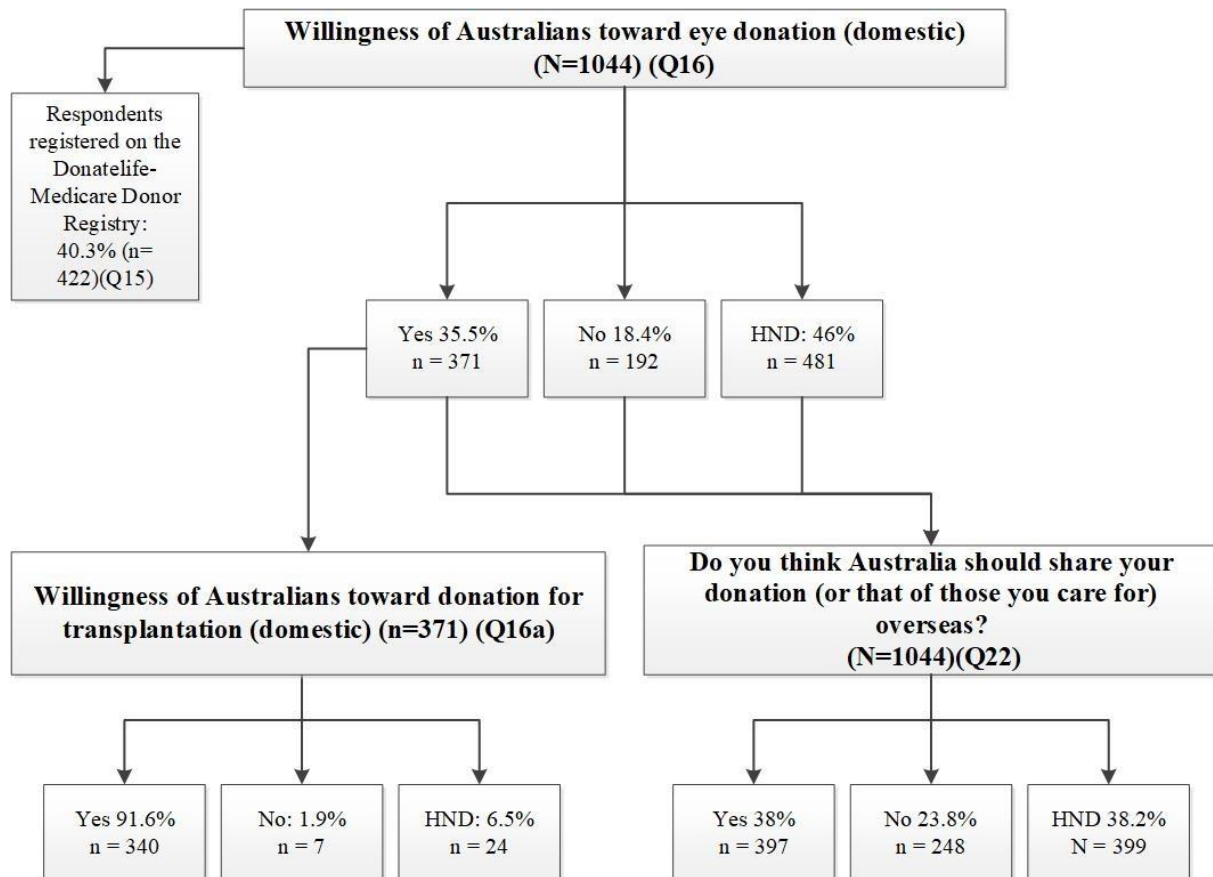


Figure 4.2.1: Australian’s willingness. Willingness of Australian Respondents towards general organ and tissue donation and then corneal donation domestically, and their willingness to export their corneal donation (yes, no, or that they had not decided (HND) (Q=question).

3.3 Willingness to export CT

When specifically asked if Australia should export their corneas on their death, (Q22 in SUP09), 38% ($n=397$) indicated yes, 23.8% ($n=248$) indicated no and the remaining 38.2% ($n=399$) had not decided (See Fig 1). Our analyses found no significant relationship between respondent demographics and characteristics of gender, age, where they lived, vision impairment, Aboriginal and Torres Strait Islander, transplant recipient, waiting for a corneal transplant, born in Australia, or healthcare worker, and their willingness to export (Table 4.2.1). Conversely, we did find a significant relationship between willingness to export and those who had registered on the DonateLife Register ($p < .001$)(Q15 SUP09), and those willing to donate their eyes domestically ($p < .001$ (Q16 SUP09). Significance did not extend to the sub-group of those who said yes to donation for transplantation domestically (Q16a in SUP09) ($p = .612$). (Table 4.2.1; Figure 4.2.1).

3.4 Qualitative commentary

Those who had not decided on exportation were asked to explain their reservations. We identified 5 key themes, from their commentary, being: (1) don't know, (2) need time to think about it, (3) more information needed, (4) up to others to decide, and (5) general concern (see Table 4.2.2).

On the completion of the survey, respondents were offered an opportunity to provide a closing comment, with n=163/1044 selecting to do so. The majority of comments were from those willing to export (n=73/168, being 18.4% 73/397 of total 'yes' group). We summarise, their responses in Table 4.2.3, categorised based on their response to exportation.

Theme	Overview of comments
Don't know	I didn't know this was an option / Don't know what questions to ask.
Need time to think about it	I need to discuss with my family / Depends how they feel at the time / I think I'm just avoiding the uncomfortable topic. On the one hand, I'm dead and my organs will decay anyway. On the other hand, something about it still makes me uncomfortable. I guess I assumed it would be something I'd deal with when I am old. / Reluctant to think about being dead.
More information needed	How it will be used or decided / How can it be done without waste or damage / What is the success rate in other countries when using imported corneal tissue / A guarantee it gets there / Concern other country will sell it / More information.
Up to others to decide	Up to my family / The professionals will know what to do with it.
Concern	It's scary / I would want to know the criteria, e.g. is it for profit? / Going to the rich not the poor.

Table 4.2.2: Respondent Reservations on exporting their corneas. Overview of the 5 key reservations of the 38.2% (n=399) respondents that had not decided on exporting their corneas.

Response (% , n/N=1044)	Overview of comments
Yes (18.4, n=73/397)	Your survey has made me think about this issue / Should go to the most needy - anywhere in the world / Simply put, I became an organ donor to enhance or save the life of fellow human beings, and it's never mattered in any way where the recipient(s) come from.
No (13, n=32/248)	Not donating my eyes / I will not be donating any of my body to anyone / Should look after our own country only / It's quite eerie to think about it / I have strong values / Don't want them sold or going overseas.
HND (15.8, n=63/399)	I will leave it to my family and professionals to decide / I don't know enough / As long as it's not sold for money (apart from reimbursement for freight) it doesn't bother me where it goes / So long as it was done ethically and morally I would have no issue.

Table 4.2.3: Respondent closing commentary. Overview of the closing commentary from respondents who said yes or no to exportation or who had not decided (HND).

4.0 DISCUSSION

Our study indicated there are more Australians (38% n=397) willing to export their corneas than not (23.8%, n=248). The ‘yes’ group had few reservations about the process, viewing it as a humanitarian act. They recognised it had the potential to assist recipients of other countries who awaited a corneal transplantation and would otherwise be unable to receive such treatment without their donation. While this supports our exploration of a routine export system for Australia, further planning and information would be required prior to implementation. For example, a consent-for-export mechanism would assist in ensuring that those wishing to export had the option to do so.

Conversely, some respondents (23.8%, n=248) said “no” to exportation. They were predominantly concerned that Australian recipients in need may be neglected, or the corneal tissue may be misused or wasted when exported. Their concerns are currently valid as there is no public information explaining how the process would occur, and they therefore have minimal information to guide their decision making. This indicates, that if Australia were to proceed with developing a routine export system, then it should provide information that describes the process. A withdrawal mechanism within a consent-for-export process would also ensure the wishes of those that declined, were respected and met, and their donations were retained in Australia. We wonder, however, if individuals in this group would be willing to export once information regarding the practice was readily available and clearly explained.

Interestingly, 38.2% (n=399) indicated they had not decided. This was the largest responder group. This represented an important group to emphasise because, as previously described, at the time of our e-survey, corneal tissue exportation was not common practice in Australia and information regarding the existence was not provided in pre-consent information; nor in public campaigns or on websites, nor at the point-of-donation. This meant the Australian population, in general, has not been presented with the facts necessary to make a decision. This group represented a core group of Australians who, once informed appropriately, could respond either yes or no. Moreover, Australians in this group may be willing to export if fully informed. The qualitative results from these respondents indicated that more information prior to the point-of-donation was necessary for their decision making.

Our results also indicated that before Australia routinely exports corneas, further examination of Australian’s willingness to export may be required. For example, would the next-of-kin in real-world situations permit the exportation of their loved ones’ cornea? Additionally, a carefully coordinated and crafted national and/or jurisdictional public education campaign may be required to present information about exportation, clearly indicating how the process works. It could be monitored, and the options made available to donors. This would assist members of the public in their decision making, well before the time of donation, when donor families are required to make a quick decision. Such a campaign may also require examination of the consent process, with consent-for-export a potential inclusion. Transparency, and the inclusion of consent-for-export are particularly important for the ‘no’ group who may adamantly insist that their donation is not exported. Without communicating or providing an option to opt-in or out, this may unintentionally defy the wishes of the donor, undermine the public’s trust in the sector, and in turn their willingness to donate for a range of needs in the future. This may directly impact recipients in Australia, and beyond, who require a corneal transplant.

While our research demonstrates that a third of Australians are willing to donate, we did not find significant differences in willingness amongst respondents based on demographic and characteristic lines. Our only exception was in relation to those already registered on the DonateLife Register and those who had already decided their own end-of-life donation for transplantation decision. Perhaps these groups, more than others, had already been exposed to the general concept of donation, and were more familiar and aware of how the system and sector functioned in Australia. Making the leap from just domestic to international, may have been less confronting to these respondents possibly due to their existing knowledge. As the current Australian system does not provide details on where Australian donations are currently allocated to (e.g. it does not indicate that donations may be allocated in other parts of Australia either), then perhaps this group did not mind where the donation would be sent, and instead focused more on the act of donation as a wholistic act based on the premise of helping others. As this group had pre-determined their donation decision, this also supported the premise that informing

the public about donation, allowing them to consider their donation in full before their death and the moment of donation, is a powerful motivator in their decision making.

4.1 Limitations

While using an online panel sample method allowed a baseline understanding of the populations' opinion, we acknowledge that those who participated were incentivised to participate, though as our questions presented new concepts, we do not believe it influenced our outcomes one way or another. Using another sampling method in the future may offer a comparison. Additionally, the methodology used did not allow for in-depth analysis of why respondents selected to export or not. Further research e.g. focus, or democracy groups may provide greater detail in the future, and could unearth opinion, influences on opinion, and transition group respondents from one viewpoint to another, once presented with the facts about exportation.

While we found no significance in willingness from health professionals in our sample group, as 92% of our participants indicated they were healthcare workers, the results may propose a bias in their response. Therefore, future studies comparing health care professional and non-health care professional group motivation may explain our findings. Future research could also examine sub-categories such as socio-economic groups and education level.

With no prior examination of this subject matter, we have no way of knowing if the Australian population responded similarly to other populations, how they compared with nations that do routinely export or if this is consistent with their opinion about the exportation of other human biologicals (e.g. blood, bone, reproductive materials). As the first survey of this nature, we cannot determine how changes in opinion or willingness have altered over time, however our research can be used as a baseline indicator to help gauge adaption going forward. Further comparative studies of this nature could contextualise our Australian responses, and may offer nations, particularly those already exporting, the opportunity to examine, revise and improve their services and transparency with their own population. Our sample size was large enough to suggest that several sub-characteristics were not significant to our respondents' willingness to export (e.g. gender, vision impairment, born overseas), though we wonder if, via focus or democracy groups, this could be examined in more detail.

4.2 Recommendation

If Australia decided to routinely export, then informing the public before the point-of-donation, indicating that exportation is an option, is an essential planning feature. We also recommend that donors are consented specifically for exportation in a similar manner to consenting for research. It is important that public messages in this regard, are carefully crafted so exportation messaging does not undermine existing domestic messaging. The eye tissue, donation and eye care sectors would also need to develop an allocation system that worked in unison to ensure Australian domestic demand (being transplant, training and research) was catered for simultaneously to export demand. Finally, Australia would need to clearly explain the process, e.g. how, and why they donate to particular countries, and under what arrangements. Such mechanisms could include:

1. Tick-box added to the DonateLife Register asking donors to indicate their willingness to donate for export if domestic demand was met at the time of their death.
 - a. This could be accompanied with an explanation of why this system exists and how export locations are selected and monitored.
2. Provision of public information, e.g.:
 - a. Eye banks, peer associations etc. indicating on their website that they participate in exportation and may export if domestic demand was met at that time. This is accompanied by an indication of how they determine their export partners.
3. Routinely offer Australian donors the option to consent-for-export, by:
 - a. Updating the donor consent process and forms to include export information to capture consent.
 - b. Donor coordinators/eye bankers incorporate consent-for-export into their point-of-donation conversation.

4. Implement a nationally coordinated system to ensure exported corneal tissue are allocated, tracked, monitored and reported nationally, by:
 - a. Ensuing transparency and safeguards are in place to protect the Australian donation.
 - b. Development of export allocation criteria.

We reiterate that the benefits of the DonateLife Register and the pre-death chance to consider the options were key motivators in our respondent's willingness to export. We cannot underestimate the value of informing populations prior to the point-of-donation. It alleviates concerns, allows for questions to be answered, and ensures the system is accountable and trackable. It removes taboos such as trafficking and profit which are independent factors not necessarily related to exportation but often assumed or confused as one in the same. By presenting the information, and removing the taboos, Australians would have access to the necessary information they need to make their own decision.

To close, our research suggests that a significant proportion of Australians are willing to export their end-of-life corneal donation. Conversely, there are Australians not willing to participate, or are undecided. Collectively, they warrant discussion on the development of a formal and transparent export system, inclusive of a consent-for-export opt-in or opt-out option. Lastly, developing such a system for Australian corneal tissue, may assist other nations and tissue type custodians who may also wish to examine their export process and population willingness, and ultimately ensure donor wishes are respected.

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4.3 Public opinion on national and international allocation of donated corneal tissue?

ABSTRACT

Background: Eye banks in Australia and elsewhere, routinely allocate and move corneas domestically, and at times internationally, to meet recipient transplant demand. While the practice provides corneas to recipients who would otherwise be unable to undergo a corneal transplant, there has never been an analysis of the public's opinion regarding the movement of donations beyond their immediate geographical location. Consequently, there is no way of knowing if current allocation and movement practices meet public expectations. **Method:** We e-surveyed n=1044 Australians to determine how they would like their donation used and allocated, and how they propose it be managed. We tallied their responses to ascertain their hierarchical preference to a range of scenarios based on 4 key questions relating to where to allocate, how to use the donation, how they would like to be informed and how the practice should be managed. **Results:** Respondents assumed domestic allocation, while international allocation and movement was not assumed but supported. They wanted to be consented or at the least informed, and provided with information on the process while leaving the actual decision and management to professionals. They favoured use, including for training, research, and exportation over waste. **Discussion:** Despite not being informed or consented, the current practice of moving corneas nationally meets expectations. International movement is supported though to a lesser extent. The decision to move corneas intra-nationally and/or internationally should be left to the professionals – assuming donors are informed and/or consented for the overall premise of the movement.

KEYWORDS: cornea, transplant, allocation, consent, national, international, Australia

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1.0 INTRODUCTION

End-of-life corneal donations recovered by eye banks, are generally allocated locally as a priority. They can, however, be moved and allocated to recipients at various other locations nationally, and at times internationally. The movement provides corneal tissue to recipients in locations where they would otherwise be unable to access corneal tissue for sight-restoring corneal transplantation.

While the movement of corneal tissue, at least nationally, has been a staple aspect of eye banking since inception,¹ there has been no examination anywhere in the world of the public's awareness of the practice. Nor more broadly, what happens to their donation when it is moved from a local jurisdiction, or if and how the public approves. Additionally, limited information is available on how they expect their donation to be managed and handled during the transfer. Public opinion on its movement and how and where it moves and under what arrangements has never been examined. Therefore, there is no way of knowing if current allocation-movement practice meets contemporary expectations of the donating public or if steps to provide education, information and additional consent are necessary. For example, where do they feel it should be moved to and how, and under what arrangements?

In international terms, 23% of all global transplants (being 42,251 of 184,576 corneal transplants) are currently performed with corneas moved across national borders.² Despite this figure, there remains an estimated 12.7 million recipients globally, who await a corneal transplant.² Most of these individuals live in low-middle-income nations.² Therefore, international allocation may remain a central aspect of allocation until import destinations build and sustain their own eye bank.

Evaluating population opinion on allocation (movement) practice, both nationally and internationally, may assist eyes banks and nations to determine who to allocate to, and how. As the public are ultimately the donors, their input in developing allocation systems is essential to ensuring a robust contemporary national and international allocation service is retained and enhanced. There are a range of scenarios that require investigation. For example, does the public support allocation: locally, nationally, internationally or for research or training? And do they prefer to allocate based on the need or ability to pay, and should the movement be consented for?

Due to the lack of available data on any of the issues that might be relevant to understanding public opinion on corneal tissue movement, both intra-nationally (being city/town, and state/territory) and internationally (being beyond the nation's border), we undertook a study within our own nation, Australia, as an example population, to gather public opinion and commence evaluation. We used Australia as it had been reported as a nation potentially meeting demand³ and hence self-sufficient, and may therefore be in a position to recover additional corneas not required for Australians, and export them to other nations.³⁻⁶ Additionally, Australian Eye Banks currently share corneas intra-nationally, and they do engage in *ad hoc* humanitarian allocation within the Western Pacific region. These aspects are undertaken without specific consent or awareness of the Australian public and donors.⁶ Thus, this has the potential to place Australian Eye Banks and the wider human donation system in an invidious position with regard to the public's expectation of best practice and how or whether current practice could or should be enhanced.

To examine public opinion on the range of issues, we conducted an e-survey of Australians (n=1044). We have previously reported on the respondent's overall willingness to allocate their corneal tissue internationally.⁷ Those findings indicated 38% (n=397) said yes, 23.8% (n=248) said 'no', and 38.2% (n=399) were 'undecided'. We found no significance of their willingness based on general demographics (i.e., age, gender, place of residence and so on), though registration on the Australian DonateLife Register was identified as the key motivator of increased willingness to export ($p < .001$).⁷ We now focus on how respondents believed allocation should or should not occur. These issues included *the how* – who should collect and how should corneas be distributed, and *the where* – which country/s and who should decide. This included partnership arrangements (e.g. with third party distributors or hospitals at the import location), how allocation destinations are determined, and if donors should be allowed to decide - or if it should indeed be left to the eye tissue and eye care sectors (health professionals) to determine how and where donations are allocated domestically and

internationally. Finally, we asked respondents how they would like to be notified of their options to participate in intra-national and international allocation.

Our intent was to ensure that we understood current public awareness and also unearth foundation information on public preferences. This would allow a better understanding of public opinion in order to guide reform, system design and implementation at the national and eye bank levels. This information is essential for ensuring the public's wishes are met within the contemporary climate. Finally, we hope our research inspires other nations, or those managing other human biological types, to evaluate their practice and ascertain if their national and/or international allocation aligns with their population's expectations.

2.0 MATERIALS AND METHOD

We obtained ethical approval for this study from the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC#18-1374H).

2.1 Collection method

Our full methods and validation process have been previously published.⁷ In summary, we designed and validated an e-survey ready for use via Qualtrics XM (USA) (<https://www.qualtrics.com>). We recruited respondents from the Qualtrics banked online panel. Respondents were Australian residents over the age of 18 and selected to match the 2016 Australian Bureau of Statistics demographic population groups for: state/territory, age, gender, Aboriginal or Torres Strait Islander or born overseas.⁸ A sample size of 1000 provided ample statistical power for the analysis to detect an effect of the independent variables on the dependent variable, assuming the power of 0.80, with a small effect size and alpha of $p = 0.05$. The final e-survey in full is available in SUP09, and the responses based on general demographics is available in our prior report.⁷

2.2 Data and statistical analysis

We used IBM SPSS Statistics, version 26, software system (USA) to tally responses and determine preference hierarchy. After data cleaning to remove incomplete responses ($n=22$), we had full information from $n=1044$ respondents.

Responses presented in this paper were extracted from four key questions within the e-survey, these being, in brief:

1. Where logistically respondents would like their donation to be allocated to, e.g. Australia or overseas (Question (Q) 18 in SUP09)
2. In the event that Australia was meeting surgical eye transplant needs, at the time of their death, how they would prefer their donation to be used, e.g. for research in Australia or exported (Q20);
3. What process and allocation steps they would like the Australian donation and eye care professionals to consider and/or prepare prior to doing so, e.g. via a tick box on the consent form or verbal mention at the point of donation (Q23); and
4. What process and allocation steps they would like the Australian donation and eye care professionals to consider and/or prepare, prior to doing so, e.g. if allocating internationally, partnering with AusAid or providing to those who can re-pay Australia (Q24).

Each question listed a range of scenarios. For example, with regard to 'where' to allocate to (Q1), they could indicate their intent for: town/city, their state/territory, Australia, Western Pacific and/or other nations. Respondents had to indicate if they supported each scenario by selecting one of four options, being: 1. 'yes', 2. 'no', 3. 'leave that to professionals to decide', and 4. 'had not decided' (HND). Respondents were asked to respond to each scenario within each question.

3.0 RESULTS

Results are presented based on the four key questions.

3.1 Where to allocate

As some questions may have multiple answers a ranking system or highest response was considered. Respondents were firstly asked to indicate where they would be comfortable with their donation being geographically allocated. Overall, they did not differentiate between intra-national allocation options of town/city vs. state/territory movement with a 'yes' response of between 27-33% (Table 4.3.1). Their assumption was that their donation could go anywhere in Australia, with some simply selecting 'Australia' without providing a response to local town/city (1.4%, n=15) or state/territory (2.1 %, n=22).

As shown in Table 4.3.1, Australian allocation was the most dominant direct 'yes' response (32.6%, n=341) followed by New Zealand (18.5%, n=193), and then any country where there was evidence of need (14.8%, n=155). All other options received similar 'yes' response rates, being: Neighbouring countries of Asia-Pacific (13.1%, n=137); Commonwealth Countries (13.4%, n=140); and Asia Pacific Economic Countries (APEC) (11.7%, n=122). Finally, Country Specific (directed-donation) was the least selected (2.0%, n=21). Despite the 'yes' responses, in all scenarios, respondents overwhelmingly indicated that the professionals should decide.

While there were several responses as 'no' and 'HND' for each scenario, overwhelmingly and similarly to the 'yes' responses, these were hierarchically ranked by 'leave it to the professionals'. Regardless, we note that domestic and international scenarios displayed different 'no' responses. For example, all domestic scenario 'no' responses were between 5.6-6.6%, while international scenario 'no' responses were between 15.8-21.1%. HND however were all ranked relatively similar across all scenarios, being from 18.1-26.8%. With the exclusion of Specific Country/Other which was an option for those wishing to list a nation, the blank unanswered responses displayed division between domestic (1.4-2.1%) and international scenarios (3.3-4.1%).

3.2 How they would like their donation to be used

Respondents were asked, in the event that Australia did not need their donation for an Australian transplant recipient at their moment of death, how else they would like their donation to be allocated. Their response hierarchy from high to low, based on their 'yes' responses, were: Stay in Australia to train Australian surgeons (31.3%, n=327), with a similar response for Stay in Australia to assist Australian Research (30%, n=313). The next highest response was for the donation to Go Overseas to help a person in need of a transplant (18.4%, n=192) (Table 1). Export for research or surgeon training overseas merited a similar response (10%, n=105) to Going overseas to help research in another country (10.2%, n=106). A small number of individuals indicated that they would wish to withdraw their donation in the instance that Australia was not going to need their donation nationally at the time of their death (4.6%, n=48).

Conversely, the highest selected 'no' scenario was 'withdraw donation' (34%, n=354), indicating use over waste was preferred. Approximately 23% of individuals did not want their donation to go overseas for surgical training or research whereas this number fell to 16% when considering international allocation. In contrast, only 10% replied 'no' for surgical training or research in the national context. The most notable response was that approximately 40% of individuals indicated that the health professional should decide on what happens to their donation. Between 17-28% of individuals HND what should be done with their corneas.

Similarly, to Q1 (Q18 in the e-survey), the 'no', 'HND' and 'blank' responses exhibited a domestic and international divide. Along with the 'yes' responses, they were all out-ranked by 'leave it to the professional' for every scenario (ranging from 39-40.2%).

3.3 How they should be allowed to participate

In terms of how they would or would not like to be informed or consented, respondents indicated that a tick box on the consent form was the most favourable (35.6%, n=372) with a similar proportion favouring a tick box on the Australian DonateLife register website (<https://donatelife.gov.au/register-donor-today>) (34.7%, n=363). It was also clear that almost one third of respondents ('yes' 32.6%, n=340) wanted information online about exportation. Finally, discussion at the point of donation (31.1%, n=325) was the least favoured route although this was not significantly different ($p>0.05$) to the other responses (Table 4.3.1). There was a similar response (30-35%) across all replies in terms of allowing the professionals to decide.

With regard to question 3, respondents said 'yes' to these scenarios, more so than for any other scenario within other questions. The 'yes' response also outranked 'leave it to the professionals' on 2 of the 4 scenarios relating to the placement of a tick-box on the DonateLife register and a tick-box on the consent form. The option 'leave it to the professionals' was selected more than 'no' 'HND' or left 'blank' for every scenario, and we noted that this question had the least 'blanks' (1-2.5%) across all of the scenarios across all questions.

3.4 How movement should be managed

Respondents were asked who Australia should export to and where and how. Overall, their responses indicated that they would prefer to leave it to the professionals to decide across all scenarios (ranging from 35-39.2%)(Table 4.2.1). Respondents selected 'leave it to the professionals' more than 'yes' 'no' 'HND' and those left 'blank'. While they presented relatively equal zeal across all scenarios, we highlight the outlier of 'Active Conflict Zones' as the least favoured scenario ('no' 21.7%, n=227). Regardless of the export destination, respondents favoured scenarios where some sort of formal agreement and transparent structure was in place, e.g. partnering with existing formal agencies or leveraging from existing professional relationships. Australia's ability to re-coup some or all costs associated with the transfer was relatively similar, perhaps suggesting that respondents were unaware of the costs involved with recovering, preparing, and allocating donations.

4.0 DISCUSSION

Through our research, our respondents offered some clarity on how and where the Australian public believed their donations could be allocated, and how. They indicated that allocation anywhere domestically was viewed as acceptable and also assumed. The transition to international allocation, while less familiar and less favourable was also supported. They indicated that the final decision to use the donation domestically and/or internationally should be left to the professionals – assuming they were informed and/or consented for the overall premise of the movement.

As presented in Q3 above, where Australians were asked how they would like to be informed/involved about the movement of their donation, they indicated favourably a desire to include an 'intent to move' tick box on the DonateLife Register, and an additional tick box on the consent at the point of donation. They indicated that while they wished to be informed and proactively opt-in or out, that when it came to the day-to-day decisions on where and how donations are moved to, they believed the decision should be decided by the health professionals. They merely wanted to know where and how their donation may be used and be consented (or not consented) under these terms.

While respondents believed that the professionals should decide on the day-to-day aspects of cornea tissue allocation and movement, they also indicated that they expected the professionals to make decisions carefully. On the whole, they did not mind which country the tissue was allocated to, as long as the export destination and partner surgeons etc. were formally approved, and it was confirmed that it was going to a recipient in need.

As a majority of respondents approved of allocating across the whole nation, this suggested that the current domestic Australian tissue sharing arrangements between Australian eye banks, meets the public's expectations of national allocation. Conversely, as there were respondents who said 'no' – and they represented a core element of the community, then the current practice could, as previously

described, be enhanced by a consent step, or at the least being informing that the donation may be moved outside of their immediate location to other parts of Australia.

4.1 Other factors

Firstly, it is of interest that respondents were reluctant to export to active conflict zones. Their response may reflect concern for the recipient who may not have access to post-operative care, or a desire to ensure the recipient is not worse off because of the surgery. It may also speak to the notion that while need would still be great in conflict zones, if the donation could not be safely delivered (and was wasted), used effectively, or if it was used to support war, then allocation elsewhere may be a better use for the donation.

Secondly, we were encouraged by respondent preference to allocate donations to research in Australia or export rather than withdraw their offer of donation. The level of response was similar to that observed with surgery donations, suggesting that the public had a strong interest in research, at least domestically. This is especially important when there is both overwhelming global surgical need, and increased research tissue need domestically.⁴ With regard to allocation toward research, we believe further exploration of how donation to research can be encouraged is essential. This allocation would be beneficial to Australian eye banks, researchers, donors, and those seeking medical treatment.

Thirdly, we note that our Australian public respondents exhibited similar allocation opinion to Australian and global eye tissue and eye care sector members interviewed in prior research conducted by our co-authors Machin, Sutton, and Baird.⁹⁻¹¹ Our public respondents echoed the notion that donors should be consented or at the least informed about corneal tissue movement internationally. The public's belief in leaving it to the professionals to decide also complements what the sector believed, whereby they advised against direct donation practices.¹¹ As our research with the Australian public indicated, this is because donors do not know which recipients and locations are in more need than another, nor which surgeon is qualified, or the degree of available post-operative services and so on. Finally, their allocation prioritisation hierarchy of local, then national, and then international allocation mirrors the allocation pattern advised by the sector interviewees.^{9,10} This suggests that the public and professionals hold similar views on how the practice of corneal tissue movement should be managed.

4.2 Limitation

There were limitations, in addition to those we described in our prior paper⁷ that specifically relate to the 4 questions explored in this paper. For example, some respondents left some scenarios blank. Some did not select intra-national scenario options, and instead selected only a national scenario option. This is difficult to interpret. Did they miss the scenario, become fatigued by the questions, did not want to answer, found it too difficult to answer, did not have an opinion either way or did they interpret the national scenario hierarchically as encompassing the intra-national scenarios, and therefore making the lesser options superfluous.

While the current study utilised responses from Australian participants, it is important to put this into a global context and compare our results globally. Global comparisons would considerably strengthen the findings in this field of research. Unfortunately, however, there are no other comparable studies with which to compare our current findings, and we have no understanding of how the Australian public's response to corneal tissue movement compares to respondents in other nations, nor how this compares with the movement of other human biologicals such as skin, bone, artificial reproductive material and so on.

As we conducted our e-survey before the global outbreak of COVID-19 we remain unsure as to how perspectives of sharing or moving corneas has been impacted by the pandemic. For example, could perspectives be influenced by the degree of community transmission in one population or another or changes in jurisdictional and nationalistic agendas and priorities, and how would this impact both intra-national and international allocation and movement opinions? Perhaps, their response would also change if respondents were asked to consider this from the perspective of the recipient as well as the perspective of the donor.

Finally, we acknowledge that our e-survey did not include a specific question set on the types of organisations or funding mechanisms they believed should be engaged in the movement of their tissue. Future studies could explore their opinion on the engagement of government, non-profit and for-profit organisations involved in the recovery, movement and/or use of their donation. Exploration of their awareness, regarding how corneal tissue is funded or could be funded in the future, would also be valuable.

