Review of the Australian organ donation, retrieval and transplantation system

Final Report

12 December 2018

Building a better working world

Acknowledgement

The Review wishes to acknowledge the organ donors and their families who have saved and transformed the lives of Australians needing a transplant through organ donation.

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Acronyms and abbreviations

ACTA	Australasian Transplantation Coordinators Association
AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
ANZCOTR	Australia and New Zealand Cardiothoracic Organ Transplant Registry
ANZDATA	Australia and New Zealand Dialysis and Transplant Registry
ANZIPTR	Australia and New Zealand Islet and Pancreas Transplant Registry
ANZLTR	Australia and New Zealand Liver Transplant Registry
ANZOD	Australia and New Zealand Organ Donation Registry
AODR	Australian Organ Donor Register
AOMS	Australian Organ Matching System
APRN	Advanced Practice Registered Nurse
ARIA+	Accessibility and Remoteness Index of Australia
COAG	Council of Australian Governments
CPIP	Clinical Practice Improvement Program
DBD	Donation after Brain Death
DCD	Donation after Circulatory Death
DNL	DonateLife Network
dpmp	Deceased donors per million population
EDR	Electronic Donor Record
HLA	Human leukocyte antigen
ICU	Intensive Care Unit
IDAT	Introductory Donation Awareness Training
IHPA	Independent Hospital Pricing Authority
IRODT	International Registry in Organ Donation and Transplantation
JAG	Jurisdictional Advisory Group
KDPI	The Kidney Donor Profile Index
KDRI	The Kidney Donor Risk Index
KPI	Key Performance Indicators
MBS	Medicare Benefits Schedule
MP	Minister of Parliament
NEP	National Efficient Price
NHMRC	National Health and Medical Research Council
NOMS	National Organ Matching System
NWAU	National Weighted Activity Unit
ODHSF	Organ Donation Hospital Support Funding
PBS	Pharmaceutical Benefits Scheme
RTAC	Renal Transplantation Advisory Committee
The 2015 Review	*Review of the implementation of the national reform agenda on organ and tissue donation and transplantation,* Ernst and Young 2015
The Act	*Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth)
The Best Practice Guidelines	The Best Practice Guidelines for Offering Organ and Tissue Donation in Australia

The Bill	*The Australian Organ and Tissue Donation and Transplantation Authority Bill* 2008
The Clinical Guidelines	*Clinical Guidelines for Organ Transplantation from Deceased Donor,* The TSANZ 2017
The Ethical Guidelines	*Ethical Guidelines for Organ Transplantation from Deceased Donor,* NHMRC 2016
The Framework	*The Data Governance Framework,* The OTA
The Human Tissue Acts	*Human Tissue Act 1983* (NSW)*; Transplantation and Anatomy Act 1979* (Qld)*; Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas)*; Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT)*; Human Tissue Transplant Act 1979* (NT)
The OTA	The Australian Organ and Tissue Donation and Transplantation Authority
The Privacy Act	*The Privacy Act 1988* (Cth)
The Review	*Review of the Australian organ donation, retrieval and transplantation system*, Ernst and Young 2018
The Steering Committee	The Organ Review Steering Committee
The TSANZ	Transplantation Society of Australia and New Zealand
TLRG	Transplant Liaison Reference Group
VTRTAC	Victorian and Tasmanian Renal Transplantation Advisory Committee

1. Executive summary

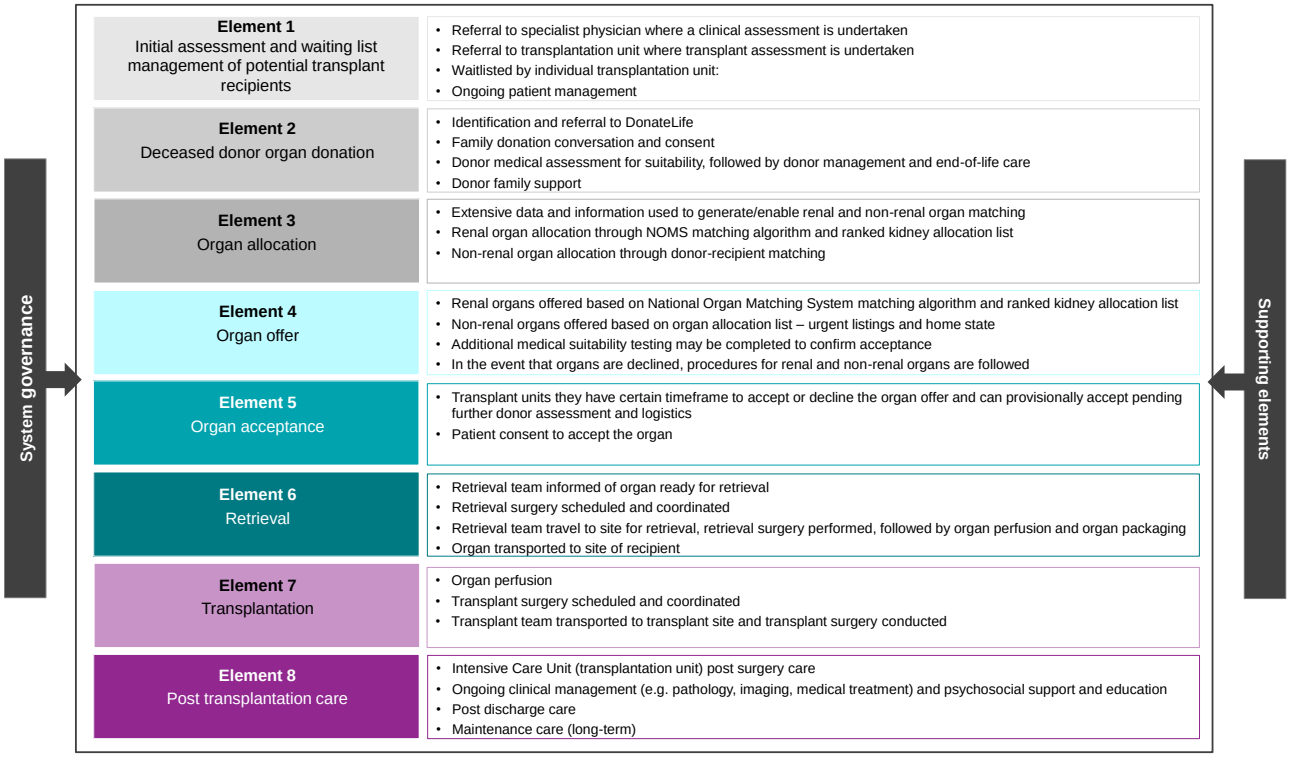
1.1 Introduction

1.1.1 Organ donation, retrieval and transplantation in Australia

Organ transplantation is a highly effective treatment for advanced organ failure that relies on donation from living or deceased persons.[1] Organ donation is when a person allows an organ of theirs to be legally removed, either by consent while the donor is alive or after death with the assent of the next of kin.[2]

A summary overview of eight key elements or steps of the Australian organ donation, retrieval and transplantation functional model are outlined in Figure 1. This diagram outlines the key steps or processes regarding how the current system operates. A more detailed version of the functional model can be found in Figure 2.

Figure 1: Summary overview of the Australian organ donation, retrieval and transplantation functional model



On 2 July 2008, the Australian Government announced a national reform package to establish Australia as a world leader in best practice organ donation for transplantation and achieve a

[1] The Transplantation Society of Australia and New Zealand (TSANZ) 2016, *Clinical Guidelines for Organ Transplantation from Deceased Donors Version 1.0 – April 2016*, viewed June 2018 <https://donatelife.gov.au/sites/default/files/TSANZ%20Clinical%20Guidelines%20for%20Organ%20Transplantation%20from%20Deceased%20Donors_Version%201.0_April%202016.pdf>.

[2] U.S. National Library of Medicine 2018, *Medline Plus: Organ Donation*, viewed November 2018 <https://medlineplus.gov/organdonation.html?PHPSESSID=acbbc427bed0eff2d9555e2f5caa4524>.

significant and lasting increase in the number of transplants for Australians. A key feature of the reform was the establishment of the Australian Organ and Tissue Donation and Transplantation Authority (OTA) which was designed to spearhead the reform agenda.

Since 2009, the number of deceased organ donors has increased by 106 per cent and the number of transplant recipients by 75 per cent.[3] This increased activity is placing significant pressure on downstream resources and workforce planning for organ retrieval and transplantation services. Researchers reported to the media that there was widespread variation in jurisdictional practice. This included wait listing and organ offer, allocation and acceptance processes. As well as retrieval, transplantation and post transplantation resources. In particular, the inequities experienced by Aboriginal and Torres Strait Islander people were highlighted on *The 7.30 Report* in December 2017.[4]

In recognition of this, The Minister for Health, the Hon Greg Hunt MP, and the Minister for Aged Care and Minister for Indigenous Health, the Hon Ken Wyatt AM, MP, jointly wrote to all Australian Health Ministers on 21 December 2017. They expressed their concerns relating to the disparity of access to the kidney transplantation waiting list for Aboriginal and Torres Strait Islander people. The letter advised it was the goal of the Australian Government to maximise the benefit to as many Australians as possible through transplantation and, as such, there was a need to ensure that the health system has the capability and capacity to optimise every donation and transplantation activity.

In April 2018, the Council of Australian Governments (COAG) Health Ministers considered the issue of pressure on downstream services from an increased donation rate. Acknowledging the issues facing Aboriginal and Torres Strait Islander people, the COAG Health Council agreed that the Australian Government would undertake a review of the Australian organ donation retrieval and transplantation system.

1.1.2 The Review of the Australian Organ Donation, Retrieval and Transplantation System

Purpose of the Review

The Australian Government Department of Health engaged EY to undertake the Review of the Australian Organ Donation, Retrieval and Transplantation System ('the Review') which commenced in May 2018. The Review was to consider current systems, practices and processes in the retrieval and transplantation sector. This included equity of access for all Australians, wait listing criteria, as well as organ offer, allocation and acceptance processes.

The Review was overseen by the Organ Review Steering Committee ('the Steering Committee'), which was led by the Australian Government Department of Health and comprised representatives from the OTA, nominated jurisdictions and a senior clinical specialist.

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[3] The Australian Organ and Tissue Donation and Transplantation Authority, 2017, *Australian Donation and Transplantation Activity Report 2017*, viewed September 2018, <https://donatelife.gov.au/sites/default/files/2017%20Australian%20Donations%20and%20Transplantation%20Activity%20Report.pdf>.

[4] *Organ transplant system tipped towards non-Indigenous patients,* 2017, radio program, ABC Radio, Sydney 14 December 2017.

The Review was to provide recommendations and evidence-based advice to inform the development of a future national strategy for the retrieval and transplantation sector in order to optimise deceased donation opportunities for maximum transplantation outcomes.

Review approach

The Review comprised an extensive consultation process and was supplemented by the collection of submissions from stakeholders, as well as a document, literature and data review.

Over 230 key stakeholders were consulted through the Review. This included Australian Government and jurisdictional government officials, training colleges and peak bodies, clinicians, transplant recipients and donor families.

1.2 Summary of key findings and recommendations

The summary key findings and recommendations for the Review (for a full explanation of the key findings and recommendations, see Sections 5, 6 and 7), against each of the elements of the Australian organ donation, retrieval and transplantation functional model (illustrated in Figure 1 and Figure 2), are described in

Table 1.

Table 1: Summary of the key findings and recommendations of the Review

Element	Key findings	Recommendations
Overarching Element: System Governance	• Australia had the highest percentage of growth in donation in the 9th year of reform compared to other countries that have undertaken national reform programs to increase organ donation (Spain, United Kingdom and Portugal). • A new national strategy is required in order to continue to drive performance of the system and meet key capacity issues, with a particular emphasis on innovative approaches to national workforce planning and coordination of retrieval and transplantation. • The states and territories, and their constituent Local Hospital Networks, should remain the primary vehicle for the delivery of organ donation, retrieval and transplantation services. • The OTA is best placed to lead strategic priorities and these initiatives; however, change will be required to the current agreement between the Australian Government and the state and territory governments. Further, additional resources will be required to enable the OTA to effectively undertake this role. • Current approaches for research and development and the adoption of new evidence-based practices in the Australian organ donation, retrieval and transplantation system are not undertaken in a planned and coordinated manner.	**Recommendation 1:** The Australian Government working in collaboration with states and territories use this report to guide the development of a future national strategy for the retrieval and transplantation sector to optimise every deceased donation opportunity for maximum transplantation outcomes. **Recommendation 2:** The Australian Government working in partnership with states and territories, develop a long-term national workforce strategy for the organ donation, retrieval and transplantation sectors. **Recommendation 3:** All Australian Governments resolve that the OTA should take a national strategic or coordination role under its existing legislation in regards to the following organ donation retrieval and transplantation issues: • National planning and service development • National standards and guidelines development • Advocacy for the donation, retrieval and transplantation system • Provision of advice to national research funding bodies based on advice obtained from the Transplantation Society of Australia and New Zealand (TSANZ) and other clinical advisers • Data collection, analysis and reporting to drive change and clinical best practice • National planning for the adoption of new evidence-based practice including new tissue typing and ex vivo organ perfusion technologies. **Recommendation 4:** The OTA should provide advice, based on guidance obtained from the TSANZ and other clinical advisers, to research funding organisations on the priorities for research in organ donation and transplantation.
Element 1: Initial assessment and wait listing management of potential transplant recipients	• Extensive evidence was reported in all the organ transplantation programs of the occurrence and challenge of late referrals of potential recipients to the transplantation program for assessment. • The assessment processes and waiting list management utilised by non-renal (liver, heart and lung) transplantation programs throughout Australia are reported to be generally consistent across transplantation programs by clinicians. • However, data show that there is large variation in waiting list numbers which may reflect non-uniform practices in wait listing potential recipients and the management of waiting lists for non-renal organs. • The assessment processes and waiting list management utilised by renal transplantation	**Recommendation 5:** All transplantation programs work with the continuing medical education pathways to improve the understanding of eligibility of patients for transplantation and the referral pathways among clinicians. **Recommendation 6:** The OTA, through the TSANZ, oversee a clinical review of waiting list practices and management across all non-renal transplantation units in Australia, including the application of the *Clinical Guidelines for Organ Transplantation from Deceased Donors* ('the Clinical Guidelines') for non-renal transplantation and data management. The findings from the clinical review should be used to identify best practice in waiting list practices and management, as well as better enabling benchmarking to drive performance improvement across transplantation units.

Element	Key findings	Recommendations
	programs throughout Australia vary greatly, resulting in variable performance and inequity. • This is primarily due to widespread variability in: (1) the use of the assessment criteria used to assess potential kidney transplant recipients; and (2) the process used to manage patients on the kidney transplantation waiting list. • There is widespread variability in waiting list practices for people receiving dialysis across Australia and the gap is widening. This is particularly apparent for Australians living in rural and remote locations and was reported by clinical stakeholders to be an issue in culturally and linguistically diverse populations. • Inequity is particularly experienced by Aboriginal and Torres Strait Islander people due to a number of inherent barriers that require further review and attention. These barriers to transplantation have been noted by Lawton, et al to be challenging, however are not insurmountable. An inability to overcome these impediments will continue to limit kidney transplantation in Aboriginal and Torres Strait Islander Australians. • There is no nationally agreed formal process for patients to obtain a second opinion if they are declined for kidney transplantation. • A potential recipient's visibility and oversight of their position or rank on the waiting list is currently limited. However, this is likely to be improved as planned strategies and systems are implemented. • There is currently no consistent approach to the education and consent of patients across Australia.	**Recommendation 7:** All Australian governments consider strategies to improve access to non-renal outreach clinics for assessment for transplantation, including an emphasis on work up for transplantation as close as possible to the potential recipient's place of residence. **Recommendation 8:** The OTA, through the TSANZ, commission a clinical review of the application of the Clinical Guidelines for kidney transplantation across all kidney transplantation units in Australia to assess the extent of variability in the use of these guidelines. **Recommendation 9:** Based on findings from the above mentioned clinical review, a national policy for the management of kidney transplantation waiting lists is to be agreed. It should seek to improve inequities in access to waiting lists and implement best practice waiting list management. **Recommendation 10:** The OTA, through collaboration with transplantation units, should publish the performance parameters for the management of kidney transplantation waiting lists annually in a clearly accessible form for the public. This includes the number of people and the proportion of Aboriginal and Torres Strait Islander and culturally and linguistically diverse people on dialysis on waiting lists to enable assessment of access to kidney transplantation for these groups. **Recommendation 11:** All patients on long-term dialysis programs should be informed by their treating medical specialist of the possibility of transplantation and their compliance with the waiting list acceptance criteria. **Recommendation 12:** All kidney transplantation programs should implement formal outreach arrangements with rural dialysis units as a condition of funding within the state or territory. These rural outreach arrangements must include a clearly defined pathway to kidney transplantation for rural residents, including specifically designed pathways for Aboriginal and Torres Strait Islander people, as well as a commitment to 'work up' a potential kidney transplantation recipient as close to their place of residence as possible. **Recommendation 13:** All kidney transplantation programs should implement formal arrangements with Aboriginal Community Controlled Health Organisations to increase the understanding of transplantation as a possibility for Aboriginal and Torres Strait Islander patients on dialysis. **Recommendation 14:** All dialysis units should have formal arrangements in place with a kidney transplantation program for the assessment of

Element	Key findings	Recommendations
		dialysis patients for possible kidney transplantation. **Recommendation 15:** All kidney transplantation programs should implement a formal process for the provision of a second opinion to potential transplant recipients who are determined to be ineligible for transplantation. **Recommendation 16:** The OTA through the TSANZ review the information provided to all potential recipients of organ transplantation to improve the understanding of the range of options that may arise if suitable donated organs are identified.
Element 2: Deceased donor organ donation	• Since 2015, organ donation in Australia has increased by 17 per cent and the rate of organ donation was 20.8 deceased donors per million population (dpmp) in 2017 (compared to the target of 25 dpmp in 2018). • The national organ donation target of 25 dpmp has been set based on modelling and currently the demand in every state is reported to be much higher than possible donation rates. • The total national demand for organ transplantation is not known at this time. • Donation performance continues to vary considerably by state and territory and by hospital. However, donation performance is not currently accessibly published to provide transparency of donation performance. • The positive growth experienced in organ donation performance is predicted to continue with projections of organ donation rates indicating that a dpmp of 27.1 will be achieved in 2025. • Consideration of resourcing of the system going forward is required in order to continue to drive organ donation performance as well as manage resourcing pressures downstream. • In 2016, Aboriginal and Torres Strait Islander organ donations made up 2.4 per cent of total organ donations in Australia. However, 9 per cent of the Aboriginal and Torres Strait Islander population were on dialysis. • Key reasons for low donation rates include poorer overall health precluding donation, health literacy of donation among health services, remote residence and community and cultural beliefs and ways of life. • Organ donation is limited in the non-European population. • Advances in transplantation care have underpinned a broadening of the acceptability of donated organs suitable for transplantation, however this has led to some inconsistency of	**Recommendation 17:** An epidemiological study into demand for organ transplantation in Australia to better understand the organ donation rates required to meet demand should be commissioned by the Australian Government. **Recommendation 18:** Based on the findings from the above study, the COAG Health Council should review the national organ donation target to ensure that donation strategies are designed to meet the expected demand for organ transplantation. **Recommendation 19:** The donation performance by each hospital with a total inpatient activity of over 20,000 National Weighted Activity Units (NWAU) per annum annually should be published on the DonateLife website in an easily accessible and user-friendly format to assist in identifying variability in performance and enabling benchmarking to more effectively manage hospital performance. **Recommendation 20:** As part of the development of the future national strategy for the retrieval and transplantation system, the Australian Government working in partnership with states and territories should develop a national Aboriginal and Torres Strait Islander and culturally and linguistically diverse population's organ donation strategy to improve donation rates in these groups. It should be based on the findings from this Review, and the work of the TSANZ (the Improving access to and outcomes of kidney transplantation for Aboriginal and Torres Strait Islander people project). The strategy should be developed in collaboration with the National Aboriginal Community Controlled Health Organisation, its affiliates and the states and territories. **Recommendation 21:** An advisory group of key stakeholders should be established as part of the strategy development to provide oversight and input into Aboriginal and Torres Strait Islander issues relating to organ donation. **Recommendation 22:** The OTA through the TSANZ, should undertake a review and revision of

Element	Key findings	Recommendations
	clinical practice in the acceptance of some organs. • There is an increasing number of donors who have been exposed to multi-resistant bacteria prior to donation and require additional testing to ensure that the recipient is not exposed. • The AODR was established initially as a register for intent, however the Australian Health Ministers' Conference agreed in 2005 that the AODR would be changed to a register of consent. • The concept of registering a person's decision about becoming an organ donor for transplantation after death is considered useful by most key stakeholders. • The AODR remains a useful system for recording the consent of potential donors, however the accessibility for potential donors is currently limited. • The aggregated data and reporting from the AODR is limited and does not include detail such as the use of the AODR by minority groups. • The difficulty of the process of registration through the current channels limits the potential to lift the prevalence of registration. • South Australia continues to be the jurisdiction with the highest proportion of their population registered, however the current links between the South Australian driver's license based scheme and the AODR remain problematic. • While the legislative provisions may vary depending on the jurisdiction regarding the rules which preclude the meeting of donor families and transplant recipients, the purpose remains the same: to protect the identity of those who have donated organs, or received transplantation. • There is divided opinion among donor families and recipients as to whether Australian policy should be changed to enable direct contact. • The donor family experience has anecdotally improved in recent years, however there remain some areas for improvement in the consistency and availability of support across the donation process.	the national standards for donor organ assessment and medical suitability of donors. **Recommendation 23:** All key stakeholders should consider the Australian Organ Donor Register (AODR) as the primary focus for the registration of an individual's decision about becoming an organ donor for transplantation after death across Australia. The focus should shift from the AODR being a record of donor consent to a record of donor intent. In doing so, consideration should be given to previous arrangements, including the driver's license based system, and the decision of the Australian Health Ministers' Conference regarding its purpose. **Recommendation 24:** The Australian Government should design and implement strategies to improve the number of registrations on the AODR, in particular for Aboriginal and Torres Strait Islander people and other groups of non-European heritage and data should be captured on the use of the AODR by different demographics in the Australian population in order to inform strategies to improve registration rates. **Recommendation 25:** The strategies to improve the AODR registrations should be broadened to include links to social media and other entry portals. This will enable greater visibility and accessibility of the AODR. **Recommendation 26:** States and territories establish a nationally uniform process for arrangements for donor families and recipients over the age of 18 to be identified to each other based on the principle of mutual informed consent.
Element 3: Organ allocation	• Allocation of non-renal organs closely aligns with offer and acceptance. The allocation process follows the Australasian Transplantation Coordinators Association national rotation list. • The allocation process can be time consuming and inefficient due to the ring-around process. • Generally non-renal allocation processes are consistent across transplantation units and	**Recommendation 27:** The introduction of concomitant sharing of donor profiles with all transplantation programs once the matching process has progressed beyond the home state offer should be considered and implemented as part of the OrganMatch functionality. This should be considered as part of a review of the heart, lung and liver organ allocation process in order to improve the efficiency of the organ matching process in liver, heart and lung transplantation.

Element	Key findings	Recommendations
	align closely to the Clinical Guidelines with some variability in allocation of liver and lung due to advancements in transplantation techniques. • The impending review of the National Organ Matching System (NOMS) kidney allocation algorithm to be conducted by the TSANZ and the Renal Transplant Advisory Committee is timely. • There is no Aboriginal and Torres Strait Islander health expertise or community input into the revision of the cadaveric kidney donation algorithm currently utilised by the NOMS (and soon to be utilised by OrganMatch). • The current renal organ matching system, the NOMS is due to be replaced by OrganMatch in April 2019 and will have improved capability and functionality compared to the current system. • The Review found that current governance and resourcing arrangements will not be adequate to support the expansion of OrganMatch in the future. • Tissue typing services in Australia are comprehensive and responsive to the needs of transplantation clinicians and patients, however there is limited benchmarking of their performance. • Tissue typing technologies are expanding and becoming increasingly complex, the introduction of these new technologies is not implemented in a planned and coordinated way at a national level. • The State Balancing System was implemented when donation rates varied considerably between the jurisdictions. Given donation rates have become more aligned nationally, there was agreement that its materiality in the current environment should be assessed. • The State Balancing System has the potential to slow progress in improving organ donation and transplantation practices and increase inequity of the allocation of high quality organs.	**Recommendation 28:** The planned review of the kidney matching algorithm to be conducted by the TSANZ should include Aboriginal and Torres Strait Islander health expertise and community representation. **Recommendation 29:** The planned review to be conducted by the TSANZ of the kidney matching algorithm should take into account the latest science to ensure that the algorithm remains relevant to contemporary kidney transplantation best practice. **Recommendation 30:** The replacement of the NOMS to OrganMatch is a key opportunity to improve the organ allocation process and must be adequately resourced and managed at a national level. The Australian Government should consider what is required to effectively implement and optimise OrganMatch in the future. **Recommendation 31: A** national plan should be developed by all Australian Governments for the adoption of new tissue typing technologies. **Recommendation 32:** A system for national benchmarking of tissue typing service performance be implemented nationally by all Australian Governments. **Recommendation 33:** The OTA, through the TSANZ undertake a review of the State Balancing System to determine the impact on the efficiency, effectiveness and equity of the allocation process. Any proposed changes should then be modelled and reviewed to understand their impact.
Element 4: Organ offer	• The offer process for renal and non-renal allocation is time-consuming, inefficient and risks losing the consent of the family for donation. For example, the Australasian Transplant Coordinators Association reported that 68 per cent of organs offered were declined at least once by a transplantation unit in 2017 leading to time delays in acceptance. This was reported to be particularly burdensome on donor families. • The EDR is extensively used across Australia as the initial point of donor assessment, however its current functionality – in particular the PDF	**Recommendation 34:** As per Recommendation 27, the introduction of concomitant sharing of donor profiles with all kidney transplantation programs in OrganMatch at the commencement of the matching process should be considered to improve the efficiency of the process of organ offer process for transplantation. **Recommendation 35:** The OTA to commence a process to plan arrangements for an extensive upgrade to the output of the Electronic Donor Record (EDR) (or an alternative platform, such as utilising the functionality of OrganMatch), in collaboration with donation and transplantation

Element	Key findings	Recommendations
	output – presents challenges regarding its utilisation and the ability to share accurate and timely information. As such, the PDF output of the EDR requires upgrading. • The implementation of OrganMatch provides an opportunity to improve the sharing of donor profiles and its functionalities could be explored to facilitate improved surveillance and safety.	specialists, to improve its functionality. The upgrade should facilitate rapid time feedback to improve surveillance and safety. The plan should then be considered by the Australian Government for approval.
Element 5: Organ acceptance	• Advances in acceptability of organs by transplantation units has resulted in variability of acceptance practices for organs from extended criteria donors across jurisdictions. • More transplantation units are now considering a greater range of organs based on age as well as comorbidities and disease profiles. • Current data systems do not enable to capture of reasons for offer declines and the analysis of system bottlenecks affecting offer acceptance. • Advances in acceptability of organs by transplantation units has resulted in variability of acceptance practices for organs from extended criteria donors across jurisdictions. • More transplantation units are now considering a greater range of organs based on age, as well as comorbidities and disease profiles.	**Recommendation 36:** The OTA, through the TSANZ, should develop a clinical review process and optimise the use of extended criteria donated organs. **Recommendation 37:** The OTA, through the TSANZ, should develop a process to monitor the incidence of organ offer decline decisions and a process to clinically review those decisions.
Element 6: Retrieval	• The retrieval system for solid organ donation is currently under pressure due to increased donation rates and limited national planning for future demand. • There is an impending shortage of resources for retrieval resulting in inefficiencies, risks to quality and safety and the potential to decline retrieval due to logistical reasons. • Aviation services contractual arrangements are negotiated locally in each transplantation unit – often without a standing contract. There is currently no national approach to the sourcing or procurement of aviation services for the organ retrieval process. • There is international evidence that shows the benefits of 'de-coupling' retrieval teams from transplantation. Australia is currently utilising a hybrid system where 'de-coupling' retrieval services is more readily used for abdominal organ retrieval procedures. However, a 'de-coupled' model for all organ retrieval is not currently supported by all clinicians or the current funding model. • There is no evidence of national oversight or a detailed nationally focused resource plan for the expansion of organ retrieval services to meet the likely increase in demand.	**Recommendation 38:** The OTA should develop a national organ retrieval resource plan to more effectively manage and coordinate processes and training programs across Australia to meet the expected increase in organ retrieval demand. **Recommendation 39:** The current organ retrieval tasking system should be retained; however, its adequacy should be reviewed in two years' time by the OTA to ascertain whether a national tasking system is required as demand increases. **Recommendation 40:** Consideration should be given to the development of national sourcing of aviation services by the states and territories to support organ retrieval services in a more coordinated manner. **Recommendation 41:** All Australian governments consider developing a national plan to optimise the use of perfusion technologies and ensure that best practice technology is available to transplantation units.

Element	Key findings	Recommendations
	• The provision of cardiothoracic retrieval services in South Australia and the Northern Territory would be enhanced by the development of retrieval surgery skills within the cardiothoracic teams based in Adelaide. • The provision of abdominal retrieval services in the Australian Capital Territory and Tasmania would be enhanced by the development of abdominal retrieval surgery skills in the surgical teams based in Canberra and Hobart respectively, along the lines of the abdominal organ retrieval services currently operating in Darwin. • Ex vivo perfusion technology use is already well established in heart and lung transplantation and evidence is emerging in its role in liver and kidney transplantation.	
Element 7: Transplantation	• The resource coordination and management of transplant surgery remains a challenge at every centre, however solutions to this challenging problem inherently lie in local resolution. • National oversight is required to identify underperformance and resource inefficiencies to design strategies to improve overall performance in transplantation rates.	**Recommendation 42:** The OTA should provide a national oversight role to identify opportunities for practice improvement in relation to the operational management of transplantation procedures.
Element 8: Post transplantation care	• Kidney transplantation programs generally have well established networks for returning transplantation patients to their home community including handover of ongoing care (with support) provided by a local specialist in most cases. • The heart, liver and lung transplantation programs do not generally have post transplantation care networks developed with the relevant specialists close to where the patient resides. Whilst this model has served these programs well in the past it is unsustainable in the future given the projected increase in the population of post transplantation patients. • The transition from paediatric care to early adult care is problematic for many transplant recipients and must be specifically managed and resourced in all paediatric transplantation programs. • Post transplantation outcomes experienced among Aboriginal and Torres Strait Islander people are currently much worse than those experienced by non-Indigenous Australians. Further work is required to identify issues affecting graft and patient survival and design strategies as part of the TSANZ project. • Patient experience data post transplantation is not currently collected consistently within the system. The introduction of mechanism to measure experience may greatly benefit the	**Recommendation 43:** The heart, lung and liver transplantation programs develop post transplantation models of care that includes shared care with an appropriate locally based clinical team after the initial period of post transplantation stabilisation, particularly in the case of rural and regional patients. **Recommendation 44:** Each paediatric organ transplantation program, and its affiliated adult transplantation program, develop explicit pathways for transition to adult care if these pathways are not already in place. **Recommendation 45:** Each transplantation unit should provide comprehensive rehabilitation for patients post transplantation with a focus on employment and social participation. **Recommendation 46:** Patient reported outcome measures be added to all organ transplant outcome registries.

Element	Key findings	Recommendations
	effectiveness of policy and outcomes in transplantation.	
Supporting element 1: Data and information management	• Access to data held by the OTA which is not currently distributed to all government representatives is only granted with the consent of all nine government representatives. This impairs the management of the organ transplantation programs. • Comprehensive and robust national patient outcome registries exist for kidney, heart, lung and liver transplantation. However, all registries could be enhanced by the addition of more information on reasons organs have been declined by the transplantation unit, the number and characteristics of patients waiting for kidney transplantation, patient reported outcomes, and the use and outcomes of organs donated from extended criteria donors. • The entry of patient data into the outcome registries is laborious and consumes a lot of time and resources from clinical staff and is often completed on a voluntary basis. • The OTA is currently working with states and territories to develop a Data Governance Framework with the aim to improve data management and access.	**Recommendation 47:** The states and territories should facilitate access to and sharing of nationally agreed de-identified datasets among jurisdictions through continued support to the OTA to develop and implement its data governance framework. **Recommendation 48:** National patient outcome registries for heart and lung transplantation should be formally and comprehensively supported by the OTA and funded to reflect their purpose. **Recommendation 49:** Consideration should be given by the OTA to the consolidation of all registries into one central system. **Recommendation 50:** Consideration be given by the states and territories to the automation of data submission to the organ transplant outcome registries via the electronic medical records operating in most transplantation units. **Recommendation 51:** Measures of access to the kidney transplantation programs and data relating to the profile and numbers of patients on the kidney transplantation waiting list as well as outcomes from the use of organs from extended criteria organ donors should be considered by the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) for inclusion in the data set that is collected and reported.
Supporting Element 2: Financing arrangements for the system	• The current national Activity Based Funding model does not adequately cover costs in the circumstance where retrieval is undertaken (and a cost is incurred) and transplantation does not eventuate. The current model allocates retrieval costs to the recipient; however, if the transplant does not occur, the transplantation unit is not reimbursed for the cost of the retrieval. • There is anecdotal evidence that the costs of the retrieval and inpatient phase of care have increased substantially in recent years. This is due to factors such as the introduction of ex vivo perfusion technologies, new immunosuppressant medication as well as the extended length of stay incurred with rising rates of Donation after Circulatory Death (DCD) donated organ transplantation. This appears to be reflected in the national Activity Based Funding model through increasing price weights. • The current Australian Revised Diagnosis Related Groups classification arrangements for organ transplantation are not sufficiently refined to accurately price the difference in	**Recommendation 52:** The Independent Hospital Pricing Authority (IHPA) conduct a costing study and classification review for the classification of organ donation, retrieval and transplantation to take into account the cost impact of the use of DCD donated organs and organs from extended criteria donors and to appropriately attribute retrieval costs. **Recommendation 53:** Consideration be given by the Australian Government to applying indexation to the Organ Donation Hospital Support Funding (ODHSF) at the same rate as the indexation of the National Efficient Price as determined by the IHPA annually. **Recommendation 54:** The IHPA conduct a costing study and classification review for the classification of non-admitted pre and post organ transplantation care. **Recommendation 55:** Consideration should be given by the Australian Government for the proscription of access to the Medicare Benefits Schedule (MBS) for the recipients of organ transplantation other than kidney transplantation be removed from the next version of the General Explanatory Notes 13.33 of the MBS.

Element	Key findings	Recommendations
	costs between DCD and Donation after Brain Death (DBD) donated organ transplantation. • The Australian Government funding contribution to hospitals to support organ donation has not been indexed since its inception. • The current Tier 2 classification is not sufficiently refined to allow differential pricing of the wide spectrum of pre-transplantation assessment. • The current General Explanatory Note.13.33 of the Medicare Benefits Schedule proscribes claiming for post transplantation care, with the exception of kidney transplantation. • Current funding arrangements for the review of the kidney algorithm is not comprehensively funded. • The OrganMatch project is currently funded up until it goes live on 2 April 2019 and includes an additional year of funding to April 2020 for managed support, infrastructure and licensing. It does not include budget for any application system enhancements.	**Recommendation 56:** The funding allocated to the implementation of OrganMatch should be reviewed by the Australian Government to take into account the need to model the potential outcomes of any altered algorithms that will be utilised within the new system.
Supporting Element 3: Research for the organ donation, retrieval and transplantation system	• A range of research activities have been identified during the Review which are not currently coordinated through a national system aligned to the national strategy. • There are a number of research activities taking place that should be considered in future research strategies.	**Recommendation 57:** The OTA should provide national oversight and coordination of research activities after consultation with the TSANZ and other clinical advisers and consider the following research opportunities and priorities: • The place of ex vivo perfusion technologies in kidney and liver transplantation. • Point of care testing for kidney transplant recipients in remote Australian communities. • The possible use of monthly administration of immunosuppressant medications in remote communities following organ transplantation. • Alternative donor matching technologies. • Organ donation patterns in minority and marginalised communities within Australia. • The reasons why families change their mind after agreeing to organ donation. • The overall demand for organ transplantation in Australia (see Recommendations 17 and 18).

1.3 Priorities for action

1.3.1 An organised, nationally driven strategy to meet the expected increase in organ transplantation volumes

The objective of this Review is to provide evidence-based advice and recommendations to inform the development of a future long-term strategy for Australia's retrieval and transplantation sector for deceased donation. The Review has highlighted the significant progress that has been made in moving Australia towards developing one of the world's best organ donation, retrieval and transplantation systems, in alignment with the national reform agenda which commenced in 2009. The progress in the system can be attributed to the sustained effort of the Australian Government and state and territory governments working together in joint action.

Nevertheless, the Review found that the continued growth of the system has begun to put strain on the capability and capacity of the system to maintain continued growth in donation and transplantation. Further, the Review found variability in donation, retrieval and transplantation practices and performance across Australia, resulting in inequity of access and outcomes by Australians. As such, this Review endorses the commitment of all Australian governments, agreed through the COAG Health Council, to establish a future long-term strategy for the retrieval and transplantation sector. It is important that the strategy is underpinned by an epidemiological study on end-stage organ disease. Further, the strategy needs to include: (1) input from key stakeholders including donor families, recipients and potential recipients, and (2) performance and accountability measures to ensure that progress is maintained.

