

Sector Opinion, on How Corneal Tissue Should Be Exported, and to Whom – Using the Example of Australia as an Export Nation

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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.

Key Words: Transnational activity, export, import, corneal tissue, Australia

Globaly, an estimated 12.7 million people await a corneal transplant.¹ 53% 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 adhoc. 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,

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e.g. scaled-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.

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 EBRs, 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.

RESULTS

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-Resource Exporting EBR 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-Resource Exporting EBR, 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 unload 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 didn't (or shouldn't) 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 resource 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-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.

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 1, which are accompanied by selected commentary from the interviewees.

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 adhoc. 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 medi-tourists). 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. Though 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

Table 1: 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.

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>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 (GAEBEA)	
	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</i>

		<i>misinterpretation. And then people are going to get the wrong idea. And then there will be issues moving forward. (High-Resource, importing MD)</i>		Partner, support, leverage from existing not-for-profit eye care organisations, professional societies and Australian aid programs	
	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>		Encourage a person (patient-recipient) centric approach, e.g. informed and/or consented to use imported CT	
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>	7. Plan carefully	Economics: examine socialised pricing, gratis, full fee, or funding for capacity development aspects)	<i>If you run a program in deficit, you'll be out of business in no time, so think about the economics. (High-Resource Exporting EBER)</i>
	Design the system as a non-profit and non-commercial activity			Prevent jeopardising Australia's domestic system	
	Align with Australian principles and ethical guiding documents (e.g. EBBANZ, TBP, NHMRC, WHO)			Develop non-profit and non-commercial system	
	Implement a formal national export position statement for Australia			Establish stakeholder relations	
	Seek federal funding to support a national approach			Coordinate with guidance soft tools	
	Ensure agreement between import and export Departments of Health			Prepare a risk management strategy, e.g. to prevent issues during consent, allocation, transfer or use, or public backlash and future donation consent withdrawal if not presented and planned appropriately	
	Ensure agreement between import and export Departments of Foreign Affairs			Continue to examine the subject from various perspectives, e.g. other human biological transnational providers	
	Develop core criteria to guide import destination selection			Confirm the practicality of how a national process will function alongside the domestic system	
	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 adhoc. provision or to surgeons to take overseas)	<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>	8. Implement processes and systems	Track, monitor and audit the process (not just the clinical outcomes), e.g., efficiency and efficacy and Stewardship	<i>EBAANZ ... needs to be seen as an independent player in this process ... but it's important they are part of that coordinating process. (Australian EBER)</i>	
Determine costs fairly, for import and export partners, but not to the detriment of Australians or the EBs			Regulate/report to the national body and Australian Government		
Collect and report statistical data and outcomes (consider inclusion in the Australian Corneal Graft Registry)			Develop export policies and work instructions, based on ethical principles, minimum standards and a quality ethos		
Exported CT are selected and allocated within the same regulatory and quality approach as provided to Australian recipients and surgeons			Factor in logistics and transfer times, e.g. freight process, export license needs etc.		
Receiving country to meet core criteria			Plan for additional recovery and allocation, e.g. EB manpower and consumables supply		
Receiving surgeons/hospitals registered in the national body			Plan for direct transfer from the Australian EB to the import EB or transplant centre, or engage third parties if deemed appropriate and safe.		
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					
Exportation used as short-term solution for import nation			<i>Be very careful because the sector is moving into for-profit. (High-Resource Importing Other)</i>		
Australia must support the importer to achieve best possible domestic human eye tissue and transplant services	<i>Someone ultimately take legal responsibility for distribution. (Australian Other)</i>			<i>Don't use middlemen ... don't create a situation where you're not dealing directly with your recipient, medical, medical staff. (High-Resource, Importing EBER)</i>	
Allocate within a humanitarian principles-based approach					
Break down silos, and historic power differentials between nations					
Support training in the import nation (e.g. eye bankers, donation coordinators/councillors, physicians, nurses, managers and so on)	<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>				
	<i>Teach them how to fish. (High-Resource Importing MD)</i>				
	<i>Maintain self-sufficiency so we don't become dominated by one huge bank in the USA, one huge bank in Australia that flood the market because they can, at the lowest price and I think that we, we do need to be self-sufficient. (High-Resource Importing MD)</i>				

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.

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 adhoc. 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 there 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 un-governed 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 hoarding, 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.

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 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.

Secondly, we reviewed recommendations based on the *World Health Organisation'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). 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 (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

Table 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.

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	75	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 /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: This matrix demonstrates how the ten most frequently recommended nations (ranked as 1 to 5 alphabetically), meet the interviewees own recommendations, based on a 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

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

does not undermine their current system and own development. Therefore, the specific named nations, recommendations 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.

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 indicates 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 efforts.

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 are unfamiliar with, and ensuring Australian donations are 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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