

Final report

Analysis of the Australian tissue sector

*Organ and Tissue
Authority*

November 2016

Disclaimer

This report has been prepared by PricewaterhouseCoopers Australia (PwC) for the Organ and Tissue Authority. In preparing this document we have only considered the circumstances of the Organ and Tissue Authority. This document is not appropriate for use by persons other than the Organ and Tissue Authority, and we do not accept or assume responsibility to anyone other than the Organ and Tissue Authority in respect of the document.

This report must not be copied, reproduced, distributed, or used, in whole or in part, for any purpose other than that detailed in our Engagement Contract with the Organ and Tissue Authority without the written permission of the Organ and Tissue Authority and PwC.¹

¹ Liability is limited by a scheme approved under Professional Services Legislation

Summary

The Australian tissue sector is diverse and in certain areas is undergoing very rapid change. Awareness of the extent of this change within the sector however, is very limited given current governance arrangements and the opaque nature of current market structures. This is of major concern. These issues need to be urgently recognised, understood and addressed in major but targeted sectorial change to ensure the sustainability of the Australian tissue sector into the future.

The importance of these changes is two-fold:

- Tissue transplantation is the most commonly performed transplant received by patients. There is a real risk that there will not be an efficient, effective or transparent domestic musculoskeletal, skin and heart tissue sector within 10 years.
- There is a risk that a lack of clarity and transparency in any policy framework that may be developed could negatively impact public confidence in altruistic donation more broadly.

The findings of this report are informed through extensive consultation: 84 stakeholders were interviewed and an online survey was distributed that received 60 responses. Quantitative data has been supplemented with freedom of information requests. All jurisdictions, their respective tissue banks, Commonwealth and regulatory agencies participated in this consultation process, along with other important sector participants. Generally, the level of constructive sector engagement was high, with the vast majority of major stakeholders acknowledging the challenges the sector faces. Opinions then differed in how best to overcome these challenges.

Key findings of this report are structured into three parts: understanding the current supply and demand dynamics in the sector; understanding the challenges that the sector has in responding to these changing supply and demand dynamics; and, recommendations for overcoming these challenges.

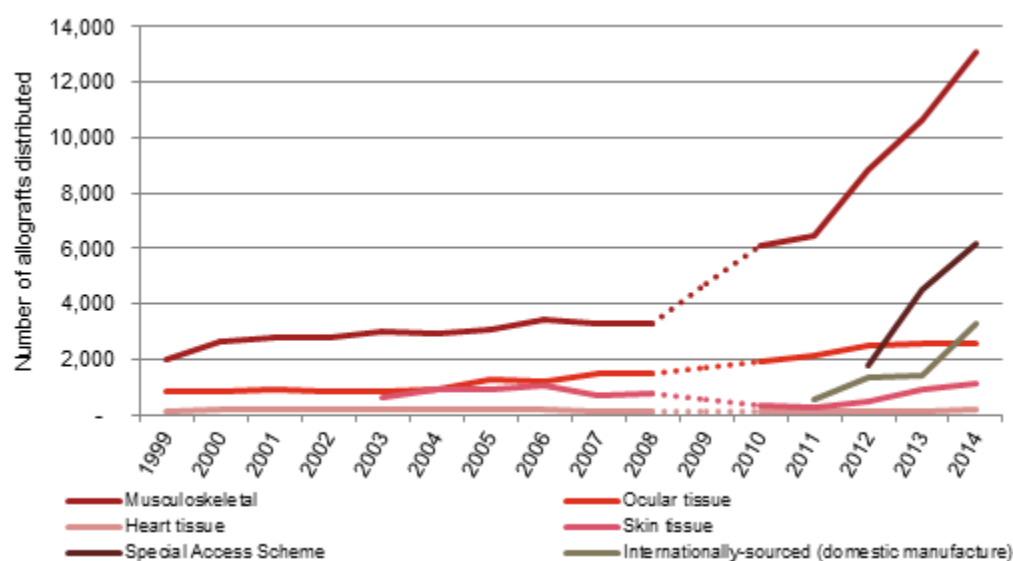
A fourth component was included within the original scope of work: consideration of future industry structures which could underpin the sustainability of a domestic tissue sector. The findings of this analysis demonstrate that further work is required to understand the sector and define key policy principles before identifying an appropriate future sector structure. That being said, this report does provide comment on the various sector models that were initially identified in the Statement of Work that may inform options for any future tissue policy framework.

1 Demand and supply dynamics

Domestic demand is far outstripping domestic supply

At a sector level, domestic demand is far exceeding domestic supply, both in terms of the volume and type of allografts required for all tissue types except for ocular, which has greater supply than demand. This additional demand could be met through increased donation and domestic technological advances or substitution with synthetics in the foreseeable future, however a clear policy framework is required to underpin the major sector redevelopment required to facilitate this.

Figure 1 - Number of allografts distributed by tissue type

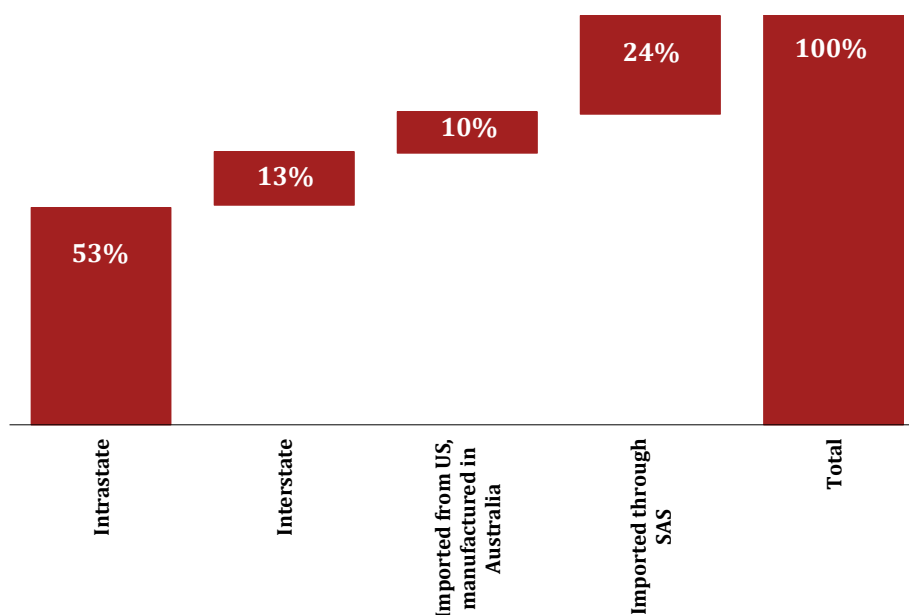


Dotted lines are assumed trends between the two datasets.²

- The number of allografts used domestically has grown by 350% between 2009 and 2014. Conversely, domestic supply of tissue is estimated to have grown by 250% over the same period.
- The bulk of the difference between domestic use and domestic supply has been made up through imported tissue and allografts. In 2009, it is understood that imports were only used in exceptional circumstances and did not comprise a significant component of supply. In 2014 they made up 34% of total supply. The sector is becoming progressively more reliant on overseas supply to meet rapidly growing and changing domestic demand. Musculoskeletal products account for the bulk of this growth, however skin products also make up a growing proportion.

² 1999 to 2008 data from Australian Organ and Tissue Donation And Transplantation Authority (2009) *National Eye and Tissue Network Implementation* report prepared by Health Outcomes International, and 2010 to 2014 data from Tissue bank survey responses, PwC survey: Tissue Sector – Economic Analysis 2015

Figure 2 - Single allografts supplied by source (2014)



- The vast majority of stakeholders consulted understood there to be very little reliance on overseas supply and understood importation was limited to exceptional circumstance Special Access Scheme (SAS). It is unclear whether any stakeholders have a clear view of the total magnitude and growth of this international supply given the absence of any requirement for centralised reporting and documentation.

Significant differences exist between tissue types

Importantly, the nature of demand differs by tissue type. Understanding the supply and demand nuances of each tissue type, and accounting for this during any process of change, is critical to targeting the areas of greatest need while preserving the well-functioning components of the sector.

• Changing demand for musculoskeletal allografts

There have been major changes in musculoskeletal tissue provision with which the majority of the sector have not kept pace. This includes growing and unmet demand for biotechnologically-enhanced tissue, shifts in femoral head collection and the development of a major private provider of musculoskeletal products operating across multiple jurisdictions. Unmet demand hinges on two factors: lack of local supply (donors) and inability to manufacture the advanced products which are in growing demand by clinicians. In both these areas, international import solutions have been adopted to meet demand. However, stakeholders involved with importation identified a strong preference for using domestic over international supply if domestic donation rates, retrieval processes and funding barriers could be overcome. There has also been strong interest from international companies seeking to gain greater access to the Australian market place. It is estimated that there is sufficient clinical demand for musculoskeletal supply to increase by 50% to 100% of current levels.

• Ongoing and underlying demand for skin

There remains an unmet underlying demand for skin. Stakeholders indicated that if skin was readily accessible there would be additional clinical demand outside of the current stockpiling function for serious burns, for example, for use in breast reconstruction surgery. Access to skin products through the SAS has also increased rapidly, further hinting at this unmet demand. It is estimated that there is sufficient clinical demand for supply to double (increase by 100%).

- **Need to increase heart tissue supply, particularly paediatric heart valves**

There remains an unmet underlying demand for heart tissue, especially paediatric heart valves, although it must be stressed that this demand is off a very low base. It is estimated that there is sufficient clinical demand for heart tissue supply to increase by 10% to 50% of current levels.

- **Ocular tissue managed**

Ocular tissue differed to the other three tissue groups examined in this review. Under the guidance of a national professional association, Eye Bank Association of Australia and New Zealand (EBAANZ), eye banking operates functionally, transparently and inclusively. While participants spoke of increasing regulatory burdens, eye banking was minimally affected by the challenges experienced in the provision of other tissue types. Domestic supply meets current demand and the participants are well placed to ensure that supply sustainably meets future demand. Overall, ocular tissue banking is working effectively and provides some good examples of what is possible in the sector, however it could still benefit from improvements in national policy, governance, coordination and harmonisation across the broader tissue market in Australia.

Concerns over long-term financial sustainability

The financial sustainability of banks has improved somewhat since 2009. However, financial reforms are needed to ensure the sustainability of the sector over the coming decade. These reforms revolve less around marginal changes to the status quo and more around major shifts in the way the sector is financed; is organised; invests in R&D; establishes clinical feedback loops and competes internationally. From a financial sustainability standpoint, key areas of note are:

- The majority of banks are not investing in research, development and technology and face barriers in doing so based on access to funding and the existing cost recovery system. As a result, many aspects of the Australian allograft market lag behind the products demanded by clinicians, which are available in international markets. Closing this R&D gap and fostering innovation in the domestic sector is critical to its survival and long-term sustainability.
- The rapidly changing nature of musculoskeletal tissue use and methods for its domestic retrieval are undermining the financial sustainability of other tissue types, namely skin and hearts. Musculoskeletal tissue derived from live donor femoral heads has traditionally been used by banks to cross-subsidise the costs of skin and heart tissue as well as functioning as a gap filler to low levels of deceased donations in Australia. Stakeholders reported that the costs for skin and heart tissue far exceeded their regulated price (despite the ability of stakeholders to influence this price through the cost-recovery framework). Furthermore, musculoskeletal is the highest volume, high turnover tissue type and given that banks are reimbursed on implant, become very important from a cash-flow perspective when funds may not be reimbursed to the bank for up to five years. This cash-flow issue is accentuated when compared to the very low volume of heart tissue and skin tissue (which can be reimbursed years after the initial cost has been incurred). Due to the much shorter shelf-life of ocular tissue, this time lag between donation and transplant is not an issue to reimbursement.
- Notwithstanding the need to address this cross-subsidisation through reviewing the current cost-recovery framework (and application of this framework by banks), the 'financial' appeal of different tissue types has major implications for equity and the longer-term sustainability of the industry. A focus by some banks on only musculoskeletal tissue diminishes the wider ability of jurisdictions to collect and supply all tissue types. This point is also intertwined with certain jurisdictions essentially cross-subsidising / funding a national system. Stakeholder consultations did not identify this as a current issue, primarily due to the fact this was seen as an altruistic sector. However, it is a weakness in the longer term sustainability of the

sector, especially as all governments are likely to face increased fiscal pressure, and the perception of altruistic drivers may shift as market structures change.

- Increasing regulatory costs and the lead time required for regulatory approval in TGA product approval processes were identified by some stakeholders as a major point of financial pressure. Others noted these costs but did not consider them a major burden given the current practice of directly passing on these costs through the cost recovery framework.
- Finally, a number of banks and jurisdictions indicated that increased regulatory pressures (both financial and resource) were being minimised through increasing cost synergies possible through multi-tissue banks.

2 Challenges in the Sector

Through consultations, a number of key challenges to the sustainability of the sector were identified. This report considers all tissue types as the one sector, however, when looking at the challenges posed and steps forward, it becomes clear that different tissue types within the sector require different levels of intervention. The challenges to the sector include:

- **Tissue banking suffers from a lack of shared objectives**

Different perspectives exist as to the role and objectives of tissue banking (eg to meet donor wishes or deliver patient outcomes in a sustainable and efficient manner). The lack of organised coordination between individual banks and between jurisdictions leads to the absence of central policy direction and lack of oversight.

As a result, frameworks (legislative, service delivery, clinical feedback and funding) are not harmonised to deliver on patient outcomes. This void has fostered new market entrants which have resulted in competitive, inefficient practices especially in the provision of more ‘financially’ desirable products (musculoskeletal). The lack of a coordinated reporting mechanism has resulted in the capacity, demand, trends and justification for change being unclear, and the sector is left without an established evidence base to underpin change.

- **Lack of policy has created ambiguity**

There is an implicit (and in some cases, explicit) reliance on federal agencies (Therapeutic Goods Administration (TGA) and Private Health Insurance Branch of the Department of Health (PHI)) to effectively “regulate” policy aspects of tissue banking. Without a separately agreed point of reference (such as a national policy), many jurisdictions trust that benchmarks relating to the sourcing and not-for-profit trade of tissues are embedded in decisions by the TGA for the supply of products, and in decisions relating to cost-recovery undertaken by the PHI. While sourcing and not for profit trade issues may fit with the scope of TGA consideration where these factors influence the safety and/or quality of the tissue the lack of national policy on internationally sourced and not-for-profit trade in tissues creates ambiguity. There is a mismatch in jurisdictional responsibility in tissue banking and in an agreed policy approach to the provision of tissues.

- **Barriers to tissue supply**

There are institutional and relational barriers which limit supply from potential donors. There is potential to access a much wider pool of donors if some of these barriers are addressed. Primarily, these relate to donor identification, access and screening mechanisms.

There is a clear contrast between stakeholder perceptions and current market forces, with tissue bank stakeholders indicating no marked desire for international supply of tissues unless a significant need required it. The data collected as part of this study indicate a

high level of demand by end users that already needs to be met through international supply. Unless domestic supply is increased, reliance on overseas supply is likely to remain, if not increase. This direct contradiction in attitudes between tissue banks and end users must be resolved if the sector is to meet domestic demand into the next decade.

- **Lack of standardised cost recovery approach**

The lack of standardised costing, at both federal and state tiers of government creates uncertainty in the application of cost recovery rules. Many banks are effectively self-regulating, being conservative on costs given the altruistic nature of the sector. The practice of benchmarking costs against costs from other banks to ensure their prices are middle of the range, rather than accurately costing their products, was also reported by a number of stakeholders. This has in turn resulted in financial unviability, particularly for more expensive-to-handle tissues (such as for heart and skin tissues).

- **Little investment in research and development**

Existing funding structures do not promote investment in research and development, or in manufacturing processes to produce newer generation products. Without this funding, publicly-funded banks are constrained in their ability to adapt to changing clinical needs, while not-for-profit banks are reliant on charitable funding. While bound by the same cost-recovery principles, there is no transparency regarding the way in which private providers are able to fund processes to produce newer products that have been critical in meeting domestic demand in recent years.

The long term sustainability of the domestic sector rests upon its ability to innovate and meet rapidly changing clinical demand and hence, investigation of funding mechanisms (or incentives) to make this happen is critical.

- **Variability of clinical feedback loops**

Some public and not-for-profit tissue banks are not flexible and accountable to market requirements and there is inconsistency in, or in some cases a lack of, appropriate clinical feedback loops or consumer-led (clinician) drivers for change. This is not the case for ocular tissue which has clearly established clinical feedback loops nationwide. Additionally, clinical preferences differ across institutions and jurisdictions and dependent on those preferences, drive demand for different allograft use.

Some tissue banks therefore act on the advice of a known circle of clinicians and are not held accountable to provide for other market segments. An example of this is contrasting the significant importation of musculoskeletal products for dental use identified through the Special Access Scheme against the very limited, speculative, mention of potential dental demand by banks during consultation or dental representation by any industry bodies.

3 Recommendations

Change should proceed with considered urgency to address the challenges identified above. However, a considered approach is required given the sector is complex and fragmented with few clear policy levers or governance mechanisms to manage change. Furthermore, given the current operations within the sector differ dramatically from the widespread stakeholder understanding, the type and scale of change is not immediately obvious to the key stakeholders.

The guiding principles to inform this change should be as follows:

- the aims, objectives and success of the sector should be outcome focused. This aligns with the broader ethos of the Australian health sector and ensures all decisions work back from effectively and efficiently enhancing patient outcomes and meeting clinical requirements

- change shouldn't undermine the current strengths of the sector, it should recognise these aspects and build upon them
- resources invested in change should be commensurate with the scale of the sector. Care needs to be taken to ensure the costs of large scale change do not outweigh the potential benefits
- differences between tissue types need to be recognised and reflected in changes: there is not necessarily a one-size-fits all solution
- recommendations should be seen as a package, with successful change resting on addressing all areas. Addressing recommendations in isolation will not bring about the change required in the sector.

The following recommendations apply equally across tissue types to drive harmonisation and consistency across the sector as a whole. However, the level of intervention will reflect the extent of challenges for each tissue type, which do differ across the sector.

PwC's recommendations are as follows:

Recommendation One: Status quo

That governments recognise that the current operation of the tissue sector will not prove feasible to sustain supply to meet domestic needs over the medium to long term.

Recommendation Two: National policy framework for the tissue sector

There is a clear need for a national policy framework for the tissue sector that is agreed between all governments. PwC consider that to inform the development of a transparent and accountable national policy framework objectives, priorities and underpinning policy positions must be developed and agreed by all governments.

A National Taskforce, or similar, should be established comprised of Commonwealth and state participants who have policy responsibility and accountability for the tissue sector.

Patient needs, clinical feedback and service delivery considerations should be reflected through the appropriate industry and community associations who should also have a seat at the table.

The National Taskforce would require Ministerial backing and resourcing (Commonwealth, States and Territories) to drive the process of change.

The Taskforce should address the following needs as a matter of priority.

Clear national policy framework and articulation of sector principles

A core national policy framework is required to clearly articulate the policy principles of the sector. This document is urgently required to harmonize and align differing perceptions of the role and responsibilities of the sector. It is also critical in directing change and measuring the outcomes of a sectoral change process.

Clearly defined policy principles are required on:

1. Ethical framework
2. Donated tissue supply
3. Exportation of donated tissue

4. Governance and oversight of the sector
5. Transparency, data, reporting accountability
6. Standards of practice
7. Scope of service
8. Clinical purpose
9. Funding arrangements
10. Research and development
11. Role of professional associations

The policy principles should be developed as follows:

1. Ethical framework

A set of national ethical principles should be developed to guide the collection, manufacturing and distribution of tissues. Within the framework, parties should be identified for their responsibilities in maintaining the ethical standing of the industry. Additionally, ethical principles should be codified in legislative, regulatory and policy frameworks to give effect to their consistent application.

2. Donated tissue supply

A national position should be developed on self-sufficiency to specify the desired future state of supply of donated tissues. The position should stipulate when, how and in what circumstances imported tissues be supplied to meet Australia's clinical needs for allografts, and the extent to which domestic donation should be relied upon and supported. Once a position is specified, activities that support this objective can be tailored.

3. Exportation of donated tissue

As with identifying a position on self-sufficiency, a national position on exportation should be developed. The position should specify the extent to which domestic needs be prioritised and secured, and if additional supply should be pursued to be able to export to other countries.

4. Governance and oversight of the sector

There already is a diverse mix of government and private sector participants (not-for-profit and for-profit). Stakeholders viewed that this was unlikely to change and, if anything, the role of private participants is likely to grow. The health sector can operate very effectively with this mix however this environment requires oversight, regulation and transparency.

There is not currently the oversight, regulatory or transparency arrangements in place to support the current public-private sector mix, let alone growth of the private sector (not-for-profit or for-profit). Without this, a high degree of uncertainty and ambiguity exists within the sector. Actions should be taken to formalise:

- reporting and information sharing from the TGA to all governments regarding importation and approvals of products
- consistent data reporting arrangements of tissue banks to all governments

- agree principles and specified definitions as they relate to cost recovery or “non-profit trade” that reflect those adopted across all other jurisdictions
- the preferred national model for tissue banking arrangements, building on existing arrangements and opportunities. The model developed should specify how best to segment the tissue banking system to deliver on national and state and territory needs.

5. Transparency, data, reporting accountability

Greater transparency, data collection and accountability for reporting needs to be instilled to better understand the operation, distribution and use of allografts across Australia. This is particularly important to provide the evidence base for developing policy responses within the sector. To give effect to this a position should be developed on what information needs to be collected, who is responsible for this and what the mechanisms are for enforcing this to:

- define data requirements, specifically identify and agree what data is required, the mechanism to facilitate regular data reporting, who is responsible for data collection and dissemination and understanding the mechanisms to fund this collection.
- specify reporting and accountability requirements on tissue banks to government to support oversight under the national policy

6. Standards and practice

To build the focus of the sector to meeting patient outcomes, greater connection and understanding of clinical needs should be embedded in tissue banking. Practices should be established to build clinical feedback loops into banking operation and develop clinical standards of practice to better project and deliver on clinical needs.

7. Scope of service

Objectives should be developed among jurisdictions to define how each state and territory considers its role in tissue collection, processing and distribution. Priority and supporting arrangements across jurisdictions may be developed in view of delivering on national objectives as they relate to tissue banking. For example, some jurisdictions may be better placed to collect and process certain types of tissues than others and so may consider that their scope of service can provide for others’ needs beyond their borders.

8. Clinical purpose

Linked to objectives of donated tissue supply, a position should be developed as to the sector’s clinical purpose. PwC consider that the sector needs to orient itself to delivering on patient needs and outcomes, followed by the role in fulfilling donor wishes. That is, that donor wishes be filled only where and when a need for donated tissue is required. The position should be implemented across practice for donor consent, access and retrieval.

9. Funding arrangements

Funding arrangements for the sector should be reviewed and reset to deliver on the defined objectives. This includes to consider the sector’s cost recovery principles, the role of the private sector (not-for profit and for profit) and contestability for certain sector functions (eg. retrieval, manufacture etc.). Specifically this requires:

- a review of the current industry funding structure, specifically the PHI cost recovery framework, to assess whether it serves the needs of a rapidly evolving sector, and to understand whether the framework and current price schedule are driving perverse sector structures. Guidelines should be developed for the assessment of cost recoverable amounts by the Department of Health

- to determine an appropriate governance process and contestability arrangements to allow for the participation of private sector participants (not-for-profit and for profit) in an ethical, transparent and accountable manner
 - specifically – what parts of the market are contestable, what governance arrangements need to be put in place, what levels and incentives exist within contracts to mitigate risk while driving the desired outcomes and finally, what is the appropriate model to ensure a healthy level of competitive tension and protect against a monopoly provider
- funding allocation and equity among jurisdictions should be established to invest in future tissue banking arrangements.

10. Research and development

Clearly recognising the need for ongoing research and development as central to the sector's sustainability, a position should be developed which articulates where the responsibility for research and development lies (government vs. private sector). This should be supported through:

- identifying the most pressing research and development requirements
- mapping the capability of the domestic sector to currently meet these requirements, including to consider synergies that might exist with universities, other research institutions and banks, and acting on these accordingly
- establishing or amending legislative architecture to promote both technological investment and an ambit that can manage the evolving and advanced nature of many of the newer generation tissue-derived products.

11. Role of professional associations

A consistent characteristic of a functioning tissue sector in overseas jurisdictions is strong sector leadership. This is also demonstrated domestically with EBAANZ providing the leadership, self-regulation and reporting which has guided the development of eye tissue into a sustainable sector.

Stronger professional leadership and representation would benefit other tissues within the sector to complement national coordination, self-regulating quality and standards, driving innovation, coordinating advocacy and collaboration.

Strengthened engagement with professional associations and suppliers is also important in view of any potential structure changes including the consolidation of any tissue collection, processing and distribution services.

Specific elements for further investigation include:

- better engagement with clinicians, including specification of clinical feedback loops and reporting to build accountability to end-users of allografts
- development of standardised practices that are periodically reviewed, including the continued sharing of best practice among tissue banks.

Existing arrangements for all other tissue types should be reviewed to identify how to strengthen professional representation. This may include developing informal and formal relationships to existing committees of end-users (for example, the Australian Orthopaedic Association, the Australia and New Zealand Society of Cardiac and Thoracic Surgeons and the Australia and New Zealand Society of Oral and Maxillofacial Surgeons). This would assist

to build linkages with end-users and tissue banks, as well as to bring consistency to practice and standards, in line with delivery of other services that support clinical practice.

Direct linkages to outcome registries should also be established for all tissue types to improve the clinical outcome feedback loop of use of allografts within the clinical community, as has been achieved with the Australian Corneal Graft Registry. Options for this may include, for example, the Australian Orthopaedic Association National Joint Replacement Registry to capture allografts used in joint surgery. Similar opportunities for use of existing reporting infrastructure may exist for other allografts.

Ideally, the principles and policy base would be established and agreed by Commonwealth, State and Territory Ministers to give effect to the harmonisation of practices that follow.

Recommendation Three: Structural reform of the Australian tissue sector

Any reform of the sector should be informed by an already established clear national policy framework.

The initial Statement of Requirement asked PwC to assess options for the sector to deliver on future needs. However, as the work progressed, it became quickly evident that without a strong evidence base and agreed framework against which it is to deliver, it is too early to assess the options.

For the sake of completeness, tissue bank and government responses with regard to the potential structural options are reported on in the body of this report to inform any sector restructure in the future. However, before regard is given to the future state and structure of the sector, Recommendation Two must first be implemented.