1.3.2 Governance to optimise future growth and sustainability of the donation, retrieval and transplantation system

The Review found that the current governance arrangements for the system require enhancement in order to drive continued growth and sustainability of donation and transplantation outcomes. The Review found that governance arrangements are well developed across the donation elements of the system; however, they are complex and variable for retrieval and transplantation.

Currently states and territories, and their constituent Local Hospital Networks, are the primary vehicle for the delivery of organ retrieval and transplantation services and it should remain this way. However, there are a range of national issues impacting the organ retrieval and transplantation system which require national oversight and coordination to resolve, particularly as the new strategy and best practice advances are implemented.

The OTA is best placed to take on this role and drive the implementation of the strategy and the recommendations from this Review. To date, the OTA have focused their attention on donation, as directed by policy priorities and government funding. The current legislation provides for the OTA to have oversight and some responsibility over the retrieval and transplantation system; however current resource allocations limit the OTA's influence. For the OTA to effectively take on this strategic planning and service development role the following will be required: (1) changes to agreements between the Australian Government and the states and territories; and (2) additional resources. Additional resources will be required for the OTA, as well as additional Australian Government funding for state and territory health systems.

The Review found that there is limited input into governance structures and strategic aspects of the system by consumers, and both Aboriginal and Torres Strait Islander and culturally and linguistically diverse communities. In designing and implementing strategies to overcome barriers

to access and achieving optimal outcomes for all Australians, the consideration of these perspectives will be critical to ensure that strategies are appropriate and effective.

1.3.3 A nationally driven approach to improve organ donation and transplantation rates among Aboriginal and Torres Strait Islander Australians and Australians who live in rural and remote locations

Aboriginal and Torres Strait Islander Australians

Aboriginal and Torres Strait Islander Australians experience a higher burden of disease and poorer life expectancy than non-Indigenous Australians. This is largely driven by cardiovascular disease, kidney disease and liver disease and often results in end-stage organ failure.[5]

Organ transplantation is an established form of treatment that is acknowledged as the best, and frequently the only life-saving therapy, for end-stage organ failure.[6] There is a five-to ten-fold reduction in mortality for patients who have received a kidney transplant compared to those who remain on dialysis.[7]

As described by Khanal, Lawton, Cass and McDonald (2018), the incidence and prevalence of end-stage kidney disease is higher among Aboriginal and Torres Strait Islander Australians than non-Indigenous Australians, particularly among those aged 15-64.[8] This means that Aboriginal and Torres Strait Islander people have a greater demand for organ transplantation than non-Indigenous Australians. However, fewer than two per cent of Aboriginal and Torres Strait Islander Australians are wait listed for transplantation, compared to 9.5 per cent of non-Indigenous people on dialysis.[9] The Review found that access to transplantation was influenced by donation rates and variable wait listing practices across transplantation units.

The Review found that family consent rates to donation are significantly lower in Aboriginal and Torres Strait Islander families (20 per cent) than non-Aboriginal and Torres Strait Islander families (67 per cent).[10] Clinicians also reported that patients from populations with smaller numbers in the Australian community, such as Aboriginal and Torres Strait Islander Australians, will not have the same probability of finding a match within the allocation algorithms as their immunological profiles will be under represented in the donor pool. Therefore, the Review found that it was important that Aboriginal and Torres Strait Islander donation rates continue to increase in order to improve the potential for suitable matches. The significance of immunological matching is discussed in further detail in Section 6.2.3.

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[5] Chinnaratha M, et al, 2014, 'Liver transplantation outcomes for Australian Aboriginal and Torres Strait Islanders', *Liver Transplantation* vol. 20 No.7, pp. 798-806.

[6] World Health Organisation 2018, *Donation and transplantation: WHO Task Force on Donation and Transplantation of Human Organs and Tissues*, viewed November 2018, <http://www.who.int/transplantation/donation/taskforce-transplantation/en/>.

[7] Chapman C, Kanellis J, 2018, 'Kidney donation and transplantation in Australia: more than a supply and demand equation', *Medical Journal of Australia* Vol. 209, No. 6, pp. 242-243.

[8] Khanal N et al, 2018 'Disparity of access to kidney transplantation by Indigenous and non-Indigenous Australians' *Medical Journal of Australia* Vol. 209 No. 6 pp. 261 – 266.

[9] Ibid.

[10] The Australian Organ and Tissue Donation and Transplantation Authority, "DonateLife Audit 2018" (received December 2018).

The Review also found that some jurisdictions had established strong referral and shared care processes; this included outreach services and strong Aboriginal and Torres Strait Islander community linkages to enable access to wait listing for Aboriginal and Torres Strait Islander Australians. On the other hand, Aboriginal and Torres Strait Islander people in other jurisdictions experienced barriers to wait listing due to distance, travel costs and access to appropriate specialists for assessment for transplantation.

With adjustment for age and diabetes prevalence, Lawton found that survival for both Aboriginal and Torres Strait Islander Australians and non-Indigenous Australians has improved over time despite an increasing burden of comorbid conditions.[11] However, there remains a large gap in survival rates between Aboriginal and Torres Strait Islander Australians and non-Indigenous Australians. The Review found that survival rates of Aboriginal and Torres Strait Islander people are influenced by a number of factors including organ matching and post transplantation care. Limited access to medical services means that Aboriginal and Torres Strait Islander Australians often experience greater difficulty in accessing post transplantation care. As such, they were less likely to adhere to post transplantation care requirements, increasing their risk of infection and graft survival.

In order to maximise the benefits of transplantation to as many Australians as possible, a nationally coordinated approach to improve organ donation and transplantation rates among Aboriginal and Torres Strait Islander Australians should be a key part of the new strategy. This would assist to overcome barriers to wait listing and transplantation outcomes and improve overall health outcomes for Aboriginal and Torres Strait Islander Australians. This Review notes the importance of the project being undertaken by the TSANZ to identify the specific hurdles, service gaps and practical challenges faced by Aboriginal and Torres Strait Islander Australians receiving treatment of renal disease. This work will also further inform the future strategy. The Australian Government Department of Health similarly acknowledges its importance, as recognised by the funding arrangements currently in place with the TSANZ to address these issues.

Australians living in rural and remote locations

Around seven million people – about 29 per cent of the population – live in rural and remote areas of Australia.[12] They experience unique challenges due to their geographic isolation and often have poorer health outcomes than Australians living in major cities.[13] In line with this, the Review found that Australians who live in rural and remote locations experience higher rates of chronic organ disease, yet experience significant barriers to transplantation.

The Review found that Australians living in very remote areas have more than six times the rate of kidney and urinary diseases and just under double the rate of dialysis compared to Australians

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[11] Khanal N, above n.8.

[12] Australian Bureau of Statistics, 2017 *Regional Population Growth: Australia, 2016 – 17,* Catalogue No: 3218.0, Canberra, viewed October 2018 <http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/3218.0Main+Features12016-17?OpenDocument>.

[13] Australian Institute of Health and Welfare, 2018, Australia's Health 2018, Australia's health series no. 16. AUS221, Canberra, viewed October 2018 <https://www.aihw.gov.au/reports/australias-health/australias-health-2018/contents/table-of-contents>.

living in major cities.[14] However, Australians living in rural and remote locations are about half as likely to receive a kidney transplantation.[15] This is due to factors such as distance, travel costs, access to appropriate specialists, access to appropriate assessment and access to post transplantation services. The Review found that people living in rural and remote locations were significantly less likely to be wait listed for kidney transplantation compared to Australians living in major cities.[16] This means that Australians living in rural and remote locations are not receiving the same level of access to assessment, or are being assessed late, which dramatically decreases the potential health outcomes from transplantation.

The Review recommends a nationally coordinated effort to improve access to transplantation and reduce inequities for Australians living in rural and remote locations as part of the future strategy. Detailed strategies that aim to improve access to transplantation for Aboriginal and Torres Strait Islander people and Australians living in rural and remote locations are detailed further in Sections 5, 6 and 7 of this report.

[14] Ibid; Australia and New Zealand Dialysis and Transplant Registry, "Remoteness Dialysis and Transplantation Data 2013 – 2016" (received September 2018).

[15] Ibid.

[16] The Australian Organ and Tissue Donation and Transplantation Authority, "Dialysis and Transplant Numbers per state by Remoteness" (received October 2018).

2. Introduction and Terms of Reference

2.1 Organ donation, retrieval and transplantation

Organ transplantation is a highly effective treatment for advanced organ failure that relies on donation from living or deceased persons.[17] Organ donation is the process in which a person allows an organ of theirs to be legally removed, either by consent while the donor is alive or after death with the assent of the responsible relative or guardian.[18] The procedure for removing the organ from the organ donor is called organ retrieval. The most commonly donated, retrieved and transplanted organs in Australia include the heart, liver, lungs and kidneys. Pancreas and intestine donations retrievals and transplantations are also performed in Australia, but are less common.

As a treatment, transplantation meets a very specific need in the management of end-stage organ failure as a form of organ replacement therapy. Transplantation should be considered as a final treatment option for end-stage organ disease in the context of wider population based interventions that aim to prevent or manage chronic organ disease, thereby reducing the overall health burden of end-stage organ failure.

2.2 Background and context to the Review

On 2 July 2008, the Australian Government announced a national reform package to establish Australia as a world leader in best practice organ donation for transplantation and achieve a significant and lasting increase in the number of transplants for Australians. The objectives of the reform were to:

- Increase the capability and capacity within the health system to maximise donation rates
- Raise community awareness and stakeholder engagement across Australia to promote organ and tissue donation.

As part of the reform, the Australian Government committed $151.1 million over four years (2008–2012) to implement evidence-based reforms that were designed using international and national best practice models with a proven track record of maximising donation rates.[19] The reform package was endorsed by COAG on 3 July 2008.

A key feature of the reform was the establishment of the OTA which was designed to spearhead the reform agenda. The OTA was funded to establish a coordinated and consistent national approach to the reform, and to provide governance to a network of organ and tissue donation agencies.

In 2015, the Australian Government commissioned EY to undertake a review of the implementation of the national reform agenda on organ and tissue donation ('the 2015 Review'). The 2015 Review found that although progress had been made in implementing the reform agenda, a number of areas required further improvement in order to meet its objectives. As such, 24 recommendations were made; many of which have been actioned and some are still in

[17] The Transplantation Society of Australia and New Zealand, 2017, above n.1.

[18] U.S. National Library of Medicine, 2018 above n.2.

[19] *Explanatory Memorandum, Australia Organ and Tissue Donation and Transplantation Authority Bill 2008* (Cth).

progress (see Section 3.2 for further detail on the 2015 Review).

Action against the recommendations from the 2015 Review has continued to drive progress in the national reform agenda and has meant that Australia continues to be one of the highest performing countries in quality, safety and health outcomes from organ and tissue donation. However, recent studies have revealed that: (1) an increase in organ donation activity has placed pressure on retrieval and transplantation resources and services across Australia; and (2) inconsistent practices across the country has resulted in inequities within the system.

Since 2009, the number of deceased organ donors has increased by 106 per cent and the number of transplant recipients by 75 per cent.[20] This increased activity is placing significant pressure on downstream resources and workforce planning for organ retrieval and transplantation services. As a result, researchers reported to the media that there is widespread variation in jurisdictional practice. This includes wait listing, organ offer, allocation and acceptance processes, as well as retrieval, transplantation and post transplantation resources.

Dr Paul Lawton highlighted the inequities experienced by Aboriginal and Torres Strait Islander Australians in an interview with the *7.30 Report* in December 2017. The interview emphasised the large disparity in access between Aboriginal and Torres Strait Islander and non-Indigenous Australians to wait listing and kidney transplantation.[21] Of note, fewer than two per cent of Aboriginal and Torres Strait Islander Australians were put on a waiting list for transplantation, compared to 9.5 per cent of non-Indigenous Australian on dialysis.[22] Dr Lawton's research revealed that an Aboriginal and Torres Strait Islander Australian from remote Australia has one tenth of the chance of receiving a transplant as a non-Indigenous Australian in the same position. On the other hand, Aboriginal and Torres Strait Islander Australians on dialysis in urban areas have one third of the chance of being transplanted.[23]

In recognition of the need to act on these inequities, The Minister for Health, the Hon Greg Hunt MP, and the Minister for Aged Care and Minister for Indigenous Health, the Hon Ken Wyatt AM, MP, jointly wrote to all Australian Health Ministers on 21 December 2017. They expressed their concerns relating to disparity of access to the kidney transplantation waiting list for Aboriginal and Torres Strait Islander Australians. The letter advised that it was the goal of the Australian Government Department of Health to maximise the benefit of transplantation to as many Australians as possible. As such, there is a need to ensure that the health system has the capability and capacity to optimise every donation and transplantation activity.

In April 2018, the COAG Health Ministers considered the issue of pressures on downstream services from an increased donation rate. Out of that meeting, acknowledging the issues faced by Aboriginal and Torres Strait Islander Australians, the COAG Health Council agreed that the Australian Government would undertake a review of the Australian organ donation, retrieval and transplantation system.

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[20] The Australian Organ and Tissue Donation and Transplantation Authority, 2017, above n.3.

[21] ABC Radio, 2017, above n.4.

[22] Ibid.

[23] Ibid.

2.3 Review of the Australian organ donation, retrieval and transplantation system

On 9 July 2018, Minister Wyatt wrote to the Australian Health Ministers to advise them of the COAG Health Council's agreement to undertake a review of the Australian organ donation, retrieval and transplantation system. The letter identified that the Review would take into consideration current systems, practices and processes in the retrieval and transplantation sector. This included equity of access for all Australians, wait listing criteria, and organ offer, allocation and acceptance processes. The letter also advised of the establishment of the Steering Committee to oversee the Review and provide guidance to ensure the Review was robust, accurate and effective. The Steering Committee was to be led by the Australian Government Department of Health and comprising representatives from the OTA, nominated jurisdictions and a senior clinical specialist.

The Australian Government Department of Health engaged EY to undertake the Review, which commenced in May 2018 and was completed on 7 December 2018.

The Terms of Reference for the Review included two phases of work. EY were engaged to undertake Phase 1 only.

The Terms of Reference for Phase 1 of the Review were:

a) Review current systems, practices and processes in the donation, retrieval and transplantation sector including:
   - Waiting list criteria and management including equity of access for all Australians
   - Organ offer, allocation and acceptance processes
   - Transplant patient consent procedures for sub-optimal organs (e.g. Hepatitis C positive donor to Hepatitis C negative recipient)

b) Consider where there may be jurisdictional variations in above systems, practices and processes to identify opportunities for best practice through national collaboration

c) Analyse cross jurisdictional retrieval and transplantation processes

d) Consider current Commonwealth and jurisdictional resourcing for retrieval and transplantation services which includes:
   - Tissue typing
   - Retrieval teams
   - Transport and travel
   - Transplant surgery
   - Outpatient care (pre and post transplantation)
   - Interstate retrieval

e) Consider existing modules and arrangements to identify the optimal systems, resourcing and workforce requirements to support future donation activity.

Completion of Phase 1 of the Review was to provide recommendations and evidence-based advice to inform the development of a future national strategy for the retrieval and transplantation sector to optimise every deceased donation opportunity for maximum transplantation outcomes.

Eye and tissue donation and transplantation was out of scope for the Review.

To oversee Phase 1 of the Review the Australian Government was to establish a high-level committee comprising senior government officials and key sector stakeholders to:

- Consider the findings and recommendations of Phase 1 of the Review
- Draft a future strategy for the retrieval and transplantation sector to ensure it has the capacity and capability to support every donation and transplantation opportunity
- Make recommendations on the draft strategy to a future COAG Health Council meeting.

2.4 The approach and consultation process for the Review

The Review comprised an extensive consultation process. It was supplemented by the collection of submissions from stakeholders, as well as a document, literature and data review.

Consultations were undertaken through a combination of face-to-face and telephone interviews, and included both group and individual consultations. Stakeholders were initially identified by the Australian Government Department of Health and the OTA, with additional stakeholders in each state and territory identified by representatives of the OTA's Jurisdictional Advisory Group (JAG). Additional stakeholders for consultation were also identified during the consultation process.

Over 230 stakeholders were consulted as part of the Review. This included Australian Government and jurisdictional government officials, training colleges and peak bodies, clinicians, transplant recipients and donor families. The consultation methods are described in Table 2.

Table 2: Consultation methods

Consultation method	Description of approach
National stakeholder consultations	• These consultations were conducted with national stakeholders who could provide an overarching view of the systems, practices and processes across the organ donation, retrieval and transplantation sector. This included outcomes, optimal systems, resourcing and workforce requirements across Australia, as well as policy planning and strategy.

State-based consultations	• These consultations were used to engage stakeholders at the local level and to understand jurisdictional processes, variation and challenges. Consultations were undertaken with the following groups in each state and territory:
	  - Lead clinicians
	  - Jurisdictional representatives from each state or territory
	  - Relevant executives in Local Hospital Networks and public hospitals
	• Donor families, transplant recipients, patients awaiting transplant and community organisations.

Other stakeholder consultations	• These consultations were conducted with other relevant stakeholders who had a view on the system and future opportunities. These were identified and confirmed with the Australian Government Department of Health and the OTA, with consultation undertaken by submission, face-to-face or via telephone.

The stakeholders consulted as part of the Review are in Appendix B. Written submissions were collected from stakeholders who could not attend a consultation and wanted to participate in the Review.

A range of data, literature and documents were reviewed to identify and validate findings. A list of data, literature and documents reviewed can be found in Appendix C. Findings from all data collection methods were then triangulated to develop the findings and recommendations set out in this report.

The Review was guided and informed by the Australian Government Department of Health, the OTA, the Steering Committee and other sector stakeholders. The Steering Committee included representatives of the Australian Government Department of Health and the OTA, as well as specialists in the area of donation and transplantation and state and territory representatives. The Steering Committee was used to provide input into the methodology and approach, feedback on reports, as well as testing and validating the findings and recommendations.

2.5 Guide to this report

The following provides a guide to the remainder of the report:

- Section 3– describes the progress of the national reform program since the 2015 Review
- Section 4 – describes the current context of organ donation, retrieval and transplantation in Australia
- Section 5 – describes the findings from the Review relating to the overarching element of the system, including issues and recommendations
- Section 6 – describes the findings from the Review relating to the functional elements of the system, including issues and recommendations
- Section 7 – describes the findings from the Review relating to the supporting elements of the system, including issues and recommendations
- Section 8 - describes the conclusion to the Review.

Although pancreas and intestine donation and transplantation procedures are performed in Australia, they are performed in small numbers. This report provides some insight into pancreas and intestine transplantation in Australia, however the Review mostly focused on kidney, liver, heart and lung donation, retrieval and transplantation.

3. The 2015 review of the implementation of the national reform agenda on organ and tissue donation

3.1 Background and purpose of the 2015 Review

While progress had been made since the start of the national reform program in 2009, the OTA as well as other key stakeholders acknowledged that donation rates needed to increase substantially in order to move from 16.9 dpmp in 2014 to meet the target of 25 dpmp by the end of 2018. In response, the Assistant Minister for Health at the time, Senator the Hon Fiona Nash, announced the 2015 Review of the implementation of the national reform agenda on organ and tissue donation and transplantation on 26 May 2015.

The 2015 Review examined the effectiveness of the implementation of the national reform agenda, with particular reference to the role of the OTA and the wider health system's response (See Appendix E for Terms of Reference). The final report, *Review of the implementation of the national reform agenda on organ and tissue donation and transplantation*,[24] was released on 2 February 2016.

The Review examined and outlined 24 recommendations across the following key areas (for details of recommendations see Section 3.2):

- Strategy
- Governance of the OTA
- Performance
- Audit of donation practices
- Funding policy
- Awareness strategies, communication and donor family support
- Community Awareness Grant Program
- AODR
- EDR
- New organ perfusion technologies
- Eye and tissue donation and transplantation
- Issues outside the scope of the Review.

The Australian Government's response to the EY report was published in March 2017, recognising the importance of the Review in capturing the key achievements and challenges in increasing Australia's organ and tissue donation rates.[25]

[24] Ernst and Young, 2015, *Review of the implementation of the national reform agenda on organ and tissue donation and transplantation*, Australian Government Department of Health, Canberra, viewed June 2018, <https://www.health.gov.au/internet/main/publishing.nsf/Content/B3432FD1002E6DC5CA257FB1001C4622/$File/Review%20of%20the%20implementation%20of%20the%20national%20reform%20agenda%20on%20organ%20and%20tissue%20donation%20and%20transplantation.pdf>.

[25] Ibid.

3.2 Progress against the recommendations from the 2015 Review

In March 2017, the Australian Government announced that it accepted all 24 recommendations put forward in the 2015 Review. The Australian Government's response reiterated their commitment to increasing Australia's organ and tissue donation rates, addressing each recommendation and identifying areas for further activity. The responsibility to implement the recommendations was predominately for the OTA, with assistance from other stakeholders. The Australian Government Department of Health had responsibility to establish the changed governance arrangements and the supporting legislation.

Of the 24 recommendations, seven are yet to be fully implemented. Six require further actioning and have been included in the OTA's 2018-2019 to 2021-22 Strategic Plan,[26] and another relates to the agreed implementation outcomes from the Analysis of the Eye and Tissue Sector. The status of each recommendation, as well as a high-level assessment of the progress against each recommendation as of October 2018, are listed in Table 3.

Table 3: Progress and status against 2015 Review of the implementation of the national reform agenda on organ and tissue donation, SOURCE: The OTA[27]

Recommendation		Action/progress against recommendation	Status
1	The DonateLife Network, led by the OTA, should implement the 2015 budget measures assigned to the Network expeditiously as planned with a national focus emphasised on the Targeted Hospital Improvement Program. In addition, the DonateLife Network should continue to implement the other 2015- 2016 strategic priorities.	$10.2 million of funding was allocated towards a two-year measure titled *Accelerating Growth for Transplantation.* This involved. This funded: - DonateLife collaborative run over two years in 26 DonateLife Network hospitals with the most potential for donation - The Clinical Practice Improvement Program (CPIP) which established reportable key performance indicators that are key to achieving best-practice organ and tissue donation - The OTA to continue to monitor CPIP KIPs with jurisdictions through data analysis and bi-annual progress reports.	Completed
2	The OTA, DonateLife Network and transplantation sector should continue to progress the allocation of donated organs on a national basis, following the implementation of the Australian Organ Matching System (AOMS).	In 2015, the OTA partnered with the Australian Red Cross Blood Service to develop the Australian Organ Matching System, which has since been rebranded as OrganMatch. OrganMatch will facilitate optimal matching of donor organs to transplant recipients.	OrganMatch is scheduled for implementation in April 2019.[28]
3	The proportion of Intensive Care Unit specialists, staff and trainees who	The OTA has implemented this recommendation via its *Learning*	Completed

[26] The Australian Organ and Tissue Donation and Transplantation Authority, 2018, *2018-2022 OTA Strategic Plan: Progressing Australian organ and tissue donation and transplantation to 2022*, viewed July 2018, <https://donatelife.gov.au/sites/default/files/OTA%202017-18%20Strategic%20Plan.pdf>.

[27] The Australian Organ and Tissue Donation and Transplantation Authority, "2015 EY Review – Implementation of the recommendations" (received September 2018).

[28] Note: The system functionality has the capacity to improve allocation algorithms in elements such as survival matching, improved immunological matching and specific donor registries (e.g. Hepatitis C positive donors, increased viral risk donors). Post-implementation, the Commonwealth and Jurisdictions have agreed to optimise the functionality of OrganMatch to enhance patient outcomes.

Recommendation		Action/progress against recommendation	Status
	participate in the Family Donation Conversation Workshops should be monitored by the DonateLife Network by hospital.	*Management System* which has the functionality to monitor and report on participation rates in Family Donation Conversation Workshops, including the upload of retrospective participation data. This information can be downloaded by jurisdictions in a summary report bi-annually.	
4	The number of living kidney donations should be reported and reviewed by the DonateLife Network and reported on the OTA website.	The OTA's level of reporting has been expanded to include all live donors, including those who are eligible for the Supporting Living Organ Donors Program. Living Kidney Donations are reported in the OTA's Annual Report and the annual *Australian Donation and Transplantation Activity Report* and Fact Sheets published on the OTA website.	Completed
5	The Australian Government should consider amendments to the Australian *Organ and Tissue Donation and Transplantation Authority Act 2008* to establish a Board of governance of seven to nine people to govern the OTA.	The *Australian Organ and Tissue Donation and Transplantation Authority Amendment (New Governance Arrangements) Act* received Royal Assent on 30 November 2016. From 1 July 2017 the Amendment Act amended the OTA Act establishing a Board to govern the OTA and transferring the role of 'Accountable Authority' under the *Public Governance, Performance and Accountability Act 2013* from the CEO to the Board.	Completed
6	The Chair of the Board of governance should be an experienced leader of public hospital organisations, but need not be a clinician.	Dr Mal Washer was appointed Chair of the OTA board from 1 July 2017. This appointment satisfies the requirements of the *Australian Organ and Tissue Donation and Transplantation Authority Amendment (New Governance Arrangements) Act* that the Chair of the Board must have substantial experience in, or substantial knowledge of at least one of the following fields: (a) public administration; (b) business; (c) management.	Completed
7	The skill base of the Board should include community leadership, health promotion expertise, DonateLife Network clinical expertise, transplantation clinical expertise, consumer experience and communication skills.	*The Australian Organ and Tissue Donation and Transplantation Authority Amendment (New Governance Arrangements) Act* 2016 requires that a person is not eligible to be appointed to the Board (other than the Chair) unless the person meets the requirements of 13F subsection (4). 13F subsection (4) outlines the required fields a person is to have substantial experience in, or substantial knowledge of, to be eligible for appointment as a Board member (other than the Chair).	Completed
8	The Chair should be nominated by the Australian Government, the deputy chair nominated by the states and territories, with the balance of members nominated collectively by the COAG Health Council members.	This process of nomination and appointment is set out in the *Australian Organ and Tissue Donation and Transplantation Authority Amendment (New Governance Arrangements) Act 2016.*	Completed
9	The members should be appointed for a term of four years by the Australian Government Minister, with staggered appointments at the commencement of Board of	All OTA Board members have been appointed for a four-year period.	Completed

Recommendation		Action/progress against recommendation	Status
	governance operations.		
10	The OTA should prominently publish the following data on the performance of the DonateLife Network: – Donation rates by jurisdiction – quarterly for New South Wales, Queensland, Victoria, South Australia and Western Australia and annually for Tasmania, Australian Capital Territory and Northern Territory. – Numbers of people on the transplantation waiting list for each organ type annually. – Deaths on the waiting list for each organ type annually. In addition, the OTA should further consider the publication of donation performance (appropriately risk adjusted) by hospital.	The data on performance set out in Recommendation 10 has all been included and published on either the OTA website or in the OTA Annual Report.	Completed. Hospital donation performance is currently available via a link to the Australia and New Zealand Organ Registry on the OTA website.
11	States and territories should clearly define who is responsible for organ donation rates within their jurisdiction and monitor the implementation of the DonateLife Network positions within their constituent Local Hospital Networks.	The Australian Government has confirmed that organ donation and transplantation is a state and territory responsibility. State and Territory Funding Agreements between all Jurisdictions and the Australian Government have been entered in for the period of 1 July 2018 – 30 June 2020.	Completed
12	The DonateLife Network, led by the OTA, should define minimum standards for auditing of organ donation practices and seek the endorsement of the COAG Health Council for these standards.	The Clinical Practice Improvement Program (CPIP) Phase 3 was endorsed by all jurisdictions (through JAG) and is being implemented in all DonateLife Network hospitals. CPIP 3 identifies seven standards/elements of clinical strategic focus with associated reportable key performance indicators (KPIs). These KPIs are key to achieving best-practice organ and tissue donation in the intensive care and emergency department environment. From 1 July 2018 the DLN quarterly National/jurisdiction and hospital dashboards will include reporting on CPIP3 KPI's.	Recommendation 12 is included in the 2017-2021 OTA Strategic Plan.
13	The audit of potential donors should be expanded as planned to include DCD donors, so that both donation pathways are reflected in the DonateLife Audit.	Since 2016, DCD donors have been reflected in the DonateLife Audit.	Completed
14	The OTA should publish the breakdown of state and territory DonateLife Network funding clearly on the OTA website. This should include a table demonstrating the share of the state and territory funding allocated to each jurisdiction for each year including 2015-16.	The OTA has been reporting this data since the OTA Annual Report from 2015 -16.	Completed

Recommendation		Action/progress against recommendation	Status
15	All Australian governments should advocate the inclusion of tissue typing and the surgical procedures for organ retrieval, transportation and transplantation activity in the 2015/16 IHPA Pricing Framework as an in-scope public hospital service, noting that this is a proposal which is already being considered.	The Surgical procedure for organ retrieval and transplantation activity has been included in the IHPA Pricing Framework. The inclusion of tissue typing and transportation for donation and transplantation is still under consideration.[29]	Recommendation 15 is included in the 2017-2021 OTA Strategic Plan, subject to consultation and agreement with the Jurisdictions. [30]
16	The Australian Government should consider the implementation of a further national awareness campaign that is timed to coincide with the implementation of enhancements to the AODR and has the objective of improving the prevalence of AODR registration among the community, noting that this forms part of the current budget measure.	Funding for an online advertising campaign to coincide with the implementation of online donor registration consent on the AODR has been allocated.	Completed
17	The proposed Board of governance should consider the DonateLife Community Awareness and Education Program annually, including the Stakeholder Engagement Framework, to ensure a nationally consistent, evidence-based approach to communications about organ and tissue donation for transplantation.	Items for consideration were covered as Board Agenda Items in 2017 and 2018.	Completed
18	The OTA should consider the DonateLife logo in light of the concerns expressed by donor families and the OTA should consult donor families on appropriate donor memorials throughout Australia.	The OTA has contributed funding for a national donor memorial to be constructed at the National Arboretum, as well as contributions for state based memorials including in Western Australia (City Beach foreshore) and Tasmania. In respect to the DonateLife Logo, the Board found that a potential re-brand would carry considerable financial implications as well as social repercussions within the donor families and recipient's communities. The Board agreed no further consideration of Logo at this stage.	Completed
19	The proposed Board should consider the key criteria for selection of grant recipients prior to the commencement of the grant	Items for consideration were covered as Board Agenda item during 2017.	Completed

[29] Note: Initial funding for posthumous organ donation activity, including retrieval was applied in 2016 through an increased price weight for the NEP for transplant activity by approximately 2%. In 2017 of the 1,467 transplanted organs retrieved 732 (50%) were not retrieved by the transplanting unit. 20% of all retrievals are undertaken by a team from a different state to the transplantation unit. There are also a number of cases where resources and costs are incurred in working up the donor but no retrieval surgery subsequently occurs. In 2017 this occurred in 132 cases (21%). In 2017 there were also 104 organs retrieved but not transplanted due to the medical suitability of the organ for transplant. IHPA have also identified inconsistent reporting of posthumous organ procurement activity across jurisdictions AIHW is looking at reviewing definitions of care type to inform how best to recognise when posthumous care types are applied and also a review of application in circulatory death cases.

[30] Note: Jurisdictions will continue to work on consistent development and application of Care Type definitions, including revision for brain death. In addition, IHPA is to consider de-coupled funding for posthumous organ donation activity from Transplantation.

Recommendation		Action/progress against recommendation	Status
	recipient selection process.		
20	Once the enhancement to the AODR is fully operational, a further campaign to increase enrolment should be undertaken as planned.	The OTA received funding as part of the 2015 Budget to support delivery of the national online donor registration campaign. This funding concluded on 30 June 2017. The Australian Government agrees with this recommendation in principle. Beyond 2017, advice on the direction of the campaign will be sought through the Board, to be established in line with recommendations 5-9.	Beyond 2017, advice on the direction of the campaign will be sought through the Board, to be established in line with recommendations 5-9.
21	The EDR should be enhanced as planned to record all referrals to the DonateLife Network (not only those that proceed to donation) and the reasons for any decision not to proceed to donation.	The Australian Government has engaged with states and territories to implement Recommendation 21. Through CPIP 3 jurisdictions have agreed to implement routine referral according to local jurisdictional criteria and the proposed data collection tool is the DonateLife Audit. Scoping work is required in regards to enhancement of the EDR to access establishment and maintenance costs.	Completed, but further scoping work is required in regards to enhancement of the EDR to access establishment and maintenance costs.
22	States and territories through the COAG Health Council should align their privacy and health records legislation to facilitate the full electronic implementation of the EDR and allow access to the EDR for research purposes.	The Australian Government has announced its support for this recommendation but leaves the responsibility over legislation to the states and territories.	Recommendation 22 is included in the OTA's current strategic plan, subject to consultation and agreement with Jurisdictions.
23	The effectiveness of organ and perfusion technologies should be evaluated by the Australian Health Minister Advisory Council (AHMAC) and the COAG Health Council and consideration given to their ongoing utilisation in the future, with costs reflected in the retrieval services IHPA price recommended at Recommendation 15.	The Australian Government has worked closely with states and territories on the implementation of this recommendation.	Recommendation 23 is included in the 2017-2021 OTA Strategic Plan, subject to consultation and agreement with Jurisdictions. This recommendation will be led by the Australian Government Department of Health.
24	Following the completion of the Economic Analysis of the Eye and Tissue Sector, through the COAG Health Council, states and territories should agree the implementation of any recommendations that allow for a national and standardised approach to the supply of eyes and tissues for transplantation, including amending jurisdictional human tissue legislation.	Through the COAG Health Council, states and territories have agreed to implementing Recommendation Two of the Analysis of the Eye and Tissue Sector, the development of a national policy framework to guide reform of the Australian tissue banking sector.	Underway. The Commonwealth Department of Health, in collaboration with states and territories, is leading the work needed to develop a national policy framework for the eye and tissue banking sector

4. The organ donation, retrieval and transplantation system in Australia

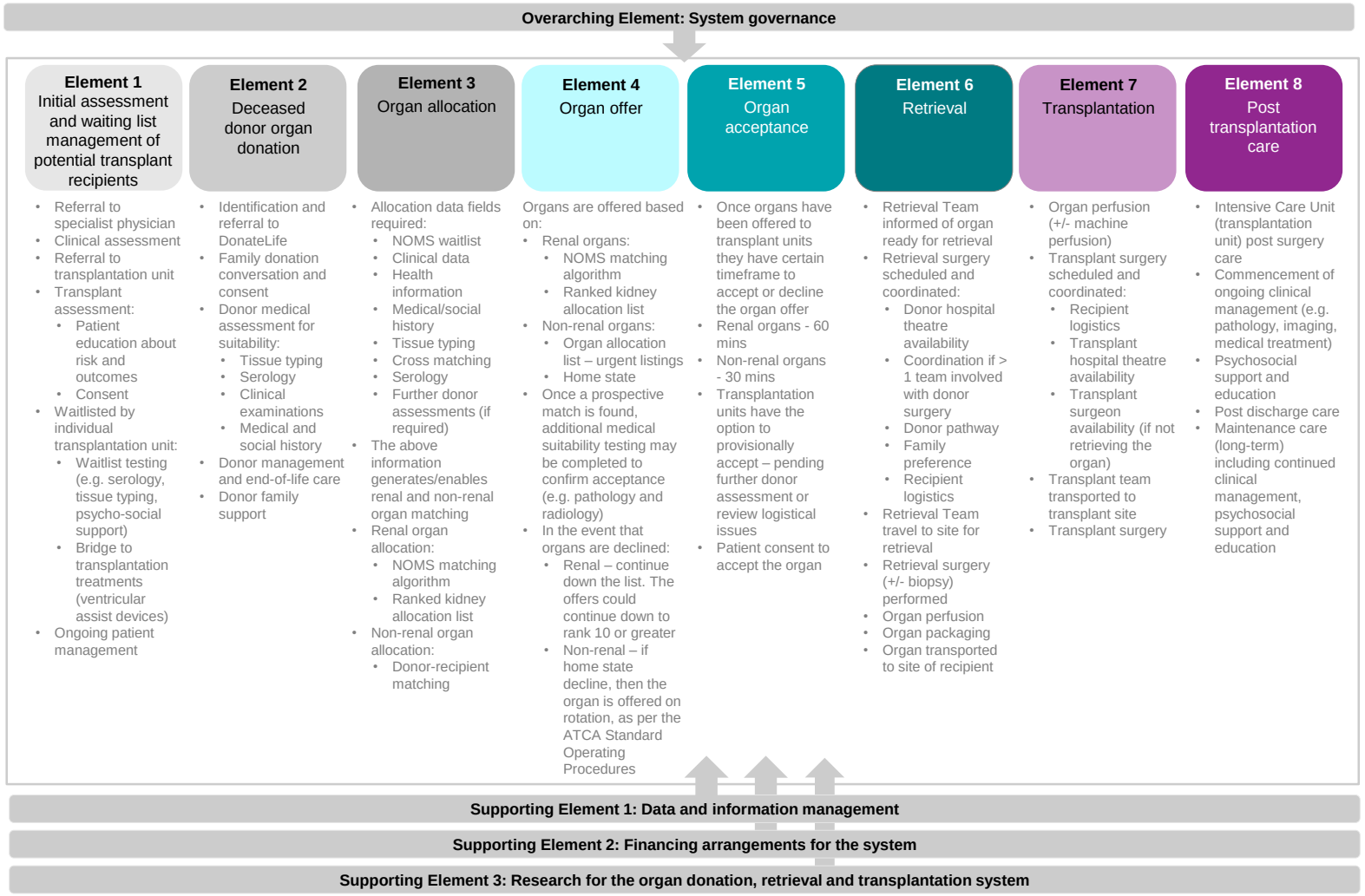
4.1 The organ donation, retrieval and transplantation functional model

The eight key elements or steps of the Australian organ donation, retrieval and transplantation functional model are outlined in Figure 2.[31] In addition, the diagram also highlights the overarching elements which support the organ donation, retrieval and transplantation process.