4.3 Recommendations

Based on our respondents, we believe that nations like Australia can continue to move corneal tissue nationally. In addition, it is clear that generally there is an appreciation that international movement could also occur (if not needed nationally at that time) and acknowledge that the public and the professionals have similar opinion on how donations should be allocated. Therefore, there would appear to be a global zeitgeist and powerful foundation evidence to encourage corneal tissue allocation and movement practice reform – especially for those allocated internationally. As Australian donors are currently neither consented, informed nor aware that their donation is moved from its location of recovery, then steps to address this are essential. At the least donors should be informed that their donation may be moved nationally or internationally, though preferably consented, and a decision matrix must be implemented that defines where and how donations should be allocated to.

The practice of corneal tissue movement could be improved to meet the expectations of the eye tissue and eye care sectors and the public. For example, we recommend nations:

1. Determine if informing only vs. informing and consenting for corneal tissue movement (similarly to consenting for research) is necessary. This includes determining if:
 - a. consent for allocation and movement occurs as opt-in or opt-out
 - b. if this is required for domestic and/or international movement
 - c. public domains (e.g. donation and eye bank websites) present this information
2. Develop a system that ensures local and then national demand is routinely met before routine international allocation.
3. Leverage from existing nation-led aid efforts and partnerships e.g. governments or NGOs.
4. Confirm how partner hospitals, surgeons and recipients are selected, and what costing systems are in place (e.g. gratis, discounted cost or at cost +/- freight cost) within the arrangements.
5. Develop information campaigns to ensure national and international corneal movement systems are transparent to the public.
6. Carefully craft messaging regarding international movement to ensure it does not undermine domestic messaging or those of other tissue types in the nation.

To close, Australians we surveyed were willing to move their corneal tissue donation across their nation, and support international allocation, on the proviso they were, at the least, informed, and preferably consented to the general premise that their donation may be moved nationally or internationally. In turn, the Sector must put in place mechanisms to ensure allocation-movement practice is transparent, accountable, and considerate of contemporary public expectations.

5.0 ACKNOWLEDGEMENTS

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1. (Q18) Please indicate where you would be happy for your donation to go, to assist those in need of an eye transplant. You may select more than one option.					
n=1044	Yes %(n)	No %(n)	HND %(n)	Blank %(n)	Professionals Decide %(n)
Your local town/city	27.3(285)	5.8(61)	20.7(216)	1.4(15)	44.7(467)
Your state/territory	27.1(283)	6.6(69)	20.1(210)	2.1(22)	44(460)
Australia	32.6(341)	5.6(59)	18.1(189)	2(21)	41.6(434)
New Zealand	18.5(193)	15.8(165)	25.5(266)	4.1(43)	36.1(377)
Neighbouring countries of Asia-Pacific	13.1(137)	20.3(212)	26(273)	4(41)	36.5(381)
Commonwealth Countries	13.4(140)	19(199)	26.8(280)	3.7(39)	37(386)
Asia Pacific Economic Countries (APEC) Countries	11.7(122)	21.1(221)	26.7(279)	4(41)	36.5(381)
Any country where there is evidence of need	14.8(155)	18.9(197)	25.1(262)	3.3(34)	37.9(396)
Specific Country/Other*	2(21)	10.9(114)	23.6(247)	47(490)	16.5(172)
*Of the n=21 who replied "yes", 13 listed a specific donation country. Of these respondents, n=6 were not born in Australia. There were n=4 that selected nations of their birth, n=6 selected nations where they had friends/family. Nations mentioned included in no particular order: Argentina, Burundi, India(n=2), Kazakhstan, North Korea, Malaysia, Sweden, USA (n=3), and Vietnam.					
2. (Q20) In the event that Australia was meeting surgical eye transplant needs, at the time of your death, how would you prefer your donation to be used? You may select more than one.					
n=1044	Yes %(n)	No %(n)	HND %(n)	Blank %(n)	Professionals Decide %(n)
Stay in Australia to train Australian surgeons	31.3(327)	9(93)	17.4(182)	2.1(22)	40.2(420)
Stay in Australia to assist Australian research	30(313)	9.8(102)	17.2(180)	3.4(36)	39.6(413)
Go overseas to help a person in need of a transplant	18.4(192)	16.7(174)	21.1(221)	3.7(39)	40(418)
Go overseas to help another country to train their surgeons	10(105)	23.1(241)	22.1(231)	5.5(57)	39.1(409)
Go overseas to help research in another country	10.2(106)	22.7(237)	22.6(236)	5.2(54)	39.3(411)
Withdraw the donation	4.6(48)	34(354)	28.2(295)	9(94)	24.2(253)

3. (Q23) If Australia were able to provide enough corneas to meet the surgical need within Australia, and did not need your eye donation (or that of those you care for) at the time, and was to share your donation with other nations, please indicate what process and allocation steps you would like the Australian donation and eye care professionals to consider and/or prepare, prior to doing so. The Donation and Recovery Process:					
n=1044	Yes %(n)	No %(n)	HND %(n)	Blank %(n)	Professionals Decide %(n)
Provide information regarding overseas sharing on the DonateLife/Medicare/Eye Bank websites	32.6(340)	10.2(107)	20.9(218)	1(11)	35.2(368)
Place a tick box on the Donor Registry, indicating your intent to share overseas in the event that Australia did not need it at that time	34.7(363)	12(125)	21.9(229)	1.6(17)	29.8(311)
Include overseas sharing information in the face-to-face conversation, with hospital staff/eye bank staff, during the end-of-life consent and decision-making process	31.1(325)	12(125)	22.1(231)	2.1(21)	32.7(342)
Place a tick box on the consent form, indicating willingness to share overseas or retain in Australia	35.6(372)	11.7(122)	20.6(215)	2.4(25)	29.7(310)
4. (Q24) If Australia were able to provide enough corneas to meet the surgical need within Australia, and did not need your eye donation (or that of those you care for) at the time, and was to share your donation with other nations, please indicate what process and allocation steps you would like the Australian donation and eye care professionals to consider and/or prepare, prior to doing so. This section examines the eye care allocation process (Please indicate how you would like Australia to decide on who to share your donation with):					
n=1044	Yes %(n)	No %(n)	HND %(n)	Blank %(n)	Professionals Decide %(n)
Countries Australia has a government humanitarian aid relationship with (AusAid)	28(293)	9. (103)	22.1(231)	1.4(14)	38.6(403)
Countries where humanitarian eye care providers, recognised by Australia, have evidence of existing eye care training and infrastructure programs	27.8(291)	10.7(112)	21.1(221)	2.7(27)	37.6(393)
Countries where Australian eye transplant surgeons provide voluntary surgery or training	27.4(286)	10.6(111)	22.5(235)	3.1(31)	36.5(381)
Countries able to reimburse Australia the processing and freight costs (mid-high-income countries)	17.4(182)	14.3(149)	25.6(267)	4(42)	38.7(404)
Countries unable to reimburse Australia, and require humanitarian assistance (low-mid-income countries)	20.4(213)	13(136)	24.1(252)	3.5(37)	38.9(406)
Locations based on the practicalities of freight, logistics, time, and tissue handling techniques	20.1(210)	12.3(129)	24(251)	3.9(40)	39.6(414)
Active conflict zones	13.8(144)	21.7(227)	24.4(255)	5.1(52)	35(366)

Table 4.3.1: Responses to *How* and *Where* corneal tissue can be moved to. *HND: Have Not Decided.*

4.4 Chapter Conclusion

Chapter 4 showed that Australians are willing to export their corneas on their death. They shared similar opinions to sector experts (Chapter 3), in terms of where and how the practice should occur and that donors should be consented or at the least informed. Overwhelmingly they expected the sector to develop a robust and transparent system on their behalf.

The results also showed that there are Australians who do not want to donate for exportation. Therefore, to ensure their wishes are met, a consent step is advised. Lastly, the results indicated that a substantial number of Australians are still undecided on this answers. This latter group warrant the development of publicly available information regarding this option prior to the point of donation, as well as at the point of donation, to ensure they have access to the relevant information necessary to make a decision one way or the other. Overall, it indicated that more education of the public needs to be undertaken in this area to allow them to make an informed decision rather than leaving it to the sector experts. In turn this will aid in lifting the profile of the donation sector within the general public, to a higher level.

This is the final research chapter in this thesis. Alongside Chapters 1, 2 and 3, it presents key information and recommendations to support Australia when considering their exportation engagement. Next, Chapter 5 consolidates the outcomes and recommendations from throughout the thesis to answer the question ‘Should Australia export corneas?’ Finally, it collates the key recommendations from throughout the thesis into 3 key recommendations and presents future opportunities within this field of enquiry.

Chapter 5.0

Discussion – Should Australia export corneas?

Chapter 5: Discussion – Should Australia export corneas?

1.0 INTRODUCTION

Influenced by the PWCR,¹ that indicated Australia was in a position to consider CT exportation, and with awareness that an estimated 12.7 million people were awaiting a corneal transplant around the world,² the central tenet of my thesis was to establish whether Australia had the potential to routinely export CT without hindrance to Australian services. The research presented in my thesis simultaneously allowed me to investigate whether AUEBs unknowingly turned away donations that could be recovered to support domestic demand alongside the possible provision of CT for routine exportation. I also investigated the concept of determining if the sector supported this notion, and whether Australians were accepting of exporting their donation to recipients in other countries, if domestic demand had been met at the time of their death. Finally, the research provided the opportunity to capture information about how exportation occurs and offers recommendations to support Australia with exportation, within the boundaries of bioethics, legal and financial obligations, and the expectations of the public, without reducing access to Australian recipients.

As the movement of CT across national borders is a global practice with global implications, a secondary aspect of the study was the opportunity to derive information that described current export and import practice and provided foundation information regarding the impact on both export and import nations. Collectively, the findings offered suggestions on how the practice could be implemented in Australia, and offered the opportunity for other nations that may also be considering exportation and importation, or reviewing their current involvement, to evaluate or reconsider their position.

At the start of my thesis, there were no available data in the field and no assessment of the sector or the public, to offer guidance or set the boundaries. Therefore, this thesis remains the preeminent body of work in this field.

1.1 Key findings

My findings supported the observation that AUEBs currently unknowingly turn away donations that could be recovered and exported. They also indicated that the eye care and eye tissue sectors support in principle, Australia exporting, and that the Australian public would also be accepting of exporting their donation to recipients of other countries if domestic needs were being met. Finally, AUEBs could export CT within the boundaries of bioethics, legal and financial obligations, without reducing access for Australian recipients if several steps were implemented to prevent undermining EB services in Australia and the import nations. Chapter 5 will outline these findings and the concomitant recommendations.

1.2 Establishing the study

In order to undertake this study, I needed to explain key concepts such as ‘need’, ‘demand’, ‘wait lists’ and ‘surplus’, which had previously been undescribed in the literature. This not only provided a basis for discussing if and how Australia was meeting demand and/or need but offered the first sector explanation of how these statuses are achieved and how they move and influence domestic and then international allocation. In this definition, I indicated that allocation for research need was also a demand that impacted AUEBs and the volume of tissue that could be exported. By including research allocation, I ensured that all possible aspects of domestic need and demand were considered simultaneously to, or alternatively to exportation.

1.3 Key data collection tools

The lack of any data or existing hypotheses within this field led me to conduct the first quantitative analysis of CT use, in terms of collected vs. non-collected; the first grounded theory sector interviews to collect information about the practice and to answer the problem; and finally, the first review of public opinion on willingness to export CT through an analysis of the Australian public’s opinion.

2.0 METHODS

A triangulation, mixed methods approach was essential for unearthing key information for this research and ensuring the results from one aim assisted the development and outcome of the next. Collectively, this approach ensured the question was addressed from a variety of ways, prevented bias, and offered the detail necessary to develop a final recommendation in this thesis (Chapter 5). The data supported the findings by providing a baseline of information and knowledge on the subject. This provided a reference point for future research as well as offering recommendations for sector development and service implementation.

Within the mixed methods approach, several research approaches were implemented. In particular, aim 2 (Chapter 3) involved grounded theory semi-structured interviews. This approach is favoured in the medical and social sciences and is used when there is no prior information available about a subject matter or a question. By using this method, I was able to collect valuable information, examples and vignettes about exportation and importation from a range of perspectives, and determine the interviewees opinion on Australia's routine export potential. I do not believe the depth of detail I obtained could have been achieved by any other research method, such as an e-survey. Aim 3 (Chapter 4) also involved complex sociological research methods in order to extract foundation opinion on willingness to export within a sample population group. The approach used Chi-Square (Pearson's) and bivariate correlation coefficients to examine associations between categorical variables within a generalist population sample group. It was intentionally generalist because it was original research and I wanted to obtain a generalist as well as baseline understanding of willingness to export amongst the Australian population. Going forward, this method could be used again, however more in-depth approaches, e.g. democracy or focus groups, interviews, or real-time observations of willingness at the point of donation, could be used to extend knowledge or delve deeper.

While the research does indicate that Australia could export, it simultaneously stipulates that to do so, the system must be planned and coordinated to ensure that it is transparent and does not undermine the current export or import situation of a nation's EB and eye care service. It should also maintain access to safe good quality CT for recipients, and support donor wishes. It proposes adherence to, or steps toward a suite of recommendations described throughout this thesis and summarised within this Chapter.

Having determined that there are a range of recommendations to prefix export engagement, I concluded that just because Australia has the potential to export, it does not automatically mean it 'should' export. The fixation on 'should' is too absolute and does not consider the complexities and challenges involved in donation, transplant, and international exchange. Therefore 'should' must be accompanied by 'only' and 'if'. The premise then changes to "Australia should only export if its actions to do so do not undermine donors, recipients and EB systems in either nation" or "Australia should only export if the EB and the system can be fully funded to undertake such actions" or "Australia should only export if the EB can be better co-ordinated in terms of supply/demand to undertake such actions, and have mechanisms in place to do this." It does however still stand that if Australia exports, then it will need to develop an export program. The export program would provide the parameters of the practice to ensure that there is an understanding between the participating nations (export and import), and it is traceable, and sovereignty is respected regardless of how frequent exportation occurs. This way activities are controlled and transparent, with equitable and fair distribution, and services are enhanced in both nations.³

Chapter 5 will now describe how the research was conducted, data collected, and results used to support each hypothesis (outlined on page 171). It then consolidates the recommendations extracted from Chapters 1-4 into three key overarching themed action recommendations. It places the recommendations within the contemporary Australian context, where Australia remains a WHO Western Pacific regional leader, during a period of increased need for health security, geopolitical change, and a global pandemic. While my conclusion focuses on Australia as an exporter, the recommendations could be adapted to the global arena, other nations or biological fields that seek to examine their own position as exporters and/or importers.

Collectively, the thesis and its recommendations respond to its initial aims of ensuring that should export nations, like Australia, decide to routinely export, that such practice does not undermine domestic services nor those of the import nation. This is especially important because, there are already an estimated 12.7 million people, globally, awaiting a transplant,² and according to the 2019 WHO World Report on Vision “*projections show that global demand for eye care is set to surge in the coming years due to population growth, ageing, and changes in lifestyle.*”⁴ This means nations around the world must examine their current practice and CT access levels, to provide services to those with corneal vision impairment, and consider how they can improve services to prepare for future need and demand while meeting and maintaining the expectations of their donating public and the relevant seminal recommendations in the fields.

2.1 Key question

My key question was to determine that if, in the event that corneal donations are not needed in Australia at the time of the donation, should Australia export the donation? Abbreviated as: Should Australia export corneas?

2.2 Hypothesis

I hypothesised that AUEBs could export surplus CT without hindrance to current Australian services, and that:

1. AUEBs currently unknowingly turn away donations that could be recovered and exported;
2. Australians would be accepting of exporting their donation to recipients of other countries if domestic need had been met; and
3. AUEBs could export CT within the boundaries of bioethics, legal and financial obligations, without reducing access for Australian recipients.

To examine my hypothesis, that Australia could export without hindrance to Australian services, I developed 3 key aims (outlined below). Each aim became one part of the mixed methods triangulation approach, with their own independent piece of research. (Figure 5.1) Each piece, while independent, assisted in the development of the next piece of research and collectively answered the question: Should Australia export corneas?

2.3 Aims

1. Quantify potential surplus levels of CT within Australia;
2. Undertake a qualitative study of the views of stakeholders in the eye tissue and eye care sectors, on the issues surrounding surplus management and export potential; and
3. Use population survey methods, to ascertain the willingness of Australians to export donated CT when domestic use has been met.

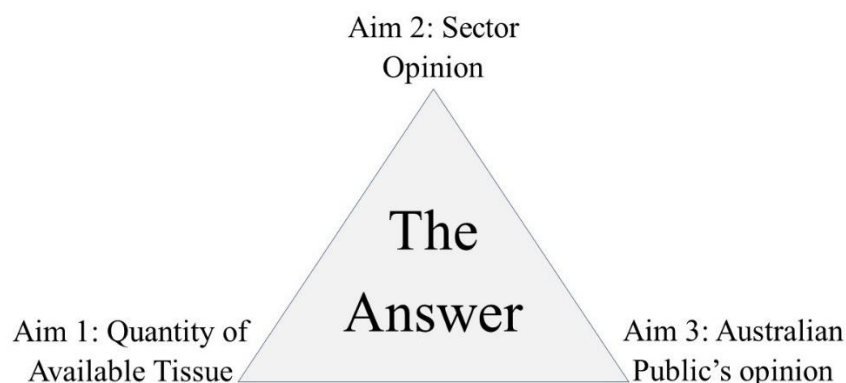


Figure 5.1: Each Aim presented within the mixed method approach.

3.0 ADDRESSING EACH HYPOTHESIS

3.1 Hypothesis 1(Aim 1): AUEBs unknowingly turn away donations that could be recovered and exported.

In undertaking the research to explore this hypothesis, I connected with all AUEBs which are currently located in Adelaide, Brisbane, Melbourne, Perth, and Sydney, to establish a collection tool to track collected vs. non-collected CT donations over a 12 month period from October 2018 to September 2019 from AUEBs (Chapter 2). (The tool and dictionary are located in SUP04 on page 194; SUP05 on page 195. This research indicated, for the first time, that there were sufficient quantities of potential donors that were declined, but could have been recovered for export allocation. It simultaneously captured information on recovery patterns and highlighted that AUEBs decline donations more so because of manpower and resource limitations, rather than because domestic demand is met all of the time. It also means that AUEBs may not always meet domestic demand, all of the time due to this resource limitation. While examination of domestic demand (inclusive of demand for surgery training and research allocation) was not the initial intent of this thesis, the nexus of interdependence is apparent and actions to safeguard and improve access for domestic demand also supports access and services for international allocation. Therefore, while the research confirms Australia's export potential, it simultaneously confirms that AUEBs must evaluate their current domestic recovery and allocation practice as more donations were not pursued due to manpower and resource limitations rather than because of need and demand being met at that time. Therefore, I propose that AUEBs seek more resources to support recovery of greater quantities of CT donations to meet domestic demand all of the time. I will expand on this suggestion within the recommendation section of this Chapter.

3.2 Hypothesis 2 (Aim2): AUEBs could export CT within the boundaries of bioethics, legal and financial obligations, without reducing access for Australian recipients.

To determine if Australia should export, it was essential to understand if this was practical or appropriate. Therefore, I designed the research to extract opinion from those who worked in the eye tissue and eye care sectors in Australia and elsewhere (Chapter 3). By interviewing members of the eye tissue and eye care sector, the research captured, for the first time, information on how exportation and importation currently occurs, and opinion on how it could and should occur in the future. As Australia is not currently a routine exporter, then the inclusion of non-Australian professionals from a range of areas within the eye care and eye tissue fields, and in particular those that export and import, enriched the research. It also offered Australia the opportunity to learn from other global leaders in the fields. Overwhelmingly, the research indicated that eye tissue and eye care professionals held beliefs similarly described by scholars external to the eye tissue and eye care fields. These indicated that exportation improved global comradery and demonstrated solidarity, was an act of reciprocity and political citizenship, shared resources, and honoured the premise of personhood. All of which become a powerful force binding social groups together.⁵⁻⁷

The research indicated that the eye tissue and eye care sectors did support Australia exporting, on the proviso that a range of steps were implemented to prevent undermining Australia and the export nation EB systems. Additionally, the interviewees indicated that Australia must prioritise low-middle income nations in the Western Pacific Region who were in need, and that the donation was provided fairly in terms of cost, and with partners that held similar beliefs to Australia (e.g. non-profit partners). They also cautioned the use of third party distributors until there was greater information available to define their role and responsibility and confirmed that additional costs to engage third-parties was justifiable.

They also indicated that the practice of exportation and importation to-date, globally, was not well understood or defined, and was provided without national oversight or governance. Additionally, they highlighted that corneal surgery and access to CT has not been prioritised in the global eye care space and subsequently this has had a direct impact on the inability to effectively address allocation. This has left the eye tissue sector to self-decide on where to export to and when. The issues are not effectively resolved, and access is not equitable. There was also concern that allocation practices to-date may

directly impact the import nations ability to develop their own EB system. As such, they advised that Australia should carefully consider how and where they export.

Finally, my research highlighted that there was no uniform global or national policy, anywhere in the world, that informed or consented donors for CT exportation. Despite the current limitations, this research indicated that the eye tissue and eye care sector would support the development and implementation of an export consent step (either opt in or out), or at the least, information on this topic being made available for the public and donors about the practice of exportation, and the potential exportation of their donation. Finally, they drew the line at donor directed international allocation. This is consistent with domestic allocation practice.

3.3 Hypothesis 3 (Aim 3): Australians are accepting of exporting their donation to recipients of other countries if domestic demand has been met.

Having surveyed a sample of the Australian population (selected based on the Australian Bureau of Statistics demographic data for all Australian States/Territories)(Chapter 4), this research demonstrated, for the first time, that there were sufficient numbers of Australians who would be willing to export their CT on their death. This warrants the development of a routine export program – to provide them with the opportunity to export should their donation not be needed domestically at the time of their death. Conversely, the research indicated that there are members of the public that do not wish to participate or are unsure, and this warrants information and a system to improve information sharing about the practice of exportation and offer those that do not want to export their CT on their death the option to decline. Through this research I determined that there was a paucity of publicly available information to guide the public with their decision making regardless of their willingness to export or not.

Finally, while the research indicated that the public were happy to leave the details and decisions on the ‘how and where’ to the health professionals, importantly, they did want to be consented-for-export (either through an opt-in or opt-out mechanism), or at the least, aware that their donation may be exported. They wanted to have access to information on the ‘how and where,’ and how decisions are made, though they opted to leave the day-to-day decisions to the professionals. This thesis therefore proposes that Australia reviews and implements the distribution of new information regarding exportation, to inform Australians of international allocation prior to the point of donation. Further steps to, at least, inform that the donation may be exported, at the point of donation, though preferably consented, would also enhance the process. These step could also be extended to domestic allocation, whereby donors are informed that their donation may be moved intra-nationally.

4.0 RECOMENDATIONS

This thesis unearthed and presented a wide range of detailed recommendations within each sub-chapter. For the purpose of this Chapter, they are consolidated into 3 clear overarching themed strategies, that can be developed simultaneously. They are: 1. Review and reform domestic services, 2. Implement a donor export awareness program, and 3. Develop a national export allocation program.

4.1 Review and reform domestic services.

As indicated in sub-chapter 1.4, 2.2, 3.2 and 4.2, in order to allocate internationally, Australians must be assured that domestic need, or at least, its demand, is routinely met. Australia must examine its process of placing caps and quotas on AUEBs. If there are operating theatres available and surgeons available at the same time, and there are donors willing to donate, then AUEBs must automatically be allowed to recover and provide the CT (see Figure 1.4.2 on page 36). Access to CT for domestic use, in a nation where its community is willing to donate should not be hindered because of imposed caps on the AUEBs. Meaning the AUEBs should not be the growth limiting step in the system. Federal and state/territory governments and affiliated donation agencies must work together with the AUEBs, surgeons and surgical facilities, to fund and ensure that donations are not declined when they could have been allocated to meet a booked request in Australia.

Additionally, as described in section 1.4, work needs to be conducted within the Australian eye care and eye tissue sectors to examine how wait times and wait lists are impacted by AUEB CT allocation levels, and how this compares across the jurisdictions or to other nations. This would assist AUEB to consider how they could improve their national sharing arrangements. It is important that changes toward wait lists and wait times is incremental and effective⁸ and based around the demand at the transplant level. A further body of work to examine if a wait time duration changes the need and demand cycles would also be valuable. For example, meeting demand may not be as powerful if it was determined that a recipient waited an extensive period of time because of limited access to CT. Therefore, evaluating how long Australian recipients wait – because of CT access, may provide further valuable information for system enhancement and quota/cap budgeting design.

Investment into e-type systems, nationally, while already underway through the implementation of the National Electronic Donor Registry,⁹ could be enhanced to routinely include capturing of declined eligible donation rates and reasons for decline by the AUEB/donation agency, as described in Subchapter 2.4. Should Australia become a routine exporter then digital systems could be extended to capture intra-national sharing and international exportation (Figure 1.4.2 on page 36 and 5.2 on page 176). Finally, national system examination could be extended to examine allocation and funding for domestic training and research use, simultaneously to export considerations. Block-chain technologies may enhance the integration of these various data sets, and aid tracking across domestic and international allocation for transplant, research, and training. In summary, international exportation will not succeed or meet the sector and public's expectations without addressing domestic quotas and caps, allocation, data collection and tracking systems.

4.2 Implement a donor export awareness program.

As my research indicated in Chapters 3 and 4, there is agreement between the sector members and the public, to inform the public about CT movement and/or implement consent steps at the point of donation. Additionally, people tend to have a strong sense of ownership to their bodies¹⁰ and the trust in the system determines if donors donate or withdraw donation,¹¹⁻¹² then at the minimum, public health policy and systems should be developed¹³ to prepare and support the Australian public with their informed decision regarding CT exportation on their death. Information and/or consent processes must inform donors of the potential or actual downstream use.¹⁴ Without doing so, consent cannot be valid as the donation would be obtained under deceit or false assumptions.³

Federal and state governments, donation agencies and AUEBs must work together to develop and incorporate a nationally consistent consent-for-export option, similar to the consent-for-research option within the end-of-life conversation and consent process, and include it as a 'tick' option on the DonateLife Registry (<https://DonateLife.gov.au/register-donor-today>). Additional research and discussion is required to determine if this option should be presented as an opt-in-to-export or opt-out-of-export, and if the process directly indicates that donation 'will' be exported or 'may' be exported. Furthermore, development of information and scripts to assist sector professionals, who engage in the end-of-life conversation with the donor's next-of-kin (NoK) is essential. This ensures the language and vocabulary is consistent, the option is disassociated from any illegal black market and negative connotations, the donors are reassured that it does not undermine access for Australians, and they are informed that the export system has strict governance and monitoring in place (which I describe in the next section). While there may be concern that this creates too many choices and becomes too complex for emotionally bereaved NoK,³ it is essential for maintaining trust that the option be presented. Over time, the more mainstream the option becomes, the less burdensome it will appear.

While the end-of-life conversation about exportation is important, as indicated by my research, it is essential to provide information about the option to export, and the export process, publicly. This could be provided in public forums, traditional health information campaign forms (e.g. pamphlets in health facility waiting rooms for those without digital access), and digital health information sites, e.g. on social media and websites of DonateLife, EBBANZ and/or individual AUEB. This way, donors and NoK have access to the information before the point of donation. This offers the opportunity for their consideration and the opportunity for greater conversation regarding the practice. Online systems,

should provide authentic access to information, convey messages regarding the option in a neutral manner, debunk false information or common misconceptions, and provide details on the benefits of donation domestically and internationally, and the logistics of how they can donate for both.¹⁵⁻¹⁷ Media campaigns may also assist,¹⁸ though unfortunately, this method may present as sensationalistic¹⁹ if not handled and planned appropriately.

Finally, there were some Australians who were surveyed, and we presented in sub-chapter 4.2, that were unaware that the eye could be donated – even domestically, and there were others whose description was not always accurate e.g. they were not aware it could be preserved and kept long enough to be transferred to another location. Therefore, there is an opportunity to simultaneously revamp general domestic eye donation awareness, as well as export awareness.

Any attempts to develop a public information campaign must include regular repetitious messages long-term²⁰ rather than be one off. This is because there will be significant time gaps between point of information provision and point of death for many Australians. For instance, a member of the public informed today may not die for several decades. Finally, such campaigns could leverage from existing organ and tissue and blindness prevention campaigns nationally and globally.

4.3 Develop a national export allocation program.

To provide a national approach to exportation, then a national Sector-Wide Approach (SWAp) is needed. This requires the formation of a stakeholder group, inclusive of federal and state/territory government health departments, donation agencies, EBAANZ, AUEBs, and eye care professionals engaged in services where CT is used domestically and/or internationally, with additional input provided to the Department of Foreign Affairs and Trade (DFAT). By taking a SWAp, the program has a greater chance of success rather than if conducted in a ‘piecemeal’ approach by non-engaged actors, which could be problematic.^{13,21} SWAap ensures the sector collectively identifies key operational issues and suggests ways for managing risk and constraints. This fosters unity through harmonisation, co-ordination, and synchronisation,²² prevents reinvention of the wheel, leverages from existing services and expertise – which may result in the program being developed quicker,¹⁵ with reduced complexity and the channelling of funding through multilateral actors and initiatives, thereby reducing the number of parallel bilateral programmes.²³

My research could not determine where the national program would sit but I propose that in the short term, until an alternative placement is determined, that its foundations are established as a joint collaborative effort between EBAANZ, the state/territory and federal health departments (inclusive of the Organ and Tissue Authority - OTA). Within this model, EBAANZ would lead, and perform the administrative day-to-day activities, e.g. develop policy, vet requests, collate data and assist AUEB with export. It would also ensure that there is a clear pathway for transparency and reporting of practice is in place, by liaising with the sector, jurisdictional and federal departments of health. This would ensure the program details were accessible to other departments, such as DFAT, which would be a vital partner to engage, as the program in essence involves the international sharing of human donations provided by Australian citizens and residents. It simultaneously ensures that the program can be monitored for the security and reassurance of the Australian public and the donor’s NoK. The relationship with DFAT and other departments could develop into supporting AUEBs who experience a financial gap when providing to low-middle-income nations, by financially subsidising or assisted them, through the nation’s foreign aid and health securities portfolios. This may be particularly so if exporting to nations where Australia has current bilateral partnership arrangements or in the area of ‘soft diplomacy’. This could work well, as the gift of donation is highly beneficial to both the donator and receiver, meaning it is mutually and contextually beneficial to both nations.²⁴ We present the export program stakeholder matrix in Figure 5.3.

In this model, EBAANZ as the sector representative would also provide agreed export data to GAEBAs as part of that organisations global data capturing program.²⁵ Individual AUEBs who are EBAANZ members would use the support services, tools and guidelines provided by EBAANZ to ensure their exportation met the standards clearly outlined in the policy tools developed through the National Export Program.