Contents

Disclaimer	i
Summary	ii
1 Context	3
2 Sector snapshot	5
3 Supply and demand	12
4 Challenges	32
5 Options	49
6 Recommendations	62
Appendix A Data source list	72
Appendix B Consulted stakeholders	73
Appendix C Review context	77
Appendix D Survey	81

Abbreviations

Abbreviation	Description
AATB	American Association of Tissue Banking
ACT	Australian Capital Territory
AHMAC	Australian Health Ministers' Advisory Council
ANZOD	Australia New Zealand Organ Donation Register
ARTG	Australian Register of Therapeutic Goods
BAA	Biotherapeutics Association of Australasia
BHBB	Barwon Health Bone Bank, Geelong
Blood Service	Australian Red Cross Blood Service
cGMP	Code of Good Manufacturing Practice
CTTWA	Cell and Tissue Therapies WA
DTBV	Donor Tissue Bank of Victoria
EBAANZ	Eye Bank Association of Australia and New Zealand
ETEA WG	Eye and Tissue Economic Analysis Working Group
HOI	Health Outcomes International
HNEBB	Hunter New England Bone Bank
HPC	Hematopoietic Progenitor Cells
NBA	National Blood Authority
NSW	New South Wales
NT	Northern Territory
OTA	Organ and Tissue Authority
PHI	Private Health Insurance Branch
PwC	PricewaterhouseCoopers
QLD	Queensland
SA	South Australia
SATB	South Australian Tissue Bank
SHVB	Sydney Heart Valve Bank
Tas	Tasmania
TGA	Therapeutics Goods Administration
VIC	Victoria
WA	Western Australia

Definitions

In this report, the terms **tissues** and **allografts** are used. Tissues are taken to mean the unaltered donated human tissue. Allografts are tissues that have been handled, processed or adapted for clinical application. A single tissue may be used to make multiple allografts.

In addition, references are made to **public banks, not for profit banks** and **private providers**. **Public banks** are tissue banks that provide some or all tissue retrieval, processing, storage and distribution services for allografts. These banks are government entities and are supported by state government funding. **Not for profit banks** are independent, non-government entities that provide tissue retrieval, processing, storage and distribution services for allografts and hold charitable status. **Private providers** are companies which provide various tissue retrieval, processing, storage and distribution services for allografts under contract to, or independently of government.

The term **transfers** are when a collected tissue is transferred to a bank/provider for processing, or when an allograft/tissue is transferred between banks/providers. **Distribution** is used to describe when an allograft has been released and distributed to a surgeon for implant.

1 *Context*

This project has been commissioned by the Organ and Tissue Authority (OTA) according to the Australian Health Minister's Advisory Council (AHMAC) and endorsed by the Eye and Tissue Economic Analysis (ETEA) Working Group Statement of Requirement.

This report presents an overview of the tissue sector, as informed by stakeholders in tissue banking, government and clinical sectors. It is also informed by a high level assessment of the costs and benefits of options to support the future of tissue banking. It is intended to inform future work to improve the efficiency and effectiveness of tissue banking in Australia to meet clinical needs over the next five to ten years.

1.1 *Background to this analysis*

This report delivers on an agreement by AHMAC to better understand the current and future capacity of the tissue sector to support patient health outcomes relating to donated tissue.

- In 2009, the Australian Government implemented the Council of Australian Government endorsed national reform programme for organ and tissue donation for transplantation. The integration of the tissue sector was identified as a measure in the national reform programme and this report is a key component of that work.
- The path of change for the tissue sector has been complicated by a number of factors:
 - Fragmentation, with the sector growing organically from localised State operations, governing legislation existing at the State level and no national governance structure
 - Funding, centered on cost recovery which is applied in different ways among banks, and in some cases, is complemented by alternative private or public funding sources
 - Lack of visibility around both supply and demand for both current and future demand for most tissue products

These challenges have been pointed out in a number of past reports, all of which have played an important role on the path to ongoing sector development. Key reports include a 2009 review undertaken by Health Outcomes International (HOI) and a review in 2011 by the OTA 'Options for more Effective Eye and Tissue Retrieval, Processing and Storage'. The needs outlined in those reports, including the need to independently review the sector to identify options for change, have been the catalyst for this piece of work.

1.2 *Scope of this review*

Against this backdrop, this review seeks to:

- develop a profile of the current allograft sector
- undertake consultations to understand stakeholder views on options for the sector over the next 10 years, and their appetite for international supply options
- collate data on the sector's supply and demand, as provided by stakeholders
- analyse current and projected clinical demand for donated eye and tissue products (allografts) and the extent to which existing demand is met
- assess retrieval requirements and processes, and options for improved efficiency

- assess the strengths and weaknesses of the current model for eye and tissue banking
- assess the sustainability of the Australian sector
- assess the impact of the Biologicals Regulatory Framework on the sector
- present options for improved efficiency and effectiveness of eye and tissue banking and the costs, benefits and risks of each option, including aspects as they relate to:
 - financial
 - altruistic donation and transplantation
 - challenge of community expectations such as equal rights to health care, breach of ethical values such as non-commercialisation or profiteering from donated human tissues and cells
 - risks associated with external dependency of access to a critical resource (e.g. skin allografts).

Information presented in this report has been drawn from quantitative inputs from tissue banks across Australia, existing datasets (refer Appendix A) and Freedom of Information (FOI) requests collected in late 2015. Information gathered has been supported by consultations with stakeholders (full list at Appendix B), also engaged in late 2015. This project has received input from the ETEA Working Group.

The report structure follows:

- Chapter 2: Sector snapshot
- Chapter 3: Supply and demand
- Chapter 4: Challenges
- Chapter 5: Options
- Chapter 6: Recommendations

2 Sector snapshot

2.1 Tissue banking

Eye and tissue banks form, collectively, the tissue sector whose role it is to collect donated human tissue, process and store these tissues and then distribute them to clinicians for surgical use. Herein, this review refers to the tissue sector, which includes each of the tissue types considered. Tissue banks adopt different roles in the tissue consent, collection, processing and distribution supply chain.

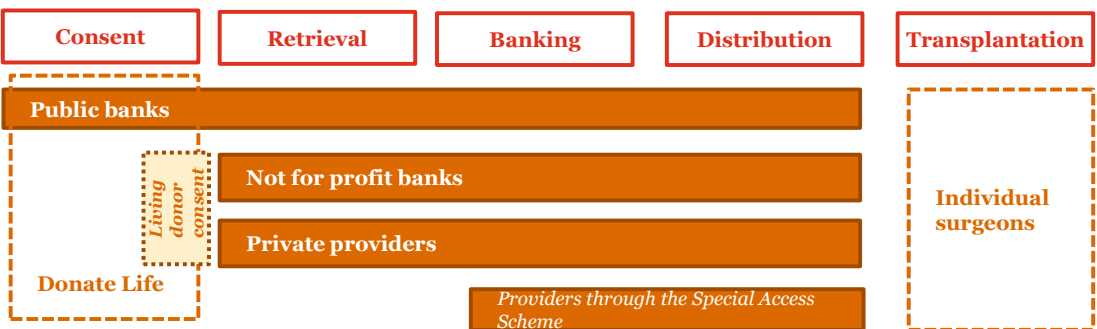
Foremost, banks play a role in processing, banking and distributing tissues. All deceased donor tissue banks are supported by DonateLife staff who play an important role in coordinating the deceased donation referral process. In some cases, banks will also undertake donor consent activities. These processes are guided by jurisdictional arrangements for death notification and consent processes. For example, automatic notification systems exist in New South Wales, Western Australia and Queensland, while others have been developed through individual state-based arrangements with hospital, mortuaries, and in community settings. Restrictions on access to donor bodies also limit the role of banks in some jurisdictions.

With consent and retrieval requirements differing according to each jurisdictions' governing legislation, the role that tissue banks can fulfil differs. For example, the qualification of retrievalists varies, where some jurisdictions allow technicians to undertake these activities, others require a medically-trained professional. All eye banks undertake retrieval activities for ocular tissue through the referral of donors to the eye banks.

The collection of live donor femoral heads from hip replacement patients is the exception to donor notification and referral processes; consent collection is by arrangement with orthopaedic units, from which most banks access tissues for processing and onward distribution. Consent and collection in the case of live donor tissue is managed directly by the banks.

Once collected, tissue can be processed, and is stored and distributed by tissue banks. A schematic of the approximate division of roles among banks is shown in Figure 3.

Figure 3 - Schematic of the tissue provision process



2.2 Participants in the tissue banking sector

Australia's clinical community is serviced by 15 tissue banks (refer Table 1).

A number of banks also provide services to store skull flaps.³

Of the 15 tissue banks, there are publicly-funded, part publicly-funded and not-for-profit banks and private providers who deliver tissue services. The funding profiles and activities of banks are described in the following section.

Table 1 - Tissue banks and allograft providers

Tissue bank	Musculoskeletal tissue – deceased donors	Musculoskeletal tissue – live donor	Ocular tissue	Heart tissue	Skin tissue
New South Wales					
NSW Tissue Banks, including the NSW Bone Bank and NSW Lions Eye Bank ⁴	✓	✓	✓		
Hunter New England Bone Bank	✓	✓			
Sydney Heart Valve Bank				✓	
Rachel Forster Bone Bank*		✓			
Queensland					
QLD Tissue Bank	✓	✓	✓	✓	✓
Victoria					
Lions Eye VIC			✓		
Barwon Health Bone Bank		✓			
Donor Tissue Bank of Victoria	✓	✓		✓	✓
Western Australia					
PlusLife WA	✓	✓			
WA Lions Eye Bank			✓		
Cell and Tissue Therapies WA ⁵				□	

³ Skull flaps are an autograft as part of clinical treatment of a patient

⁴ NSW Tissue Banks operate under a shared TGA licence

⁵ Cell and Tissue Therapies WA ceased manufacturing heart valves in March 2016, though is supplying valves from storage until all tissue has been allocated

Tissue bank	Musculoskeletal tissue – deceased donors	Musculoskeletal tissue – live donor	Ocular tissue	Heart tissue	Skin tissue
South Australia					
Eye Bank of South Australia			✓		
South Australia Tissue Bank		✓			
Australian Capital Territory					
ACT Bone Bank/DonateLife ACT ⁶	✓		✓		
Other					
Australian Biotechnologies	✓	✓			

*Demand and supply information from the Rachel Forster Bone Bank was not provided. Information presented for musculoskeletal tissue is therefore collated from a partial dataset.

During 2015, at the time of this review, a number of other organisations identified an interest in engaging in tissue donation and supply. The Australian Red Cross Blood Service (Blood Service) has been assisting the Donor Tissue Bank of Victoria to consider how to better project supply and demand for tissue products. The Blood Service has indicated that they have particular experience that is transferrable to tissue donation and supply, and would be willing to explore opportunities to leverage this experience to ensure a viable supply of tissue products.

The not-for-profit Zaidee's Rainbow Foundation (the Foundation) has been working with government agencies to identify how it may play a role in increasing living and deceased donor tissue collection (for all tissue types). The Foundation has conveyed to PwC that they would like to establish a stand-alone retrieval centre to facilitate tissue donations and supply these to processing centres, much like the American Procurement Organisational model.

In addition, a private provider has been supporting the development of a newly-established, not-for-profit tissue retrieval organisation, which will undertake similar functions to those proposed by the Foundation. PwC understand that the focus of this organisation will be to enhance collection of live donor musculoskeletal tissue across jurisdictions, to then provide the tissue to banks for processing. The private provider intends to migrate all collection and retrieval activities it undertakes to the not-for-profit tissue retrieval organisation to enable it to focus on processing and distribution activities.

Both organisations have an interest in expanding into deceased collection to enhance nation-wide supply.

2.2.1 Financial performance of tissue banks

Compared to 2009,⁷ tissue banks have slightly improved their financial performance, but on the whole, the sector remains in operational deficit.

⁶ ACT Bone Bank retains a licence for the retrieval of deceased musculoskeletal tissue only. Currently not active. DonateLife ACT retrieves optical tissue and dispatches to NSW Lions Eye Bank for processing, storage and distribution.

In the 2009 review, six of the 13 banks that provided financial data showed a significant financial deficit (>15%).⁸ Comparatively, in 2014:⁹

- four of the 12 banks that provided financial data were in significant financial deficit (>15% of revenue)
- an additional four banks suffered from moderate financial deficit (0-15% of revenue)

During consultation, many banks expressed that they suffered financial stress, and that cashflow remained a problem particularly for those banks that store tissues for longer periods, and hence, await reimbursement until those tissues are implanted.

Since 2009, reported revenue has more than doubled growing from an estimated \$13.0m¹⁰ in 2008 to \$25.8m in 2014. Expenditure concurrently increased over the same period, from \$14.3m¹¹ in 2008 to \$28.1m in 2014. Since 2009, recovery of costs through the PHI has expanded, with banks reporting less reliance on other sources of funding. Over the past five years, sector expenditure has consistently exceeded sector costs, and in aggregate, the sector operates in structural deficit. Banks reported that deficits are attributed to unforeseen costs for capital, maintenance and operation. Others acknowledged limitations to their cost recovery accounting. For example, one bank reported that it had not been, until recently, recouping costs for tissue provided to public patients, despite this accounting for approximately half of their supply.

Tissue bank revenue is summarised in Table 2 below.

Table 2 - Tissue banks revenue (\$'000s)

	2010	2011	2012	2013*	2014
Revenue	11,353	10,836	11,144	19,576	25,749
Fee-for-service income (cost recovery)	10,903	10,386	10,683	19,037	24,996
Government funding*	0	0	0	177	338
Charitable funding#	75	0	0	0	0
Private investment	0	0	0	0	0
Other	374	450	461	362	415

*The large increase in revenue reported in 2013 is due to the absence of 2010-2012 data for Queensland Tissue bank. The Government funding represented here is funding provided to the Queensland Tissue Bank in years 2013 and 2014. #Charitable funding in 2010 was provided to the Lions Eye Bank from the Lions Committee of Management.

⁷ Australian Organ and Tissue Donation And Transplantation Authority (2009) *National Eye and Tissue Network Implementation* report prepared by Health Outcomes International

⁸ Australian Organ and Tissue Donation And Transplantation Authority (2009) *National Eye and Tissue Network Implementation* report prepared by Health Outcomes International

⁹ Financial information was not provided by the Rachel Forster Bone Bank, South Australia Tissue Bank or Cell and Tissue Therapies Heart Valve Bank WA

¹⁰ The 2008 figure in the HOI report was \$11.2m. This has subsequently been adjusted to 2014 dollars for comparability, using a target inflation rate of 2.5%

¹¹ The 2008 figure in the HOI report was \$12.3m. This has subsequently been adjusted to 2014 dollars for comparability, using a target inflation rate of 2.5%

The key points to note on revenue are:

- **Fee-for-service:** Banks operate on a cost-recovery basis for service provision of the tissues included on the Australian Register for Therapeutic Goods (ARTG). Tissues are reimbursed upon implantation by private health insurers against listed prices on the Part B- Human Tissue Prostheses list, administered by the federal Department of Health. This is the primary mechanism for bank cost recovery. Tissues used in the public system are similarly reimbursed depending on state government arrangements, but are largely tied to the listed prices on the Prostheses list. Further information can be found in Appendix C. Of all funding sources fee-for-service income comprised of 97 per cent of income in 2014 compared to 87 per cent of income in 2008.
- **Government funding** – is provided to public banks as block funding to support operational expenses. It supplements services provided by the banks not received under the PHI. If a surplus is drawn in a given year, it is typically provided back to that state's Treasury, rather than accrued for reinvestment.
- **Charitable funding** – not-for-profit banks may be supported by charitable funding. Reported expenditure here includes “top-up” funding from the Lions Committee of Management. However, PwC are aware that a number of banks have trust funds that can be called-upon as needed.
- **Private funding** – is provided to private organisations to support investment, and operation where expenses are not recovered through fee-for-service. No investment was reported by banks.
- **Other funding** – not-for-profit banks reported revenue from fundraising activities and trust fund dividends. This was the second biggest source of funding after fee-for-service income.

Data provided does not reflect the significant in-kind support provided to many banks that was reported through consultations. This includes support for the operation, accommodation and staffing required to deliver services. For example, PlusLife receives in-kind support from DonateLife for deceased identification and consent activities.

Table 3 presents expenditure reported by banks between 2010 and 2014.

Table 3 – Tissue banks expenditure (\$'000s)

	2010	2011	2012	2013*	2014
Expenditure	11,892	11,957	12,588	22,152	28,099
Staff costs	5,409	5,650	5,946	11,509	12,373
Operational costs	3,512	4,101	3,838	6,780	10,393
Capital/equipment	353	188	411	594	836
Other	2,618	2,018	2,392	3,268	4,496

*The large increase in expenditure reported in 2013 is due to the absence of 2010-2012 data for Queensland Tissue bank

Over the reporting period, expenditure on staff and operational costs as a percentage of income has dropped, driven by a significant increase in 'Other' expenses. Expenditure accounted for:

- **Staff costs** – accounted for 44 per cent of all expenditure
- **Operational costs** – totalled 37 per cent of all tissue bank expenditure

- **Capital and equipment costs** – accounted for 3 per cent of expenditure; reflecting the sentiment among many stakeholders that financial arrangements left little ability to invest in newer technology or equipment
- **Other expenditure** – accounted for 16 per cent of all expenditure. A small amount of this attributed to expenses relating to testing facilities which is shared with other functions associated with a bank, however, the majority of other expenditure is not defined by survey respondents.

2.2.2 Tissue banking staffing

In line with the doubling of sector revenue, the capacity of tissue banks has also proportionately grown. Since 2008, the sector has grown from a reported 85 full-time equivalent staff (FTE), to an estimated 135 FTE in 2014, excluding temporary staff. However, this estimate is based on survey responses from banks and may fail to capture in-kind staffing resources, such as surgical registrars and other clinicians who assist in tissue banking collection activities and staff who hold multiple responsibilities.

List of banks	Number of FTEs ¹²
New South Wales	
NSW Bone Bank	
Lions NSW Eye Bank	12*
Hunter New England Bone Bank	2.3
Sydney Heart Valve Bank	1.2
Rachel Forster Bone Bank	0.6
Queensland	
QLD Tissue Banks	34.0
Victoria	
Lions Eye VIC	4.7
Barwon Health Bone Bank	1.0
Donor Tissue Bank of Victoria	16.7
Western Australia	
PlusLife WA ¹³	20.1
WA Lions Eye Bank	2.9
Cell and Tissue Therapies WA ¹⁴	
South Australia	
Eye Bank of South Australia	2.2
South Australia Tissue Bank	3.0
Australian Capital Territory	
ACT Bone Bank/DonateLife ACT ¹⁵	4.0
Other	
Australian Biotechnologies	30.5
TOTAL	135.2

*Staff were reported in aggregate for the NSW Bone Bank and Lions NSW Eye Bank

¹² In most instances, general hospital surgical staff are involved in donor identification, consent and retrieval of live donor femoral heads

¹³ In WA DonateLife Network staff manage all organ donations and are also involved in donor identification for deceased eye and tissue donors

¹⁴ Cell and Tissue Therapies WA staff (10.4 FTE) are not included in the total – as the bank has ceased manufacturing grafts and the 10.4 FTE primarily work in areas other than heart valve donation

¹⁵ DonateLife ACT staff manage all organ and eye donation in the ACT.

2.3 Regulatory and financial framework for tissue banking

Tissue banking is oversighted by state and territory governments who have policy and statutory responsibilities for tissue banking under their respective legislative regimes.

2.3.1 Regulatory framework

Safety and quality is regulated by the Therapeutic Goods Administration (TGA) against the Biologicals Framework, which requires compliance against the code of Good Manufacturing Practice (cGMP) and inclusion of tissue-derived therapeutic goods on the Australian Register of Therapeutic Goods (ARTG). The TGA assess regulatory compliance and establish licensing of banks to manufacture allografts for clinical use.

The States provide the legislative Human Tissue Act Framework which broadly states that there will be no trade in human tissue, and provides for the retrieval of tissue for banking with appropriate consent.

2.3.2 Financial framework

Additionally, the federal Department of Health holds responsibilities in its role in assessing the cost-recoverable price for allografts distributed in Australia under the Private Health Insurance (PHI) scheme. It accepts applications for ARTG-included products, which it assesses to develop the benefits payable to private health insurers as set out in the Part B-Human Tissue Items Prostheses List ('the PHI').

Further information on governance and regulatory frameworks is provided at Appendix C.

3 *Supply and demand*

The categories of tissues considered in this review are:

- Musculoskeletal tissue – live and deceased donors: which include whole femoral heads, milled bone, soft tissues (such as tendons), struts, whole bone and processed products such as cancellous bone and demineralised bone matrix. Live donor tissues (whole femoral heads) are retrieved from hip replacement patients.
- Ocular tissue: including corneas and sclera.
- Skin tissue which is retrieved from deceased donors, and is used primarily in burns surgery.
- Heart tissue: including pulmonary and aortic valves, which are primarily retrieved through deceased donation, but can also be donated by heart transplant recipients.

The snapshot of national supply and demand for tissues is presented in Table 4. This summarises perspectives shared by stakeholders through consultations, along with data collected through surveys, which captured information regarding tissue supply and demand over the past five years, and freedom of information requests.

Overall, PwC find that domestic demand substantially exceeds domestic supply across many tissue types. PwC also find that demand is likely to increase sharply over the next decade, particularly for musculoskeletal allografts. There is less certainty within the sector as to whether domestic supply can match this increase in demand over time, particularly in view of technological advancement and clinical preferences that are changing the nature of the demand for allografts. Supply and demand needs are currently met by eye banks, and it is expected that eye banks will continue to meet these needs into the future.

This chapter is structured as follows:

- Section 3.1 Tissue Supply
- Section 3.2 Tissue demand
- Section 3.3 Musculoskeletal tissue
- Section 3.4 Ocular tissue
- Section 3.5 Heart tissue
- Section 3.6 Skin tissue

Table 4 - National supply and demand of tissues

Tissue type	Total supply (2014 allografts)	National demand met	Intrastate demand met	Imported tissues (2014)		Potential unmet domestic demand	Future demand	Future supply	Likelihood of supply – demand gap
				Imported tissue manufactured in Australia ¹⁶	Imported allografts (SAS)				
Musculoskeletal	17,799	✗	✗	2,436	4,680	50-100%	- Exponential growth - Joint replacements driving demand - Dental applications growing - Changing practices and technology	- Supply not keeping pace with technological change and changing clinical practice - Live donor tissue collection growing	High
Heart	181	✗	✗	-	-	10-50%	- Ongoing need for paediatric heart valves - Pulmonary valves for endocarditis and congenital heart disease (growing need due to early life clinical intervention)	- Sustained shortage of paediatric heart valves - Challenges with donation (donors, access, capacity)	Moderate
Skin	2,580	✗	✗	-	1,471	100%	- QLD and Victorian Burns units have consistent need, some in NSW - Autograft and synthetic substitutes used elsewhere	Challenges with donation (donors, access)	High
Ocular	2,624	✓	✓	-	22	0%	- More partial thickness lamellar transplants - Aging population- in line with population growth (~7% pa)	Managed through clinical scheduling	Low
TOTAL	23,184			2,436	6,173				

¹⁶ Imported tissues manufactured in Australia are those deceased, unprocessed musculoskeletal tissues that are imported to Australia and then manufactured to produce the final allograft product

3.1 Tissue supply

3.1.1 Tissue collection

In 2014, a total of 4,216 heart, musculoskeletal and skin tissue donations were made from 3,980 unique donors.¹⁷ Of these tissues:

- 3,704 were donated by living donors (3,687 femoral head donations, and 17 heart tissue donations)
- 512 were donated by deceased donors, of which 323 were tissue-only donors. The remaining 189 donors also donated organs

In addition to these donations, there were 1,162 eye donors in 2014 (of which, 908 were eye only donors).¹⁸

As a percentage, live donor tissues comprise 88 per cent of all tissue donations. Of these, 34 per cent are provided by donors to New South Wales, followed by Queensland, and then Victoria.

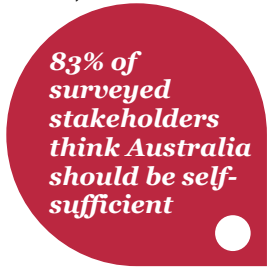
Of deceased donations, 63 per cent of tissues were donated by tissue-only donors. These donations were predominantly from Queensland. The remaining tissue donations from deceased individuals came from organ donors who also donated tissue.

A number of stakeholders identified a need to address the conversion of potential deceased tissue donors to enhance supply. These views considered that there is a need to address barriers, such as automatic death notification, enhanced support for tissue-only consent and retrieval processes, and streamlined selection criteria. Stakeholders considered it important to highlight the need to address conversion of potential deceased tissue donors based on the international recognition that deceased donation is key to sufficiency in all tissue types and that femoral head banking programs are less efficient not only from a financial perspective (due to significant expenditure committed to donor identification and screening with very low tissue yield) but also from tissue quality perspective (no weight bearing grafts can be manufactured).

3.1.2 Supply barriers

Data provided through consultations and from TGA data suggests that there is a significant undersupply of musculoskeletal tissues across all tissue banks, as well as demand which exceeds supply for heart and skin tissue. For eye banks, supply met demand, in that no patient was denied surgery due to a lack of eye tissue.

Where supply limitations existed, bank stakeholders cited a range of reasons; ordered responses to the survey are at Table 5. Many stakeholders considered that stringent requirements for donor selection and regarding licensing requirements of the new regulatory framework impeded supply most.