Each of the elements in the diagram are described in further detail in this section, as well as some of the nuances that differ from the model presented in Figure 2.

[31] The Australian Organ and Tissue Donation and Transplantation Authority, above n.3.

Figure 2: The elements of the organ donation, retrieval and transplantation process, SOURCE: the OTA[32]



[32] The Australian Organ and Tissue Donation and Transplantation Authority, above n.3.

4.2 System governance

4.2.1 Governance of the national reform agenda

The Australian Government's National Reform Agenda was to be delivered in partnership with states and territories, clinicians and the community. As part of Measure 1 of the National Reform Agenda, the Australian Government passed the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* ('the Act') to establish the OTA.[33] The OTA commenced operation on 1 January 2009 and is an independent statutory agency within the Australian Government Health portfolio.[34] As stipulated in the Act (see *Governance of the Reform Agenda*), the OTA's role is to work with a wide range of stakeholders to establish a coordinated and consistent national approach to the delivery of the reform. The Australian Government has maintained overall oversight of the reform, reviewing progress and implementing changes in order to drive achievement of the objectives.

Governance of the Reform Agenda

The Australian Organ and Tissue Donation and Transplantation Authority Act 2008 (Cth)

The Australian Organ and Tissue Donation and Transplantation Authority Bill 2008 ('the Bill') was passed to establish the Australian Organ and Tissue Donation and Transplantation Authority (the OTA). The OTA's main responsibility has been to spearhead the national approach to provide world leading access to transplants and improving transplantation outcomes for Australians. The Act provided legislative framework to implement the measures included in the Australian Government's $151.1 million world's best practice reform package for organ and tissue donation and transplantation announced in July 2008.

The OTA is a prescribed agency for the purposes of the Financial Management and Accountability Act 1997 and that Act applied to the operations of the OTA.

The OTA is a statutory agency and consists of a Chief Executive Officer (CEO) and its staff. The staff are engaged under the Public Service Act 1999. The CEO managers the OTA and is directly accountable to the Australian Government Minister for Health.

Australian Organ and Tissue Donation and Transplantation Authority Amendment (New Governance Arrangements) Bill 2016 (Cth)

Following the recommendations of the 2015 Review, new governance arrangements for the OTA were established including a Board. The Board assumed all responsibilities that were assigned to the OTA's CEO, with exception of the day-to-day administration of the OTA. In particular, the Board replaced the CEO as the 'accountable authority' for the purposes of the Public Governance, Performance and Accountability Act 2013. In addition, the COAG Health Council acquired a role in the process for nominating Board members.

The new governance arrangements did not change the OTA's functions. The Bill's commencement date was 1 July 2017.

Following the 2015 Review (see Section 3 for further detail), the Australian Government recommitted to the delivery of the reform through the implementation of all recommendations,

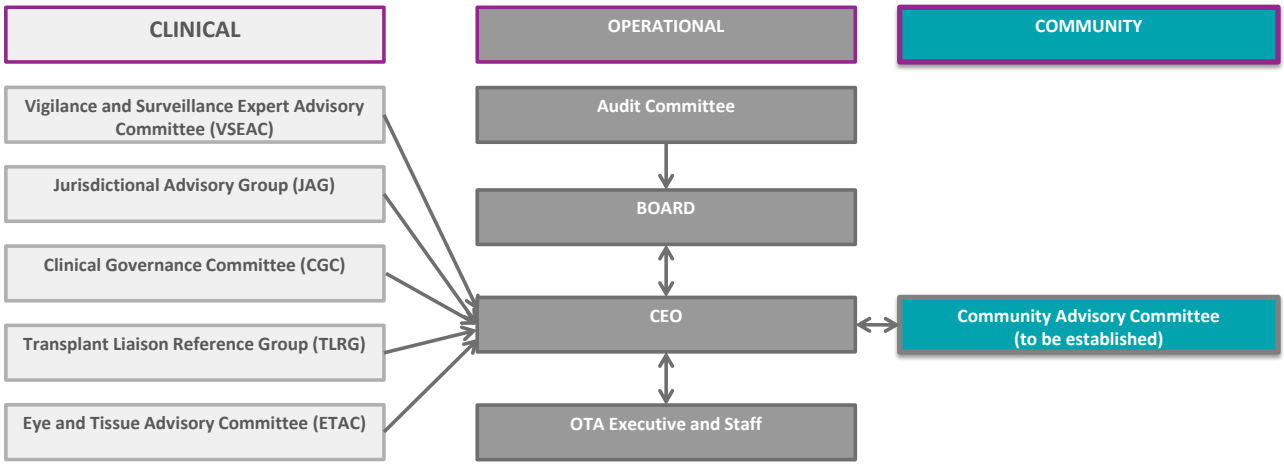
[33] *Australian Organ and Tissue Donation and Transplantation Authority Amendment (New Governance Arrangements) Act 2016* (Cth).

[34] The Australian Organ and Tissue Donation and Transplantation Authority, *About Us*, viewed June 2018, <https://donatelife.gov.au/about-us>.

including the establishment of the OTA Board.

The OTA has established, as part of the reform agenda, a number of advisory groups and committees. These advisory groups provide clinical, operational and community expertise for reviewing system performance and providing input into system improvements. The current structure of the committee and advisory groups and reporting structures of OTA are illustrated in Figure 3.

Figure 3: OTA committees and advisory groups and reporting structures (2018) SOURCE: The OTA[35]



4.2.2 Governance of donation, retrieval and transplantation practices

The OTA established the DonateLife Network in 2009 following commencement of the national reform program. As part of this arrangement, the Australian Government, through the OTA provides funding to each state and territory to employ hospital-based medical and nursing specialists in organ donation. A DonateLife Agency has been established in each state or territory and provides oversight of donation and transplantation services in over 90 hospitals across all jurisdictions. In October 2018, the DonateLife Network employed 150 full-time equivalent positions. It is noteworthy that DonateLife agencies do not necessarily deliver all of Australia's tissue banking arrangements and services, in certain jurisdictions DonateLife agencies do not facilitate the donation and retrieval of tissue.

Funding to the states and territories is provided through two-year funding agreements which require each jurisdiction to maintain an organ donation service delivery model that is: (1) consistent with the national reform approach; and (2) in accordance with relevant ethical guidelines and clinical protocols. Funding agreements include an agreed performance and reporting framework to enable the OTA to monitor progress in each jurisdiction.

Donation, retrieval and transplantation activities are guided by standards and guidelines. These are designed to provide guidance for professionals within the system regarding expectations and best practice. The standards are also used in the review of activities by the OTA and/or its committees and advisory groups in order to identify safety and quality issues.

[35] The Australian Organ and Tissue Donation and Transplantation Authority, 2018, *Annual Report 2017 – 2018,* Canberra, viewed November 2018, <https://donatelife.gov.au/about-us/strategy-and-performance/annual-report-0>.

Donation, retrieval and transplantation activity and outcome data is to be reviewed by the clinical governance groups within a Local Health Network to monitor quality and safety and to advise on improvements.

There are a number of professional national, jurisdictional and organ specific associations and committees which provide input into the governance of the system, including, but not limited to:

- The Transplantation Society of Australia and New Zealand
- The Australian and New Zealand Society of Nephrologists
- Transplant Liaison Reference Group
- Organ specific Vigilance and Surveillance Expert Advisory Committee
- Australian and New Zealand Intensive Care Society
- College of Intensive Care Medicine of Australia and New Zealand
- Australasian Transplant Coordinators Association
- Transplant Nurses Association
- State based and organ specific transplant Advisory Committees

The key guidelines, standard operating procedures and governance structures for each element of the donation, retrieval and transplantation system are outlined in Appendix D.

4.2.3 Governance of the Australian Organ Donor Register

The Australian Government Department of Health has policy authority for the Australian Organ Donor Register (AODR). The Australian Government Department of Human Services administers the AODR on behalf of the Australian Government Department of Health.

4.3 Element 1: Initial assessment and waiting list management of potential transplant recipients

This element includes:

- Recipient eligibility assessment
- Referral for assessment
- Enlisting and accession of the potential recipient on the waiting list
- Management of the health of the potential recipient while on the waiting list.

4.3.1 Recipient eligibility assessment

In order to provide a framework for access and equity to a life-saving or life-transforming transplantation for all Australians, principles and guidelines have been developed to provide a framework for assessing eligibility. The overall principles for consideration for transplantation include:

- Organ transplantation should be considered only when patients who have reached the end-stage of their organ disease and (with the exception of kidney transplantation) have exhausted all alternative treatment options
- Organ transplantation should be offered only to patients who have a reasonable prospect of achieving an acceptably good quality and duration of life after transplantation
- Organ transplantation should aim to balance the individual needs of the patient with the overall benefit to the community.

These principles form the basis of the *Clinical Guidelines for Organ Transplantation from Deceased Donors* ('the Clinical Guidelines')[36] which are used by transplant clinicians when undertaking assessment for eligibility. While there are specific inclusion and exclusion criteria for each organ detailed in the Clinical Guidelines, there are general conditions that currently apply across all organs:

- Age: With the increasing success of transplantation, the age range considered suitable for transplantation has steadily increased
- Comorbidities: Exclusion criteria generally include conditions or combinations of conditions that would result in an unacceptably high risk of mortality or morbidity during or after transplantation (e.g. active malignancy, severe cardiac disease, or chronic infection).
- Behavioural risk factors: Ongoing substance abuse including excessive alcohol consumption, cigarette smoking and illicit drug use are generally considered contraindications to transplantation. These lifestyle factors increase the risk of poor transplantation outcomes.
- Inability to adhere with complex medical therapy: This may be as a result of chronic cognitive or neuropsychiatric deficits in the absence of a carer capable of facilitating adherence to therapy.

[36] The Transplantation Society of Australia and New Zealand, 2017, above n.1.

The Clinical Guidelines are supported by the National Health and Medical Research Council's (NHMRC) *Ethical Guidelines for Organ Transplantation from Deceased Donors* ('the Ethical Guidelines').[37] These guidelines provide an overview of the ethical principles that are to be adhered to when assessing the eligibility of patients for transplantation:

1. Decision making regarding allocation must involve explicit evaluation of the risk and benefits to the potential recipient as well as the need to ensure the appropriate use of scarce health resources.
2. There must be no unlawful or unreasonable discrimination against potential recipients on the basis of:
    a. Race, religious belief, gender, marital status, sexual orientation, social or other status, disability or age
    b. The need for a transplant arising from the medical consequences of past lifestyle
    c. Capacity to pay for treatment
    d. Location of residence (e.g. remote, rural, regional or metropolitan)
    e. Previous refusal of an offer of an organ for transplantation
    f. Refusal to participate in research.
3. Decisions regarding eligibility and allocation will take into account the following ethically relevant factors:
    a. Relative urgency of need
    b. Medical factors which affect likelihood of success (e.g. comorbidities, tissue matching)
    c. Relative severity of illness and disability
    d. Relative length of time on the waiting list
    e. Likelihood that the recipient will be able to comply with the necessary ongoing treatment after transplantation.[38]

4.3.2 Referral for a transplant assessment

To undertake an assessment to be wait listed for organ transplantation in Australia, patients must be referred by their treating clinical or specialist physician to a transplant physician. If the treating physician determines that transplantation may be an appropriate course of treatment based on the patient's condition, they may consider referral for transplantation. At this time, discussions are undertaken with the patient to determine their wishes for future treatment for their condition and to explain the benefits and risks of transplantation. If the patient agrees to undergo assessment, the referral will proceed to the appropriate transplantation unit.

Timely referral for assessment is an important part of this process as evidence demonstrates that late referral leads to poorer patient outcomes (mortality and increased duration of

[37] The National Medical Health and Research Council (NMHRC) 2016, *Ethical Guidelines for Organ Transplantation from deceased Donors,* Australian Government, Canberra, viewed June 2018, <https://www.tsanz.com.au/organallocationguidelines/documents/NHMRCEthicalGuidelinesforOrganTransplantationfromDeceasedDonors.pdf>; Please note that the 2007 Guidelines for ethical practice for health professionals are currently under review currency, relevance and consolidation.

[38] Ibid.

hospitalisation).[39] Early referral enables patients to be assessed for suitability and wait listed as early as is medically appropriate, optimising the potential for positive transplantation outcomes.[40]

The guidelines used in Australia for organ transplantation

The Clinical Guidelines for Organ Transplantation from Deceased Donors aims to achieve an appropriate balance between the needs of patients with end-stage organ failure and the need to maximize the overall benefit to the community. The ethical principles set out in the NHMRC's Ethical Guidelines for Organ Transplantation from Deceased Donors underpin the Clinical Guidelines (see above).

The TSANZ is the primary body responsible for developing the eligibility criteria for organ transplantation, as well as protocols for the allocation of deceased organ donor organs to wait listed patients in Australia. As such, the Clinical Guidelines are produced by the TSANZ in collaboration with the OTA and DonateLife. The current version of the Clinical Guidelines were developed by the advisory committees of the TSANZ with written feedback sought through a targeted consultation process. The current version of the Clinical Guidelines were released in May 2017 and replace all previous sets of guidelines.

Previous versions of the Clinical Guidelines (previously known as Organ Transplantation from Deceased Donors: Consensus Statement on Eligibility Criteria and Allocation Protocols) were released in June 2011 (version 1.1), May 2012 (version 1.2), January 2014 (version 1.3), and April 2015 (version 1.4).

4.3.3 Assessment for transplantation

Comprehensive, multidisciplinary assessment of people for transplantation is a complex and time consuming process, largely determined by individual case complexity. Thorough medical and psychological assessments are required in order to identify any contraindications to transplantation and to inform an estimation of the risks and benefits of transplantation for each individual. The assessment process for medical suitability for transplantation includes a number of screening tests and investigations such as serology, radiology, Nucleic Acid Testing, cardiology, respiratory etc.

During the assessment phase the person will also receive education and information about the risks, benefits and expected outcomes of transplantation. This takes place over a series of meetings including consultations with clinicians and patient education sessions, with provision of supplementary reading material.

The time it takes for patients to undergo assessment to be wait listed varies between transplantation units based on individual practices.

Recipient consent to organ transplantation

The decision by potential recipients to accept the offer of an organ is based on their understanding of the risks and benefits, as they relate to their individual circumstances. Decision making is particularly complex when the organ being offered may have a lower likelihood of providing optimal outcomes. For example, potential recipients who are stable on medical therapy may find the expected outcomes of transplantation with such an organ is less acceptable compared to potential recipients who are advanced in age or extremely unwell (and might see it as an opportunity to increase their survival prospects). Organs that may carry an unacceptable level of risk for some potential recipients may provide benefit for others.

[39] Ibid.
[40] Ibid.

The acceptability of donor organs that may pose an element of risk should be discussed with both the potential recipient and their carer at the time of wait listing (rather than at the time of the organ offer). For example, the introduction of new and safe antiviral therapy for Hepatitis C infection may result in the possible use of an organ from a Hepatitis C infected donor into a recipient without Hepatitis C. The provision of adequate counselling and education about the procedure including the risks, benefits and what will happen if the procedure does not go ahead is critical. This allows each person to consider their options and ultimately provide informed consent if they choose to proceed.

4.3.4 Waiting list management

Waiting list practices follow the Clinical Guidelines and are influenced by the clinical judgement of the transplant clinicians. Once the assessment process has been completed and a patient is deemed eligible for transplantation, it is at this point that they are formally listed for transplantation. This occurs when the potential recipient's assessment data are sent to the state-based tissue typing lab, which maintain the list to enable allocation and cross matching at the time of offer (see Section 4.5). The tissue typing labs send samples of all recipients' blood to each other so that the blood is available for tissue typing when a donor is identified.

Factors affecting the potential recipient's suitability for transplantation may change over time due to patient behaviour or as the disease progresses. Potential recipients' wait listed for organ transplantation are regularly reviewed to ensure that they remain eligible to receive a transplant. On a monthly basis, potential recipients are required to provide blood samples to the tissue typing labs. The blood and tissue type is screened to detect changes in sensitisation and sera is also used for cross-matching against potential donors. This monthly process is extremely time consuming and resource intensive.

Potential recipients will also undergo additional ad hoc reviews if there is a potential change to suitability for waiting list eligibility due to a worsening of their condition. In the case of the renal organ waiting list, if the review reveals that the potential recipient is no longer thought to be suitable for a transplant, they will be removed from the waiting list. This could be a permanent or temporary removal from the list depending on individual circumstances.

Waiting lists for non-renal organs are less dynamic due to factors such as the scarcity of organs, the disease profile of potential recipients and the availability of other treatments. Therefore, patients remain on the waiting list and are clinically managed to meet the eligibility criteria.

In order to understand the type of organ required to suitably match to recipient according to size, blood type and other medical suitability requirements, potential recipients undergo a transplant assessment within the transplantation unit to which the patient was referred. Further detail on organ matching is outlined in Section 4.5.

4.4 Element 2: Deceased donor organ donation

This element includes:

- Registration for organ and tissue donation for transplantation (Section 4.4.1)
- Organ donation (Section 4.4.2)
- Deceased organ donation performance (Section 4.4.3).

4.4.1 Registration for organ and tissue donation for transplantation

The AODR was established in 2000 and is the national register of consent for organ and tissue donation for transplantation decisions after death. The AODR is administered by the Australian Government Department of Human Services, on behalf of the Australian Government Department of Health. The AODR is used to record individuals who have agreed to donate organs and/or tissues in the event of their death. Registration can be done online through:

- Medicare online account through myGov
- Express Plus Medicare mobile app
- Online form on the DonateLife website
- The *Australian Organ Donor Register form for Donors* (hard copy submitted by return post or at Centrelink)
- Online form on the Australian Government Department of Human Services website.

In July 2017, a new streamlined channel was launched by the Minister for Aged Care and Minister for Indigenous Health, the Hon Ken Wyatt AM MP, which enables people to register through DonateLife to the AODR.[41] The OTA and DonateLife Network have promoted the new online form to encourage more Australians to register their intent for organ donation in a simplified way.[42]

While all states and territories previously recorded donation registration through the drivers' licensing system, South Australia is the only jurisdiction where registration for organ and/or tissue donation for transplantation after death continues to be captured through drivers' license arrangements. This registration data is transferred from the South Australia license database held by the South Australian Government to the AODR monthly.

Background to the AODR

The original purpose of registration on the AODR was to reflect a person's intention to donate, with legal consent still required from the potential donor's next of kin. Over time, concerns regarding both the ability of family members to override individual decisions and the quality of AODR data (in particular the records transferred from state government databases and the Road Transport Authorities), resulted in the AODR arrangements needing further consideration.

In April 2004, Health Ministers agreed to establish an AHMAC Organ Donation Working Group tasked with providing advice on how to implement Ministers' endorsed position that:

- Expressed wishes of the deceased should be given effect
- There should be no requirement for express consent from the family if the deceased had consented
- Legislation in each jurisdiction should clearly reflect this.

[41] The Honorable Ken Wyatt, 2018, 'Making giving the gift of life your new year's resolution', media release, 31 December 2017, viewed June 2018 <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2018-wyatt001.htm>.

[42] Ibid.

In an AHMAC communiqué in January 2005, it was announced that Health Ministers had received a report from the AHMAC Organ Donation Working Group 'confirming that, under existing laws, Australian adults can legally express their consent to donate their organs and tissues after death without the need for family consent'. It was also noted that the while existing laws allowed for donation to proceed in Australia for ethical reasons, this would not remove the consent of family members.

The AHMAC Organ Donation Working Group recommended the AODR operate as Australia's single national register of consent and that this consent must be 'informed consent'. Health Ministers agreed for the AODR to become a register of consent from 1 July 2005.

In moving from a register of intent to consent it was the Australian Government's intention the strengthened AODR would:

- Only record legally valid consent or refusal to donate particular organs and tissues for people aged 18 years and over, as expressed by a signed and dated consent statement.
- Only record 'intent' for people aged 16 and 17. A 'yes' intent record would mean that a family's permission will still be an absolute pre-requisite for donation to proceed. A 'no' intent record would mean that donation will not proceed unless the family advises that the person has changed their mind.
- Not include records for people aged under 16.
- Maintain existing records that do not meet the formal legal requirements of consent as 'intent' records, with the same implications as above, until such time as each registrant has had the opportunity to upgrade their registration to consent.
- As far as possible, match registrations to Medicare records to facilitate updating of address details and opportunities for upgrading and updating of registrations when the individuals concerned interact with the Medicare system.

To ensure the integrity of the AODR it was also agreed that organ donation for transplantation registrations collected through the drivers' license system would no longer be transferred to the AODR. This was supported and agreed at that time by the corresponding Road Transport Ministers' Council. There was no agreement to continue the arrangements of transferring registration from the South Australian drivers' licensing system to the AODR – this is an anomaly that has continued to the present.

4.4.2 Organ donation

The donation of organs and tissues for the purpose of transplantation takes place within a legal context in Australia and is the responsibility of the states and territories under their respective Human Tissue Acts and the associated regulations that govern dealings with human tissue.[43] The Human Tissue Acts generally set legal requirements for the certification of death, consent to donation, donation of organs, eyes and tissues, as well as the disclosure of information about donors and recipients.

The Best Practice Guidelines for Offering Organ and Tissue Donation in Australia

The Best Practice Guidelines for Offering Organ and Tissue Donation in Australia ('the Best Practice Guidelines') were published in July 2017 by the OTA, in consultation with the DonateLife Network and peak professional bodies. They outline the preferred approach to be taken for all potentially suitable donors. This includes early referral to DonateLife to explore suitability for donation and to facilitate someone's wish to be an organ or tissue donor. The initial assessment of referrals by DonateLife involves liaison with medical staff with donation and transplantation expertise to determine donor suitability. The practice of

[43] See *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT).

routine referral and assessment at the point of planned end-of-life care within intensive care units and emergency care departments has been adopted as a key performance indicator within the DonateLife Network 'Clinical Practice Improvement Program Phase 3'.

A key focus of the Best Practice Guidelines is to provide specialist support to families of potential donors. This is through a collaborative approach between the treating clinical team and the DonateLife donation specialist to discuss donation with the family and support them during the end-of-life care of their family member. The Best Practice Guidelines includes checking the AODR before the family donation conversation and sharing the status of AODR status with the family so they can make an informed decision about donation.

Under the deceased donation pathway, as a person nears the end of their life, steps are taken to determine the potential for organ donation. Whether donation occurs after brain death or after circulatory death has an impact on how the donation process occurs and which organs can be donated. Hospital based DonateLife staff generally work within the Intensive Care Unit (ICU) and work closely with ICU staff to determine donation potential using the Best Practice Guidelines. Each component of the donation process is closely supported and facilitated by a dedicated network of specialist staff members. The DonateLife Network underpins this system and consists of over 250 staff members holding medical, nursing and administrative roles in 90 hospitals across Australia.

Once it is deemed that the person may be a potential organ donor, an authorised medical personnel access the AODR to confirm their organ donation decision. Authorised medical personnel are those persons approved by the Australian Government Department of Human Services to have access to the AODR on an ongoing basis. Authorised medical personnel may conduct AODR checks with the Australian Government Department of Human Services either over telephone or via a secure online system. DonateLife donation specialists are generally the authorised medical personnel and will regularly perform the AODR checks.

Family or enduring guardian consent prior to donation is obtained for all organ donations, where possible. To confirm family or enduring guardian consent, a specialist within the ICU may commence conversations between the potential donor and/or their family or enduring guardian. A DonateLife donation specialist conducts the family interview to complete the consent paperwork and to obtain important health information and medical and social history about the donor. Registration on the AODR is not required for organ donation to proceed, however it is a key factor that has been demonstrated to lead to follow through with consent to donate. Data provided by the OTA indicated that 90 per cent of families agree to donation when their loved one is registered on the AODR and the family is aware of the deceased's donation decision.[44]

Consent to organ donation

Consent to organ donation after death in Australia is governed by the respective Human Tissue Acts of each state and territory, as well as national guidelines issued by the NHMRC. The requirements and format for obtaining deceased donor consent varies between each jurisdiction.

The NHMRC's Organ and Tissue donation after death, for transplantation: guidelines for ethical practice for health professionals outline a national approach, which should be adopted by all jurisdictions. In addition to individual donor consent, the guidelines stipulate that best practice requires further consultation with

[44] The Australian Organ and Tissue Donation and Transplantation Authority, "Donor family consent" (Received October 2018).

and consent from the deceased donor's family. These guidelines are commonly adhered to in practice.

Nevertheless, there are still legislative variations in place. In New South Wales, the authority to remove tissue for transplantation requires consent in writing by the potential donor. Its South Australian counterpart, sets a lower threshold, stipulating that donation may proceed if the designated officer believes, through making reasonable enquiries that the deceased person had expressed the wish for donation. A jurisdiction like Queensland is different again, as they legislate the requirement for family consent. Queensland legislation confers that consent must be sought from the next senior available next of kin of the deceased person as well.

Once consent is provided for organ donation to progress, additional tests are undertaken to confirm the potential donor's suitability. This includes tissue typing, serology, clinical examinations and medical and social history. DonateLife and hospital personnel manage the donor and their end-of-life care to optimise the donation opportunity. Support is to be provided to the donor families through the entire process through DonateLife (see below for further detail on the donor family experience).

The donor family experience

The Best Practice Guideline for offering Organ and Tissue Donation in Australia 2017, outlines the preferred approach to be taken for all potential donations. A key element of which is ensuring that specialist support and a collaborative approach is utilised to enhance the donor family experience. As discussed above, when a potential donor is identified a conversation occurs with the donor family to explain the donation and consent process. It is the responsibility of the treating clinical medical team to ensure that the family understands that death has occurred or is expected to occur. This process is supported by staff in the ICU where the potential donor is being cared for and the DonateLife donation coordinator. The following describes how the process should work.

DonateLife donation specialists and the treating hospital clinical team work together throughout the donation process to manage the patient's end-of-life care, to provide clinical care to optimise the donation opportunity, and to support the family through the entire process. The treating clinical team also works with a Family Donation Conversation Trained Specialist to discuss and plan the next steps, including the family donation conversation. The AODR is checked before the team planning meet so that the patient's registration status can be shared with the family to inform the decision-making process.

The transition from a conversation about death to a conversation about organ donation should not be rushed. A Family Donation Conversation Trained Specialist is to be actively present and participates in the family discussion. Once it is confirmed that the family provide consent for organ donation and that donation is viable, the next steps are explained and the Family Donation Conversation Trained Specialist and treating clinical team will continue to support the family throughout the process.

Once donation is complete, DonateLife remain in contact with the family to link them to the psychosocial support they require. DonateLife facilitate a letter writing service which allows both the donor family and recipient to establish and maintain anonymous contact should they wish to.

Further support is offered to families after donation and includes providing a general update on the recipients who benefited from the donation. As well as a package of donor family support resources with information about grief and the process of donation, and guidelines on the exchange of anonymous correspondence with transplant recipients.

A Donor Family Study is undertaken by the OTA to gain an understanding of the family experience of the donation process and their perception of the care they received from the treating clinical team and the DonateLife donation specialists before, during and after their donation experience.

4.4.3 Deceased organ donation performance

Deceased organ donation rates across Australia have improved dramatically since2009, demonstrated in an overall national increase of 106 per cent. The highest growth rates have been achieved in Victoria (220 per cent) and Western Australia (168 per cent).[45] New South Wales and Victoria have maintained the largest volume of donations across all jurisdictions since the establishment of the reform, as would be expected given the size of their population compared to other jurisdictions. Donation performance is discussed further in Section 6.2.1.

[45] The Australian Organ and Tissue Donation and Transplantation Authority, "Growth in Organ Donation" (received July 2018); The Australian Organ and Tissue Donation and Transplantation Authority, "Donation Numbers 2000 - 2017" (received July 2018).

4.5 Element 3: Organ allocation

This element includes:

- Renal allocation
- Non-renal allocation

Once consent for donation is received and it is deemed that the organs are suitable for donation, the process for organ allocation commences. The allocation process is complex and varies considerably between renal and non-renal organs.

Both renal and non-renal organ allocation considers the clinical, health, medical and social history of both donor and potential recipient, tissue typing, cross matching and serology. They are influenced by a number of factors including, medical urgency of potential recipients, recipient capacity to benefit, donor and recipient matching, as well as logistical factors.

4.5.1 Renal allocation

The renal allocation process is currently undertaken using the National Organ Matching System (NOMS) which calculates the ranked order of kidney recipients based on an algorithm. The algorithm has been set up based on the Clinical and Ethical Guidelines.

Components within the NOMS that currently determine the rank order of recipients for a renal donation include:

1. Immunological compatibility e.g. the avoidance of severe acute rejection (through blood group compatibility and the avoidance of high level human leukocyte antigen antibodies)
2. Immunological matching (or the degree of human leukocyte antigen matching)
3. The waiting time on dialysis
4. Paediatric status – recipients under 18 years of age receive a bonus score, improving their rank
5. The State Balancing System.
6. The state and territory of the donor and recipient - priority is given to the recipients in the same state as the donor.

All donated kidneys go through a three-level allocation process coordinated through the NOMS as described in Figure 4, for national, state and interstate allocation.

Figure 4: Renal allocation hierarchy as determined by the NOMS allocation system, SOURCE: the OTA[46]

In Levels 1-6, allocations and offers are made using the national algorithm, with highly sensitised and closely matched human leukocyte antigen patients prioritised first. Within these levels preference is given to recipients within the donor home state and paediatric recipients. On average, about 20 per cent of deceased donor kidneys are transported interstate through national allocation.[47] If the kidney has gone through allocation levels 1-6 and has not been accepted, it is then considered in the State Balancing System (Level 7).

If not allocated nationally from the national algorithm or the State Balancing System then the kidney(s) will be allocated according to the allocation algorithm of the state in which they were donated. This can be done through the NOMS. In 2017, approximately 20 per cent of kidneys were allocated based on national allocation. Of the remaining 80 per cent, approximately 75 per cent are accounted for by state allocation and another five per cent by interstate allocation.[48]

The State Balancing System

The State Balancing System or payback system of the kidney algorithm was initially implemented to allow the number of kidney donations within a state to equal the number of transplants performed with that state. It aims to ensure that no state was disproportionately affected by the national allocation levels 1-6.

The system provides a mechanism for the allocation of organs interstate where they are required. A tally is kept of kidneys allocated to other states. States with the highest levels of kidneys allocated out of state receive increased priority as a means of balancing the allocation system.

4.5.2 Non-renal allocation

The allocation of non-renal organs is not as complex as renal organs. There are primarily three factors that determine the allocation of a non-renal organ to a recipient:

- Blood group compatibility
- Age
- Size match.

The process for allocating donor organs with recipients is undertaken by the tissue typing clinicians in collaboration with the clinicians caring for the donor organs and the potential recipient. Based on the information collected from the donor assessment and the potential recipient's transplant assessment and the tissue typing results, the organ is allocated to the best possible match from the home state first, then best possible match from the urgent listings and then will be allocated to the best possible match according to the state rotation allocation list.

The state rotation allocation list is maintained and governed by the Australasian Transplantation Coordinators Association and is supported by the National Standard Operating Procedures: *Organ Allocation, Organ Rotation, Urgent Listing, Auditing Process (Version 2) (SOP001/2017)*.[49] Prior to commencing the allocation process, the allocation list can be obtained from the Australasian Transplantation Coordinators Association. The National Standard Operating Procedures: *Organ Allocation, Organ Rotation, Urgent Listing, Auditing Process (Version 2) (SOP001/2017)* provide a step-by-step guide for the allocation of heart, lung, liver, pancreas and multiple organs.

[46] The Australian Organ and Tissue Donation and Transplantation Authority, "Kidney Proportion of Offers and Acceptances for 2017" (received September 2018).

[47] The Australian Organ and Tissue Donation and Transplantation Authority "Organ Retrieval and Transplantation by Jurisdiction 2017" (received August 2018).

[48] National Organ Matching System, as provided by the OTA "Kidney Proportion of Offers and Acceptances for 2017" received (September 2018); The Australian Organ and Tissue Donation and Transplantation Authority "Organ Retrieval and Transplantation by Jurisdiction 2017" (received August 2018).

[49] The Australasian Transplantation Coordinators Association et al, 2017, *National Standard Operating Procedures: Organ allocation, organ rotation, urgent listing and auditing process, Version 2.1,* Canberra, viewed August 2018, <http://www.atca.org.au/files/ATCA_TSANZ%20SOP%20001.2017.pdf>.

4.6 Element 4: Organ offer

This element includes:

- Renal organ offer
- Non-renal organ offer
- Multi-organ offer.

Once the allocation process is complete and a suitable match is found, the donated organ is offered to the transplantation unit caring for the potential recipient. As part of the organ offer process, an initial brief phone call is made to the transplant coordinator. The phone call is followed by the provision of de-identified donor information via a pdf format of the Electronic Donor Record (EDR) in a secure email.

Once the EDR is reviewed against the potential recipient's record, additional medical suitability testing may be requested, particularly for extended use organs, such as those treated for Hepatitis C, organs exposed to multi-resistant bacteria and other factors such as older donors.

The organ offer process differs for renal and non-renal organs. These are explained below.

4.6.1 Renal organ offer

Renal Organs (kidneys) are offered according to the NOMS list. The NOMS list dictates the offering order of kidneys to transplantation units, the ranked NOMS list begins with:

- National Levels 1 to 3
- Combined transplant
- Urgent
- National Levels 4 to 6
- National payback
- State urgent
- State paediatric
- State human leukocyte antigen matches/waiting list
- Interstate

There are some instances where variation to this process occurs. For example, pre-emptive transplantation is not part of the NOMS algorithm and represents a process variation that conflicts with the TSANZ guidelines for eligibility for transplant.

The offering process for renal organs can be very time consuming, as often the kidneys are not accepted in the first few rankings. If rank 1 declines, the offered is then given to rank 2 and so on, until the organ is accepted or it is deemed unnecessary to continue, for example if offer is at rank 20.

In some jurisdictions, the offering process is slightly altered to improve timeframes. For example, if transplantation Unit X have kidney ranks 1, 3, 5 and 9 they will request consideration for all ranked offers in the initial phone call, rather than having to make four separate phone calls (concurrent transplantation unit offers).

4.6.2 Non-renal organ offer

Non-renal organs (heart, lung, liver, intestine, pancreas and pancreas islets) are offered according to the Clinical Guidelines[50] and the *National Standard Operating Procedures – Organ Allocation, Organ Rotation, Urgent Listing, Auditing Process', Version 2.1 ATCA-TSANZ SOP 001/2017*[51]:

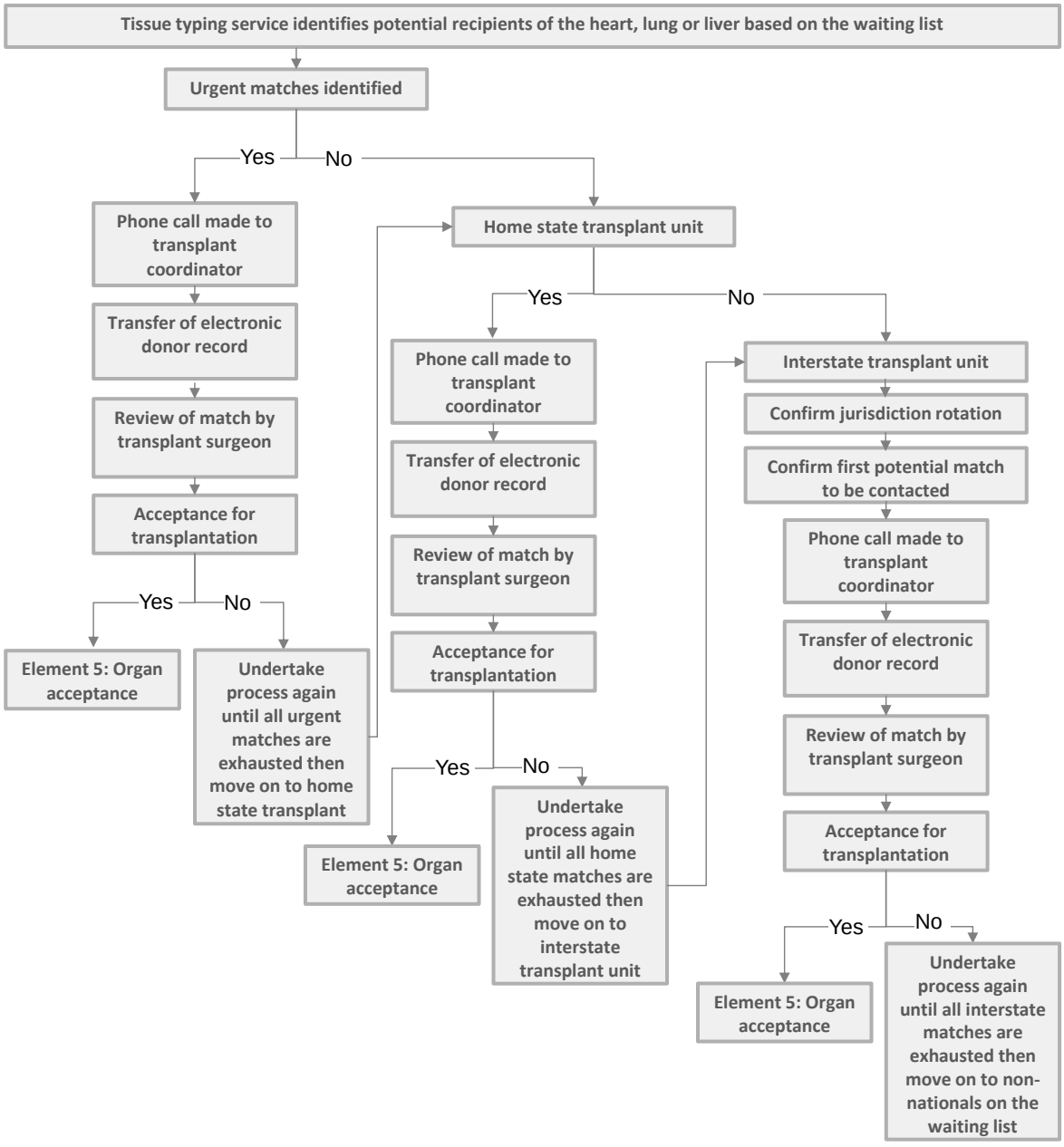
a) Organs are offered to the home state first unless there is a patient on an Urgent Listing or the home state does not offer relevant transplantation services (i.e. heart and lung transplant).
b) If the home state declines the offer and the organ is deemed medically suitable to offer on, the organ is offered according to the Australasian Transplant Coordinators Association and TSANZ Organ Allocation Rotation to ensure a fair and equitable distribution.
c) The offer is rotated through each jurisdiction as appropriate, in strict turn until either the organ is accepted or all units have declined the offer.
d) If all transplantation units decline the offer, it is then rotated through units with Non-Nationals (citizens of other countries that are not permanent residents of Australia) awaiting transplantation.