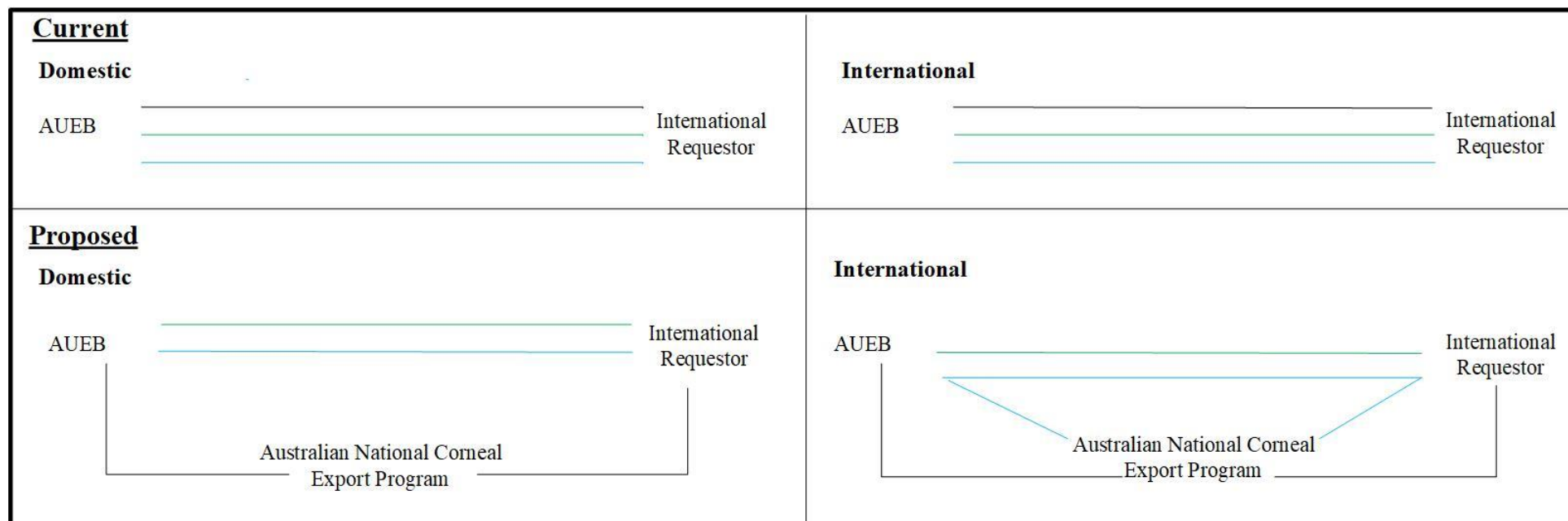


Figure 5.2: Current and proposed allocation and export systems. Indicates how each step in the process is currently managed, and how it could be managed in the future. The steps are: 1. confirm/agree to allocate (black); 2. dispatch (green); and 3. management of the reimbursement (funds transfer). In this example, the steps can apply to both domestic and international allocation. The proposed Australian National Corneal Export Program included in the proposed section is described in Figure 5.3.

While ensuring the program meets Australian standards of engagement, it must also work towards meeting the United Nation's Sustainable Development Goals²⁶ and in particular Number 3 (SDG#3)(titled: *Ensure healthy lives and promote well-being for all at all ages*),²⁷ and capacity development initiatives, and relevant global and national seminal soft guiding tools as listed in Box 5.1.

Global health:

The Paris Declaration on Aid Effectiveness²⁸ – as Australia is a signatory to the Declaration; The Accra Agenda for Action,²⁹ Sydney Statement of Global Health Security,³⁰ the International Health PartnershipPlus (IHP+) which has now transformed into the Universal Health Care 2030 Goals (UHC2030),³¹ Australia is also a partner of the UHC2030, and the outcomes from the Oviedo Convention 1997.³²

Global eye tissue and eye care: WHA63.22 Guiding principles on human cell, tissue and organ transplantation,³³ The Global Alliance of Eye Bank Association's The Barcelona Principles,³⁴ International Council of Ophthalmology Statement on eye tissue,³⁵ and the WHO's World Report on Vision.⁴

Nation specific: Australian Council for International Development's Code of Conduct,³⁶ EBAANZ Bioethical framework,³⁷ Vision2020 Australia, and the suite of international development related policies published by the Royal Australian and New Zealand College of Ophthalmology.³⁸⁻⁴²

Box 5.1: Relevant global and national guiding tools

As outlined in sub-chapter 3.3, the program must prioritise Western Pacific Region recipients, and within that, those from low-middle-income nations and neighbouring nations, with allocation based on evidenced need at that location, and on agreed selection criteria and partnership agreements that meet Australia's regional health security and humanitarian aid program and planning requirements. The agreement must also align with the goals of the import nation in a synergized manner, horizontally, and be designed to decrease dependence long-term.

To improve equitable access, the program must implement a socialised export funding model (as suggested in sub-chapters 3.5 and 3.6), whereby low-middle-income nations are provided CT at a lower fee. If funding gaps appear and the AUEB is unable to buffer the lost revenue because of the gap, then the AUEB/program are encouraged to work with relevant domestic or import nation federal and jurisdictional governments or non-state actors, e.g. vetted sector NGOs, public-private partners, DFAT (AusAid) or other health security agencies/affiliates to find the funds to cover the gap. This prevents AUEB from bearing the brunt of the cost deficit incurred when exporting to those nations unable to reimburse Australia or having to self-select to export to only those nations able to reimburse them. It also prevents disadvantaging waiting recipients in low-middle-income nations because of the financial limitations of the individual AUEB. While low-middle-income nations should be prioritised, it is important to recognise that high-income nations such as New Zealand (NZ), also request CT from Australia, and NZ in particular, as a member of EBAANZ, has an existing reciprocal agreement in place.⁹ Therefore, the model must have the flexibility to provide to high-income nations as required, however, those nations should be provided CT at the same fee as an Australian recipient, and without derailing agreements to support low-middle-income nations first.

Through the model, EBAANZ would develop a suite of policies and associated tools to outline how the program functions at the national and AUEB level. For example, the implementation of an electronic portal to track allocation nationally and internationally may be a valuable asset. The policy could also outline where national and then AUEB jurisdiction responsibility and processes rest and confirm equitable and ethical allocation is in place. Materials may also include, outcome data response forms, export documentation, and procedural documents regarding where and how to export. It could also coordinate the allocation of Australian corneas to key agreed nations as part of a coordinated support program for such nations, on behalf of AUEB, as a national collective.

This research (as outlined in sub-chapters 3.3 and 3.5) also confirmed that there is little information to explain the role and responsibilities of third party distributors/brokers. Their involvement appears to be unregulated. Therefore, until their role and fees are clear, AUEB should seek to allocate directly to the import EB or transplant facility in the import nation, and where possible prevent third party distributor/brokerage usage. This ensures a clear chain of custody for the donation, reduces costs, and encourages the development of a collegial relationship directly with the import provider, which in turn may lead to further collaborative opportunities beyond simply exporting.

The program must also engage external advisors to assist in developing policy and practice. This would strengthen their program, ensure export practices were developed in consideration of Australian donors and recipients, and export actions were considerate of the import nation. For example, engagement of peer Associations such as PacEYES – an ophthalmological society comprising of health organisations, ophthalmologists, nurses, and other eye care providers from across the Pacific Region, would enhance engagement and appropriate provision of CT to the region. This ensures there is no “antagonistic push on the East from the West,”⁴³ or program paralysis because of cultural or practical differences⁴⁴ e.g. when the notion of fairness differs.⁴⁵ It also prevents an exporter-centric (Australian-centric) homogenized approach from undermining the intent of the act and ensures those involved behave responsibly when globally engaged.⁴⁶

Additionally, as described in my research, any action to export – particularly to low-to-middle-income nations, or those without a robust EB system of their own, needs to be provided in consideration of the long-term needs of that nation. Provision must go hand-in-hand with the provision of capacity support and assurance that the import transplant facility and healthcare provider can work towards long-term self-sustainability of their own EB and/or corneal surgical services – with an agreed exit strategy in place. While capacity development cannot be enforced or may not be required, it is essential that Australia offers these services as part of the exchange, to the import nation. Such services could involve collegial or formal knowledge and skill exchange in a range of procedural or quality activities, such as infrastructure support to build or train staff, or bilateral exchange programs where eye tissue and eye care professionals visit the import nation and vice versa. In this, providing a solution towards self-sustainability becomes more important than simply providing the CT. With these key points, any export program for Australia would require the inclusion of development professionals or health professionals familiar to the field of eye tissue and/or eye and health care development to ensure culturally appropriate and practical solutions are proposed and implemented in the import nation.

When considering external advisors or engagement with other organisations, it was highlighted that the public I surveyed (Chapter 4) and the sector experts I interviewed (chapter 3) were adamantly opposed to the notion of profiting from the end-of-life donation, and there was consensus on supporting the poor. Their beliefs are consistent with the literature in the field of human biologicals where states Titmuss⁷ “profit motive [goes] against the altruistic monopoly.” Additionally, Frow⁵ proposed that “without the poor benefiting, such a system can create a cartel from which the poor are excluded.” With this in mind, the Australian export program would need to ensure that those it selected to engage or partner with, meet the contemporary expectations of Australians and the sector, and conducted themselves in accordance with the relevant seminal guiding tools, as listed in Box 5.1. Partnership must also reflect and support horizontal engagement, e.g. through investigating how post-operative ophthalmology services could be enhanced and how access to operating theatres could be increased.

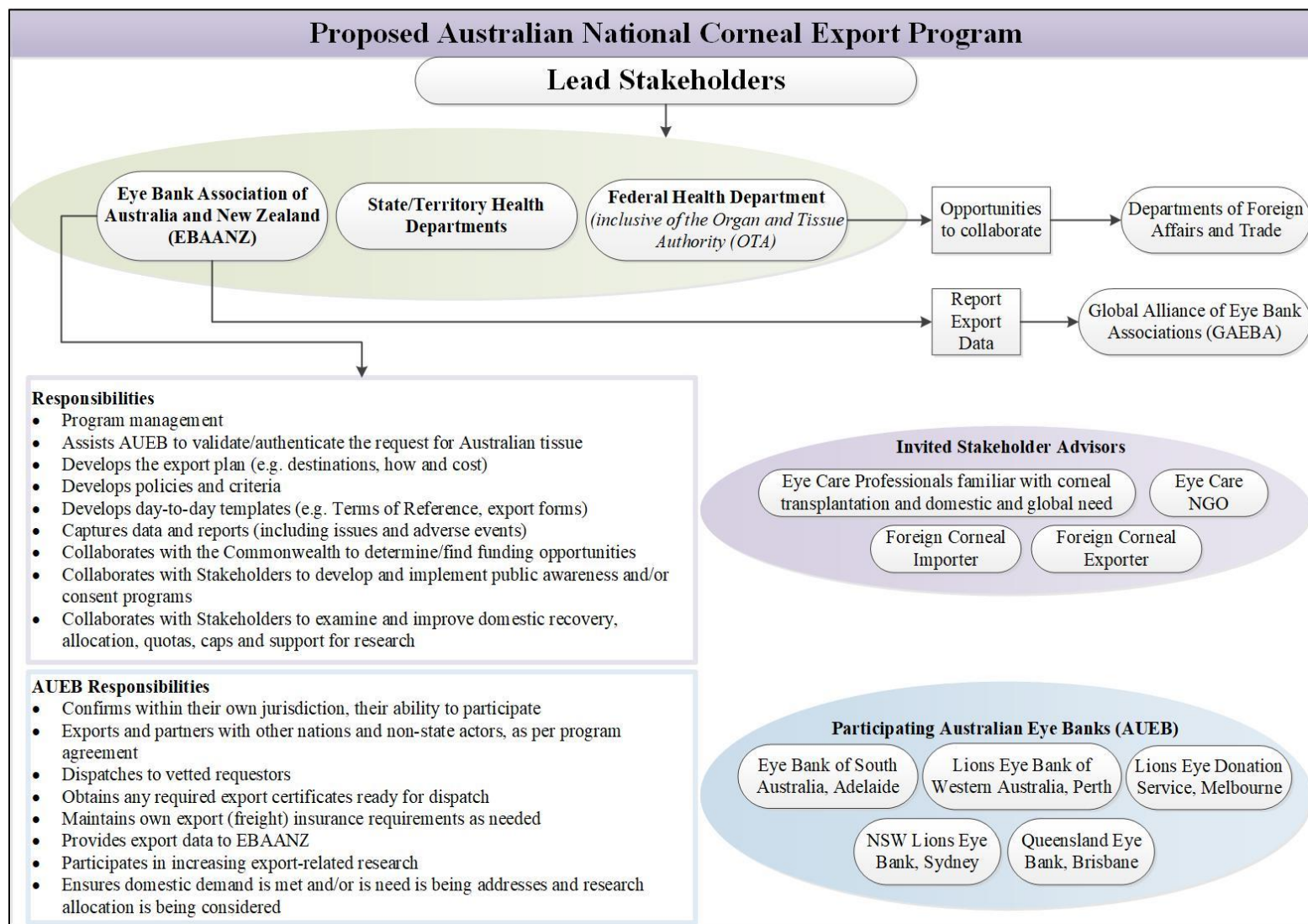


Figure 5.3: Proposed Australian national export system

4.4 Where to export.

In terms of where to export to, I highlighted in sub-chapter 3.3, that our sector experts advised Australia prioritised destinations based on a 3 key criteria, which I then placed into a decision matrix (Table 3.3.3 on page 100). The key criteria were, 1. Western Pacific, 2. neighbours and 3. low-middle income nations. Papua New Guinea, Indonesia and several Pacific Island Nations meet this criterion and were mentioned by our interviewees. While we cannot confirm if Australia will actually select to export to these nations in the future or if indeed they require Australia's assistance or are ready to commence corneal transplant service development, the matrix we developed can assist Australia in destination decision making in the future. I will now explore the key recommended destinations, suggested by the interviewees in sub-chapter 3.3, to determine if they have real-world validity, though I re-emphasise that this is hypothetical because analysis at the import nation is essential before any engagement by Australia.

4.4.1 Papua New Guinea:

In the instance of Papua New Guinea, it is identified as a nation with the highest rate of low-vision and blindness in the Pacific⁴⁷ and they are without an EB. PNG already engages with Australian and international eye care NGOs⁴⁸ including the Lions Clubs, which have a strong affiliation with EBs around the world, including 3 of the 5 AUEBs being Lions affiliated.⁴⁹ While there is no indication on how and where corneal services or CT services fits into the Papua New Guinea agenda, it is likely that they could benefit from CT and EB collaboration and support from Australia – assuming they are in a position to commence corneal transplant service development. Additionally, this nation is a key strategic partner for Australia, as its closest neighbour. Australia has invested heavily into supporting PNG in a range of areas, with programs such as the *Papua New Guinea-Australia Comprehensive Strategic and Economic Partnership* (CSEP), most notable.⁵⁰ The CSEP launched in 2020 by Australia's Prime Minister Scott Morrison, provides “*an enduring and overarching framework for deepening bilateral cooperation across security, trade and investment, governance, development cooperation, health, education, gender equality, climate change, people-to-people and institutional links, underpinned by a commitment to achieving concrete outcomes by 2030*”. Therefore, AUEB collaboration with Papua New Guinea, should Papua New Guinea require assistance, could provide a compatible and valuable opportunity for both nations.

4.2.2 Indonesia:

Indonesia, similarly, is a nation that meets the recommended criteria of our interviewees (sub-chapter 3.3), however unlike Papua New Guinea, Indonesia has its own EBs – including a Lions EB in Jakarta. Therefore, Australia would need to consult with Indonesia to determine if and how Australia could support their existing EB services. Should it be determined that there is an opportunity for the nations to collaborate, then this would contribute to the wider efforts for improved relations between the two nations. Most recently, this has been bolstered by the *Australia-Indonesia Health Security Partnership*.⁵¹ A AU\$20-35 million program spanning 5 years (2019-2024), designed to support the health security of Indonesia. While predominantly focused on infection prevention and control, there may be opportunities for the eye tissue and eye care sector to integrate and leverage from existing relations.

4.2.3 Pacific Island Nations:

The Pacific Island Region (excluding Australia and New Zealand), which is home to 2.3 million people, who are spread across 14 nations and an estimated 15% of the world's surface,⁵² may also benefit from Australia's support. Their relatively low geographic dispersion means that it may not be practical for some Pacific nations to develop and maintain their own EB and they may be reliant long-term on imports or the transfer of their waiting citizens to nations that can perform the surgery on their behalf. This emphasises the need to ensure export and capacity planning is considerate of the unique circumstances of each import nation, and the partnership arrangements are tailored to meet different situations, rather than enforcing a homogenised one-size-fits-all approach. While some smaller nations may never be self-sufficient in providing CT, this should not prevent their establishment of strong corneal prevention,

treatment, and post-operative programs from being developed. With this in mind, the engagement of advisors from both larger and small nations would assist Australia with developing appropriate partnerships and programs for the importer.

4.2.4 Existing export relations:

While the 3-point criterion we describe is important for future destination decision making, existing engagement should not be forgotten or left high-and-dry. For example, Australia provides *ad hoc* CT to Myanmar, Cambodia, and Noumea – all low-middle-income nations, and routinely to NZ - a higher-income nation.⁹ They are all located in the Western Pacific Region, yet geographically further away than Papua New Guinea and Indonesia. Examination of existing partnerships may be required to see how best they meet the contemporary recommendations we describe, and what steps need to be addressed in order for exportation to these nations and continue or cease.

NZ in particular has a unique relationship through their joint EBAANZ partnership and long-term Trans-Tasman arrangement across a range of medical and non-medical related fields.⁹ As such, AUEBs have been providing CT to NZ for many years. There is no reason why this exchange cannot continue however we do highlight that if Australia is continually exporting donations to NZ over a prolonged period of time, without any evaluation of the practice or evidence of a reduced demand from NZ, then Australia may need to review the terms of the arrangement to ensure Australia's export into NZ is not undermining NZ and preventing NZ from building and sustaining their own EB services. As NZ is also a high-income nation and regional leader, then we take this one step further by highlighting that NZ has the potential to assist other Pacific Island Nations, rather than remaining a receiver of Australian CT. Other nations, like Canada are in a similar position, whereby they routinely import CT from their neighbour, the USA. In 2020 however they developed a national consensus plan, in part to reduce their import dependence and examine how they could become self-sufficient and in turn share their donations with other nations in need.⁵³ Thus a world class state of the art national scheme, developed in Australia, could in essence be rolled out to other nations with similar intent, and ultimately provide for a global framework that was unified and implemented in the not-for-profit space for a range of countries.

4.5 Barriers to progression

We acknowledge that there remains significant barriers within Australia and abroad that could undermine efforts to develop an effective and transparent export program. I will list these below:

4.5.1 Limited stakeholder engagement:

Firstly, Stakeholders do not work together effectively. For example, Australia's organ programs and regulatory licenses are federally managed but the health system where donors are recovered and surgeries are performed, is state/territory managed. This means that despite national or collective intent, each AUEB functions differently depending on which jurisdiction they reside. For example, as we described in Chapter 2, some jurisdictions were unable to collect whole jurisdiction data on declined donors, and some were limited by imposed caps and quotas. This creates unnecessary barriers for the AUEB. Improvements in governance must target a range of actors⁴⁶ and, as Farrell indicates⁵⁴ when referring to the politics of the blood sector, "political leadership in circumstances where law, as well as ethics, science and commerce all play a role but are not determined" must be considered. Additionally, the multitude of state and non-state actors adds additional and complex layers.⁴⁶ For example, NGOs who work in the global eye care development space do not always work collaboratively and often duplicate the same work. They may provide aid support to another nation but they each work in different cities or with different partners within that nation. Australia would need to navigate the complexities and limitations of engaging non-state actors and determine how those organisations work with or against the nation they claim to support and how compatible they are for Australia when exporting human tissue.

4.5.2 Impact of COVID-19:

Secondly, COVID-19 may have altered Australia's ability to logistically provide exports, and geopolitical shifts in recent months may have altered the willingness of Australians to export. While

there is no data on wait lists and wait times in the national and global corneal transplant space, it is safe to assume that COVID-19 has impacted corneal transplant wait lists in some parts of Australia – though more so globally, due to the cessation of elective surgeries and reduction in community level early detection and prevention (e.g. reduction in optometry visits). According to the OECD, elective surgery wait lists and wait times globally will likely increase at least in the short-term, which will magnify the imbalance between supply and demand.⁸ With economies also impacted, the tipping points between the haves and have-nots, or in other words those who can reimburse the EB and those that cannot, may change. This may result in more requests for CT below an export EB reimbursement rate. This would challenge the EB by forcing them to go against the recommendations, by providing based on an importers ability to pay rather than based on equitable allocation principles. Alternatively, it may force them to swallow the short-fall or cease sharing abroad altogether which again impacts wait lists and wait times elsewhere, and most likely impacting the world's poorest. It is essential then, that AUEB exportation activity does not 'aggravate global inequities' by going against the recommendations.³ Therefore, alternative funding support from DFAT (AusAid) or affiliated or independent sources would assist to allocate equitably in the region.

4.5.3 Donor perception:

Third, there may be fear or concern from within the eye tissue and donation field that informing donors that corneal donations are exported may undermine domestic access. For example, the assumption that it is negatively associated with black market profiting and trading, resulting in their donation withdraw for a range of donation type. With nothing in the public domain to guide the conversation, then as we describe in sub-chapter 3.4, this assumption may well be founded. Therefore, the sector must have plans and guidelines in place and carefully craft and plan education campaigns and export programs with a range of stakeholders and communication specialists based on these guidelines, if the sector is to move forward in this space.

4.5.4 Lack of global coordination:

Fourth, this body of work unfortunately emphasised that, like other areas of global health,⁵⁵ the practice of corneal allocation in the global space is fragmented – meaning it is poor or lacking coordination²³ and based on individual agendas and divergent interests.⁵⁶ Like all global health arenas, this fragmentation is increased by the dominance of non-state actors²² which in this instance is represented by the eye care NGOs and the multiple individual EB organisations and distributors/brokers around the world. There is a complex interplay or lack of interplay by all stakeholders, who focus on vertical (allocation) rather than a horizontal (system development) approach.²² In essence current practice is ungoverned, under reviewed, under reported and unclear, and in need of reform at the global, national, jurisdiction and EB/transplant centre levels. Based on my interviews and the limitation of prior publication in this field⁵⁷ current export allocation practice appears inequitable and appears to undermine progress in import nations. Australia is therefore well positioned, as a relatively nascent exporting nation without long-held export ties and practices in which to unravel, to design a system from the ground-up that meets contemporary expectations on all sides of the arrangement.

4.5.5 Prioritisation of surgical treatment:

Finally, there lacks a willingness to address and prioritise surgical services as part of the wider health securities approach. This is especially so in low-middle-income nations where Meara et al., pointedly indicate “it has been absent from the discourse.”⁵⁵ As CT is provided predominantly for surgery then by way of association it too is not prioritised.

Therefore, it is fair to say, when considering elective, rather than urgent corneal transplantation, in comparison to other health issues, e.g. contagious disease or conditions or episodes that result in death, that elective surgeries lack the urgency to attract attention and swift change.⁵⁸ Steps to transition surgical services, and by association, EB services and CT allocation, from an inferior position in the health service order to a position that requires redress, could offer dynamic and unique valuable soft power for Australia when reviewing services domestically and internationally.

Any engagement of Australia with regards to exportation must be conducted in a manner that ensures its activities are not contributing to the development of a human-bodies marketplace, and that donors

and the public were aware, and it did not undermine domestic services. Engagement in an effective national export program and a national donor information and/or consent campaign, as described in my thesis conclusion, would prevent such activities from occurring and could simultaneously offer value for Australia, in terms of diplomacy as well as good governance, and could be considered a global public good.⁴⁶ Therefore, strategies to elevate and scale-up the urgency of supporting surgical services and affiliated services like an EB, is necessary.⁵⁵

5.0 FURTHER WORK AND OPPORTUNITIES

Further work must be conducted to examine the global impact of CT export and import practice, and examine how as a national and global EB and eye care sector, the practice and organisations involved can be evaluated for compatibility/incompatibility to the relevant guiding frameworks, including their commitment to SDG#3, national health securities agendas, and the recommendations outlined in this thesis. Steps to evaluate the role of state and non-state actors in the exchange of CT are also required, as my work indicated current practice is contributing to global maldistribution, and is not effectively aligned to the position and needs of the exporter nor importer.

Further research on donor willingness to export via the NoK, at the point of (real-time) donation, would provide essential evidence to support a suite of public education campaigns and donation consent tools. Such research must be carefully crafted to ensure the peculiarity of discussing exportation, in a nation where information about the practice is not publicly available, does not upset grieving families or create unnecessary concern. The vocabulary and approach implemented must indicate that the approach will be based on a transparent program and has no association with illegal black market activity.

Further comparisons with other nations who export or import, and other human biologicals, may also enrich understanding. Additional exploration of health professional and public awareness concerns, and willingness, would also enhance and consolidate the evidence we already present.

Sector wise, examination of how this work can support global development and health securities is important. For example, perhaps steps to develop further research or guiding documents to define the role and responsibilities of third party distributors/brokers will assist Stakeholders (and the third party) to determine how and when to work together and how the chain-of-custody is managed. There lacks binding legislation or agreements and guiding documents, other than The Barcelona Principles, to guide and discuss the activity.

Scoping exercises to determine CT demand (and where possible need) within the Western Pacific Region – prioritising low-middle-income and neighbouring nations would also be a valuable exercise. This would assist Australia with developing an export program. This could be done in consultation with key agencies in the eye care field who are engaged in capacity and/or health security work. And finally, a scoping exercise to evaluate the NZ domestic system and the impact of Australia's long-term exportation to them, would help reduce NZ dependence on Australian imports, potentially position them as a future export provider to other Pacific Island Nations, and offer Australia valuable insights into how their historic import practice impacted on import nation they engaged.

Finally, the perspective of the importer, rather than the exporter, requires address. More so, this needs to be examined in terms of their capacity to develop their own EB system, corneal services, their commitments to their waiting recipients and their expectations of exporters and capacity development agency partners. Further investigation into how importation has (or has not) impacted their ability to-date would further strengthen conversation between exporters and importers.

Examining how the national export program we describe for Australia can be applied to other nations or globally, would be a valuable opportunity for all Stakeholders. Finally, how CT services in general can support efforts towards horizontal system modelling strategies, rather than just vertical allocation provision would be valuable. For example, how can they support a range of conditions, ocular tissue needs and infrastructure builds, rather than focusing only on exporting. Or could events such as training infection control be opened up to provide training to tissue bank professionals, rather than just providing the training for the eye bankers? In summary, the approach would maximise the resources to broaden

the output across a range of needs and elevate the wider health services rather than just the singular act of allocating for export.

6.0 CLOSING REMARKS

In closing, the act of matching supply with demand domestically and internationally, is more ‘art than science.’¹⁵ It is complex, multi-faceted and influenced by the stakeholders, culture, values, economies, and the existing status of EB and eye care services in both export and import nations.

This thesis demonstrates for the first time that there is scope within Australia to routinely export CT, and there are opportunities for Australia to pave the way as contemporary allocation architects. Australia should only export if its actions to do so do not undermine donors, recipients and EB systems in Australia or the nation they export to.

The ability to share Australian donations within the Western Pacific Region would be an act of reciprocity, that fosters collaborative partnerships and relationships,²⁴ supports recipients who seek treatment, provides regional health security to Australia during a time of change and unrest, and supports import nations towards sustained EB and corneal treatment services. Finally, if donors are informed and/or consented-for-export, it offers greater donation options to those wishing to donate, should they be willing to support recipients in other nations.

By sharing the gift of donation beyond Australia’s borders, this practice, if performed well, has the potential to demonstrate that the time old tradition and principles of the *gift relationship*⁷ remains a central tenant of twenty first century practice and ultimately supports personhood, human solidarity, political citizenship, and is an act of humanity.^{5,6,24} In essence, Frow states⁵ “the gift is not the possession itself but the cultural meaning and social contract it represents.” Therefore, any engagement strengthens the social bonds and is a source of social capital – not economic capital. This in essence mirrors the intent of bilateral partnership agreements already established between the Australian Government and the PNG and Indonesia Governments that I have presented, and highlights that the gift of reciprocity in this instance means to give is to receive.

My thesis explored the idea of possible CT donation for exportation. There are sufficient quantities of donations to export, and both the professional sector as well as the public appeared to be generally in acceptance, and support of Australia’s engagement. My thesis also identified that there was a dearth of information in this area, indicating that further work in this field is required. It also highlighted a need to examine domestic CT use and domestic systems simultaneously to examining exportation. I have provided some recommendations and insights through this thesis and a number of published papers, to alert the community that this area is uncharted, in need of further development, and essential for the improvement of access and allocation of CT nationally and globally.

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APPENDIX

01: SUPPLEMENTAL DATA REFERENCED IN PUBLISHED PAPERS

SUP 01: Chapter 1 - Inclusion and exclusion criteria

In addition to examining the clinical impact (e.g. recipient outcomes), our dominant interest was to examine non-clinical impact. We wished to explore these non-clinical themes as to how and why export and import nations were selected; the impact of for profitization and commodification; an explanation of how tissue-for-export was selected, priced, funded or gifted; evidence that donors were informed of potential exportation and/or consented for export; and evidence to support the validity and appropriateness of TNA engagement and practice. For example, we wished to ascertain if CT TNA assisted in providing universal equitable access to CT; prevented waste, and supported donor wishes, or conversely, if CT TNA took advantage of those without routine access or those with over supply; thereby undermining national efforts towards self-sustainability.

We reviewed academic literature over a 100-year period, capturing conversation and research prior to the known commencement date of 1961.

1.1 Inclusion criteria

Our initial search explored deceased and CT donation only. As this resulted in few published articles, we performed a secondary search, with other biologicals originally excluded, in the hope that CT TNA may be captured within other literature. We outline our inclusion criteria in Table 1 (page 190).

1.2 Exclusion criteria

We excluded literature pertaining to living persons and live trafficking, CT for domestic training, research and future technologies, and other human biologicals (however we reintroduced some human biologicals into our second inclusion criteria search). We excluded review papers briefly mentioning TNA, and those that did not provide adequate analysis, nor data beyond simple comment of known TNA. We avoided common terms such as “saving sight” and “sight-saving” to avoid generalist eye care related literature. We intentionally sought academic literature, due to its peer-reviewed nature and our interest in peer analysis. While professional associations, textbooks, newsletters, editorials, magazines, blogs, presentations, websites, guiding documents along with other grey literature provide valuable commentary and direction, and instruct practice and professionalism, they were excluded as they did not provide original research or academic analysis. Our specified exclusion criteria are outlined in Table 2 (on page 190).