83% of surveyed stakeholders think Australia should be self-sufficient

¹⁷ Australia and New Zealand Organ Donation Registry (2015) Australian Eye and Tissue Data: 2014 Year End Report Chapter 6: Tissue and Eye Donation. Australia and New Zealand Dialysis and Transplant Registry, Adelaide, Australia. 2015. Pages 6, 7, 9 Available at: www.anzdata.org.au

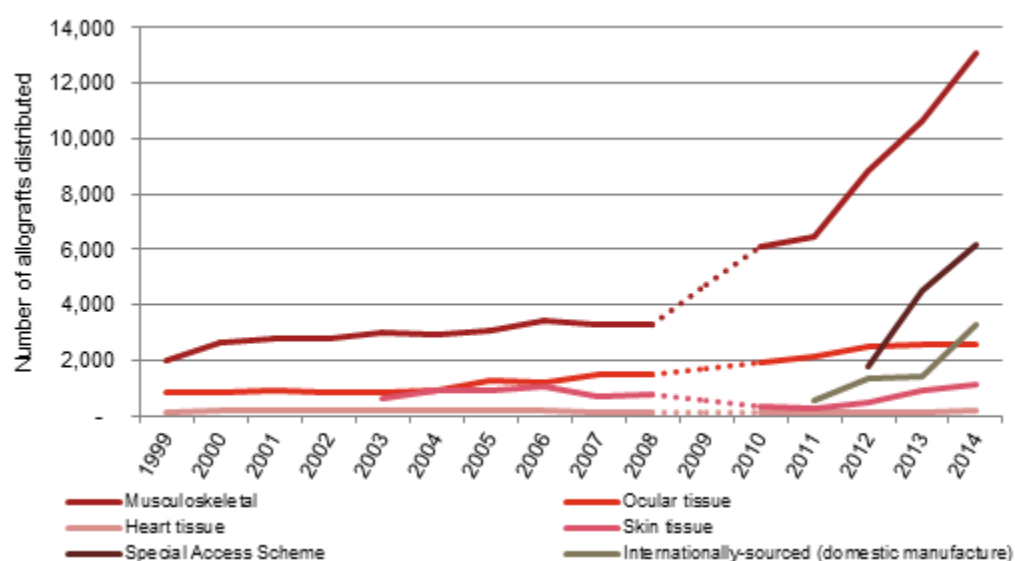
¹⁸ Australia and New Zealand Organ Donation Registry (2015) Australian Eye and Tissue Data: 2014 Year End Report Chapter 6: Tissue and Eye Donation. Australia and New Zealand Dialysis and Transplant Registry, Adelaide, Australia. 2015. Pg. 12 Available at: www.anzdata.org.au

Table 5- Supply constraints (ranked by tissue bank stakeholders)

Average ranking	Reasons for supply constraints
1	Regulatory barriers
2	Donor rates ¹⁹
3	Access to donors ²⁰
4	Donor testing requirements and availability of licenced, validated testing
5	Funding

3.1.3 Tissue distribution

As shown in Figure 4 musculoskeletal tissue (deceased and live donor combined) is the most distributed allograft nationally. Both ocular tissue and skin tissue distribution has grown over the last five years. Heart tissue distribution has remained relatively static; however, PwC is advised that this is limited largely due to the ability of banks to access suitable donors.

Figure 4 - Number of allografts distributed by tissue type

Note that the dataset from 1999 to 2008 is from the 2009 report²¹, while the 2010 to 2014 dataset is from the current analysis.²² As such, changes from 2008 include differences in assumptions and limitations across the two datasets. Dotted lines are assumed trends between the two datasets.

¹⁹ Rates of donation within the population

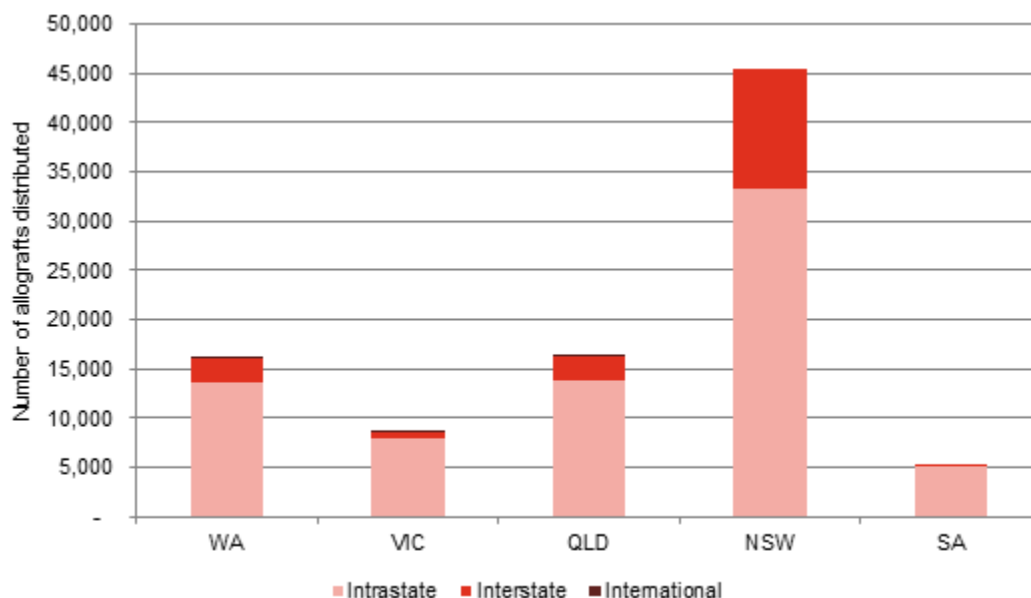
²⁰ Access to donors captures barriers which impair donation, such as notification, consent, time and communication,

²¹ Australian Organ and Tissue Donation And Transplantation Authority (2009) *National Eye and Tissue Network Implementation* report prepared by Health Outcomes International

While tissue banking largely serves the needs of the jurisdictional surgical communities in which the banks are located, there is distribution across states to fulfil shortfalls in other states. Figure 5 presents the intra and inter-state movement of allografts. No central coordination exists for the movement of all allografts. The majority of banks tend to have a high reliance on informal networks with a select few surgeons who often comprise large segments of their supply, in particular, musculoskeletal and heart tissue.

Figure 5 - Aggregate allograft distribution among states (over five years)

9



The exception to this is eye banking which has a nationally coordinated approach for ocular tissue distribution developed under EBAANZ. Each eye bank operates to serve its local surgical community, but will, in urgent cases, release tissue interstate under nationally agreed allocation protocols. Eye banking stakeholders were quick to point out that they consider the movement of ocular tissue is highly undesirable due to the suggested degeneration of tissue in air transportation, and shorter windows of viability as compared to other tissues.²³ Tight supply and demand forecasting and scheduling conventions assist eye banks to mostly minimise movement of ocular tissue except in special cases.

In addition to supply of allografts, a number of centres collect tissues on behalf of banks to enhance supply. These are then processed by the receiving bank and are supplied under agreement between:

- NT supply QLD with heart valves
- ACT supply NSW with ocular tissue
- Tasmania retrieves eyes for Victoria; femoral heads for QLD Bone Bank (direct arrangement with Launceston General Hospital) and on occasion, heart tissue for Victoria
- VIC supply live donor femoral heads to a private provider.

²² Tissue bank survey responses, PwC survey: Tissue Sector – Economic Analysis 2015

²³ Analyses produced by The Australian Corneal Graft Registry demonstrate a benefit to outcome when corneas are transplanted within the same State in which they are donated, compared to sending corneas interstate for transplantation. The underlying reasons for this are not clear and can only be speculative. However, the result does indicate that in Australia, clinical outcomes are enhanced when eye donation, eye banking, and transplantation all take place in the same State

Femoral heads are collected by Rachel Forster Bone Bank for internal use within the hospital in which they are collected. The Hunter New England Bone Bank collects femoral heads and distributes these both intra- and inter-state to requesting surgeons. The Barwon Health Bone Bank collects and supplies non-irradiated bone from femoral heads to three local hospitals in Geelong, and periodically receives and supplies requests to supply to hospitals outside Geelong (with a few previous cases of supply to Tasmania). The interstate distribution of each tissue type is discussed in further detail in the following sections.

3.1.4 International distribution

The distribution of allografts internationally appears to occur on a bank-by-bank basis. While some allografts distributed internationally were reported through surveys, there is no national visibility of tissue exported from Australia outside of the TGA. The TGA has some visibility via the requirement for export permits to export human tissues; in which the internal volume of the immediate container within which the material is packed exceeds 50 mL.

PwC learned of instances whereby Australian ophthalmologists sourced corneas from Australia for altruistic surgical applications in neighbouring countries. In other cases, small amounts of other allografts were distributed to support specific surgeons overseas. In all cases, the cost recovery mechanism is unknown. In addition, the aspects of equity to supply, and risks associated with quality are not explicitly addressed due to a lack of a nationally-agreed approach to exportation.

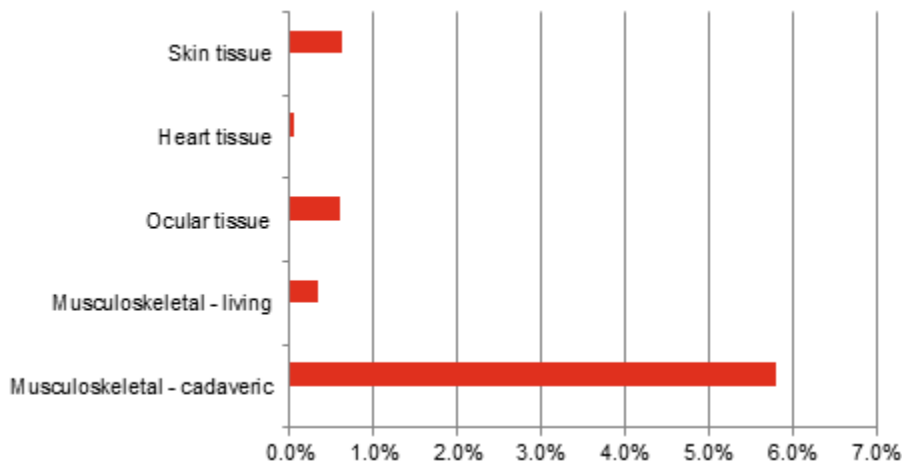
3.1.5 Tissue loss

While tissue loss exists, as a result of expiry discard rates and allograft return policies, it is not a major contributor to the supply issues present in the sector. Across all tissues, 1.9 per cent of tissues are discarded as a result of the expiry date being reached²⁴. This is mainly attributable to deceased donor musculoskeletal tissues, which report the highest discard rates (5.8 per cent).

Conversely, heart tissue has the lowest discard rate (0.05%), and live donor musculoskeletal tissue has the second lowest discard rate. The low levels of discard for live donor musculoskeletal tissue is due to the ability to screen donors ahead of collection, enabling contraindications (criteria used to identify transmission risk factors) to be identified early, and only suitable tissue collected. Slightly higher discard rates for deceased donor musculoskeletal tissues likely reflect expiry (due to a diversity of allograft types) and the associated scope for clinical preferences and needs to change over time.

²⁴ Tissue loss data does not include tissue loss as a result of tissues not meeting quality criteria. Aside from those tissues discarded due to expiry, bank stakeholders also cited that regulatory reasons, non-compliance with standards, non-viability, donor testing (such as an inability to conduct malarial testing on deceased blood) and lack of clinical need may lead to a collected tissue not being processed/stored.

Figure 6 - Percentage of tissues discarded due to expiry



Most banks accept returns for distributed allografts that aren't used by surgeons according to local policy. The exceptions are Barwon Health Bone Bank, Lions NSW Eye Bank, Cell and Tissue Therapies WA and Australian Biotechnologies who do not accept returns.

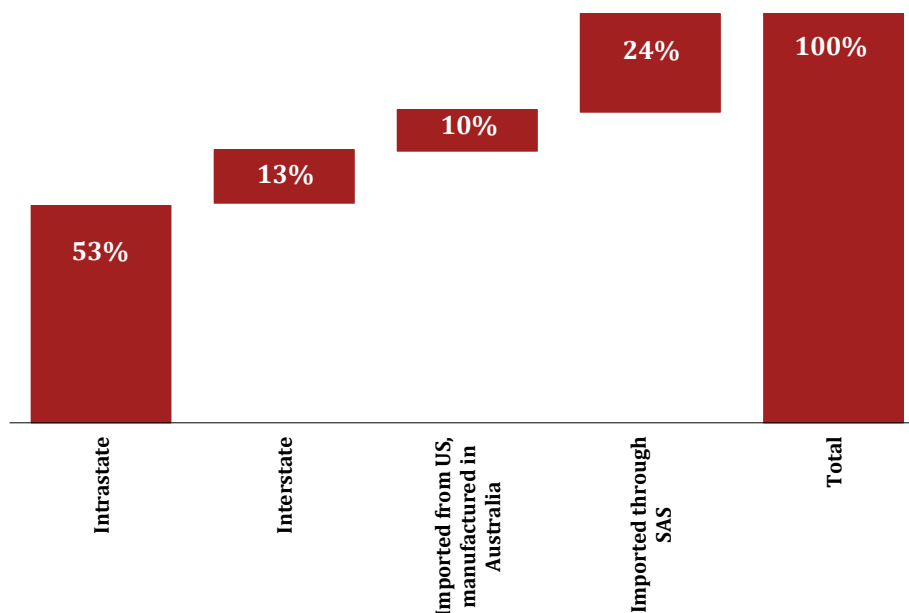
Ocular tissues are a special case; tissues are pre-cut specific to patients and so, typically can only be used by the requesting surgeon. Uncut ocular tissue returns are accepted by most eye banks, but are a relatively rare occurrence as tissues are usually used as distributed. Out of the ocular tissue banks, Lions NSW Eye Bank is the only bank that does not accept returns.

3.2 Tissue demand

PwC has identified that there is growing demand for all tissue types, and that supply of tissues does not meet demand for musculoskeletal, heart and skin tissue.

In analysing supply data, 2014 tissue demand was met through:

- imported allografts which constituted 24% of all supply in 2014, relative to total Australian supply in whole number terms
- an additional 10% of allografts are manufactured in Australia, but use tissue sourced internationally
- 53% of domestically-sourced allografts are provided to users within the states in which the tissue is collected
- an additional 13% of domestically-sourced allografts are collected within one state and provided interstate for use (Figure 7).

Figure 7 - Single allografts supplied by source (2014)

While the characteristics of supplied allografts differ between imported- and domestically-provided allografts, total numbers indicate a large unmet domestic need. Products are sourced from overseas via the TGA's Special Access Scheme (SAS) are for application in dental practice. There is also, as well as significant importation of TGA approved of demineralised bone matrix products for use in orthopaedic surgery. All of the 10% of allografts manufactured in Australia using internationally-sourced material are musculoskeletal.

3.2.1 Overseas tissue supply

In response to a lack of supply for musculoskeletal allografts from domestic banks, a private provider has secured TGA licensing to source international tissue from America to supplement its domestic supply. This enables the provider to supply a greater volume of allografts to Australian clinicians. Between 2011 and 2015, this has accounted for over 9,000 allografts to supplement domestic supply of musculoskeletal allografts.

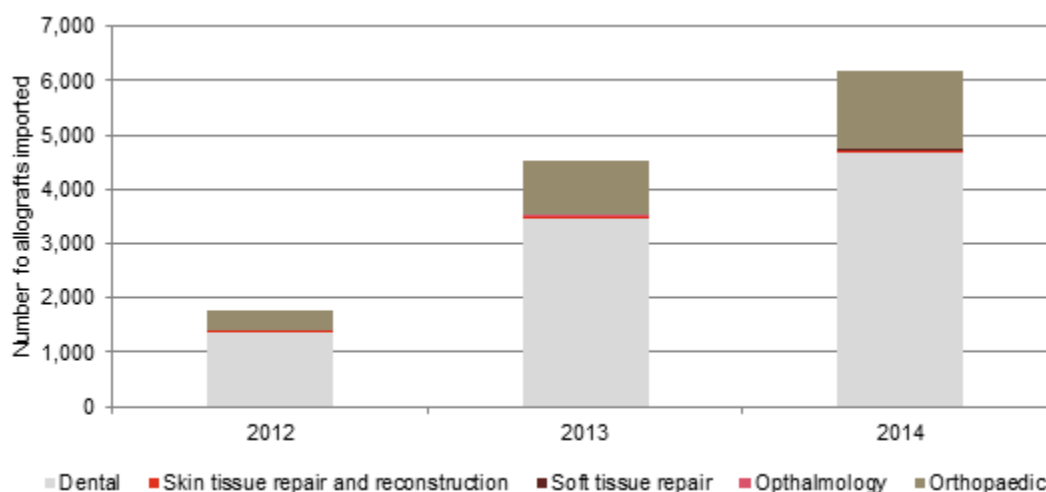
In addition, allografts included on the ARTG by other private providers can be accessed by clinicians, and may be produced using international tissue supply.

3.2.2 Allografts not available in Australia

This report identifies the supply and demand of allografts as reported by surveyed stakeholders. However, while allografts are primarily distributed through banks, surgeons will on occasion access human-derived tissue products through the TGA's SAS to supplement clinical needs, particularly for unique products not available in Australia.

Allografts that are currently unavailable in Australia, but are in demand by clinicians, provide insight into future demand. Analysis of these products may specify changing demand, or gaps in domestic supply that clinicians are seeking to supplement from elsewhere.

Clinicians can access the TGA's SAS to secure supply of non-ARTG allografts. Approvals are granted for specific patients, and so, limit the supply to a specific clinical application. Among products that can be accessed through the SAS are musculoskeletal and skin allografts as well as amniotic membrane for ocular use. Through FOI requests, PwC accessed information regarding all importation of allografts over the years 2012, 2013 and 2014 and categorised these into the applications for which they are primarily used. Over this short time frame it is clear that demand has grown significantly.

Figure 8 - Number of single allografts imported by year (2012-2014)

In particular, importation of allografts used primarily for dentistry applications has grown significantly. In 2014, this figure totalled 4,683 allografts and is driven by demand particularly from NSW and VIC, as shown in Figure 9.

Figure 9 - Number of allografts imported by state (2014)

With the exception of deceased donor skin imported, there is also demand for acellular dermal matrix. Ophthalmologic applications represented here are for amniotic membrane users only.

Based on recent trends, it is likely that imported allografts will continue to provide a significant part of Australian supply. It is important to note that imported products under the SAS are accessed through clinical disclaimers under which patients sign waivers regarding their use. In addition, the costs of imported products are borne by individual patients, as these are not included on the ARTG, and therefore not listed on the PHI Prostheses list. A growing trend towards SAS-accessed products marks a significant shift from traditional models and costing approaches for allograft supply that bear implications to the future sector. It also highlights that there exists a gap in the domestic supply of allografts.

3.2.3 *Unmet demand*

Stakeholders were consulted to understand what needs existed for allografts, and if there is currently unmet or suppressed demand. Perspectives were sought on specific allograft types that are not serviced by domestic supply and are subsequently substituted, or serviced through importation of allografts.

Consultations identified that amniotic membrane is imported by banks themselves: eye banks would occasionally (4-8 times per year) import amniotic membrane for corneal surgery (predominantly from New Zealand), as no other equivalent alternative was available in Australia. The use of amniotic membrane remains a preference among some surgeons who had formerly accessed it directly from Australian eye banks before production ceased due to the high regulatory burden of cost and compliance compared to benefit. There are also instances in which cryopreserved skin has been imported by Victoria following major bushfire events.

The majority of surveyed surgeons considered that surgeons do not repress demand, nor inflate demand due to a perceived lack of availability. However, approximately half considered that there is *some*, or *a lot* of hidden demand in which surgeons opt for the use of alternatives where they would otherwise have a clinical preference to use allografts.

PwC considers that the extent of hidden demand within the clinical community is poorly understood, particularly for musculoskeletal allografts.

3.3 *Musculoskeletal tissue*

The analysis of musculoskeletal tissues has been divided into two types: live donor allografts (i.e. femoral heads and associated processed products) and musculoskeletal deceased donor allografts (all other musculoskeletal tissues, including soft tissues, whole bone, and processed allografts).

3.3.1 *Tissue banks*

In Australia, there are five tissue banks that collect, process and distribute both live and deceased donor allografts (WA, QLD, VIC and two in NSW), and four tissue banks that collect and distribute live donor allografts only (one in Victoria, two in NSW and one in SA). Until 30 May 2014, the ACT Bone Bank collected and distributed small numbers of femoral heads. One bone bank is a unique case when considering musculoskeletal allograft production; it collects deceased and live donor tissues and, under contract, releases all tissues to a private provider for processing who then distributes allografts first to meet local surgical needs, but also to other surgeons if requested. As the private provider is also supplied live donor tissues from other jurisdictions for processing, they are themselves considered a tissue bank for this analysis.

3.3.2 *Tissue storage*

On average, the storage time for deceased donor allografts is between 2 months and 3 years, depending on the supply and demand of the individual banks. For live donor allografts, storage time ranges from 2 months to 2 years. Of the allografts stored, on average only 3.2 per cent of deceased and 0.3 per cent of live donor allografts are discarded due to expiry date being reached, ranging between 0-10 per cent for deceased, and 0-1 per cent for live donor, depending on the individual bank.

3.3.3 *Tissue distribution*

From consultations and TGA documents, PwC has identified that there is a high, unmet demand among surgeons. Banks have worked to scale up their supply, and as they have done so, demand has correspondingly increased as surgeons become aware of new availability of allografts. There is also variance in the type of allograft requested. High volume products such as milled bone are typically available upon request. Conversely, specialised products, such as custom bone allografts and tendon allografts are less available.

Based on data provided by banks on requests they receive from surgeons, VIC received the greatest number of requests for deceased donor allografts in 2014 and this was the general trend over the past five years. Over this period, WA has exhibited a significant decline in deceased donor allograft requests, while NSW has remained consistent. WA received the greatest number of live donor allograft requests. PwC did not have a complete dataset against which to match requests to NSW and QLD banks.

Comparing distribution to reported requests made by surgeons to banks, all states reported broadly meeting their demand, although VIC has some unmet requests. However, data provided does not capture demand that is not formally requested to banks, including sourcing by surgeons of allografts through the SAS scheme, or suppressed demand.

Figure 10 – Deceased donor musculoskeletal allografts distributed by state

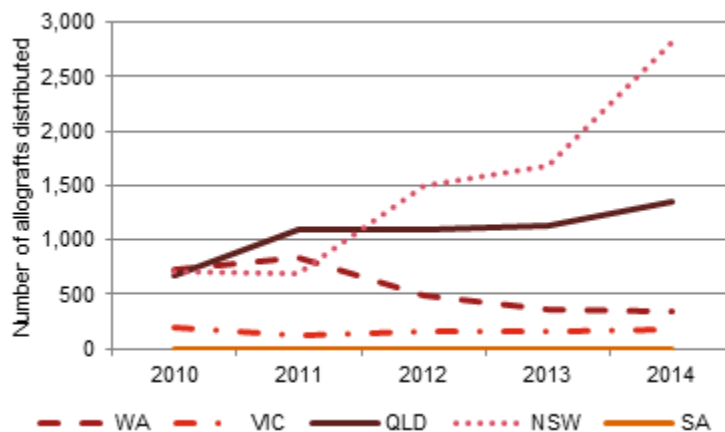
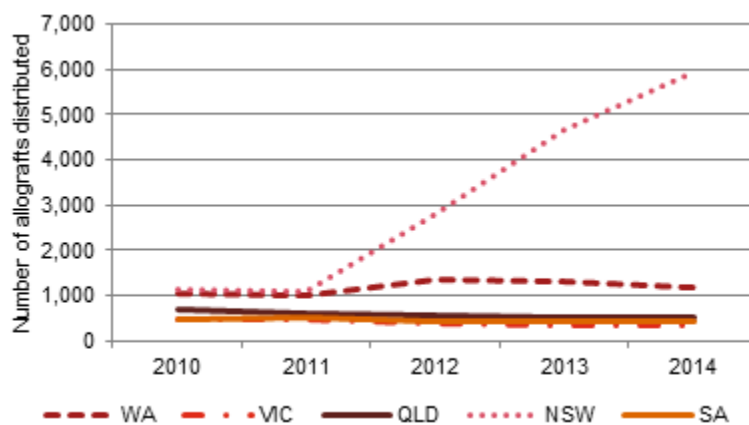


Figure 11 - Live donor musculoskeletal allografts distributed by state

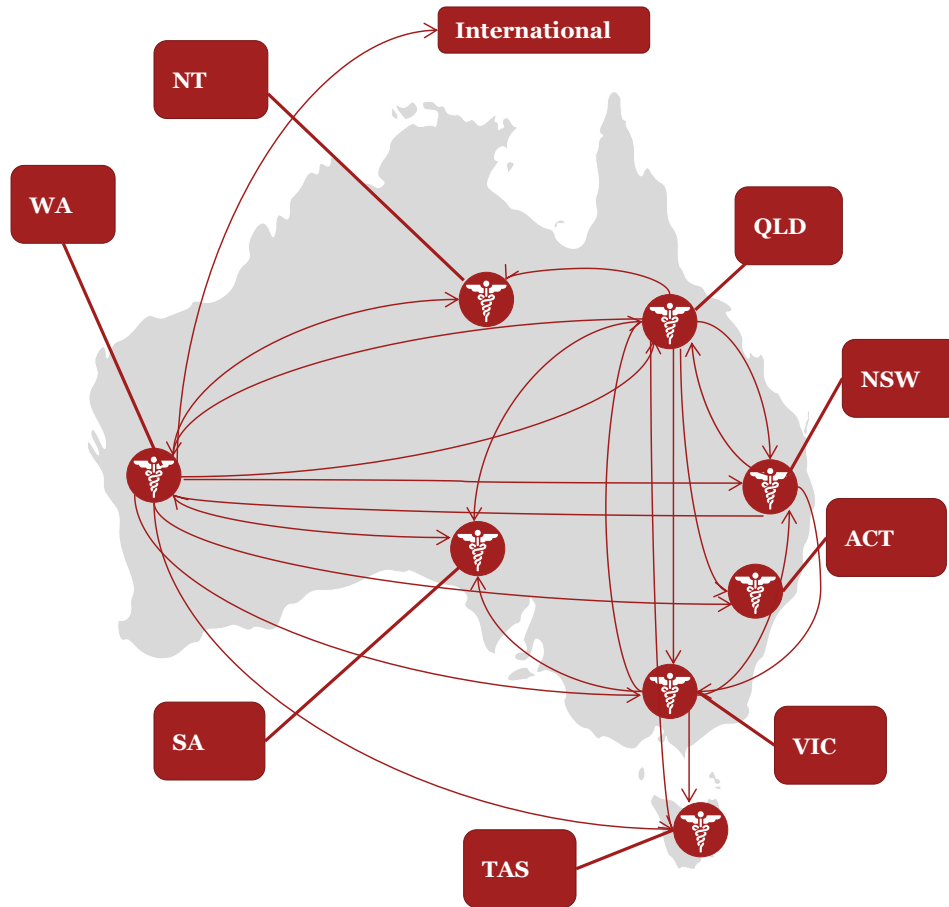


Of distributed allografts:

- 20% of allografts are distributed interstate and internationally, with NSW being the biggest interstate supplier of deceased donor musculoskeletal allografts.
- QLD supplies 22 per cent of its supply to other states (of which 12 per cent is distributed to NSW and 4 per cent to VIC).
- WA and NSW each distribute the greatest proportion of their total live donor musculoskeletal allograft supply outside of their state.
- WA has distributed 16 per cent of its supply interstate (10 per cent to NSW, 3 per cent to each of QLD and SA). WA is also the only state to distribute internationally, with 10

deceased donor allografts distributed for specific surgical cases in Singapore and NZ (in 2014).

Figure 12 - Interstate distribution of musculoskeletal allografts (over five years)



*Missing from this analysis is the one Bank's data.