The offer process is closely linked with allocation and acceptance and is illustrated in Figure 5.

[50] The National Medical Health and Research Council, above n. 37.

[51] The Australasian Transplantation Coordinators Association, above n.54.

Figure 5: Non-renal offer process



Urgent listings exist for potential heart, liver and lung recipients. When a patient's survival is estimated to be days or weeks without transplantation, the patient may be placed on the urgent list and the next compatible donor organ available from anywhere in Australia or New Zealand will be offered for that patient.

Each jurisdiction (except Australian Capital Territory) has its own non-renal organ allocation rotation which is developed by the Australasian Transplantation Coordinators Association and the TSANZ and applied by each jurisdiction. The Australasian Transplantation Coordinators Association annually review the allocation and rotation processes of the jurisdictions and have found variation in the application of both the rotations and the *Australasian Transplantation Coordinators Association and the TSANZ Organ Allocation Rotation Standard Operating Procedure*.

4.6.4 Multi-organ offer

Combined transplant listings (e.g. liver and kidney, heart and kidney) are required to be formally approved by local jurisdiction transplant committees. Relevant interstate committees and DonateLife Agencies are required to be notified formally of the listing. Organs should not be allocated to recipients for combined transplants prior to completion of this formalised process. The only exception to this is heart and lung block offers, and kidney and pancreas offers.

4.7 Element 5: Organ acceptance

For the offer process to be complete, acceptance of the organ as suitable for transplant into the potential recipient must be completed. This process differs for renal and non-renal organs due to the different allocation processes:

- For non-renal organs: The transplantation unit indicate their acceptance to the unit that is offering the organ. The acceptance process often requires additional testing in order to confirm acceptance. Transplantation units are allocated thirty minutes to either accept or decline an organ offer.
- For renal organs: The NOMS means that the kidney allocation list is more straightforward and the transplantation unit accepts the match based on the information provided through the system. Renal transplantation units are allocated one hour to either accept or decline a kidney offer.

Once the organ is accepted by the respective units, consent from the potential recipient is required. Gaining potential recipient consent requires full explanation of the outcomes and potential risks as a result of transplantation. The decision by potential recipients to accept the offer of an organ is based on their understanding of the risks and benefits as they relate to their individual circumstances. Decision making is particularly complex when the organ being offered may have a lower likelihood of providing optimal outcomes. For example, potential recipients who are stable on medical therapy may find the expected outcomes associated with transplantation of such an organ less acceptable than would potential recipients who are advanced in age or extremely unwell who might see this as increasing their survival prospects. Organs that may carry an unacceptable risk for some potential recipients may provide benefit for others.

4.8 Element 6: Retrieval

This element includes:

- Transportation of retrieval teams
- Retrieval procedure
- Organ transportation and packaging arrangements
- Use of new technology in retrieval
- Performance of the Australian organ retrieval services.

The donation specialist coordinator liaises closely with the transplant coordinator in the relevant transplantation unit once an organ has been accepted for transplantation. This is a complex and time-consuming process involving multiple stakeholders to coordinate retrieval and transplant surgeries within the required timeframes. There is also the need to manage a variety of logistical factors including timing to accommodate the donor family's needs, the availability of operating theatres, and the retrieval team's availability and travel arrangements.

4.8.1 Transportation of retrieval teams

There is jurisdictional variance in the use of transport networks for the mobilisation of organ retrieval teams. In some jurisdictions the transplantation units which provide the retrieval team organise retrieval team travel, while others rely on their respective DonateLife agency.

Modes of transportation of retrieval teams vary and can use combinations of road (police escort, taxis, and private vehicles) and air travel (commercial aircraft or chartered jet). The road and air services used will vary depending on jurisdictional contracts, jurisdictional preferences, case urgency and geographical logistics.

4.8.2 Retrieval procedure

The retrieval procedure generally takes place in the hospital where the donor is situated and is completed by retrieval surgical teams who may or may not be the same as the transplant surgical team. However, there are a variety of models for the delivery of retrieval services across jurisdictions and transplantation units, and ad hoc arrangements for cross border retrieval.

In general, there are two types of retrieval teams:

1. Abdominal retrieval teams which retrieve liver, pancreas and kidneys
2. Cardio-thoracic retrieval teams which retrieve heart and lungs.

The composition of these teams is dependent on the donation pathway and the jurisdictional health system requirements.

Retrieval surgery is performed (which may include a biopsy for additional testing) at a time that is optimal for the viability of the organs. Where there are multiple organs required for retrieval, both types of the retrieval teams may be used to retrieve the abdominal and cardiothoracic organs.

4.8.3 Organ transportation and packaging arrangements

Donation specialist coordinators and/or transplant coordinators are responsible for organising transport arrangements for organs for transplantation. The mode of transport, distance and whether the organ is accompanied or unaccompanied depends on the organ.

Road transportation arrangements may include police escort, couriers, commercial aircraft for kidneys (occasionally liver, lungs and pancreas) and chartered jets for surgical teams and interstate pick-ups. In all states, transportation of kidneys is managed by donation specialist coordinators. Non-renal organ transportation is usually managed by transplant coordinators.

The person responsible for the labelling, packaging and documentation of organs and donor vessels in the donor theatre varies between jurisdictions. This person may be either the donation specialist coordinator, the perfusionist (who is a member of the abdominal retrieval team) or a transplant coordinator (who is a member of the cardio-thoracic team). However, the principles of labelling and packaging are the same.

4.8.4 Use of new technologies in retrieval

Retrieval services in some jurisdictions utilise technology and mechanical devices to support organ perfusion post retrieval. Utilisation of this equipment in select cases of kidney, heart and lung retrieval may enable the transplant team to maintain the organ in an optimal condition for longer periods of time. This allows for planning of the transplant surgery and accommodating unforeseen delays or transport of the organ over a greater distance.

Advanced perfusion technology, such as ex vivo perfusion technology, allows for techniques to evaluate the quality of an organ, active rehabilitation of organs after procurement and prior to implantation. Ex vivo perfusion technology allows for increased time between organ retrieval and implantation.[52] Ex vivo perfusion technology is not currently widely available across Australia, as the technology is still emerging and requires additional training for clinicians. Further, the cost of purchasing and maintaining the ex vivo perfusion technology is high. Each machine costs between $300,000 to $500,000 AUD to procure, with consumables for each use costing between $20,000 and $50,000 AUD.[53]

Following retrieval, the organ is supported, ready to be transported to the transplantation site. Ex vivo perfusion technology may be used in assisting in the retrieval and transportation process.

When a team has used ex vivo perfusion technology to manage the organ, an additional plane must be chartered for the machine and resources required with its use. Although the retrieval outcomes improve significantly from the use of the perfusion technology, costs of the retrieval process increase significantly. According to the Independent Hospital Pricing Authority (IHPA), the average cost of organ retrieval per separation nationally was almost $28,000 AUD. With additional costs of chartered flights, retrieval costs may increase to upwards of $30,000 to $40,000 AUD depending on the number of charters required and the distance travelled.

The utility of ex vivo perfusion for transplantation

After explant, perfusing donor organs outside the donor's body enables assessment, measurement, prolonged protection and even better treatment of those organs prior to surgical implantation in the transplant recipient. This concept has been best applied to medically extended donor organs including physiologically marginal organs and questionable about suitability for transplant or organs with an expected long ischaemic period before implantation, for example, due to Donation after cardiac Death (DCD) or logistics (surgical team is already operation, long transport distances, or a need for time to crossmatch or to get a donor Nucleic Acid Test). The latter situations are all particularly common in the Australian donation landscape. Further, there are suggestions the future will see all organs placed on such a system to improve, optimise and even individualise them for the new recipient.

These ex vivo perfusion machines, as seen below have proved most useful in the heart (Figure 6), and lung (Figure 7 and 8), or kidneys transplant fields. Similar early work is actively underway in the liver transplant arena. The challenge is that the machines are expensive to buy, typically have expensive consumables and require significant local skilled staff and space to operate. This is true particularly for heart, lung and liver perfusion devices. Cost-effectiveness studies have not done to any extent, except in kidney transplantation. In theory, following ex vivo assessment, a better functioning heart, lung or liver graft could save significant patient morbidity, mortality, as well as ICU and hospital costs.

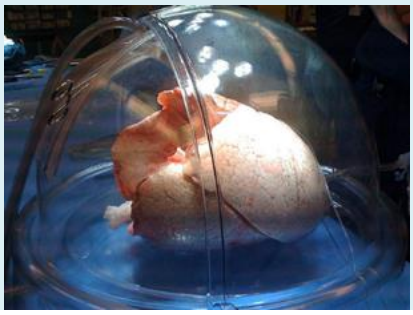
[52] Schraufnagel DP et al, 2018, 'Devices for ex vivo heart and lung perfusion', *Expert Review of Medical Devices* vol. 15, Issue.3, pp.183-191.

[53] Note: Costing of Ex Vivo perfusion technology varies between organs and international literature.

Figure 6: Transmedic, ex vivo heart perfusion, SOURCE: Dhital, et al 2015[54]

Figure 7: Ex vivo lung perfusion machine console, SOURCE: Cypel and Keshavjee 2016[55]

Figure 8: Ex vivo lung perfusion lung under assessment dome, SOURCE: Cypel and Keshavjee 2016[56]



4.8.5 Performance of the Australian organ retrieval services

In 2017, a total of 1,595 organs were retrieved across Australia.[57] Table 4 illustrates the total number of organ retrieval procedures performed by each state or territories retrieval teams.

[54] Dhital KK, 2015, above n.51.

[55] Cypel M, Keshavjee S, 2016, above n.52

[56] Ibid.

[57] The Australia and New Zealand Organ Registry, as received by the OTA, "Retrievals by unit 2009 – 2018 Jan-Sept" (Received October 2018).

Table 4: Total organ retrievals performed in 2017 (by state or territory), SOURCE: ANZOD[58]

State or territory	Total organ retrievals
Queensland	319
Northern Territory	7
Western Australia	178
Victoria	523
New South Wales	487
South Australia	81
Total	1,595

In Australia organ retrieval teams perform retrievals within the home state and may also perform organ retrievals across state borders. In 2017, approximately 30 per cent of retrievals and 20 per cent of organs transplanted occurred across jurisdictions.[59]

As most states have a renal transplantation unit, a large proportion of kidney retrieval procedures are performed by the home state retrieval service. Kidney retrievals in Tasmania were performed by Victorian and New Zealand retrieval teams whereas kidney retrieval procedures in the Australian Capital Territory were performed by retrieval teams from New South Wales.

For non-renal organs, organ retrieval procedures are more commonly performed by interstate retrieval teams. This is most common for heart and lung retrieval procedures as there are fewer heart and lung transplantation units across the country. This means that retrieval procedures for heart, lung and liver are more commonly performed by the transplanting unit. In 2017, 86 per cent of lung retrieval procedures, 74 per cent of heart retrieval procedures and 68 per cent of liver retrieval procedures were performed by the transplanting unit that the organ was allocated to.[60]

4.9 Element 7: Transplantation

There are a variety of models for the delivery of transplantation services across jurisdictions and transplantation units. Once it is confirmed that the retrieval is to be undertaken, the transplantation is confirmed and the resources in the transplantation unit are prepared and coordinated (including all personnel and resources) by the transplant coordinator. Transplant coordination occurs before successful retrieval is confirmed.

Once the potential recipient is prepared for surgery, the transplant surgery takes place. This may or may not be performed by the same surgical team as the retrieval team (i.e. may be in different hospital within the state or interstate). The transplantation takes place and often takes some hours; the duration often depends on the organ, the experience of the transplant surgeons and the specific circumstance of the recipient. Successful surgical transplantation relies on clinical expertise, adequate and skilled workforce and rigorous management from identification of organs for donation to transplant surgery.

[58] Ibid.

[59] The Australian Organ and Tissue Donation and Transplantation Authority, above n. 44.

[60] The Australia and New Zealand Dialysis and Transplant Registry, above n.56.

Ex vivo perfusion technology may be used in the transplantation process in order to allow for increased flexibility in transplant timing, enable more time to optimise the medical status of organs and recipients prior to surgery and ultimately improve the potential outcomes from surgery.

Transplantation numbers have increased overall since the implementation of the reform in 2009. However, they vary greatly between organs and across states and territories as illustrated in Figure 9 to Figure 14. Kidneys are the most commonly transplanted organ, whereas pancreas and intestine organ transplantations are performed on a much smaller scale currently in Australia. New South Wales and Victoria perform the most organ transplantations and have continued to do since 2009. The lowest number of transplantations can be seen in Western Australia and South Australia.

Figure 9: Lung transplant counts 2009-2017 (per state/territory), SOURCE: ANZOD[61]

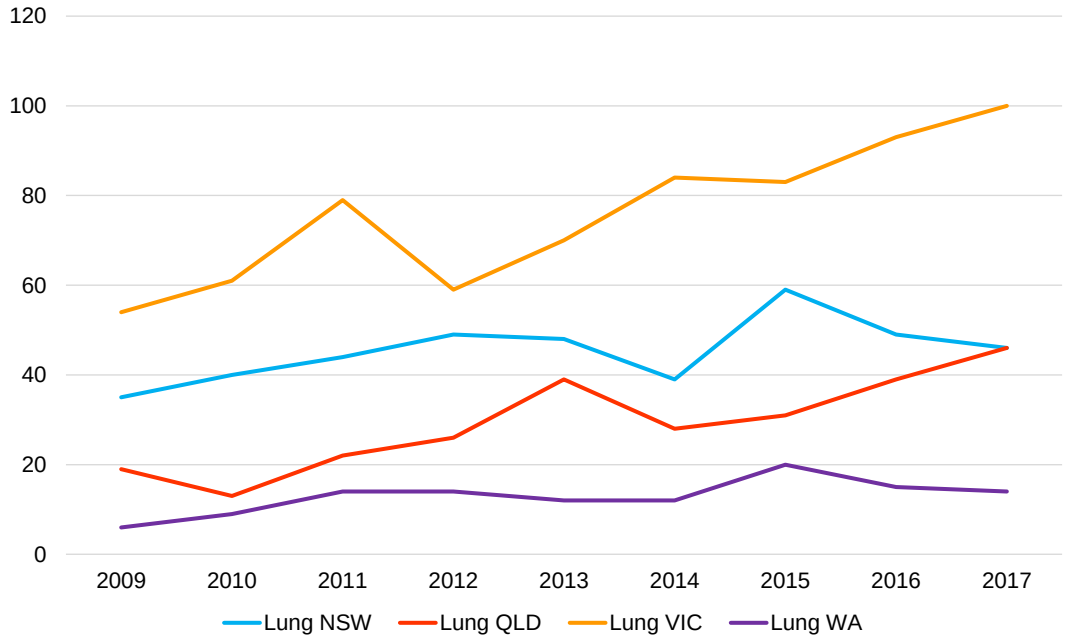
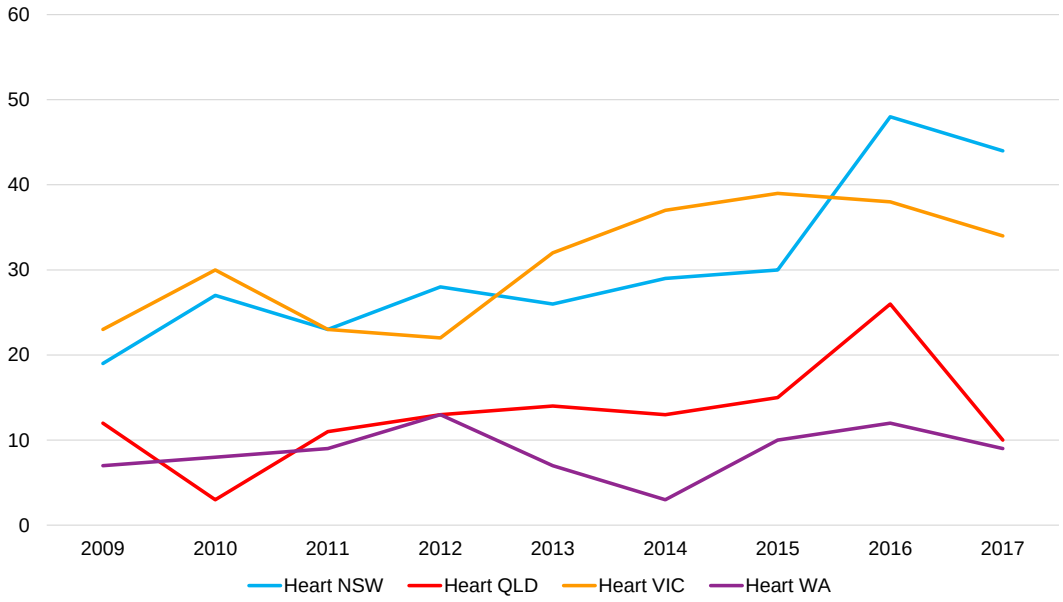


Figure 10: Heart transplant counts 2009-2017 (per state/territory), SOURCE: ANZOD[62]



[61] Australia and New Zealand Organ Registry, as received by the OTA, "Transplant Procedure Growth 2009 – 2017 – Lung" (received September 2018).

[62] Australia and New Zealand Organ Registry, as received by the OTA, "Transplant Procedure Growth 2009 – 2017 – Heart" (received September 2018).

Figure 11: Liver transplant counts 2009-2017 (per state/territory), SOURCE: ANZOD[63]

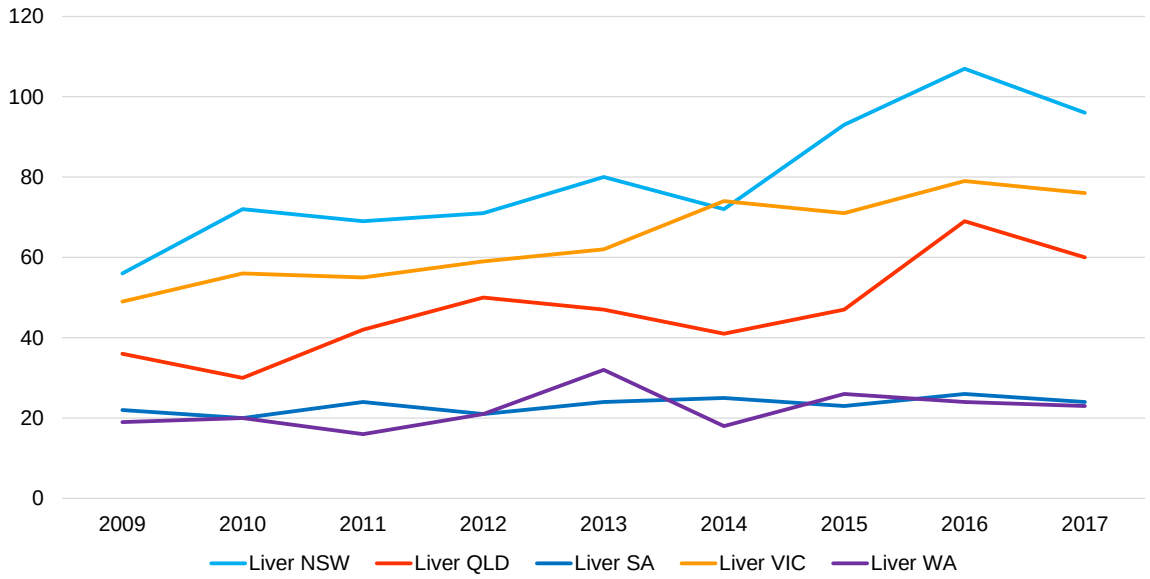
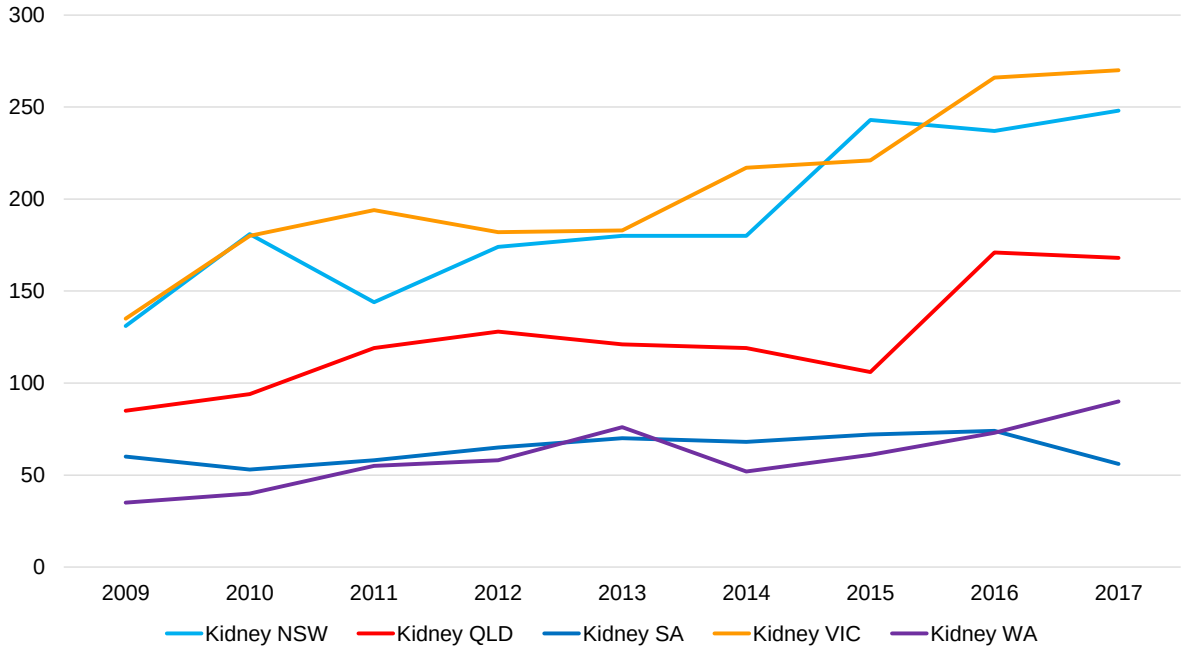


Figure 12: Kidney transplant counts 2009-2017 (per state/territory), SOURCE: ANZOD[64]



[63] Australia and New Zealand Organ Registry, as received by the OTA, "Transplant Procedure Growth 2009 – 2017 – Liver" (received September 2018).

[64] Australia and New Zealand Organ Registry, as received by the OTA, "Transplant Procedure Growth 2009 – 2017 – Kidney" (received September 2018).

Figure 13: Intestine transplant counts 2009-2017 (per state/territory), SOURCE: ANZOD[65]

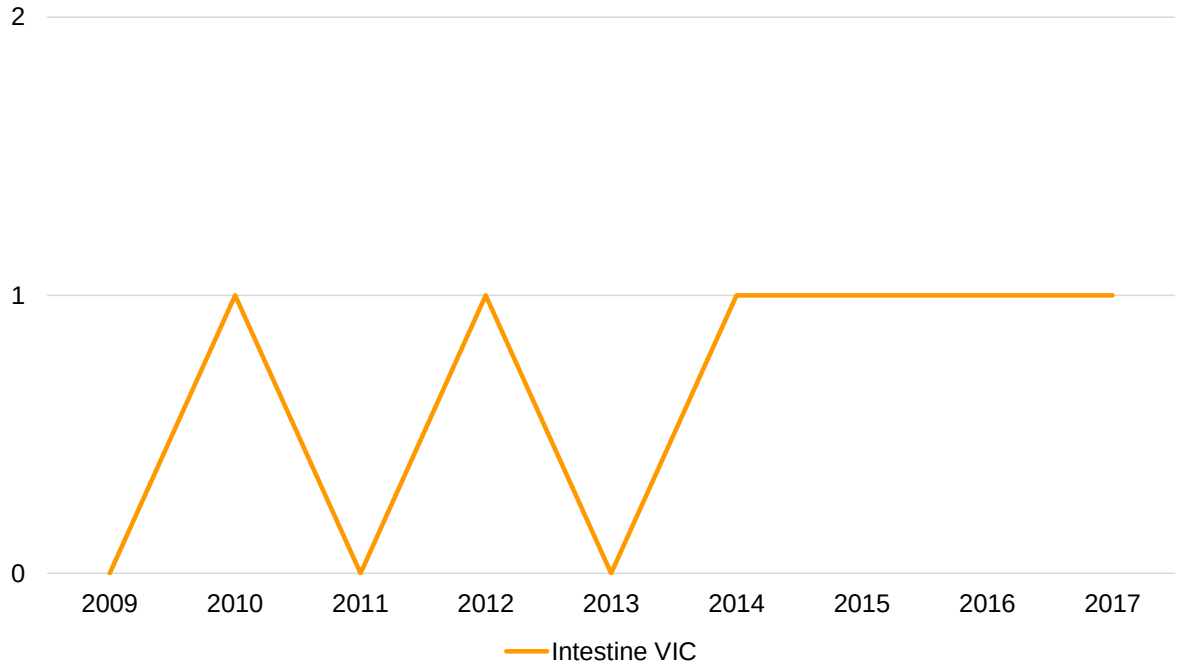
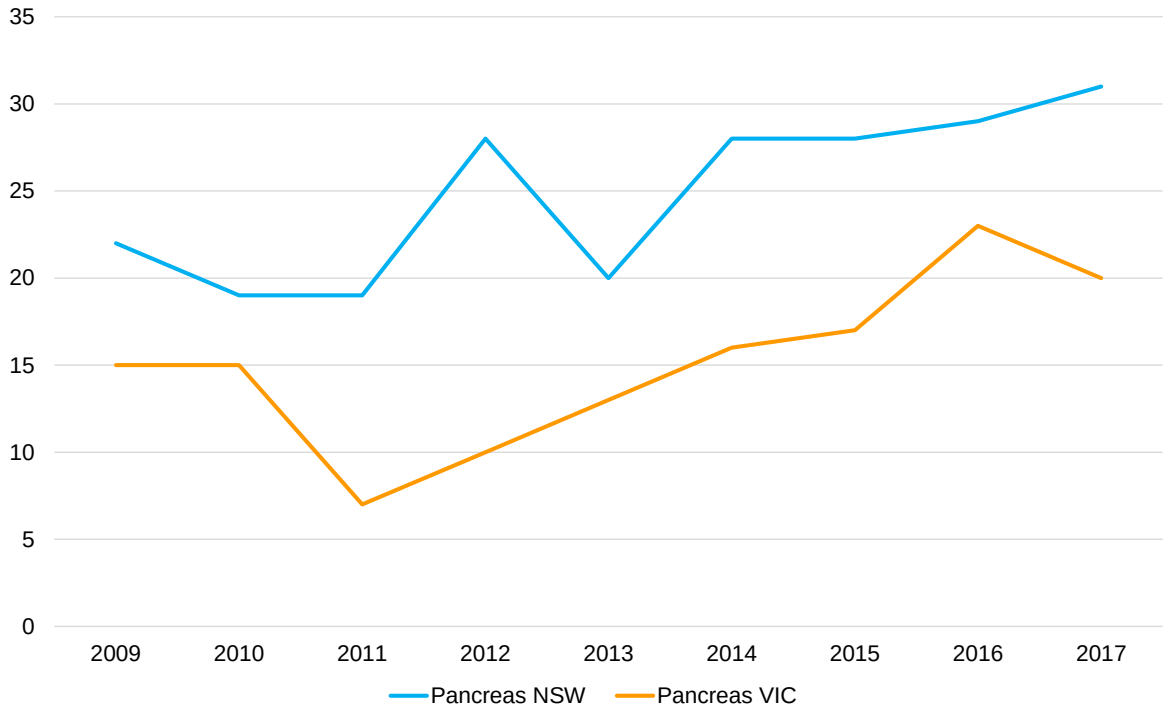


Figure 14: Pancreas transplant counts 2009-2017 (per state/territory), SOURCE: ANZOD[66]



[65] Australia and New Zealand Organ Registry, as received by the OTA, "Transplant Procedure Growth 2009 – 2017 – Intestine" (received September 2018).

[66] Australia and New Zealand Organ Registry, as received by the OTA, "Transplant Procedure Growth 2009 – 2017 – Pancreas" (received September 2018).

4.10 Element 8: Post transplantation care

Post transplantation care is undertaken in the ICU immediately after surgery (other than kidney and pancreas recipients). Care is a combined responsibility of both the ICU and the transplant teams. Intensive care is maintained for approximately one week or until the recipient is deemed well enough to be discharged from ICU into the general medical ward.

Kidney and pancreas transplant recipients generally go straight to the ward post transplantation surgery. Renal recipients are initially followed up daily in the transplantation clinic with daily post transplantation bloods and reviews in the first two to four-week period. This frequency is dependent on the renal function stability and whether there is any rejection of the transplanted kidney.

During time in hospital, ongoing clinical management is commenced. This includes pathology, imaging, medical treatment, pharmacy, dietetics, physiotherapy, etc. This is also the time when psychosocial support commences to assist with counselling or connection to appropriate services as required. Education is given to the recipient and family prior to discharge, including pharmacy education regarding medications and a drug list for the patients to follow.

Following discharge from hospital, lung, heart, liver and pancreas transplant recipients remain under the care of the transplantation unit. Post transplantation reviews are generally initially required weekly for liver, lungs, heart and intestinal, then the frequency is gradually reduced according to how the patient responds to medication and whether there are any post transplantation complications. Kidney transplant recipients on the other hand are referred to a post transplantation physician for ongoing care and a script for all medication requirements. This may be a transplant physician attached to the transplantation unit or their referring local physician. Patients are required to return to post transplantation clinics or appointments every three months following discharge, with extended time between visits as time goes on and as deemed appropriate by the transplantation clinician.

Supporting elements

4.10.1 Data and information management

Information relating an individual's health, is regulated by privacy legislation at a both a federal and state and territory level. At a federal level, the right to collect and use sensitive information is granted to the OTA and other Australian Government entities through the *Privacy Act 1988 (Cth)*[67] ('The Privacy Act') and managed through the Australian Privacy Principles.[68] Specifically, information relating to public sector health service providers, namely patient information generated by individual transplantation units are managed at a state and territory level. Separate bodies of legislation govern the collection, management and distribution of personal information within each jurisdiction. As such, each state and territory remain the custodians for their patient data.

[67] *The Privacy Act 1988* (Cth).

[68] Schedule 1; *The Privacy Act 1988* (Cth).

Data in relation to the organ, donation retrieval and transplantation system is collected across Australia. The databases in which key donation, retrieval and transplantation is collected are outlined in Table 5.

Table 5: Data hosts and owners

Data type	Databases
Australian Government	• Medicare Benefit Schedule (MBS) data • Pharmaceuticals Benefits Scheme (PBS) data • The Australian Organ Donor Register (AODR) • DonateLife Audit • Electronic Donor Record (EDR)
State and territory health departments	• Inpatient data
The Australian Red Cross Blood Service	• The NOMS
Outcomes registries	• Australia and New Zealand Intensive Care Society Adult Patient Database • Australia and New Zealand Liver Transplant Register • Australia and New Zealand Cardiothoracic Organ Transplant Register • Australia and New Zealand Islets and Pancreas Transplant Register • Australia and New Zealand Organ Donation Registry (ANZOD) • Australian and New Zealand Dialysis and Transplant Registry (ANZDATA)

The ANZOD was established in 1989 in Australia and 1993 in New Zealand to record and report on all organ donation after death. The ANZOD reports monthly and includes the numbers of deceased organ donors and the number of recipients benefiting from donation. Donation data is uploaded from the Electronic Donor Record (EDR) in each hospital to The ANZOD.

Transplantation units contribute activity and outcome data to national organ specific outcome registries for kidney (ANZDATA), heart and lung (Australia and New Zealand Cardiothoracic Organ Transplant Register), liver (Australia and New Zealand Liver Transplant Register) and pancreas (Australia and New Zealand Islets and Pancreas Transplant Register) transplant reporting. The ANZDATA also collects and reports the incidence, prevalence and outcome of dialysis treatment and kidney transplantation for patients with end-stage kidney disease across Australia and New Zealand. The performance of the system is reported through each registry yearly, via an annual report with interim findings published on an ad hoc basis.

Data sharing agreements with each jurisdiction must be in place to allow data to be fed into these sources for analysis and reporting. The *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* [69] stipulates that a clear function of the OTA is to collect, analyse, interpret and disseminate information relating to organ or tissue donation and transplantation matters. Currently the consolidation, analysis and release of organ donation data across jurisdictions require agreement from the custodian jurisdictions.

Funding to maintain the outcome registries is provided by the Australian through the OTA.

[69] *The Australian Organ and Tissue Donation and Transplantation Authority Act* 2008 (Cth).

Additional funding is also provided through specialist colleges and the New Zealand Government.

4.10.2 Financing arrangements for the system

Different funding arrangements apply to the different elements of the system. These are explained in detail below.

Element 1: Initial assessment and waiting list management

As directed by the National Reform Agreement, Australian Government funding is provided to hospitals for the initial assessment and waiting list activities undertaken in hospital. The funding level is based on the National Efficient Price. Outpatient activities undertaken as part of the Initial Assessment and Waiting List element are sometimes covered through the Medicare Benefits Schedule. Funding for tissue typing and blood services vary between jurisdictions:

- Victorian tissue typing and blood services are block funded with some additional Activity Based Funding to operate services for both Victoria and Tasmania.
- Queensland and Western Australian tissue typing and blood services are funded through block funding only.
- South Australia receives block funding to operate South Australian and Northern Territory tissue typing and blood services.
- New South Wales tissue typing and blood services are funded through Activity Based Funding and operate services for both New South Wales and the Australian Capital Territory.

Element 2: Deceased organ donation

Funding for some deceased donation activities is covered by Australian Government funding agreements with states and territories. States and territories also contribute varying levels of funding to support donation. There are two types of funding agreements entered into between the Australian Government, through the OTA, and each state and territory health department: (1) Organ Donation Hospital Support Funding (ODHSF); and (2) DonateLife Network - State and Territory Funding.

In 2012, the AHMAC agreed a revised and simplified ODHSF model that provides a contribution towards the costs associated with organ donation activity (up to the point of the donation - retrieval procedure) based on actual and intended organ donors, and the cost of transferring an intended donor from a regional hospital to a larger hospital solely for the purpose of donation, utilising data as provided by ANZOD. The ODHSF funding agreements are entered into with jurisdictional health departments, with funding agreements separately negotiated for private hospitals in the Australian Capital Territory and the Hospital and Health Services in Queensland.

Element 3: Organ allocation

The OTA provides funding to the Australian Red Cross Blood Service for the operation of the NOMS. Tissue typing services are funded through the respective state and territory health departments.

Element 4: Organ offer

The National Reform Agreements for Australian Government funding jurisdictions and hospitals for organ offer activities within the hospital setting. If additional testing is required during the offer stage, the tissue typing services are engaged and funded as per the state or territory arrangements mentioned above.

Element 5: Organ acceptance

Organ acceptance activities and resources are also covered through the National Reform Agreements for Australian Government funding (National Efficient Price) to jurisdictions and hospitals.

Element 6: Retrieval

Retrieval activities are funded through the National Reform Agreements for Australian Government funding to jurisdictions and hospitals. Perfusion technology is also funded by individual units and where ex vivo technology is being used, full or partial funding has been received from philanthropic sources to support the purchase of the technology.

In areas of specialised need, funding is provided by the states and territories to establish a national centre for transplantation. For example, the Paediatric Heart Transplant Centre in Victoria. Funding for this centre supports the activities required to undertake retrieval services for paediatric donors and potential recipients.

Element 7: Transplantation

The National Reform Agreement prescribes funding to jurisdictions and hospitals for transplantation services under Activity Based Funding. Tissue typing services required during this time are covered through the above-mentioned funding arrangements. Further, organ perfusion, cross border charging arrangements and activities that occur in specialised centres are covered under the above-mentioned arrangements.

Element 8: Post transplantation

Inpatient services for post transplantation are funded under Activity Based Funding through the National Efficient Price. Outpatient services are funding through MBS and PBS for renal transplantation. However, there are restrictions on MBS access in other transplant services. These are explained in detail in Section 7.2.2.

As demonstrated in Table 6, the funding arrangements for the organ donation, retrieval and transplantation system are complex. The funding arrangements are explained in further detail following the table.