SUP 02: Chapter 3 - Review papers capturing clinical aspects of transnational activity

EB	Eye Bank
ECD	Endothelial Cell Density
DSAEK	Descemet Stripping Automated Endothelial Keratoplasty
DTT	Preservation to Transplant Time
NA	Not Applicable
ND	No information
PKP	Penetrating Keratoplasty
PTT	Preservation to Transplant Time
Y	Yes

Legend

Reference	Author's Conclusions	HREC approval identified	Adherence to the Declaration of Helsinki	Exporter (and EB provider)	Importer	Domestic	Imported	Donor Age	Death to Preservation Time (DPT) in hours	Preservation-to-Transplant Time (PTT) in days	Storage medium	Transport packaging	Transport method	Surgeon's experience	Surgical technique	Endothelial Keratoplasty (EK) only: Cut by surgeon/eye bank	Recipients informed of import tissue use
Ababneh OH, Al Omari AF. Outcomes of Penetrating Keratoplasty with Imported Corneas Compared with Local Corneas. Cornea. 2016;35(9):1211-1215.	The success rate for PKP remains relatively high (average 87%) with both local and imported corneas. Despite the longer preservation-to-transplant time, and older donor age for imported corneas, no significant difference in graft outcomes was seen between the 2 groups.	Y	Y	USA - accredited EB, being: Tissue Banks International (Baltimore), North Carolina EB (Salem), and International Sight Register (Tampa)	Jordon	71	75	Domestic: 37.6 +/- 20.2 Imported: 45.6 +/- 18.6	less than 24 hours	Domestic: 4.5 +/- 2.2. Imported: 8.6 +/- 2.9	Optisol-GS	Expandable polystyrene container on wet ice	Shipped (unclear if the term 'shipped' refers to transfer over water or if this is a general term that encompasses air transfer)	ND	PKP	NA	ND
Hu FR, Tsai AC, Wang LJ, Chang SW. Outcomes of Penetrating Keratoplasty with Imported Donor Corneas. Cornea. 1999;18(2):182-187.	Endothelial changes in imported donor corneas do occur after transportation, but the surgical success rate may not be influenced significantly if the PKP is performed within 7 day after donor death. However, the ECD in the clear grafts 4 years after surgery is low.	ND	ND	USA - Cincinnati Eye Bank	Taiwan	0	68 imported (63 transplanted)	73.0 +/- 4.5	2.5 +/- 1.0	7.39 +/- 2.2	Optisol-GS or Dextsol	Sponge holder inside a Styrofoam box with polyfoam refrigerant pads inside	Air freight (4.8 +/- 1.6 days after death) / land transfer (45-60 minutes)	ND	63 PKP (5 Lamella not followed in this study)	NA	ND
Lekhanont K, Vaniketi K, Nimvorapun N, Chuckpaiwong V. Outcomes of Descemet stripping automated endothelial keratoplasty using imported donor corneas. BMC Ophthalmology. 2017;17:41	DSAEK with imported donor corneas provided rapid and good visual rehabilitation. The percentages of endothelial cell loss were comparable to those achieved in Western series using domestic corneas in which fresher tissues were available for transplantation.	Y	Y	USA - EBAA accredited EB	Thailand	0	102	63.85 +/- 15.94	12.52 +/- 7.45	8.9 +/- 1.89	Optisol-GS	Plastic bag, in polystyrene container on wet ice	Flight and overland - 48 hours	Novice surgeons	DSAEK	Surgeon x 33 / Exporting EB x 69	ND

Nakagawa H, Inatomi T, Hieda O, Sotozono C, Yokoi N, Iliakis B et al. Clinical outcomes in Descemet Scrapping Automated Endothelial Keratoplasty with internationally shipped pre-cut donor corneas. Am J Ophthalmol. 2014;15:750-5	The outcomes of DSAEK, with internationally shipped pre-cut donor CT were acceptable and that the additional ECD loss, associated with international shipment, was minimal and did not affect the clinical results.	Y	Y	USA - Sightlife Eye Bank, Seattle and Lions VisionGift, Portland	Japan	0	134	59.5 +/- 12.4	8.585 +/- 4.03	5.05 +/- 2.30	Optisol-GS	Foam block, zip-lock bag, polystyrene container at 2-8 degrees C	Flight 10-11 hours plus overland transfer of approximately 7 hours	ND	DSAEK	EB	Y
Shimazaki J, Shinozaki N, Shimmura S, Holland EJ, Tsubota K. Efficacy and safety of international donor sharing: a single-center, case-controlled study on corneal transplantation. Transplantation. 2004;78(2):216-220	Corneal transplantation using foreign corneas are as effective and safe as those using domestic donor corneas, despite longer preservation times.	Y	ND	Requested from - USA or Australia 5 to 7 days before surgery	Japan	118 (matching pairs)	118 (matching pairs)	Domestic: 67.9 +/- 14.4 Imported: 66.1 +/- 9.9	Domestic: 11.3 +/- 6.9. Imported: 6.1 +/- 2.7	Domestic: 4.1 +/- 0.2 Imported: 5.79 +/- 2.0	ND	Styrene foam with ice	Flight	Experienced	PKP	NA	Yes. Those who preferred domestic, were registered with the Cornea Center Eye Bank.
Singar-Ozdemir E, Burcu A, Oral B, Yalniz-Akkaya Z, Uzman S, Kaderli AT, Ormek F. Effect of donor cornea on the surgical outcomes of penetrating keratoplasty: Imported cornea versus domestic cornea. Experimental and Clinical Transplant. 2018. DOI: 10.6002/ect.2018.0056	The study observed no significant difference in clinical outcomes during and after PKP between imported and domestic corneas.	Y	Y	USA - Tissue Bank International (Baltimore)	Turkey	100	100	Domestic: 52 +/- 18.09. Imported: 58 +/- 20.06	Domestic: 4.38 +/- 2.96. Imported: 12.03 +/- 4.76	Domestic: 3.17 +/- 2.96. Imported: 5.25 +/- 0.89	Domestic: Eusol-C (Alchimia) Imported: Optisol-GS-GS-GS	No information	Domestic: nil Imported: 22.5 hours air transport	ND	PKP	NA	Stated as: In line with legal requirements of the country, either a domestic or import cornea was used regardless of the patient's situation.
Varssano D, Russ V, Linhart Y, Lazar M. Air transportation of corneal tissue: experience with local compared to transatlantic donor corneas. Cornea. 2005; 24(6):674-677.	Air transport of corneal tissue, including loss of time due to travel and handling, did not compromise corneal transplantation success rate. Corneas transferred more than 10 hours performed as well as domestic corneas.	ND	ND	USA - multiple, accredited eye banks	Israel	31	95	Domestic: 54.0 +/- 15.8 Imported: 52.9 +/- 19.7	Domestic: 2.16 +/- 1.57. Imported: 5.63 +/- 3.00	Domestic: 3.13 +/- 2.38 Imported: 8.8 +/- 2.29	Optisol-GS	Wet ice and insulating plastic	1-2 air freights, including transatlantic for 10 or more hours	Trained	PKP	NA	ND
Wagoner MD, Gonnah ES, Al-Towerki AE. Outcome of primary adult optical penetrating keratoplasty with imported donor corneas. Int	Excellent graft survival was achieved with international corneas for eyes with keratoconus, stromal dystrophy, and stromal scarring, but not for those with corneal oedema.	Y	ND	USA - EBAA accredited EB	Saudi Arabia	0	885	55	6 hours 24 min	8.8	Optisol-GS	Polystyrene container	Flight 13-14 hour	ND	PKP	NA	ND

Ophthalmol. 2010;30:127-136.																	
Yamazoe K, Yamazoe K, Shinozaki N, Shimazaki J. Influence of the pre-cutting and overseas transportation of corneal grafts for Descemet Stripping Automated Endothelial Keratoplasty on donor endothelial cell loss. Cornea. 2013;32(6):741- 744.	Imported pre-cut donor corneas from overseas eye banks are a valuable source of donor corneas for DSAEK. The cell loss associated with pre- cutting and the overseas transplantation of corneal grafts on donor endothelial cell loss is acceptable.	ND	ND	ND	Japan	0	124	64.8 +/- 8.6	9.0 +/-4.1	5.26 +/- 0.98	Optisol-GS	Styrene foam with ice	Air freight / and chartered truck for land transfer the day before surgery	NA	DSAEK	EB	NA

SUP 03: Chapter 3 - Review papers capturing non-clinical aspects of transnational activity

EB	Eye Bank
CT	Corneal Tissue
TNA	Transnational Activity

Legend

Reference	Objective	Outcomes - in relation to TNA	Conclusion - in relation to TNA
Gain P, Jullienne R, He Z, Aldossary, M, Acquart S, Cognasse F, Thuret G. Global Survey of Corneal Transplantation and Eye Banking. <i>JAMA Ophthalmic.</i> 2015;3:E1-E8.	Describe the worldwide situation of corneal transplant supply and demand.	148 participating nation EB reports, on 184,576 corneal transplants, 22.8% of which involved imported CT.	There is a considerable shortage of CT. TNA is one component of current service provision. Strategies to address shortage through corneal donation must continue in all countries.
Martin DE, Kelly R, Jones GLA, Machin H, Pollock GA. Ethical issues in Transnational Eye Banking. <i>Cornea.</i> 2017;36(2):252-256.	Perform a principle-based normative analysis of potential common dilemmas in transnational eye banking activities.	The paper identified key ethical concerns regarding TNA and self-sufficiency, highlighting a paucity of research into the examination of TNA on export and import nations. Proposed recommendations, with emphasis on the ethical aspects.	Further analysis of specific ethical issues in EB is necessary to inform development of guidelines and other governance tools that will assist policy makers and professionals to support ethical practice.
Weiss B, Dakkak M, Rockl G, Sukhu B, Mohr J, Maru K. Development of national system performance metrics for tissue donation, production, and distribution activity. <i>Cell Tissue Bank.</i> 2017;18(3):281-296.	To provide an overview of the data process and provide visibility to the Canadian tissue donation, production and distribution activities for 3 years (January 1 2013 - December 31 2015), and provide an overview of the 2012 Canadian Blood Service's eye and tissue banking workshop. Note: the paper examined eye banking alongside tissue banking.	The paper outlines that many hospitals import allografts directly from the US. Canadian banks operate within publicly funded provincial health care systems. Eye and tissue banks indicated a lack of human resources, research and development, capital funding and the constraints of operating within a hospital environment that hampered development of advanced processing capability.	A decrease in corneal transplantation activity in an environment where jurisdictions are importing corneas from the US to supplement local production is a concern.

SUP 04: Chapter 2 - Data dictionary tool

Data Dictionary		
Instructions	Please contact our Lead Researcher Heather Machin for any questions	
	Collect data monthly. Send that data, at the completion of that month	
	Report on the deaths that you are aware of through your current routine reporting system	
	Report on known hospital and coronial deaths only	
	For those without jurisdiction wide or regionally automated death notification systems, or if your system is supported/triaged by hospital based nurse coordinators, please continue to report on only those deaths that you receive information about within routine practice. Do not seek death/donor data from hospital nurse coordinators if that is not part of your routine practice. Our Researchers will define the jurisdiction death-reporting differences within the published end-results document	
	If your death reporting system changes during the data collection period, please notify our Researchers immediately so we may adjust the collation, and document that within the analysis process	
Language for this project	Recovery	The process of recovering consented donated tissue from donors
	Utility	How the recovered tissue was used or not used
	Collection	The collection of data for this Project
	Eligible Donor	Met the donation medical and social criteria
	Potentially Eligible Donor	The donor review process was not completed, yet it appeared that the donor potentially meets the criteria
Inclusion/exclusion criteria	Include	With the exception of the total death numbers, please only include data on known eligible or potentially eligible corneal donors
	Exclude	All amnion donors, known ineligible donors and the utility of sclera and scleral patch graft donations
Location		
Before Commencing	Please inform our Lead Researcher of your defined Urban/Rural boundaries prior to submission of your first monthly tally, for example:	
	Urban	Recoveries that are within your usual/practical recovery area - this could be based on a specific distance (e.g. within 180km) or time (e.g. under 3 hours)
	Rural	Recoveries that are outside of the defined 'urban' usual/practical recovery area
Total		
No. of Deaths	All known hospital/coronial deaths	
No of. Notified reviewed Medical Records	From all deaths, reported in 'No. of Deaths' - how many did the eye bank review (medical chart) in order to ascertain eligibility? <i>(Known Data Collection Error: Due to the different reporting systems, it is anticipated that this number may not reflect actual potential donors. Please report as able.)</i>	
No. of potential donors:	How many known eligible or potentially eligible donors could be recovered this month? <i>(This data will assist in calculating the overall available donors within the current notification system. From this figure our Researchers will breakdown how many these donors were recovered or not recovered within following columns.)</i>	
RECOVERED		
Utilised	Total Donors	How many donors did your eye bank recover from?
	Total Eyes	How many eyes were recovered from the total donors? <i>(We expect to see this number reflected between: Transplants, Training, Research, Determined unsuitable after recovery - and discarded, and Wasted or Expired.)</i>
	Transplanted	Transplanted - all surgical types
	Training	Corneas used for training of eye bankers and surgeons
	Research	Provided to ethics approved research
Not Utilised	Determined unsuitable after recovery - and discarded	Recovered and on further assessment, were deemed unsuitable for transplantation - but were not consented for research
	Wasted or expired	Wasted (damaged in processing) or expired - excluding those tallied in 'Determined unsuitable after recovery - and discarded'
DECLINED		
Age	Unknown	If the donor was declined prior to a completion of the medical (chart review) or consent process - resulting in the age being unknown by the Eye Bank
	<20 to 80> brackets	Provide details of how many declined donors were of a particular age
Reason Why	Need: Demand met at that time	The Eye Bank met all scheduled surgeon requests
	Service: Too late or manpower issue (would have collected if service capacity/need allowed)	The tissue would have been collected however service capacity issues occurred, such as: multiple-deaths at the same time requiring staff to recover based on proximity; not enough staff; time of recovery would have been outside of the recommended recovery period; and issues outside of the eye bank control (e.g. natural disaster).
	Notes	

SUP 05: Chapter 2 - Monthly data reporting tool

Monthly Data	TOTAL DONORS Deaths/Notifications/Eligibility checks			RECOVERED - Eligible tissue (obtainable from EBAANZ if needed)							DECLINED - eligible tissue									
	No. of DEATHS	No of. notified/ reviewed medical records	No. of potential donors	Utilised					Not Utilised		TOTAL DONORS	Age						Reason why		Notes
				TOTAL DONORS	TOTAL EYES	Transplanted	Training	Research	Determined unsuitable after recovery - and discarded	Wasted/ expired		age unknown	<20	20-40	40-60	60-80	80>	Need: Demand met at that time	Service: Too late or manpower issue (would have collected if service capacity/need allowed)	
Urban																				
Rural																				

SUP 06: Chapter 3 - Formal semi-structured interview tool

1. Please tell me about yourself: nationality, profession, years in your field of expertise.
2. Where globally do you think there is need for CT?
 - a. How did you come to your decision?
 - b. How do you decide who gets the tissue?
 - c. Do you include/consider research and training as 'need'?
 - d. Is there any national/regional eye care or tissue/organ plans outlining this?
3. Some say importing is good, others say it is bad. What do you think?
 - a. Can you give me an example of good/bad?
 - b. What does it mean to the import nation?
 - c. What does it mean to the export nation?
4. Are there any risks to the recipient who receives an imported cornea?
 - a. Does this impact their short/long-term surgical outcome?
 - b. Is it any different to domestic surgical outcomes?
 - c. Are there any relevant statistics that you know of?
 - d. Are there any instances where you wouldn't provide tissue?
5. Who do you think is responsible for the decision to export, and subsequently selection, move, manage and monitor tissue movement?
 - a. Is there more than one professional body who should be involved?
 - b. What if there are third party transfers/distributors - does this change things?
 - c. Are there laws or regulations you know about that apply to transnational activity?
6. What can you tell me about the money side? There's gratis, cost recovery, for-profit and sliding cost scales for different tissue grades.
 - a. Does this matter for transnational activity?
 - b. Is this ethical?
 - c. Is this equitable?
 - d. Are there solutions you see?
 - e. Do you know how much you provide/procure tissue for - in USD? – where applicable to interviewee.
7. Right now, eyecare NGO humanitarian groups request tissue - often at gratis. What do you think about that?
 - a. Should they have unlimited supply?
 - b. Should they pay?
 - c. Are there any criteria they should complete before provision of tissue?
 - d. How/where do National/Regional Eye Care Plans fit into this request – are they relevant?
8. There has been some suggestion of competitive and aggressive market behaviours being used by some in the sector. What do you know about that? Does this impact transnational movement in any way?
 - a. How did you decide that - can you give me an example?
 - b. Does this behaviour matter?
 - c. Does this behaviour impact recipients?
 - d. Does this impact the country?
 - i. If no, then why not?
 - ii. If yes - can you give me an example
9. Are donors/NoK or the community informed of, and consented for, exportation of their donation? [Regardless of yes/no, proceed to 9.a 'should'.]
 - a. Should donors/NoK, the community, be informed of, and consented for exportation of their donation?

- i. Should they be involved in the export conversation and decision making?
 - ii. How would we do that?
 - iii. Should they have any say in where the tissue goes?
- 10. Final question: Australia is considering exporting CT? What do you think about that?
 - a. What advice would you give Australia?
 - b. Would this change Australia's relationship with other countries?
 - c. How would this impact Australia's reputation?
 - d. Where should they export too?

Table 1: The semi-structured interview tool, validated in stage 1, and used during stage 2 interviews to guide the conversation with participants. (CT-Corneal Tissue, NGO-Non-Government Organisation, USD-US dollars, NoK-Next-of-kin/Carer)

SUP 07: Chapter 3 - Method and validation process

This study involved a 2-step design approach (Figure 1). Stage 1 is outlined in this Supplementary. Stage 2 is outlined in the main body of the publication.

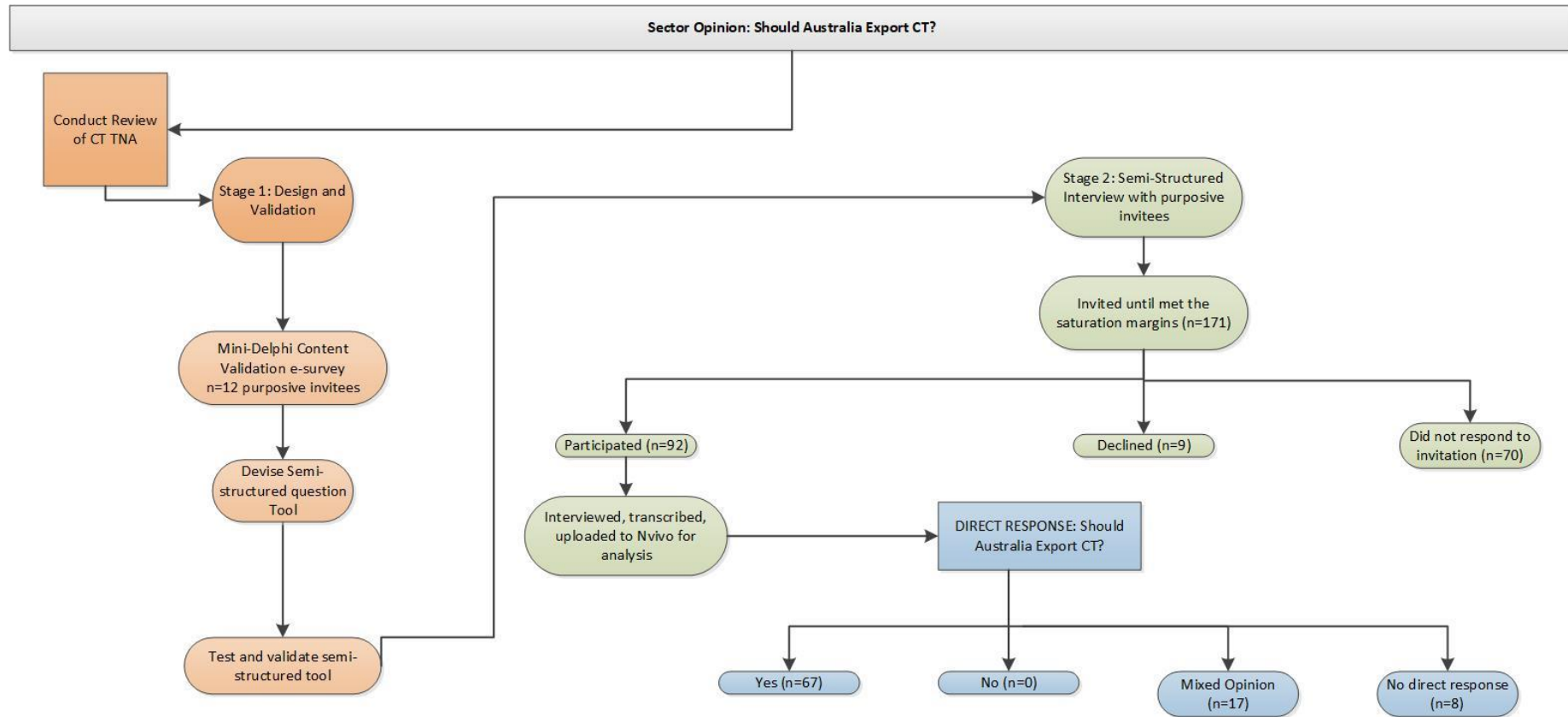


Figure 1: The Two Stage Approach.

1.1 Stage 1 interview tool design and validation

To determine our question set, and validate our interview question tool, we conducted a content, face-validation, mini-Delphi survey stage (stage 1), with sector experts. This approach pin-pointed key themes on our subject matter, providing the starting point in terms of where the consensus or complexities may rest. Additionally, it highlighted aspects that required further examination. Responses that required further examination were then incorporated into our Stage 2 semi-structured interview questionnaire. Stage 1 occurred between November-December 2018.

The stage 1 survey tool (Table 1, below) was provided in English, via email, to participants, as a Microsoft Excel attachment. We used our corneal tissue (CT) Transnational Activity (TNA) issue review experience¹ to devise our question set. It contained 103 questions, separated into 11 sub-chapter. being: 1. Global Eye Care Need (n=5), 2. Import (n=3). 3. Export (n=3), 4. Clinical/Surgical outcomes for CT imported across Jurisdictional Borders (JB) (=7), 5. Global Capacity Development / Humanitarian Efforts (n=10), 6. Ethics (n=18), 7. Distribution and Tracking Mechanisms (n=13), 8. Agencies (n=13), 9. Cost and CT Grade (n=13). 10. Law, Regulation and Consent (n=8), and 11. Other (n=10). Respondents were provided with an alternative close-answer question set (yes, no, maybe, not my area of expertise or not applicable) and an open comment section. This took place between November-December 2018.

1.4 Participants

We purposively invited n=12 participants. All 12 consented and completed the survey. Participants were selected, based on their position in a relevant sector. Relevant sectors included: Eye Banking (EB)ing, corneal ophthalmology, other tissue type/banks, CT allocation and distribution (exporter, importer, brokers), capacity development in the blindness prevention sector (civil societies), and tissue/human biological sectors (law, ethics and peer associations). The participants demonstrated 5 or more years in a relevant sector, awareness of current issues and future developments, and either: publications in a related topic; executive position in a related association/organisation; a review position for a related international journal; educator of related course topics; or had extensive CT cross-border experience. e.g. CT placement or distribution, and first-hand-knowledge.

1.5 Survey responses

There were several points of agreement amongst the Stage 1 participants, e.g. they all agreed that CT TNA could be legal and ethical, if done in the right way. However, they differed in terms of what they perceived to be the right way. There were other points of conflicting response. For example, allocating tissue under humanitarian principles (provision at no cost) were perceived by some as acceptable, as it assisted in equitable allocation, however to others, it was perceived as unacceptable due to the potential to undermine the import nations ability to build their own EB network, or cover the financial costs of the exporting EB. As such, conflicting responses became the basis for the questionnaire in Stage 2. This ensured further examination of the complexities, concepts and friction points. Moreover, understanding and navigating these complexities would strengthen recommendations to Australia's human tissue EB sector and governing bodies, and prevent Australia from engaging in contestable or ineffective practice.

From the survey, we narrowed down our questions, and created our semi-structured interview tool. It contained 10 questions, with a series of sub-questions. The majority were open-ended questions, with some binary. The questionnaire was validated through a mock-interview with a randomly chosen Stage 1 participant, to ensure: appropriateness, duration, interviewer presentation and style (reflectivity), and absence of bias. Conducting the interview via distant phone interview format was used to ensure a naturalistic and comfortable environment was developed for the participant. We also tested the post-interview recording, transcription, data storage and analysis software process. Finally, the test interview participant provided feedback on the interviewer's technique, the questions, and the process. The participant stated that the questions, technique and approach was acceptable, however pre-interview information and instructions could have been enhanced. These findings were incorporated into the next stage, with additional information included in the Participant Informed Consent Form (PICF), a scheduling outlook-invite template, and a pre-interview one-on-one discussion before pressing record.

2.0 REFERENCE:

1. Machin H, Arslan J, Baird PN. Examining the impact of corneal tissue transnational activity, and transplantation, on import and export nations: a review of the literature. *Cornea*. 2020; 39:795-800.

Table 1: Stage 1 e-survey tool

Instructions

Please complete the questionnaire as honestly as possible.
We are seeking your opinion - not that of the organisation you are employed in or are partnered with.
With the exception of our Principal Investigator (Paul Baird) and Research Lead (Heather Machin), your involvement in this project, and your responses, will be anonymous and de-identified.
As this questionnaire is designed to assist our researchers to narrow down key themes and points of interest, we ask that you provide comment regarding your response/s where possible. You may also wish to comment on the questions/sections or suggest other themes for our exploration.
What next? After this questionnaire, our researchers may return to you with other questions as we consolidate the list. Your participation will result in our researchers devising specific questions for a semi-structured one-on-one interview with other, anonymous, volunteer members of our wider community. We may also conduct the final interview with you as a final questionnaire pilot test process.

Abbreviations/definition

CT	Corneal Tissue
EB	Eye Banks
E/I	Export or Import
JB	Jurisdictional Borders - This may include State, Nation, Regional Borders. Please use comment section to explain your response
ISBT128	A tracking-labelling system
GAEBA	Global Alliance of Eye Bank Associations
NGO	Non-Government Organizations such as civil societies
Project Notify	A global vigilance and surveillance database for Medical Products of Human Origin
WHO	World Health Organization

Question Set	Yes	No	Maybe	Don't know (not my areas of expertise)	n/a	Comment - explain your answer
Global eye care need						
Global Corneal Tissue (CT) transplant need is being met						
The global community tracks wait lists						
The global community is tackling need adequately						
Your nation develops CT strategies as a collective, in line with a national eye health plan						

Other nations develop CT strategies as a collective, in line with a nation eye health plan						
Import						
Importation supports equitable access to CT for import nation						
Importation undermines the importing nations EB/eye care system						
Should nations not meeting scheduled surgical need be involved in exportation?						
Export						
Exportation supports equitable access to CT in export nation						
Exportation undermines exporting nations EB/eye care system						
Should nations meeting scheduled surgical need - who have excess, automatically export?						
Clinical/surgical outcomes for CT imported across JB						
Does the movement of CT impact surgery for the import recipient?						
Does the movement of CT impact long-term outcomes for the import recipient?						
Does pre-cut CT impact the movement of CT?						
Does pre-loaded CT impact the movement of CT?						
Does the storage medium impact the movement of CT?						
Are recipients informed that CT may/is imported for their surgery?						
Are recipients provided with a choice of local vs. imported CT for their surgery?						
Global capacity development / humanitarian efforts						
CT is distributed equitably						
EB, NGOs and/or humanitarian agencies select export destinations in a systemised fashion						
Do NGO/humanitarian groups track or take responsibility for CT use?						
Jurisdictions are tracking imports						
Jurisdictions are tracking exports						
Exporters are tracking and controlling how CT is used						
Importers are tracking and controlling where CT comes from						

NGO and E/I groups involved in the cross-JB use of CT do so in line with WHO blindness prevention sector strategic recommendations						
NGO and E/I groups involved in the cross-JB use of CT do so in line with WHO human biologicals sector strategic recommendations						
NGO and E/I groups involved in the cross-JB use of CT do so in line with UN Convention on Human Rights						
Ethics						
Is the movement of CT ethical						
CT selected for export is done so based on import recipient's need						
CT selection for export is done so based on importer/recipients ability to pay						
Does involvement in exportation reflect economic power of a country						
Does profit play a role in the movement of CT						
Does sectorial competition play a role in the movement of CT						
Does commodification play a role in the movement of CT						
Does the provision of accompanied medical devices/injector/applicators influence the movement of CT						
Does patent of technique or device/injector/applicator impact the movement of CT						
Does participation in E/I emulate market behaviour						
Are donors informed that their donation may be used across JB						
Should donors be informed that their donation may be used across JB						
Should surgeons be informed that import tissue is being used						
Is surgeon status/position the most important factor in distribution						
Is recipient need the most important factor in distribution						
EB and NGO and others, involved in the cross-JB movement of CT, do so in line with the Barcelona Principles						
Are you aware of any counterfeit activities involving CT						

Are you aware of any black-market-trafficking activities involving CT						
Distribution and tracking mechanisms						
Should E/I be managed directly one-on-one by just the exporter and importer						
Do Online (Amazon like) distribution systems have a place in the sector						
Should online (Amazon like) distribution systems be tracked and accountable						
Does brokerage alter the treatment and traceability of CT use and movement						
Does third party partnerships/transfers of CT, alter the treatment and traceability of CT use and movement						
Does the reputation (status) of the importer matter						
Does the ISBT128 system help track E/I movement						
Can National/Regional Electronic Donor Record systems help track E/I movement						
CT of a lower grade or close to expiration should go to research						
CT should be given based on next on the list and next available CT type (e.g. matched to need - cut-type)						
CT should be given to transplant, research and training needs based on next on the list and next available CT type (e.g. matched to need - cut-type)						
EB should automatically provide CT to all civil societies or requests for CT for use overseas						
EB should automatically provide CT to civil societies who have a clear programmatic plan						
Agencies						
Should National EB Associations manage the movement of CT involving their nation?						
Should National EB Associations monitor the movement of CT involving their nation?						
Should governments manage E/I of CT						
Should governments monitor E/I of CT						
Should Project Notify manage E/I						
Should Project Notify monitors E/I						
Should the WHO manage E/I						
Should the WHO monitor E/I						
Should GAEBA manage E/I						
Should GAEBA monitor E/I						

Should the International Council of Ophthalmology or the Corneal Society/s manage E/I						
Should the International Council of Ophthalmology or the Corneal Society/s monitor E/I						
Is there a role for the International Agency for the Prevention of Blindness in the JB movement of CT?						
Cost and CT grade						
One set price should be set						
Exporters should fix the price						
Exporting governments should fix the price						
Importers should fix the price						
Import governments should fix the price						
Price should be adaptable to meet what an importer can afford						
Sliding scales should be used to price tissue depending on quality (grade, expiration date)						
CT should go to the highest bidder						
High-resource nations should be charged higher - to cover the short fall for what low-resource countries can afford						
High-resource health systems should cover the cost, and provide CT at no cost to low-resource nations						
Civil societies should pay for CT provided for their programs						
CT of a lower grade or close to expiration should be discounted (placed on sale)						
Bulk order discounts should be offered						
Law, regulations and consent						
Is the movement of CT across JB, legal?						
Does the movement of CT comply with an exporter's regulations?						
Does the movement of CT comply with an importer's regulations?						
Do country-to-country sanctions matter to the movement of CT?						
Do donor consent forms include a box/section regarding consent to export?						
Are donors notified at the point of donation, that their CT may be placed across JB?						
Are there public donor education campaigns notifying the public of potential CT placement across JB?						

CT from nations with regulations are better for E/I?						
Other						
Excess CT should be utilised for surgery today rather than research towards our future						
Excess CT should be utilised for research towards our future, rather than surgery for today						
CT should be used for surgery, research or training without discrimination?						
Do you consider the movement of CT a form of trade?						
Do trade agreements apply to the movement of CT?						
Should trade agreements apply to the movement of CT?						
Could this body of research we are conducting be useful to other human biologicals?						
Can you define surplus? - please provide in comment section						
Is there a member of the community (national/global) who you think should be interviewed by our researchers? If so, please provide their name, professional details and email address and why they should be included. Note: for privacy reasons, we will not notify you of our approach to that individual nor their agreement to participate.						
Do you have any remaining comments, or do you recommend any other areas of enquiry regarding the movement of CT across JB?						

SUP 08: Chapter 3 - Interviewee commentary

We provide a sample of interviewee commentary relating to questions 2 and 3. They include comments from eye bankers (EBer), medical doctor/director/ophthalmologists (MD), broker/third party/distributors (Distributor), and civil society and government professionals (Other). Inclusive of those from low-middle to high income nations that either export, import or do neither and Australians, as Australia was our wide research projects test nation to examine if nations like Australia should export.