3.3.4 Future demand

Orthopaedic surgeons and bone banks reported a marked increase in demand for musculoskeletal allografts. This was driven by a demand from clinicians to access processed grafts, including milled bone products, as well as cubes and putties, not previously available to practice. In particular, demand for demineralised bone matrix is likely to grow. The use of allografts in surgeries has also grown, with joint replacement surgeries, reconstructive and spinal surgeries driving demand.

Stakeholders also suggested that demand among dental and neurosurgery professions will likely expand. The availability of tailored products that are easier-to-use and come designed for specific applications (e.g. smaller quantities for use in dentistry) is enhancing demand. This observation was backed up by the significant increase in dental products sourced from overseas through the SAS. Demand for non-irradiated bone is considered to remain relatively static, with its application a preference among specific clinicians.

Newer technologies and allografts identified by stakeholders include demineralised bone matrix and bone gel. In the longer term, 3D printing ('bioprinting') is expected to provide fit-for-purpose grafts for bone, tumour and spinal implantations for reconstructive surgical procedures.

3.4 Ocular tissue

3.4.1 Tissue banks

Ocular tissue includes cornea, sclera and lamellar grafts, and is distributed from eye banks in VIC, WA, QLD, NSW and SA. VIC and WA banks are non-government banks, while QLD, NSW and SA are public banks. ACT retrieve a small amount of ocular tissue and provide it to the NSW Eye Bank for processing and distribution.

3.4.2 Tissue storage

On average, the storage time for ocular tissue ranges from 2 days to 21 days, depending on the supply and demand of the individual banks, as well as whether the banks utilise normothermic or hypothermic storage (shown below). Of the tissues stored, on average 0.6 per cent of ocular tissue is discarded due to the expiry date being reached. This ranges from 0 to 2 per cent discarded depending on the individual bank.

Cold storage (0-7 days) ²⁵	Normothermic storage (6-30 days) ²⁶
QLD ²⁷	WA
SA	Vic
	NSW

3.4.3 Tissue distribution

Eye banks have a structured approach to managing supply and demand for ocular tissue. Banks do not administer a waiting list; rather, surgeries are scheduled ahead of time, against which the bank will match tissue requirements. As banks have a good understanding of likely donations, staff work closely with the ophthalmology community to communicate any supply concerns and scheduling issues.

If, for some reason, the local supply of corneas is not met, surgeries are rescheduled unless it is an urgent case, however emerging practice is that an interstate eye bank will supply the necessary corneas to the local eye bank to meet the case load. The use of normothermic storage has helped banks to provide certainty in supply and enable them to better plan. Surpluses are managed among other eye banks, as well as through slowing collection of corneas (through temporarily adjusting donor selection criteria to only collect from the most clinically desirable donors) to match scheduled surgeries.

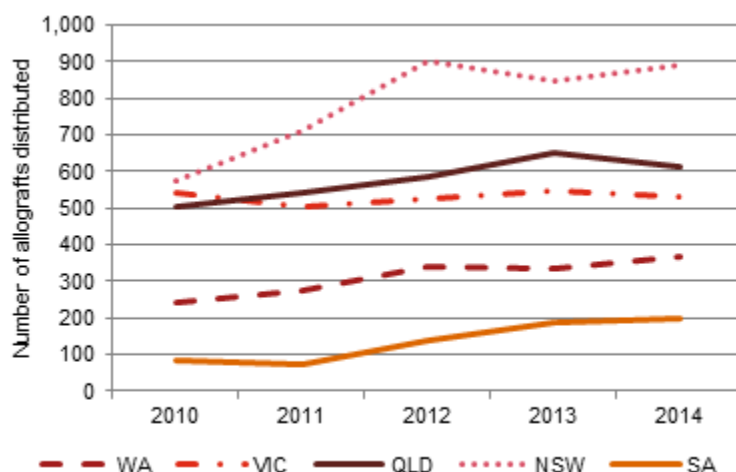
Overall, the number of ocular tissues distributed over the last five years has exhibited an increasing trend. NSW has consistently distributed the highest amount of ocular tissue. SA has distributed the least amount of ocular tissue over the last five years. Each bank has grown its distribution capacity to meet a growing clinical need for ocular tissue. Notably, NSW has undertaken significant efforts to address logistical and operational barriers to improve its service, particularly in improving its access to potential donors.

²⁵ Rated to 14 days but actually used routinely up to 7 days

²⁶ Can be used earlier than 6 days under exceptional (urgent) release. Average in Australia is 14-21 days, to a maximum of 30 days.

²⁷ QLD plans to submit its dossier to the TGA in June 2016 to adopt normothermic storage for ocular tissue.

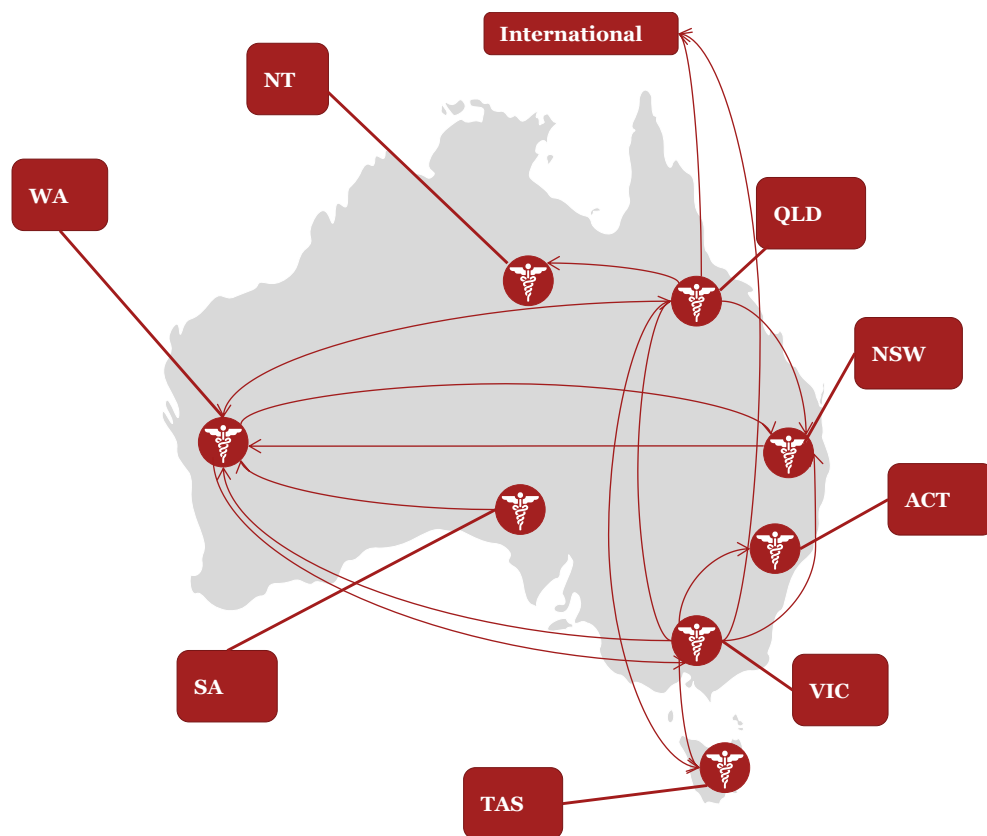
Figure 13 - Ocular tissue distributed by state



Of all the ocular tissues distributed by Australian tissue banks:

- ocular tissue constituted the highest number of internationally distributed tissues over the last 5 years (109 tissues, 29 of which are from QLD and 80 sourced from VIC). All were distributed directly to the NZ National Eye Bank (an EBAANZ member bank)
- 6 per cent of collected tissue is supplied interstate
- VIC distributed the most ocular tissues interstate (319 tissues), most of which were to Tasmania, which does not have an Eye Bank; 12 per cent of its total supply.
- This was closely followed by QLD, which provided 290 tissues, comprising of 10 per cent of its total supply. Partly, these movements can be attributed to the larger populations and capacity of banks to secure and store ocular tissue.

Figure 14 - Interstate distribution of ocular tissue (over five years)



3.4.4 Future demand

Ophthalmologists and eye banks reported that there is an increasing demand for corneal transplantation due to the improved clinical outcomes of surgical techniques using partial thickness lamellar transplants. This has effectively 'lowered' the threshold in which ophthalmologists can utilise allografts to treat patient cases, increasing the overall demand. Additionally, the increasing age of the population means that those accessing or needing corneal transplants has grown, and may increase the pool of patients requiring a new transplant over their lifetime.

Newer technologies, approaches and allografts identified by stakeholders include:

- Amniotic membrane, which is currently imported under the SAS, and has an underlying domestic demand not currently serviced within Australia
- Cell-based therapies, including:
 - artificial corneal material which is used as a last resort among clinicians
 - bioengineered corneas, which may not be readily available and used for 10-30 years
- Cross-linking for keratoconus to stem collagen fibre degradation, potentially reducing the number of keratoconus patients requiring transplant into the future (these effects are not yet known)
- Tissue-matching technology to match donors to recipients, which is increasing being revisited as an option for transplant among a sub-group of patients.

3.5 Heart tissue

3.5.1 Tissue banks

Heart tissue is distributed from banks in VIC, QLD and NSW, of which VIC and QLD banks are multi-tissue banks. Until early 2016, WA had a not-for-profit, relatively small bank that processed heart tissue for implantation while exporting all of its tissue interstate to NSW and VIC. The NSW heart valve bank is also small employing only 1.2 FTE and being located at St Vincent's Hospital is part of the NSW Health System.

Collection of heart tissue is affected by limited supply. Many potential donors are unsuitable for donation due to contraindications, and prominently, age (donors must be younger than 65 years of age). Very small contributions to supply are secured from live donor tissue donations from heart transplant recipients.

3.5.2 Tissue storage

Though heart tissue can be stored for up to five years, on average, the storage time for heart tissue ranges from 1 month to 4 years, depending on the supply and demand of the individual banks, as well as the type of heart tissue. Of the tissues stored, on average 0.05 per cent of heart tissue is discarded due to the expiry date being reached. This ranges from 0 to 8 per cent discarded depending on the individual bank. These figures are distorted by the fact that WA did not accept returns for heart tissues due to the logistical barriers to doing so.

3.5.3 Tissue distribution

There is an ongoing unmet demand for paediatric heart valves, which due to varying valve size requirements, are always in shortage. An aging population, and increased survival rates into adulthood for patients with congenital heart disease, mean that there is also a growing demand for pulmonary valves. Demand for aortic valves remains for use in patients suffering endocarditis or older patients, however, xenograft and mechanical valve use displaces some of this demand (as aortic valves fail over 10-15 year periods, and so require later surgery). Due to the limitations in heart tissue supply, particularly for paediatric valves, between 10-50 per cent of requests are unable to be met.

Table 6 - Number of heart tissue requests and allografts distributed by state (2014, as reported by surveyed banks)

State	Number of requests	Number of allografts distributed
WA	6	3
VIC	15	13
QLD	100	59
NSW	156	106
SA	0	0

NSW has distributed the greatest number of heart tissues since 2012 through increasing its donor pool from heart transplant recipients. However, an overall comparison of requests and distributions of heart tissue shows that there is insufficient supply to meet demand across all states.

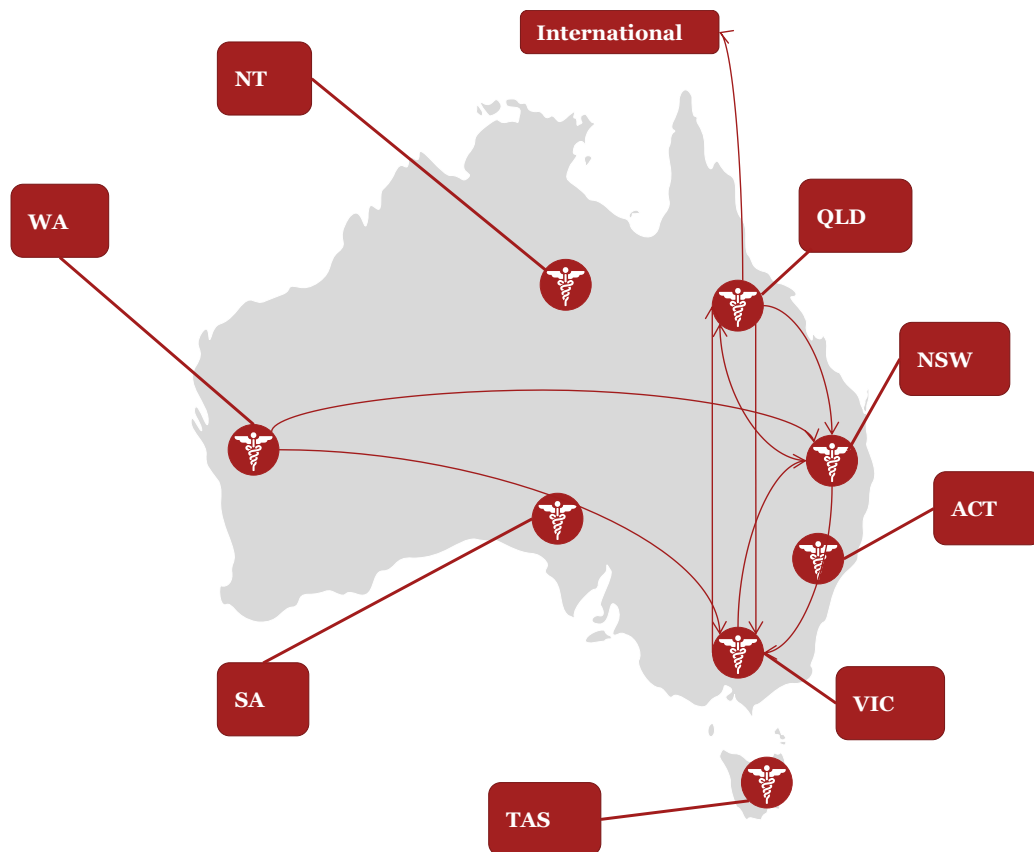
Figure 15 - Heart tissues distributed by state



Over the past five years:

- QLD has distributed the greatest percentage of collected tissue with 35 per cent of its collected heart tissues (131 allografts) distributed to other states
- WA donated all of its heart tissue to NSW and VIC, providing 23 valves over the past five years
- QLD distributed four heart tissues internationally.²⁸

²⁸ These instances of international distribution were for emergency and routine cases in 2014 at the request of the NZ heart valve bank

Figure 16 - Interstate distribution of heart tissue (over five years)

3.5.4 Future demand

Cardiac surgeons and heart valve banks noted the underlying unmet need for paediatric heart valves, particularly for neonatal settings. The lack of availability is limited by donor supply and no viable clinical alternatives. Due to the increased expected life of patients with congenital heart disease, demand for pulmonary valves is projected to increase. While aortic valve replacement is limited (due to the short lifespan of the valve once implanted), demand is expected to remain relatively static for use in older patients. Xenografts are often used as alternatives to aortic valve replacements where allografts are unavailable. Mechanical valves remain an alternative however, PwC was advised by a number of surgeons that due to the need for sustained anti-coagulant use, they are less desirable.

Sydney Heart Valve Bank identified that they are exploring local development of decellularised heart valves for Australian supply.

3.6 Skin tissue

3.6.1 Tissue banks

QLD and VIC are the only banks to store skin tissue in Australia. The banks support the public major burns units in their respective states, and will on request, dispatch skin allografts to surgeons in other jurisdictions.

Skin allografts are used to treat burns victims, and as such, are in high demand particularly following disasters. Burns surgeons cite an ongoing shortage of skin tissue in Australia, which is confined for use by surgeons in specific cases; much more would be used in clinical practice if it were available. VIC bank suggests that 10 times more skin tissue would be used in the state if it were more available. In periods of significant unmet need, for example following the 2009 Victorian bushfires, cryopreserved skin is imported from the USA.

Availability and a desire to improve burn patient outcomes has led to the development and use of synthetic skin dressings and autologous skin grafts. Notably, the development of cultured epithelial autograft (CEA) has displaced the need for use of deceased donor skin among other burns units (WA, SA). NSW is looking at adding skin tissue to its donor collection over the next 18 months.

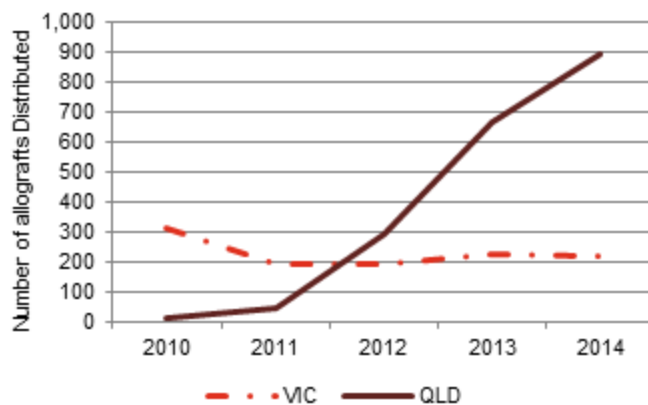
3.6.2 Tissue storage

The reported storage time for skin tissue ranges extends up to 1.5 years, depending on the supply and demand of the individual banks. Across the two banks, between 20-50 per cent of skin tissue is discarded due to processing reasons including regulatory and professional standards barriers, donor testing and logistical constraints. Less than 1 per cent of skin tissues are discarded due to the expiry date being reached.

3.6.3 Tissue distribution

VIC has been the most consistent supplier of skin in Australia and has received an increasing number of requests since 2011, notably in most recent years. Comparatively, QLD has significantly increased its skin tissue distribution over the last five years due to an increased capacity to retrieve and make available tissues.

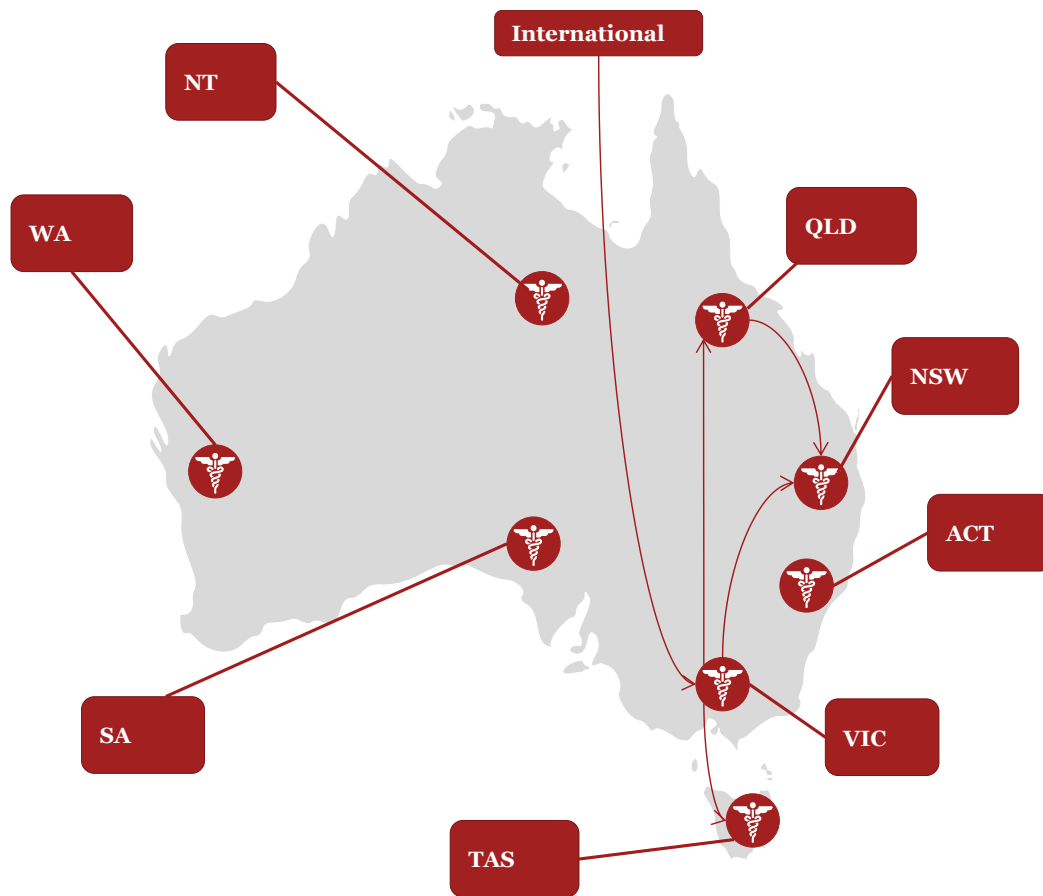
Figure 17 - Skin tissues distributed by state



Over the last five years:

- requests for skin tissue made to the QLD bank have always been met. However, PwC were advised that the recent Ravenshoe gas explosion exhausted the QLD bank's skin supply
- VIC experiences a frequency of between 10-50% requests that are unable to be met due to insufficient supply
- QLD predominantly supplies intrastate, but does distribute to a single surgeon in NSW who has a preference for skin tissue
- the banks are continually working to enhance a stockpile of supply to manage peaks in demand such as has been witnessed in recent major burns events.

Figure 18 - Interstate distribution of skin tissue (over five years)



3.6.4 Future demand

Burns surgeons and the two major tissue banks report an increasing need to stockpile skin tissue, particularly for use in disaster settings. While skin tissue could be used in a greater number of applications – as it is currently rationed for use only in specific cases – the scale of demand is not well documented as all skin available is able to be utilised. Demand is partially offset due to the use of autografts, and dermal substitutes among other states, which limits demand to the eastern states only.

PwC is advised that with greater availability, skin tissue could be used in a greater number of burn cases (without having to ration supply), but also other applications, including breast augmentation surgery. A number of stakeholders advised us that while skin tissue demand is likely to be sustained over the next ten years or so, the emergence and increasing use of substitutes will likely displace this need within a 30-year time frame.

Newer technologies and allografts identified by stakeholders include:

- Accellular dermis, which is currently imported through the SAS scheme
- Artificial dermis matrices which incorporate cellular products
- Autologous tissue engineering, considered by some stakeholders to obviate future skin allograft use (over the next 30 years or so)
- Biobrane (synthetic dressing)
- Skin culture
- Bioprinting of skin

4 Challenges

PwC sought stakeholder perspectives on the operation of the sector, opportunities for improvement, trends and expected change. Through consultations, PwC has found that in many cases:

- funding arrangements are driving unintended outcomes, and constraining the ability of banks to remain viable and adapt to changing needs
- industry structures are inflexible to change.

Together, the structural organisation of the sector is hindering the efficient and effective operation of the sector, and has resulted in:

- competition, including government vs. government and government vs. non-government entities
- a lack of oversight and reporting mechanisms
- inconsistent standards in donor selection and how these are applied in securing safe supply.

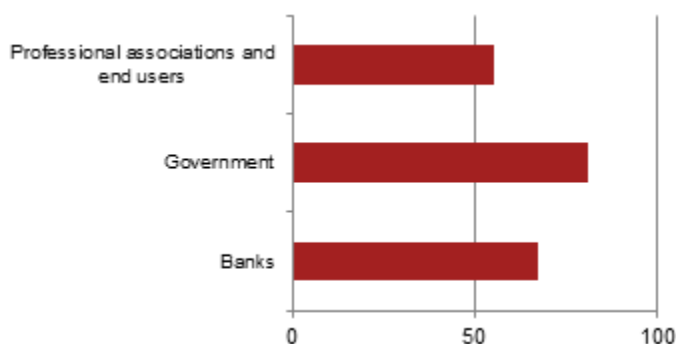
This section presents challenges identified by stakeholders through consultations.

4.1 *The need for sectoral change*

Consulted stakeholders identified many of these challenges and pointed to a wide range of barriers to the efficient operation of the sector. The majority of stakeholders communicated to us a strong need for change.

Of banking stakeholders consulted, only 36% considered that the future supply of tissues will match future demand. Eyes are likely to meet any future Australian demand. The importance of reform to promote an efficient and effective system was widely-acknowledged by all categories of stakeholders asked. As Figure 19 shows, government stakeholders ranked the need for sectoral reform highest followed by bank and professional association and end user stakeholders.

Figure 19 – Reported need for sectoral change (average ranked level of importance for sectoral reform (on a scale 0 to 100) by stakeholder groups)



The perspectives and insights of stakeholders as to why these challenges exist are presented in the following chapter.

4.2 Financial sustainability and cost recovery

Differences, distortions and deficiencies in the funding structure for the sector have been a major shaping factor in the current sector structure and trajectory. The financial sustainability of the sector is structurally unviable under the current funding model.

4.2.1 Financial sustainability of the sector

Financial viability of banks within the sector is unsustainable over the long-term and hinders the ability of the sector to invest in technology and meet changing clinical needs. Many consulted stakeholders considered that this is due to banks operating on an “uneven playing field” given the difference in jurisdictional funding arrangements.

Many banks are operating at, or near to a loss. Stakeholders considered that the financial deficit of banks is linked to the ability to secure revenue in a given year, manage ongoing and increasing operating and regulatory costs. While the cost recovery mechanism should theoretically cover all costs, banks cited an inability to incorporate capital improvements, research and development as barriers to viable operation, as well as an increasing reliance on in-kind support. Some banks pointed to the increasing compliance requirements under the TGA as a major impact on their operating costs, including the long lead time required to achieve regulatory approval for products (upward of twelve months). Others noted these costs but did not consider them a major burden given the ability to directly pass through these costs under the cost recovery framework.

Cell and Tissue Therapies WA advised PwC that they ceased operations following the expiration of their TGA licence in March 2016 due to the regulatory burden and costs of operation.

The differing models within jurisdictions also present discrepancies in the cost recoverable amount, and ability for banks to invest and sustain themselves. Across Australia’s tissue banks there are:

- state-funded banks operating with block funding (a set baseline budget for operation) or through a cost centre (a budget administered through a government entity, some of whom operate with a requirement to return surpluses to their respective Treasury)
- public banks surviving on cost recovery and ‘in-kind’ support, such as being provided their premise or administrative costs by the hospital they are co-located with
- private provider that processes deceased and living donor musculoskeletal tissue to meet local jurisdictional needs, and also processes living donor musculoskeletal tissue sourced from and provided to other jurisdictions
- not-for-profit banks who primarily operate on cost recovery and also receive funding from organisations like the Lions Committee of Management and charitable donations.

Different funding models present different capacities among banks to sustain and provide tissues for clinicians. This also produces different needs in cost recovery, and ability for banks to invest in newer generation products and maintain outreach with clinicians and potential donors. The varying profile, and viability, of banks is also influenced by the types of tissues they provide; the two major multi-tissue banks in QLD and VIC effectively manage a national stockpile of skin, while others provide individual tissue types.

In contrast, the NSW Government has a contract with a private provider for the provision of some musculoskeletal tissue banking services. The terms of this arrangement are commercial-in-confidence.