Table 6: Funding arrangements for the organ donation, retrieval and transplantation system (by element), SOURCE: The OTA[70]

	Element 1: Initial assessment and waitlist management (potential recipient)	Element 2: Deceased donation (potential donor)	Element 3: Organ allocation	Element 4: Organ offer	Element 5: Organ acceptance	Element 6: Retrieval (donor)	Element 7: Transplantation (recipient)	Element 8: Post transplantation (recipient)

Public funding	National Health Reform Agreement:
	• Australian Government (NEP)
	• Australian Government (NEC)
	• Jurisdiction inpatient
	• Tissue typing
	• Blood Service:
	  • VIC: Block Funded / some Hospital ABF
	  • SA: Block Funded (inc. NT State Agreement)
	  • NSW: Activity Based Funding
	• QLD HSQ: Block Funded
	• WA PathWest
		State and Territory Funding Agreements DonateLife Network – OTA
		Organ Donation Hospital Support Funding (ODHSF) - OTA
			National Organ Matching System (NOMS)/Blood Service - OTA	National Health Reform Agreement:
				• Australian Government (NEP)
				• Jurisdictions
				Tissue typing:
				• Blood Service:
				  • VIC: semi Block Funded
				  • SA: Block Funded (inc. NT State Agreement)
				  • NSW: Activity Based Funding
				• QLD HSQ: Block Funded
				• WA PathWest
				State and Territory Funding Agreements DonateLife Network – OTA
					National Health Reform Agreement:
					• Australian Government (NEP)
					• Jurisdictions
						National Health Reform Agreement:
						• Australian Government (NEP)
						• Australian Government (NEC)
						• Jurisdictions
						Tissue typing:
						• Blood Service
						  • VIC: semi Block Funded
						  • SA: Block Funded (inc. NT State Agreement)
						  • NSW: Activity Based Funding
						• QLD HSQ: Block Funded
						• WA PathWest
						State and Territory Funding Agreements DonateLife Network – OTA
						Organ perfusion/ consumables
						Organ transport - multi-organ and perfusion:
						• Retrieval team transport
						• Cross border charging arrangements
						Nationally Funded Centers (e.g. Peadiatric Heart Transplant Centre)
							National Health Reform Agreement:
							• Australian Government (NEP)
							• Australian Government (NEC)
							• Jurisdictions
							Tissue typing:
							• Blood Service
							  • VIC: semi Block Funded
							  • SA: Block Funded (inc. NT State Agreement)
							  • NSW: Activity Based Funding
							• QLD HSQ: Block Funded
							• WA PathWest
							Organ perfusion/ consumables
							Cross border charging arrangements
							Nationally Funded Centers (e.g. Peadiatric Heart Transplant Centre)
								National Health Reform Agreement
								• Australian Government (NEP)
								• Australian Government (NEC)
								• Jurisdictions
								Nationally Funded Centers (e.g. Peadiatric Heart Transplant Centre)
								Outcome registries - OTA

Patient funding	Medicare Benefits Schedule Pharmaceutical Benefits Scheme							Medicare Benefits Schedule Pharmaceutical Benefits Scheme

[70] The Australian Organ and Tissue Donation and Transplantation Authority, "System funding and resourcing" (received July 2018).

5. Key findings and recommendations: System governance

This section describes the findings and recommendations for the Review relating to the governance arrangements for the Australian organ donation, retrieval and transplantation system.

5.1 Governance of the Australian organ donation, retrieval and transplantation system

The Review found that the strategic direction and governance arrangements for the organ donation, retrieval and transplantation system have largely been effective to date and have contributed towards significant progress in driving the reform agenda. The current arrangements have provided the framework and accountability measures to drive performance, particularly in organ donation, which in turn has driven performance in retrieval and transplantation. However, the Review found that in order to continue to overcome downstream capability and capacity pressures, meet future demand and achieve best practice, a new strategic plan and appropriate governance structures are required.

For system governance, the findings of the Review relate to:

- Strategic planning for the Australian organ donation, retrieval and transplantation system (Section 5.1.11)
- Governance of the retrieval and transplantation system (Section 5.1.2)
- Adoption of evidence-based practice (Section 5.1.3).

5.1.1 Strategic planning for the Australian organ donation, retrieval and transplantation system

The aim of the Australian Government's national reform program has been to implement a nationally coordinated world's best practice approach to organ and tissue donation for transplantation in collaboration with the states and territories, clinicians and the community sector. As such, DonateLife's objectives, mission and strategic priorities have focused on improving donation rates. The OTA's Strategic Plan, *Progressing Australian organ and tissue donation and transplantation to 2022*[71] is an organisational document to guide its priorities in delivering the implementation of the national reform agenda. It has four key objectives focused on improving donation performance.

As of December 2016, Australia was ranked 17th in the world in respect to actual deceased organ donors (up from 28th in 2008-09). Australia has had the highest percentage of growth in donation

[71] The Australian Organ and Tissue Donation and Transplantation Authority, 2018, *2018-2022 OTA Strategic Plan: Progressing Australian organ and tissue donation and transplantation to 2021*, viewed September 2018, <https://donatelife.gov.au/sites/default/files/ota_strategic_plan_2018-2022.pdf>.

in the 9th year of reform when compared to countries that have undergone similar national organ donation and transplantation reform programs.[72] Although strategies have been effective in improving donation performance in Australia, continued success has resulted in downstream pressure on the system. While it is important to continue to increase donation rates to provide greater access to transplantation, the system requires strategies focused on improving capability and capacity issues within retrieval and transplantation services in order to alleviate inequities and facilitate access to life-saving transplantation for all Australians. This includes identifying and implementing innovative strategies that relieve workforce pressures and effectively manage resources, such as developing a training pathway for nurse practitioners in transplantation.

The use of nurse practitioners in the United States

A nurse practitioner is a registered nurse educated and authorised to function autonomously and collaboratively in an advanced and extended clinical role. They play a central role in providing patient education, increasing patient compliance and managing comorbidities for to optimise patient outcomes.

Nurse practitioners, known as Advanced Practice Registered Nurses (APRNs) in the United States, have become an integral part of the organ donation and transplantation system. Their role in transplantation assessment and post transplantation care assists to alleviate the clinical workload of transplant medical specialists, improving efficiency and allocation of resources. In 2017, there were 166,280 Advanced Practice Registered Nurses employed in the United States and 1,585 endorsed nurse practitioners in Australia.

While the role of nurse practitioners in Australia continues to develop across a spectrum of health care services, the Australian legislative landscape current limits the scope of practice. A nurse practitioner's scope of practice varies between state and territories. For example, there are no restrictions placed on nurse practitioners prescribing medication in Tasmania or Western Australia, whereas additional accreditation is required in South Australia, Queensland, New South Wales, Victoria and the Australian Capital Territory. The Northern Territory on the other hand prohibits nurse practitioners from prescribing medication and they are only legally permitted to possess and dispense medicines.

As the endorsed nurse practitioner workforce expands in Australia, their role and the value they can provide as an innovative method in improving efficiency in the healthcare sector requires consideration and the necessary legislative environment to effectively operate.

The Review found that that the Australian Government has acted at the right time to review the current performance of the system to develop a new strategy. Stakeholders highlighted the need to address capacity issues in the system through improvements to strategy and governance arrangements.

[72] International Registry in Organ Donation and Transplantation, 2017, *Final Numbers 2016*, viewed July 2018, <www.irodat.org/img/database/pdf/IRODaT%20newletter%20Final%202016.pdf>; Manyalich M, Costa AN, Paez G, 2010, '2009 International Donation and transplantation activity', *Organ and Tissue Cells* vol. 13, pp. 146 – 150; The Australia Organ and Tissue Donation and Transplantation Authority, 2017, *Comparing International Organ Donation Outcomes 2017*, viewed July 2018 http://www.donatelife.gov.au/sites/default/files/9_2017%20Comparing%20International%20Organ%20Donation%20Outcomes.pdf; Note: Measurement of donation performance, for example the definition of DPMP may very depending on each country.

Donation and transplantation is internationally recognised as a highly effective, life-saving treatment. Health systems around the world have invested in strategies to improve access to transplantation with mixed results. For example, with 40 donors and more than 100 transplant procedures per million population in 2015, Spain is the leading jurisdiction worldwide in providing transplantation services to its patient population.[73] The Spanish rates are derived from a specific organisational approach to ensure the systematic identification of opportunities for organ donation and their transition to actual donation and to promote public support for the donation of organs after death. The approach includes three specific objectives:

1. Promoting the identification and early referral of possible organ donors from outside of the intensive care unit to consider elective non-therapeutic intensive care and incorporate the option of organ donation into end-of-life care
2. Facilitating the use of organs from expanded criteria and non–standard risk donors
3. Developing the framework for the practice of donation after circulatory death.

Similar to Australia, the strategies of Spain's *Organizacion Nacional de Trasplantes* have focused on donation as a means of driving access to transplantation. Personnel from the *Organizacion Nacional de Trasplantes* explain that good organisation in the process of deceased donation and continuous adaptations of the system to changes are always the basis of successful results in organ donation and transplantation.[74]

As Australia has continued to improve the organisation of the donation process resulting in an increased supply of organs for transplantation, however further work is required to the system in order to enable equitable access transplantation nationally.

Summary of key findings

- Australia had the highest percentage of growth in donation in the 9th year of reform compared to other countries that have undertaken national reform programs to increase organ donation (Spain, United Kingdom and Portugal).
- A new national strategy is required in order to continue to drive performance of the system and meet key capacity issues, with a particular emphasis on innovative approaches to national workforce planning and coordination of retrieval and transplantation.

Recommendations

Recommendation	Description
Recommendation 1	The Australian Government working in collaboration with states and territories use this report to guide the development of a future national strategy for the retrieval and transplantation sector to optimise every deceased donation opportunity for maximum transplantation outcomes.
Recommendation 2	The Australian Government working in partnership with states and territories, develop a long-term national workforce strategy for the organ

[73] Matesanz R, et al, 2017, 'How Spain reached 40 deceased organ donors per million population', *American Journal of Transplantation* Vol.17 Issue: 6, pp. 1447-1454.

[74] Wiley, 2017, *How Spain achieved a remarkably high rate of deceased organ donation*, viewed July 2018 <https://www.eurekalert.org/pub_releases/2017-01/w-hsa010617.php>.

Recommendation	Description
	donation, retrieval and transplantation sectors.

5.1.2 Governance of the retrieval and transplantation system

Discussion of findings

States and territories, and their constituent Local Hospital Networks, are currently the primary vehicle for organ retrieval and transplantation services and it should remain this way; as the primary responsibility for the delivery of public sector health services in Australia lies with the states and territories under the National Health Reform Agreement. However, there are a range of national issues impacting the organ retrieval and transplantation system, and national reform agenda with a particular focus on organ donation, which require national coordination. The system would benefit from governance structures that provide oversight of the end-to-end processes in organ donation, retrieval and transplantation, in particular enhanced coordination of retrieval and transplantation. This would assist to minimise missed opportunities in donation, ensure effective use of donated organs and provide more opportunities to help Australians who require transplantation.

The OTA is best placed to lead the development of these end-to-end governance arrangements, as current legislation provides for the OTA to have oversight and some responsibility over the retrieval and transplantation system. To date, the OTA have focused their attention on implementing the national reform agenda with a particular focus on organ donation. For the OTA to extend their governance focus to embrace the enhanced coordination of the retrieval and transplantation elements of the system and be the key driver of the new strategy, they will require adequate funding and support from the Australian Government.

Countries with the highest performing organ donation, retrieval and transplantation systems (i.e. Spain, Croatia and the United States of America) all have dedicated structures within the system aimed to drive the performance of the system. The Spanish Ministry of Health created the *Organizacion Nacional de Trasplantes* in 1989 as an agency in charge of the coordination and oversight of donation, procurement, and transplantation activities in a politically decentralised country, albeit with an adequate legislative and technical framework from the transplantation perspective.[75] The *Organizacion Nacional de Trasplantes* has end-to-end oversight of all organ donation, retrieval and transplantation activities, enabling monitoring of performance and the ability to drive strategic change to improve donation and transplantation outcomes.

Summary of key findings

- The states and territories, and their constituent Local Hospital Networks, should remain the primary vehicle for the delivery of organ donation, retrieval and transplantation services.
- The OTA is best placed to lead strategic priorities and these initiatives; however, change will be required to the current agreement between the Australian Government and the state and territory governments. Further, additional resources will be required to enable the OTA to effectively undertake this role.

[75] Matesanz R, 2017, above n.85.

Recommendations

Recommendation	Description
Recommendation 3	All Australian Governments resolve that the OTA should take a national strategic or coordination role under its existing legislation in regards to the following organ donation retrieval and transplantation issues: • National planning and service development • National standards and guidelines development • Advocacy for the donation, retrieval and transplantation system • Provision of advice to national research funding bodies based on advice obtained from the TSANZ and other clinical advisers • Data collection, analysis and reporting to drive change and clinical best practice • National planning for the adoption of new evidence-based practice including new tissue typing and ex vivo organ perfusion technologies.

5.1.3 Adoption of evidence-based practice

Discussion of findings

The Review found that there are a multitude of research bodies that currently inform and drive the evolution of the Australian organ donation, retrieval and transplantation system. Research is a valuable part of innovation and improving practices to drive patient outcomes. However, the Review found that there are a number of research projects taking place with no national coordination. As a result, the investment in research and development, along with the adoption of new evidence-based practices, techniques and technologies, is often ad hoc. See Section 7.3.1 for more detail.

National and international practice highlights the importance of a systematic approach to research and development as an essential part of improving quality and safety and remaining at the forefront of best practice. For example, the National Health Service in the United Kingdom has developed the National Health Service Blood and Transplant Research and Development Programme. The Programme is run by the National Health Services Blood and Transplant Service and includes partnerships with top class universities with the aim to drive effective application of novel technologies, processes and products to drive the advancement of clinical practice. Further, Spain also provides oversight and coordination of research and development approaches through the *Organizacion Nacional de Trasplantes*. The *Organizacion Nacional de Trasplantes* maintain partnerships with universities and other research bodies and are the responsible body for disseminating new information.

Summary of key findings

- Current approaches for research and development and the adoption of new evidence-based practices in the Australian organ donation, retrieval and transplantation system are not undertaken in a planned and coordinated manner.

Recommendations

Recommendation	Description
Recommendation 4	The OTA should provide advice, based on guidance obtained from the TSANZ and other clinical advisers, to research funding organisations on the priorities for research in organ donation and transplantation.

6. Key findings and recommendations: The eight elements of the donation, retrieval and transplantation functional model

This section describes the findings and recommendations for the Review against each of the eight elements of the Australian organ donation, retrieval and transplantation functional model, as illustrated in Figure 2.

6.1 Element 1: Initial assessment and waiting list management of potential transplant recipients

For element 1, the findings of the Review relate to:

- Referrals to transplant medical specialists (Section 6.1.1)
- The assessment process prior to transplantation for non-renal organs (Section 6.1.2)
- The assessment process prior to transplantation for renal organs (Section 6.1.3)
- Potential transplantation recipient education and consent (Section 6.1.4).

6.1.1 Referrals to transplant medical specialists

Discussion of findings

Outpatient specialist clinics have an important role in improving transplantation outcomes through delivering transplant education and referral systems for organ transplantation.[76] Stakeholders reported that there are persistent problems reported by organ transplantation clinicians with late referrals to specialist transplantation clinicians which continues to impact the outcomes of transplantation.

Referrals are considered late when a disease is in its late stages and the health of a potential recipient has declined to the point to which the benefits of transplantation may be reduced.[77] Late transplantation referrals require either: (1) additional management to improve their health to an optimal level prior to transplantation; or (2) the health of the potential recipient is so poor that it precludes the patient from transplantation.

The Review found that the reasons cited for late referrals included gaps in assessing appropriateness for referral and patient education. Transplantation clinicians reported that there was vast variability in the understanding of the benefits of transplantation among referring clinicians and potential recipients, as well as variability in referral processes.

[76] Kucirka, L M, Purnell, T S, & Segev, D L, 2015, 'Improving Access to Kidney Transplantation: Referral is Not Enough'. *The Journal of the American Medical Association* Vol. 314 Issue 6, pp.565–567.

[77] The Australia and New Zealand Dialysis and Transplantation Registry, 2016, *38th Report, Chapter 1: Incidence of End Stage Kidney Disease*, Australia and New Zealand Dialysis and Transplant Registry, Adelaide, viewed October 2018 <http://www.anzdata.org.au>.

Internationally there has been investment in the education of donation clinicians and key stakeholders in order to improve donation outcomes.[78] However, there is limited evidence of investment internationally in continuing education programs for clinicians involved in transplantation. Clinical stakeholders reported that with improved education and training of referring clinicians, as well as improved information sharing between referring clinicians and potential recipients, both barriers may effectively be overcome.

Summary of key findings

- Extensive evidence was reported in all the organ transplantation programs of the occurrence and challenge of late referrals of potential recipients to the transplantation program for assessment.

Recommendations

Recommendation	Description
Recommendation 5	All transplantation programs work with the continuing medical education pathways to improve the understanding of eligibility of patients for transplantation and the referral pathways among clinicians.

6.1.2 The assessment process prior to transplantation (non-renal organs)

Discussion of findings

Transplant assessment

As outlined in Section 4.3.1, both Clinical and Ethical Guidelines are used when assessing the eligibility of potential recipients for wait listing and transplantation.[79] The Review found that adherence to the Clinical and Ethical Guidelines for assessment of potential heart, lung and liver transplant recipients was generally consistent across transplantation programs and clinicians working within those programs.

The Review found that transplantation clinicians generally accommodate patient needs by conducting transplant assessment in the patient's local area where possible. However, most recipients have to attend a transplant clinic to finalise assessment processes. Transplant recipients reported that this was sometimes problematic, particularly for those from rural and remote regions. This was compounded if those from rural and remote regions were also from lower socio-economic groups, Aboriginal and Torres Strait Islander people and children. Assessment at the

[78] The Australian Organ and Tissue Donation and Transplantation Authority, 2013, *Fact Sheet: International approaches to organ donation reform*, viewed August 2018, <https://donatelife.gov.au/sites/default/files/files/OTA_Fact_Sheets__International_approaches_to_organ_donation_reform_November_2013.pd>.

[79] In line with the National Reform Agenda's objectives to establish a safe equitable and transparent national transplantation process, The Transplantation Society of Australia and New Zealand has developed a set of eligibility criteria, inclusive and exclusive, for patients to be listed for organ transplantation as part of the Clinical Guidelines. Decisions relating to eligibility will not take into consideration ethically irrelevant factors, including race, religion, gender, sexual orientation, social status, capacity to pay and the need for transplant arising out of past behaviour. The criteria does however take into consideration factors relating to urgency of need, medical factors, severity of illness, time on the wait list as well as likelihood that the recipient will comply with ongoing treatment after transplantation. The eligibility criteria is different for each organ.

transplantation clinic for those not located within the transplantation unit region sometimes required relocation of the potential recipient, and at times their family, for an extended period, as well as additional costs. This was seen as a barrier to receiving appropriate assessment and access to transplantation.

The benefits of outreach clinics for liver transplantation have been explored by Hulley, et al and were found to increase access to specialists for review and access to the waiting list, improved satisfaction of both clinician and patients and assisted in improving inequities in transplantation.[80] The Review found that access to outreach clinics were variable across Australia resulting in inequity of access for Australian living in some particular rural and remote locations. The Review found that it may be useful for states and territories to explore the findings from Hulley, et al, and consider the unique context of Australia's rural and remote populations in designing approaches and allocating resources to improve inequities of access to non-renal assessment for transplantation waiting lists.

Assessment and eligibility criteria for heart liver and lung transplantation

Heart

The essential indicator required for heart transplantation is the presence of end-stage heart disease where no alternative therapy is available. Examples of end-stage heart disease include but are not limited to, irreversible cardiogenic shock, intractable symptomatic heart failure, the need for permanent mechanical cardiac support, frequent discharges from an automated implantable cardioverter defibrillator or intractable angina despite optimal medical interventional and surgical treatment. All patients that are listed for heart transplantation have severely impaired quality of life, with an estimated survival of less than two years should transplantation not take place. Patients that suffer from conditions that may result in an unacceptably high mortality risk from heart transplantation or preclude active rehabilitation after transplantation may be excluded from transplantation. Examples of these include active malignancy, complicated diabetes, morbid obesity, active substance abuse and uncontrolled infections.

Liver

Patients that are eligible for liver transplantation must suffer from chronic liver disease with life-threatening complications. The principle indication is a Model for End-Stage Liver Disease score of greater than 15 in an adult, or a Paediatric End-Stage Liver Disease score of greater than 17 for children. Patients may also be suitable candidates if they have small hepatocellular carcinomata. Additional indications include liver disease that would result in a two-year mortality rate of greater than 50 per cent without liver transplantation.

Lung

Due to the scarcity of donor lungs, lung transplantations are offered only to patients who have a life expectancy of less than two years without transplantation where no alternative treatment is available. Patients must satisfy the inclusion criteria of respiratory failure despite optimal medical, interventional and surgical treatment; and/or poor quality of life, potentially with intractable symptoms and repeated hospital admissions. Similar to heart and liver, the presence of comorbidities such as active malignancy, irreversible significant dysfunction of other organs or body systems, substance abuse and non-curable chronic infection, may exclude patients from consideration.

[80] Hulley J L et al, 2013, 'PTH-150 Benefits of a Liver Transplant Outreach Clinic: Increased Referrals and Patient Satisfaction', *British Medical Journal,* Vol. 62 Issue: 1, pp. 272.

Waiting list management for non-renal organs

Once a potential recipient is wait listed for non-renal organ transplantation, it was reported by clinicians that patients are managed consistently across jurisdictions, transplantation clinics and clinicians. Heart, lung and liver transplant surgeons reported that the waiting list access process works well, particularly when there is an urgent listing. The clinicians working within these transplantation programs consistently reported that the process used for moving potential recipients up the waiting list, if their health deteriorates, was effectively used in a collaborative and respectful way between transplantation units.

However, the Review found that it is difficult to form an accurate, real time, national view of the waiting lists for non-renal organs. Unlike renal organs, which require an accurate national waiting list for the renal allocation algorithms, a national view of waiting list data for non-renal organs is less readily available. The Review found that non-renal organ waiting lists are maintained by the state-based transplantation units and are not currently readily shared nationally.

Table 7 illustrates the number of active patients on the waiting lists for non-renal organs (October 2018) for each state and territory. Each state presented has a transplantation unit for the identified organs, with a children's liver transplantation unit included in both Queensland and New South Wales.

Table 7: Number of active patients on the liver, lung, heart, kidney/pancreas and pancreas islets waiting list as of October 2018, SOURCE: NOMS [81]

Organ	NSW	QLD	SA	VIC	WA
Liver	23	52	9	54	0
Lung	35	46	6	33	10
Heart	34	24	2	12	7
Kidney/Pancreas	23	2	7	26	2
Pancreas Islets	11	2	3	7	0

The data show a large variation in waiting list numbers across transplantation units across Australia. Some variation may account for population size; however, it may also indicate inaccuracy of waiting list data as well as variability in wait listing practices and waiting list management. The data indicates that there are non-uniform practices occurring across Australia in wait listing potential recipients and the management of waiting lists for non-renal organs.

Summary of key findings

- The assessment processes and waiting list management utilised by non-renal (liver, heart and lung) transplantation programs throughout Australia are reported to be generally consistent across transplantation programs by clinicians.
- However, data show that there is large variation in waiting list numbers which may reflect

[81] Note: Due to the ad hoc collection of data relating to the non-renal organ waiting lists as described above, this information may not be completely accurate. In addition, the wait lists are extremely dynamic in nature hence the expression of wait list numbers at a single point in time. As discussed throughout this Report, it is currently impossible to identify the demand for non-renal transplantation. As such, a denominator cannot be expressed for these figures; National Organ Matching System as received by the OTA, "Active Recipients on NOMS October 2018", (received November 2018).

non-uniform practices in wait listing potential recipients and the management of waiting lists for non-renal organs.

Recommendations

Recommendation	Description
Recommendation 6	The OTA, through the TSANZ, oversee a clinical review of waiting list practices and management across all non-renal transplantation units in Australia, including the application of the Clinical Guidelines for non-renal transplantation and data management. The findings from the clinical review should be used to identify best practice in waiting list practices and management, as well as better enabling benchmarking to drive performance improvement across transplantation units.
Recommendation 7	All Australian governments consider strategies to improve access to non-renal outreach clinics for assessment for transplantation, including an emphasis on work up for transplantation as close as possible to the potential recipient's place of residence.

6.1.3 The assessment process prior to transplantation (renal organs)

The Review found that there is widespread variability in: (1) the use of assessment criteria used to assess potential kidney transplant recipients; and (2) the process used to manage patients on the kidney transplantation waiting list.

Discussion of findings

Assessment

The Review found that unlike assessment for non-renal organs, a considerable portion of the assessment for a kidney transplantation can take place close to the potential recipient's local residence. This is due the capability and capacity of renal and general medical services in non-tertiary settings. Where assessment took place in the potential recipient's local area, and this was outside of a metropolitan area, this was often assisted by outreach clinics run by transplant physicians or by physicians that have been trained within the state-based transplantation unit. In all other cases, assessment for kidney transplantation will take place at the transplantation unit.

The Review found that barriers to assessment were more likely experienced by those who lived in rural and remote regions. Of the 12,706 patients on dialysis and requiring a kidney transplant in 2016, 619 patients were located in either remote or very remote locations in the Northern Territory, Western Australia or Queensland (96 per cent of these patients identified as Aboriginal and Torres Strait Islander).[82] However, the is evidence that people living in rural and remote locations, particularly Aboriginal and Torres Strait Islander people, are less likely to be listed on a transplantation waiting list than people living in metropolitan regions.[83]

[82] The Australia and New Zealand Organ Registry as provided by the OTA, "Remote Dialysis Patients 31 December 2016" (received November 2018); The Australia and New Zealand Organ Registry as provided by the OTA, "Prevalent Transplant Recipients by Remoteness 31 December 2016" (received November 2018).

[83] Ibid.

As discussed previously, access to local assessment for kidney transplantation (through both outreach clinics and trained physicians in assessment) was reported to greatly improve access for rural and remote recipients. However, the Review found that outreach clinics were not in place consistently across all renal transplantation programs. In some states and territories access to assessment was only available or predominately available in large urban centres, creating inequities across the jurisdiction.

The Review found that the use of Clinical Guidelines for assessing the eligibility of patients for kidney transplantation were variable, resulting in different waiting list practices. Some clinicians used a narrower application of the Clinical Guidelines for transplantation resulting in less people being considered as 'eligible'. A key area of difference in application was the threshold for maximum Body Mass Index of a potential recipient that they would consider for transplantation. Additionally, it was observed that there was variability in the acceptable age difference between recipient and donor considered for transplantation across Australian kidney transplantation programs. This was considered to be a result of the differing levels of risk appetite and experience of transplantation clinicians in assessing potential recipients for eligibility.

The Review also found that there is no formal process agreed nationally for patients to obtain a second opinion if they are declined for kidney transplantation. Recipients or potential recipients reported that if they were declined for transplantation within their state and would like a second opinion, in some circumstances, their only option is to travel interstate to another transplantation program at their own expense for a second opinion. Given the variability between transplantation clinicians in the assessment process, the right to a second opinion, as provided for in the Ethical Guidelines determined by the NHMRC, should be available to the potential recipient when required.

Assessment and eligibility criteria for kidney transplantation

Eligibility for kidney transplantation is determined based on likelihood of survival. Patients eligible for kidney transplantation must have end-stage kidney failure, requiring dialysis or an impending requirement for dialysis. It is also expected that the transplanted organ is likely to have an 80 per cent likelihood of surviving for at least five years after transplantation. Comorbidities that may have a significant impact on the life expectancy of a kidney transplant recipient, including cardiac disease, vascular disease, diabetes mellitus and malignancies, may exclude patients from transplantation.

Referrals for renal transplantations are initially assessed by the transplanting hospital, involving a transplant physician and a surgeon. As the number of kidneys donated continue to increase in Australia, transplanting hospitals are starting to apply less stringent criteria, maximising the accessibility for transplantation to all Australians.

Access to assessment for Aboriginal and Torres Strait Islander people

The Review found that patient level factors such as ethnicity, age and socio-economic status played a role in the quality and timing of transplant education and access to transplantation for potential recipients.[84] This was particularly evident in the experience of Aboriginal and Torres

[84] Kucirka, L M, 2015, above n. 88.

Strait Islander people.

Aboriginal and Torres Strait Islander stakeholders and research groups reported that access to wait listing for kidney transplantation for Aboriginal and Torres Strait Islander people was significantly lower than non-Indigenous people.[85] At the end of 2015, 1.9 per cent of all Aboriginal and Torres Strait Islander dialysis patients were on the waiting list, in contrast to 9.5 per cent of non-Indigenous dialysis patients.[86] Table 8 demonstrates that the dialysis units with the largest percentages of Aboriginal and Torres Strait Islander patients have some of the lowest rates of wait listing and the highest rates of dying on dialysis.

Table 8: Breakdown by dialysis unit of patients commencing dialysis, the percentage of those people who identify as Aboriginal and Torres Strait Islander, percentage of those wait listed within two years and those who died and were not waitlisted, SOURCE: ANZDATA[87]

State	Patients initiating dialysis at age <65 from 2005-2014	Aboriginal and Torres Strait Islander dialysis users	Percentage wait listed 2 years after commencing dialysis	Percentage who died within 2 years of commencing dialysis (never on the waiting list or received a live donor transplant)
NT	359	96.70%	3.30%	13.10%
NT	409	81.20%	7.60%	19.10%
QLD	340	67.90%	12.60%	20.00%
QLD	282	52.50%	18.40%	13.80%
WA	710	51.10%	16.90%	13.80%
SA	798	16.20%	36.60%	11.50%
WA	313	12.50%	28.80%	11.80%
WA	458	11.80%	22.50%	12.70%
NSW	564	7.40%	29.40%	11.20%
QLD	345	7.20%	26.10%	12.50%
NSW	354	6.20%	32.80%	14.40%
VIC	327	5.80%	30.30%	12.80%
QLD	617	4.90%	28.80%	11.50%
ACT	249	4.80%	32.10%	7.60%
VIC	372	3.00%	39.00%	12.10%
NSW	811	2.60%	28.70%	12.30%
VIC	849	2.50%	37.60%	8.50%
VIC	681	1.50%	43.00%	8.40%
VIC	347	1.20%	36.90%	9.20%

[85] Lawton P et al, 2017, 'Organ Transplantation in Australia: Inequities in Access and Outcome for Indigenous Australians' *The Official Journal of the Transplantation Society and the International Liver Transplantation Society,* Vol: 101 Issue: 11, pp. 345-346.

[86] Australia & New Zealand Dialysis & Transplant Registry. *The 39th Annual ANZDATA Report*, viewed October 2018 <http://www.anzdata.org.au/v1/report_2016.html. Updated January 30 2017>.

[87] The Australia and New Zealand Dialysis and Transplantation Authority, as provide by the OTA "EY Data: Dialysis and Waiting List" (received August 2018).

State	Patients initiating dialysis at age <65 from 2005-2014	Aboriginal and Torres Strait Islander dialysis users	Percentage wait listed 2 years after commencing dialysis	Percentage who died within 2 years of commencing dialysis (never on the waiting list or received a live donor transplant)
NSW	248	1.20%	50.80%	7.70%
NSW	538	1.10%	31.20%	10.60%

Lawton, et al reported that when Aboriginal and Torres Strait Islander patients understand the potential advantages of kidney transplantation and all else is equal, they still have a quarter of the chance of non-Indigenous patients of receiving a kidney transplant.[88] This is supported by a number of research papers which indicate that there are disparities in wait listing and transplantation of Aboriginal and Torres Strait Islander people compared to non-Indigenous people, beyond those explained by measured comorbidities.[89]

The Review found that barriers to wait listing of Aboriginal and Torres Strait Islander people included time between commencing dialysis and assessment for wait listing, concerns among kidney specialists about poorer outcomes, real or perceived discrimination and obtaining informed consent.[90] The Review also found that additional barriers reported by stakeholders included access to health care services, health literacy and in some cases cultural beliefs.

Although barriers are significant, they were not described as insurmountable by key stakeholders in the Review. Barriers can be overcome through collaboration with Aboriginal and Torres Strait Islander communities and their leadership co-design strategies to address the issues. The Review found that it is timely that the TSANZ undertake the project to address inequities of access and outcomes in transplantation experienced by Aboriginal and Torres Strait Islander people.

Regular reporting of the performance of the kidney transplantation waiting list, including the number of Aboriginal and Torres Strait Islander people on the waiting list, would provide: (1) improved visibility of access; (2) improve the focus on the issue nationally; and (3) a basis for measuring performance.

Access to assessment for Australians located in rural, regional and remote locations

The Review found that unlike assessment for non-renal organs, a considerable portion of the assessment process (or 'work up') for a kidney transplantation can take place close to the potential recipient's local residence. This is due to the capability and capacity of renal and general medical services in non-tertiary settings. Where assessment took place in the potential recipient's local area, and this was outside of a metropolitan area, assessment was often assisted by outreach clinics run by transplant physicians or by specialist physicians that have been trained within the state-based transplantation unit. In all other cases, assessment for kidney transplantation will take place at the transplantation unit.

As discussed previously, access to local assessment for kidney transplantation (through both outreach clinics and trained physicians in assessment) was reported to improve access for rural

[88] Lawton P, 2017, above n. 97.

[89] Khanal, N. et al, 2015, 'Differences in access to kidney transplantation for Indigenous Australians' *World Congress of Nephrology*, Cape Town, South Africa.

[90] Lawton P et al, 2017, above n. 97; Cass A. et al, 2003, 'Renal Transplantation for Indigenous Australians: Identifying the Barriers to Equitable Access', *Ethnicity and Health* Vol.8, no. 3, pp. 111-119.

and remote recipients. However, the Review found that outreach clinics were not in place consistently across all renal transplantation programs. In some states and territories access to assessment was predominately available in large urban centres thus creating inequities across the jurisdiction.

The Review found that Australians living in rural and remote regions had the highest demand for transplantation nationally, however were less likely to be referred and assessed for transplantation and were less likely to be wait listed than those living in metropolitan and inner regional areas. In 2016, 90 per cent of patients listed on the kidney waiting list resided in either metropolitan or inner regional areas.[91] However, the Review found that a greater proportion of the population were on dialysis in rural and remote regions, indicating a greater need for transplantation. Table 9 highlights that the proportion of the population on dialysis is higher in remote and very remote Australia; however, the transplantation rate for patients on dialysis is considerably lower in these regions.

Table 9: Number of patients on dialysis and number of patients undergoing kidney transplantation in 2016 as a proportion of the population and proportion of dialysis patients, SOURCE: ANZDATA[92]

	Major cities	Inner regional	Outer regional	Remote	Very remote
Population in 2016	16,634,069	4,254,984	1,992,704	282,892	186,328
Number of patients on dialysis in 2016	9,272	1,748	1,067	470	149
Number of kidney transplants in 2016	765	198	91	12	8
Proportion of dialysis patients transplanted in 2016	8.25%	11.33%	8.53%	2.13%	5.37%

As illustrated in Figure 15 and Table 10, the Review found that the proportion of dialysis patients transplanted in metropolitan and inner regional areas has increased overall from 2013 to 2016. By contrast, the transplantation rate has declined in remote areas over the same time period. Further, the Review found that there has been a growth in dialysis patients between 2013 and 2016, yet the growth rate for transplantation has been inconsistent and variable. As demonstrated in Table 11 and Table 12 the year-on-year growth for dialysis and transplantation from 2013 to 2016 has not been proportionate, illustrating an increasing unmet demand across inner and outer regional areas, as well as remote and very remote areas. A national strategy is required to enable an increase in transplantation rates in rural and remote Australia to account for the increasing demand for transplantation in the future.

[91] The Australia and New Zealand Dialysis and Transplantation Authority, as received by OTA, "2016 Kidney Waitlist data by remoteness" (received October 2018).

[92] Ibid.