1.1 Q2: Should Donors be consented-for-export?

1.1.1 In support (yes responses):

1. *"At the end of the day we are all humans, and it doesn't matter if people want to donate. It's just a donation. But the people that donate they should know that the tissue from, of their family, might travel many miles and end up in another country. Although we know that it doesn't matter, maybe [it] is something that is important for the family. And probably, we should inform in a smooth way, that the tissue can help people from all over the world, something like that."* (Low-Middle-income Importing MD)
2. *"It would probably encourage other donors to give."* (Low-Middle Neither MD)
3. *"There needs to be complete transparency with the donor family. So, if there is a potential of it going overseas, and it certainly needs to be, the cards need to be on the table right from the start."* (Australian EBer)
4. *"Tissues are very emotional, particularly in the South Asia, where they would be, big headlines in the newspaper that the tissue is being sold to another country for-profit."* (Australian MD)
5. *"It is ethically justifiable or respectful to explain to a donor family that tissue may be used locally or overseas."* (Australian MD)
6. *"I think families would be very keen that it's used somewhere rather than not."* (High-Income Importing Distributor)
7. *"I think given, sort of the culture in our country, I think the answer's probably yes. It's better to inform them than to not inform them, because you want to be as transparent as possible in an ideal world. In my opinion, it wouldn't matter, but it does matter to some people, and I think, out of respect for that, we should probably be informing donor families and potential donors."* (High-Income Exporting EBer)

1.1.2 Not in support (no responses):

1. *"It's a fine line. I think Sometimes you can end up giving people too much information that they don't need at the time. We're asking a very delicate question in an extremely difficult time in people's lives, and to, to go into, making sure that they completely understand that the tissue could go overseas could become a troublesome conversation. But in saying that, I also believe in relative full disclosure. I think that people should be told, but to me it makes no difference ... We're not, we don't say that it's only going to be in Queensland, it's only going to be in our jurisdiction, we don't say that it's not, and perhaps that's good enough."* (Australian EBer)
2. *"Personally, I don't think so. I think when you're giving the gift of human tissue, you should be giving. You should be altruistically giving this gift, knowing you are giving it to an organisation who's going to do the best for it. ... I think you start opening up a huge can of worms, with deciding where you are going to send the tissue. And then you might have people starting to say I don't want it going overseas, I want it to stay here, and then you'll have people saying, well I don't want it to go to that nationality or that religion. So, I think. I think what it should be is, are you happy to donate? Is this what your wish is? Do you want to uphold the wishes of your loved ones? I don't think it should matter where it's going to. If, if somebody needs to have their sight restored through donated tissue, then I think everyone should be treated equal."* (Australian EBer)
3. *"Really it depends on, it depends on each patient, each family. Maybe it will be good if some donors, or family donors want to be informed about results of their donation. I think some donors, or some families don't care about that, don't care about the issue at present. But it*

would be good if there is some information about the destiny of the country who receives it.” (Low-Middle-Income Importing MD)

4. “If the tissue establishment will be, will be making profit out of it, I think they should be informed. If the tissue being exported will help exactly the same purpose that is being transplanting in another human being, I don't see the point.” (unclear Other)
5. “Look, according to ethics of the eye bank. They say that we should not disclose, after we received that tissue. Should not disclose where the tissue is going, and whom the tissue is going. Similarly, on the recipient side. We should not also tell whose tissue is, whose tissue. From whom this coming. This is ethics, basically. But if the person is interested, that donor, and says that there's no problem, you can tell me. Then there's no harm, you can take consent and then send it. But that consent, has to be taken in a way, that I have no objection to giving the tissue to another country. But best thing is not to disclose.” (Low-Middle-Income Importing MD)
6. “Families here, reported back to the media in some cases, and we made a decision here, especially in the world of oversupply, that we're not going to risk upsetting the family because that could be so damaging to all of us. That's how we approach it.” (High-Income Exporting EBer)
7. “I think, most people just do not have the expertise available to be able to fully grasp the current system, in terms of transnational movement of tissues. I think it would just be like a battleground for politics and popularism. It would be like; oh someone is steeling our eyes. I just, I don't see any good coming out of it.” (High-Income Importing MD)
8. “Our job, our duty, is to be good Stewards of the tissue. And, like I told you earlier, donor and donor's family decided to donate their precious gift in the hardest moment. They just lost their loved one and they're going through a rough time. But they decide to, to donate part of their family members to us. And if the tissue is not placed anywhere, if we just wasted, I don't think we did a good job on that. So, if the tissue is, if the demand is met in United States, and there's no one to get the cornea right now, to get a transplant in the United States, then [I] think we would definitely have to look somewhere else to place the tissue.” (High-Income Importing Distributor)

1.2 Q3: Should donors be able to decide where their donation is exported to?

1.2.1 General Commentary:

1. “If we were open and transparent about where it goes, I don't think it would be a problem. It's basically enforced. However, there would be some people I think that would then not donate.” (Australian Other)
2. “It seems unreasonable and racist. But if that's the way they feel in their insistent upon it, I would use the cornea for local or research.” (High-Income Exporting MD)
3. “I guess if they say it can't go there, we have to honour that”. (Low-Middle-Income Neither MD)
4. “Certainly, for the next-of-kin, that's important as part of the grieving process to understand or to have some control over where things would go ... they should have the choice if it's going to go overseas, that potentially, they should have a choice about where it goes to.” (Australian EBer)
5. “I think that is a reasonable thing, yeh. I think if they say not to be used outside of Australia or not to be used outside of – hummm, then you could say, not to be used outside of my suburb ... Look I think, I think the ownership of the tissue really is with the donor and with their family, so I think that they should be able to direct it, similarly with their, able to decline to donate as well.” (Australian MD)
6. “I don't think that you need to list particular countries or particular regions that it goes to. I think that that gets, it gives the, it creates nationalistic effect by doing so. So, what you should do is say, would you donate your tissue to help any other human being rather than help people from just New South Wales or just whatever. We don't currently ever do things like that, people can consent based on race or gender, because we don't, we basically have laws in Australia against discriminating people on that, on those basis, and we also have a discrimination, anti-

- discrimination thing based on race, and I think that that applies in this situation, too. So not discriminating based on race should just be 'do you want to donate to anybody, any human' and that is sort of, probably tentatively covered already under our consents, but is not specifically stated at the moment, that they would be exported to a third party country." (Australian Other)
7. "It should be an issue of trust of the organisation, that the organisation will elect and select where does tissue go. And that the donor family senior next-of-kin, abrogate that responsibility to the organisation or the experts that require that tissue. It could be emergency tissue. I think that that should not be encouraged." (Australian MD)
 8. "I don't think it's practical, isn't it? Once they provide us the consent, it should be for everyone. It should be for the needy population everywhere in the globe. That's what I think. I mean to bracket them ... then it, it brings up those boundaries' things, the religious things, the cultural issues. Everything consumed there. So, we have to make a consenting mechanism in a way where the patient's only constant [is to] give a constant. Okay, it can be used, and it stops there." (Low-Middle-Income Exporting MD)
 9. "If there is exportation, they should at least be told we are going to export it to another country to help people, but not at a profit. I mean I see this is a double-edge-sword. If you inform the next-of-kin, that I'm going to send your loved one's cornea overseas to help other people, I think the first thing that the next-of-kin think of, would be that they are, kind of like, tissue or organ trading, and I don't think they will be very comfortable. It may jeopardise the countries donation, eye donation efforts." (High-Income Importing EBer)
 10. "Anything that sort of fosters xenophobia is not good thing at all." (High-Income Exporting EBer)
 11. "I would say not to that degree of specificity, because that's part of our responsibility as eye bankers of being good stewards of that gift. A member of the general public is not necessarily in a position to know where that particular gift might, might be best used. So, I would say, informed consent and opportunity to object, for example, to international use in general, OK. Specificity and directing where donation should be used. I would draw a line there." (High-Income Exporting EBer)
 12. "I think that when you donate a tissue, you are doing something good, and you should not be able to choose. It's completely anonymous, and you should not be able to choose who can have this tissue. So, you are donating to another human being. You are donating to, in our place, to a public tissue establishment that will do the best they can to not waste this tissue, so you should not decide if [it] can be exported or not, or if you allow to be exported or not." (Unclear Other)
 13. "The eye bank should be declaring that, but an individual should not be demanding that." (High-Income Importing EBer)
 14. "I just don't think that's practical or sensible." (Australian Other)
 15. "Yes. So, they definitely have accepted the donation. But instead of doing a blank, a statement of, I don't want this tissue to go, I think a common theme ... is where, where there have been wars that we have fought in, as an exclusion. So, with military personnel, veterans, they may say, I don't want that to go to, to Japan or to Vietnam or maybe the Middle East. And so instead of excluding that country, we just say no international donation. I believe that's what happens." (High-Income Exporting EBer)
 16. "This is the sort of thing I'm saying about the inherent, of ethical dilemmas, of such undercurrents happening. Because we know that people who donate do sometimes have quite strong views about who might receive tissue ... I know [this] has been debated ... and I don't know that it's been completely resolved yet, as to things such as, can you put limitations on your donation. Ultimately, an eye bank does not have to accept a donation if they feel that ethically, that [the] donor is putting unreasonable conditions on it. But what would be the question, is [it] being an unreasonable condition? Some people may feel that importing and exporting that tissue elsewhere is unreasonable. Ethically, though, it's discriminating in some way or another. So, the jury's out. I think clearly there's a global need, but I don't really think that people necessarily who donate, are really aware and participate a lot in the bigger discussion about transnational transferred of tissue and things like that. I don't think they're informed enough. I

think their individual expectation, probably is that inevitably it's going to go to someone within their own region. Unless they're informed otherwise.” (High-Income Importing EBer)

17. *“Directed donation is [a] sensitive ethical dilemma, and I don't believe we can tolerate requests from donors for directed donation. I believe that's unethical. They need to consent to the use of the tissue, for whatever purposes the eye bank, sees appropriate, or don't consent. I believe that's probably the most ethical and appropriate way.” (Australian MD)*
18. *“Is directed donation ever acceptable? Yeah, I think so. I mean we respect the donor family's wishes in pretty well, every other way. We currently don't allow them to specify recipients on other basis, such as gender or race. But we do allow them to say, no, I don't want to be used for research or no, I don't want to be used for teaching and I only want it to be used clinically for transplantation. I would have thought it would be acceptable for them to be asked if they're happy if it needs to be exported.” (High-Income Importing MD)*

SUP 09: Chapter 4 - E-survey questionnaire

1.1 This document

This document outlines the screen/display pathway of the e-survey. All participants must complete the consent process prior to being directed to the e-survey. An automated thank you will appear after the submission of the last question.

Not seen by the participant:

- Grey boxes: The boxes indicate where the question has been allocated an action, e.g. end of question, skip questions, additional questions.
- Sections and page breaks: These indicate where a new section appears to the participant.
- Numbers in brackets after text options: This is for tracking purposes.

1.2 Consent

[Information provided before commencement].

1.3 Consent to Participate

I have read/or have had read to me in a language that I understand, the above/attached information, and I understand the purposes, procedures and risks of this research project as described within it. I confirm that I am an Australian citizen or permanent resident over the age of 18 years. I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in this project according to the conditions outlined above. The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form without permission

☐ Yes (1)

☐ No (2)

Skip To: End of Survey If Information to read before consenting Consent to Participate I have read/or have had read to me in... = No

Q1 Are you a permanent resident or citizen of Australia?

☐ Yes (1)

☐ No (2)

Skip To: End of Survey If Are you a permanent resident or citizen of Australia? = No

Q2 Where do you live?

- ☐ Queensland (1)
 - ☐ South Australia (2)
 - ☐ Tasmania (3)
 - ☐ Victoria (4)
 - ☐ Northern Territory (5)
 - ☐ New South Wales (6)
 - ☐ Western Australia (7)
 - ☐ Australian Capital Territory (8)
-

Q3 Gender

- ☐ Male (1)
 - ☐ Female (2)
 - ☐ Other (3) _____
-

Q4 Age

- ☐ Type in age (1) _____
-

Q5 Religion

- ☐ Christian (1)
- ☐ Jewish (2)
- ☐ Muslim (3)
- ☐ Hindu (4)
- ☐ Buddhist (5)
- ☐ No religion (6)
- ☐ Other (7)

Q6 Do you work in the healthcare or medical science sector?

- ☐ Yes (2)
- ☐ No (1)

Display This Question:

If Do you work in the healthcare or medical science sector? = Yes

Q6a Please outline if this is as a doctor, nurse etc. and which sub-specialty

End of Block: Section 1: In this section we will be asking general questions about yourself.

Start of Block: Eye and transplantation

Q7 Are you of Aboriginal or Torres Strait Islander descent?

☐ Yes (1)

☐ No (2)

Display This Question:

If Are you of Aboriginal or Torres Strait Islander descent? = No

Q7a How do you ethnically identify? (e.g. White European, Indo-Chinese)

Q8 Were you born in Australia?

☐ Yes (1)

☐ No (2)

Display This Question:

If Were you born in Australia? = No

Q8a Which country were you born in?

Display This Question:

If Were you born in Australia? = No

Q8b Which year did you move to Australia?

Q9 Do you have relatives/close friends living in another country?

☐ Yes (2)

☐ No (1)

Display This Question:

If Do you have relatives/close friends living in another country? = Yes

Q9a Please indicate which countries

Q10 Do you have a vision impairment that is not corrected by contact lenses or glasses?

☐ Yes (2)

☐ No (1)

Display This Question:

If Do you have a vision impairment that is not corrected by contact lenses or glasses? = Yes

Q10a Please describe your vision impairment

Q11 Have you been a recipient of a transplant involving human donated eye tissue?

☐ Yes (1)

☐ No (2)

Q12 Are you awaiting a transplant involving human donated eye tissue?

☐ Yes (1)

☐ No (2)

Q13 Has a close relative/someone you've cared for been a recipient of a transplant involving human donated eye tissue?

☐ Yes (1)

☐ No (2)

Q14 Is a close relative/someone you're caring for awaiting a transplant involving human donated eye tissue?

☐ Yes (1)

☐ No (2)

Q15 Have you registered yourself on the Australian Medicare, DonateLife Registry to be a donor on your death?

☐ Yes (1)

☐ No (2)

Q16 Regardless of being on the Donor Registry, are you intending to donate your eyes on your death?

☐ Yes (1)

☐ No (2)

☐ Haven't thought about it (3)

Display This Question:

If Regardless of being on the Donor Registry, are you intending to donate your eyes on your death? = Yes

Q16a Do you intend to consent to donate for transplantation?

- ☐ Yes (1)
 - ☐ No (2)
 - ☐ Haven't thought about it (3)
-

Display This Question:

If Regardless of being on the Donor Registry, are you intending to donate your eyes on your death? = Yes

Q16b Do you intend to consent to donate for research and/or training?

- ☐ Yes (1)
 - ☐ No (2)
 - ☐ Haven't thought about it (3)
-

Q17 Have you ever been the end-of-life next-of-kin (primary carer) to someone else?

- ☐ No (1)
 - ☐ Yes (3)
 - ☐ Prefer not to answer (4)
-

Display This Question:

If Have you ever been the end-of-life next-of-kin (primary carer) to someone else? = Yes

Q17a Were you approached to discuss donation of their eyes, on their behalf?

- ☐ Yes (2)
- ☐ No (1)
- ☐ Can't remember (3)
- ☐ Prefer not to say (4)

Display This Question:

If Were you approached to discuss donation of their eyes, on their behalf? = Yes

Q17b Did you consent to allow the donation of their eyes?

- ☐ Yes (1)
- ☐ No (2)
- ☐ Can't remember (3)

Display This Question:

If Did you consent to allow the donation of their eyes? = Yes

Q17c Please share:

	Yes (1)	No (2)	Can't remember (3)
Did the donation take place? (1)	☐	☐	☐
Was the consent for transplantation? (2)	☐	☐	☐
Was the consent and/or for research and training? (3)	☐	☐	☐

End of Block: Eye and transplantation

Start of Block: Section 2: In this next Section, we will be asking your opinion regarding if and

Q18 Please indicate where you would be happy for your donation to go, to assist those in need of an eye transplant. You may select more than one option.

	Yes (1)	No (2)	I will leave it to the professionals to decide where it's needed (3)	Haven't thought about it (4)
Your local town/city (1)	☐	☐	☐	☐
Your State/Territory (2)	☐	☐	☐	☐
Australia (3)	☐	☐	☐	☐
New Zealand (4)	☐	☐	☐	☐
Neighbouring countries of Asia-Pacific (5)	☐	☐	☐	☐
Commonwealth Countries (6)	☐	☐	☐	☐
Asia Pacific Economic Countries (APEC) Countries (7)	☐	☐	☐	☐
Any country where there is evidence of need (8)	☐	☐	☐	☐
Specific Country/Other (9)	☐	☐	☐	☐

Q19 Please indicate where you would be happy for the donation of those in your care to go, to assist those in need of an eye transplant. You may select more than one option.

	Yes (1)	No (2)	I will leave it to the professionals to decide where it's needed (3)	Haven't thought about it (4)
Your local town/city (1)	☐	☐	☐	☐
Your State/Territory (2)	☐	☐	☐	☐
Australia (3)	☐	☐	☐	☐
New Zealand (4)	☐	☐	☐	☐
Neighbouring countries of Asia-Pacific (5)	☐	☐	☐	☐
Commonwealth Countries (6)	☐	☐	☐	☐
Asia Pacific Economic Countries (APEC) Countries (7)	☐	☐	☐	☐
Any country where there is evidence of need (8)	☐	☐	☐	☐
Specific Country/Other (9)	☐	☐	☐	☐

 Page Break

Q20 In the event that Australia was meeting surgical eye transplant needs, at the time of your death, how would you prefer your donation to be used? You may select more than one.

	Yes (1)	No (2)	I will leave it to the professionals to decide where it's needed (3)	Haven't thought about it (4)
Stay in Australia to train Australian surgeons (1)	☐	☐	☐	☐
Stay in Australia to assist Australian Research (2)	☐	☐	☐	☐
Go overseas to help a person in need of a transplant (3)	☐	☐	☐	☐
Go overseas to help another country to train their surgeons (4)	☐	☐	☐	☐
Go overseas to help research in another country (5)	☐	☐	☐	☐
Withdraw the donation (6)	☐	☐	☐	☐

Page Break

Q21. In the event that Australia was meeting surgical eye transplant needs, at the time of death of those in your care, how would you prefer your donation to be used? You may select more than one.

	Yes (1)	No (2)	I will leave it to the professionals to decide where it's needed (3)	Haven't thought about it (4)
Stay in Australia to train Australian surgeons (1)	☐	☐	☐	☐
Stay in Australia to assist Australian Research (2)	☐	☐	☐	☐
Go overseas to help a person in need of a transplant (3)	☐	☐	☐	☐
Go overseas to help another country to train their surgeons (4)	☐	☐	☐	☐
Go overseas to help research in another country (5)	☐	☐	☐	☐
Withdraw the donation (6)	☐	☐	☐	☐

 Page Break

Q22 Do you think Australia should share your donation (or that of those you care for) overseas?

- ☐ Yes (1)
- ☐ No (2)
- ☐ Haven't made up my mind (3)

Display This Question:

*If Do you think Australia should share your donation (or that of those you care for) overseas? =
Haven't made up my mind*

Q22a please outline your reservations and/or what further information you require in order to support your decision either way.

End of Block: Section 2: In this next Section, we will be asking your opinion regarding if and

Start of Block: Section 3: You have now completed the e-survey. In this section, we ask you to r

Q23 If Australia was able to provide enough corneas to meet the surgical need within Australia, and did not need your eye donation (or that of those you care for) at the time, and was to share your donation with other nations, please indicate what process and allocation steps you would like the Australian donation and eye care professionals to consider and/or prepare, prior to doing so. The Donation and Recovery Process:

	Yes (1)	No (2)	I will leave it to the professionals to decide where it's needed (3)	Haven't thought about it (4)
Provide information regarding overseas sharing on the DonateLife/Medicare/Eye Bank websites (1)	☐	☐	☐	☐
Place a tick box on the Donor Registry, indicating your intent to share overseas in the event that Australia did not need it at that time (2)	☐	☐	☐	☐
Include overseas sharing information in the face-to-face conversation, with hospital staff/eye bank staff, during the end-of-life consent and decision-making process (3)	☐	☐	☐	☐
Place a tick box on the consent form, indicating willingness to share overseas or retain in Australia (4)	☐	☐	☐	☐

Q24 If Australia was able to provide enough corneas to meet the surgical need within Australia, and did not need your eye donation (or that of those you care for) at the time, and was to share your donation with other nations, please indicate what process and allocation steps you would like the Australian donation and eye care professionals to consider and/or prepare, prior to doing so.

This section examines the eye care allocation process (Please indicate how you would like Australia to decide on who to share your donation with):

	Yes (1)	No (2)	I will leave it to the professionals to decide where it's needed (3)	Haven't thought about it (4)
Countries Australia has a government humanitarian aid relationship with (AusAid) (1)	☐	☐	☐	☐
Countries where humanitarian eye care providers, recognised by Australia, have evidence of existing eye care training and infrastructure programs (2)	☐	☐	☐	☐
Countries where Australian eye transplant surgeons provide voluntary surgery or training (3)	☐	☐	☐	☐
Countries able to reimburse Australia the processing and freight costs (mid-high-income countries) (4)	☐	☐	☐	☐
Countries unable to reimburse Australia, and require humanitarian assistance (low-mid income countries) (5)	☐	☐	☐	☐
Locations based on the practicalities of freight, logistics, time and tissue handling techniques (6)	☐	☐	☐	☐
Active conflict zones (7)	☐	☐	☐	☐

Q25 Do you have any general comments or other suggestions regarding eye donation use in Australia or sharing it with waiting recipients in other nations in the event that Australia does not need it at that time?

SUP 10: Chapter 4 - Methodology and validation process

We commenced our research question design by completing a review of transnational activity.¹ We then interviewed global eye care and eye tissue sector members to identify key themes.² This was followed by the development and validation of our e-survey tool (Stage 1 – outlined in this Supplemental document) and finally our formal Qualtrics XM (USA) e-survey (Stage 2) as described in the main text (Figure 1).

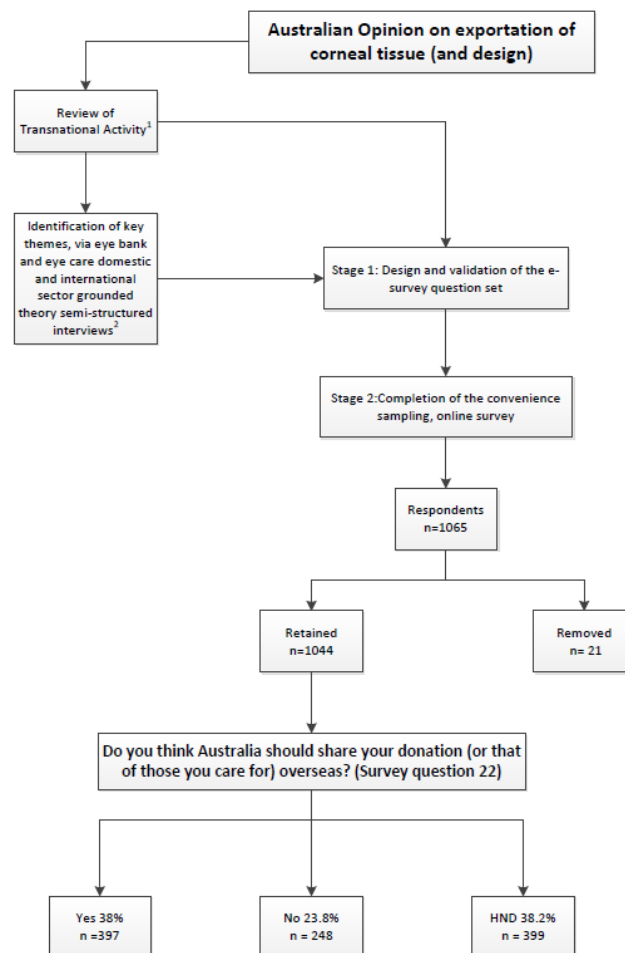


Figure 1: The design, validation and research steps used to ascertain the willingness of Australians to export their corneal tissue donation on their death. HND = Have not made up their mind.

1.1 Stage 1

Our e-survey was designed to examine a range of scenarios pertaining to the willingness of Australians to donate their corneal tissue for domestic and then international allocation. The scenarios (e.g. Question 22: Do you think Australia should share your donation (or that of those you care for) overseas?) presented in our final questionnaire (SUP01 on page 189), were devised through our examination of transnationalism¹ and our collection of key themes and recommendations, from Australian and international eye care and corneal sector members.²

We devised our grounded theory pilot e-survey tool, and uploaded it to the Qualtrics XM survey online software tool. We described corneal tissue transnational activity as *donation sharing* within the e-survey, to ensure that the respondents did not associate unethical trading or the black-market movement

of human body parts and transplant tourism, with our examination of nationally planned and permitted activity. We excluded words such as “trade” or “export”.

in total, n=13 purposively selected individuals not familiar with our project or field of work completed the pilot e-survey. Participant consent was presumed by their decision to click-ahead from the survey home page, to question 1 on the next page. The home page provided information on the survey, the research project and the stakeholders. It contained a pdf. downloadable information sheet that explained the research in full. The information sheet provided contact information for Qualtrics and our human research ethics committee. Finally, as the subject matter discussed death and donation, which may be confronting for some, we provided contact details for *LifeLine*, a free counselling service in Australia.

To ensure our questions were understood and answered correctly, our pilot group were additionally asked to provide feedback on the survey itself (e.g. the approach, respect for the subject matter, length, phraseology and so on). Their responses were supportive with no context changes identified, other than spelling or arrangement of the question order. Their feedback was incorporated and assisted in validating and finalising the e-survey. Stage 1 took place in June 2019.

1.2 The e-survey

The e-survey (SUP01 on page 189) was provided in English, with an estimated completion time of 6-10 minutes. Questions were designed to ensure relevant bio-psychosocial aspects (e.g. a recent death in the family) were captured and approached respectfully. The final e-survey involved 25 questions, 12 of which included sub-questions, that appeared depending on the respondent’s initial response. The e-survey commenced with standard demographic questions (e.g. age, gender). We added generalist questions relating to donation, vision impairment and donation allocation domestically and internationally. For example, we asked the participant if they had a vision impairment that could not be corrected by glasses, or if they had received a corneal transplant and so on. We included these as we wanted to understand if respondents who had found themselves in these situations had a greater or lesser affiliation to the sharing of donations outside of Australia. We hoped to determine if Australians with vision impairment, or those who had (or were awaiting) a transplant and those who knew someone who had donated, would have a greater or lesser emotive willingness to share and prevent suffering in others, regardless of their location. We also asked respondents if they were on the Donor Registry, if they were Aboriginal or Torres Strait Islander, born outside of Australia or had an affiliation with other nations through friends or family (as we wanted to examine if their connection to Australia and other nations increased or decreased their willingness to share their donation overseas). Finally, we asked if the respondent worked in the health or medical science field to determine if those within a related field had a greater or lesser response to the concepts we proposed.

We were aware that several of our questions would be new to the participants, as transnational activity is not widely discussed or understood in the Australian context and as such we did not expect our participants to have a definitive decision on their desire to export their donation or not, without having the opportunity to truly understand what was involved. We felt that by presenting them the questions, in this manner, it replicated the current Australian setting where donors are not aware, and as such would need to decide on the spot at the point of donation, if Australia were to commence exportation today, without any information provided. We believed this approach would highlight that donors do not have the full facts at their disposal at the point of donation to make a sound and informed decision. In our e-survey we ask donors specific questions, for example, can we export your corneal tissue if it is not needed in Australia? In this instance participants had the option to say Yes, No or had not decided.

2.1 REFERENCES

5. Machin H, Arslan J, Baird PN. Examining the impact of corneal tissue transnational activity, and transplantation, on import and export nations: a review of the literature. *Cornea*. 2020. 39(6):795-800.
6. Machin H, Sutton G, Baird PN. Should nations with surplus donated corneal tissue, export to those without? A review of sector opinion via the example of one nation – Australia. *Cornea*. 39(10):1334-1340, October 2020.

02: TEMPLATES (not provided in Appendix 01 Supplementary Material)

TEM 01: Chapter 3 - Part 1 pilot PICF

**CENTRE FOR EYE RESEARCH AUSTRALIA
THE ROYAL VICTORIAN EYE & EAR HOSPITAL**

Participant Information and Consent Form - Sector Expert interview

Full Project Title:	Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation – Question validation Test Group
Document tracking:	Version 2 – August 31 st 2018
Principal Researcher:	Professor Paul Baird
Associate Researcher(s):	Heather Machin RN
Location:	Royal Victorian Eye and Ear Hospital (including Eye and Ear on the Park, St Andrews Place, East Melbourne) and the Centre for Eye Research Australia

This Participant Information and Consent Form is 7 pages long. Please make sure you have all the pages.

1. Introduction

You are invited to take part in this research project. This is because you have been identified as an expert in your field. This research project is interested in finding out about sectorial opinion, and the current and potential utility status of human corneal tissue – with particular emphasis on exportation and importation modes, in Australia, and within the global context.

This Participant Information and Consent Form contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project to help you decide whether or not to take part in the research.

Please read this information carefully. Feel free to ask questions about any information in the document that you don't understand or want to know more about. You may also wish to discuss the project with your employer. Feel free to do this.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. Once you understand what the project is about and if you decide to take part in it, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to participate in the research processes that are described; and
- Consent to allow us to use your sector opinion as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. Purpose and Background

This research is one component of a wider project designed to understand the management and utility of corneal tissue in Australia. To do so, the project seeks to ascertain the current global status regarding utility – with specific emphasis on exportation and importation. This information will assist in ascertaining how Australia could/should improve utility in the future and provide guidance on if/how Australia could/should manage routine exportation or importation.

Global experts from a wide range of backgrounds and sector involvement will be invited to participate in this research.

This research has been initiated by Professor Paul Baird as the Principal Researcher and Supervisor to PhD Candidate Heather Machin RN.

3. Procedures, and What is Involved

Participation in this project will involve:

- Completing an e-questionnaire. This will assist our researchers to device and validate specific questions ready for use with the wider community
- Participate in subsequent questionnaires or one-on-one private interview if required to narrow down the questions as part of the validation process
- Permit your e-responses to be stored as per point 11 of this Consent Form
- Permit any subsequent meeting to be recorded and transcribed – for the researchers use.

4. Possible Benefits

There will be no immediate benefits to your practice from your participation in this research, however findings may indicate possible future partnerships and development opportunities and provide evidence to assist other countries or tissue sectors reviewing their utility.

5. Possible Risks

There are no risks involved in this project however we accept the delicacy of the conversation and information shared. Our researchers will adhere to strict ethical and privacy law requirements.

6. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation.

7. Managing utility/surplus issues while on the project

While you are participating in this research project, we ask that you continue with your routine practices.

8. Alternatives to Participation

You may choose not to participate in this project.

9. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

The decision whether to take part or not to take part, or to take part and then withdraw, will not affect your current relationships with personnel in the Eye Bank and wider sectors.

Before making a decision, a member of the research team will be available to answer any questions you have about the research project. Sign the Consent Form only after you have had a chance to ask questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before withdrawal. This notice will allow that person or the research supervisor to inform you if there are any special requirements linked to withdrawing.

10. Results of Project

Our researchers will provide you with a result outline as the project progresses.

11. Privacy, Confidentiality and Disclosure of Information

The information we collect from you will be retained for 15 years. At the end of this period, the electronic data will be deleted from databases and servers and paper data will be shredded and destroyed. Electronic data – inclusive of recorded interviews – will be stored on the Centre for Eye Research Australia, University of Melbourne server in a specific project folder. Only those researchers on the project will have access to this information is password protected – on a secure network, which will be protected by administrator rights specifically set up by Information Technology. Any paper copies stored in a locked filing cabinet.