4.2.2 Cost recovery

While cost recovery should provide an equal and transparent source of funding across all tissue types, consultation revealed this was not the case. Rather, significant differences exist

in the way cost recovery is understood and applied, resulting in significant differences across the sector.

Cross-subsidisation as a mechanism for funding

Discussions with tissue banks uncovered that in some tissue banks cross-subsidisation from femoral head collection is used as a primary mechanism for supporting the revenue for banks. Despite the existence of a cost recovery mechanism for all tissues, some banks relied upon the costs recovered for the supply of femoral heads to offset the costs of other tissues to ensure that total operating costs were met. PwC suspect that this relates largely to the high volume in terms of availability and demand of femoral heads which ensure cash flow for these particular banks. For one major bank, femoral heads accounted for approximately 60% of revenue, and represented the most cost-reliant tissue provided. While this bank is working with business advisors to better develop their supply and demand forecasting and diversification of products (into tendons, skin and cardiac tissues), the reliance on femoral head collection was a significant driver of their financial viability.

Reported 'buffers' embedded within the PHI price for femoral heads enable some banks to plan and support other tissue distribution activities. A large number of consulted stakeholders noted that the introduction of a private provider that is expanding its scope to collect femoral heads inter-jurisdictionally was impacting on their ability to remain financially viable due to the cross-subsidisation practice described above..

Other tissue products – skin- are life-saving and only used within the public hospital system. The lack of market from private elective surgery makes it distinct from drivers in musculoskeletal products, and requires that public funding support its collection and distribution for viability.

PwC also identified discrete instances of past practice in which public patients were not charged for tissue provision. In one case, a bank provided 50% of its tissues to private patients, and the other 50% to public patients, from whom the costs were not recouped. This bank has advised us that they have since amended their practices to capture these patients, but had been absorbing these costs over a number of years.

Bank benchmarking

The PHI Prostheses List is the pivotal funding source and model upon which each bank sustains itself, however banks apply the model differently for a range of reasons. Some of the reasons are that some banks don't wish to be seen to be making a margin on prices or to be pricing themselves 'out of the market' by pricing higher than their peers. In both these instances, these particular banks are referencing the PHI process of other banks to 'benchmark' the cost of their tissue against others. In doing so, they are first identifying 'what the price should be' rather than applying the true costs of the service.

A number of banks identified that the costing of tissues had been assessed by parties external to their operations, but that the costing may require periodic reassessment to incorporate changing operating costs. Other banks lacked the ability to appropriately capture operating costs well.

Self-regulation of fees: banks limiting amendment applications and applying different accounting approaches

While some commonalities exist in the way banks define cost recovery, banks appear to be approaching the mechanism of recovering costs in markedly different ways. Some banks would back-cast operating costs and divide it by the average number of distributed tissues to come to the estimated cost recoverable amount, while others would undertake a bottom up cost allocation for each allograft type. A number of smaller banks stated that greater clarity on cost recoverable components would assist them to improve the way in which they account for, and can claim for the cost of providing tissues.

In addition to the differing practices for applying cost recovery concepts, banks are not making full use of the amendment application process for PHI listings. The PHI Branch will accept amendment applications twice per year, but have advised us that applications received from banks are fairly limited. PwC suspects that this is partly due to the paperwork requirements of preparing an application; many banks cited document preparation as an additional administrative burden to everyday banking responsibilities.

4.2.3 Other factors affecting financial sustainability

Storage of tissues

One of the stark differences observed in this review was of the delays in cost recovery due to prolonged storage potential of different tissue types. Skin and heart tissue, in particular, require significant ongoing storage costs which are not experienced in eye banking due to their management of demand and limited tissue 'shelf life'. Many other tissues, on the other hand, require longer-term storage (up to five years), and have costs reimbursed upon implantation. This has major issues on a bank's cash flow.

This means that banks are absorbing the costs of storage in addition to lost revenue from any discards, or returns, before they are able to access PHI reimbursements. The projected demand is also poorly known among banks, which affects the bank's ability to forecast, plan, and estimate cash flow over time. One major bank has brought in advisers to assist with their business planning and cash flow management.

Economies of scale- processing capacity

The scale of tissue collection significantly affects the ability of a bank to provide, invest and continue outreach for its tissues. Smaller, single-tissue banks (non-ocular) were under the greatest financial pressure and regulatory burden. For those banks collecting femoral heads, the ability to scale up operations and subsequently support further investment is limited.

Smaller banks also expend similar regulatory and baseline operating costs as larger banks, but without scale, are constrained in their ability to adapt. Whereas, larger multi-tissue banks reported the ability to capture clinical, regulatory and governance synergies by processing multiple tissue types.

Price-setting for public sector

As a central body for setting the cost recoverable price for tissues, the PHI also acts as the benchmark to which the public sector reimburses tissue banks. In this way, the PHI Branch also 'in effect' sets the public sector costs for tissue use; a major source of both revenue and expenditure within state health systems.

Research and development, improvement costs not covered

The costs of research and development are not covered under the cost recovery mechanism of the PHI. Many banks noted that their ability to supply clinicians with newer products require upfront investment that they are unable to support under existing public funding arrangements. An inability to fund investment through public funding mechanisms is one of the sector's greatest challenges identified in this review.

The lack of investment or seed funding through existing funding structures was a barrier for many banks to their ability to invest in research and development, or in capital to develop newer generation products. Many banks producing musculoskeletal tissues were aware that they were lagging behind clinician expectations and forcing them to seek supply elsewhere. Those banks which have secured private funding have seen a significant increase in demand for their newer-generation products and have increased market share.

Examination of the tissues bought in from overseas through the SAS clearly indicates demand for technologically enhanced products which are not currently available through Australian banks.

4.3 Cooperation among banks

Differences in standards, approaches and jurisdictional practices has led to inconsistent cooperation among banks.

4.3.1 Inconsistency of approach

Consultations revealed that banks employed different approaches in working together to meet supply needs. In some cases, formal Memorandums of Understanding existed, while in others, engagement between banks was ad-hoc. Others again did not engage across borders. Additionally, PwC uncovered examples of surgeons bypassing local banks to secure allograft supply from interstate banks.

While cooperation, where it existed, appears to meet supply needs, there is no national coordination of supply. Cooperation largely appears to be based on relationships rather than formal structures. Analysis of SAS requests suggests that a significant number of surgeons bypass banks. The exception to this is eye banking which has in place formalised agreements for supply and distribution of corneas between states.

4.3.2 Inconsistent standards in donor acceptance

The structure of state-based banks has encouraged some ‘competition’ among those banks accessing and supplying donated tissue. Different interpretations of the regulatory requirements has effectively created different supply pools within the population. This occurs because though all banks meet TGA requirements, some voluntarily have higher requirements than those required by the TGA. For example, the application of different selection criteria between jurisdictions has resulted in some supply of donated tissue to interstate banks, where a local bank would not accept that tissue due to their criteria.

For example, stakeholders advised of examples of potential donors not meeting selection criteria in Victoria but who did get accepted in Queensland. For example, Queensland have accepted a donor where the GP suspected the donor experimented with recreational drugs, whereas Victoria did not, which is a clinical risk management decision, not a capability one.

In addition, the lack of capacity to secure consent and retrieve tissues in some banks restricts their ability to collect live donor tissue from hospitals within their local area. As a result, other organisations are filling the void left by local banks and collecting otherwise discarded tissue.

With respect to interstate distribution of tissue, there are instances of clinicians ‘shopping around’ among banks when seeking a particular tissue, where in other cases this function is facilitated by the tissue bank itself. While not cost driven, banks are potentially missing out on understanding local clinical needs through diverted demand of clinicians whom are accessing and maintaining relationships with different banks.

4.3.3 Interaction of private providers

The entrance and growth of an Australian private provider has affected the way in which services are provided across states. Some banks report that the expansion of the private provider’s services into other jurisdictions is having an impact - particularly as a result of the increases in their collection of femoral heads from other states.

The addition of the private provider’s engagement in femoral head collection within other jurisdictions complicates the ability for state oversight. The shift in musculoskeletal tissue provision has expanded at a pace with which public and not-for-profit banks have not kept up. As the Australian private provider starts collecting from hospitals that have previously provided (and in one case, currently provides) femoral heads to public tissue banks, there is

concern about potential ‘competition’ for public and not-for-profit banks in retaining their local supply of femoral heads. This could undermine the financial viability of public and not-for-profit banks in their ability to continue to support services for other tissues.

The counter argument made by the Australian private provider is that in many instances femoral heads had not traditionally been collected in many jurisdictional hospitals or locations by local tissue banks and that there was no foreseeable likelihood of this happening given the resources of local banks. Hence, tissues that have previously been going to waste were now being retrieved and those hospitals involved were glad it could now be collected and used.

Many stakeholders considered that the inclusion of private providers, or clinical access to tissue from overseas private providers enables those providers to focus on production of more ‘financially desirable’ products and to capture future demand for these particular musculoskeletal tissues. While many stakeholders acknowledged that private providers are able to produce biotechnologically-enhanced tissues not otherwise produced by local tissue banks – and so, provide a valuable clinical service and critical supply to the local market – many raised concern over the long term effect of this process whereby private providers (on or off shore) could potentially secure musculoskeletal tissue supply as a privately-controlled commodity.

Foremost, stakeholders were concerned over the lack of transparency, and potential market dominance of the one Australian provider. Consultations uncovered that a handful of public hospitals in other jurisdictions are also exploring options for collection of femoral heads by the same private provider. Some stakeholders noted that the efficiency and professionalism of the Australian private provider’s operations, and their ability to boost local supply was a positive step forward for the sector. Others viewed their operation as undermining the altruistic principles of the sector, specifically pointing to the potential for trade in human tissue. At the heart of this issue was concern of a lack of transparency and governance over the operations of the Australian private provider as the contract levers are at the behest of one jurisdiction and individual hospitals in other jurisdictions. Under the existing arrangements, some States identified that their regulatory power was limited, and that without engagement in the governing contract, had limited ability to build in oversight into musculoskeletal policy or reporting on service provision emerging in their state.

4.3.4 Professional practice

Eye banking has clear lines of organisation in its connections with clinicians and across eye banks through the EBAANZ. These relationships enable the eye banks to clearly understand clinical needs, adapt to those needs and continually improve practice. The EBAANZ produces standards and reporting, and holds annual conferences which connect ophthalmologists with banks and researchers and enables the sector to have clear oversight. Additionally, EBAANZ is closely affiliated with the Global Alliance of Eye Banking Association, which captures all European, North American and South American banks.

While the Biotherapeutics Association of Australia (BAA) act as the professional association for musculoskeletal tissue there was great discrepancy in opinion among the members as to its organisational and coordination capabilities. While our review is not considering the merits of the BAA, it was clear from some stakeholders that tissue banking did not have a cohesive national voice that spoke to the sector’s needs, nor coordinated activities that furthered practice in the sector.

Among the reasons identified was that sector views were diverse and needs across jurisdictions and clinical communities differed significantly. It was also suggested that there was limited capacity within the BAA itself to be able to commit significant resources to undertake professional activities, create standards, or undertake reporting and analysis roles on behalf of the sector. PwC understand that the BAA is supported by generous in-kind support; while EBAANZ has a part-time secretariat (funded by an eye bank not EBAANZ itself) BAA does not. Overseas professional societies have full-time secretariats in Europe and the US.

Others advised that BAA has represented the tissue banking sector well as its peak body for a number of years. BAA has held practice improvement related scientific meetings, has provided services to its tissue banking community (guidelines, recent bio-vigilance framework) and has interacted on behalf of its membership in national and international fora.

The issue remains that the tissue sector is divided on the effectiveness of its peak body and this matter must be resolved if the sector is to be consistently and collaboratively represented both nationally and internationally. The Australian professional societies will also need to consider how they will meet the needs of the multi-tissue banks which have increased from one to three over the last three years.

4.3.5 Allocation and equity of supply

Banks have adopted a similar approach in each jurisdiction as to how they prioritise and allocate tissues. For eyes, this is codified through the EBAANZ. First, intrastate needs are prioritised through formal relationships, then intrastate informal needs (such as ad hoc calls from surgeons), followed by interstate (depending on bank relationships) supply.

While the process appears to work well to meet surgical needs for tissues, clinicians are not connected into the availability of tissue supply (especially for musculoskeletal and heart tissues). It is not always clear when and how tissues are collected and distributed, which has the effect of reducing clinician confidence in local supply, and limits oversight of upcoming shortages or tissue availability. Some considered that the traditional model of supplying locally and responding to a small pool of surgeons is ill-equipped to support any national or regional approaches to matching tissue supply to changing demand needs.

Eyes, however, are scheduled in, and planned in advance of tissue release, enabling clinicians to understand local availability and build confidence in that supply. Eye banks are able to quickly share information on local needs, and availability.

PwC found some instances of surgeons repressing their requests to local banks for tissues following experiences of low availability; these surgeons were moderating their requests to banks, “double guessing” what might be available, and seeking to not dwindle their local bank’s supply unless absolutely necessary. Other instances existed where a local lack of products had resulted in surgeons directly dealing with banks in other states, unaware of change in supply or products available locally. As a result, both banks and clinicians have a poor understanding of tissue needs and availability, despite an effort of outreach by both communities.

In addition, the various funding models across jurisdictions raised issues of financial discrepancies in cost recovery for some banks when tissues are distributed inter-state. Larger banks, funded through state governments appear to shoulder the costs for interstate supply of tissues, especially the supply of skin and heart tissues. While clinical preferences within jurisdictions differ (Western Australia does not use skin tissue or heart valves), some stakeholders considered that skin and heart tissues were banked for the broader national good and that while tissues operate on a cost recoverable basis, the capital, and other costs of running a bank are worn by those states providing these tissues.

4.3.6 Education and training

At present, there is no national qualification or certification requirement among tissue banking professionals. While this stems from jurisdictional requirements which designate different requirements for skills or qualifications for retrievalists, a number of stakeholders identified that the lack of national qualification recognition means that the sector is lacking professional identity. For example, in Tasmania, SA, NT and the ACT, retrievals for tissue

must be undertaken by medical officers (typically a surgeon); in WA a medical officer must be present, and in other jurisdictions retrievals can be undertaken by non-medical officers or authorised officers (such as bank, nursing or mortuary staff).²⁹ These stakeholders were not identifying a training deficiency – staff in the tissue banking sector are highly qualified – rather, it meant there was no professional accreditation, or opportunity among bankers themselves to act as a specialised sector in itself. A handful of stakeholders identified that if demand for tissues continues to grow, there may be a need to develop a skilled workforce profile that recognises the specialised skills of tissue banking staff.

These stakeholders considered that there may be efficiencies in planning and retaining professional tissue banking staff who would be equipped to undertake and manage all aspects of tissue banking. Centralised recognition or accreditation would also make workforces translatable across jurisdictions, and aligned in practice if jurisdictional retrieval requirements were consistent.

4.4 Legislative harmonisation

Tissue donation, banking and transplantation is not governed by a national policy framework. Each state-based legislative framework differs, and contains inconsistencies and ambiguity that don't reflect change in the sector. Notably, this is reflected in the inability of legislation to remain current to technology and changing practices within the sector. Aspects of sectoral legislative uncertainty are explored as follows.

4.4.1 Implicit extension of responsibilities of PHI

Due to a lack of regulatory power, or of a framework that meets the challenges of managing new entrants and products, many states are implicitly looking to the Commonwealth to provide leadership and ethical oversight.

Principles of cost recovery for tissue collection and distribution are embedded within each jurisdiction's legislation. However, interpretations of 'non-profit trade' vary considerably, and the ability to 'run a surplus' or capture costs are not strongly governed within states despite a requirement within their own legislation to ensure for "non-profit" trade. Stakeholders conveyed to us that, as a result, states rely on the PHI process to ensure "non-profit" assessments are integrated in listed prices under an assumption that the PHI ensures that no buffer is achieved in cost recovery applications. In doing so, there is the assumption that banks are operating within the bounds of state legislation, and that ethical components of allograft processing and distribution are being abided by, despite state governments not having a role in the assessment process.

Jurisdictions also considered that in having a national agency undertaking this assessment, this would bring consistency to its interpretation. However, in doing so, stakeholders have created a gatekeeper role in the PHI to "monitor" not-for-profit trade of tissues that is not realised in Commonwealth legislation. Some stakeholders also considered that in the TGA's assessment for the supply of products that there is an implicit assessment of not only safety, but also the ethical procurement of tissues; which falls beyond the TGA's remit (discussed further in this section).

While jurisdictions hold responsibility for tissue banking, the implicit reliance on Commonwealth regulators, while not outwardly reported, indicates a significant gap in ethical frameworks and legislative interpretation against which banks can act consistently. This is compounded by the fact that neither the TGA or PHI process have the 'ethical' scope which is being sought within their official remit.

²⁹ Australian Organ and Tissue Donation and Transplantation Authority (2011) Report on the options for more effective eye and tissue retrieval, processing and storage: Prepared for the Chief Executive Officer Organ and Tissue Authority, July 2011

4.4.2 Ill-equipped to manage newer generation products

There is a lack of governance around and regulatory oversight for processing, manufacturing and distribution processes as they relate to biotechnologically-enhanced products.

Most jurisdictions noted that the legislation that bounds tissue banking within their states is dated and was established to function when human tissue use was transplanted as donated (like organs, did not incorporate a processing stage before use).

This has meant that legislative frameworks have failed to keep up with newer generation products (that are derived from human tissues, but involve significant processing stages) and subsequently left states with little oversight, regulatory power or ability to keep pace with surgical needs. For example, governance of allografts which are sourced from elsewhere, or are composite products (are part of a kit or are only partly-human derived) is largely unaddressed by existing state regulatory frameworks. Some states identified that it is difficult to measure how and when these products were used by surgeons due to a lack of reporting power enabled through their legislation.

4.4.3 Role of non-government providers

In some states, the role of non-government providers in musculoskeletal allograft provision was also impeded by their legislative frameworks. A number of jurisdictions identified that they were actively looking at reviewing their legislation to enable non-government providers to play a role in tissue collection and distribution; mirroring aspects of the NSW legislative model. For example, the Western Australia Government has undertaken a targeted consultation process to determine how flexibility may be incorporated into its legislation to enable commercial and non-profit providers to support ethical and sustainable tissue provision.

4.4.4 Marketing vs. education: prescribed and permitted

Legislative restrictions and differing interpretations of ‘marketing’ and ‘education’ in some states is creating ambiguity in the role of organisations.

In Queensland and Victoria, tissue banks are prescribed and oversighted by the state departments of health. Providers of tissues (anyone who provides tissues in that state whom are not a prescribed bank) are issued permits to distribute tissues within those jurisdictions, but operate under permitted boundaries. Some stakeholders considered that this imposed a major difference operationally in that prescribed banks were bound by strict interpretations in their ability to ‘market’ tissues. However, permitted providers (such as overseas suppliers) could effectively ‘market’ tissues in their education sessions to health professionals.

These stakeholders considered that the ability of local banks (prescribed banks) to meet local demand was limited by constraints on their ability to outreach to surgeons. However, our consultations with jurisdictions suggest this is most likely related to resource capacity of banks to engage with surgeons and overly conservative interpretation of ‘marketing’ rather than legislative barriers.

A number of stakeholders identified that private, international suppliers were increasingly seeking to distribute products within states. Some stakeholders identified that some suppliers had already been working for approval with states to refine the definition of ‘advertising’ within the reading of the relevant Acts to allow for their activity.

4.4.5 Make a profit

“For profit” terminology differs throughout the sector and attracts significant scrutiny within the sector. Foremost, this is driven by the opinion of many stakeholders that as an altruistic sector – based on altruistic donation – that there should be no association of profit in the collection, process or distribution of tissues. As already raised, this has had implications in the reading of “cost recovery” across organisations, and their ability to either run a surplus or to “make a profit”, where margins are delivered to shareholders such as state treasuries, or to reinvest in other activities. Many viewed that no organisation should be drawing any margin

at any point in the tissue distribution process, while others considered that the distinction lay in the functions undertaken; the actual collection of tissues should not “make a profit”, but that a return must be built into processing to support investment activities.

The scope to run an apparent surplus in the cost-recoverable pricing of distribution to enable reinvestment activities remains opaque, and is considered by some as “making a profit”. A number of organisations already use the “surplus” gained in musculoskeletal tissue to cross subsidise other tissue types while others saw it as an opportunity to reinvest in other sector activities, such as to promote donation, undertake greater outreach among surgeons, or drive research and development.

4.4.6 Ambiguity over regulatory power

The regulatory power within relevant legislation does not empower all jurisdictions to adopt and enforce oversight. Some governments reported capacity and responsibility gaps in their frameworks which disempowered their role in overseeing jurisdictional tissue provision. For example, PwC observed the importation of tissues to a large state operating prescribed banking and permit systems. The state authorities were not aware of the detail of the distribution of tissues into that state, and were not adequately empowered to regulate surgeons importing it due to a lack of reporting requirements and capacity to compel information. The state is effectively operating without full information on the trade and distribution of tissues within its jurisdiction, and with ambiguity over the powers to intervene and regulate it.

Different arrangements within jurisdictions also require only some banks to report and remain accountable to state departments, while others operate fully independent of government oversight. Some jurisdictions acknowledged that they had few levers with which to regulate newer organisations seeking to operate within their jurisdiction, and suggested that there was limited appetite for legislative change to enable it.

4.4.7 Scope for change

There are a number of implications that result from the lack of harmony and differing legislative approaches between jurisdictions. These are discussed below.

Figure 20– Average scale of government respondents who thought the following policy issues would benefit from a nationally-agreed policy position (0 = disagree, 100 = strongly agree)



Lack of shared, codified objectives

Stakeholders are passionate about their sector and there is a clear commitment to the altruistic nature of donation. However, tissue banking suffers from a lack of shared objectives.

Among stakeholders, PwC identified that many held differing perspectives as to the role and objective of tissue banking. Some considered it was to fulfil donor wishes first and foremost, while others took a clinical demand perspective as the primary driver. Others again had perspectives on the types of tissues which should be made available, and held specific views on biotechnologically-enhanced products, importation and funding.

The lack of shared objectives has stemmed from the absence of a nationally-agreed policy document which develops standards and objectives for banking practice to which legislative, service and funding frameworks can adapt to deliver against.

Without harmonised approaches, banking was considered by some to be reactive to needs, and always ‘catching up’.

Reliance on Commonwealth role

Government stakeholders considered that there was a national role particularly as it relates to tissue compliance, regulation for safety and pricing, and in work to harmonise approaches. With a significant gap in any policy settings that set objectives for tissue banking, many states looked to rely on Commonwealth interpretations, or regulatory roles to fill those gaps.

In addition to the assumed role in assessing “profiteering” under the PHI list, some stakeholders also considered that, without a national ethical framework, there are imbued assumptions of ethics within TGA assessments. These stakeholders considered that the TGA’s assessment for the supply of products not only considered safety, but also takes into account the source of that tissue and whether it was ethically procured. However, ethical procurement is only within TGA’s scope if it influences the tissues’ quality, safety and efficacy.

Additionally, the TGA is limited in its ability to assess products sought through the SAS for their ‘uniqueness’ to other products domestically available. They are therefore constrained in establishing justification for restricting clinician access to “like” products being imported. In particular, this can be the case for very similar products (eg. demineralised bone matrix) that are available in smaller quantities from international suppliers than are available in Australia.

A number of agencies indicated an openness to an expanded Commonwealth role in providing policy support to improve tissue banking; a role most of these stakeholder saw fell with the OTA. However, stakeholders iterated that if change were to occur the boundaries of state’s primary responsibility in health policy and governance must be respected.

4.5 Reporting and oversight

4.5.1 Oversight of use, trends and changes limited

With the exception of the EBAANZ, historically no centralised, national reporting mechanism exists for tissues. The Australian and New Zealand Organ Donation Registry (ANZOD) undertook to develop the first national picture of tissue donations in 2012. The registry collects de-identified donor information for each tissue type and aggregated reporting for transplants and recipients, collated through a Minimum Data Set Template. It has worked with the OTA and stakeholders to standardise terminology of tissues. No clinical or surgical outcomes are reported through ANZOD.

The lack of national oversight, particularly of trends in clinical use and needs, reduces the ability of the sector to adapt to those changing needs. In addition, a lot of value could be derived from insights gleaned from trends and movement of tissues.

Additionally, the aggregated tissue data types that are collected do not provide insights to demand for specific allografts, particularly for musculoskeletal tissues and the enhanced versions of these tissues. Rather, existing data represent the donation pathway, and not the processing aspects of tissue provision and how this delivers optimal patient care. Some stakeholders identified that reporting through ANZOD and EBAANZ duplicated reporting procedures and may result in disjointed data due to differing interpretations and data accuracy provided by banks.

While perceptions among stakeholders were that although the sector was managing with the current reports, clinicians saw value in a centralised reporting mechanism that would enhance the sectors responsiveness to changing needs. Improved reporting was also seen as important to building a case for funding within the sector and in improving biovigilance within the sector.

4.5.2 No standardised approach to accountability and monitoring

While efforts are made to improve the availability of information, no standardised approach exists for the tissue sector (eyes are standardised through EBAANZ processes). The TGA cGMP requires record keeping that traces tissues, and consultations unveil that banks indeed undertake reporting, including surgical, and sometimes, clinical outcomes, but the way in which this information is collected across tissue banks is inconsistent, and is not collected and reported nationally. Additionally, no reporting mechanism exists or is required to provide clinical insights to tissue use.

On the other hand, eye banking has clear reporting mechanisms through the Australian Corneal Graft Registry which is the longest existing registry in the world of clinical outcomes having recorded and tracked over 30,000 transplants over 30 years. It presents a comprehensive picture of corneal transplants across Australia and is used to inform clinical practice and identify risk factors.

The tracking and record management associated with distribution is as follows (as per tissue bank survey responses):

- Ocular tissue: Australian Corneal Graft Registry form is distributed with the tissue to be completed by the surgeon. All implantations are then recorded on the Registry indefinitely. Recipient follow-up occurs 2 months after implantation
- Cardiac tissue: In some cases, implantation data is recorded by the surgeon and sent back to distributing heart valve bank at 1 month and 6 months post-implantation
- Musculoskeletal tissue: Varying data recorded across banks; most sought surgical outcome reports, with some collecting clinical outcome information at periodic intervals post-implantation. Two banks reported that they sought clinical outcome information at 18 months and 2 years following surgery to identify any post-surgery infections, structural failure or other, and one bank has collected over 16 years of data of this type
- Skin tissue: Varying data is recorded across the two banks.