Figure 15: National proportion of dialysis patients that were transplanted during 2013 – 2016 by remoteness categories, SOURCE: ANZDATA[93]

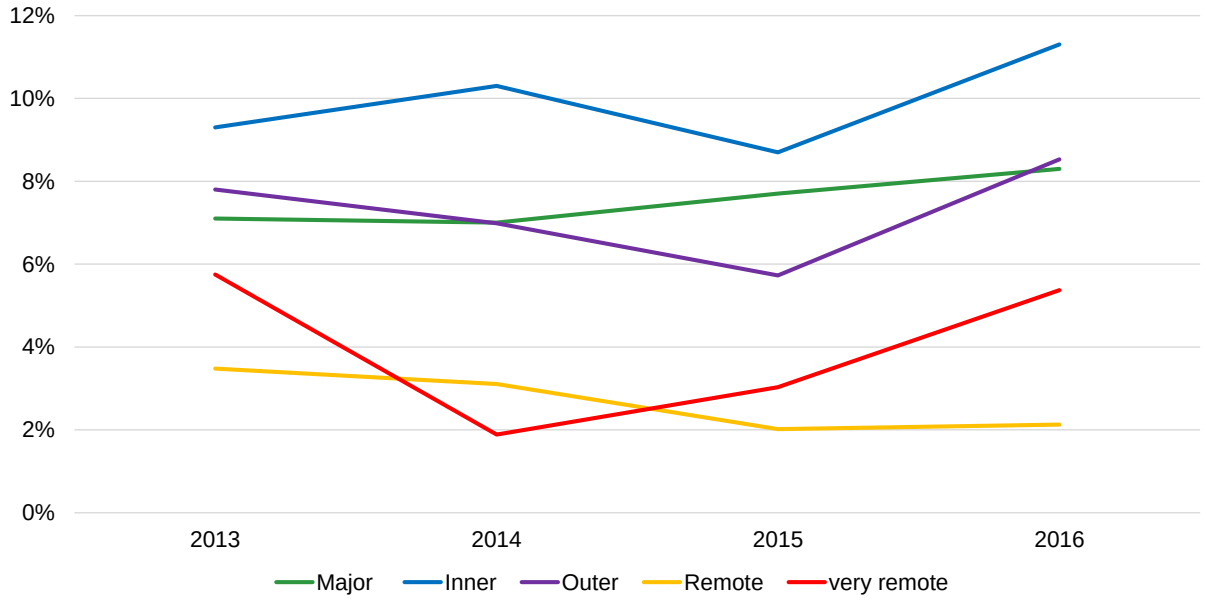


Table 10: National proportion of dialysis patients that were transplanted during 2013 – 2016 by remoteness categories, SOURCE: ANZDATA[94]

Year	Major cities	Inner regional	Outer regional	Remote	Very remote
2013	7.10%	9.30%	7.80%	3.48%	5.75%
2014	7.00%	10.30%	6.98%	3.11%	1.89%
2015	7.70%	8.70%	5.73%	2.02%	3.03%
2016	8.30%	11.30%	8.53%	2.13%	5.37%

Table 11: Year on year growth for number of dialysis patients from 2013 – 2016, SOURCE: ANZDATA[95]

Year	Major city	Inner regional	Outer regional	Remote	Very remote
2014	102%	107%	107%	112%	122%
2015	101%	103%	108%	116%	125%
2016	101%	99%	100%	105%	113%

[93] The Australia and New Zealand Dialysis and Transplantation Registry, as received by the OTA, "Transplantation rate by remoteness 2013 - 2016" (received October 2018).

[94] The Australia and New Zealand Dialysis and Transplantation Registry, as received by the OTA, "Transplantation rate by remoteness 2013 - 2016" (received October 2018); Note: Low sample sizes for remote and very remote categories result in a large variability in percentages.

[95] Ibid.

Table 12: Year on year growth for number of patients on dialysis that are transplanted from 2013 – 2016, SOURCE: ANZDATA[96]

Year	Major city	Inner regional	Outer regional	Remote	Very remote
2014	100%	119%	96%	100%	40%
2015	111%	88%	88%	75%	200%
2016	108%	129%	149%	111%	200%

Access to assessment for culturally and linguistically diverse populations

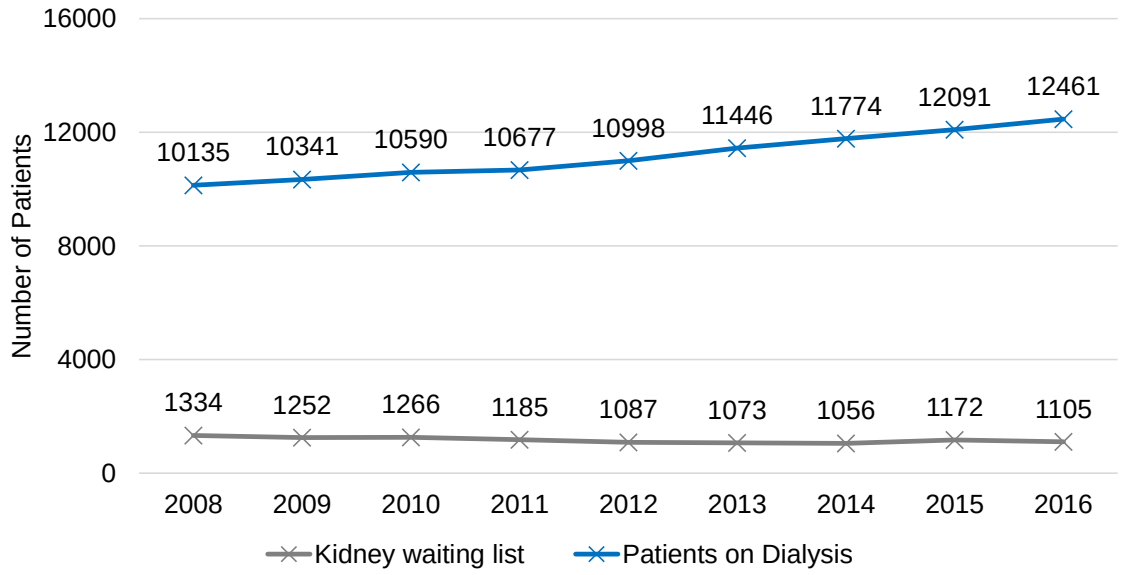
The Review noted that it was reported that culturally and linguistically diverse populations can experience barriers to accessing transplantation. This is due to factors such as access to appropriate assessment and understanding the benefits of transplantation for end-stage organ disease. However, data were not available to adequately determine the extent of issues of inequity.

Waiting list management for donated cadaveric kidneys

The Review found that the management of the kidney transplantation waiting list variable between rural and remote areas, between jurisdictions and between renal transplantation units within jurisdictions. Figure 16 illustrates that the number of patients on dialysis is increasing nationally, however the number of patients waiting for kidney transplantation is slowly declining. This raises questions as to whether the rate of accession to the waiting list is sufficient to meet demand.

[96] Ibid.

Figure 16: Number of patients on the kidney waiting list compared to the number of patients on dialysis 2008 – 2016, SOURCE: ANZDATA[97]



At the end of 2016, 7.5 per cent of patients on dialysis in Australia were wait listed for transplantation, compared to 15.5 per cent of patients on dialysis in Spain being wait listed.[98] This further suggests that Australia has not kept up with demand for kidney transplantation.

As demonstrated in Table 13 there is large variation in the number of potential recipients wait listed between NSW and Victoria compared to Queensland, South Australia and Western Australia.

Table 13: Kidney waiting list data 2016, SOURCE: ANZDATA[99]

	NSW	VIC	QLD	SA/NT	WA	Tas	NT	ACT	Total
Number of patients on dialysis at 31 Dec 2016	3,987	3,040	2,376	806	1,345	229	636	287	12,706
Number of active patients on waitlist at end of 2016	360	383	103	62	40				948
Waiting list as proportion of total number of patients on dialysis	8.4%	11.7%	4.3%	4.3%	3.0%	-	-	-	7.5%

This is particularly of concern when 11.7 per cent of dialysis patients in Victoria were listed on the renal waiting list, whereas only 3 per cent of dialysis patients in Western Australia were wait

[97] The Australia and New Zealand Dialysis and Transplant Registry, 2017 *40th Annual ANZDATA Report Chapter 6: Australian Transplant Waiting list,* viewed August 2018, <http://www.anzdata.org.au/v1/report_2017.html>.

[98] The Australia and New Zealand Dialysis and Transplant Registry,as provided by OTA, "EY Data: Wait listing – kidney (2016)" (received August 2018).

[99] Ibid.

listed.[100] Further, Table 14 demonstrates that Western Australia has more potential recipients on the waiting list that have previously received a transplant than those who have not.

Table 14: State and territory breakdown of patients on the renal waiting list with no previous transplant versus one or more, SOURCE: NOMS[101]

State	Total patients on the waiting list with no previous transplant	Total patients on the waiting list with 1 or more previous transplant
NT	0	0
NSW	316	62
VIC	264	98
QLD	74	35
SA	72	18
WA	20	29
TAS	0	0
ACT	0	0

Summary of key findings

- The assessment processes and waiting list management utilised by renal transplantation programs throughout Australia vary greatly, resulting in variable performance and inequity.
- This is primarily due to widespread variability in: (1) the use of the assessment criteria used to assess potential kidney transplant recipients; and (2) the process used to manage patients on the kidney transplantation waiting list.
- There is widespread variability in waiting list practices for people receiving dialysis across Australia and the gap is widening. This is particularly apparent for Australians living in rural and remote locations and was reported by clinical stakeholders to be an issue in culturally and linguistically diverse populations.
- Inequity is particularly experienced by Aboriginal and Torres Strait Islander people due to a number of inherent barriers that require further review and attention. These barriers to transplantation have been noted by Lawton, et al to be challenging, however are not insurmountable. An inability to overcome these impediments will continue to limit kidney transplantation in Aboriginal and Torres Strait Islander Australians.
- There is no nationally agreed formal process for patients to obtain a second opinion if they are declined for kidney transplantation.

Recommendations

Recommendation	Description
Recommendation 8	The OTA, through the TSANZ, commission a clinical review of the application of the Clinical Guidelines for kidney transplantation across all kidney transplantation units in Australia to assess the extent of variability in the use of these guidelines.

[100] Ibid.

[101] The National Organ Matching System as proved by the OTA, "EY Data: Wait listing – Kidney July 2018" (received August 2018).

Recommendation	Description
Recommendation 9	Based on findings from the above mentioned clinical review, a national policy for the management of kidney transplantation waiting lists is to be agreed. It should seek to improve inequities in access to waiting lists and implement best practice waiting list management.
Recommendation 10	The OTA, through collaboration with transplantation units, should publish the performance parameters for the management of kidney transplantation waiting lists annually in a clearly accessible form for the public. This includes the number of people and the proportion of Aboriginal and Torres Strait Islander and culturally and linguistically diverse people on dialysis on waiting lists to enable assessment of access to kidney transplantation for these groups.
Recommendation 11	All patients on long-term dialysis programs should be informed by their treating medical specialist of the possibility of transplantation and their compliance with the waiting list acceptance criteria.
Recommendation 12	All kidney transplantation programs should implement formal outreach arrangements with rural dialysis units as a condition of funding within the state or territory. These rural outreach arrangements must include a clearly defined pathway to kidney transplantation for rural residents, including specifically designed pathways for Aboriginal and Torres Strait Islander people, as well as a commitment to 'work up' a potential kidney transplantation recipient as close to their place of residence as possible.
Recommendation 13	All kidney transplantation programs should implement formal arrangements with Aboriginal Community Controlled Health Organisations to increase the understanding of transplantation as a possibility for Aboriginal and Torres Strait Islander patients on dialysis.
Recommendation 14	All dialysis units should have formal arrangements in place with a kidney transplantation program for the assessment of dialysis patients for possible kidney transplantation.
Recommendation 15	All kidney transplantation programs should implement a formal process for the provision of a second opinion to potential transplant recipients who are determined to be ineligible for transplantation.

6.1.5 Potential transplantation recipient experience

Accession on the waiting list

The Review found that waiting list information is not currently published or made readily available to potential recipients on the waiting list. Notwithstanding the many factors that are considered in the management of transplantation waiting lists, it was found that patients on a waiting list were often unaware of their position or rank on the list or how the waiting list is managed. The Review notes that a pilot program to improve patient oversight of the waiting list is planned in Victoria. The pilot will aim to improve a patient's visibility by providing digital access to their assessment outcomes and position on the waiting list. Enhancing clinical visibility is also planned. A feature of the OrganMatch clinician portal will allow clinical staff improved access to patient outcomes of matching and patient ranking on the list.

Education and consent

The Review found that while the Clinical Guidelines stipulate that patient education is to occur at the time of wait listing, different units have different approaches to education and consent of potential recipients. Some units reported that at this point in the process, potential recipients should understand and provide initial consent regarding the types of organs and level of risk that they will accept. This would then be recorded and final consent would be collected during the acceptance and process (see Section 6.5). However, this approach was not uniform across units and resulted in different consenting processes across the country.

Potential transplant recipient education

The provision of education is critical in allowing potential transplant recipients to make an informed decision in relation to transplantation. This includes informing the potential recipient of the risks, benefits and what may happen if the procedure does not go ahead. Support and counselling services should also be provided as part of this process.

The acceptability of donor organs that may pose an element of risk should be discussed with both the potential recipient and their carer at the time of wait listing, rather than at the time of the organ offer. This allows for an informed consent without the time pressures associated with the organ offer process. This conversation should introduce the idea and discuss the risks and acceptability of organs from extended criteria donors. For example, the introduction of new and safe antiviral therapy for Hepatitis C infections now permits the possible use of an organ from a Hepatitis C infected donor into a recipient without Hepatitis C infection. This discussion is critical so that each person can consider their options and ultimately provide informed consent if they choose to proceed.

Summary of key findings

- A potential recipient's visibility and oversight of their position or rank on the waiting list is currently limited. However, this is likely to be improved as planned strategies and systems are implemented.
- There is currently no consistent approach to the education and consent of patients across Australia.

Recommendations

Recommendation	Description
Recommendation 16	The OTA through the TSANZ review the information provided to all potential recipients of organ transplantation to improve the understanding of the range of options that may arise if suitable donated organs are identified.

6.2 Element 2: Deceased donor organ donation

For element 2, the findings of the Review relate to:

- Australia's organ donation performance (Section 6.2.1)
- Projected organ donation performance (Section 6.2.2)
- Aboriginal and Torres Strait Islander and non-European donation rates (Section 6.2.3)
- Donor assessment and donated organ acceptance (Section 6.2.5)
- The Australian Organ Donor Register (Section 6.2.5)
- The Donor family experience (Section 6.2.7).

6.2.1 Australia's organ donation performance

Discussion of findings

As described in Section 2.1, the Australian Government's national reform program has aimed to establish a world's best practice approach for organ and tissue donation for transplantation for Australia. The progress of this reform, particularly in donation rates, was initially described in the 2015 Review.[102] Through observing best practice systems (such as Spain, Portugal and Croatia) and implementing the key strategies and structures that have been demonstrated to influence donation rates, Australia has continued to experience growth in organ donation performance. [103]

Australia's donation rate has continued to improve since the 2015 Review. There were 510 deceased organ donors in 2017, representing an increase of 17 per cent since 2015.[104] Further, Australia's rate of donation was 20.8 dpmp in 2017 (compared to the target of 25 dpmp in 2018). This represents a 15 per cent growth in dpmp from 2015 and an 82 per cent increase since 2009.[105]

The Review found that there was a combination of factors that contributed to the improved donation rates over the past decade. This included strategies that aim to improve the utility of organs previously considered not medically suitable (see Section 6.2.1) and improved efficiency and effectiveness of the donation process. However, Australia still lags behind other countries in donation performance, as outlined in Figure 17.

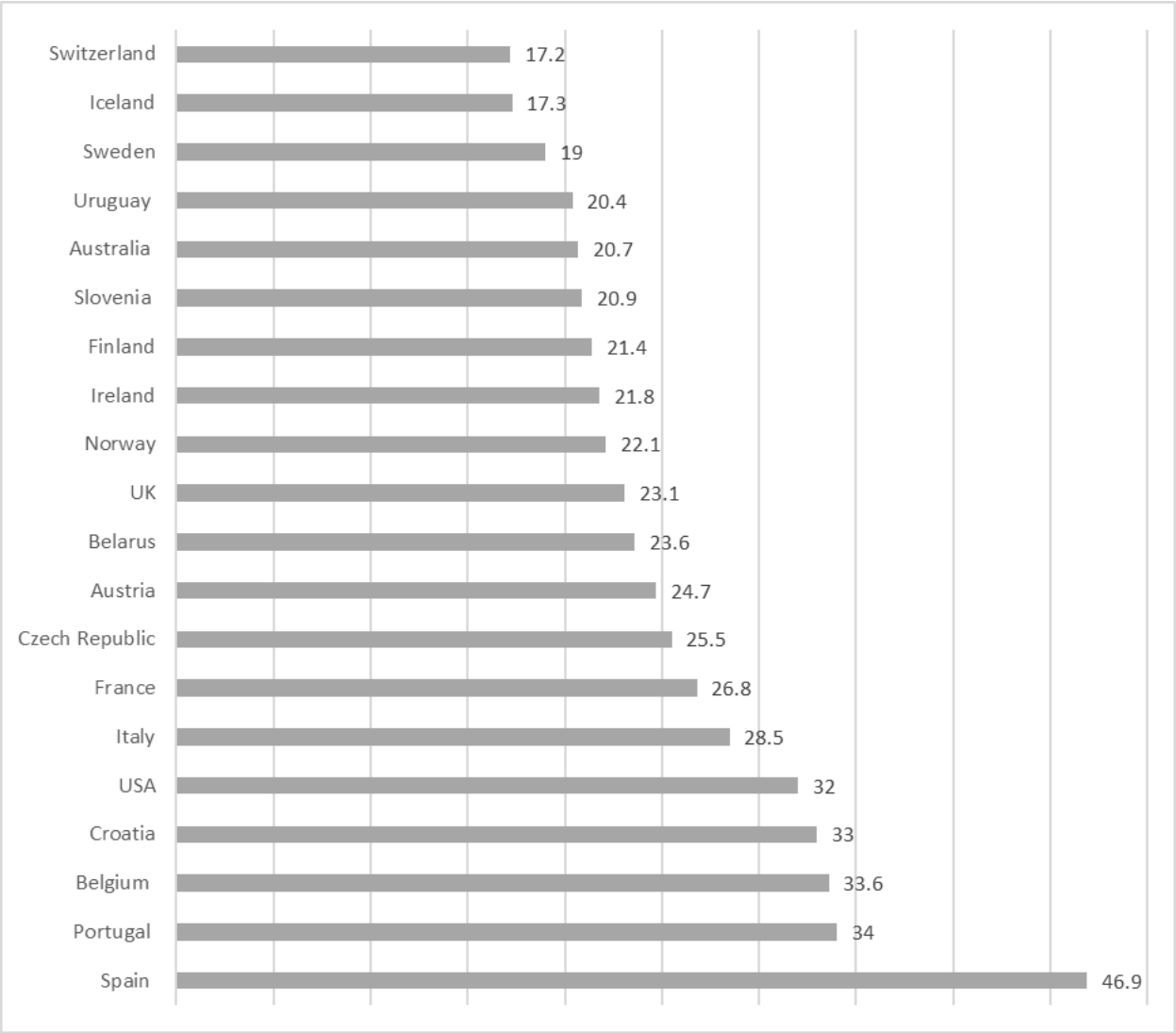
[102] Ernst and Young, 2015, above n.34.

[103] The Australian Organ and Tissue Donation and Transplantation Report, 2017, above n.3.

[104] Ibid.

[105] Ibid.

Figure 17: Top 20 World Wide Actual Deceased Donors 2017 (dpmp), SOURCE: IRODaT [106]



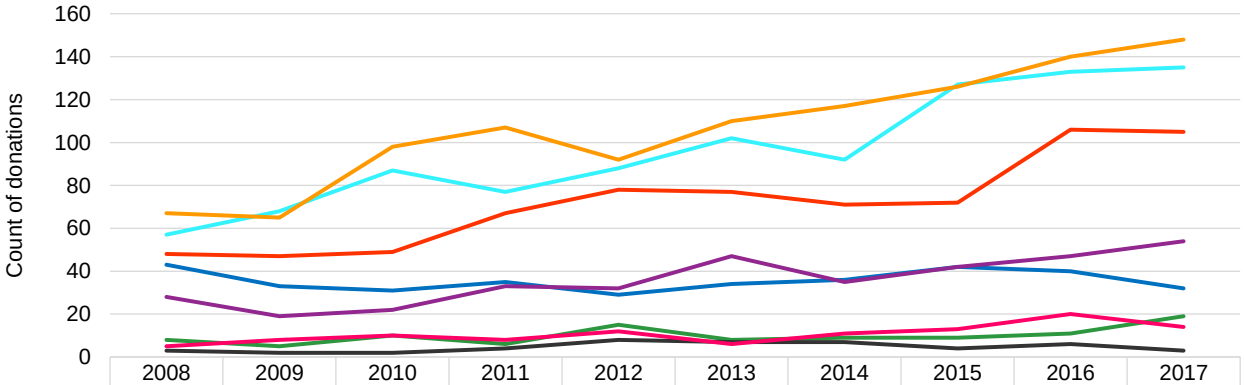
According to the International Registry in Organ Donation and Transplantation, Australia was ranked 16th in the world in 2017 based on donation rates. Although Australia has a higher growth in donation rates, when compared to Spain (when it was at the same stage of reform) the Review found that there were a number of factors that currently inhibit Australia's potential to achieve best practice in organ donation including variability in state and territory and hospital organ donation performance.[107]

As illustrated in Figure 18, donation performance varies greatly between states and territories. The states with the highest growth in donation since 2008 were New South Wales (237 per cent increase) and Victoria (221 per cent increase). In contrast, South Australia's donation performance experienced a negative growth of 26 per cent.

[106] International Registry of Donation and Transplantation, 2018, *IRODaT International Registry in Organ Donation and Transplantation, Preliminary Numbers 2017,* viewed August 2018, <http://www.irodat.org/img/database/pdf/NEWSLETTER2018_June.pdf>.

[107] The Australian Organ and Tissue Donation and Transplantation Authority, 2017, *Comparing International Organ Donation Outcomes 2017,* viewed August 2018, <http://www.donatelife.gov.au/sites/default/files/9_2017%20Comparing%20International%20Organ%20Donation%20Outcomes.pdf>.

Figure 18: Donation performance numbers 2008 - 2017 by state and territory, SOURCE: ANZOD[108]



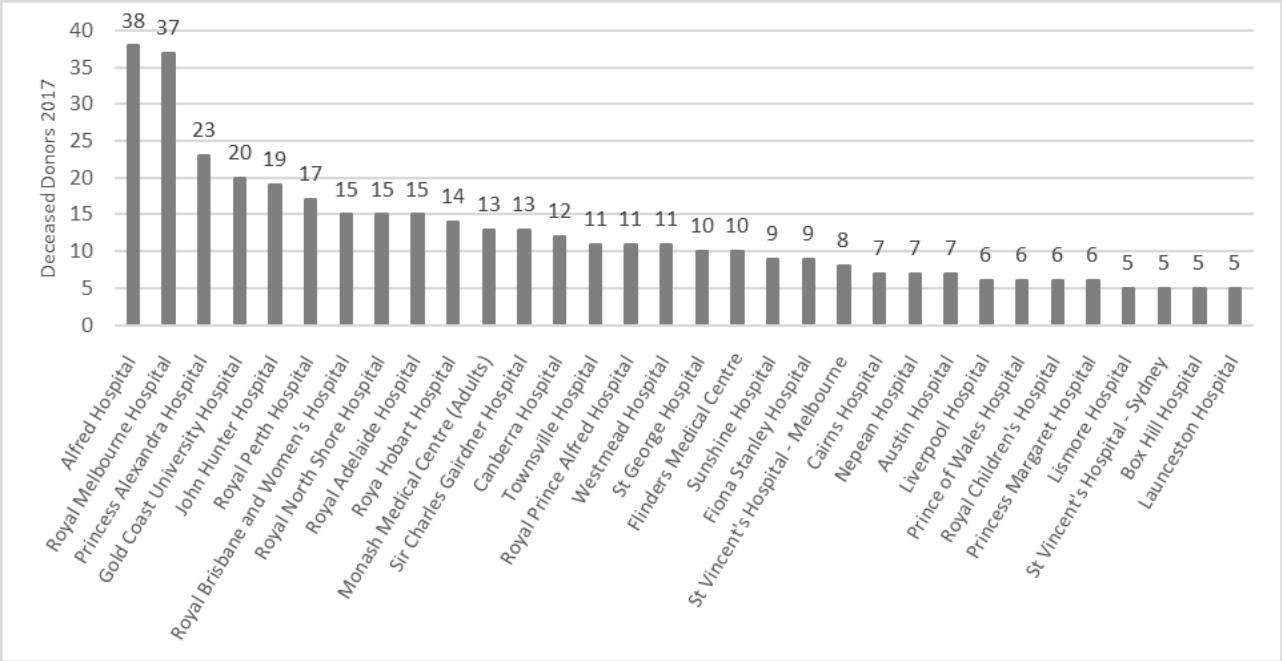
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NSW	57	68	87	77	88	102	92	127	133	135
VIC	67	65	98	107	92	110	117	126	140	148
QLD	48	47	49	67	78	77	71	72	106	105
SA	43	33	31	35	29	34	36	42	40	32
WA	28	19	22	33	32	47	35	42	47	54
TAS	8	5	10	6	15	8	9	9	11	19
NT	3	2	2	4	8	7	7	4	6	3
ACT	5	8	10	8	12	6	11	13	20	14

The Review found that the inconsistency of donation rates and donation performance across states and territories is stark and compounded by inconsistency in donation rates across hospitals.

[108] The Australia and New Zealand Organ Donation Registry, as provided by the OTA, "Growth in Organ Donation", (received July 2018).

Figure 19 demonstrates that there are certain major hospitals which maintain comparatively low organ donation rates. For the purposes of comparison, only the larger hospitals in Australia (based on total hospital activity as measured by the total National Weighted Activity Units (NWAU) per annum) are included in this figure.

Figure 19: Deceased donors in 2017 of top 32 hospitals, SOURCE: ANZOD[109]



Although there are a small number of hospitals across Australia close to reaching best practice levels in donation, the inconsistency in donation rates across hospitals currently limits Australia's potential to provide life-saving transplants equitably across Australia.

The Review found that current systems to do not effectively enable public monitoring of the target through nationally published performance reports. Although some reports are published on hospital performance against the targets nationally, the usability and accessibility could be improved to enable effective benchmarking and access to the reports.

The Review found that while there are benefits to the publication of donation performance by hospitals, there were divided opinions among stakeholders as to how this data would be received and used. Some stakeholders were concerned that the variable nature of each hospital (e.g. size, case mix, ethnic mix of the local community, etc.) would impact performance data and may not be a meaningful illustration of performance. Some stakeholders reported that performance requires broader consideration of the parameters for reporting, for example the number of end of life conversations that occurred with a trained specialist. Those in favour of publishing hospital donation performance believed greater transparency would enable greater understanding of national performance and benchmarking to encourage improvement.

In order to address inconsistency in donation rates in Spain, the *Organizacion Nacional de Trasplantes* implemented a '40 dpmp Plan'. It set out the strategies for the achievement of the target, which they have since achieved.[110] As part of Australia's strategy to improve donation rates, a target was set for 25 dpmp based on modelling undertaken by the OTA, which was agreed by

[109] The Australia and New Zealand Organ Donation Registry, 2018, *ANZOD Annual Report Metrics 2018*, The Australian Organ and Tissue Donation and Transplantation Authority, Canberra, viewed September 2018 <https://donatelife.gov.au/about-us/strategy-and-performance/national-performance-data>.

[110] Matesanz, R, 2017. Above n. 86.

the COAG Health Council. However, it does not consider the prevalence of end-stage organ disease in Australia and therefore the demand for transplantation. As a result, achievement of the target may not necessarily indicate the effective management of end-stage organ disease across the entire Australian population.

Clinicians noted that although demand will always exceed supply, a consideration of demand is necessary to inform objectives of the donation program in Australian and encourage continued growth in organ donation. In order to effectively plan services to enable improvement across the system, the Australian Government needs to understand total demand for organ transplantation and this would require an epidemiological study on the prevalence of end-stage organ disease amenable to organ transplantation.

Summary of key findings

- Since 2015, organ donation in Australia has increased by 17 per cent and the rate of organ donation was 20.8 dpmp in 2017 (compared to the target of 25 dpmp in 2018).
- The national organ donation target of 25 dpmp has been set based on modelling and currently the demand in every state is reported to be much higher than possible donation rates.
- The total national demand for organ transplantation is not known at this time.
- Donation performance continues to vary considerably by state and territory and by hospital. However, donation performance is not currently accessibly published to provide transparency of donation performance.

Recommendations

Recommendation	Description
Recommendation 17	An epidemiological study into demand for organ transplantation in Australia to better understand the organ donation rates required to meet demand should be commissioned by the Australian Government.
Recommendation 18	Based on the findings from the above study, the COAG Health Council should review the national organ donation target to ensure that donation strategies are designed to meet the expected demand for organ transplantation.
Recommendation 19	The donation performance by each hospital with a total inpatient activity of over 20,000 National Weighted Activity Units (NWAU) per annum annually should be published on the DonateLife website in an easily accessible and user-friendly format to assist in identifying variability in performance and enabling benchmarking to more effectively manage hospital performance.[111]

[111] A National Weighted Activity Unit (NWAU) is a measure of health service activity expressed as a common unit which is used to compare and value each public hospital service.

6.2.2 Projected organ donation performance

Discussion of findings

The positive growth experienced in organ donation performance is predicted to continue towards 2025. The rate of national growth from 2008 and 2017 was 157 per cent.[112] As outlined in Table 15, if donation performance followed the trajectory of 257 per cent growth from 2007 – 2017, Australia is expected to achieve a dpmp of 27.1 by 2025. This projection assumes that the population continues to grow at 1.6 per cent each year, and no downstream resourcing (in retrieval and transplantation) limits growth. This expected growth has been accounted for in the *OTA Strategic Plan 2018-2019: Progressing Australian organ and tissue donation and transplantation to 2021*, through the objectives to optimise donation opportunities and enhance systems to support donation and transplantation.[113]

Table 15: Forward projections for organ donation performance, SOURCE: The OTA[114]

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Number of donors	198	229.1	260.2	291.3	322.3	353.4	384.5	415.6	446.7	477.8	508.9	539.9	571	602.1	633.2	664.3	695.4	726.5	757.5
Population @ 1.6% Growth (m)	-	-	-	-	-	-	-	-	-	-	24.6	25	25.4	25.8	26.2	26.6	27.1	27.5	27.9
DPMP	-	-	-	-	-	-	-	-	-	-	20.7	21.6	22.5	23.3	24.2	24.9	25.7	26.4	27.1

For organ donation rates to continue to improve, consideration of the resources required to maintain donation rates at that level is required. Further, the resources required in downstream services, such as retrieval and transplantation, also needs to be considered. The Review found that recent increases in organ donation rates across Australia have had a marked impact on resourcing of the system and needs to be carefully managed going forward, see Section 6.6.

Summary of key findings

- The positive growth experienced in organ donation performance is predicted to continue with projections of organ donation rates indicating that a dpmp of 27.1 will be achieved in 2025.
- Consideration of resourcing of the system going forward is required in order to continue to drive organ donation performance as well as manage resourcing pressures downstream.

[112] The Australian Organ and Tissue Donation and Transplantation Authority, above n. 120.

[113] The Australian Organ and Tissue Donation and Transplantation Authority, 2018, *Progressing Australian organ and tissue donation and transplantation to 2022*, Canberra, viewed October 2018, <https://donatelife.gov.au/sites/default/files/ota_strategic_plan_2018-2022.pdf>.

[114] The Australian Organ and Tissue Donation and Transplantation Authority, "Growth in Organ Donation" (received August 2018).

6.2.4 Aboriginal and Torres Strait Islander and non-European donation rates

Discussion of findings

In 2017 there were 12 organ donations from Aboriginal and Torres Strait Islander people, representing 2.4 per cent of total donations in Australia (see Table 16).[115]

Table 16: Aboriginal and Torres Strait Islander organ donors per population, SOURCE: ANZOD

	2011	2012	2013	2014	2015	2016	2017
Proportion of population	2.5%	-	-	-	-	2.8%	-
Number of donors	3	4	8	7	11	20	12
Proportion of donors	0.9%	1.1%	2.0%	1.9%	2.5%	4.0%	2.4%

The Review found that this is partly influenced by family consent to donation rates, with the current family consent rate for deceased donation in Aboriginal and Torres Strait Islander people being approximately 20 per cent, compared to 67 per cent for non-Aboriginal and Torres Strait Islander people.[116] Considering that Aboriginal and Torres Strait Islander people account for approximately nine per cent of people commencing kidney dialysis each year and have a higher demand for organ transplantation treatment,[117] it was found that it is important that Aboriginal and Torres Strait Islander donation rates continue to increase in order to improve the diversity of HLA genetics in the donor pool and facilitate improved organ matching in the current organ matching algorithm, as explained in *HLA compatibility in NOMS*.

Human leukocyte antigen (HLA) compatibility in NOMS

The current allocation system, known as the NOMS, places a heavy emphasis on immunology when matching potential recipients to organs in the potential organ donor pool. This connection is determined mainly on HLA compatibility. The HLA gene is unique for each individual, however clinicians reported that individuals within the same community or population have a higher chance of being HLA compatible.

HLA matching in transplantation is difficult to achieve as there is great HLA gene diversity across different populations. Common HLA can be common across all populations and thus can facilitate matching across populations. However, there are a small number of common HLA overall. Patients from populations with smaller numbers in the Australian community will not have the same probability of finding a match within the allocation algorithms as their HLA diversity will be under represented in the donor pool. Patients who are Aboriginal and Torres Strait Islander, Asian or African may have HLA types that are not as common in the current donor pool which consistent predominantly of donors of European descent and therefore, may find it more difficult to find a match.

[115] The Australia and New Zealand Dialysis and Transplant Registry, 2017, *40th Annual ANZDATA Report Section 4: Deceased organ donor profile,* viewed October 2018, <http://www.anzdata.org.au/anzod/ANZODReport/2017/c04_profile_v1.0_20171109.pdf>.

[116] The Australian Organ and Tissue Donation and Transplantation Authority, "The 2018 DonateLife Audit" (received December 2018)

[117] Kidney Health Australia, 2018, *Kidney Fast Facts: Fact Sheet,* viewed October 2018, <https://kidney.org.au/cms_uploads/docs/kidney-fast-facts-fact-sheet.pdf>.

As reported by the Australian Institute of Health and Welfare, Aboriginal and Torres Strait Islander people experience widespread socioeconomic disadvantage and health inequality in comparison to non-Indigenous Australians.[118] For example, Aboriginal and Torres Strait Islander people are twice as likely to live with signs of chronic kidney disease. Due to generally poorer overall health, many Aboriginal and Torres Strait Islander people may be precluded from organ donation even if they wished to opt for transplantation. The Review found that the overall health experienced by Aboriginal and Torres Strait Islander people, as well as the health literacy of health services and individuals in relation to organ donation were barriers to organ donation. Key stakeholders within the Aboriginal and Torres Strait Islander community pointed to a study aimed at understanding the Indigenous Australian patient's understanding of chronic kidney disease. This study demonstrated that Aboriginal and Torres Strait Islander people are interested in transplantation but feel poorly informed and confused about their options.[119] They also revealed that differences in cultural beliefs and lifestyles contributed to low donation rates. These vary from community to community and amongst individuals within a community, thus emphasising the importance Aboriginal and Torres Strait Islander community leadership in improving organ donation rates among Aboriginal and Torres Strait Islander people.

Communication and integration between the OTA, the DonateLife network, Aboriginal and Torres Strait Islander health services and the community are often ad hoc resulting in a more limited understanding of the donation process. A study published by the International Society of Nephrology likened the issues in Australia with that of Canada, as both countries have high rates of chronic kidney disease and poor access to effective therapies.[120] Canadian representatives were consulted as part of the Review's consultation process, which revealed that education and flexibility were key to overcoming the barriers that faced the Indigenous population in Canada.

Further details of the barriers experienced by Aboriginal and Torres Strait Islander people and effective methodologies for overcoming these barriers need to be investigated and defined further. This may be achieved through the study being undertaken by the TSANZ, *Improving access to and outcomes of kidney transplantation for Aboriginal and Torres Strait Islander people* and due to be completed in 2019. It was also announced on 25 October 2018, that Kidney Health Australia has been allocated $300,000 in Australian Government funding to conduct national consultations that will inform the drafting of the *Caring for Australians with Renal Impairment Indigenous Guidelines.* These 20 consultations, will ensure that Aboriginal and Torres Strait Islander people play a fundamental role in developing the guidelines to improve Aboriginal and Torres Strait Islander kidney patient outcomes.

The Review also found that organ donation is limited in the non-European population. Table 17 illustrates donation rates in the non-European population in 2016.

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[118] Australian Institute of Health and Welfare 2018, above n. 13.

[119] Anderson,K et al, 2008, 'All they said was my kidneys were dead: Indigenous Australian patients' understanding of their chronic kidney disease, *Medical Journal of Australia,* Volume. 189, Issue: 9, pp. 499-503.

[120] Yeates.K et al, 2009, 'Indigenous people in Australia, Canada, New Zealand and the United States are less likely to receive renal transplantation' *Official Journal of the International Society of Nephrology,* vol. 76, Issue. 6, pp 659 – 664.

Table 17: Donation rates in non-European populations in Australia, 2016. SOURCE: ANZOD

Ethnicity	Total donations	Proportion of total donations
New Zealand European	4	1%
New Zealand Maori	5	1%
Pacific Islander	3	1%
North African and Middle Eastern	2	0%
Asian	34	7%
American	4	1%
Sub-Saharan African	3	1%

In 2016, 26 per cent of the Australian population (approximately 6.1 million people), identified as having been born overseas, it is evident from Table 17 that non-European populations contribute a much lower proportion of donated organs than Australian and European populations.[121] If donation rates are to continue to improve, careful consideration is required of barriers preventing certain demographics from consenting to organ donation.

Summary of key findings

- In 2016, Aboriginal and Torres Strait Islander organ donations made up 2.4 per cent of total organ donations in Australia. However, 9 per cent of the Aboriginal and Torres Strait Islander population were on dialysis.
- Key reasons for low donation rates include poorer overall health precluding donation, health literacy of donation among health services, remote residence and community and cultural beliefs and ways of life.
- Organ donation is limited in the non-European population.

Recommendations

Recommendation	Description
Recommendation 20	As part of the development of the future national strategy for the retrieval and transplantation system, the Australian Government working in partnership with states and territories should develop a national Aboriginal and Torres Strait Islander and culturally and linguistically diverse population's organ donation strategy to improve donation rates in these groups. It should be based on the findings from this Review, and the work of the TSANZ (the *Improving access to and outcomes of kidney transplantation for Aboriginal and Torres Strait Islander people* project). The strategy should be developed in collaboration with the National Aboriginal Community Controlled Health Organisation, its affiliates and the states and territories.
Recommendation 21	An advisory group of key stakeholders should be established as part of the strategy development to provide oversight and input into Aboriginal and

[121] Australian Institute of Health and Welfare, 2018, above n.14.