Any information obtained in connection with this project that can identify you will remain confidential and securely stored. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to publish the results in appropriate peer-reviewed scientific journals.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Presentation of information will only be at the group level and no individual identifying data will be made available.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named in this document if you would like to access your information.

12. Injury

Not applicable to this research project.

13. Reimbursement for Your Costs

You will not be paid for your participation in this research.

14. Ethical Guidelines

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the Royal Victorian Eye & Ear Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15. Who Can I Contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For Further Information or Appointments

If you require further information concerning this Project, please contact researcher Ms Heather Machin RN via: (03) 9929 8377 / heather.machin@unimelb.edu.au

For Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact,

Position: HREC Secretary

Telephone: (03) 9929 8525

Email: ethics@eyeandear.org.au

You will need to tell the Secretary the name of one of the researchers listed above.



SECTOR EXPERT INTERVIEW CONSENT FORM

Full Project Title: Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation.

I, _____, have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this project according to the conditions in this document.

I will be given a copy of the Participant Information and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form without or permission.

Participant's Name (printed)

Signature

Date

Witness (Required when participant cannot read this document for him/herself except where an interpreter is used.)

Name of Witness to Participant's Signature (printed)

Signature

Date

Declaration by researcher*: I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed)

Signature

Date

* A senior member of the research team must provide the explanation and provision of information concerning the research project. *Note:* All parties signing the Consent Form must date their own signature.

REVOCATION OF CONSENT FORM

(To be used for participants who wish to withdraw from the project.)

Revocation of Consent Form

Full Project Title: Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation.

I, _____, hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any relationships.

Participant's Name (printed)

.....

Signature

Date

TEM 02: Chapter 3 - Part 1 pilot invitation

Emailed in September 2018.

Dear XXX

As you know, I am doing my PhD, and I'm looking at import and export of corneal tissue. As part of the process I seek to understand the sector's opinion in this regard. For this, I intend to do a series of formal interviews.

Anyhow, to do this, I need to ensure the questions I use for the interviews have been confirmed via a validation process (mini-Delphi face validation) through a small test group, and I wondered if, anonymously, you would like to be part of that test group for me? I am keen to ensure I have a wide group of experts – from a variety of experience and exposure levels, involved in the test group. In particular I want someone from [insert background] who understands eye banking. If you were able to please let me know (note, I am asking you as an individual, and not you as an employee – I seek your opinion).

This research has been ethics approved.

The end result of this test group process is for me to confirm the final series of relevant questions for use in a formal and wider sector interview process.

What's involved:

- Independent, private participation – you will not be meeting with a group. This will all be done via email, form completion and/or communication directly with me on the phone, skype or face-to-face etc.
- I will send you the questions via email. Might take you an hour to complete.
- After that, I may contact you again with more questions or talk to you directly.
- I will provide you with full participant consent and instructions prior to your commencement.
- Your participation will be anonymous to everyone except my Supervisor and Principal Investigator (Paul Baird) and I.

Please let me know if you are interested and I will contact you with the necessary information once I have my pilot group members confirmed.

Thank you

Heather

TEM 03: Chapter 3 - Part 2 formal PICF



**CENTRE FOR EYE RESEARCH AUSTRALIA
THE ROYAL VICTORIAN EYE & EAR HOSPITAL**

Participant Information and Consent Form - Sector interviews

Full Project Title:	Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation
Document tracking:	Version 3 – 12th December 2018
Principal Researcher:	Professor Paul Baird
Associate Researcher(s):	Heather Machin RN
Location:	Royal Victorian Eye and Ear Hospital (including Eye and Ear on the Park, St Andrews Place, East Melbourne) and the Centre for Eye Research Australia

This Participant Information and Consent Form is 6 pages long. Please make sure you have all the pages.

1. Introduction

You are invited to take part in this research project. This is because you have been identified as a sector member in your field. This research project is interested in finding out about sectorial opinion, and the current and potential utility status of human corneal tissue – with emphasis on exportation and importation relevant to Australia, and the global context.

This Participant Information and Consent Form contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project to help you decide whether or not to take part in the research.

Please read this information carefully. Feel free to ask questions about any information in the document that you don't understand or want to know more about. You may also wish to discuss the project with your employer. Feel free to do this.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. Once you understand what the project is about and if you decide to take part in it, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read;

- Consent to take part in the research project;
- Consent to participate in the research processes that are described; and
- Consent to allow us to use your sector opinion as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. Purpose and Background

This research is one component of a wider project designed to examine corneal tissue exportation and importation. This research will explore this subject in the global context. This will subsequently assist Australia, specifically, to examine if they could/should participate in transnational activities in the future.

Global sector members from a wide range of backgrounds and involvement will be invited to participate in this research.

This research has been initiated by Professor Paul Baird as the Principal Researcher and Supervisor to PhD Candidate Heather Machin RN.

3. Procedures, and What is Involved

Participation in this project will involve:

- Completing a semi-structured verbal interview via distance communication methods with one of our Researchers, in English. This is anticipated to take 20-25 minutes. The interviewer will seek your opinion on several aspects of the exportation and importation process, for example: what are the issues, where responsibility may rest, how decisions are made, and, if and how Australia could/should participate in these activities.
- Permitting your interview to be recorded, transcribed and stored – for the researchers use, as per point 11 of this Consent Form.

4. Possible Benefits

There will be no immediate benefits to your practice from your participation in this research, however findings may indicate possible future partnerships and development opportunities and provide evidence to assist other countries or human tissue sectors with a review of their own utility.

5. Possible Risks

There are no risks involved in this project however we accept the delicacy of the conversation and information shared. Our researchers will adhere to strict ethical and privacy law requirements.

6. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation.

7. Managing utility/surplus issues while on the project

While you are participating in this research project, we ask that you continue with your routine practices.

8. Alternatives to Participation

You may choose not to participate in this project.

9. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

The decision whether to take part or not to take part, or to take part and then withdraw, will not affect your current relationships with personnel in the Eye Bank and wider sectors.

Before making a decision, a member of the research team will be available to answer any questions you have about the research project. Sign the Consent Form only after you have had a chance to ask questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before withdrawal. This notice will allow that person or the research supervisor to inform you if there are any special requirements linked to withdrawing.

10. Results of Project

Our researchers will provide you with a result outline as the project progresses.

11. Privacy, Confidentiality and Disclosure of Information

The information we collect from you will be retained for 15 years. At the end of this period, the electronic data will be deleted from databases and servers and paper data will be shredded and destroyed. Electronic data – inclusive of recorded interviews - will be stored on the Centre for Eye Research Australia, University of Melbourne server in a specific project folder. Only those researchers on the project will have access to this information. It will be password protected – on a secure network, which will be protected by administrator rights, specifically set up by the Information Technology Department. Any paper copies shall be stored in a locked filing cabinet.

Any information obtained in connection with this project that can identify you will remain confidential and securely stored. It will only be disclosed with your permission, except as required by law.

If you give us your permission by signing the Consent Form, we plan to publish the results in appropriate peer-reviewed scientific journals and/or present them at scientific/sector meetings. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Presentation of information will only be at the group level and no individual identifying data will be made available.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be collected. You also have the right to request a recording of your interview. Please contact one of the researchers named in this document if you would like to access your information.

12. Injury

Not applicable to this research project.

13. Reimbursement for Your Costs

You will not be paid for your participation in this research.

14. Ethical Guidelines

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the Royal Victorian Eye & Ear Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15. Who Can I Contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For Further Information or Appointments

If you require further information concerning this Project, please contact researcher Ms Heather Machin RN via: (03) 9929 8377 / heather.machin@unimelb.edu.au

For Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact,

Position: HREC Secretary

Telephone: (03) 9929 8525

Email: ethics@eyeandear.org.au

You will need to tell the Secretary the name of one of the researchers listed above.



SECTOR INTERVIEW CONSENT FORM

Full Project Title: Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation.

I, _____, have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it, and I am over the age of 18.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this project according to the conditions in this document.

I will be given a copy of the *Participant Information and Consent Form* to keep.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form without or permission.

Participant's Name (printed)

Signature

Date

Witness (Required when participant cannot read this document for him/herself except where an interpreter is used.)

Name of Witness to Participant's Signature (printed)

Signature

Date

Researcher's Name (printed)

Signature

Date

REVOCATION OF CONSENT FORM

(To be used for participants who wish to withdraw from the project.)

Revocation of Consent Form

Full Project Title: Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation.

I, _____, hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any relationships.

Participant's Name (printed)

.....

Signature

Date

TEM 04: Chapter 3 - Part 2 formal invitation

Emailed to participants between December 2018 and March 2020 (example of non-Australian invitation).

Dear [insert name]

In your capacity as a sector leader, I would like to invite you to participate in a research project I am involved in at the Centre for Eye Research Australia-University of Melbourne.

The Research: This research is one component of a wider project, designed to examine corneal tissue exportation and importation. The outcomes of this research will assist the wider global community - but specifically Australia, when examining if they could/should participate in transnational activities in the future. You do not need to be Australian as we are seeking perspectives from a wide range of countries, resource levels and positions - regardless of engagement in exports, imports or neither.

What's involved: Your participation will involve one, 20-25-minute semi-structured interview – conducted in English, with one of our Researchers. This will take place via distance communication methods at a mutually convenient time. Your involvement and responses will be de-identified – and only known to the Researchers.

For your reference, this research has full Human Research Ethics Approval, from the Royal Victorian Eye and Ear Hospital Melbourne, and has been initiated by Professor Paul Baird as the Principal Researcher and Supervisor to PhD Candidate Heather Machin RN.

Please let me know if you are available to participate. I attach the participant consent form in advance for your perusal and signature. Once signed, we can schedule in an interview time.

Thank you for your consideration

Heather

TEM 05: Chapter 4 - Part 1 pilot PICF



**CENTRE FOR EYE RESEARCH AUSTRALIA
THE ROYAL VICTORIAN EYE & EAR HOSPITAL**

Participant Information Page

Full Project Title:	Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation – <i>Aim 3: Public opinion e-survey validation pilot process phase</i>
Document tracking:	Version 1 – 21.05.2019
Principal Researcher:	Professor Paul Baird
Associate Researcher(s):	Heather Machin RN
Location:	Royal Victorian Eye and Ear Hospital (including Eye and Ear on the Park, St Andrews Place, East Melbourne) and the Centre for Eye Research Australia
PIC provision format	The information in this document will be pasted onto the home page of the e-survey online platform. Consent will be confirmed by the participant clicking 'yes to participate'.

1. Introduction

On death, Australians can voluntarily donate their eyes, and in particular, their cornea (located at the front of their eye). This donation helps provide sight restoring transplant surgery to those inflicted with an eye condition or injury. The donation can also assist Australian researchers exploring a wide range of medical conditions and diseases and assist in training Australian eye surgeons.

Australia has a robust donation and allocation system in place and at times has more donations than are needed by the doctor that week. In comparison, many other nations do not have such a robust system and routinely seek assistance from abroad to provide services to their waiting recipients. Therefore, this research project seeks to understand the opinion of Australian citizens and permanent residents, regarding the sharing of their eye donation (or the eye donation of those in their care) with waiting recipients in other nations.

This Participation Information Page contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project to help you decide whether or not to take part in the research.

Please read this information carefully. Feel free to ask questions about any information you don't understand or want to know more about.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. Once you understand what the project is about and if you decide to take part in it, you may click [yes to participate] below. In doing so, you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to participate in the research processes that are described;
- Consent to allow us to use your responses as described; and
- You confirm that you are an Australian citizen or permanent resident over the age of 18 years.

2. Purpose and Background

This research is one component of a wider project designed to understand the management and utility of donated corneal eye tissue in Australia and seeks to examine if Australia should share their donations with other nations in the event that, at that point in time, Australia was meeting need. This research is part of a pilot phase to evaluate the validate the e-survey prior to final preparation and formal presentation to the Australian public.

This research has been initiated by Professor Paul Baird as the Principal Researcher and Supervisor to PhD Candidate Heather Machin RN.

3. Procedures, and What is Involved

Participation in this project will involve:

- Completing an anonymous e-survey.
- Completing an anonymous post-survey evaluation of the e-survey. This will assist our researchers to devise and validate the survey ready for final use with the wider, lay, Australian population.

4. Possible Benefits

There will be no immediate benefits from your participation in this research, however findings may indicate possible future opportunities for Australia, and ensure Australian wishes are met at the time of donation.

5. Possible Risks

There are no risks involved in this project however we accept the delicacy of the conversation and information shared. Our researchers will adhere to strict ethical and privacy law requirements.

7. Alternatives to Participation

You may choose not to participate in this project.

8. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, please contact our researchers. Your decision as to whether to take part or not to take part, or to take part and then withdraw, will not affect your current relationships with your healthcare providers or the donation agencies. Please do not change your practices.

Before making a decision to participate, please contact a member of the research team to answer any questions you have about the research project, should you need. Click 'yes to participate' only after you have had a chance to ask questions and have received satisfactory answers.

9. Privacy, Confidentiality and Disclosure of Information

The information we collect from you will be retained for 15 years. At the end of this period, the electronic data will be deleted from databases and servers and paper data will be shredded and destroyed. Electronic data – inclusive of recorded interviews - will be stored at the Centre for Eye Research Australia, University of Melbourne on a password projected server in a specific project folder on a secure network. Only those researchers mentioned on the project will have access to this information-. Any paper copies stored in a locked filing cabinet.

Any information obtained in connection with this project that can identify you will remain confidential and securely stored. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to publish the results in appropriate peer-reviewed scientific journals.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Presentation of information will only be at the group level and no individual identifying data will be made available.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named in this document if you would like to access your information.

10. Injury

Not applicable to this research project.

11. Reimbursement for Your Costs

You will not be paid for your participation in this research.

12. Ethical Guidelines

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the Royal Victorian Eye & Ear Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13. Who Can I Contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For Further Information on the Research

If you require further information concerning this Project, please contact researcher Ms Heather Machin RN via:

Phone: (03) 9929 8377

Email: heather.machin@unimelb.edu.au

For Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact,

Position: HREC Secretary

Phone: (03) 9929 8525

Email: ethics@eyelandear.org.au

You will need to tell the Secretary the name of one of the researchers listed above.

14. Life Line Counselling Services

This research will examine end-of-life decision making, and as such, may ask some confronting questions. If you find yourself in position where you need to talk to anyone, please contact Life Line.

Phone: 13 11 14

Website: <https://www.lifeline.org.au/>

CONSENT TO PARTICIPATE

I have read/or have had read to me in a language that I understand, the above information, and I understand the purposes, procedures and risks of this research project as described within it.

I confirm that I am an Australian citizen or permanent resident over the age of 18 years.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this project according to the conditions outlined above.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form without or permission.

Click **Yes to Participate**

TEM 06: Chapter 4 – Part 2 formal e-consent to proceed



**CENTRE FOR EYE RESEARCH AUSTRALIA
THE ROYAL VICTORIAN EYE & EAR HOSPITAL**

Participant Consent Page

Full Project Title:	Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation – Aim 3: <i>Public opinion e-survey validation pilot process phase</i>
Document tracking:	Version 1 – 21.05.2019
Principal Researcher:	Professor Paul Baird
Associate Researcher(s):	Heather Machin RN
Location:	Royal Victorian Eye and Ear Hospital (including Eye and Ear on the Park, St Andrews Place, East Melbourne) and the Centre for Eye Research Australia
PIC provision format	Pasted onto the home page of the e-survey. The 'yes' button placed under the information must be selected prior to commencing the e-survey. Those who indicate 'no' will not proceed to the e-survey.

CONSENT TO PARTICIPATE

I have read/or have had read to me in a language that I understand, the attached project consent information, and I understand the purposes, procedures and risks of this research project as described within it.

I confirm that I am an Australian citizen or permanent resident over the age of 18 years.

I freely agree to participate in this project according to the conditions outlined above.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form without or permission.

Select:

- Yes [proceeds to the e-survey]
- No [does not proceed to the e-survey]

TEM 07: Chapter 4 - Part 2 formal information provided



**CENTRE FOR EYE RESEARCH AUSTRALIA
THE ROYAL VICTORIAN EYE & EAR HOSPITAL**

Participant Information Page

Full Project Title:	Eye Banks, exports and Australian Opinion: Exploring national utility of human corneal tissue donation – Aim 3: <i>Public opinion e-survey validation pilot process phase</i>
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Principal Researcher:	Professor Paul Baird
Associate Researcher(s):	Heather Machin RN
Location:	Royal Victorian Eye and Ear Hospital (including Eye and Ear on the Park, St Andrews Place, East Melbourne) and the Centre for Eye Research Australia
PIC provision format	PDF. Provided on the home page of the e-survey

1. Introduction

On death, Australians can voluntarily donate their eyes, and in particular, their cornea (located at the front of their eye). This donation helps provide sight restoring transplant surgery to those afflicted with an eye condition or injury. The donation can also assist Australian researchers exploring a wide range of medical conditions and diseases and assist in training Australian eye surgeons.

Australia has a robust donation and allocation system in place and at times has more donations than are needed by the doctor that week. In comparison, many other nations do not have such a robust system and routinely seek assistance from abroad to provide services to their waiting recipients. Therefore, this research project seeks to understand the opinion of Australian citizens and permanent residents, regarding the sharing of their eye donation (or the eye donation of those in their care) with waiting recipients in other nations.

This Participation Information Page contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project to help you decide whether or not to take part in the research.

Please read this information carefully. Feel free to ask questions about any information you don't understand or want to know more about.

You have been invited to participate in this study project because you have already registered and identified yourself as interested in participating in research, conducted via Qualtrics, who will communicate with you on our behalf. This will ensure your privacy is maintained as outlined in 8.0 of this document. Your decision to proceed, and participation, in this research is voluntary. If you do not wish to take part, you do not have to. Once you understand what the project is about and if you decide to take part in it, you may consent and commence the e-survey.

In doing so, you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to participate in the research processes that are described;
- Consent to allow us to use your responses as described; and
- You confirm that you are an Australian citizen or permanent resident over the age of 18 years.

2. Purpose and Background

This research is one component of a wider project designed to understand the management and utility of donated corneal eye tissue in Australia and seeks to examine if Australia should share their donations with other nations in the event that, at that point in time, Australia was meeting need.

This research has been initiated by Professor Paul Baird as the Principal Researcher and Supervisor to PhD Candidate Heather Machin RN.

3. Procedures, and What is Involved

Participation in this project will involve:

- Completing an anonymous e-survey.

4. Possible Benefits

There will be no immediate benefits from your participation in this research, however findings may indicate possible future opportunities for Australia, and ensure Australian wishes are met at the time of donation.

5. Possible Risks

There are no risks involved in this project however we accept the delicacy of the conversation and information shared. Our researchers will adhere to strict ethical and privacy law requirements.

6. Alternatives to Participation

You may choose not to participate in this project.

7. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. Your decision as to whether to take part or not to take part, or to take part and then withdraw, will not affect your current relationships with your healthcare providers or the donation agencies. Please do not change your practices.

If you have any questions, please contact Qualtrics, who you have registered with. They will liaise with our researchers to answer your questions. Proceed through the consent

process, only after you have had a chance to ask questions and have received satisfactory answers.

The survey will contain a variety of question types. The opening questions (e.g. gender, age, State/Territory you reside) will be compulsory. The remaining questions will involve a variety of non-compulsory questions (e.g. yes/no, multiple-choice, open response questions) specific to our study. The survey is expected to take 6-10 minutes to complete.

8. Privacy, Confidentiality and Disclosure of Information

The survey response we collect from you will be retained for 15 years. At the end of this period, the electronic data will be deleted from databases and servers and paper data will be shredded and destroyed. Electronic data will be stored at the Centre for Eye Research Australia, University of Melbourne on a password protected server in a specific project folder on a secure network. Only those researchers mentioned on the project will have access to this information. Any paper copies shall be stored in a locked filing cabinet. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, the survey will be presented on a secure online platform.

Your participation, via Qualtrics will be conducted in accordance with the agreement you have already made privately, with that organisation. Only your deidentified anonymous responses will be transferred to our researchers.

As your participation is anonymous to our researchers, they will not be able to identify you, and they will not be able to contact you. Survey responses will be electronically collated and presented at the group level only. We plan to publish the results in appropriate peer-reviewed scientific journals, and/or presentation.

If you would like to know more about your involvement in the study or about any aspect of the research at any stage, please contact Qualtrics. They will liaise with our researchers to provide you with access to your survey response.

9. Injury

Not applicable to this research project.

10. Reimbursement for Your Costs

You will not be paid for your participation in this research.

11. Ethical Guidelines

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the Royal Victorian Eye & Ear Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12. Who Can I Contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

First point of contact

As your first point, please contact Qualtrics, who you have registered with. They will liaise directly with our researchers. This will ensure you remain anonymous to our researchers.

Phone: (02) 8310 8031

For Further Information on the Research

If you require further information concerning this Project, please contact researcher Ms Heather Machin RN via:

Phone: (03) 9929 8377

Email: heather.machin@unimelb.edu.au

For Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact,

Position: HREC Secretary

Phone: (03) 9929 8525

Email: ethics@eyeandear.org.au

You will need to tell the Secretary the name of one of the researchers listed above.

13. Life Line Counselling Services

This research will examine end-of-life decision making, and as such, may ask some confronting questions. If you find yourself in position where you need to talk to anyone, please contact Life Line.

Phone: 13 11 14

Website: <https://www.lifeline.org.au/>

03: ADMINISTRATIVE

ADM 01: Data management plan



University of Melbourne Research Data Management Plan

The purpose of the Data Management Plan (DMP) is to define the basis for successful management of the project data, records, and all related information.

This document contains instructional text which should be removed prior to finalising the DMP. Place 'N/A' in sections which are not applicable to your DMP – your plan is a living document and should be updated throughout the course of your project.

Please contact the Research Data Management team for assistance with Data Management Plans at research-data@unimelb.edu.au or see the online [Managing Data @Melbourne](#) program for guidance.

1. Getting Started

a. <i>Project title</i>	Eye Banks, Exports and Australian Opinion: Exploring national utility of human corneal tissue donation.
b. <i>ID</i>	Enter an identifier for this project – this could be a project ID, or other ID, or you can leave blank TBC
c. <i>Grant reference number</i>	NHMRC: APP1150637
d. <i>Ethics approval Number</i>	HREC#18-1374H
e. <i>PI Name(s)</i>	Name of Principal Investigator(s) and any other main researcher(s) on the project. Ms Heather M Machin (Main Researcher)
f. <i>DMP author name</i>	The author or contact person for this DMP. This can be the same as the PI name. Ms Heather M Machin
g. <i>Faculty / Department</i>	Enter any faculties or institutions involved in this project. Ocular Genetics Unit, Centre for Eye Research Australia, RVEEH, University of Melbourne.
h. <i>Project start date</i>	The date on which work on this project started or will start. This date can be approximate. 20.02.2018.
i. <i>Project end date</i>	The date on which work on this project ended or will end. This date can be approximate. 20.02.2021.
j. <i>Project description</i>	Australian Eye Banks (AUEB) - responsible for the recovery, processing, and distribution of human corneal tissue (HCT) to waiting recipients - are at a unique juncture, with willingness to donate HCT for sight-restoring corneal transplant surgery surpassing scheduled surgical need. As HCT expires after 7-30 days (depending on the storage technology), and due to the bio-psychosocial connotation surrounding tissue donation, the AUEB and the donor sector are

DMP template version 1.1

seeking solutions to manage 'surplus' HCT. Exportation of surplus HCT is one management option. The Project will investigate aspects of exportation in comparison to other options, to inform and guide sector decision making; prevent undermining of other aspects of human biological and eye care sectors; and retain engagement with Australian donors.

2. Developing your DMP (about your data)

<i>a. Data types</i>	What types of data will you collect, create or reuse? Aim 1: Expert sector interviews Aim 2: Data regarding Eye Bank Services, re: declined eligible donations and why they were declined Aim 3: a). Focus Group, and b). online survey.
<i>b. File formats</i>	Aim 1: Word, excel, recorded and uploaded to NVIVO. Aim 2: Excel. Aim 3: Word, excel, online survey (survey monkey) and NVIVO.

3. Ethics and Legal Issues

<i>a. Ethics and Legal</i>	How will you manage any ethical issues? Full Project: HREC of the Royal Victorian Eye and Ear Hospital. Aim 2 only: NHMRC's NMA Certification process and further registration approval required by the affiliated bodies of 5 individual Eye Banks in Australia and the Eye Bank Association of Australia and New Zealand.
<i>b. Copyright and IP</i>	How will you manage copyright and Intellectual Property Right (IPR) issues? As the University of Melbourne Policy.

4. Organisation, Storing and Backing up your Data

<i>a. Backup</i>	Centre for Eye Research Australia (CERA) server's routine back-up system.

<i>b. Security</i>	How will you manage access and security? Files will only be accessible to the Principle Investigator Paul Baird, and Main Researcher Heather Machin.

5. Documenting and Describing your Data

<i>a. Documentation</i>	Aim 2: Data dictionary, collection template for the eye bank multi-site, and a collation template retained by our Main Researcher to tally national data from the collection templates.
<i>b. Quality</i>	Data Dictionary

6. Sharing and Preserving your Data

<i>a. Sharing</i>	The Principle Investigator and Main Researcher will share data within their secure file. Aim 2: Data will be shared back to the collaborating eye banks as part of the feedback process. Aim 1 & 3: a summary of results will be provided to those who indicate interest at the completion of the project.
<i>b. Restrictions</i>	No.

Further Optional Questions

These questions expand on some areas and also deal with post-project arrangements for data. Please fill in if appropriate.

7. Data Storage – Digital Data

a. <i>Volume of digital data</i>	Minimum.
b. <i>Storage type, location and backup</i>	Server of the Centre for Eye Research Australia, on: H:\PhD This server is routinely backed-up by the department.
c. <i>Access, confidentiality and security</i>	Aim 1-3: The Principle Investigator and the Main Researcher. Aim 3b (the online survey such as survey monkey): Will be accessible only to those involved in this project – all security requirements for the online site will be followed.
d. <i>Storage of pre-existing data</i>	Via CERA drive: H:\PhD

8. Data Storage - Non-Digital data

a. <i>Non-digital data types</i>	Minimal.
b. <i>Storage location</i>	H:\PhD
c. <i>Safeguards and requirements</i>	See part 7 above.
d. <i>Other requirements</i>	n/a

9. Intellectual Property, Copyright and Ownership

a. <i>Contracts and Agreements</i>	nil known at present. We will partner with eye banks and their professional association via a collaborator consent process. Data/information utilised by others will be acknowledged – under permission (if not already published).
b. <i>Ownership</i>	Centre for Eye Research Australia.
c. <i>Pre-existing data</i>	Any data requested from the Eye Bank Association of Australia and New Zealand (or opportunities with groups such as the Lions Eye Donation Service) re: their own pre-existing data, may be obtained to help demonstrate current data and sector utility. Permissions from those groups will be obtained and they shall be acknowledged and consulted.

10. Post-project data retention, sharing and destruction

a. <i>Data to retain</i>	All data will be retained for 15 years.
a. <i>Pre-existing data</i>	Access to pre-existing data from other groups will not impact this project. The inclusion will be a bonus but without it, it just means we will need to find alternative/published methods of demonstrating existing utility patterns.
b. <i>Duration</i>	15 years.
c. <i>Non-digital Data</i>	See # 7.
d. <i>Digital Data</i>	See # 7.
e. <i>Licencing</i>	See # 7.

ADM 02: Riot certification



04: ETHICS AND GOVERNANCE

ETH 01: Overview

RVEEH 18/13874H provided ethics approval for the whole project. Chapter 2 involved further national approval from the South East Sydney Health District (18/139(HREC/18POWH/292) and site governance and data transfer with each participating eye bank. Of note, Melbourne's Lions Eye Donation Service is a component of the CERA-RVEEH and covered under 18/13874H.

The project was conducted in accordance with Declaration of Helsinki and The Barcelona Principles.

Ethical constraints

We were aware that our subject discussed death. Therefore, when conducting our public e-survey (Chapter 4) we included contact information for *LifeLine*, a free telephone support service in Australia, within the PICF (TEM05 on page 242 and TEM07 on page 248).

Confidentiality and data control

1. Our Data manage plan is outlined in Appendix ADM01 on page 252.
2. Confidentiality and data control is outlined within individual PICF (TEM01 on page 227, TEM03 on page 235, and TEM05-07 on pages 242-251) for project presented in Chapters 3 and 4.
3. Participants in Chapter 3 and 4 were deidentified. Chapter 3 participants were allocated numbers based on the order in which they agreed to participate.
4. Communication with individual participating eye banks involve in Chapter 2 are outlined within Appendix 04.

Dissemination of results

1. Chapter 2 eye bank participants were involved in the publication.
2. Chapter 3 individual participants were informed of the first paper publication.
3. Chapter 4 individual participants were awarded the option to contact to enquire.

Risk of harm

We were aware that our subject discussed death. Therefore, when conducting our public e-survey (Chapter 4) we included contact information for *LifeLine*, a free telephone support service in Australia, within the PICF (TEM05-07 on pages 242-251).

Reflexivity

The researcher was conducted in full via distance-mode. Chapter 2 and Chapter 4 was conducted through survey software system.

Chapter 3 involved Zoom Telephone Conferencing (or iphone if the Zoom connection was missed) and Amazon Transcription. In most instances, interviews were audio only however some participants selected to keep the camera on. We accommodated camera-on and -off requests accordingly. Interviewees were instructed that the interviewer would remain partial and intentionally reduce their verbal interaction, in order to ensure the respondent's response was not interrupted. Those with the camera where informed that the researcher would remain relatively still and would not use gestures or non-verbal ques to influence the respondent.

Research integrity training was completed. Certificate is available in Appendix ADM02 on page 257.

ETH 02: HREC approval 18/13874H (project in full)

Signatures covered for security.



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Research Office

T. +61 3 9929 8525

ethics@eyeandear.org.au

Reference Number: 18/1374H

Project Title: Eye Banks, Exports and Australian Opinion:
Exploring National Utility of Human Corneal Tissue
Donation

Principal Investigator: Professor Paul Baird

Thank you for submitting the above research project for ethical review. This project was considered by the Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (HREC) at its meeting on 19 April 2018.

I am pleased to inform you that ethical approval will be granted for this project, however, it is subject to the following amendment/clarification:

- Application Q2.2.4 to be amended to Yes.
(Reference: National Statement Sections 1.1, 1.3)

The changes requested above should be confirmed in writing and forwarded to the HREC Secretary. Please use 'track changes' for documents that need to be resubmitted.

In order to facilitate the HREC's consideration of your project, please provide the requested information as soon as practical.

Yours sincerely

Kerryn Baker
Secretary
Human Research Ethics Committee

24 April 2018

ETH 03: HREC amendment approval 18/13874H (in date order)

Signatures covered for security.



the royal victorian
**eye and ear
hospital**

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ethics@eyeandear.org.au

HREC Number: 18/1374H

Project Title: Eye Banks, Exports and Australian Opinion: Exploring
National Utility of Human Corneal Tissue Donation

Principal Investigator: Professor Paul Baird

I refer to your amendment dated 31 August 2018 requesting an amendment to the
Participant Information & Consent Form and questionnaire for the above listed project.

The HREC Chair approved the above amendment. This decision will be ratified by the full
Human Research Ethics Committee at the next meeting scheduled for 11 October 2018.
This amendment can proceed from the date of this letter. No further correspondence will
be provided on this amendment unless the HREC requests additional information.