All banks identified that adverse events were reported by surgeons to the distributing bank and through the bank, on to the TGA. Banks also all recorded using utilisation forms or other to track allografts, recipients and implanting surgeons to map use of all allografts. Some banks identified that they checked in with hospitals to which they had distributed allografts which had not ultimately been used for an intended patient (due to a cancellation or other).

A range of barriers to standardise upward reporting were identified, including: a lack of requirement to do so; additional reporting burden; privacy of patients; lack of clinical follow-up (in terms of measuring tissue performance and difficulties in doing so, even if pursued); and lack of a representative professional body pursuing this.

Many banks identified privacy as the major barrier to implementing a national reporting mechanism for tissue banking. The issues associated with privacy across jurisdictions, and particularly in dealing with small volumes that could potentially identify donors and donor recipient information, were identified as a problem which was addressed for organ donation reforms, but would require significant change to overcome for tissue donation. Primarily this related to assurances of data management by smaller, and non-government banks.

Stakeholders identified additional issues relating to the increasing use of newer generation musculoskeletal tissues which can be pooled, or part of a compound tissue product, and so are more difficult to track from donation through to use and outcomes.

A lack of requirement for national reporting on financial information beyond their local arrangements compromises the ability of government to monitor the financial accountability and viability of the sector as a whole. Lack of transparency of the viability of tissue banking, and of use among clinicians limits the ability for banks and governments to respond to changing needs, including understanding improvements, trends, uptake, and importantly risks, for the use of particular tissues.

PwC are aware, however, that efforts are being made to bring standardisation to nomenclature of tissues in alignment with ISBT-128, and in developing standardised donor questionnaires.

4.5.3 Existing registries could be linked

Some stakeholders identified that there is scope to link existing registries to improve the way in which tissue outcomes are reported and monitored. For example, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) has the capacity to link to tissue bank data and connect tissues to their clinical outcomes. This would require a small amount of funding to implement, and could present retrospective information not previously captured. ANZOD was the other nearest registry to represent tissues, but as mentioned, does not capture clinical outcomes.

Without comprehensive reporting of implantation outcomes, banks and clinicians are unable to assess and measure risks, and inform clinical practice.

4.5.4 Understanding of clinical needs limited

Many banks expressed that they had links to clinicians, particularly through their own medical directors and advisory boards. However, due to different preferences and practices across the surgical community they did not have clear sight on future needs, particularly for clinicians whom may be potential users but have no present relationship with their local bank. While this was particularly evident in musculoskeletal tissue use, there was some evidence that the full needs of other clinicians, for example cardiovascular surgeons, were not fully understood.

Eye banks maintained a close connection to their surgical community through EBAANZ. The two burns units in Queensland and Victoria were also closely affiliated with their tissue banks.

Changes in the use of tissues are also largely unknown, or reliant on the expertise of a few surgeons. Stakeholders identified instances where surgeons use the SAS to secure supply of newer products, and that tissue banks were unaware of the true demand for these (eg. dental allografts). In other cases, a demand may exist for newer products, but surgeons were not communicating this.

Additionally, PwC encountered anecdotes of clinicians who either repressed their demand or did not engage with tissue banks due to perceptions of limited supply. A lack of feedback loop across the surgical community means that tissue banks are not, or have only a snapshot of potential demand. Clinical stakeholders to this review pointed to pockets of other surgeons whom they considered would be potential users of allografts, but were not engaged in their local tissue banks.

4.5.5 Lack of awareness among clinicians of tissue availability

Beyond the clinicians associated with tissue banks, the lack of broader surgical engagement means that there appears to be a low level of awareness of the availability of tissues. Clinicians recalled instances of engaging with tissue banks to later have difficulty in accessing supply, after which they did not revisit. The continuity of relationships between clinicians and tissue banks appeared to be most important in linking banks back to their users. However, for clinicians not long-affiliated with banks, there appears to be a general lack of awareness or engagement.

Secondary to this, the existing relationships between clinicians and banks drove bank responses to allograft needs. Banks appeared reliant on the clinical preferences voiced through these relationships to identify what products to pursue. Some stakeholders considered that this had the adverse impact of encouraging those clinicians whose needs were not met to use substitutes or access other avenues (such as the SAS) to meet their allograft needs. As a result banks serve a close community of clinicians and may not be servicing other market segments.

In addition, banks suffer from a lack of consumer-led change as there are limited user advocates voicing changed needs or practices to which banks must respond. The reimbursable nature of tissues through the PHI means that patients and clinicians are not influenced by price signals. Additionally, the differing clinical preferences across institutions are not voiced in a way that drives banks to respond to different allograft use. Clinicians and professional associations are also limited in their capacity to be able to advocate for change among their other responsibilities.

4.6 Standards and consistency

4.6.1 Supply constraint: Donor pool limitations

There were multiple factors identified through consultations which affected the supply of tissues. These are discussed below.

Multi-tissue donor identification

Many stakeholders considered that there were limitations in identifying the wider pool of available tissue donors beyond those identified through multi-organ donation processes. Some of the barriers identified by stakeholders, included: a lack of capacity among donor coordinators to undertake wider-ranging donor identification; a push for DonateLife staff to secure or prioritise organ donation over tissue donation (tissues were a co-benefit from organ donors, but were not sought as tissue-only donations); notification systems in different jurisdictions (in some, coronial or hospital notifications limited the pool); and, a lack of geographical reach (potential donors in regional, or non-serviced hospital areas).

Different selection criteria

The TGA regulations are intended to present banks with flexibility to undertake donor selection to meet requirements rather than to prescriptively set how banks undertake selection. Many banks have adopted different selection criteria which were considered by many stakeholders to be more risk averse than the regulations require. Discrepancies among banks mean that donation thresholds vary among jurisdictions, and in some cases, have resulted in donations crossing into other states for acceptance.

Some stakeholders involved in donation coordination raised concerns over the periodic adjustment of selection criteria by eye banks, which caused confusion and a need to vary processes from time-to-time. Reasons cited by eye banks were that they had a clear view of donation needs to meet planned surgeries, and that if all potential donors were accepted, tissues could be potentially discarded as there was no recipient to match the tissue to. Given the shorter storage period for ocular tissues, it was generally considered that an adjustment to meet clinical needs, rather than prioritising the wishes of a donor was appropriate in comparison to other tissues where there is a need to 'stockpile' tissues for future use; eye banking specialists considered it unethical to be collecting unneeded tissue. It would also be undesirable from a financial perspective.

Tissue returns

Along with different selection criteria being applied to donations, banks also adopted different practices for tissue returns. While returns are complicated by transportation and logistics, the different practices do result in tissue loss. A number of stakeholders identified to PwC that the lack of control over allografts once distributed to a hospital mean that there is a risk of mishandling and storage if returns are accepted. The process for a bank to accept returns has to be approved by the TGA however, so there is oversight of this practice. That being said, there is a national lack of consistency in the way in which returns are managed

that means that tissues are being lost to supply due to the lack of tissue return processes in some banks..

Awareness and training of donation coordination staff

A number of stakeholders identified that the awareness and training of donation coordination staff may in some cases limit access to potential tissue donors. Partly, this was attributed by stakeholders as a lack of awareness among coordination staff who were trained primarily to secure organ donations, but also in connections between tissue banks and these donation staff. Competing priorities of banks and of donation staff were cited by some tissue banking staff as a barrier to identifying potential donors.

Tissue coordination and retrieval processes

The retrieval processes within jurisdictions also differed, potentially introducing inefficiencies. For example, in some jurisdictions, multiple staff would be called out to undertake retrievals (eg. enucleators and musculoskeletal retrievalists, or in other cases, medically-trained practitioners) which, if undertaken by holistically-trained staff, could require the one retrieval team only.

Live donor femoral head retrieval by public banks is also poorly coordinated; largely reliant on the relationships with individual hospitals and their orthopaedic units. A lack of capacity among local banks has established the opportunity for other organisations to provide collection services.

Eye banks noted that the number of retrieval rates for corneas has increased due to the transition of a number of eye banks to normothermic storage which enables banks to better plan for demand through longer storage periods, and has improved the sector's capacity to respond and coordinate donation processes.

4.6.2 Regulatory and financing requirements

Most stakeholders cited regulatory requirements as a recent challenge to tissue banks. Banks have clearly committed significant time to preparing dossiers and reporting requirements under the new Biologicals Framework. While a challenge, a handful of stakeholders acknowledged that the introduction of consistent regulation has improved practices within the sector. Additionally, financial support from the OTA has brought most banks into coherence with the framework for which they were grateful. Discussions with banks identified that ongoing regulatory requirements will be subsumed into future cost recovery applications under the PHI to support staff undertaking regulatory-related functions.

A handful of stakeholders raised that there are residual components of the framework to be addressed for full implementation. This includes the release of guidelines for making amendments to products on the ARTG, which the TGA should be releasing soon.. Additionally, funding for the regulatory introduction of the framework was extended by the OTA into early 2016.

Stakeholders also identified that there is scope for improving the applications process to the PHI. One tissue bank noted that there is some time lag experienced when submitting a price listing amendment (as listings were not considered to be forward-looking so banks were incurring costs before they can apply higher prices). Through consultations, it was clear that not all banks were across regulatory processes or fully-understood their application, usually to the detriment of the operation of the bank. The scale of regulatory burden has accelerated consolidation to multi-tissue banks that are able to exploit scale synergies in the provision of tissues. Smaller tissue banks have the least capacity to respond to changing regulatory requirements, with some identifying an intention to close, while other are exploring ties with other organisations to remain viable into the future.

4.7 Community confidence and support

4.7.1 Security of supply

Some stakeholders raised concerns over the ability of the tissue sector to retain public confidence in tissue donation due to perceptions of poor management/lack of coordination. Tissue banking and surgical use of tissue is dependent on supply of altruistic donations, and the risks to supply are not, in some stakeholder views, reflected in practices.

For example, the diversion of tissues through private entities for processing was considered by many as a risk to public perception and trust if the handling and transfer of tissues was not properly understood by the community. Risks to future tissue supply would additionally present risks to the confidence of the surgical community in tissue banking being able to meet their ongoing needs.

Counter to this perspective was one held strongly by some stakeholders that if the community was transparently made aware of the interaction of private providers, and were given option for prior and informed consent, then there may be no risk to future supply. The role of private providers in the tissue sectors of other countries and the role of private providers in other areas of the Australian sector were given as examples.

Consultations identified the perception that Australia is largely self-sufficient in providing tissue for clinical use. Stakeholders were asked of their perspectives on international supply. Responses were mixed; some stating that provided regulatory oversight was sufficient to ensure standards around sourcing and quality of tissues was maintained that it did not present a risk, while others considered importation of tissues would lack control and potentially present safety and quality risks. Others cited ethical and private market dominance concerns on reliance on international suppliers. However, there was limited interest flagged among stakeholders to pursue avenues for international supply. This is despite the fact that in 2014, up to 35% of all allograft supply is currently supplied from international sources. This highlights the difference between the current perception of the sector by major government and banking stakeholder and the reality, driven by end users and clinical demand.

4.7.2 Community awareness of tissue donation

Many stakeholders also noted that potential donors have a low level of awareness regarding tissue donation. While organ donation is well known within the community, tissue donation is lesser known, despite the fact that many more patients benefit from tissue transplants than benefit from organ transplants. A number of tissue banks identified that donor families at times would approach them for donation, having either existing awareness, or having become aware following a deceased loved one's inability to donate their organs.

The broader lack of awareness of tissue donation and use also constrained the sector's ability to communicate for change. Without recognition of the public good delivered by tissue banking, governments and other stakeholders find it difficult to mount a case for public investment or the need for sectoral change. Despite the broader-ranging delivery of surgical services using tissue donations that affect the public, awareness remains low of the applications and need for donation; many stakeholders considered tissue banking to be the "poor cousin" of organ donation, and so found it difficult to attract funding necessary to provide newer generation products that ultimately benefit the public.

Additionally, the perceived life-enhancing, rather than life-saving nature of most tissues made it difficult to gain public attention and support for the sector. Many stakeholders cited a need for a campaign such as that delivered for organ donation to raise awareness within the community.

4.7.3 Consent and communication processes

In each jurisdiction, donors are required to provide consent for tissue donation, for either or both, transplantation and research uses. While donating families are supported by

DonateLife staff, it was not clear to what extent this process enabled full and transparent disclosure of the use, and potential uses of donated tissues.

Many stakeholders felt that consent processes were not always transparent and forthcoming with the use and handling of donated tissue. These stakeholders considered that donating families likely have a limited understanding that tissue would be processed and would not be in a position to be able to absorb and reflect on potential donation if given information upon a family member's death. The association of organ donation being a one-for-one transplantation for life-saving purposes may, through association, distort donating family understanding of the use and distribution of these tissues. These stakeholders considered that there was a need to promote and educate the community on tissue donation and uses more broadly.

Additionally, inconsistencies in the approach employed for consent – in some cases, verbally, in person, or by written form – raised concerns among some stakeholders that full disclosure and transparency was not always provided to donating families or living donors.

Some stakeholders also raised the need to secure more tissues for research purposes. Some eye banking staff, for example, considered that there were many research applications that with minimal investment could provide significant clinical benefit through the use of donated tissue. These stakeholders noted that, funding aside, further work may be needed in the consent process to secure tissues directed for research use only. Consultations with donor coordinator staff identified that the vast majority of consent approvals grant tissue use for both transplant and research applications.

While tissue banking for heart, skin and musculoskeletal was directed to meeting local needs, the ability of eye banking to meet local demand has raised the question of international supply of corneas by Australian banks. Eye banking stakeholders considered that there would be capacity within the sector to supply internationally, and indeed, there are discrete cases where this has already occurred (primarily within the Asia-Pacific region through voluntary programs run by Australian ophthalmologists). However, some stakeholders considered that the ethics of international supply had not fully been addressed, as consent processes do not necessarily identify that donated tissues may be exported for use elsewhere. Issues of funding and responsibility for international supply were also identified.

5 Options

PwC have developed, in concert with the ETEA Working Group, initial options against which to consider how the tissue sector might make operational efficiencies and improvements to deliver on the objectives. These options were tested through stakeholder consultation. Two key outcomes should be noted.

First, all options were considered against stakeholders understanding of the status quo. However, this study has revealed that the status quo differs significantly to stakeholder understandings, especially around international reliance. Second, it is clear that further finessing is required to the options tested with stakeholders to give greater consideration of models adopted elsewhere and to specify how each model might be implemented in practice.

Both these outcomes point to a requirement for further work. Hence, the options tested during this study, and presented below, should only be considered an initial guide to stakeholder perception at the time of the survey.

The description of the options, developed with the ETEA Working Group, that were presented to stakeholders through an online survey are described as follows:

- **Status quo – the current system.** This was specified as a de-centralised operational model, run by independently operated units (banks, suppliers) within jurisdictions, covering one or more aspects of tissue banking, under public or private governance arrangements including not-for-profit public and private operations or for-profit operations (e.g. privately owned contracted manufacturers and sponsors of imported grafts). Production and distribution is ad-hoc. It must be noted that this initial specification of the status quo did not include reference to international supply of tissues that was uncovered during the course of the review.
- **Centralised (regional model)** – a sector which operates from regionalised hubs which manage and coordinate eye and tissue retrieval, processing, allocation and distribution within regional boundaries. Policies are established towards efficient regional governance and demand-supply balance.
- **Centralised (national model)** – a sector which is managed and coordinated by a central agency. This is a model consisting of centralised manufacturing and de-centralised procurement and tissue distribution. Policies are established towards national efficient governance and demand-supply balance
- **International and/or private Australian supply (shortfalls only)** – one of the above operational models supplemented by international and/or private Australian supply to meet supply shortfalls on an ad-hoc basis
- **International supply (full reliance)** – removal of domestic supply, importation of all eye and tissue needs
- **Fully privatised national model** – opening the sector to private suppliers to meet all eye and tissue needs
- **Other** – an alternative system as described by the survey respondent

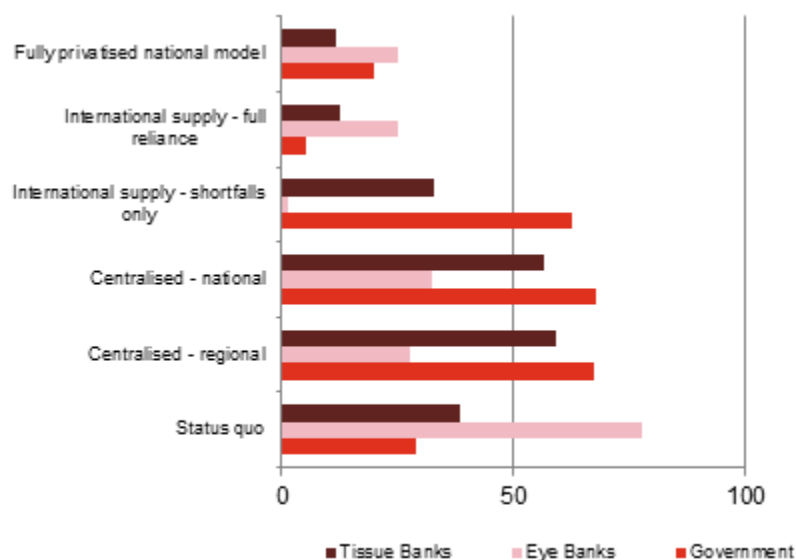
While results of the analysis are presented below, PwC has not specified a prescribed model for the sector. PwC considers that the sector first needs to address the more pressing issues identified in this review and spelt out in the recommendations.

5.1 Option analysis

Stakeholders recorded preferences for centralised models when surveyed (Figure 21). Of the six operating models presented government stakeholders favoured centralised models

relative to other options presented to them. There was little support for international or privatised models among stakeholders.

Figure 21 - Ranked appropriateness of different operating models (average of ranked responses between 0-100)



Preferences of government stakeholders reflect that regional or national centralised operating models may be the most appropriate, or that international supply for shortfalls is supported, but that there is a need to improve the processes that govern whichever structure is pursued. Government stakeholders commented that:

- eye banking operated on an effective ‘regional’ basis as its status quo, and that this model was efficient and effective
- a national approach, like has been adopted for the organ and blood sector, is needed for tissue banking. This approach would provide the national oversight needed to inform and address manufacturing and distribution issues
- that standardisation and streamlining of collection criteria and processes would greatly benefit the sector and bring greater consistency in practice
- more cost-effective operating structures need to be pursued due to the variation of activities across the sector. Many suggested that consolidation of some banks be considered
- enhanced capacity is needed among tissue banks to be responsive, innovate and provide for future needs of Australians.

Like government respondents, tissue bank stakeholders ranked centralised or status quo operating models as more appropriate than other models. Markedly, eye banks (split out here to demonstrate differences in operation) by far favour the status quo over other operating models. Eye banks also supported international supply or fully privatised models more than tissue bank stakeholders.

Many respondents commented on issues within the existing sector structure, rather than presenting a strong preference for one operational model as compared to another. However, stakeholders were closely aligned to operational models like or slightly adapted from existing operational structures. Responses provided include:

- the sector is altruistic and should be retained in that way

- funding arrangements across states skew the ability of banks to service end users, while the cost recovery model constrains the ability of banks to innovate
- eye banking is sustainable and efficient as it currently operates and should not be altered in line with tissue banking arrangements
- regulatory requirements are significant and may benefit from streamlining
- ethical and quality standards may be compromised in models that import tissues

Care needs to be taken when interpreting these responses as neither government nor tissue bank respondents were aware of the high reliance on the private provider and international supply of tissue in meeting the current clinical needs of end users in the Australian market.

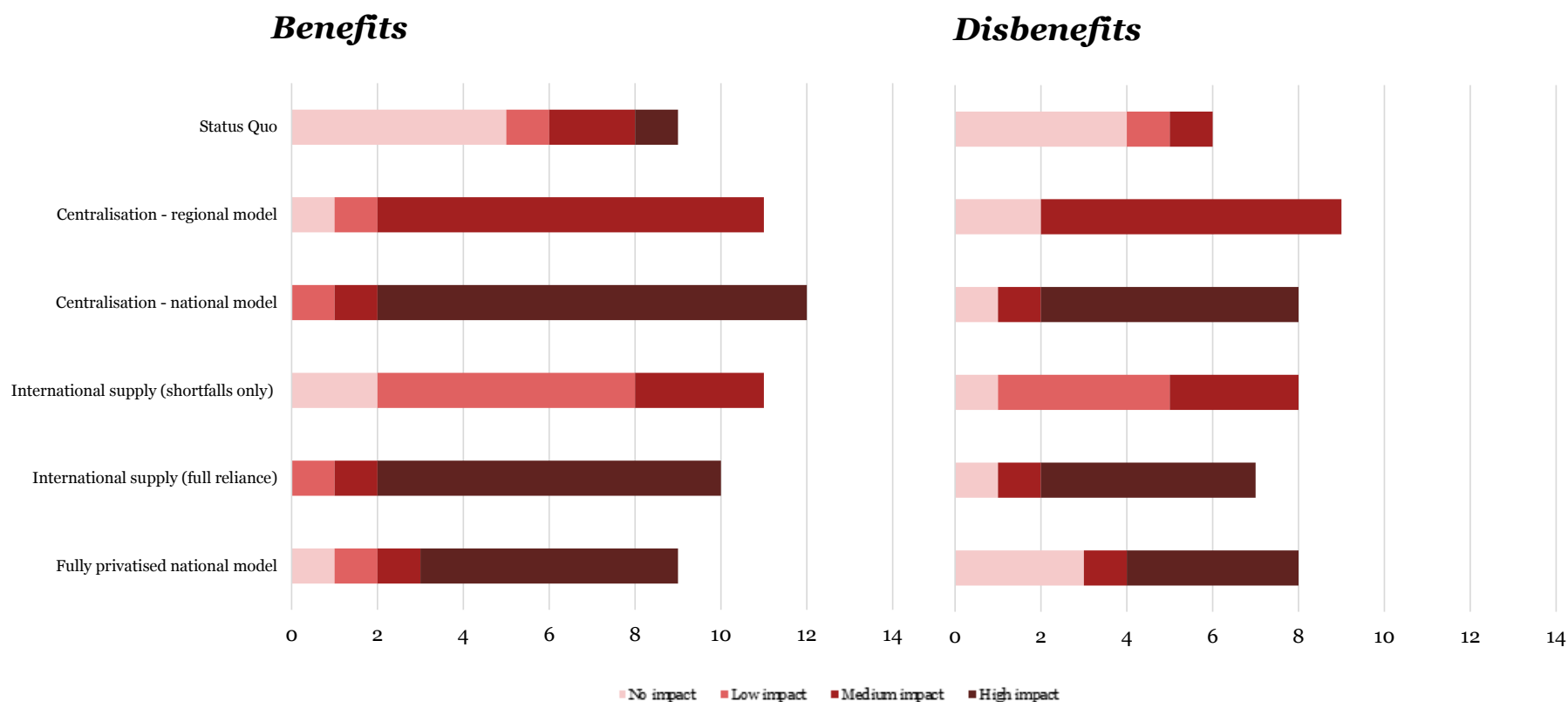
5.1.1 *Government responses*

The responses of government stakeholders as to the impact of each proposed operating model is presented in Figure 22. The highest impacts were associated with national centralisation and international/private supply structures which would require significant reform if pursued. Government stakeholders commented that:

- the status quo would continue to underperform if nothing is changed, and that the future sustainability of tissue supply would become an issue into the future. However, the eye banking status quo should be retained as it is suited to meet both current and future demand in a relatively efficient manner.
- the centralised regional model may offer benefits in understanding regional demand and supply and subsequently improve governance and financial sustainability of tissue banks. It also allows banks to be responsive to local demand and retain activity within the bounds of a given jurisdiction's regulatory reach, and favours larger hubs for processing, with smaller banks focused on retrieval. Negative impacts may include a tendency to carry forward the existing 'silo culture' and a need to consider funding allocations and picking 'winners and losers'.
- a centralised national model would likely deliver the greatest impact in terms of cost-efficiencies, and allow for alternative sources of supply if demand increased, but would likely be challenged by jurisdictional differences and need for political intervention to create change. Negative impacts include a loss of regional expertise, as well requiring significant government intervention to develop cross-jurisdictional agreements and national harmonisation of legislation.
- International supply for shortfalls allows for an alternative source of supply and is a risk mitigation tool where local supply cannot be secured. Implementation may create additional cost and require that importation is well-controlled. Risks associated with trade and commercial arrangements would need to be considered when local supply requires limited importation. Implementation may also distort supply of products which are 'more profitable' against those with 'public good' characteristics.
- Full reliance on international supply was thought to erode local altruistic donation culture in Australia, and potentially carry a high cost impact. Some stakeholders also consider that internationally-sourcing would not meet international norms of self-sufficiency and risk loss of supply if international constraints occurred. Benefits include the ability of Australians to access newer products not currently available to them, which would significantly change the market for tissue provision. Government stakeholders did not consider there to be any greater safety risk associated with imported products than local products, assuming current regulatory requirements were complied with.

- A fully privatised national model would deliver reliability of supply and may reduce state government administrative burden and costs. However, implementation may have a cost impact (in both ethical and financial terms) and may limit availability of rarer “needed” products due to their reduced market. Some stakeholders suggested that lower donation rates may prevail and have a significant impact in the long term. Other suggested that greater private participation, with the right oversight and incentives was critical to increasing donor rates.

Figure 22 – Number of government respondents against the relative impacts of each proposed operating model



Respondents were asked to rate the impact of changes to the sector under each option presented if it were implemented. Respondents were asked to rate if the impact had 'no', 'low', 'medium' or 'high' impact, and if that impact was positive (a benefit) or negative (disbenefits). Responses have been set side-to-side to allow comparison. For example, the majority of government respondents in this graphic consider there to be a high beneficial impact from implementation of a centralised national model, with one stakeholder considering there would be a medium beneficial impact, and one suggesting no impact. Conversely, stakeholders consider that there would be a high negative impact from implementation of that model (in this case, largely due to the costs). Responses indicate that stakeholders are split on the most appropriate structure and consider that each option carries benefits and risks.