Recommendation	Description
	Torres Strait Islander issues relating to organ donation.

6.2.5 Donor assessment and donated organ acceptance

Discussion of findings

In order to increase the number of donated organs, advancement of techniques, technology and care has been a key feature of organ donation reform internationally. Specifically, in the achievement of 40 dpmp, Spain have: (1) promoted the early identification and referral of possible organ donors from outside of the ICU to consider elective non-therapeutic intensive care and incorporate the option of organ donation into end-of-life care; (2) fostered the use of expanded and nonstandard risk donors; and (3) developed the framework for the practice of DCD.[122] These advancements have resulted in the expansion of the potential donor pool leading to an increase of donations overall.

The Review found that improvement in Australia's organ donation performance has been impacted by techniques that optimise the use of expanded and nonstandard risk donors and improve transplantation outcomes as well as improved practices in the identification of potential donors (DCD and DBD). However, the Review found that practices were not uniform across Australia.

As discussed in Section 6.2.1, Australia's donation rate has continued to improve since the 2015 Review with 510 deceased organ donors in 2017, representing an increase of 17 per cent since 2015.[123] This was found to be a direct impact of the extended consideration of organs that were previously considered not suitable for donation. This has come about from improved techniques to optimise the use of organs. Further, donation techniques and practices have specialised enabling the use of organs that were considered too old or lower quality. Expanding the donor pool naturally results in a higher number of donations.

While organ donation has increased as a whole, the Review found that there is variability in the assessment and acceptance of organs for donation between jurisdictions. Table 18 highlights data from the 2017 DonateLife Audit, which demonstrates the jurisdictional variation in the proportion

[122] Matesanz R, 2017, above n.85.

[123] The Australian Organ and Tissue Donation and Transplantation Authority, 2017 above n.3.

of cases where potential donors were assessed as not medically suitable for donation prior to family discussion occurring.

Table 18: Proportion and number of potential donors that did not proceed to family discussions as assessed not medically suitable, SOURCE: The OTA[124]

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Total
Potential donors[125]	471	423	371	96	188	39	26	56	1670
Proportion of potential donors where donation was requested	62%	76%	59%	73%	75%	69%	35%	64%	n/a
Number of potential donors where donation was not requested – assessed as not medically suitable prior to family discussion	51	33	62	9	9	2	6	7	179
Proportion of potential donors where donation was not requested – assessed as not medically suitable prior to family discussion	11%	8%	17%	9%	5%	5%	23%	13%	n/a

In 2017, there were 179 potential donors in Australia that did not proceed to discussion with the donor's family because they were accessed as not medically suitable for organ donation.[126] In 2017, the Northern Territory and Queensland had the highest proportion of potential donors assessed as not medically suitable, with 25 per cent and 17 per cent respectively. In contrast, only eight per cent of potential donors in Victoria were deemed not medically suitable.

The volume of potential donors that are deemed not medically suitable is indicative of the variability in advancement of donation and transplantation techniques and the stringency of acceptance criteria applied in each state and territory, particularly for kidney transplantation. This supports the anecdotal evidence that Victoria has a much larger risk appetite and less conservative approach to the use of the acceptance criteria, particularly in relation to the larger jurisdictions, New South Wales and Queensland.

However, the Review found that current Clinical Guidelines may not take into consideration the additional assessments required in expanding the criteria for potential organ donors. For example, the rise of donors who have been exposed to multi-resistant bacteria has meant that additional assessments are required in order to confirm the acceptability of potential organs and this has added additional time and cost to the assessment process.

Like Spain, Australia also has in place structures that assist in the early identification and referral of possible organ donors from outside of the ICU to consider elective non-therapeutic intensive care and incorporate the option of organ donation into end-of-life care. Legislation in each state

[124] The Australian Organ and Tissue Donation and Transplantation Authority, "2017 potential donors, percentage of requests and percentage assessed not medically suitable" (received November 2018).

[125] Note: This definition of "potential donor" is consistent with the OTA's definition, used for internal comparisons. The pool of potential donors is derived from the number of neurological deaths, where the donor did not have Cancer or HIV, was intubated and did not have an unexpected cardiac arrest.

[126] The Australian Organ and Tissue Donation and Transplantation Authority, above n.134.

and territory provide the boundaries on how these discussions, referrals and end-of-life care may take place prior to death and donation. However, the Review found that legislation varies between states and territories, enabling some jurisdictions to commence the pathway to donation with potential donors more easily than others.

Variability in ante mortem intervention for DCD organ donation and its effect on successful organ transplantation

Ante mortem interventions for DCD are treatments that are given to a patient before their death, which are not necessarily for the benefit of the patient's health. The purpose of ante mortem treatment is to improve the quality and function of the donated organ for transplantation.

Legislation governing ante mortem intervention varies between the jurisdictions, and as a result, the quality of organs and donation outcomes also vary across jurisdictions.

Using New South Wales and Victoria as an example:

- The Guardianship Act 1987 (NSW) only permits the next of kin's consent to treatment as valid where the treatment is carried out for the purpose of promoting and maintaining the health and well-being of the patient.
- In Victoria, the Guardianship and Administration Act 1986 (VIC) varies slightly, taking into consideration the 'best interests' of the patient when determining consent for the administration of treatment. The use of 'best interests' in Victorian legislation leaves a wider scope for interpretation. As such, Victorian clinical staff classify the use of ante mortem intervention to be in a patient's best interest as it respects and aligns with their wish to be an organ donor.

In 2017, there was 32 DCD donations from New South Wales, whereas the numbers in Victoria were almost doubled, with 62 DCD donations.

Summary of key findings

- Advances in transplantation care have underpinned a broadening of the acceptability of donated organs suitable for transplantation, however this has led to some inconsistency of clinical practice in the acceptance of some organs.
- There is an increasing number of donors who have been exposed to multi-resistant bacteria prior to donation and require additional testing to ensure that the recipient is not exposed.

Recommendations

Recommendation	Description
Recommendation 22	The OTA through the TSANZ, should undertake a review and revision of the national standards for donor organ assessment and medical suitability of donors.

6.2.6 The Australian Organ Donor Register

Discussion of findings

The Australian Organ Donor Register (AODR) is the only national register for Australians to record their decision about becoming an organ and tissue donor for transplantation after death. In 2004–05, the Australian Health Ministers' Conference agreed that the AODR would be changed from a register of intent to a register of consent. The stated aim of this change was 'to ensure that the known wishes of the deceased, whether consenting or objecting, are respected and followed

through'.[127]

In July 2018, South Australia (68 per cent) and Tasmania (48 per cent) had the highest proportion of their population registered on the AODR. The Northern Territory (12 per cent) and Victoria (24 per cent) had the lowest number registered. Table 19 demonstrates the number of registrations on the AODR by state and territory, as at July 2018. Figures include both intent and valid consent registrations.

Table 19: AODR Registrations July 2018, SOURCE: Australian Government Department of Human Services[128]

State	Total number of Registrations *includes intent and valid consent registrations	Population	Percentage of population registered on AODR
SA	952,197	1,398,432	68%
TAS	203,672	421,161	48%
NSW	2,488,080	6,306,543	39%
WA	755,000	2,048,146	37%
QLD	1,081,621	3,900,648	28%
ACT	77,225	327,755	24%
VIC	1,002,723	5,087,214	20%
NT	23,446	189,222	12%
Total	6,583,964	19,679,121	33%

South Australia continues to be the jurisdiction with the highest proportion of their population registered as organ donors. Evidence suggests that the registration rates have been greatly assisted by the continued use of the drivers' licensing legacy system.[129] Some stakeholders consulted in the Review highlighted the effectiveness of the licensing system in registering organ donation intent compared to other jurisdictions which rely on the AODR only.

The Review found that there was debate as to whether the AODR should record potential donor intent or consent. The AODR registration is currently considered as consent, and the legal requirements prescribed must be satisfied to permit organ donation. Critics of the AODR put forward that the AODR's potential bedside function has become an indication of intent to donate, rather than consent, as in nearly all cases a consent process is undertaken with the donor's family before donation proceeds. A survey conducted by Kidney Health Australia into consumer perceptions of organ donation and transplantation found that supporting an individual's pre-

[127] Australian Health Ministers' Conference, Joint Communiqué: *Transplant donor's wishes to prevail,* media release, 28 January 2005, viewed September 2018 <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-mediarel-yr2005- jointcom-jc005.htm>.

[128] Australian Government Department of Human Services, "AODR July 2018: Grand Total Intent Registrations by Age Group" (received August 2018).

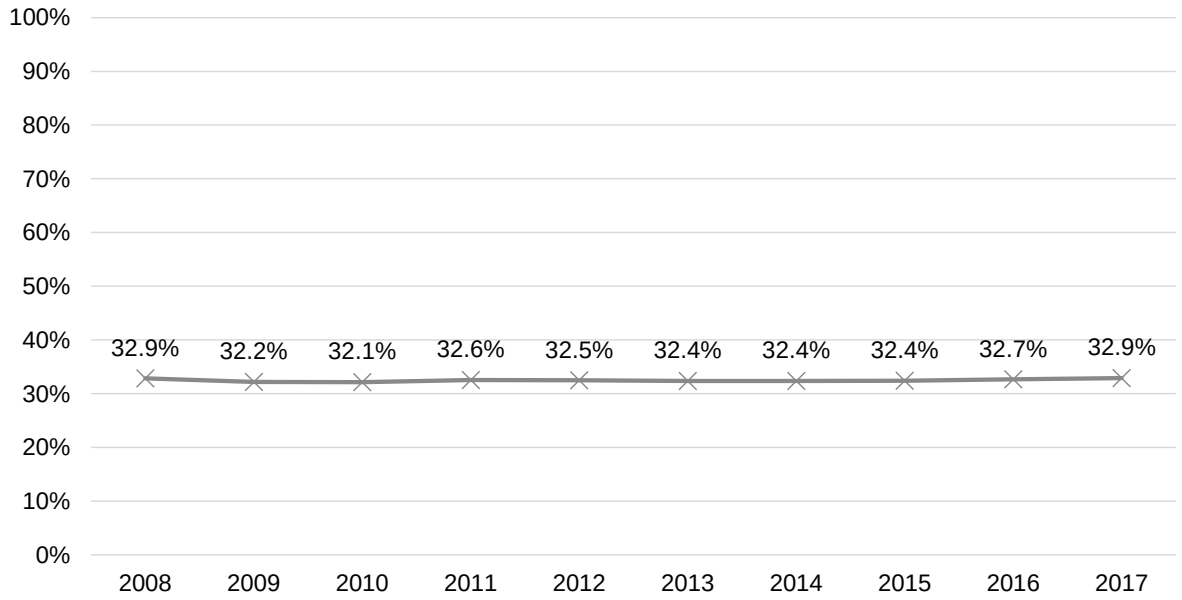
[129] Note: In South Australia, residents can register their intent to be an organ donor through the drivers' licensing system. South Australian drivers' licensing paperwork includes a section for residents to complete regarding their organ donation preferences. However, the current system runs separately from the AODR.

arranged intentions to donate, even if the family is not in agreement at the time of donation, should be the priority focus in Australia for organ donation registration.[130]

Nevertheless, users of the AODR indicated that the DonateLife pathway for registration improved accessibility and the AODR was easy to use. Further, donor coordinators reported that it was helpful for checking donor consent and understanding donor intentions across the country. Donor coordinators also reported that it was particularly helpful to understand the donor's status on the AODR before approaching a conversation with their families. Across all DonateLife Network hospitals, it was found that the family consent rate increased from 60 per cent to 93 per cent where the donor was registered on the AODR, compared to situations where the potential donor's intentions were not registered, between January and June 2018.[131]

Whilst the national numbers of registrations have increased since 2017, the proportion of new registrations on the AODR from 2008 to 2017 has remained stagnant at around 32 per cent of the total Australian population.[132] Figure 20 highlights the percentage of the Australian population registered on the AODR from 2008 to 2017. Critics of the AODR expressed the view that the current identification protocols and the consequent entry requirements to the AODR for potential donors limits the potential of the registry, particularly if it is a register of intent rather than consent, resulting in a low return on investment.

Figure 20: Proportion of eligible Australian population registered on AODR from 2007 – 2017, SOURCE: Australian Government Department of Human Service and Australian Bureau of Statistics[133]



As noted above, Victoria has the second lowest percentage of registrations on the AODR. Nevertheless, in 2017 Victoria achieved the highest dpmp rate of 23.4, with the highest number of deceased organ donors. Further, critics have highlighted that availability of aggregated data from

[130] Kidney Health Australia, 2017, "Organ Donation Consumer Survey 2017" (received September 2018).

[131] The Australian Organ and Tissue Donation and Transplantation Report, "Jurisdictional Hospital Dashboard Jan – Jun 2018" (received July 2018).

[132] Australian Government Department of Health of Human Services as provided by the OTA, "AODR Registration Numbers 2007 – 2017" (received November 2018).

[133] Ibid.

the AODR is limited and is not currently useful in order to inform decision making and investment. For example, the current data from the AODR does not provide detail on the demographic groups accessing the register.

The Review found that despite investment to create a register that is intended to increase donations, the current functionality and accessibility impairs the attainment of this objective. Consideration of other ways that potential donors can register their intent and consent may be useful. Furthermore, consideration of shifting the focus of the AODR from potential donor consent to potential donor intent may be worthwhile in reducing the requirement for complex identification protocol, and thus increase the accessibility and ease of the use of potential donor registration. In shifting the AODR from a register of intent rather than consent, alternative pathways for registration may be considered such as linking with the driver's license based system and social media platforms may be utilised to improve the reach of the AODR and streamline the process for potential donor registration.

Finally, collection of data on the demographics that register on the AODR may be useful to identify strategies to improve registrations and donation rates. For example, data on Aboriginal and Torres Strait Islander and culturally and linguistically diverse population's registrations are not currently collected yet these groups currently donate at lower rates than other populations groups.

Summary of key findings

- The AODR was established initially as a register for intent, however the Australian Health Ministers' Conference agreed in 2005 that the AODR would be changed to a register of consent.
- The concept of registering a person's decision about becoming an organ donor for transplantation after death is considered useful by most key stakeholders.
- The AODR remains a useful system for recording the consent of potential donors, however the accessibility for potential donors is currently limited.
- The aggregated data and reporting from the AODR is limited and does not include detail such as the use of the AODR by minority groups.
- The difficulty of the process of registration through the current channels limits the potential to lift the prevalence of registration.
- South Australia continues to be the jurisdiction with the highest proportion of their population registered, however the current links between the South Australian driver's license based scheme and the AODR remain problematic.

Recommendations

Recommendation	Description
Recommendation 23	All key stakeholders should consider the AODR as the primary focus for the registration of an individual's decision about becoming an organ donor for transplantation after death across Australia. The focus should shift from the AODR being a record of donor consent to a record of donor intent. In doing so, consideration should be given to previous arrangements, including the driver's license based system, and the decision of the Australian Health Ministers' Conference regarding its purpose.
Recommendation 24	The Australian Government should design and implement strategies to improve the number of registrations on the AODR, in particular for Aboriginal and Torres Strait Islander people and other groups of non-European heritage and data should be captured on the use of the AODR by different demographics in the Australian population in order to inform strategies to improve registration rates.
Recommendation 25	The strategies to improve the AODR registrations should be broadened to include links to social media and other entry portals. This will enable greater visibility and accessibility of the AODR.

6.2.7 The donor family experience

Discussion of findings

As described in Section 4.4.2, the donor family or enduring guardian plays an integral role in the donation pathway once a potential organ donor is identified. In practice, the next of kin or an enduring guardian is required to provide consent prior to organ donation under the deceased donation pathway. Based on findings from the 2015 Review, the donor family experience has anecdotally improved in recent years. However, the current Review identified that there remain some areas for improvement.

Donor families reported that support during the donation process was provided through hospital support staff and DonateLife. This included information packages and correspondence through scheduled mail and phone services. Whilst these support systems are available to all donor families, donor families have the option to opt out. The Review found that although support was available, the consistency and extent of support through the donation process and post donation was variable.

The Review also found that extended donation timeframes were a major barrier that inhibited donation. Donor families reported that timeframes for undertaking the donation process were not always clear and some families reported that access to critical information was prolonged in some cases. As a result, family members were often unwilling to wait the time required to organise donation, or retracted their initial consent when extended timeframes were experienced. This is further explained in Section 6.5.2.

DonateLife coordinates and invites donor families to attend remembrance ceremonies that honour organ donors annually. The majority of donor families consulted attended these ceremonies and believed they are an appropriate and respectful way to remember their loved

ones.

Without compromising the identity of donors and transplant recipients, DonateLife also offers donor families and transplant recipients an opportunity to write and exchange letters with each other. DonateLife affirmed that this service was beneficial as some. However, not all donor families were interested in knowing how their decision changed someone's life. The decision to respond is left solely to transplant recipients. The Review noted that donor families (and transplant recipients) were disappointed when they did not receive any confirmation that their letter had been received.

Each jurisdiction has in place strict legislation which govern the meeting of donor families and transplant recipients. The respective Human Tissue Acts[134] prohibit the disclosure of identifying information which may result in the identification of an organ donor or transplant recipient. As a result, health professionals are not able to facilitate the meeting of donor families and transplant recipients. While the legislative provisions may vary depending on the jurisdiction, the purpose remains the same: to protect the identity of those who have donated organs, or received transplantation.

The Review found that there was divided opinion among donor families and recipients as to whether Australian policy should be changed to enable direct contact. A community consultation forum conducted by the OTA in 2017, involving donor families and transplant recipients, revealed that many people support the idea that families and recipients should have the option of seeking direct contact, reporting that the complex issue should not be ignored and efforts should be made to address the concerns associated with direct contact.[135] Clinicians consulted as part of this Review reported that donor families and recipients who wanted to make direct contact used mediums, such as social media and news reports on donation and transplantation, to do so.

Whilst there may be benefits to establishing direct contact between donor families and transplant recipients in the instances where they choose to do so, there needs to be adequate safeguards in place to avoid inappropriate behaviour, such as requests for financial recognition and protection for child recipients and families of child donors. Donor families reported that comparable legislation that governs the use of information to help people meet would be beneficial to understanding the framework and risks associated prior to initiating contact.

The experience of the United States with direct contact between donor families and transplant recipients

The United States supports the rights of donor families and recipients to have direct contact if they choose to. Donor families and patients are allowed anonymous contact after transplantation. This process is usually facilitated by the organ procurement organisation or the transplantation program. Health care professionals have a responsibility to inform donor families and transplant recipients that they may communicate with each other if both parties agree, and establish systems to ensure that appropriate and consistent information is proved in a timely manner to donor families and transplant recipients. In addition, online platforms such as TransplantNet exist as free online forums for donor families and transplant recipients to safely and easily contact each other.

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[134] *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act* 1978 (ACT); *Human Tissue Transplant Act 1979* (NT).

[135] Martin. D, 2017, 'Report on the Community Consultative Forum: Contact between Donor Families and transplant recipients', Community Consultative Forum, *The Australian Organ and Tissue Donation and Transplantation Authority,* Victoria, viewed November 2018, <https://donatelife.gov.au/sites/default/files/Report%20on%20the%20community%20consultative%20forum.pdf>.

Direct contact between donor family and transplant recipient is only allowed after a specified period of anonymity. Generally, donor families and recipients are required to wait a period of one year before direct contact can be initiated. The length of time depends on which register the donor is listed on and, in one case, the wait was five years after donation. If the donor family and transplant recipient choose to meet, health care professionals will provide a supporting role. A discussion will be held to help the respective parties prepare for and manage the first meeting. Methods for dealing with the pressures associated with the media are also discussed in this meeting.

A recent study reporting on actual direct contact between families and recipients during a three-year period in one region of the USA, found that less than one per cent of organ donor families took the opportunity to have direct contact with a recipient.

Donor families noted that families sometimes relied on peer support groups and independent organisations outside of DonateLife. Donor Families Australia and Aussie Transplant Mates are examples of organisations that are dedicated to providing support to donor families, amongst many others – some are simple social media networks. Some donor families reported that participation in community awareness events and advocacy projects via these support organisations was beneficial and helpful in the remembrance of their loved ones and often re-affirmed their decision to donate. Some donor families noted that they do not wish to participate in any form of psychosocial support, however noted that they would like to be aware of the available options.

DonateLife currently collects family and carer satisfaction through the *National Study of Family Experiences of Organ and Tissue Donation*. This was described as useful for understanding the experiences of families and carers and improving services and processes in the donation pathway.

National Donor Family Study

The OTA conducts the National Donor Family Study to obtain information on family experiences of organ and tissue donation for transplantation.

The study collects feedback on the family's experience from early interactions with hospital and DonateLife staff and initial donation conversations, to the follow up support provided to families after a donation decision was made. This insight provides valuable evidence for the ongoing review and enhancement of the care and support provided to families before, during and after donation.

Wave 2 (2012 and 2013)

The Wave 2 study involved 285 families who made a donation decision in 2012 and 2013. A total of 319 individual family members (representing 263 donor families who consented to donation) and 12 individuals (representing 12 families) who declined donation participated.

Wave 1 (2010 and 2011)

The Wave 1 study involved 132 families who made a donation decision in 2010 and 2011. A total of 186 individual family members participated including one family member who declined donation.

Summary of key findings

- While the legislative provisions may vary depending on the jurisdiction regarding the rules which preclude the meeting of donor families and transplant recipients, the purpose remains the same: to protect the identity of those who have donated organs, or received transplantation.
- There is divided opinion among donor families and recipients as to whether Australian policy should be changed to enable direct contact.

- The donor family experience has anecdotally improved in recent years, however there remain some areas for improvement in the consistency and availability of support across the donation process.

Recommendations

Recommendation	Description
Recommendation 26	States and territories establish a nationally uniform process for arrangements for donor families and recipients over the age of 18 to be identified to each other based on the principle of mutual informed consent.

6.3 Element 3: Organ allocation

For element 3, the findings of the Review relate to:

- Non-renal organ allocation (Section 6.3.1)
- Renal allocation (Section 6.3.2)
- The National Organ Matching System and OrganMatch (Section 6.3.3)
- Tissue typing (Section 6.3.4)
- The impact of the State Balancing System on allocation of kidneys (Section 6.3.5).

6.3.1 Non-renal organ allocation

Discussion of findings

As outlined in Section 4.5.2, heart, liver and lung allocation processes often cross over with offer and acceptance processes. When a potential organ becomes available, it is allocated first to potential recipients on the national urgent list then to state waiting list in the state in which the organ will be retrieved (the 'home state'). However, if there is no match in the home state, or no match on the national urgent patient listing, allocation is decided based on a national rotation list. This is created by the Australasian Transplant Coordinators Association and is endorsed and accepted by the TSANZ and OTA. The process involves donor coordinators from the home state contacting each interstate transplantation unit consecutively until a suitable recipient is found. The allocation, offer and acceptance happens within that process. The organ allocation process was reported to take up to between 8 to 10 hours.

The Review found that the allocation process for non-renal organs out of home state was considered by some to be inefficient due to the time taken to match donors and potential recipients through the ring-around process. This was also found to increase potential risk to the viability of the organ as well as the commitment of families to consent to donation. A review of the current processes across the country may find areas where efficiencies could be made and outcomes improved.

The Review found that a system in which information is shared in real time may be a potential solution to these challenges. In the circumstances where the home state has declined the organ, information relating to the donated heart, liver or lungs could be concomitantly shared nationally with transplantation units using a data sharing platform. The platform would replace the current ring around process and overcome the abovementioned inefficiencies associated with the current system. There is a myriad of technology options available that can support the development and

maintenance of this shared platform. However, the Review noted that although the improved sharing of donor profiles will reduce donor coordinator workload, it will increase the workload for the recipient coordinator. Further, the implementation of the sharing profile will require investment in support resources to enable the successful adoption of the new ways of working.

Summary of key findings

- Allocation of non-renal organs closely aligns with offer and acceptance. The allocation process follows the Australasian Transplantation Coordinators Association national rotation list.
- The allocation process can be time consuming and inefficient due to the ring-around process.
- Generally non-renal allocation processes are consistent across transplantation units and align closely to the Clinical Guidelines with some variability in allocation of liver and lung due to advancements in transplantation techniques.

Recommendations

Recommendation	Description
Recommendation 27	The introduction of concomitant sharing of donor profiles with all transplantation programs once the matching process has progressed beyond the home state offer should be considered and implemented as part of the OrganMatch functionality. This should be considered as part of a review of the heart, lung and liver organ allocation process in order to improve the efficiency of the organ matching process in liver, heart and lung transplantation.

6.3.2 Donated cadaveric kidney allocation

Discussion of findings

As discussed in Section 4.5.1, the current computerised software system for kidney allocation involves a 25-step process to match the kidney with a recipient using the NOMS. This is presented in the form of a ranked order of kidney recipients in the allocation process. This system was designed approximately twenty years ago, and clinicians reported that the system reflected the knowledge and practice from that time.

The system is focused on the immunological profile of both the recipient and donated organ, as well as blood group compatibility, paediatric status and time on the waiting list in order to confirm a suitable match. Generally speaking, 15 per cent to 20 per cent of kidneys are allocated on a national level, accounting for highly sensitised recipients with a lower chance of obtaining a match. Approximately 75 per cent of kidneys are allocated at a state and territory level, where time on the waiting list is given more weight and the remaining five per cent are allocated for interstate recipients.

This Review found that while the NOMS has worked well in the past, it does not take into consideration the major changes and advances in the practice of kidney transplantation over the past decade, meaning it is less effective in allocating kidneys rationally and efficiently. The Review found that it is timely that the TSANZ's Renal Transplant Advisory Committee review the algorithm for kidney allocation in order to inform the implementation of the new allocation system, OrganMatch. This is discussed further in Section 6.3.3.

However, the Review found that the review and development of the algorithm, which is critical to

the successful and ethical allocation of kidneys, is currently being undertaken without Aboriginal and Torres Strait Islander health expertise or community input. It is important that the outcomes from the algorithm can be considered fair and equitable by all community members, therefore broad stakeholder input is required in the development of the new allocation algorithm.

Patient involvement in healthcare and policy is widely advocated to improve patient satisfaction and relationship with healthcare professionals.[136] As 'end-users,' patients with end-stage kidney disease are a key stakeholder group; therefore eliciting their perspectives in deceased donor kidney allocation is ethically warranted.[137] Without sufficient consultation and understanding of the specific experiences of key stakeholders, the success of the algorithm is at risk, as it may not consider all relevant factors affecting kidney allocation.

Summary of key findings

- The impending review of the National Organ Matching System (NOMS) kidney allocation algorithm to be conducted by the TSANZ and the Renal Transplant Advisory Committee is timely.
- There is no Aboriginal and Torres Strait Islander health expertise or community input into the revision of the cadaveric kidney donation algorithm currently utilised by the NOMS (and soon to be utilised by OrganMatch).

Recommendations

Recommendation	Description
Recommendation 28	The planned review of the kidney matching algorithm to be conducted by the TSANZ should include Aboriginal and Torres Strait Islander health expertise and community representation.
Recommendation 29	The planned review to be conducted by the TSANZ of the kidney matching algorithm should take into account the latest science to ensure that the algorithm remains relevant to contemporary kidney transplantation best practice.

6.3.3 National Organ Matching System and OrganMatch

Waiting list data for both renal and non-renal organs are entered into the NOMS and is used in the allocation process for both renal and non-renal organs. OrganMatch, due to be released on 2 April 2019, will replace the NOMS. When launched, OrganMatch will replicate the current allocation algorithms in the NOMS system as well as providing enhanced functionality for more easily configure algorithm tables and an OrganMatch clinician Portal which will enable more streamlined and efficient information sharing regarding donor and potential recipient profiles. However, OrganMatch has potential to provide even greater functionality in organ matching which may be

[136] Farrell C. 2004, 'Patient and public involvement in health: The evidence for policy implementation' United Kingdom Department of Health, London, viewed October 2018, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4082334.pdf; Nilsen ES et al, 2006, 'Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material', *Cochrane Database of Systematic Reviews* Vol. 3, viewed October 2018 <https://www.ncbi.nlm.nih.gov/pubmed/16856050/>.

[137] Tong, A, et al. 2012, 'Patient preferences for the allocation of deceased donor kidneys for transplantation: a mixed methods study', *BMC Nephrology* Vol. 13, No. 18, viewed October 2018, <https://bmcnephrol.biomedcentral.com/articles/10.1186/1471-2369-13-18>.

considered in future releases. For example, OrganMatch has the potential to provide the capability to improve allocation algorithms by building in elements such as survival matching, improved immunological matching and specific donor registries, such as Hepatitis C positive donors, and increased viral risk donors.

The Review found that improvement of the kidney allocation system will require a concerted effort, significant time and multiple resources. Clinical bodies, such as the Renal Transplantation Advisory Committee is not equipped to do this alone due to limited time, appropriate personnel, and a deficiency in data and overall resources. Further, the Review also found that current governance arrangements will need to be revised in order to account for the increased functionality of OrganMatch and the flow on effect that it will have on current processes.

Summary of key findings

- The current renal organ matching system, the NOMS is due to be replaced by OrganMatch in April 2019 and will have improved capability and functionality compared to the current system.
- The Review found that current governance and resourcing arrangements will not be adequate to support the expansion of OrganMatch in the future.

Recommendations

Recommendation	Description
Recommendation 30	The replacement of the NOMS to OrganMatch is a key opportunity to improve the organ allocation process and must be adequately resourced and managed at a national level. The Australian Government should consider what is required to effectively implement and optimise OrganMatch in the future.

6.3.4 Tissue typing

Discussion of findings

The Review found that, based on transplant clinician consultations, tissue typing services are used to effectively and correctly allocate both renal and non-renal organs to potential recipients. Tissue typing services in Australia are comprehensive and responsive to the needs of transplantation clinicians and patients. Meanwhile, tissue typing technologies are expanding and becoming increasingly complex. There are three services that provide tissue typing across Australia – the Australian Red Cross Blood Service, PathWest (Western Australian tissue typing service) and Queensland Tissue Products (Queensland tissue typing service). All services were reported to work effectively by the relevant transplantation clinicians, however the turnaround time varied.

The demand for tissue typing services has increased over the past decade. However, there is currently no mechanism available to review tissue typing services nationally and benchmark performance among providers to enable a better understanding of the quality of services and to drive performance.

Further, the Review found that there is currently no national mechanism for review, assessment and prioritisation of new technology in tissue typing as it enters the Australian market. Without governance around the introduction of new technology, practices and performance, tissue typing may become increasingly variable, resulting in variable outcomes for transplantation units in the

matching of organs with recipients.

The Review found that organ donor profiles and potential recipient profiles and other tissue typing information are not easily accessible to clinicians in real-time. The implementation of OrganMatch has the potential to overcome this issue through its extended functionality. However, the Review found that OrganMatch is not currently resourced to develop this function. To enable improved outcomes in organ allocation, OrganMatch will require ongoing resourcing for extended functionality. OrganMatch is further discussed in Section 6.3.3 and 7.2.3.

Technological advances in tissue typing

The role of tissue typing in transplantation is central in defining the immunological parameters required for matching. As various parts of the donation and transplantation sector change, tissue typing laboratories will need to adapt to deliver best practice transplantation immunology testing nationally.

Testing technology for HLA typing, HLA antibody detection and cross-matching is rapidly evolving and improving immunological matching. For example, developments such as high resolution HLA typing improves accuracy by producing precise results for highly sensitised patients. Luminex antibody screening is another technique which has the potential to optimise testing outcomes for patients. Recent developments in the Luminex screening tests now include analytics to improve the ability to define specific antibodies. This data can be used to select better immunological matches.

Australian laboratories must be agile to implement these new developments and technologies, with the appropriate staff training and budget to support implementation. For example, Luminex antibody screening is an expensive test and current funding for tissue typing services do not currently take into account these advancements. Technicians reported that the absence of a national decision-making body to advocate for the tissue typing services and their needs is a prominent issue that requires attention.

Summary of key findings

- Tissue typing services in Australia are comprehensive and responsive to the needs of transplantation clinicians and patients, however there is limited benchmarking of their performance.
- Tissue typing technologies are expanding and becoming increasingly complex, the introduction of these new technologies is not implemented in a planned and coordinated way at a national level.

Recommendations

Recommendation	Description
Recommendation 31	A national plan should be developed by all Australian Governments for the adoption of new tissue typing technologies.
Recommendation 32	A system for national benchmarking of tissue typing service performance be implemented nationally by all Australian Governments.

6.3.5 The impact of the State Balancing System on allocation of cadaveric donated kidneys

Discussion of findings

As discussed briefly in Section 4.5, the State Balancing System (also known as the 'pay back system') was developed to ensure equity in the allocation, offer and acceptance of kidneys across jurisdictions. The system was initially designed to 'pay back' jurisdictions which had a higher number of donated kidneys sent interstate, giving those jurisdictions a 'centre credit'. The purpose of this system is to encourage interstate sharing of kidneys where appropriate, and to ensure that jurisdictions with higher donation rates are not disadvantaged.

A centre credit becomes effective when a jurisdiction accumulates a balance variance of three kidneys (in combination with immunological matching). If a jurisdictions centre credit reaches a difference of 20, the State Balancing System comes into effect to override the allocation within the home state or territory, following which the jurisdiction with the centre credit will be allocated the kidney instead. In practice, the kidney algorithm automatically ranks states or territories with higher centre credits higher on the rotation list, increasing the opportunity for allocation of the next available organ.

The State Balancing System was implemented when donation rates varied considerably between the jurisdictions. As donation rates have become more aligned nationally, there was generally agreement that its materiality in the current environment should be assessed. However, careful consideration of the implication of removal of the system should be considered through appropriate modelling before any decision can be made.

The Review found that this element of the allocation process has the potential to increase inequity of allocation and drive under performance. The Review found that those jurisdictions which maintain small waiting lists, accept less organs for donation and provide a larger amount of organs interstate, have a higher chance of being allocated higher quality organs via the State Balancing System. This is evident from Table 20 which illustrates the number of high quality kidney allocated, offer and accepted within the State Balancing System.

Table 20: Breakdown of kidneys allocated at different levels of the allocation system based on Kidney Donor Profile Index score in 2017, SOURCE: NOMS[138]

	Kidney quality as per KDPI score in 2017					
Allocation level	**0-20**	**21-40**	**41-60**	**61-80**	**81-100**	**Total**
Multi organ	47%	47%	7%	0%	0%	100%
National	22%	34%	19%	17%	8%	100%
Interstate – home state decline	18%	35%	20%	13%	15%	100%
National – state balancing	36%	24%	16%	12%	12%	100%

[138] The National Organ Matching System, as provided by the OTA, "EY Data: National Payback" (received August 2018); Note: KDPI is a multi-factor score internationally recognised as an indicator of kidney quality. The lower the KDPI the better the kidney. The principal component of the score is age but there are other medical factors included.

As illustrated in the table, of all the kidneys allocated as part of the State Balancing System, 36 per cent are categorised into the highest quality of kidney, having a KDPI score of 0-20. In 2017, a total of 182 kidneys were allocated and offered through the State Balancing System. All of these were allocated to potential recipients in Western Australia, with only 25 being accepted for transplantation.[139]

It is evident that once jurisdictions are considered as part of the State Balancing System, they have great opportunity to be allocated higher quality organs for their potential recipients. The Review found that this resulted in inequity of allocation and reduced incentive for jurisdictions to widen their acceptability of organs.

Clinicians reported that that the State Balancing System discourages the diversification of transplantation, limits the progression in the skills of clinical workforce and inhibits improvement in quality outcomes for a range of potential recipients.

Summary of key findings

- The State Balancing System was implemented when donation rates varied considerably between the jurisdictions. Given donation rates have become more aligned nationally, there was agreement that its materiality in the current environment should be assessed.
- The State Balancing System has the potential to slow progress in improving organ donation and transplantation practices and increase inequity of the allocation of high quality organs.

Recommendations

Recommendation	Description
Recommendation 33	The OTA, through the TSANZ undertake a review of the State Balancing System to determine the impact on the efficiency, effectiveness and equity of the allocation process. Any proposed changes should then be modelled and reviewed to understand their impact.

[139] The National Organ Matching System, as provided by the OTA, "EY Data: Proportion of Offers and Acceptances for 2017" (received August 2018).

6.4 Element 4: Organ offer

For element 4, the findings of the Review relate to:

- Non-renal offer process (Section 6.4.1)
- Renal offer process (Section 6.4.2)
- The Electronic Donor Record (Section 6.4.3).

6.4.1 Non-renal offer process

Discussion of findings

The Australasian Transplant Coordinators Association produces an Annual Report, titled the *Organ Allocation Rotations Audit and Quality Control Report.*[140] This captures the offer and acceptance practices, as well as reasons for decline. The 2017 report found that there were 2,957 non-renal offers made nationally.[141] This equated to an average of 4.9 organ offers per donor nationally, with the highest number non-renal offers made per donor in South Australia (5.9), Western Australia (7.5) and the Northern Territory (8.0). Victoria had the lowest with 3.6 offers per donor.[142] The Review found that the number of offers for each jurisdiction had a considerable impact on the time taken to undertake the offer process. In the case of Victoria, undertaking 3.6 offers per donor would take approximately 3.6 hours, if the offer must be accepted or declined within 60 minutes. For South Australia this would take 5.9 hours on average, Western Australia 7.5 hours and Northern Territory 8.0 hours.