The following document/s were approved:

- Project proposal, incorporating amendment dated 31 Aug 2018
- Participant Information & Consent Form, v2 dated 31 Aug 2018
- The Pilot Test Validation Group Questions
- Process Explanation

Thank you for notifying the Committee.

Yours sincerely

Kerryn Baker
Secretary
Human Research Ethics Committee

7 September 2018



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HREC Number: 18/1374H

**Project Title: Eye Banks, Exports and Australian Opinion: Exploring
National Utility of Human Corneal Tissue Donation**

Principal Investigator: Professor Paul Baird

I refer to your amendment dated 12 December 2018 requesting an amendment to the interview questions, Participant Information & Consent Form and invitations for the above listed project.

The HREC Chair approved the above amendment. This decision will be ratified by the full Human Research Ethics Committee at the next meeting scheduled for 14 February 2019. This amendment can proceed from the date of this letter. No further correspondence will be provided on this amendment unless the HREC requests additional information.

The following document/s were approved:

- Project proposal, incorporating amendment dated 12 Dec 2018
- The Question set, v1 dated 12 Dec 2018
- Process Explanation for Aim 1, pt 2, v2 dated 12 Dec 2018
- Participant Information & Consent Form for Sector Interviews, v3 dated 12 Dec 2018
- Invitations, v1 dated 12 Dec 2018
- Formal interview tracking details, v1 dated 12 Dec 2018

Thank you for notifying the Committee.

Yours sincerely



Kerryn Baker
Secretary
Human Research Ethics Committee

17 December 2018



the royal victorian
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HREC Number: 18/1374H

Project Title: Eye Banks, Exports and Australian Opinion: Exploring
National Utility of Human Corneal Tissue Donation

Principal Investigator: Professor Paul Baird

I refer to your amendment dated 21 May 2019 requesting an amendment to conduct survey as part 1 of aim 3 for the above listed project.

The HREC Chair approved the above amendment. This decision will be ratified by the full Human Research Ethics Committee at the next meeting scheduled for 8 August 2019. This amendment can proceed from the date of this letter. No further correspondence will be provided on this amendment unless the HREC requests additional information.

The following document/s were approved:

- Project proposal, incorporating amendment dated 21 May 2019
- Participant Information Page, v1.0 dated 21 May 2019

Thank you for notifying the Committee.

Yours sincerely



Kerry Baker
Secretary
Human Research Ethics Committee

12 June 2019



the royal victorian
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hospital

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HREC Number: 18/1374H

Project Title: Eye Banks, Exports and Australian Opinion: Exploring
National Utility of Human Corneal Tissue Donation

Principal Investigator: Professor Paul Baird

I refer to your amendment dated 21 June 2019 requesting an amendment to protocol and Participant Information & Consent Form for the above listed project.

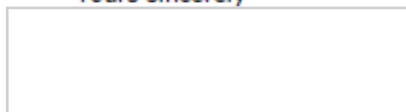
The HREC Chair approved the above amendment. This decision will be ratified by the full Human Research Ethics Committee at the next meeting scheduled for 8 August 2019. This amendment can proceed from the date of this letter. No further correspondence will be provided on this amendment unless the HREC requests additional information.

The following document/s were approved:

- Project proposal, incorporating amendment dated 21 Jun 2019
- E-Survey, Aim 3
- Public Opinion process explanation, Aim 3
- Participant Information & Consent Form, Aim 3 v2.0 dated 21 Jun 2019
- Consent Declaration, Aim 3 v1.0 dated 21 Jun 2019

Thank you for notifying the Committee.

Yours sincerely



Kerryn Baker
Secretary
Human Research Ethics Committee

4 July 2019

ETH 04: Chapter 2 – National approval request

Signatures covered for security.

25.05.2018

HREC NMA application for corneal tissue data collection project

Dear Deborah

Please find attached application documents, as advised, for review at your HREC June Meeting. As discussed, we seek approval for the collection of known and available data pertaining to collected and uncollected human cornea tissue by Australian Eye Banks.

This low risk project is Part (aim) 2 of a wider PhD research project of Ms Heather Mary Machin – an NHMRC Scholarship awardee and member of the Australian Eye Bank Community. This research seeks to ascertain if Australia has unutilised donations that could be collected and utilised elsewhere.

The full project has been approved by the HREC of the Royal Victorian Eye and Ear Hospital, and we now seek national approval for Part 2 only. This will assist in approval by individual partner eye banks across Australia. We approach Southern Eastern Sydney Health District in its capacity as an NMA Certified HREC.

Please find attached:

1. HREA New South Wales Specific Module
2. Project Protocol
3. Aim 2 Data dictionary and collection template
4. HREC Approval from the RVEEH – *this covers project inclusion support of their partner eye bank – Lions Eye Donation Service.*
5. In-principle support from:
 - a. Lions Eye Bank WA – email from Manager Lisa Buckland
 - b. Eye Bank of South Australia – email from Acting-Manager Golding-Holbrook
 - c. Queensland Bone and Tissue Bank – email from Director Nicholas Nuttall
 - d. NSW Eye Bank – Acknowledgement from Manager Jane Treloggen
6. And, for your reference: The Business Partnership Agreement template for signing post HREC approval with each eye bank

Please let either myself, or the Project Designee – Ms Machin, know if you require further information to support this application.

We thank you for your consideration

Kind Regards

Professor Paul Baird

Principal Investigator / NHMRC Senior Research Fellow / Research Leader, Education / Head, Ocular Genetics Unit, Centre for Eye Research Australia / Professorial Fellow

ETH 05: Chapter 2 – National approval confirmation (18/139(HREC/18POWH/292)



Health
South Eastern Sydney
Local Health District

HUMAN RESEARCH ETHICS COMMITTEE

Room G71 East Wing
Edmund Blacket Building
Prince of Wales Hospital
RANDWICK NSW 2031
Tel: 02 9382 3587 Fax: 02 9382 2813
SESLHD-RSO@health.nsw.gov.au
www.seslhd.health.nsw.gov.au/POWH/researchsupport

27 June 2018

Professor Paul Baird
Attention: Ms Heather Machin
L7 PHW Centre for Eye Research Australia
32 Gisborne Street
EAST MELBOURNE VIC 3004

Dear Prof Baird

HREC ref no: 18/139 (HREC/18/POWH/292)

Project title: Quantify the potential corneal tissue surplus levels within Australia

Thank you for submitting the above application for ethical and scientific review. The application was first considered by the South Eastern Sydney Local Health District Human Research Ethics Committee (HREC) at a meeting on 26 June 2018.

I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research.

Ethics approval is granted for the following site(s):

- Lions Eye Bank WA
- Eye Bank of South Australia
- Queensland Bone and Tissue Bank
- Lions NSW Eye Bank

Ethics approval is granted for the following documents:

- HREA submission AU/1/30A6314 dated 25 May 2018
- Protocol Eye Bank Data Collection v2 dated 19 June 2018
- Eye Bank Export Project Aim 2 - Data Dictionary and Monthly Collection Template

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.



**Prince of Wales Hospital &
Community Health Services**

**Prince of Wales Hospital
Community Health Services**
Barker Street
Randwick NSW 2031

4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

For Public Health Sites Only: You are reminded that this letter constitutes ethics approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website: <http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp>.

Please quote **18/139** in all correspondence.

We wish you every success in your research.

Yours sincerely

Andrew Bohlken
Executive Officer, Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the *CYMAR/ICH Note for Guidance on Good Clinical Practice*.

ETH 06: Chapter 2 - Data transfer agreements (Template)

Signatures covered for security.



DATA TRANSFER AGREEMENT

BETWEEN

NSW Lions Eye Bank (a business unit within SESLHD - 70 442 041 439) having its principal office at Level 1, North Block Sydney Eye Hospital, 8 Macquarie Street, Sydney, NSW 2001, Australia (**the Provider**).

AND

Centre for Eye Research Australia Ltd (ABN 72 076 481 984) having its principal office at Level 7, 32 Gisborne Street, East Melbourne, Victoria 3002, Australia (**the Recipient**)

Background: The Recipient has requested the Provider to provide it with the Provider Data and Provider Confidential Information for the Research.

The Provider has agreed to provide the Provider Data and Provider Confidential Information to the Recipient on the following terms:

1. Definitions and interpretation:

- a. In this Agreement and in the attached Schedules, these terms have the following meanings:
 - i. 'Agreement' means this Data Transfer Agreement;
 - ii. 'Confidential Information' means:
 1. the terms of this Agreement and its subject matter;
 2. Information that at the time of disclosure by the Disclosing Party is identified to the Receiving Party as being confidential;
 3. Information relating to or provided with any Provider Data transferred from one party to the other party; and
 4. all other Information belonging or relating to the Disclosing Party that is not generally available to the public at the time of disclosure other than by reason of a breach of this Agreement or which the Receiving Party knows, or ought reasonably to be expected to know, is confidential to the Disclosing Party;
 - iii. 'Background IP' means in respect of a party the Contributed IP of that party.
 - iv. 'Contributed IP' means all drawings, specifications, processes, techniques, samples, specimens, prototypes, designs, research and development results, test results, and other technical and scientific information and Intellectual Property which is made available for the Research by a party, during the Term of this Agreement;
 - v. 'Data Collection Template' means the template, approved by a human research ethics committee, provided by the Recipient to the Provider for data collection
 - vi. 'Disclosing Party' means the party disclosing Confidential Information;
 - vii. 'Information' means any information or data, whether oral, graphic, electronic, written or in any other form, including:
 1. forms, memoranda, letters, specifications, processes, procedures, statements, formulae, technology, inventions, trade secrets, research and development information, know how, product designs, plans, photographs, microfiche, business



records, notes, accounting details or procedures, financial arrangements or information, sales and marketing information, names and details of customers, suppliers and agents, customer lists, employee details, reports, drawings, data and technical and functional specifications; and

2. copies and extracts made of or from that information and data, whether translated from the original form, recompiled, partially copied, modified, updated or otherwise altered.
- viii. **'Intellectual Property'** includes all copyright and neighbouring rights (including rights in relation to phonograms and broadcasts), all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trade marks (including service marks), registered and unregistered designs, and circuit layouts, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields including as defined in Article 2 of the Convention Establishing the World Intellectual Property Organisation of July 1967;
 - ix. **'Project IP'** means all data, research papers, test results, experiments, products and items giving rise to Intellectual Property rights arising out of the Research project including improvement made to background IP made or developed by a party in the course of the Research but excluding the Background IP;
 - x. **'Provider Data'** means the Provider Data described in Schedule 1;
 - xi. **'Provider Confidential Information'** means the Confidential Information of the Provider;
 - xii. **'Receiving Party'** means the party receiving Confidential Information;
 - xiii. **'Recipient Confidential Information'** has the meaning given to that term in clause 9(a);
 - xiv. **'Recipient's Principal Investigator'** means the principal investigator of the Recipient described in Schedule 3;
 - xv. **'Research'** means the research project described in Schedule 2; and
 - xvi. **'Term'** has the meaning given to that term in clause 2.
- b. The following rules apply in interpreting this document, except where the context makes it clear that a rule is not intended to apply:
- i. headings are for convenience only, and do not affect interpretation;
 - ii. a reference to:



1. legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced, and includes any subordinate legislation issued under it;
2. a document, agreement or deed, or a provision of a document, agreement or deed, is to that document, agreement, deed or provision as amended, supplemented, replaced or novated;
3. a party to this document or to any other document, agreement or deed includes a permitted substitute or a permitted assign of that party;
4. a person includes any type of entity or body of persons, whether or not it is incorporated or has a separate legal identity, and any executor, administrator or successor in law of the person; and
5. anything (including a right, obligation or concept) includes each part of it;
- iii. a singular word includes the plural, and vice versa;
- iv. a word which suggests one gender includes the other genders;
- v. if a word is defined, another part of speech has a corresponding meaning; and
- vi. wherever "include", "for example" or any form of those words or similar expressions is used, it must be construed as if it were followed by "(without being limited to)".
2. **Term:** This Agreement will commence on the date this Agreement is signed by the parties and will continue for the duration of the Research unless terminated earlier in accordance with clause 10a (**Term**).
3. **Ownership:** The Provider retains ownership of and all rights in:
 - a. the Provider Data and subsets thereof; and
 - b. the Provider Confidential Information and any copies thereof.
4. **Licence:** The Provider grants the Recipient a non-exclusive licence for the Term to use the Provider Data and Provider Confidential Information to conduct academic, non-commercial experimental work. The licence excludes use of the Provider Data and Provider Confidential Information in any other way for commercial purposes.
5. **Distribution:** The Recipient will only provide the Provider Data and disclose the Provider Confidential Information to the Recipient's Principal Investigator and the Recipient's employees or students who "need to know" the same for the conduct of the Research and the Recipient must ensure that all such persons comply with the terms of this Agreement.
6. **Obligations:**
 - a. The Recipient must:
 - i. use the Provider Data only for the purposes for the Research described in Schedule 2;
 - ii. ensure that the Provider Data requested is using the approved Data Collection Template; confirm that the planned use of the Provider Data has the approval of the appropriate human research ethics committee and or animal ethics committee and that all research will be conducted in compliance with applicable laws, regulations and guidelines;



- iii. retain the Provider Data in a secure network system at such a standard as would be reasonably expected for the storage of valuable and proprietary, sensitive and confidential data;
- iv. refrain from tracing or identifying the identity of any subjects or donors who provide the Provider Data, beyond Jurisdictional State, rural or urban location, and age bracket;
- v. not attempt to contact any subjects or donors who provide the Provider Data;
- vi. on termination of this Agreement, delete the Provider Data and confirm to the Provider (in writing) that this has taken place;
- vii. comply with any applicable laws in relation to the transfer, use, maintenance, storage and deletion of the Provider Data;
- viii. comply with any written directions from the Provider in relation to the transfer, use, maintenance, storage and deletion of the Provider Data; and
- ix. comply with any requests from the Provider, upon reasonable notice to the Recipient:
 - 1. for the Provider itself or via a third party, to inspect the premises and other relevant facilities of the Recipient, in order to confirm or investigate compliance with this Agreement and review security, storage or other arrangements for the Provider data;
 - 2. request such additional information about the research and /or its progress as the Provider may, from time to time, reasonably require; and
 - 3. the Provider will bear the costs of such audits unless a data default within the procedures and processes of the Recipient is discovered, in which case the Recipient will be obliged to reimburse the reasonable costs of the Provider and any third parties.

7. Publication:

- a. The parties agree that any publication or presentation will be authored; and
- b. Any publication or presentation arising out of the Research must acknowledge the Provider.

8. Intellectual Property: ownership of all Project IP shall be vested in the Recipient.

9. Confidentiality:

- a. Subject to the publication rights in clause 7a
 - i. the Recipient must keep all Provider Confidential Information strictly confidential and ensure that the Recipient's Principal Investigator and employees and students of the Recipient do not provide the Provider Data or disclose the Provider Confidential Information to any third party without the prior written approval of the Provider (which must not to be unreasonably withheld); and
- b. The obligation of confidentiality in this Agreement does not apply to Confidential Information that without fault on behalf of either party is in the public domain; is disclosed by a third party that has a legal right to make the disclosure; is known prior to receipt; or is required to be disclosed by law.

10. Termination:

- a. The Provider or Recipient may terminate this Agreement at any time with immediate effect by giving written notice to the other party.



- b. Upon termination of this Agreement, all rights which by their nature are capable of surviving termination will survive termination including clauses 8 and 9.
- c. Any termination of this Agreement will not affect the enforceability of any other obligations of a party or rights against a party accrued at that time.

11. Return and destruction:

- a. The Recipient may retain one copy of any analyses, compilations, studies and other documents prepared by the Recipient which may contain Provider Confidential Information for its own records and the Recipient must continue to treat the copy as Provider Confidential Information subject to the terms of this Agreement. This clause 11b survives the expiry or termination of this Agreement.
- b. All Provider Data will be destroyed by the Recipient 15 years after the completion of the Research project.

12. Liability:

- a. The Recipient acknowledges that:
 - i. the Provider Data and Provider Confidential Information are being supplied with no warranties express or implied, including any warranty of accuracy, completeness, safety, merchantability or fitness for a particular purpose or warranty against infringement of Intellectual Property; and
 - ii. it uses the Provider Data at its own risk.
- b. The Recipient acknowledges that the Provider will not be liable to the Recipient for any claims or damages arising from the Recipient's use of the Provider Data or Provider Confidential Information except to the extent caused by the wilful misconduct or gross negligence of the Provider.
- c. The Recipient is liable for any act or omission by the Recipient's Principal Investigator or any employee or student of the Recipient who receives the Provider Data or Provider Confidential Information through the Recipient, which if done by the Recipient, would constitute a breach of this Agreement.
- d. The Recipient indemnifies and must keep indemnified the Provider against all actions, claims, proceedings, demands, liabilities, losses, damages, expenses and costs (including legal costs on a full indemnity basis) that may be brought against the Provider or which the Provider may pay, sustain or incur as a direct or indirect result of the Recipient's use, storage or disposal of the Provider Data except to the extent caused by the wilful misconduct or gross negligence of the Provider.

13. Non-Use of names: Neither Party shall use the name of the other Party, nor identify any member of the other Party's personnel, in any publicity, advertising, or news release without the prior written approval of the other Party

14. This Agreement:

- a. can only be amended, supplemented, replaced or novated by another agreement signed by the parties;
- b. cannot be assigned by a party without the consent of the other party;
- c. this Agreement contains the entire agreement between the parties about its subject matter. Any previous understanding, agreement, representation or warranty relating to that subject matter is replaced by this Agreement and has no further effect;
- d. is governed by the law in force in the State of Victoria and the parties submit to the non-exclusive jurisdiction of the courts of the State of Victoria, and any Court that may hear appeals therefrom;
- e. may be executed in counterparts; and
- f. and any provision of this Agreement, is not to be construed to the disadvantage of a party because that party was responsible for its preparation.



15. Giving effect to this Agreement: A party at its own expense and within a reasonable time of being requested by another party to do so, must do all things and execute all documents that are reasonably necessary to give full effect to this Agreement.

16. Waiver of rights: A right may only be waived in writing, signed by the party giving the waiver, and:

- a. no other conduct of a party (including a failure to exercise, or delay in exercising, the right) operates as a waiver of the right or otherwise prevents the exercise of the right;
- b. a waiver of a right on one or more occasions does not operate as a waiver of that right if it arises again; and
- c. the exercise of a right does not prevent any further exercise of that right or of any other right.

17. Relationship between the parties: The parties agree that:

- a. the rights, duties, obligations and liabilities of the parties shall in every case, be several and not joint or joint and several;
- b. they do not carry on business in common with a view to joint profit and do not receive income jointly;
- c. nothing contained in this Agreement constitutes any of them as joint ventures, agent, partner or trustee of any other of them, or creates any agency, partnership, joint venture or trust for any purpose whatsoever; and
- d. a party does not have any authority or power to act for, or to create or assume any responsibility or obligation on behalf of, any other party.

18. Operation of this Agreement: Any provision of this Agreement which is unenforceable or partly unenforceable is, where possible, to be severed to the extent necessary to make this Agreement enforceable, unless this would materially change the intended effect of this Agreement.



SCHEDULE 1

PROVIDER DATA:

The Provider will supply monthly data to the Recipient for a minimum 12-month period regarding Urban and Rural Human Corneal Tissue that is: (1) Total number of Donor Notifications (2) Recovered and (3) Declined – as outlined in Schedule 2.

The Recipient will supply the Provider with a Data Dictionary and Data Collection Template in which to record such data.



SCHEDULE 2

RESEARCH

The Recipient aims to quantify the potential surplus levels of Human Corneal Tissue (HCT) within Australia. Data will be collected over a prospective minimum 12-month period regarding HCT that is:

1. **Total Deaths (Known through the Providers routine hospital and coronial notification processes)**
 - a. No. of deaths
 - b. No of Notified/ reviewed Medical Records
 - c. No. of potential donors
2. **Recovered (utilised)**
 - a. Total utilised
 - i. Utilised
 - ii. Transplanted
 - iii. Training
 - iv. Research
 - b. Not Utilised
 - i. Determined unsuitable after recovery - and discarded
 - ii. Wasted/Expired
3. **Declined (not utilised).**
4. **Total Donors**
5. **Age (brackets: <20,20-40,40-60,60-80,80>)**
6. **Reason why**
 - a. Need: Demand met at that time
 - b. Service: Too late or manpower issue (would have collected if service capacity/need allowed)
 - c. Notes

This will be compared with transplant data obtained from the Eye Bank Association of Australia and New Zealand (EBAANZ) and Australia and New Zealand Organ Donor Registry, providing a numeric surplus value. End users will be engaged prior to commencement, ensuring uniformly across collection sites (Providers). Ongoing monitoring and support will be provided.

Data will be collected monthly for a minimum period of 12 months via the provided Data Collection Template. At the completion, data from all collection sites will be collated and analysed. Data will calculate the current surplus levels within Australia by quantifying the outcomes from the sample collection sites, against the collections site's utilised (transplanted) HCT rate.

The results will provide an overview of surplus levels within Australia. Evidence such as waste versus not collected, will inform on potential surplus levels and possible service scale-up potential, should the move to collect surplus be decided by the sector.

No payment between the parties will occur during the Term of this Research.



SCHEDULE 3

Recipient's Principal Investigator: :

Paul Baird
Centre for Eye Research Australia
Level 7, 32 Gisborne Street,
East Melbourne, VIC 3002
Phone: +61 3 9929 8613
Email: pnb@unimelb.edu.au

Recipient's Research Contact:

Heather Machin
Centre for Eye Research Australia
Level 7, 32 Gisborne Street,
East Melbourne, VIC 3002
Phone: +61 9929 8377
Email: heather.machin@unimelb.edu.au



Executed as an agreement on

2020

Signed for and on behalf of Centre for Eye Research Australia Ltd (ABN 72 076 481 984) by its duly authorised representative in the presence of:

.....
Signature of witness

.....
Signature of authorised representative
By executing this agreement the representative states that he/she has received no notice that his/her authority to do so has been revoked.

.....
Name of witness (please print)

.....
Name of authorised representative (please print)

Signed for and on behalf of NSW Lions Eye Bank (ABN) by its duly authorised representative in the presence of:

.....
Signature of witness

.....
Signature of authorised representative
By executing this agreement the representative states that he/she has received no notice that his/her authority to do so has been revoked.

.....
Name of witness (please print)

.....
Name of authorised representative (please print)

I (insert name of Provider's Principal Investigator) have read and understood the contents of this Agreement.

.....
Signature of Provider's Principal Investigator

I (insert name of Recipient's Principal Investigator) have read and understood the contents of this Agreement.

.....
Signature of Recipient's Principal Investigator

ETH 07: Chapter 2 – Agreement and governance *New South Wales Lions Eye Bank*



Health
NSW Organ & Tissue
Donation Service

Incorporating:
NSW Bone Bank
Lions NSW Eye Bank
Australian Ocular Biobank

Part of the
DonateLife
network



25 May 2018

T18/29952

Ms Heather Machin
Lead Researcher
Centre for Eye Research Australia
University of Melbourne
Level 7, 32 Gisborne Street
East Melbourne
VIC 3002

Email: heather.machin@unimelb.edu.au

Protocol number: TBA

Protocol title: Quantify the potential corneal tissue surplus levels within Australia

Dear Ms Machin,

Re: Request for support from NSW OTDS Research Steering Committee

We write to inform you that the NSW OTDS Research Steering Committee has reviewed the application for the above named project received 22 May 2018 and has agreed to provide in-principal support to provide access to the requested data for your research project. We note that consideration of the logistics and resources required to collect the data will be required once the data set is determined.

Let us know when you have received HREC approval. Once a data transfer agreement has been enacted, we can start supplying you with the data.

Please note we expect all research groups to provide an annual report that includes:

- Confirmation of the data received to date;
- That the NSW OTDS is acknowledged as the source of the data in all publications and presentations; and
- Provide copies or links to publications resulting from the research.

We wish you all the best for your HREC application and commencement of your project. Should you have any questions, or want to contact the committee please contact me on Jane.Treloggen@health.nsw.gov.au or 9382 7855.

Yours sincerely,



Jane Treloggen
Manager, NSW Tissue Banks
Secretariat for the NSW OTDS Research Steering Committee



Health
NSW Organ & Tissue
Donation Service

Incorporating:
NSW Bone Bank
Lions NSW Eye Bank
Australian Ocular Biobank

Part of the
DonateLife
network



SECTION 5 Agreement Statement and Signatures

By signing this document, I ...Professor Paul Baird (*Principal Investigator*) confirm that the information provided in this application is accurate and that I have read the *Conditions of Use* and agree to abide by all of the conditions.

Signature of Principal Investigator: _____

Full Name (printed): Professor Paul Baird.

Date: 22.05.2018

Signature of Co-Investigator: _____

Full Name (printed): Miss Heather Mary Machin

Date: 22.05.2018



Health
South Eastern Sydney
Local Health District

RESEARCH SUPPORT OFFICE

Room G71, East Wing
Edmund Blacket Bldg
Prince of Wales Hospital
Cnr High & Avoca Streets
RANDWICK NSW 2031
Tel: (02) 9382 3587
Fax: (02) 9382 2813

5 September 2018

Mr Pierre Georges
NSW Tissue Banks
Level 1 North Block
Sydney/Sydney Eye Hospital
Macquarie Street
SYDNEY NSW 2000

Attention: Jane Treloggen

Dear Mr Georges,

SSA Ref: 18/G/231
HREC ref no: 18/139 (HREC/18/POWH/292)
Project title: Quantify the potential corneal tissue surplus levels within Australia

I refer to your Site Specific Assessment application for the above titled project. I am pleased to advise that on 4 September 2018, the General Manager granted authorisation for the above project to commence at the Lions NSW Eye Bank.

The following conditions apply to this research project. These are additional to any conditions imposed by the Human Research Ethics Committee that granted ethical approval:

1. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and are submitted to the lead HREC for review, are copied to the Research Governance Officer.
2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project are to be submitted to the Research Governance Officer.

Please find enclosed the following documents which have been executed:

- Data Transfer Agreement.



**Prince of Wales Hospital &
Community Health Services**

Approval Letter Merge Template.doc Page 1 of 2

**Prince of Wales Hospital
Community Health Services**
Barker Street
Randwick NSW 2031

51777 301017

If you have any queries relating to the above please contact the Research Support Office on (02) 9382 3587.

Yours sincerely

Asatina Viviani-Tukutama
Research Governance Officer

Enc.

Submission Code Date: 16/07/2018
13:19:00

HREC Reference: AU/1/30A6314

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Online Forms

Declarations

(a) Declaration by the Principal Investigator and Associate Investigator(s)

HREC Reference number:	AU/1/30A6314
Project Title (in full):	Quantify the potential corneal tissue surplus levels within Australia
Principal Investigator:	Prof Paul Baird

1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC).
3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC *National Statement on Ethical Conduct in Research*.
4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
5. I undertake to conduct this research in accordance with relevant legislation and regulations.
6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC.
7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
8. I will inform the HREC and the research governance officer if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
9. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.
10. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, research governance officer, the sponsor or an independent body for audit and monitoring purposes.
11. I understand that information relating to this research, and about me as a researcher, will be held by the HREC, research governance officer, and on the Research Ethics Database (RED). This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

Signature of Principal Investigator:

Print Name: Prof Paul Baird

Date: 17/7/18

Signature of Associate Investigator:

Print Name: Ms Heather Machin

Date: 17-07-18

Submission Code Date: 16/07/2018 13:19:00 HREC Reference: AU/1/30A6314

Created with AU
Online Forms

(b) Declaration by Head of Department *(or Divisional Director or other authority) where the Principal Investigator will do the research.

HREC Reference number:	AU/1/30A6314
Project Title (in full):	Quantify the potential corneal tissue surplus levels within Australia
Principal Investigator:	Prof Paul Baird

(b) Declaration by Head of Department *(or Divisional Director or other authority) where the Principal Investigator will do the research.

- I certify that I have read the research project application named above.
- I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator.
- I certify that all researchers/students from my Department involved in the research project have the skills, training and experience necessary to undertake their role.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
- My signature indicates that I support this research project being carried out using such resources.

Name of Head of Department
(or appropriate person):

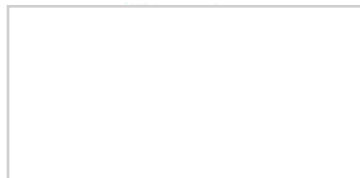
Dr Peter van Wijngaarden

Name of Department
(or relevant section):

Centre for Eye Research Australia

Signature:

Print Name:



Date: 18/7/18

* Where an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible. Investigators must not approve their own research on behalf of their Department.

Submission Code Date: 16/07/2018
13:19:00

HREC Reference: AU/1/30A6314

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(c) Declaration by Head of Supporting Department

This form is to be completed by the Head of any Department that is providing support or services to the research project, but which does not have any member(s) on the research team.

HREC Reference number: AU/1/30A6314

Project Title (in full): Quantify the potential corneal tissue surplus levels within Australia

Principal Investigator: Prof Paul Baird

(c) Declaration by Head of Supporting Department

This form is to be completed by the Head of any Department that is providing support or services to the research project, but which does not have any member(s) on the research team.

I have discussed this project with the Principal Investigator and have read the research project. I am (tick whichever applies)

☒ able to perform the investigations/services indicated, within the present resources of the Department;

☐ able to perform the investigations/services indicated, if the following financial assistance is provided:

☐ unable to undertake the investigations/services indicated, on the following grounds:

Name: Dr Peter van Wijngaarden

Date: 18/7/18

Signature:

Department:

Managing Manager - Genes for Eye Research Australia

Submission Code Date: 16/07/2018
13:19:00

HREC Reference: AU/1/30A6314

Created with AU
Online Forms**(d) Declaration by the Authority for Data Provision**

This form is to be completed by the person authorised to provide data services for research projects.

HREC Reference number:	AU/1/30A6314
Project Title (in full):	Quantify the potential corneal tissue surplus levels within Australia
Principal Investigator:	Prof Paul Baird

I have considered this proposal and consulted the appropriate personnel and I confirm that I have seen all relevant documents that are required. The Department(s) is (tick whichever applies)

- ☒ able to confirm that the data services indicated will be provided, within the present resources;
- ☐ able to confirm that the data services indicated will be provided, if the following financial assistance is provided:
- ☐ unable to provide data services indicated, on the following grounds:

I certify that I will give due regard to any ethical conditions imposed by the approving HREC when deciding whether, and in what form, I will release data to the investigator.

Name:

Jane Treloar

Date:

14/8/18

Position:

Manager, NSW Tissue Banks

Signature:

Department:

NSW Tissue Banks



Executed as an agreement on 25 May 2018 2018

Signed for and on behalf of Centre for Eye Research Australia Ltd (ABN 72 076 481 984) by its duly authorised representative in the presence of:

Carly Parfett
Name of witness (please print)

HELEN ORMONDY PhD.
Name of authorised representative (please print)

Signed for and on behalf of NSW Lions Eye Bank (ARN 70 442 041 439) by its duly authorised

he/she has received no notice that his/her authority to do so has been revoked.

MARTINA LANDO
Name of witness (please print)

Danielle Fisher
Name of authorised representative (please print)

I Paul Laro (insert name of Recipient's Principal Investigator) have read and understood the contents of this Agreement.