5.1.2 *Tissue bank responses*

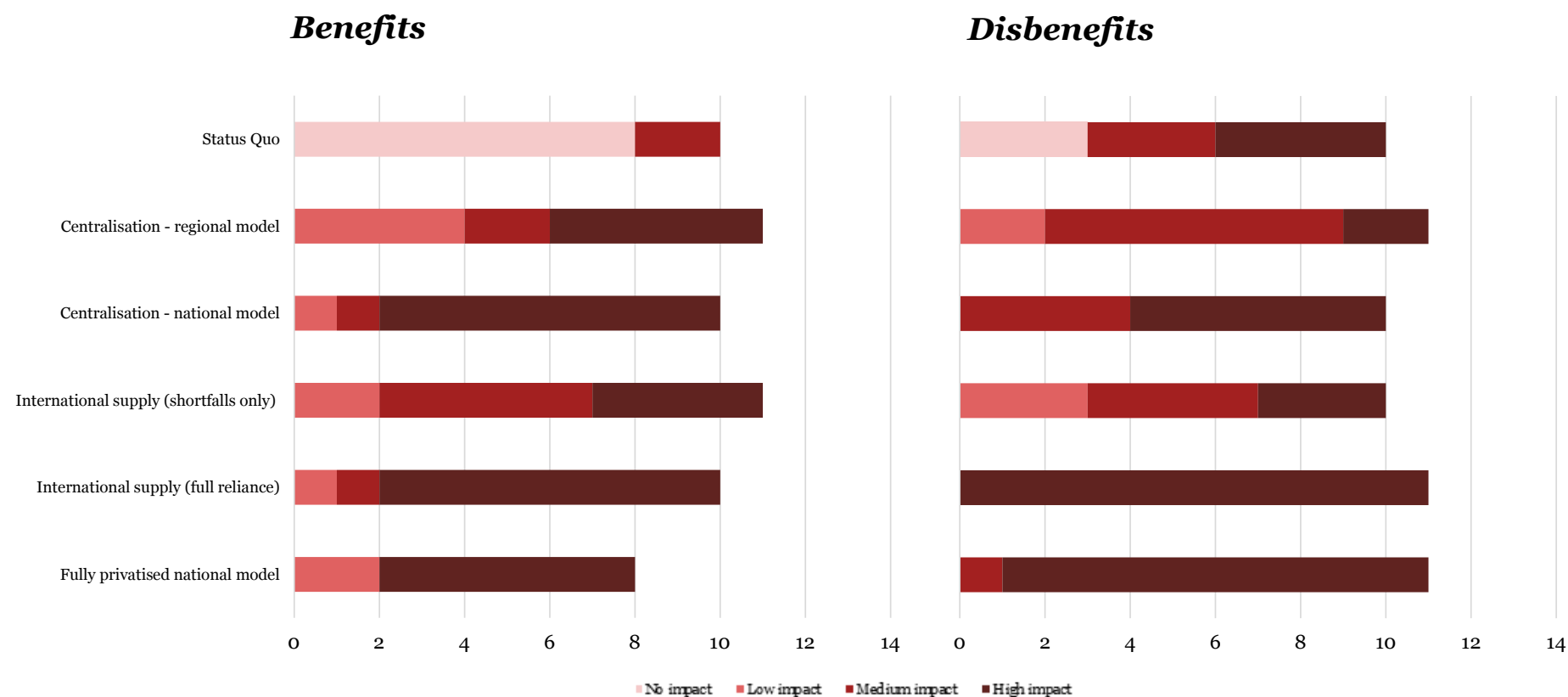
The responses of bank stakeholders as to the impact of each proposed operating model is presented in Figure 23. As compared to government stakeholders, bank stakeholders reported a greater negative impact associated with each operating model; this is closely related to the effect on existing operation under each model, which would require change. However, like government respondents, there are very divergent views on the appropriateness of the future structure. Bank respondents commented that:

- The status quo would not present any change and would continue funding inequity across states and the ability of banks to innovate. The status quo would be unlikely to keep up with demand and will lead to greater provision of 'lucrative' products at the expense of provision of other tissues. For eye banking, existing operational arrangements is responsive, cost efficient, and aligned with service needs.
- A centralised regional model would secure longer term viability of banks and reduce unnecessary transportation of allografts across states through better supply and demand planning. There would be efficiencies gained in consistent collection and distribution processes and it would be likely under this model that larger banks would become processing and distribution centres, while smaller banks would become collection centres. Fewer benefits would be derived if eye banking were consolidated in any way from its current model.
- A centralised national model may provide efficiency of scale and uniformity, but may also present regulatory risks (due to centralisation of these functions) and a loss of local ownership and connection, which is important to delivering services that meet local market needs. If adapted for eye banking, costs are projected to increase to end users. There may be impediments in implementing change due to differing governance and operational procedures across jurisdictions, and logistical hurdles to overcome. There may also be duplication and additional reporting burden as a result of centralisation, and it would be likely that there would be redundant services under this model. Benefits include improved coordination to planning and delivering upon surgeon needs, as well as to provide equitable access to services.
- International supply for shortfalls wouldn't risk viability of local services if limited to products unavailable in Australia and controlled by Australian banks. Some stakeholders consider that there is a need for control to ensure that importation is only for shortfalls otherwise it is likely importation would eventually undermine local supply and donation rates. Benefits include enabling clinical access to a wider range of products.
- Full reliance on international supply carries the greatest level of impact of all models. Implementation may risk security of supply, and present contamination and quality risks, and erode the local skill base. Under this model, the community may cease donating and there may be a loss of control of the sector. Products of preference in Australia may not be available on the international market, but on the other hand, will increase the scope of other available products.
- Some tissue banks suggested a fully privatised national model risks potential donation rates, ethical boundaries and costs to end users. There may be an eventual shift to allow for 'for profit' trade in tissue if pursued. It was suggested that donation rates would significantly decrease and there may be dangers in unethical practice.
- A number of other banks pointed to the important role that the private operator had played in improving the efficiency of the sector, increasing donor rates and driving innovation. The ability of private suppliers to efficiently and effectively operate under transparent legislation throughout the health sector was also stressed. However, stakeholder cautioned that the current market structures and opaque nature of legislation and regulation could lead to the emergence of monopolistic private providers, a situation to be strenuously avoided. Any growth in private

providers should be guided by a competitive process that maintains competitive tension, drives efficiencies and enhances the desired industry outcomes.

- One stakeholder suggested that there is a need to look at the US model of tissue services which enable national not-for-profit organisations to undertake responsibilities such as death notifications, assessment and retrievals. This would enhance donation rates and the ability to be truly self-sufficient.

Figure 23 - Number of bank respondents against the relative impacts of each proposed operating model



Respondents were asked to rate the impact of changes to the sector under each option presented if it were implemented. Respondents were asked to rate if the impact had 'no', 'low', 'medium' or 'high' impact, and if that impact was positive (a benefit) or negative (disbenefits). Responses have been set side-to-side to allow comparison. For example, the majority of bank respondents in this graphic consider there to be a high beneficial impact from implementation of a privatised model, with two stakeholders considering there would be a low beneficial impact.. Conversely, stakeholders consider that there would be a high negative impact from implementation of that model. Responses, again, indicate that stakeholders are split on the most appropriate structure and consider that each option carries benefits and risks.

5.2 Assessing options

In assessing the opportunities, risks and trade-offs of proposed options, evaluation would normally draw on the policies or governing documents relevant to the sector. The tissue sector is, however, without central policy objectives.

To assist in assessing the sustainability of the sector, and guide the assessment of options for future operation, PwC has developed a set of objectives. These have drawn on objectives of key documents from source documents such as from the World Health Organisation and National Health and Medical Research Council. These have also been developed in consideration of the inputs of the ETEA Working Group, perspectives of stakeholders consulted, including the policy needs of the sector cited to us.

The ranking criteria for option performance against each objective is listed under each objective below.

Respecting donor wishes and retaining supply

Tissue banking must be guided by its need to meet clinical needs for tissues, while respecting donor wishes.³⁰ Without a clinical need, there is not a need for donation and efforts must be directed toward meeting clinical needs; “Tissue donation is an act of altruism...that potentially benefits those in medical need.”³¹

It is not the purpose of this study to define the merits of commercialisation, however, it is clear that this is a subject that warrants further analysis. The issue of the attenuation of a tissue – how far from its original form it is and therefore the rights to commercial application attached to that tissue – is secondary to the ethics of altruistic donation and its uses. An expectation exists within the community that donated tissues are treated and used ethically and for the purpose of enhancing lives. This expectation can only be supported through transparency.

While all donor wishes may not necessarily be filled, for example when there is not a need to collect due to temporary oversupply, the confidence of the community must be retained to ensure future supply and trust in tissue banking processes. The need to retain the social capital that ensures supply through altruistic donation must be foundational to tissue donation, processing and distribution.³² The promotion of altruistic voluntary donation and increasing public awareness of public benefits is the first principle of the WHO Guiding Principles for Tissue Transplantation.³³

Additionally, international norms promote national self-sufficiency in organ and tissue donation that considers that, in particular, affluent nations provide for its own population.³⁴ The drive for self-sufficiency reflects a need for nations to act as global citizens to combat illicit activities; without policies and activities that promote self-sufficiency, these activities including transplant tourism, and human trafficking, may become unintended consequences of international supply circuits.³⁵ Where possible, tissue donation should be secured

³⁰ Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2008), Principle 4, World Health Assembly

³¹ NHMRC (2007) Organ and Tissue Donation by Living Donors: Guidelines for Ethical Practice for Health Professionals

³² NHMRC (2011) Ethics and the exchange and commercialisation of products derived from human tissues: Background and issues paper

³³ WHO 63rd General Assembly: Resolution on Human organ and tissue transplantation, WHA63.22, 21 May 2010, 2(2)

³⁴ Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2008), Principle 5

³⁵ Delmonico F L et al (2011) A call for government accountability to achieve national self-sufficiency in organ donation and transplantation *Lancet* 378, pp 1414-1418

domestically to ensure supply. This must be balanced against the need for clinicians to access newer generation allografts that may only be available internationally.

Transparency and accountability

Practices, standards and processes of tissue banking should be transparent and accountable to the community.³⁶ Clinical and ethical norms should be codified, demonstrated and progressed through continual sector improvement. To achieve consistency and retain public confidence, practices must be transparent.³⁷ Transparency of processes and practices also services to unveil inconsistencies and enable policy or organisational intervention to ensure long-term viability of tissue banking.

National accountability and organisational oversight will foster best practice and promote coordination, harmonisation and efficiency within the sector. The sector requires a reporting architecture that supports consistent and frequent reporting which supports policy oversight and consistency.³⁸ Data collection systems will also enable traceability of tissues for quality, demand and viability analysis and reporting. This is critical to support the inclusion of non-government organisations (not for profit or for profit) in the supply of allografts.

Optimising patient outcomes

For ongoing viability, tissue banking must be adaptive to changing needs. This includes societal expectations of donation, as well as an ability to shift and meet demand among clinicians for newer products. While tissue banking may have delivered on clinical needs through strongly forged relationships and unchanged demand for allografts, the growing demand among up-and-coming clinicians, as well as the entrance of newer, international suppliers, tissue banks must be more responsive to future needs.

Partly, this will be founded in the oversight and reporting roles required to track and identify changing clinical trends, but will also be linked to improve the bank's understanding of changing needs identified through both local and international best practice. The ability of tissue banks to respond to these needs, including building capacity to develop new products, will be imperative to securing community confidence in the optimal use of donated tissues. Access to these allografts should be provided equitably, in that, patients that would benefit from their use can access them whether that is through their local provider, or through another provider.

Satisfies regulatory and reporting obligations

To sustain public and clinical confidence in tissue banking, safety is paramount. While the purpose of the TGA biologicals framework is to regulate the quality, efficacy and safety of tissues used for human transplantation, there is a need for the monitoring and reporting of surgical use and clinical outcomes to ensure best practice. WHO Guiding Principles promote collaboration in data collection for adverse events, quality, safety and efficacy.³⁹

While existing tissue banking practices may be proven in terms of safety, practices should consider and continually reflect international best practice and enable policy makers and regulators with the levers required to control and oversight tissue supply and demand.

³⁶ WHO 63rd General Assembly: Resolution on Human organ and tissue transplantation, WHA63.22, 21 May 2010, 2(4)

³⁷ Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2008), Principle 2, World Health Assembly

³⁸ WHO 63rd General Assembly: Resolution on Human organ and tissue transplantation, WHA63.22, 21 May 2010, 2(7)

³⁹ WHO 63rd General Assembly: Resolution on Human organ and tissue transplantation, WHA63.22, 21 May 2010, 2(7)

Financially sustainable

Tissue banking must be sustainable over the longer-term to provide confidence and fulfil needs of patients. Measures of a sustainable sector include its ability to provide allografts in a timely and accessible manner, while providing efficiencies. While the public good of tissue donation is recognised, the banking structure requires that banks are commercially sustainable to assure this ongoing viability. Inefficiencies in practice should be identified and managed to produce the best clinical and community outcomes for public and private investment.

Self-sufficiency principles are wed to the need to retain, and in some cases, improve donor supply, with the need for banks to remain financially viable to continue to provide tissue services. If the objective of tissue banking is to meet local clinical needs, then the options for the design of that system should account for its ability to do so. While there may be cost or efficiency opportunities in international supply, the local banking sector must first be considered, as well as to identify costs to the community.

5.3 Relative performance of options

PwC's analysis of the performance of each option against the stated objectives is presented in Figure 24. This high level, initial assessment has been undertaken by qualitatively assessing the performance of each model against the criteria defined in section 5.2 using stakeholder commentary as to the risks and benefits of operating models proposed. Overall ratings reflect the considered suitability of the full model, rather than a numerical aggregation of each score against the core criteria.

The initial options presented below simplistically assumed the adoption of a given model in its entirety, to the exclusion of others. This was required to understand stakeholder's views towards the options. In reality, many of these options can operate concurrently, as shown with the current industry which blends elements of a regional international supply and private sector model. The correct future structure should look to leverage the strengths of each model to overcome the systemic challenges the sector faces which were discussed in the previous chapter.

Finally, PwC does not prescribe nor recommend pursuance of any of the operating models proposed here. Upon stakeholder consultation, it is clear that effort and focus must first be directed at addressing the systemic challenges within the sector prior to exploring and designing an operational model that may form the basis of a proposal for change. PwC's recommendations are presented in the following chapter

Figure 24 – Performance of proposed options

Model	Objectives					Key risks	Overall rating
	<i>Respecting donor wishes and retaining supply</i>	<i>Transparency and accountability</i>	<i>Optimising patient outcomes</i>	<i>Satisfies regulatory and reporting obligations</i>	<i>Financially sustainable</i>		
Status quo						- Limited donor awareness and security of supply - Some standardised reporting, but not centralised nor complete - Unable to invest in newer products - Limited accountability and standardised reporting and oversight - Lack of longer term viability of many tissue banks	
Centralised-regional model						- Potentially improved donor awareness and security of supply, but risks inconsistency in approach - Able to monitor and report on regional needs - Able to provide for most clinical needs, but not equipped to understand and respond to nation-wide needs - Potential for some lack of reporting, but mostly transparent - Mostly financially viable sector	
Centralised – national model						- Security of supply and ability influence awareness and practice - Complete and whole reporting dataset that provides national oversight - Ability to provide for most clinical needs - Full accountability and oversight of tissue collection and distribution - Could be very costly to implement, especially for low volume allografts, and would likely require increased and ongoing Commonwealth funding support. - Operationalisation of this model would likely present challenges given the current state based legislative and funding responsibilities.	
International supply – shortfalls only						- Secure supply, but risks erosion of public confidence if not transparent - Limitations in understanding all imported allografts - Access to newer products	

Model	Objectives					Key risks	Overall rating
	Respecting donor wishes and retaining supply	Transparency and accountability	Optimising patient outcomes	Satisfies regulatory and reporting obligations	Financially sustainable		
International supply – full reliance						• Greater difficult and more costly to monitor and potential for incomplete oversight • Exposed to market cost changes	
						• Risks to supply and public confidence if not tightly managed and communicated • Risks to complete reporting of distribution and use of imported allografts • Access to newer products but risks supply of 'lucrative products, and cost prohibitive to all patients • Limitations in reporting and oversight due to unknown importation unless regulated • Potentially expensive	
Fully privatised national model						• Security of supply, but need to enhance and manage public expectation and understanding • Risks lack of oversight and collection of allograft distribution and use if not correctly legislated and regulated • Access to newer products but risks supply of 'lucrative products, and cost prohibitive to all patients • Limitations in reporting and oversight due to unknown distribution unless regulated • Exposed to market cost changes • Risk of monopoly providers that erode cost efficiencies and patient outcomes	
Legend							
   							
Doesn't fulfil objective Partly fulfils objective Mostly fulfils objective Fulfils objective							

Note: This high level, initial assessment has been undertaken by qualitatively assessing the performance of each model against the criteria defined in section 5.2 using stakeholder commentary as to the risks and benefits of operating models proposed. Overall ratings reflect the considered suitability of the full model, rather than a numerical aggregation of each score against the core criteria. Many of these options can operate concurrently, and the future structure should leverage the strengths of each model to overcome the identified systemic challenges the sector faces.

6 *Recommendations*

PwC finds that sectoral change should proceed with considered urgency. Action is urgently required to address the challenges identified above. However, a considered approach is required given the sector is complex and fragmented with few clear policy levers or governance mechanisms that can easily be called upon to bring about change.

Furthermore, given the current structure of the sector differs dramatically from widespread stakeholder perception, the nature and scale of reform is not immediately obvious. 54 per cent of banks surveyed consider that future supply will meet future demand, and 36 per cent think that the current sector structure is sufficient to meet future demand. PwC's finding that in 2014 34 per cent of all allografts are internationally-sourced and further, that almost 40 per cent of musculoskeletal allografts were processed using internationally-sourced tissue suggests that perception is far from current reality. Finally, given the size of the sector and financial sustainability of many of the participants, there is a risk that hasty or ill-considered responses could weaken, rather than strengthen the domestic sector.

At the outset of this review, it was intended that various options be explored to identify the most efficient and effective means for tissue banking, however, given the challenges identified, and changing landscape that this review has identified, PwC does not recommend prescribing a specific model.

Change should proceed with considered urgency to address the challenges identified above. However, a considered approach is required given the sector is complex and fragmented with few clear policy levers or governance mechanisms to manage change. Furthermore, given the current operations within the sector differ dramatically from the widespread stakeholder understanding, the type and scale of change is not immediately obvious to the key stakeholders.

The guiding principles to inform this change should be as follows:

- the aims, objectives and success of the sector should be outcome focused. This aligns with the broader ethos of the Australian health sector and ensures all decisions work back from effectively and efficiently enhancing patient outcomes and meeting clinical requirements
- change shouldn't undermine the current strengths of the sector, it should recognise these aspects and build upon them
- resources invested in change should be commensurate with the scale of the sector. Care needs to be taken to ensure the costs of large scale change do not outweigh the potential benefits
- differences between tissue types need to be recognised and reflected in changes: there is not necessarily a one-size-fits all solution
- recommendations should be seen as a package, with successful change resting on addressing all areas. Addressing recommendations in isolation will not bring about the change required in the sector.

PwC's recommendations are as follows:

Recommendation One: Status quo

That governments recognise that the current operation of the tissue sector will not prove feasible to sustain supply to meet domestic needs over the medium to long term.

Recommendation Two: National policy framework for the tissue sector

There is a clear need for a national policy framework for the tissue sector that is agreed between all governments. PwC consider that to inform the development of a transparent and accountable national policy framework objectives, priorities and underpinning policy positions must be developed and agreed by all governments.

A National Taskforce, or similar, should be established comprised of Commonwealth and state participants who have policy responsibility and accountability for the tissue sector.

Patient needs, clinical feedback and service delivery considerations should be reflected through the appropriate industry and community associations who should also have a seat at the table.

The National Taskforce would require Ministerial backing and resourcing (Commonwealth, States and Territories) to drive the process of change.

The Taskforce should address the following needs as a matter of priority.

Clear national policy framework and articulation of sector principles

A core national policy framework is required to clearly articulate the policy principles of the sector. This document is urgently required to harmonize and align differing perceptions of the role and responsibilities of the sector. It is also critical in directing change and measuring the outcomes of a sectoral change process.

Clearly defined policy principles are required on:

1. Ethical framework
2. Donated tissue supply
3. Exportation of donated tissue
4. Governance and oversight of the sector
5. Transparency, data, reporting accountability
6. Standards of practice
7. Scope of service
8. Clinical purpose
9. Funding arrangements
10. Research and development
11. Role of professional associations

The policy principles should be developed as follows:

1. Ethical framework

A set of national ethical principles should be developed to guide the collection, manufacturing and distribution of tissues. Within the framework, parties should be identified for their responsibilities in maintaining the ethical standing of the industry.

Additionally, ethical principles should be codified in legislative, regulatory and policy frameworks to give effect to their consistent application.

2. Donated tissue supply

A national position should be developed on self-sufficiency to specify the desired future state of supply of donated tissues. The position should stipulate when, how and in what circumstances imported tissues be supplied to meet Australia's clinical needs for allografts, and the extent to which domestic donation should be relied upon and supported. Once a position is specified, activities that support this objective can be tailored.

3. Exportation of donated tissue

As with identifying a position on self-sufficiency, a national position on exportation should be developed. The position should specify the extent to which domestic needs be prioritised and secured, and if additional supply should be pursued to be able to export to other countries.

4. Governance and oversight of the sector

There already is a diverse mix of government and private sector participants (not-for-profit and for-profit). Stakeholders viewed that this was unlikely to change and, if anything, the role of private participants is likely to grow. The health sector can operate very effectively with this mix however this environment requires oversight, regulation and transparency.

There is not currently the oversight, regulatory or transparency arrangements in place to support the current public-private sector mix, let alone growth of the private sector (not-for-profit or for-profit). Without this, a high degree of uncertainty and ambiguity exists within the sector. Actions should be taken to formalise:

- reporting and information sharing from the TGA to all governments regarding importation and approvals of products
- consistent data reporting arrangements of tissue banks to all governments
- agree principles and specified definitions as they relate to cost recovery or “non-profit trade” that reflect those adopted across all other jurisdictions
- the preferred national model for tissue banking arrangements, building on existing arrangements and opportunities. The model developed should specify how best to segment the tissue banking system to deliver on national and state and territory needs.

5. Transparency, data, reporting accountability

Greater transparency, data collection and accountability for reporting needs to be instilled to better understand the operation, distribution and use of allografts across Australia. This is particularly important to provide the evidence base for developing policy responses within the sector. To give effect to this a position should be developed on what information needs to be collected, who is responsible for this and what the mechanisms are for enforcing this to:

- define data requirements, specifically identify and agree what data is required, the mechanism to facilitate regular data reporting, who is responsible for data collection and dissemination and understanding the mechanisms to fund this collection
- specify reporting and accountability requirements on tissue banks to government to support oversight under the national policy.

6. Standards and practice

To build the focus of the sector to meeting patient outcomes, greater connection and understanding of clinical needs should be embedded in tissue banking. Practices should be established to build clinical feedback loops into banking operation and develop clinical standards of practice to better project and deliver on clinical needs.

7. Scope of service

Objectives should be developed among jurisdictions to define how each state and territory considers its role in tissue collection, processing and distribution. Priority and supporting arrangements across jurisdictions may be developed in view of delivering on national objectives as they relate to tissue banking. For example, some jurisdictions may be better placed to collect and process certain types of tissues than others and so may consider that their scope of service can provide for others' needs beyond their borders.

8. Clinical purpose

Linked to objectives of donated tissue supply, a position should be developed as to the sector's clinical purpose. PwC consider that the sector needs to orient itself to delivering on patient needs and outcomes, followed by the role in fulfilling donor wishes. That is, that donor wishes be filled only where and when a need for donated tissue is required. The position should be implemented across practice for donor consent, access and retrieval.

9. Funding arrangements

Funding arrangements for the sector should be reviewed and reset to deliver on the defined objectives. This includes to consider the sector's cost recovery principles, the role of the private sector (not-for profit and for profit) and contestability for certain sector functions (eg. retrieval, manufacture etc.). Specifically this requires:

- a review of the current industry funding structure, specifically the PHI cost recovery framework, to assess whether it serves the needs of a rapidly evolving sector, and to understand whether the framework and current price schedule are driving perverse sector structures. Guidelines should be developed for the assessment of cost recoverable amounts by the Department of Health
- to determine an appropriate governance process and contestability arrangements to allow for the participation of private sector participants (not-for-profit and for profit) in an ethical, transparent and accountable manner
 - specifically – what parts of the market are contestable, what governance arrangements need to be put in place, what levels and incentives exist within contracts to mitigate risk while driving the desired outcomes and finally, what is the appropriate model to ensure a healthy level of competitive tension and protect against a monopoly provider
- funding allocation and equity among jurisdictions should be established to invest in future tissue banking arrangements.

10. Research and development

Clearly recognising the need for ongoing research and development as central to the sector's sustainability, a position should be developed which articulates where the responsibility for research and development lies (government vs. private sector). This should be supported through:

- identifying the most pressing research and development requirements

- mapping the capability of the domestic sector to currently meet these requirements, including to consider synergies that might exist with universities, other research institutions and banks, and acting on these accordingly
- establishing or amending legislative architecture to promote both technological investment and an ambit that can manage the evolving and advanced nature of many of the newer generation tissue-derived products.

11. Role of professional associations

A consistent characteristic of a functioning tissue sector in overseas jurisdictions is strong sector leadership. This is also demonstrated domestically with EBAANZ providing the leadership, self-regulation and reporting which has guided the development of eye tissue into a sustainable sector.

Stronger professional leadership and representation would benefit other tissues within the sector to complement national coordination, self-regulating quality and standards, driving innovation, coordinating advocacy and collaboration.

Strengthened engagement with professional associations and suppliers is also important in view of any potential structure changes including the consolidation of any tissue collection, processing and distribution services.

Specific elements for further investigation include:

- better engagement with clinicians, including specification of clinical feedback loops and reporting to build accountability to end-users of allografts
- development of standardised practices that are periodically reviewed, including the continued sharing of best practice among tissue banks.

Existing arrangements for all other tissue types should be reviewed to identify how to strengthen professional representation. This may include developing informal and formal relationships to existing committees of end-users (for example, the Australian Orthopaedic Association, the Australia and New Zealand Society of Cardiac and Thoracic Surgeons and the Australia and New Zealand Society of Oral and Maxillofacial Surgeons). This would assist to build linkages with end-users and tissue banks, as well as to bring consistency to practice and standards, in line with delivery of other services that support clinical practice.

Direct linkages to outcome registries should also be established for all tissue types to improve the clinical outcome feedback loop of use of allografts within the clinical community, as has been achieved with the Australian Corneal Graft Registry. Options for this may include, for example, the Australian Orthopaedic Association National Joint Replacement Registry to capture allografts used in joint surgery. Similar opportunities for use of existing reporting infrastructure may exist for other allografts.

Ideally, the principles and policy base would be established and agreed by Commonwealth, State and Territory Ministers to give effect to the harmonisation of practices that follow.

Recommendation Three: Structural reform of the Australian tissue sector

Any reform of the sector should be informed by an already established clear national policy framework.

The initial Statement of Requirement asked PwC to assess options for the sector to deliver on future needs. However, as the work progressed, it became quickly evident that without a strong evidence base and agreed framework against which it is to deliver, it is too early to assess the options.

