

Part One:

Understanding the Impact of COVID-19 on Corneal Transplant Need and Demand through the Example of Australia

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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.

Key Words: corneal tissue, need, demand, want, allocation, wait lists.

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, waitlists 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 EB, 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.

DEFINING TERMS

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

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the availability and ability of an object or action to satisfy or reduce *perceived* need.

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.

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.

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.

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.

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 (AUEB) 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.

Wait List

Recipients who are scheduled for surgery are placed on individual AUEB CT wait lists for their jurisdiction. The

list provides 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 AUEB 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 AUEB 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?

Fluctuations in Demand

While AUEB 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,

AUEB 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 AUEB from knowingly (or unknowingly) underserving (or overserving) their jurisdiction at any given time.

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.

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.

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 (Diagram 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

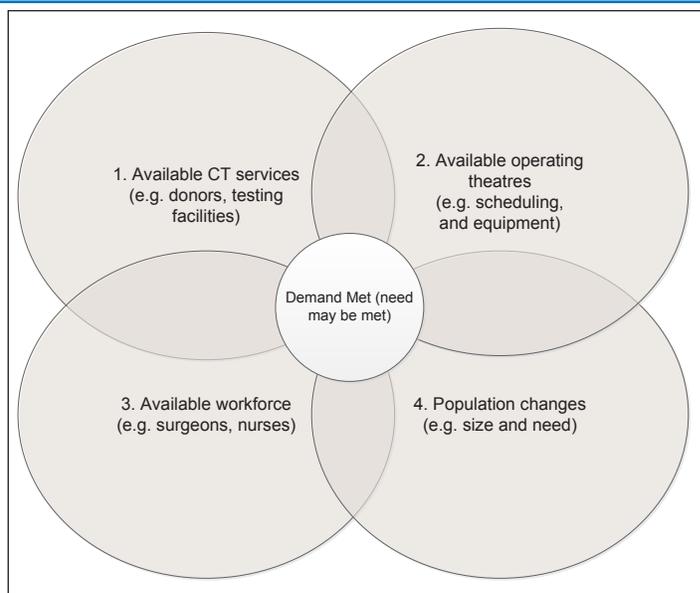


Diagram 1: Finding the Balance. When all four components move in unison, Corneal Tissue (CT) demand will most likely be met, and need could potentially be met. If one component or another, steps out of sequence, and change does not occur in unison, then neither need nor demand will be met, as one component or another will be over or undersupplied. Access to Funding underpins all for components.

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.

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 EB 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.

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 (Diagram 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 EB, 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

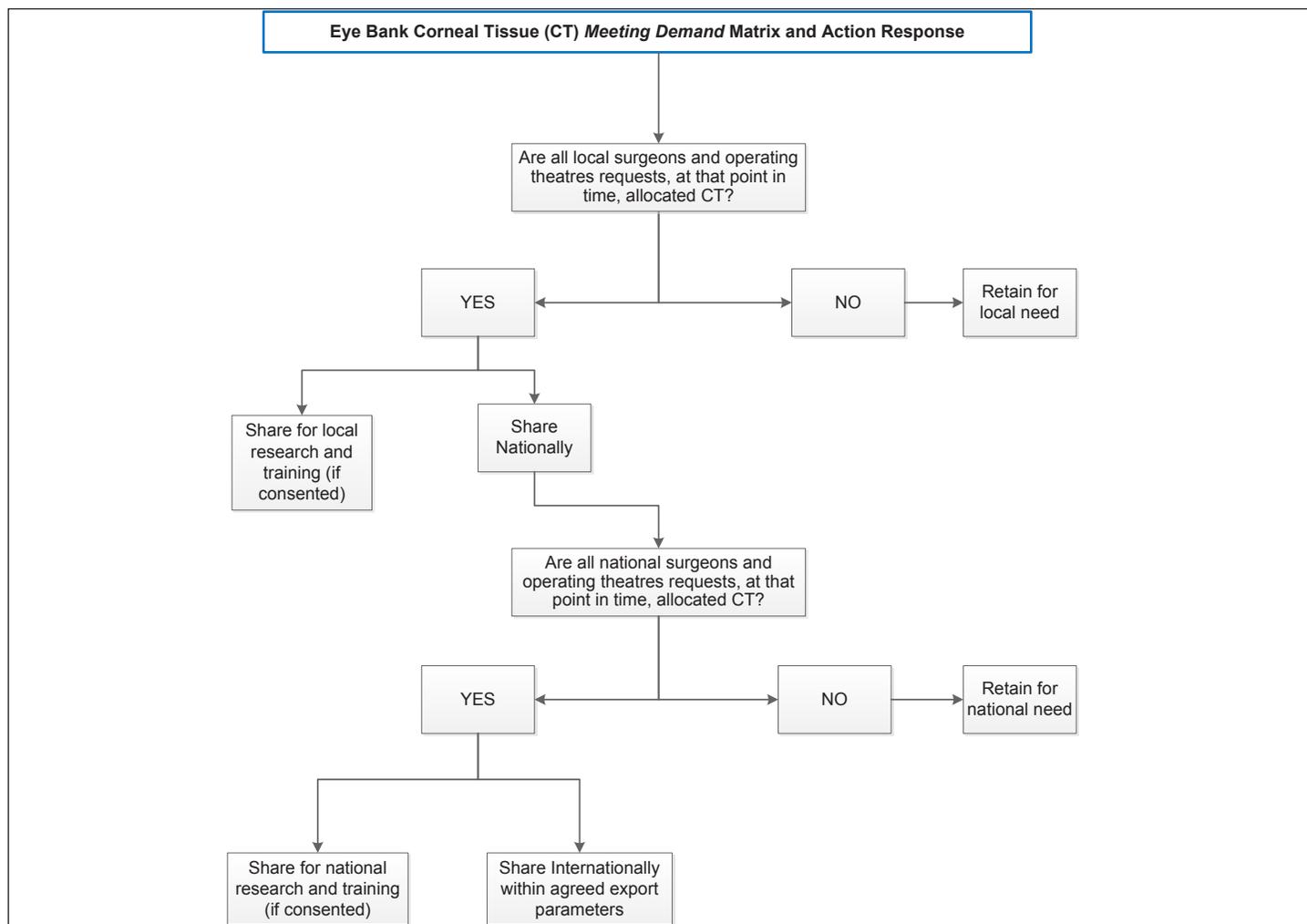


Diagram 2: The 3-Step Allocation approach assists eye banks to determine if they are meeting surgical demand, at any one time, prior to allocating elsewhere.

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.

REFERENCES

1. Australian Commonwealth Government Organ and Tissue Authority. Final report: analysis of the Australian tissue sector. Australia: Price Waterhouse Cooper. 2016. Available at: <https://donatelife.gov.au/about-us/corporate-information/government-reports> Accessed 15 April 2020.
2. Hurley J, Mentzakis E, Giacomini M, DeJean D., & Grignon M. Non-market resource allocation and the public's interpretation of need: an empirical investigation in the context of health care. *Soc Choice Welf.* 2017. 49; 117-143.
3. Frow J. *Time and Commodity Culture: Essays in cultural theory and postmodernity.* 1997. Clarendon Press.
4. Machin HM. Documenting the evolution of contemporary eye bank and corneal tissue services in Australia. *Int J Eye Bank.* 2019;2:7.