Part Two: Defining Surplus and Waste in the Pre- and Post-COVID-19 Era Via Australian and USA Examples

Heather M Machin RN, MBA,[1] Brian Philippy BCHE, CEBT,[2] Collin Ross CEBT,[3] Gerard Sutton MD,[4] Paul Baird PhD[5]

ABSTRACT

Abstract: 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 2 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.

Key Words: corneal tissue, need, demand, surplus, waste, supply lines

The 2020 COVID-19 pandemic resulted in a temporary global reduction in Corneal Tissue (CT) demand for corneal transplantation. Consequently, eye banks (EB) 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 to prepare EB that find themselves in the uncharted territory of surplus and waste.

In Part 1 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.

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.

Author Affiliation: [1]Project Officer, Lions Eye Donation Service, Centre for Eye Research Australia, Royal Victorian Eye and Ear Hospital, University of Melbourne, Australia. [2]Director of Transplant and Research, Lions Medical Eye Bank & Research Center of Eastern Virginia, Norfolk VA. [3]Vice President, Global Development, Eversight, Ann Arbor MI. [4] Professor of Ophthalmology, The University of Sydney, Save Sight Institute, New South Wales, Australia, and The University of Technology Sydne. [5]Professor. NHMRC Senior Research Fellow, University of Melbourne, Melbourne Australia

Acknowledgment: The authors thank Marisa Herson (AU) for guiding the supply and demand conversation, which led to the creation of this perspective series. .

 ISSN 2161-5546

USA Example

Pre-COVID-19, USA Eye Banks (USAEB) 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, USAEB contributed CT to 28,402 recipients in 113 nations.[6] This represented 33.1% of the 85,601 USAEB-sourced CT transplants in 2019. USAEB 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, their 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 USAEB recovered more donations to meet that demand, resulting in surplus CT to USA domestic demand. USAEB 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 international surgical services, and vice versa. Though, notably, the American 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, USAEB like many EB around the world, had no mechanism to quickly determine when and how to slow donation rates as the virus spread. The change in the demand cycle occurred in a matter of weeks. International CT outlets began to cease 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 USAEB experienced a decrease in CT services,[8] resulting in their closure or reduced hours, others 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 USAEB, in the short-term, they have entered a surplus and waste phase.

Australia Example

Pre-COVID-19, it was already proposed that Australian Eye Banks (AUEB) 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 contrast to USAEB, AUEB 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 AUEB alter their recovery criteria to meet fluctuations in booked CT requests. Therefore, AUEB do not recover CT additional to known demand. They routinely decline donations by altering the criteria. 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 USAEB, AUEB 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.

SURPLUS

As some EB 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 EB 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 EB must accept and recover

 ISSN 2161-5546

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 EB 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.

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.

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 value[12] 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 Principles[15] 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.

WASTE

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, EBs 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 shunts).

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 In this scenario, uncollected donations are either not counted in the wider donor pool, or conversely, a source of potential collection.

 ISSN 2161-5546

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.

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 EB 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 trump environmental efforts in the short term.

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. EB 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, and provide 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.

 ISSN 2161-5546

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 EB 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, EB 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 EB at the national level define the terms within the context of their EB 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. Information used 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 model); or
   b. Routinely recovered and then allocated (USAEB model)
4. If/how it can be retained for domestic training and research, and/or exported
5. 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. Finally, other aspects (e.g., allocating surplus transplant eligible CT to research rather than exporting,[16] and the environmental impact of EB) would benefit from further examination within future CT management discussions.

REFERENCES

1 Machin HM, Philippy B, Ross C, Sutton G, Baird PN. Part 1: Understanding the impact of COVID-19 on corneal transplant need and demand through the example of Australia. Under review by *Int J Eye Bank*.

2 Noël L, Martin D. Progress towards national self-sufficiency in organ transplants. Bull of WHO. 2009;87:647

3 World Health Organization. WHO guiding principles on human cell, tissue and organ transplantation. *Transplantation*. 2010;90:229–233.

4 Gain P, Jullienne R, He Z et al. Global survey of corneal transplantation and eye banking. *JAMA Ophthalmol*. 2016;134:167-73.

5 King JH. International eye-bank and American ophthalmology. *Am J Ophthalmol*. 1964;5.

6 Eye Bank Association of America. 2019 Eye Bank Statistical Report. 14 April 2020.

7 Association for Research in Vision and Ophthalmology. EyeFind Portal. Available at: https://www.arvo.org/journals-and-publications/eyefind-search/ Accessed 22 April 2020.

8 Corcoran K. April Insight: COVID-19 Research Grant Opportunity, 2019 Stat Report Released. Eye Bank Association of America, member up-date email received by Machin H. 17 April 2020.

9 Miracles in Sight. Blog: MIS using 3D printing to help shield health care workers. April 10 2020. Available at: https://www.miraclesinsight.org/mis-using-3d-printing-to-help-shield-health-care-workers/ Accessed: 22 April 2020

10 Machin HM. Documenting the evolution of contemporary eye bank and corneal tissue services in Australia. *Int J Eye Bank*. 2019;2:7.

11 Doughman DJ, Rogers CC. Eye banking in the 21st century: how far have we come? Are we prepared for what's ahead? *Int J Eye Bank*. 1(1) 2012 1 – 15

12 Waldby C, Mitchell R. Tissue economies: blood, organs, and cell lines in late capitalism. Duke University Press. London. 2006.

13 Córdoba A, Fernando Mejía L, Mannis MJ et al. Current global bioethical dilemmas in corneal transplantation. *Cornea*: 2020;39:4. 529-533.

14 Position Statement: Commodification and Profitization of human materials and ocular services. Global Alliance of Eye Bank Associations. 2017. Available at: http://www.gaeba.org/publications/ Accessed 15 April 2020.

15 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.

16 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, Vol.9, 4. doi:https://doi.org/10.1167/tvst.9.5.4

17 Frow J. Time and commodity culture: essays in cultural theory and postmodernity. 1997. Clarendon Press. London.

18 Healthy hospitals, healthy planet, healthy people: Addressing climate change in healthcare settings. World Health Organization. 2009. https://www.who.int/globalchange/publications/climatefootprint_report.pdf?ua=1 Accessed 15 April 2020.

 ISSN 2161-5546