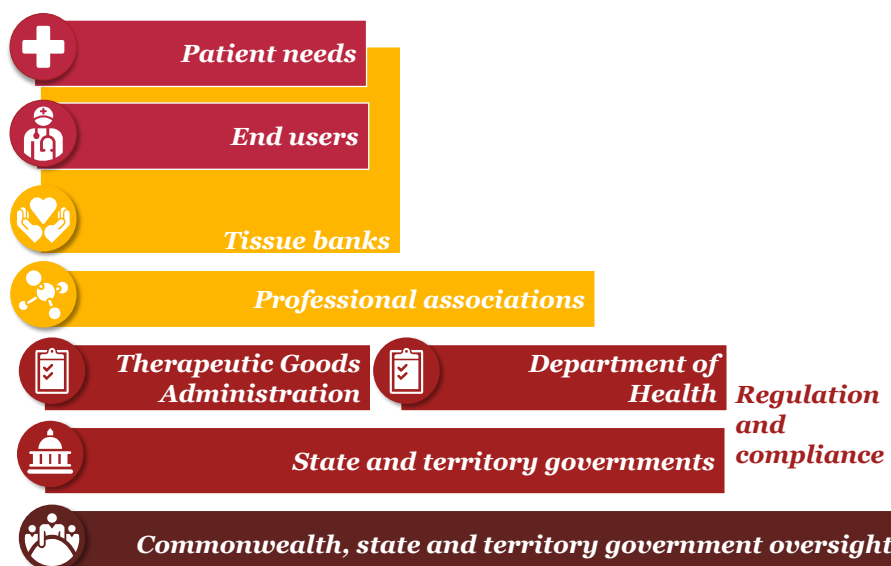
For the sake of completeness, tissue bank and government responses with regard to the potential structural options are reported on in the body of this report to inform any sector restructure in the future. However, before regard is given to the future state and structure of the sector, Recommendation Two must first be implemented.

6.1 *Structure to aspire to*

While state and territory government agencies may be best positioned to develop policy at the jurisdictional level, the need for intervention to address data deficiencies and to sustain tissue and allograft supply can only be fulfilled at the Commonwealth level. This also assists to mediate concerns that some states will “drop the ball” to allow others to “pick up” to ensure a national supply. Cross-jurisdictional engagement will keep check and ensure that national banking arrangements address both the national and state-based needs in the most equitable manner. Professional associations are best placed to engage with clinicians to ensure that the sector is responsive to their needs, and ultimately, the patient’s needs.

PwC therefore recommends that governance of the sector be adapted, as shown in Figure 25.

Figure 25 – Proposed governance structure



This could be supported by either a national or hub and spoke model. However, PwC consider that the OTA is best placed to coordinate and oversight the sector, and should carry responsibilities to convene and develop a national policy position. State and territory governments retain their role in establishing shared policy objectives with other jurisdictions and regulating and controlling tissue banking within their jurisdiction. This will be better enabled through improved transparency and accountability achieved through data collection, as previously discussed.

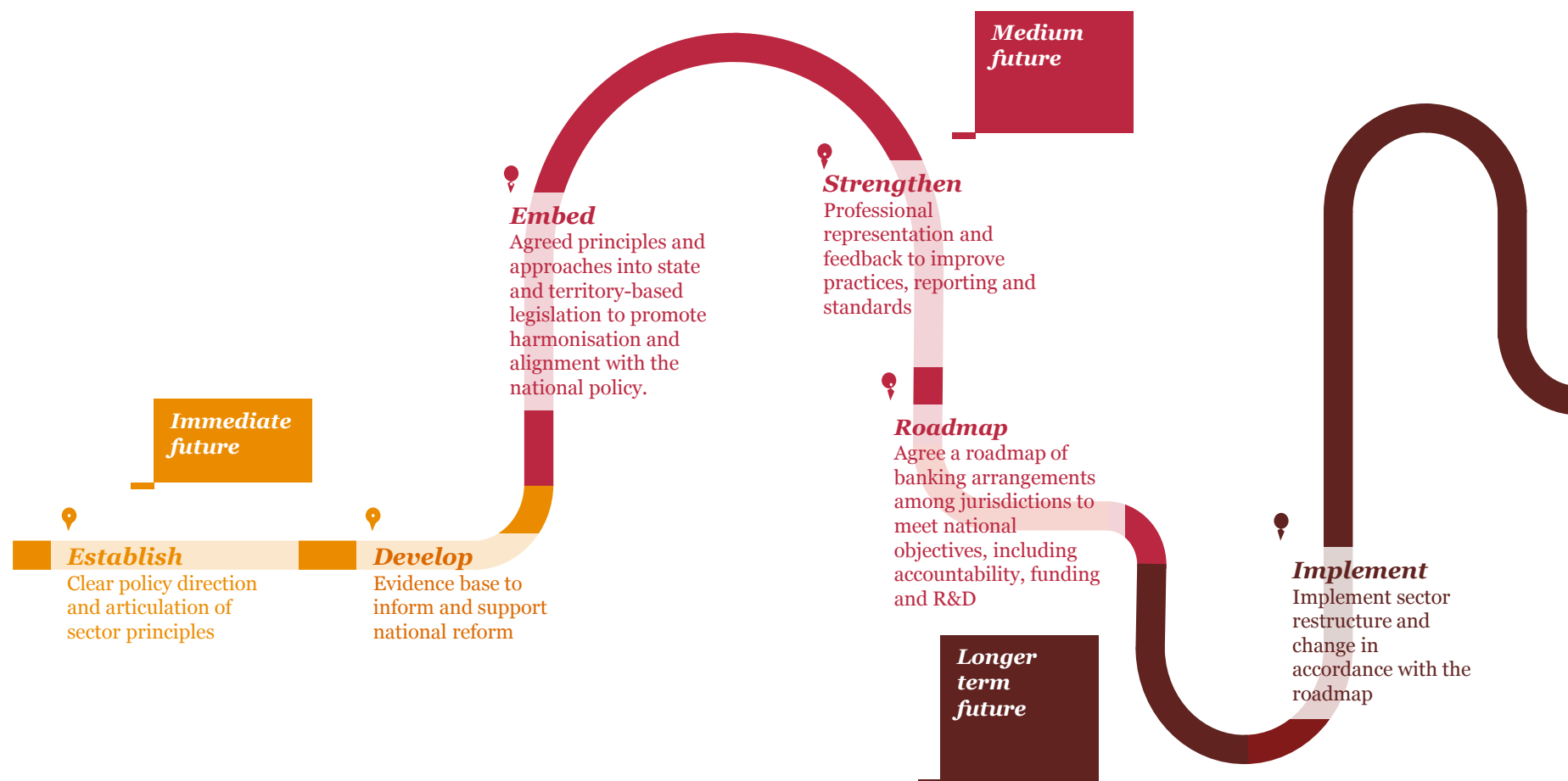
Regulation as it relates to the TGA and Department of Health should be updated to reflect the shared objectives and specified approaches agreed across jurisdictions to bring harmony to approach, and enhance information sharing.

The voice of tissue banks should be bolstered by greater professional representation. Ideally this would be achieved by enhancing the role of the BAA, alongside EBAANZ.

6.2 *Steps for implementation*

Key steps in implementation of the reforms to sector are presented in Figure 26.

Figure 26 – Sectoral reform roadmap





Appendices

Appendix A	Data source list	72
Appendix B	Consulted stakeholders	73
Appendix C	Review context	77
Appendix D	Survey	81

Data source list

Data point	Description
Survey	Responses from each of 15 tissue banks Responses from an additional 45 stakeholders
TGA Special Access Scheme	Data on all human-derived products accessed through the Special Access Scheme for years 2012-2014
Australia and New Zealand Organ Donation Registry 2013, 2014 and 2015 Mid-Year Tissue Reports	Number of tissue donations, grafts transplanted and transplant recipients were used in our analysis.
HOI 2009 Review report	Data has been extracted from this 2009 review to sketch demand over time for each tissue.

Consulted stakeholders

The following stakeholders were consulted either face-to-face, or via teleconference. The majority of these stakeholders also provided survey responses upon which data in this report has relied.

New South Wales

Director, Office of the Chief Health Officer, NSW Health	Ms Kim Stewart
NSW Eye and Bone Bank	Ms Jane Treloggen
NSW Lion's Eye Bank	Dr Con Petsoglou
NSW Lion's Eye Bank	Prof Gerard Sutton
Sydney Heart Valve Bank	Dr Lujia Gribben
Sydney Heart Valve Bank (MD)	Dr Kumud Dhital
Hunter New England Bone Bank	Ms Stephanie Beeton

Victoria

VIC DonateLife State Medical Director	Dr Rohit D'Costa
Victorian Department of Health and Human Services	Ms Karen Botting*
Victorian Department of Health and Human Services	Mr Michael Furey
Victorian Institute of Forensic Medicine	Prof Noel Woodford
Victorian Department of Justice and Regulation	Marisa De Cicco
Advisory Council	Dr Marisa Herson*
Donor Tissue Bank of Victoria	Mr Stefan Poniatowski*
Lions Eye Donation Service VIC	A/Prof Graeme Pollock*
Barwon Health Bone Bank	Mr Gavin Van de Meer
Australian Red Cross Blood Service	Ms Jennifer Williams
Australian Red Cross Blood Service	Mr David Pearce
Australian Red Cross Blood Service	Mr Chris Van Diemen
Victorian Lions Committee of Management	Mr Alf Hawken

Queensland

State Medical Director, Donatelife QLD	Dr Leo Nunnink
Qld Department of Health	Ms Ellen Hawes
QLD Tissue Banks (incorporating Eye, Bone & Skin, Heart Valve)	Mr Nicholas Nuttall*

South Australia

SA DonateLife State Medical Director	Mr Stewart Moodie
SA DonateLife Agency Manager	Heylen Laver

Manager Blood Organ & Tissue Programs, SA Health	Ms Sue Ireland
SA Tissue Bank	Mr Steve Nygaard
SA Eye Bank	Mr Stephen Pulbrook
Western Australia	
WA DonateLife State Medical Director	Dr Bruce Powell
WA DonateLife Agency Manager	Ms Melissa Smith
Project Coordinator, WA Health	Ms Julie Crouch*
WA Chief Medical Officer's Department	Dr Audrey Koay
WA Chief Medical Officer's Department	Ms Nyaree Jacobsen
PlusLife (Perth Bone and Tissue Bank)	Ms Anne Cowie
PlusLife (Perth Bone and Tissue Bank)	Ms Joyleen Winter*
Cell and Tissue Therapies WA	Dr Linda Manning
WA Lions Eye Bank	Dr Steve Wiffen
WA Lions Eye Bank	Ms Lisa Buckland
Tasmania	
DonateLife TAS State Medical Director	A/Prof Andrew Turner
DonateLife TAS Agency Manager	Ms Susan Townes
ACT	
Office of the Chief Health Officer	Dr Andrew Pengilley
ACT DonateLife State Medical Director	A/Prof Frank Van Haren
ACT DonateLife Agency Manager	Ms Kylie Downes
Northern Territory	
NT State Medical Director	A/Prof Dianne Stephens
NT Health representative	Ms Lee Wood
Australian Government	
Organ and Tissue Authority	Ms Yael Cass
Organ and Tissue Authority	Ms Judy Harrison*
Organ and Tissue Authority	Ms Eva Mehakovic
Organ and Tissue Authority	Mr Ashley Eccles*
Department of Health, Private Health Insurance Branch	Mr David O'Neill
Blood and Regulatory Policy Branch, Department of Health	Ms Catherine Winter
Blood and Regulatory Policy Branch, Department of Health	Ms Kate Griffiths-l'Anson
Therapeutic Goods Administration	Dr Glenn Smith

Therapeutic Goods Administration	Dr Tony Manderson
National Blood Authority	Mr Leigh McJames
National Blood Authority	Mr Michael Stone
Professional Associations and End Users	
American Association of Tissue Banking	Scott Brubaker
Australia and New Zealand Burns Association	Professor Fiona Wood
Eye Bank Association of Australia and New Zealand	A/Prof Graeme Pollock*
Lions Committee of Management	Mr Alf Hawken
Australia and New Zealand Society of Cardiac and Thoracic Surgeons	Professor Paul Bannon
VIC Adult Burns Service	Dr Heather Cleland
QLD Burns Surgeon	Dr Michael Rudd
TissueLife	Prof David Sonabend
Zaidee's Rainbow Foundation	Mr Allan Turner
NSW Corneal Surgeon	A/Prof Stephanie Watson
NSW Corneal Surgeon	Dr John Males
NSW Corneal Surgeon	Dr Tony Maloof
VIC eye surgeon	A/Prof Mark Daniell, Immediate Past President ANZCS
VIC eye surgeon	Dr Michael Loughnan
VIC eye surgeon	Dr Laurie Sullivan
VIC eye surgeon	Dr Alex Poon
VIC eye surgeon	Dr Jacqui Beltz
VIC eye surgeon	Prof Rasik Vajpayee
QLD eye surgeon	Dr Peter Beckingsale
QLD Eye Surgeon	Dr James McAlister
SA eye surgeon	A/Prof Richard Mills
SA eye surgeon	Dr Mark Chehade
TAS eye surgeon	Nick Downie
TAS Eye Surgeon	Dr George Smith
VIC Senior Cardiothoracic Surgeon	Peter Skillington
VIC Cardiac Surgeon	Prof David McGiffin
QLD Orthopaedic Surgeon	A/Prof David Morgan*
VIC Orthopaedic Surgeon	Neil Bergman
Private providers	

Australian Biotechnologies Pty Ltd	Ms Sharon Bryce
Australian Biotechnologies Pty Ltd	Mr Simon Berry
Medtronic Australasia	Sharyn Roberts

Outcome registries

Australia and New Zealand Organ Donor Registry	Ms Kylie Hurst
Australian Corneal Graft Registry	Dr Keryn Williams
Australian Orthopaedic Association National Joint Replacement Registry (NJRR)	Prof Stephen Graves

* Members of the ETEA Working Group

The following stakeholders provided survey responses:

Survey contributors

Eye Bank Association of America	Mr Kevin Corcoran
European Eye Bank Association	Mr Gary Jones
WA Trauma and orthopaedic surgeon	Prof Richard Carey Smith
QLD Orthopaedic Surgeon	Dr Matthew Scott-Young

Review context

Tissue banking in Australia stemmed from an identified need among surgeons for a service to collect and provide human tissues for clinical applications. Over time, the expanding demand from surgeons, and the emergence of newer technologies and processed tissues has created consolidation in the approach for tissue banking, and has resulted in organic centralisation services in many jurisdictions. The introduction of a new regulatory framework, coupled with a growing demand for specialised products and the entrance of new market providers has changed the operating environment for traditional tissue banking practices. It is in the context that this review considers the shape of the current sector, and its ability to meet future needs.

1 Context to this review

This review follows a series of efforts seeking to identify the needs within the tissue banking sector and how they can best be addressed to deliver an effective and efficient sector. In 2009, the Department of Health and Ageing engaged Health Outcomes International (HOI) to evaluate the supply and demand trends for eye and tissue donation and transplantation in Australia. The review recommended, among other findings, that the sector:

- move towards multiple smaller retrieval centres forwarding tissue to larger regional or national multi-tissue banks
- establish a National Eye and Tissue Network to develop national policies and harmonisation of procedures.

In 2011, the Organ and Tissue Authority (OTA) undertook a review of the effectiveness of eye and tissue banking, including to identify opportunities for improvement. Many of the recommendations echo those found in the 2009 HOI report. In particular, the report identified that there continues to be a need within the sector to improve coordination, harmonisation and embed sustainability within operating frameworks to meet the challenge of Australia's current and future clinical needs. Efforts have been made among jurisdictions through OTA working groups and relevant professional associations to address components of the tissue banking sector's to improve practices and coordination, however, there remains a need to focus efforts towards meeting evolving clinical needs.

Additional to the need to address governance and harmonisation aspects of the sector, is the changed regulatory environment in which tissue banking now operates. In May 2011, the Therapeutic Goods Administration (TGA) introduced the new Biologicals Framework. The framework was developed in liaison with the sector and has brought human cellular and tissue-based therapy products under a scheme of its own to more accurately reflect the complexities and characteristics of human tissues, having previously been regulated as medicines or devices. It establishes the regulatory requirements and assessment of safety and quality for tissue products, which, when approved, are included and administered through the Australian Register of Therapeutic Goods (ARTG).

Over a three-year transition period, the Australian Government allocated funding to meet the direct regulatory costs of compliance against the framework for Australian publicly-funded facilities and not-for-profit hospital supply units. This funding was extended another year, and is due to expire in early 2016.

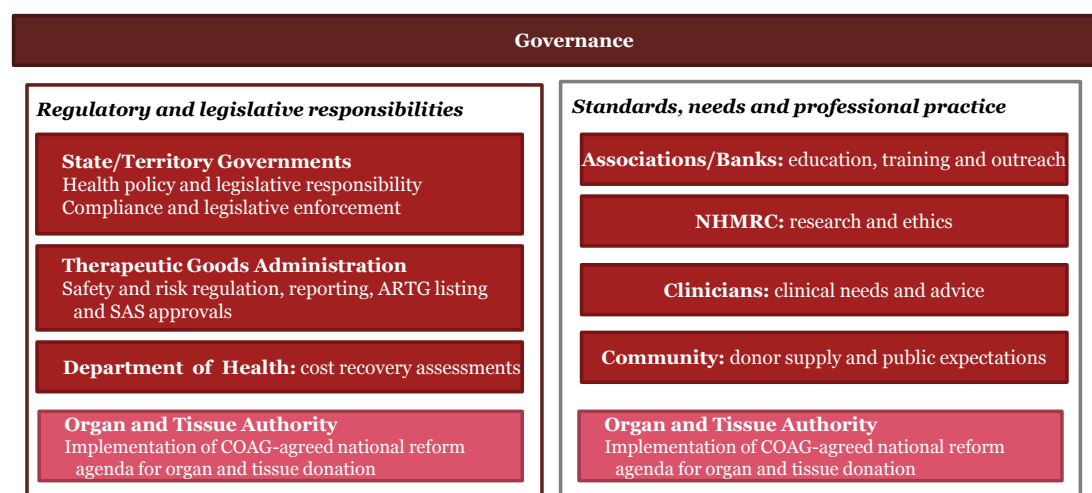
At the time of the release of the 2009 HOI report, six of the thirteen banks reviewed were running at significant financial deficit (>15% of costs); the financial viability of many tissue banks continues to challenge the sector as it adapts to the need to produce newer generation products to meet changing clinical preferences and meet the full costs of regulatory compliance expected to come into full effect in 2016. It is therefore timely that this review assess the sustainability of the sector, and the ability of tissue banking to adapt to the full regulatory costs and support future clinical needs.

2 Tissue banking context

Governance

The governance framework for tissue banking is fragmented, and is comprised of various regulatory, policy and interested parties. These are mapped in Figure 27 below.

Figure 27 - Governance, policy and regulatory entities of tissue banking



The only body with significant regulatory character is the TGA, who hold responsibilities for administering the biologicals framework and ensuring the safety, efficacy and quality of allografts. It is the primary regulatory lever for managing product risk relating to tissue use. Under the framework, all tissue banks are licensed by the TGA, and audited against their performance against the Code of Good Manufacturing Practice (cGMP). In 2013, the TGA released a revised cGMP for human blood and tissues. TGA licenses specific manufacturing steps, and may include additional conditions on licensed banks. The regulations require screening tests for donors of tissues, which must be undertaken at a TGA licensed laboratory. In addition, NAT testing is required on all deceased donations except cornea-only donors. Banks are required to meet testing, manufacturing and record-keeping requirements, and are audited by the TGA for compliance to retain their licence.

The introduction of the framework requires regulatory compliance with the cGMP and also a requirement for all therapeutic goods to be included on the Australian Register of Therapeutic Goods (ARTG) to be lawfully supplied to clinicians. The ARTG is administered by the TGA and is the comprehensive list of human-derived tissue products available in Australia that can be accessed for clinical applications. To include a product, tissue banks and suppliers (including international entities) must submit a product dossier to the TGA who makes an assessment of the clinical safety of a product. Tissues must also be collected in accordance with the TGA Order No.88, which sets standards for donor selection, testing and infectious disease control).

The federal Department of Health is responsible for assessing the cost-recoverable price for allografts distributed in Australia under the private health insurance scheme. It develops the benefits payable to private health insurers as set out in the Part B- Human Tissue Items Prostheses List. Each product has a listed fee, which varies between banks, and can be amended by banks twice annually through application to the Department of Health. At August 2015, 286 human tissue products were included.

Each jurisdiction is governed by state-based legislation which specifies the parameters within which tissue banks must operate. These are administered by the relevant state departments of health. Common to state legislation is the principle of 'no financial gain' from tissue collection and distribution. Queensland and Victoria operate under a system which prescribes tissue banks as processors and providers of human tissue, and issues permits for importation of tissues.

Standards and guidelines

As mentioned above along with the introduction of the biologicals regulatory framework in 2011 a number of mandatory standards have been introduced including a labelling standard and specific tissue standards for ocular tissue, musculoskeletal tissue, cardiovascular tissue and skin. In addition the TGA has developed the Australian Regulatory Guidelines for Biologicals and has adopted a number of international guidance documents.

The sector has produced standards and guidelines which promote better practice and provide specific guidance on protocols within the banking sector, in liaison with the clinical community. With the exception of eye banking, under EBAANZ, many of these standards are voluntary and non-universal in their application. Nevertheless, they provide an important framework against which the sector operates. Organisations with a role in tissue banking practice include:

- The Biotherapeutics Association of Australia (BAA) was established to support tissue banks and releases periodic tissue banking guidelines and reports
- The Transplantation Society of Australia and New Zealand (TSANZ) has developed eligibility and allocation criteria protocols for tissue.
- All eye banks are members of EBAANZ and follow the Association's allocation criteria and Medical Standards for Eye Donation and Ocular Tissue Banking.
- The National Health and Medical Research Council (NHMRC) who have produced research and guidance on ethics and tissue needs.

Cost recovery

The PHI Branch of the Department of Health assesses applications for cost recoverable amounts and approves the listing price on the Part B- Human Tissue Prostheses list. The list is updated by the Department twice yearly, and is the reimbursable amount for private health insurers for the use of different tissues, including enhanced products derived from human tissue. It is the primary mechanism for bank cost recovery.

Banks submit applications to list and amend their cost recovery amount on the Prostheses list. Applications must outline operating costs, and claims, against which the Department makes an assessment of. Banks must ensure they account for the true incurred costs of operation and production, as no buffers are accepted in the Department's assessment.

One issue is that payment for allografts is released upon implantation. This means that banks carry on ongoing operating cost for processing and storing unreleased tissues, which for some allografts, can span over years (particularly for heart and skin tissues, the latter of which is stockpiled). In addition, costs associated with the distribution of allografts interstate are worn by the providing bank until the allograft is implanted, and if returned, will not be recovered. Eye banks are an exception; they receive payment from banks to which they transfer.

Special Access Scheme

The SAS refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis.

The SAS allows individual patients to access unapproved therapeutic goods under a range of circumstances such as:

- early access for terminally ill patients to almost any product, including experimental and investigational products;
- access to products which have been withdrawn from the Australian market for commercial or other reasons;

- access to products provided initially to patients through a clinical trial while a marketing application is being considered; and
- access to products available overseas but not marketed in Australia.

Patient informed consent will always be a condition of the approval to supply under SAS.

Unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the TGA. Therefore, the responsibility for prescribing/using a product under SAS rests with the prescriber.

In considering requests to supply products under SAS, the TGA has a responsibility to maintain a balance between ensuring individuals gain timely access unapproved therapeutic goods and maintaining broader community interest that therapeutic products available in Australia are evaluated for quality, safety and efficacy.

To achieve this balance, the TGA has a responsibility to determine each request to supply an unapproved product on a case by case basis, taking into account the needs of the patient and the properties of the product.

In keeping with its overall charter, the TGA also has a responsibility to encourage at all times the availability of approved (evaluated) products. Thus, the various mechanisms for supply of unapproved products are intended to be temporary measures pending general marketing approval of the product. TGA requires that applications to use unapproved products justify adequately why available approved (fully evaluated) products are not suitable for use. Unfettered access to unapproved products amounts to de-facto marketing and would remove any incentive for a sponsor to seek registration of the unapproved product or for other sponsors to seek registration of alternative, similar products.

Survey

1 Survey responses

Surveys were distributed to a wide range of stakeholders, identified by the ETEA Working Group. Surveys were split into four categories to elicit information specific to stakeholders. Respondents to those surveys were:

- Tissue banks: Twenty respondents
- Governments: Twenty-four respondents
- Professional associations and end users: Fourteen respondents
- International stakeholders and private suppliers: Two respondents

2 How data has been used

Survey questions were posed to elicit data on supply and demand of allografts, and the perspectives of stakeholders on potential opportunities, barriers and future operating models. The designs of the surveys were agreed in liaison with the ETEA Working Group.

Data on revenue and expenditure was also captured through surveys. This data has been used to report on the financial viability of the sector. Data has not been disaggregated at the individual bank level as not all surveys were completed in whole (particularly in respect of demand) and reporting of specific current operating models and financials would easily identify individual banks. This reflects that survey respondents have provided data in confidence to allow for analysis of the sector as a whole. This report respects this agreement with survey respondents as to how data provided would be handled and published.

3 Survey assumptions

A number of assumptions about the data provided through surveys have been used in this analysis. These are:

- For the responses with interstate distributions that did not add up to 100%, percentages were redistributed using the existing proportions as a base.
- Banks who accept returns/do not accept returns do so for all types of tissue distributed.
- For operating models and funding models that haven't been ranked, a 'o' has been assumed.
- Describing how confident respondents are that the current sector structures for tissues is sufficient to meet future demand, less than 50 has been assumed as 'not confident' and greater than 50 as 'confident'.
- Several assumptions were made in relation to the private provider's response to the survey:
 - A ratio of 2.5 for femoral heads turned into crunch was used.
 - Whole femoral heads distributed was allocated by year based on the number of crunch allografts distributed

- 5 year averages of revenue and expenditure were provided; as such, both revenue and expenditure were allocated to the last five years based on the number of allografts distributed each year.
- All revenue was assumed to be fee-for-service income, as a breakdown was not provided.
- The data attained in relation to the Special Access Scheme included the name of the product, the state it was requested in, the year it was requested, and the quantity (presented in numerous forms). Several assumptions were made to analyse the data:
 - Quantities were provided in a mix of number of units and volume of units. As such, we have assumed that all volume figures were single units and all figures without a ‘cc’ volume measure is assumed to be in units.
 - Products were classified under their primary application.