ETH 08: Chapter 2 - Agreement and governance Eye Bank of South Australia

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au



Government of South Australia

SA Health

Southern Adelaide Local Health Network

Final Authorisation for Governance

Prof. Paul Baird
Centre for Eye Research Australia
32 Gisborne Street
East Melbourne VIC 3002

Tamme Golding-Holbrook
Ophthalmology Department – Eye Bank of South Australia
Flinders Medical Centre
Bedford Park 5042

Email Contact: heather.machin@unimelb.edu.au
tamme.golding-holbrook@sa.gov.au

Dear Prof Paul Baird and Tamme Golding-Holbrook,

OFR Number:	238.18
SSA ID Number:	SSA/18/SAC/280
HREC ID Number:	HREC/18/POWH/292
Project title:	Quantify the potential corneal tissue surplus levels within Australia
Principal Investigator:	Prof. Paul Baird
Governance Authorisation Date:	17 th December 2018

On the basis of the information provided in your Site Specific Assessment submission, I am pleased to inform you the SALHN Chief Executive Officer has granted authorisation for this study to commence at **Flinders Medical Centre, SA.**

The below documents have been reviewed and approved:

- Site Specific Assessment AU/12/2AE7319 dated 16/7/18
- SALHN/Centre for Eye Research Australia Ltd, Data Transfer Agreement
- SALHN Co-PI Agreement, Tamme Golding-Holbrook, dated 13th September 2018
- South Eastern Sydney Local Health District HREC approval letter - 27/6/2018 to 27/6/2023
- Study Protocol, Version 1 dated 16th March 2018
- Data Dictionary and Monthly Utility Template for Eye Banks, Aim 2
- Curriculum Vitae, Heather Machin, July 2018
- Curriculum Vitae, Paul N. Baird, July 2018
- Curriculum Vitae, Tamme Golding-Holbrook, September 2018
- Centre for Eye Research Australia, Medical, professional and public products Insurance VMIA Certificate of Currency – expires June 2019
- HREC reviewed documents listed on the approval letter are accepted as part of the site authorisation

The OFR reference number should be quoted in any correspondence about this matter.

TERMS AND CONDITIONS OF ETHICS AND GOVERNANCE APPROVAL

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

- If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
- Compliance with the National Statement on Ethical Conduct in Human Research (2007) & the Australian Code for the Responsible Conduct of Research (2007).
- To immediately report to the Office for Research anything that may change the ethics or scientific integrity of the project.
- Report Significant Adverse events (SAEs) as per SAE requirements available on the Office for Research website.
- Submit an annual report on each anniversary of the date of final approval and in the correct template from the Office for Research website.
- Confidentiality of research participants MUST be maintained at all times.
- A copy of the signed consent form must be given to the participant.
- Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
- All requests for access to medical records at any SALHN site must be accompanied by this approval letter.
- Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.
- Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.
- It is the responsibility of the Principal Investigator to ensure any non-SA Health personnel who conducts or monitors research meets SA Health screening requirements as per the SA Health Criminal & Relevant History Screening Policy Directive before they access any SA Health site. The cost of any such screening is the responsibility of the individual accessing the site or their employer.
- A SALHN confidentiality agreement will need to be signed by all non-SA Health staff who will require access to SA Health data.

Should you have any queries about the consideration of your Site Specific Assessment form, please contact the Office for Research on 8204 6453 via email: Health.SALHNOfficeforResearch@sa.gov.au.

Yours sincerely



Simon Windsor
Acting Manager
Office for Research
Date 21 / 12 / 18



Southern Adelaide Local Health Network (SALHN)

Co-Principal Investigator Agreement

All clinical research studies conducted within Southern Adelaide Local Health Network (SALHN) must designate an individual, qualified by training and experience, to serve as the Principal Investigator (PI). The PI must have sufficient authority, relevant scientific knowledge, and the requisite training to personally carry out or supervise all aspects of the project. This individual is responsible and accountable to SALHN for all aspects of the study protocol.

In cases where a PI is neither accredited by/credentialed through SALHN, nor a SALHN employee, an appropriate Co-PI (Clinical) shall be assigned to take clinical responsibility for the research study.

I, Tamme Golding-Holbrook, have read the above information, and I agree to take clinical responsibility for the following study:

Study Title:	Quantifying the Potential Corneal Tissue Surplus Level within Australia		
HREC Reference:	AU/12/2AE7319		
OFR Reference:	238.18		
Co-PI (Science)	Tamme Golding-Holbrook		
Position Held & Name of Institution	Medical Scientist – Acting Eye Bank Manager. Eye Bank of South Australia, Flinders Medical Centre.		
Signature:		Date:	10.9.18.
Name of Witness:	Rosemary Belbin		
Position Held & Name of Institution:	Medical Scientist - Eye Bank Co-ordinator, Eye Bank of SA, Flinders Medical Centre		
Signature of Witness:		Date:	13.9.18

This Agreement should be signed as acceptance of the conditions outlined above and returned to:

Research Governance Officer (SALHN)
Office for Research
Southern Adelaide Local Health Network
Flinders Medical Centre, Flinders Drive,
BEDFORD PARK SA 5042

E: Health.SALHNOfficeforResearch@sa.gov.au

A copy of this Agreement should be retained by both Co-Principal Investigators.

Submission Code Date: 16/07/2018
13:14:54

HREC Reference: AU/1/30A6314

Created with AU
Online Forms

23. Declarations

Please ensure all declarations relevant to this proposal are completed and signed by the relevant authorising officer/s.

a) Declaration by the Department Head / Directorate Head / Divisional Director at the site where the project will be conducted.

- I certify that I have read the research project application associated with this SSA.
- I certify that I have discussed this research project and the resource implications for this Department / Directorate / Division, with the Principal Investigator.
- I certify that all researchers/students from my Department / Directorate / Division involved in the research project have the skills, training and experience necessary to undertake their role.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
- My signature indicates that I support this research project being carried out using such resources.

Name: A/Prof Richard Mills

Position / Title:

Department:

Signature:

Date:

Submission Code Date: 16/07/2018
13:14:54

HREC Reference: AU/1/30A6314

Created with AU
Online Forms

b) Supporting Department / Directorate / Divisional Head

- I certify that I have read the research project application associated with this SSA.
- I certify that I have discussed this research project and the resource implications for this Department / Directorate / Division, with the Principal Investigator.
- I certify that all researchers/students from my Department / Directorate / Division involved in the research project have the skills, training and experience necessary to undertake their role.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
- My signature indicates that I support this research project being carried out using such resources.

Name: A/Prof Richard Mills

Position / Title: Medical Director

Department:

Signature:

Date:

Submission Code Date: 16/07/2018
13:14:54

HREC Reference: AUP130A6314

Created with AU
Online Forms

c) Declaration by data custodian/s responsible for managing data access for the databases that will be accessed by the Principal Investigator/Site Coordinator for the purposes of undertaking this project.

- I certify that the Principal Investigator / Site Coordinator responsible for this research proposal has submitted their protocol to my Office, and provisional approval has been granted for them to access the data required.

Name: Tamme Golding-Holbrook

Position / Title: Acting Eye Bank Manager

Organisation:

Signature:

Date:

Submission Code Date: 16/07/2018
13:14:54

HREC Reference: AU/1/30A8314

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d) Declaration by Head of Pharmacy at the Site that agreement has been made to dispense the drugs/pharmaceuticals required to undertake this study.

- I certify that the Principal Investigator / Site Coordinator responsible for this research proposal has provided me with a copy of the research protocol, and I have agreed on the basis of satisfactory HREC approval that this Department will dispense the drugs/pharmaceuticals required to undertake this study.

Name: not applicable

Position / Title:

Signature:

Date:

Submission Code Date: 16/07/2018
13:14:54

HREC Reference: AU/1/30A6314

Created with AU
Online Forms

e) Declaration by Site Coordinator/Principal Investigator

1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC).
3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC *National Statement on Ethical Conduct in Research*.
4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
5. I undertake to conduct this research in accordance with relevant legislation and regulations.
6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC.
7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
8. I will inform the HREC and the Research Governance Officer if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
9. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.
10. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, Research Governance Officer, the sponsor or an independent body for audit and monitoring purposes.
11. I understand that information relating to this research, and about me as a researcher, will be held by the HREC, Research Governance Officer and on the Research Ethics Database (RED). This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

Name of Principal Investigator:
Prof Paul Baird

Date:

15/8/18

Name of Site Coordinator:
Tamme Golding-Holbrook

Date:



Executed as an agreement on

2018

Signed for and on behalf of Centre for Eye Research Australia Ltd (ABN 72 076 481 984) by its duly authorised representative in the presence of:

Signature of witness

Signature of authorised representative
By executing this agreement the representative states that he/she has received no notice that his/her authority to do so has been revoked.

Name of witness (please print)

Name of authorised representative (please print)

Signature of witness

Signature of authorised representative
By executing this agreement the representative states that he/she has received no notice that his/her authority to do so has been revoked.

Name of witness (please print)

Adjunct Professor Susan O'Neill
Chief Executive Officer
Southern Adelaide Local Health Network (SALHN)
Name of authorised representative (please print)

I (insert name of Provider's Principal Investigator) have read and understood the contents of this Agreement.

Signature of Provider's Principal Investigator

I (insert name of Recipient's Principal Investigator) have read and understood the contents of this Agreement.

Signature of Recipient's Principal Investigator

Final Report / Closeout Form

This final report / site closure form is designed to give researchers the approved mechanism to provide the appropriate notification to the SALHN Office for Research upon the completion of a research project.

Please refer to the [National Statement on Ethical Conduct in Human Research](#), Sections 5.5 (covering all research) and 3.3.19 (for clinical research) for advice on the monitoring and reporting of approved research.

Instructions:

This report is required on completion or close out of the study. Researchers are required to electronically complete and submit this form to the SALHN Office for Research.

Please consider this report acknowledged by the Office for Research on receipt of the automated email response. The Office for Research will only be in contact if further information is required.

Email completed form to: Health.SALHNOfficeforResearch@sa.gov.au

Date: 05 June 2020
Office for Research application number: 238.18
Title: Quantify the potential corneal tissue surplus levels within Australia
Coordinating Principal Investigator: Golding-Holbrook Tamme
Approval expiry: Does your project still have SAC HREC approval? ☒ Yes - when does your SAC HREC approval expire? Click here to enter text. ☐ No - when did your SAC HREC approval expire? Click here to enter text.

Site details

Site name	Principal investigator	Number of participants recruited	Completion/close out date	Completed/closed out
Eye Bank of South Australia (EBSA)	Golding-Holbrook, Tamme	n/a	Closed. October 2019	☒ Completed ☒ Closed out

Please provide a summary of the research outcomes

EBSA collated 12 months of data as planned. The data tracked the recovered and non-recovered corneal donations, that occurred in conjunction with this eye bank, explaining why

a donation may or may not be recovered. The data, as per the agreement was provided to the national coordinator of this project (Machin H) who is currently collating the South Australia data with other states as part of a wider national project. The EBSA Team Members (Golding-Holbrook T and Weinel L) remain as national collaborators working to analyses the national data. It is anticipated the national paper will be submitted for publication in 2020.

How much funding was received for this research? Nil

Data retention and storage.

Data should be retained to allow for sufficient time to allow reference to them by other researchers and interested parties.

Public health institutions fall under general disposal schedule 28. As per item 6 of general disposal schedule 28, the researchers records of research including results, notes, completed questionnaires, signed consent forms, data, reports, and study findings must be kept for 15 years after the research project has been completed before being destroyed. This includes all types of research.

Universities fall under general disposal schedule 24. As per section 9 of general disposal schedule 24 research data records should be kept for a duration according to the nature of the study. For short term research projects such as study research projects, data should be kept for 1 year after last action. Research data from clinical trials should be kept for 15 years after action completed. All other research data and results should be kept for 5 years after publication, conclusion, or abandonment of the project. Data should be destroyed after the mandatory retention period.

- ☐ The data will be kept for 15 years
☒ The data will be kept for 5 years

Where will the data be stored? Locally at SAEB, and nationally at CERA as indicated in the plan and the data transfer agreement.

How will the data be kept secure? Password protected server in both locations.

Please provide a list of all publications to date, including any pending publications, conference presentations, posters etc. Please provide copies if available, if not, please email through when they are.

Nil. We are anticipating submitting for publication later this year.

Has the project been conducted according to approved protocol, including the reporting of SAE's, amendments, safety reports, protocol violations etc?

- ☒ Yes
☐ No (If no, provide comments) Click here to enter text.

Declaration

I confirm the information provided in this form is true and correct.

Chief / Principal Investigator: Click here to enter text.

Date: Click here to enter text.

Signature:



For more information

SALHN Office for Research

Ward C / Room 6A – 219

Flinders Medical Centre

Telephone: (08) 8204 6453

Email: Health.SALHNofficeforresearch@sa.gov.au

www. [www. www.sahealth.sa.gov.au/SALHNresearch](http://www.sahealth.sa.gov.au/SALHNresearch)

If you do not speak English, request an interpreter from SA Health and the department will make every effort to provide you with an interpreter in your language.

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Office for Research Final report and closeout form v1

Created: 01.12.2016

Updated 22.03.18

Updated 10.10.18

Updated 02.05.2019

ETH 09: Chapter 2 - Agreement and governance *Queensland Tissue Bank*

Metro South Health

Enquiries to: Metro South Research Governance
 Phone: (07) 3443 8050
 E-mail: MSH-RGO@health.qld.gov.au

Prof Paul Baird
 Centre for Eye Research Australia – University Of Melbourne
 Ophthalmology
 L7, PHW, 32 Gisborne Street
 East Melbourne VIC 3002

SSA AUTHORISATION: METRO SOUTH HOSPITAL AND HEALTH SERVICE

HREC Reference number: HREC/18/POWH/292

SSA reference number: SSA/18/QMS/55218 **44213**.

Project Title: Quantifying the potential corneal tissue surplus level in Australia

Dear Prof Paul Baird,

Thank you for submitting your application for authorisation of this project. On the recommendation of Metro South Research Governance Office, I am pleased to inform you that authorisation is granted for your research project to proceed at Queensland Bone & Tissue Bank, Princess Alexandra Hospital.

This approval is subject to researcher(s) compliance throughout the duration of the research with requirements as outlined in the National Statement on Ethical Conduct in Human Research 2007, Australian Code for the Responsible Conduct of Research and the [Metro South Research Management Policy and Procedures](#). The duration of this study approval is up until expiration of the reviewing HREC's approval.

Site Specific Document/s Authorised	Version	Date
Data Transfer Agreement Centre for Eye Research Australia Ltd		
Supporting Document/s Acknowledged		
Site Specific Assessment		

The following conditions apply to this research proposal. These are additional to those conditions imposed by the approving HREC.

- PowerTrials:** Please review the *Research Management – PowerTrials 2017-18 procedure to confirm if build is required*. If you require support please contact MSH-Powertrials@health.qld.gov.au.
- Lapsed Approval:** If the study has not commenced within twelve months of approval, resubmission of the study to the approving HREC and RGO is necessary.
- Proposed amendments:** Amendments that may have a bearing on site specific documentation, financial arrangements or have legal implications (e.g. amendments to contracts) must be submitted to the Governance Office along with a copy of the HREC approval letter.
- Safety Monitoring:** All safety reporting should follow the requirements as set out in the [NHMRC Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods](#).
- Annual Reporting:** A copy of the annual report (due on the anniversary of HREC approval) and final report must be supplied to the governance office along with a copy of the HREC acknowledgement.

We wish you every success in undertaking this research.

Yours sincerely,

Prof Tim Geraghty, Acting Chair Centres for Health Research
 METRO SOUTH HEALTH

8/07/18

c.c. Heather Machin Centre for Eye Research Australia & Victoria Whiting Queensland Eye Bank

Office
 Centres for Health Research
 Metro South Health

Postal
 37 Kent Street
 Woolloongabba Qld 4102

Phone
 61 7 3443 8050


Research Contracts Approval and Study Execution Form (Metro South Application Submission & Amendment Form)
PART C - FOR COMPLETION BY METRO SOUTH RESEARCH GOVERNANCE OFFICE
Name of Contracted Party: Eye Research Australia

ABN: 72 076 481 984

Type of contract: Data Transfer Agreement

Contract Total Value: \$ in Kind

HREC/SSA Ref : HREC/18/POWH/292 - SSA/18/QMS/55043 (Paul Baird/Heather Machin)

Contract Start Date: 10/9/18

Extension Options
☒ Yes

Contract End Date: 1/1/2100

☐ No

Does this contract indicate Metro South is providing a service (Sell) or is another institution providing Metro South with a service (Buy)?
☐ Revenue (sell)

☒ Expense (buy)

Compliance with MSH Financial Delegations Framework (Contract) – see section B of General Contracts Form (Under the SBFA Act, a guarantee or indemnity can only be granted in limited circumstances)
Does MSH provide indemnity, guarantee in any form to the contracting party under the contract? ☐ Yes ☒ No

If yes, complete the Indemnity Register Entry Form. Must be approved by the relevant Financial Delegate (refer to the Financial Delegations Framework, Indemnity Procedure and Indemnity Guidance Note)
Legal Advice Sought
Internal/External legal advice received and contract terms/conditions accepted? ☐ Yes ☐ No ☒ Not Applicable
Based on Contract Management Framework thresholds
Comments:
Indemnity Delegate Signature (if applicable)
Please refer to Financial Delegations Manual for confirmation of appropriate delegate.
Name:
Position:
Signature:
Date:
Metro South Research Governance Office – Recommendation for Authorisation
Name: Sonia Hancock

Position: Compliance Manager

This proposal satisfies Metro South Health Research Governance requirements and is endorsed for consideration and final authorisation. Select checkbox applicable:
☐ No contract required or ☒ Research contract is required.

☐ This study requires the granting of an indemnity and the Indemnity Register Entry form has been completed:

Signature
Date: 6/9/18

Metro South Health CE/ Delegate
Name: Prof Tim Geraghty

Position: A/Chair, CHR

My signature indicates that I authorise this research study to commence at the nominated Metro South site/s on the condition the study will be conducted as per [Metro South Research Management Policy PL2017-55](#).
Signed
Date: 29/7/18

Comments:

New Study Queensland Eye Bank

Documents For CE/ Delegate Signature (as tagged)

 Metro South Research Governance Authorisation Letter x1 ☒

 Research Agreement ☒

 Medicine Australia Standard Indemnity ☐

 Research Agreement Variation ☒

 Confidentiality Agreement ☐

Other:

Other documents

Documentation to be given to Participants

If there are any other documents to be given to participants at this site, which have not already been uploaded (eg patient diary, wallet card), please upload here.

Advertisements and Flyers

Please upload any HREC Approved Advertisements and/or Flyers if site specific changes have been made.

Other HREC Approved study related documents, requiring site specific amendments which have not been uploaded elsewhere in this form.

Please upload here.

Head of Department signature page

Declaration by delegated Department Head/s at the site where the Principal Investigator/Site Coordinator will conduct the research for the purpose of resourcing the research project.

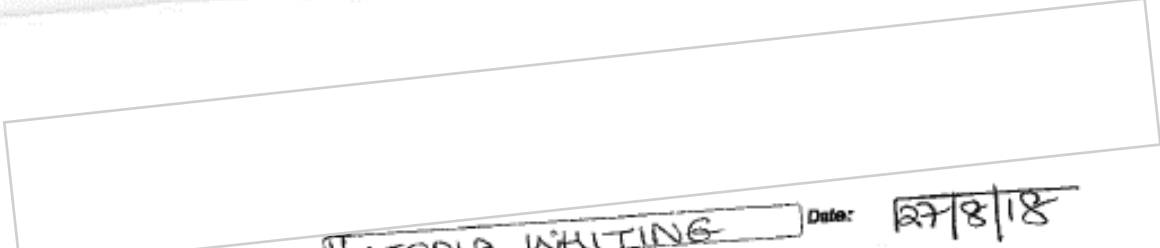
- I certify that I have read the project details in this SSA for the research project application named above.
- I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for 'Actual costs' and 'in kind' contribution.
- My signature indicates that I support this research project being carried out using such resources.

Dr Jane Olsson
Acting Director

Signature

✓ Queensland Justice Bank.

PI Signature page



Name of Assoc Investigator: VICTORIA WHITING Date: 27/8/18

Upload scanned copy of wet ink signature page here:

28 August 2018
Toll-free 1800 000 000
Project 1800 000 000
Project 1800 000 000

Page 16 of 16

Other documents

Documentation to be given to Participants

If there are any other documents to be given to participants at this site, which have not already been uploaded (eg patient diary, wallet card), please upload here.

Advertisements and Flyers

Please upload any HREC Approved Advertisements and/or Flyers if site specific changes have been made.

Other HREC Approved study related documents, requiring site specific amendments which have not been uploaded elsewhere in this form.

Please upload here.

Head of Department signature page

Declaration by delegated Department Head/s at the site where the Principal Investigator/Site Coordinator will conduct the research for the purpose of resourcing the research project.

- I certify that I have read the project details in this SSA for the research project application named above.
- I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for 'Actual costs' and 'In kind' contribution.
- My signature indicates that I support this research project being carried out using such resources.

Dr Jane Olsson
Acting Director

Signature

Name of Department

✓ Queensland Justice Bank.

PI Signature page



Executed as an agreement on

2018

Signed for and on behalf of Centre for Eye
Research Australia Ltd (ABN 72 076 481 964) by
its duly authorised representative in the presence of:

ROSENA LIMETA
Name of witness (please print)

HELEN BRANAGHY, LEGAL COUNSEL
Name of authorised representative (please
print)
4th Sept 18

Signed for and on behalf of Queensland Eye Bank
and Tissue Bank (ABN) by its duly authorised
representative in the presence of:

Lauren Watts
Name of witness (please print)

Professor Timothy Geraghty
Chair
Name of authorised representative (please
print)
Centre for Health Research

I Paul Carr (Insert name of Provider's Principal
Investigator) have read and understood the contents of this Agreement.

I (Insert name of Recipient's Principal
Investigator) have read and understood the contents of this Agreement.

Signature of Recipient's Principal Investigator

ETH 10: Chapter 2 - Agreement and governance *Lions Eye Bank of Western Australia*



2 Verdun Street, Nedlands WA 6009
t (08) 9381 0777
f (08) 9381 0700
e enquiry@lei.org.au
www.lei.org.au

Professor Paul Baird
Centre for Eye Research Australia
Level 7, 32 Gisborne Street
EAST MELBOURNE VIC 3022

27 August 2018

RE: request to conduct an e-data transfer project with Lions Eye Bank of Western Australia regarding corneal tissue surplus levels within Australia.

Dear Prof. Baird

I am pleased to advise that we approve your request to partner with the *Lions Eye Bank of Western Australia*, on the nationally approved project – HREC 18/139 (HREC/18/POWH/292), Title: Quantify the potential corneal tissue surplus levels within Australia.

This approval is subject to the following:

1. Provision of an annual up-date report.
2. Provision of a final report at the completion of the project.

I ask that you liaise, from here on, with Ms Lisa Buckland – Manager of the *Lions Eye Bank of Western Australia*.

We wish you every success in your research.

Yours Sincerely

Chris Whitelock
Chief Operating Officer
Lions Eye Institute

Our mission is to achieve excellence in scientific research and clinical practice to prevent blindness.

Affiliated with The University of Western Australia, Sir Charles Gairdner Hospital, Royal Perth Hospital and Fremantle Hospital. ABN 48 106 521 439.



Executed as an agreement on

25 May 2018

2018

Signed for and on behalf of **Centre for Eye Research Australia Ltd** (ABN 72 076 481 984) by its duly authorised representative in the presence of:

Carly Parfett

Name of witness (please print)

HELEN ORMONDY PAD

Name of authorised representative (please print)

Signed for and on behalf of **Lions Eye Bank of Western Australia** (ABN 48 106 521 439) by its duly authorised representative in the presence of:

he/she has received no notice that his/her authority to do so has been revoked.

Lisa Buckland

Name of witness (please print)

Chris Whitelock

Name of authorised representative (please print)

I PAUL BARR (insert name of Recipient's Principal Investigator) have read and understood the contents of this Agreement.

05: PERMISSIONS

PER 01: Chapter 1 - EBAANZ Executive

From: Graeme Pollock <graemeap@unimelb.edu.au>
Sent: Friday, 30 August 2019 11:43 PM
To: Heather Machin <heather.machin@unimelb.edu.au>
Cc: Lisa Buckland <LisaBuckland@lei.org.au>; Adrienne Mackey <amackey@unimelb.edu.au>; Natalie Duncalf <NatalieDuncalf@lei.org.au>
Subject: Re: ebaanz data for my PhD

Ok by me too.
Graeme

Sent from my iPhone

On 29 Aug 2019, at 23:33, Heather Machin <heather.machin@unimelb.edu.au> wrote:

Thanks Lisa and Adrienne
I will keep you posted on the submission etc. on wards and up from here.
Thank you
heather

From: Lisa Buckland <LisaBuckland@lei.org.au>
Sent: Friday, 30 August 2019 12:59 PM
To: Adrienne Mackey <amackey@unimelb.edu.au>; Heather Machin <heather.machin@unimelb.edu.au>; Graeme Pollock <graemeap@unimelb.edu.au>
Cc: Natalie Duncalf <NatalieDuncalf@lei.org.au>
Subject: RE: ebaanz data for my PhD

Supported and approved by WA.

Lisa

Lisa Buckland
Manager

<image001.png>

2 Verdun Street, Nedlands WA 6009

t 08 9381 0793

m 0422 960 292

www.facebook.com/lionseyebankWA/

www.lei.org.au/services/lions-eye-bank/

<image002.jpg> <image003.jpg>

<image004.png>

From: Adrienne Mackey [<mailto:amackey@unimelb.edu.au>]
Sent: Friday, 30 August 2019 10:34 AM
To: Heather Machin; Lisa Buckland; Graeme Pollock
Cc: Natalie Duncalf
Subject: RE: ebaanz data for my PhD

Fine by me.

From: Heather Machin <heather.machin@unimelb.edu.au>

Sent: Friday, 30 August 2019 12:23 PM

To: Adrienne Mackey <amackey@unimelb.edu.au>; Lisa Buckland <LisaBuckland@lei.org.au>;

Graeme Pollock <graemeap@unimelb.edu.au>

Cc: Natalie Duncalf <NatalieDuncalf@lei.org.au>

Subject: ~~ebaanz~~ data for my PhD

Dear All

I know you are already supporting me and allowing me to share EBAANZ data in my PhD but I just wanted to make sure that you are happy to permit me to display the below in my eye bank history paper. This will go in to the International Journal of Eye Banking. The Editor is already aware and waiting for my submission.

~~Ex:~~

- I'm only doing the last 5 years in this paper as it's when we started tracking transnational stuff in full, before that has gaps on that so this makes it nice and neat.
- I spoke to Louise and she is happy with me including the NZ data. I will not be explaining why that amount went to NZ, as NZ is not part of my story. I will just state that we sent them tissue through a Sharing arrangement and that if we need, we could import for emergencies.
- For the outside of ANZ stuff, I will just simply say that we sent to Myanmar and New Caledonia. It will not outline who (which bank) sent them and will not give a break down. Simply that 63 went out in the past 5 years under humanitarian efforts from Australian eye banks on an ad-hoc. basis.
- I won't be doing a bank data break down or anything like that. This paper is just intended as an intro as my scene setting paper to my thesis.

Table 1:

	2014	2015	2016	2017	2018	Total
Donors	1139	1415	1272	1361	1387	6574
Corneal Transplants	1894	2124	2074	2155	2231	10478
Exported CT to NZ	7	2	6	37	42	94
Imported CT from NZ	0	0	0	0	0	0
Exported CT outside of ANZ	22	0	15	17	9	63

Table 1: Donor and corneal tissue recovery and allocation rates within Australia, including transnational allocation through a formal arrangement with New Zealand (a Trans-Tasman Agreement) and ad-hoc. humanitarian purposes outside of Australian and New Zealand (ANZ) Region. (EBAANZ internal data recording from 2014 – 2018).

I will reference this as:

- Eye Bank Association of Australia and New Zealand. 2014-2018 Annual Statistics.

Data published with permission from EBAANZ.

Thank you

Heather

PER 02: Chapter 2 – Lions Eye Donation Service

From: Heather Machin
Sent: Thursday, 26 April 2018 11:36 AM
To: Graeme Pollock <graemeap@unimelb.edu.au>
Subject: RE: LEDS - involvement with Data Transfer for Heather Machin's PhD Project - Aim 2.
Thank you Graeme.
Yes. We are aware of the limitations on the green and blue areas by some banks.
Thank you
Heather

From: Graeme Pollock
Sent: Thursday, 26 April 2018 11:34 AM
To: Heather Machin <heather.machin@unimelb.edu.au>
Subject: Re: LEDS - involvement with Data Transfer for Heather Machin's PhD Project - Aim 2.
Yes.
However you must appreciate that a lot of the data (especially in the green and blue areas) will be incomplete and likely to be misleading as we don't really have a "denominator" for a lot of these fields.

From: Heather Machin <heather.machin@unimelb.edu.au>
Date: Thursday, 26 April 2018 at 11:30 am
To: Graeme Pollock <graemeap@unimelb.edu.au>
Subject: LEDS - involvement with Data Transfer for Heather Machin's PhD Project - Aim 2.
Dear Graeme
While CERA is automatically involved in my PhD data collection project, for record-keeping reasons (as we do not need to have a formal contract) would you mind emailing me back to confirm that Lions Eye Donation Service will be involved in the data transfer project. This will involve the completion of the attached template – monthly. It is to be sent to my email address. I will house the collated data on this projects drive, located on the OCU network. This will only be accessible to Paul Baird and I.
We will be commencing the data collection, most likely, in the quarter 3 of this year, once all other participating Eye Bank Partnerships are formalised.
We intend to keep you abreast of the data collection outcomes as we go.
CERA – and LEDS will be acknowledged in any publications and presentations.
Thank you
Heather Machin



PER 03: Chapter 5 – DonateLife

From: McDonald, Mark <Mark.McDonald@donatelife.gov.au>
Sent: Wednesday, 29 July 2020 12:39 PM
To: Heather Machin <heather.machin@unimelb.edu.au>
Subject: Registration research

Hi Heather, as discussed I am happy to have the information I have provided on organ donation registration published in your research and have this content acknowledged.

Well done on putting it together

Cheers,

Mark

Mark McDonald
Director, Analytics and Technology
Organ and Tissue Authority
Telephone +61261989886 | Mobile +61466512142
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www.donatelife.gov.au
<http://www.facebook.com/DonateLifeAustralia>



PER 04: Co-author/collaborator permission list

The signed permission forms from the co-authors of published material presented in this thesis, has been submitted to the University of Melbourne as part of the thesis submission process. Co-authors are listed below, alphabetically and with the relevant sub-chapter code indicating their placement within the thesis.

Janan Arslan: 1.2

Karl Brown: 1.6

Paul N Baird: 1.2, 1.3, 1.4, 1.5, 1.6, 2.2, 3.2, 3.3, 3.4, 3.5, 3.6, 4.1, 4.2

Lisa Buckland: 2.2, 4.1, 4.2

Pierre Georges: 2.2

Mona Ghabcha: 2.2

Tamme Golding-Holbrook: 2.2

Candice Leighton: 2.2

Adrienne Mackey: 2.2

Brian Philipppy: 1.5, 1.6

Collin Ross: 1.5, 1.6

Gerard Sutton: 1.3, 1.4, 1.5, 1.6, 2.2, 3.2, 3.3, 3.4, 3.5, 3.6, 4.1, 4.2

Luke Weinel: 2.2

Victoria Whiting: 2. 2

Steve Wiffen: 4.1, 4.2

Of note, co-author Professor Christine Critchley, who was involved in sub-chapters 4.1 and 4.2 passed away before the completion of this thesis. Therefore, there is no formal permission form signed by Prof. Critchley. I followed the University of Melbourne policy regarding acknowledgement of Prof. Critchley involvement in this thesis.