The Review also found that the number of offers per donor was reflective of the level of medical suitability, availability of suitable recipients, availability of suitable clinicians and resources in the transplantation units. This is illustrated in Table 21, which highlights the offer decline rates of each state in 2017.

Table 21: Offer decline number per state and territory each state in 2017, SOURCE: NOMS[143]

	NSW	QLD	SA	VIC	WA
Offers accepted	232	164	57	262	88
Offers declined	168	250	65	327	189
Percentage of total offers declined	42.0%	60.4%	53.3%	55.5%	68.2%

In 2017, there were a total of 1,802 offers made to renal transplantation units.[144] Individual units are responsible for accepting or declining organ offers. While the availability of suitable recipients remains a primary factor for organ offer decline, the difference in decline rates also reflects the

[140] The Australasian Transplant Coordinators Association et al, 2017, *National Standard Operating Procedures: Organ allocation, organ rotation, urgent listing, auditing process,* Annual Report 2017, Canberra, viewed September 2018 <http://www.atca.org.au/files/ATCA_TSANZ%20SOP%20001.2017.pdf>.

[141] Ibid.

[142] Ibid.

[143] The National Organ Matching System, as provided by OTA, The Australian Organ and Tissue Donation and Transplantation Authority, "Offer and Acceptances by transplanting state for kidneys" (Received November 2018).

[144] Ibid.

variability in accessing suitable clinicians and the availability of resources within each transplantation unit. Western Australia (68.2 per cent) and Queensland (60.4 per cent) had the highest proportion of kidney offer declines in 2017.

As described in Section 6.2.6, and as reported by stakeholders consulted, the time taken during the offer to acceptance process impacts on the overall experience in donation. In 2017, the Australasian Transplant Coordinator Association reported that 68 per cent of organs offered were declined at least once by a transplantation unit.[145] Each offer that is declined delays the time to acceptance. The Review found that this extended timeframe was particularly burdensome on donor families.

In 2017, five per cent of families did not consent to donation because of the time it would take to undertake the full donation process. Another one per cent of families per cent of families subsequently withdrew their consent due to the duration of the donation and offer process.[146] This illustrates the impact that the current offer process can have on donation rates.

6.4.2 Renal offer process

Similar to the non-renal organs, the Review found that the timeframes associated with the renal offer process were inefficiently prolonged. Clinicians reported that the entire offer process from offer to acceptance may take over 24 hours. It was also reported that kidneys have a longer life-span than non-renal organs after death and, as such, there is less urgency in finding a recipient.

Figure 21 provides a snapshot of a series of call logs undertaken by a donor specialist coordinator to offer a kidney to each individual transplantation units. It is noteworthy that the first offer was made at 02:50AM and the kidney was finally accepted 21 calls later at 4:50PM. Four individual transplantation units were contacted over these 21 calls, 11 of the calls being made to the same transplantation unit. This drawn out process was further prolonged as the retrieval process commenced five and a half hours after the final acceptance.

[145] The Australasian Transplant Coordinators Association, "Organ Allocation Rotations Audit and Quality Control Report" (received August 2018).

[146] The Australian Organ and Tissue Donation and Transplantation Authority, above n. 141.

Figure 21: Example of a call log for the renal organ offer process, SOURCE: The OTA[147]

rtoon	Co	Column3	ReasonDeclin	Comments	pteddecli	nedor	ReasonDeclinedOth	Age	Height	Weigh	AboBloodType	AboBloodRhFac	ateTime	Colu
2:50:00 AM		Left Kidney	Other	NULL	3:15:00 AM		Elevated creatine	41	170	123	O	Positive	10:45:00 PM	
3:32:00 AM		Left Kidney	Other	NULL	4:12:00 AM		Donor Hx, recipient age	41	170	123	O	Positive	10:45:00 PM	
4:51:00 AM		Left Kidney	Other	NULL	5:17:00 AM		DSA's and donor Hx	41	170	123	O	Positive	10:45:00 PM	
5:42:00 AM		Left Kidney	Other	NULL	6:01:00 AM		DSA's	41	170	123	O	Positive	10:45:00 PM	
6:10:00 AM		Left Kidney	Other	NULL	6:10:00 AM		DSA's	41	170	123	O	Positive	10:45:00 PM	
6:26:00 AM		Left Kidney	Other	NULL	6:50:00 AM		Donor Hx	41	170	123	O	Positive	10:45:00 PM	
6:53:00 AM		Left Kidney	Other	NULL	7:17:00 AM		Donor Hx recipient size	41	170	123	O	Positive	10:45:00 PM	
7:18:00 AM		Left Kidney	Other	NULL	7:19:00 AM		Donor Hx	41	170	123	O	Positive	10:45:00 PM	
7:22:00 AM		Left Kidney	NSR	DSAs	7:22:00 AM		NULL	41	170	123	O	Positive	10:45:00 PM	
9:07:00 AM		Left Kidney	NSR	Patient currently medicated with irreversible	1:57:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
9:07:00 AM		Left Kidney	Null	Late decline	9:45:00 AM		NULL	41	170	123	O	Positive	10:45:00 PM	
1:58:00 PM		Left Kidney	NSR	Age mismatch	2:30:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
2:31:00 PM		Left Kidney	NSR	Age mismatch and donor hx.	3:17:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
3:27:00 PM		Left Kidney	NMS	DSA's + Kidney function	4:20:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
4:23:00 PM		Left Kidney	Logistics	Logistics, extended warm ischaemic time	4:32:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
4:34:00 PM		Left Kidney	NSR	Recipient unwell	4:35:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
4:36:00 PM		Left Kidney	NMS	Donor pmhx	4:37:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
4:37:00 PM		Left Kidney	NSR	DSAs	4:38:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
4:39:00 PM		Left Kidney	Logistics	Logistics, warm ischaemic time	4:40:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
4:41:00 PM		Left Kidney	NSR	DSAs	4:45:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	
4:50:00 PM		Left Kidney	Null	NULL	5:10:00 PM		NULL	41	170	123	O	Positive	10:45:00 PM	

[147] The Australian Organ and Tissue Donation and Transplantation Report, “Kidney Dialysis Scenario” (received October 2018).

Summary of key findings

- The offer process for renal and non-renal allocation is time-consuming, inefficient and risks losing the consent of the family for donation. For example, the Australasian Transplant Coordinators Association reported that 68 per cent of organs offered were declined at least once by a transplantation unit in 2017 leading to time delays in acceptance.[148] This was reported to be particularly burdensome on donor families.

Recommendations

Recommendation	Description
Recommendation 34	As per Recommendation 27, the introduction of concomitant sharing of donor profiles with all kidney transplantation programs in OrganMatch at the commencement of the matching process should be considered to improve the efficiency of the process of organ offer process for transplantation.

6.4.3 The Electronic Donor Record

Discussion of findings

The EDR is used to record and transfer information from donation specialists to transplantation units to assist in the allocation, offer and acceptance process. The EDR is a platform used by clinicians and aims to provide real-time access to essential and comprehensive donor referral data, medico-social history and family consent information in a consistent format for consideration by transplantation units and donation coordination specialists. Although stakeholders consulted welcomed the introduction of the EDR in July 2014, and noted it as an essential part of the allocation, offer and acceptance process, many pointed out that the current functionality of the EDR presents some challenges.

The final output of the EDR is a PDF document based on jurisdictional privacy requirements that is extensive in length and has a maximum file size of 10MB. All clinical stakeholders reported that the length and complexity of the document is challenging when working under tight timeframes. The format of the document makes it difficult to decipher information quickly. In addition, heart transplant surgeons reported that the current size of the file does not allow for videos of heart function to be attached. This creates problems for clinicians in confirming the suitability of the heart and matching to the recipient. Therefore, all clinicians agreed it is timely for a review of the EDR.

Stakeholders identified that the EDR could be improved with the introduction of OrganMatch which has the potential functionality to improve the process for sharing donor profiles. However, the Review found that it may be worth exploring the additional functionalities of OrganMatch. For example, the potential to improve surveillance and safety, through rapid time feedback and sharing of information should be considered as clinicians reported that clinical data being used does not always match the EDR.

[148] The Australasian Transplant Coordinators Association, above n. 158.

Summary of key findings

- The EDR is extensively used across Australia as the initial point of donor assessment, however its current functionality – in particular the PDF output – presents challenges regarding its utilisation and the ability to share accurate and timely information. As such, the PDF output of the EDR requires upgrading.
- The implementation of OrganMatch provides an opportunity to improve the sharing of donor profiles and its functionalities could be explored to facilitate improved surveillance and safety.

Recommendations

Recommendation	Description
Recommendation 35	The OTA to commence a process to plan arrangements for an extensive upgrade to the output of the EDR (or an alternative platform, such as utilising the functionality of OrganMatch), in collaboration with donation and transplantation specialists, to improve its functionality. The upgrade should facilitate rapid time feedback to improve surveillance and safety. The plan should then be considered by the Australian Government for approval.

6.5 Element 5: Organ acceptance

For element 5, the findings of the Review relate to:

- Variability in organ acceptance (Section 6.5.1)
- Potential recipient consent and acceptance process (Section 6.5.2).

6.5.1 Variability in organ acceptance

Discussion of findings

Top performing international organ donation, retrieval and transplantation systems have implemented strategies that aim to broaden the number of organs accepted for organ donation.[149] Australia is positioned at the forefront of international performance, as the growth in experience of clinical staff and technological advancements in Australia now enables the use of organs that were previously considered not medically suitable for transplantation. This has increased the pool of potential organ donors as, 'extended criteria organ donors' including older donors and donors diagnosed with Hepatitis C or other co-morbidities, are now being considered for organ donation.

While the acceptance of organs donated by extended criteria organ donors have increased as a whole across Australia, the Review found that there is variability in acceptance across the jurisdictions. The Review found that there are two major reasons accounting for this variability. Firstly, there is diversity in clinical expertise within each transplantation unit, and secondly, there are differences between transplantation units when defining what

[149] Matesanz R, 2017, above n. 85.

constitutes an extended criteria organ donor.

Defining extended criteria organ donors for renal transplantation

The Review found that the American Organ Procurement and Transplantation Network's definition of extended criteria organ donors for renal transplantation is the universally shared definition.[150]

However, the Review found that whilst there may be a standard definition, this definition is outdated and not adopted by all transplantation units. Transplant clinicians reported that the standard definition is taken into consideration, however in practice, the Kidney Donor Risk Index (KDRI) is much more readily accepted.[151] The Kidney Donor Risk Index provides a more granular and accurate analysis by combining a variety of additional donor factors to summarise the risk of graft failure after kidney transplantation into a single number. Clinicians reported that kidneys with a raw Kidney Donor Risk Index of greater than two, will be classified as a kidney donated from an extended criteria organ donor. As captured in Figure 22, the Review found that in 2016, nine per cent of total kidneys transplanted were considered to be donated by an extended criteria organ donor.[152]

Definition of extended criteria donor organs for renal transplantation

The following conditions are used to determine if a kidney is donated from an extended criteria organ donor:

- The donor is aged over 60 years, or
- The donor is aged between 50 and 59 years with at least two of the following conditions: stoke as a cause of death; history of hypertension; and/or terminal serum creatinine (>1.5mg/dl)

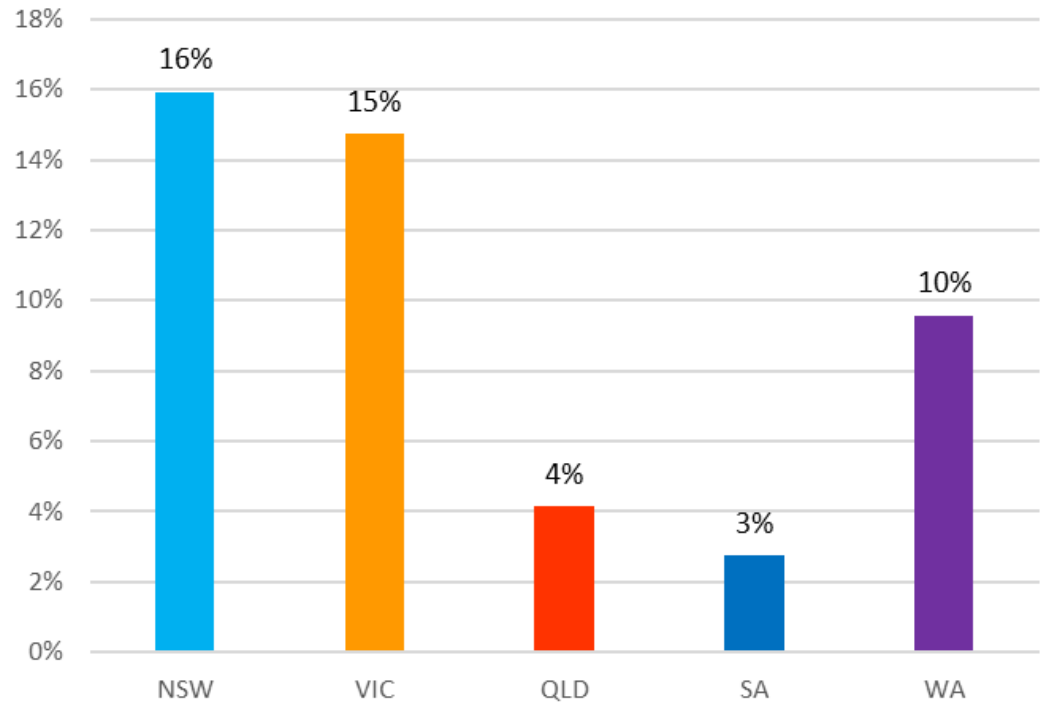
Kidneys may also be considered to be donated from an extended criteria organ donor if there is an increased risk of transmission of infection or malignancy.

[150] Organ Procurement and Transplantation Network, 2018, *Organ Procurement and Transplantation Network: Policies – Policy 3.5.1,* U.S Department of Health and Human Services, viewed November 2018 <https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf>.

[151] Note: The Kidney Donor Risk Index (KDRI) and the Kidney Donor Profile Index (KDPI) are separate metrics to measure kidney quality. The KDPI is a conversion of the KDRI into a percentile and is more commonly used in practice. The conversion of KDRI to KDPI depends on the profile of recent donors, and changes each year. Nevertheless, a KDRI score of greater than 2, when converted to KDPI approximately equates to a score of around 90 per cent (ANZDATA).

[152] The Australia and New Zealand Dialysis and Transplantation Registry, "Marginal Donor Kidney Data 2014-2016" (received November 2018).

Figure 22: Proportion of kidneys transplanted with a raw KPDI score of greater than two in 2016, per state and territory, SOURCE: ANZDATA[153]



Defining extended criteria organ donors for non-renal transplantation

The Review found that currently, there are no simple or universally accepted definitions for extended criteria organ donors for non-renal transplantation. However, clinicians reported that the following factors will be taken into consideration when determining donor suitability.

The process to define extended criteria organ donors for non-renal transplantation is much more complex, and takes into consideration a multitude of other factors such as the donor's history of smoking, donor obesity, donor diabetes and presence of trauma. The Review found that whilst the factors outlined above are always considered when defining organ acceptability, liver lung and heart clinicians reported that they are often required to exercise a level of discretion when determining whether certain criteria is applicable. Anecdotal evidence suggests that as a result of this varied practice, organs that are considered not acceptable for transplantation in one unit, may well be accepted in another, resulting in varied outcomes for potential transplant recipients.

Acknowledging that there are multiple elements that determine organ acceptability, this Review only focuses on the impact of age, size, co-morbidities and disease profiles.

[153] Ibid; Note: Percentage variability not necessarily to scale due to large variation in transplantation numbers across each state and territory.

Factors considered in defining extended criteria donor organs for non-renal transplantation

Liver

The following conditions are taken into consideration when determining if a liver is donated from an extended criteria organ donor. One condition in isolation may not necessarily indicate an extended criteria donor, but a combination of factors will:

- The donor is aged over 60 years
- The donor died from cardiac death
- High levels of inotropes
- High Aspartate Aminotransferase or Alnanine Aminotransferase
- Macro steatosis levels greater than 30 per cent
- The donor was diagnosed with obesity
- The donor was diagnosed with diabetes
- The donor was diagnosed with cardiovascular disease
- Anticipated long ischemic time
- Location of donor

Lung

The following conditions are taken into consideration when determining if a lung is donated from an extended criteria organ donor:

- The donor is aged over 55 years old
- The donor's partial pressure of oxygen measurement was less than 300 mm Hg
- The donor's smoking history
- Presence of chest trauma
- Presence of microbiologic endobronchial organisms
- Presence of malignancy
- Presence of purulent secretions or signs of endobronchial aspiration
- Presence of active viral infection

Heart

The following conditions are taken into consideration when determining if a heart is donated from an extended criteria organ donor:

- Donor is aged over 50 years old
- Echocardiographic Left ventricular ejection fraction of less than 50%
- Echocardiographic regional wall motion abnormality
- Expected donor heart cross-clamp time of greater than 6 hours
- High dose inotropic or vasopressor support (noradrenaline of greater than 0.2 ug/kg/min or equivalent sympathomimetic)
- Other Donor comorbidities including Hepatitis B, Hepatitis C or other high-risk behaviours

Age acceptability

Organ transplantation from aged deceased donors has traditionally been associated with sub-optimal outcomes and low survival rates. As technology and experience advances within the transplantation workforce, the acceptability of 'older' organs is becoming more apparent.

The benefits of expanding age criteria can be seen in Spain. The Spanish donation and transplantation system has progressively adopted criteria that accommodate for the utilisation of aged donors over the age of 60. In 2015, more than 50 per cent of the

deceased organ donors in Spain were aged over 60 years old, and over 30 per cent were older than 70 years old. This expansion has been acknowledged as a major contributor to the 40 donors per million population achieved by Spain.[154]

This Review found that Australia is progressing towards expansion in the acceptance of organs related to age. However, there is currently variation in the acceptance practices between states and territories and between organs. As illustrated in Figure 23, in 2017, Victoria accepted 83 kidneys from organ donors aged above 60 and New South Wales accepted 59. This is substantially higher than Queensland (21), Western Australia (12) and South Australia (11).[155]

Figure 23: Number of accepted kidneys for transplantation by donor age per state and territory, SOURCE: ANZOD[156]

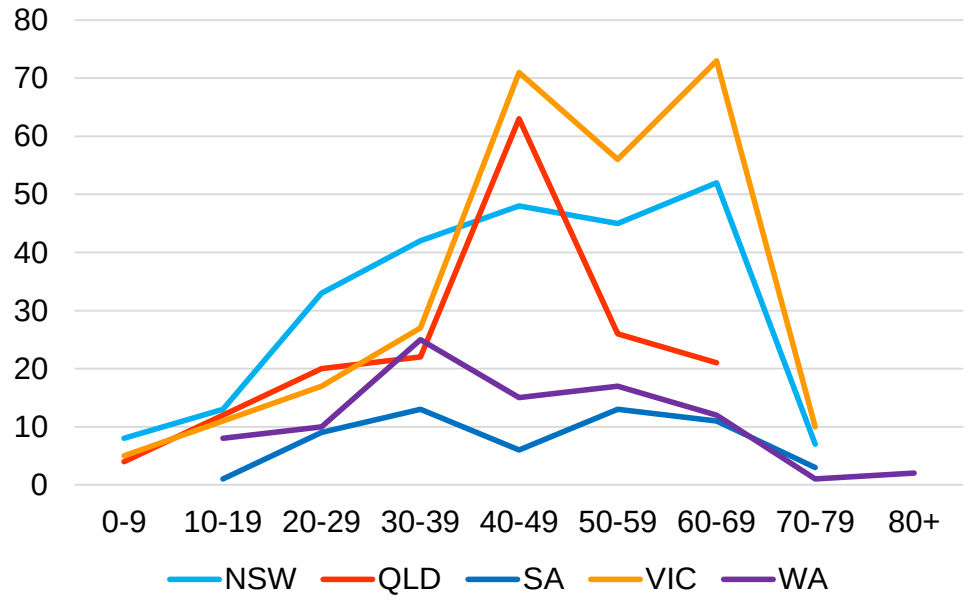


Figure 24 illustrates the number of accepted lungs for transplantation by donor age, by state and territory in 2017 and Figure 25 illustrates the number of accepted livers for transplantation by donor age, by state and territory in 2017. They show that Victoria and New South Wales accept a greater number and wider range of donor ages across kidneys, lungs and livers. The Review found that these jurisdictions are moving toward best practice and investing in techniques that enable greater success in transplanting a wider range of organs from donors of different ages.

[154] Matesanz R, 2017, above n. 85.

[155] The Australia and New Zealand Organ Donation Registry as provided by the OTA, "EY Data: Transplants by Donor Age - Kidney" (received August 2018).

[156] Ibid.

Figure 24: Number of accepted lungs for transplantation by donor age per state and territory in 2017, SOURCE: ANZOD[157]

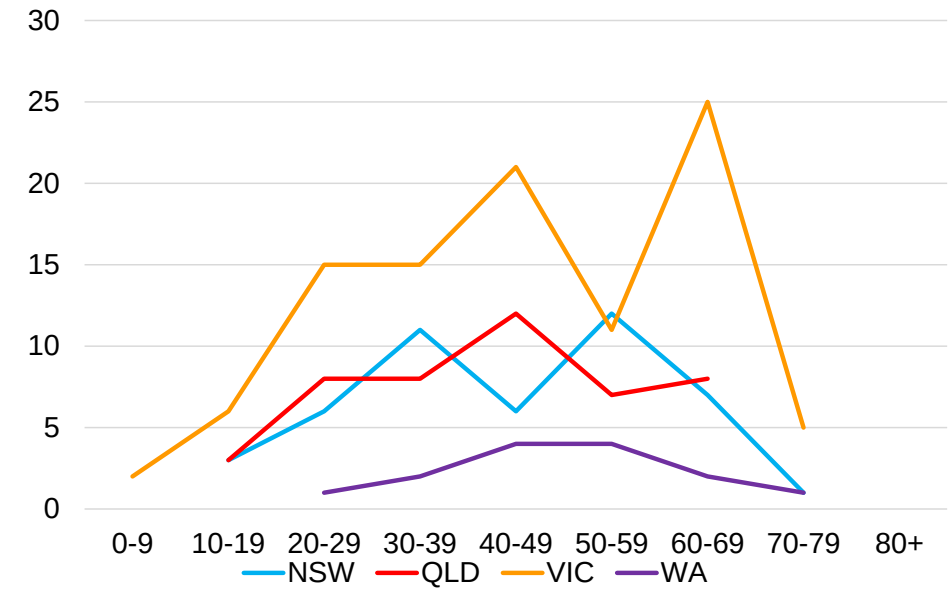
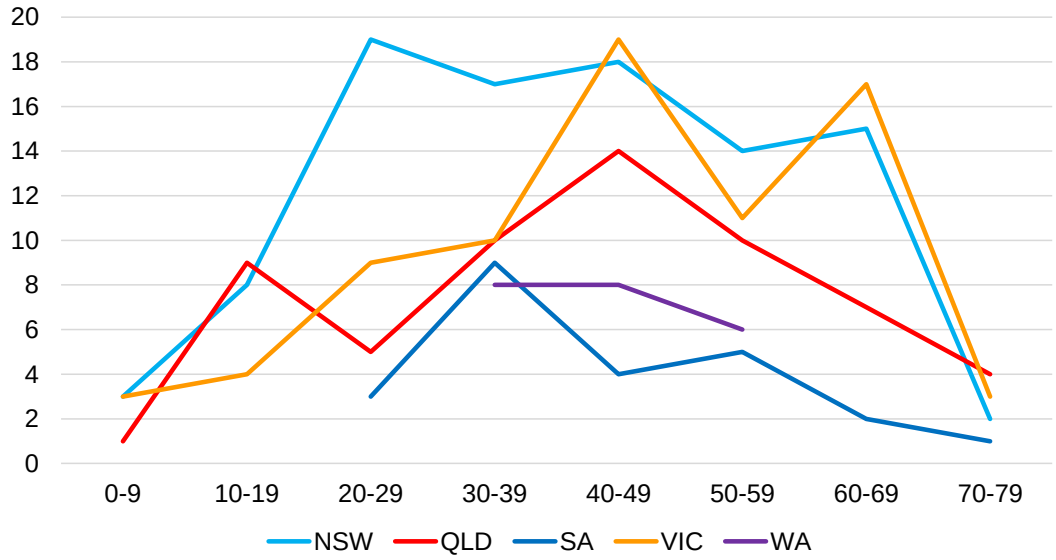


Figure 25: Number of accepted livers for transplantation by donor age per state and territory in 2017, SOURCE: ANZOD[158]



[157] Australia and New Zealand Organ Donation Registry as provided by the OTA, "EY Data: Transplants by Donor Age - Lung" (received August 2018).

[158] Australia and New Zealand Organ Donation Registry as provided by the OTA, "EY Data: Transplants by Donor Age - Liver" (received August 2018).

Size acceptability

The Review found that heart and kidney transplantation units maintain acceptance practices that align very closely to the Clinical Guidelines. This was reported to be based on the size sensitive nature of kidneys for transplantation and size and time for hearts. However, liver and lung transplantation clinicians reported that the Clinical Guidelines were adhered to less closely and practices differed slightly in allocation between transplantation units. The Review further found that the size of lungs and livers do not always preclude acceptance, as many surgeons have learnt to re-size these organs in order to meet the needs of the recipient. This has enabled increased the potential for more liver and lung matches, enabling greater access for more patients with end-stage liver or lung disease.

Comorbidity and disease profile acceptability

Through improved medical intervention, Hepatitis C can now be effectively treated. This has meant that clinicians can now effectively treat Hepatitis C affected organs during the transplantation process.

Although the extended acceptance and use of organs has meant that more Australians have access to a lifesaving transplantation, the additional treatment required to ensure optimal outcomes for transplantation results in a higher cost of care.

Organ offer declines

The Australasian Transplant Coordinators Association's annual Organ Allocation Rotations Audit and Quality Control Report, provides an analysis of organ offers and acceptances. In 2017, it reported that of the 2,957 non-renal organ offers audited, 2016 offers were declined. Organ decline reasons are currently recorded into one of four categories, 'not medically suitable', 'no suitable recipient', 'logistics' or 'other'. The Review found that the availability and analysis of these refusal decisions are currently limited.

There is an emerging consensus among stakeholders that data concerning organ acceptance and refusal decisions should be collected and reviewed. The 2017 Organ Allocation Rotations Audit and Quality Control Report, outlined that there were 2,734 reasons documented for declines. However, the current system is inadequate in its ability to report and represent more than one outcome code per organ. The Australasian Transplant Coordinators Association reported that this is an issue as there is currently no way to interpret and address how and why organs are not being utilised nationwide. A national system that allows comprehensive collection of reasons for organ decline is required to understand current behaviours, identify best practice and allow benchmarking to optimise organ donations.

Summary of key findings

- Advances in acceptability of organs by transplantation units has resulted in variability of acceptance practices across jurisdictions.
- More transplantation units are now considering a greater range of organs based on age as well as comorbidities and disease profiles.
- Current data systems do not enable to capture of reasons for offer declines and the analysis of system bottlenecks affecting offer acceptance.

6.5.2 Potential recipient consent and acceptance process

As explained in Section 4.7, the acceptance process includes confirming the acceptance and consent of the potential recipient. As stated in the Clinical Guidelines, consent is defined as a person's or a group's agreement, based on adequate knowledge and understanding of

relevant material.[159] It involves explaining benefits and risk of transplantation to enable the potential recipient to provide informed consent.

The Clinical Guidelines state that where the acceptability of donor organs may pose an element of risk to the recipient, acceptance and consent should be discussed with both the potential recipient and their carer at the time of wait listing (rather than at the time of the organ offer). As part of this, the provision of adequate counselling and education is critical to the potential recipient's ability to consider their options and ultimately provide informed consent if they choose to proceed with transplantation in these circumstances.

The Review found that discussions with potential recipients concerning the acceptance and risks involved with the acceptance of organs donated by extended criteria organ donors did not always follow the Clinical Guidelines. It was reported by key stakeholders consulted in the Review that there was variability in the timing of the acceptance and consenting process, reducing the availability of access to educational resources and opportunity for the potential recipient to confirm their acceptance.

Stakeholders reported that outcomes from the use of organs from extended criteria donors should also be made readily available to the public to facilitate informed decisions. The Review found that the collection of outcome data from the use of extended criteria donor organs is currently not available. Collection of outcome data is further discussed in Section 7.1.1.

Summary of key findings

- Advances in acceptability of organs by transplantation units has resulted in variability of acceptance practices for organs from extended criteria donors across jurisdictions.
- More transplantation units are now considering a greater range of organs based on age, as well as comorbidities and disease profiles.

Recommendations

Recommendation	Description
Recommendation 36	The OTA, through the TSANZ, should develop a clinical review process and optimise the use of extended criteria donated organs.
Recommendation 37	The OTA, through the TSANZ, should develop a process to monitor the incidence of organ offer decline decisions and a process to clinically review those decisions.

6.6 Element 6: Retrieval

For element 6, the findings of the Review relate to:

- The operation of the retrieval system (Section 6.6.1)
- The use of ex vivo perfusion technology to support transportation and enhancement of donated organ quality (Section 6.6.2).

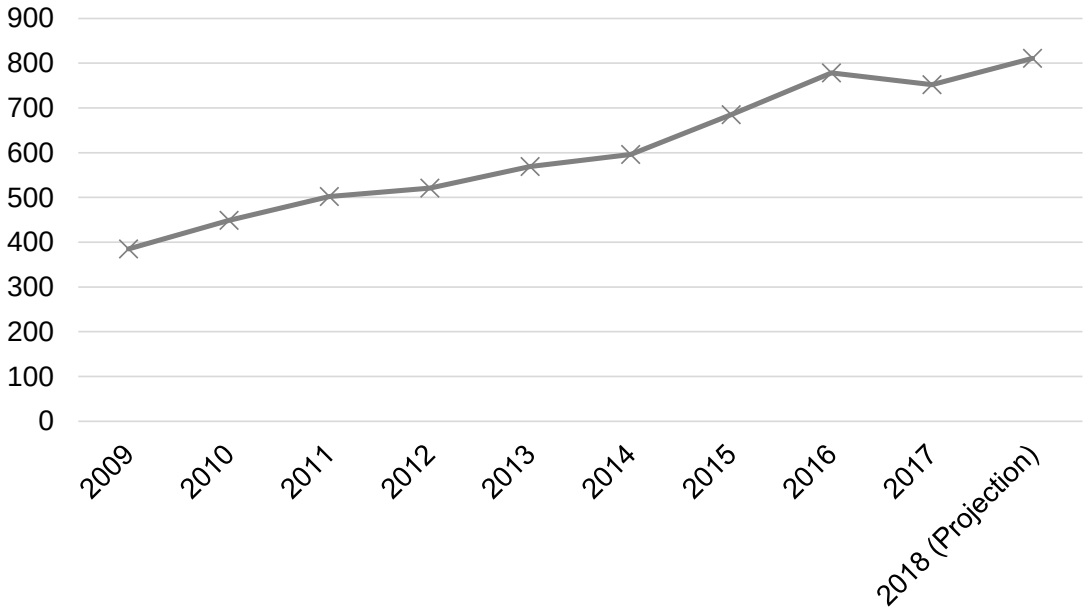
[159] The Transplantation Society of Australia and New Zealand, 2016, above n.1.

6.6.1 The operation of the retrieval system

Discussion of findings

For every confirmed donation, a retrieval team is assigned to undertake the retrieval surgery. The Review found that the increasing volume of organ donations, as discussed in Section 6.2.1, has placed pressure on retrieval teams across the country. As captured in Figure 26, retrieval procedures have steadily increased from 2009, and a positive trajectory is projected for the future. There are currently limited national strategies and resources in place to manage this additional demand, and the Review found that this poses a potential risk to the quality and safety of retrieval services.

Figure 26: Number of retrieval procedures performed each year since 2009, SOURCE: ANZOD[160]



In addition to the increase in demand organ retrievals, an added complexity is that retrieval teams are required to undertake retrieval surgeries both within their home state, and are often required to undertake retrieval surgery in other jurisdictions, depending on the location of the accepted organ. Table 22 details the retrievals from 2017, including where units were required to travel interstate for retrieval.

Table 22: Number of organs retrieved interstate by state in 2017, SOURCE: ANZOD[161]

State	Organs retrieved locally	Organs retrieved interstate	Total organs
NSW (includes ACT)	454	33	487
VIC (includes TAS)	489	34	523
SA	78	3	81
QLD	304	15	319
NT	7	0	7

[160] The Australian and New Zealand Organ Donation Registry, "Number of Retrievals by Unit 2009 – 2018 Jan – Sept" (received October 2018).

[161] The Australia and New Zealand Organ Registry, as provided by the OTA, , "Organ retrieval and transplantation by jurisdiction (Australia 2017)" (received July 2018).

State	Organs retrieved locally	Organs retrieved interstate	Total organs
WA	177	1	178

As demonstrated in Table 22, some jurisdictions retrieve more organs interstate than others, with Victoria (34 interstate retrievals) and New South Wales (33 interstate retrievals) undertaking the most interstate retrievals. The Review found that when retrieval teams are required to travel interstate, management and coordination of the resources required become more difficult. Key stakeholders from transplantation units reported that coordination of travel was a major source of challenge as there is currently no national approach to sourcing or procuring aviation services.

Further, it was reported that when retrieval teams are interstate for extended periods of time, transplantation units are left with limited resources. This was reported to result in retrieval and transplantation clinicians having to work for prolonged periods of time or meant appropriate resources were not available. This increased risks to safety and quality, as well as the potential for decline of organs due to logistical reasons. The Review found that in 2017, 146 organs were declined due to logistical reasons.[162] In other words, these organs were declined because adequate resources were not available to undertake the retrieval. Examples of organs declined or withdrawal of consent due to logistical reasons are described below.

International systems have attempted to address this challenge through establishing a 'de-coupled' retrieval service from the transplant service, whereby there is a dedicated service to optimise retrieved organs for transplantation. The United Kingdom have established the National Organ Retrieval Service in order to better manage retrieval demand and the quality of the retrieval services.[163] As a key component of the organ donation and transplantation infrastructure in the United Kingdom, the National Organ Retrieval Service provides a 24-hour service for retrieving organs through a dedicated team approach.

As demonstrated by Table 23, the retrieval process for abdominal organs (kidneys and livers) in Australia is generally undertaken by the retrieval team from the donor home state. However, it is more likely to be retrieved by the transplanting state for cardiothoracic organs (hearts and lungs). This indicates that Australia currently has a hybrid system for retrieval where a 'de-coupled' approach is used for abdominal organs, but less so for cardiothoracic organs.

[162] The Australia and New Zealand Dialysis and Transplantation Registry as provided by the OTA, "Organ Offer Declines 2015 – August 2018" (received October 2018).

[163] National Health Service Blood and Transplant 2015*, National Organ Retrieval Service Review 2015*, United Kingdom, viewed September 2018, <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1411/nors_review_report_2015.pdf>.

Table 23: Organs retrieved and transplanted interstate 2017, SOURCE: ANZOD[164]

Organ	Total number of organs retrieved for interstate transplantation	Retrieved by donor home state	Retrieved by transplanting state
Kidney	184	181	3
Heart	30	14	16
Liver	62	58	4
Lung	57	24	33

Clinical stakeholders reported that the implementation of a comprehensive 'de-coupled' model in Australia would be challenging as it would be difficult to recruit the requisite clinical expertise for a retrieval only based service. Further, heart and lung transplant surgeons reported that the sensitive nature for managing heart and lung retrieval and transplantation often requires consistency of clinical personnel, particularly in the management of perfusion technology. The Review also found that the current funding model for retrieval would make the implementation of the 'de-coupled' model difficult. Currently retrieval and transplantation procedures are coupled together in the Australian Refined Diagnosis Related Groups. A review of the funding arrangements between retrieval and transplantation is required in order to effectively and efficiently allocate costs for retrieval and transplantation. This would be required before Australia could consider the 'de-coupled' model. This is discussed further in Section 7.2.1.

Some clinicians suggested that it may be useful to develop a reimbursement model for retrieval teams that retrieve an organ in another state. This is an option that is currently being raised and implemented in some jurisdictions in rudimentary form, however the Review is not convinced that it will provide enough of an incentive to offset administrative costs.

While clinicians generally agreed that it would be best to keep with a hybrid system for now, they all agreed that consideration of the oversight and future resourcing requirements for retrieval teams is required. With the continued growth in organ donation, and the inevitable retirement of current surgeons who undertake retrieval and transplantation, it is unlikely that the current resources will be able to manage the demand into the future without national oversight, planning and adequate resourcing. The Review acknowledges that theatre access and resource coordination is an inherently local issue requiring local solutions. However, national oversight, planning and resources will enable better local solutions. For example, the provision of cardiothoracic retrieval services in South Australia and the Northern Territory would be enhanced by the development of retrieval surgery skills within the cardiothoracic teams based in Adelaide. Further, the provision of abdominal retrieval services in the Australian Capital Territory and Tasmania would be enhanced by the development of abdominal retrieval surgery skills in the surgical teams based in Canberra and Hobart respectively, along the lines of the abdominal organ retrieval services currently operating in Darwin.

Examples of donor families withdrawing consent due to delays caused by resourcing issues

[164] The Australia and New Zealand Organ Donation Registry as provided by the OTA, "2018 Retrievals Total: Organ Retrievals, Kidney, Liver Heart and Lung" (received October 2018).

Case study 1

An organ retrieval team had to delay theatre as one of their patients who had already been transplanted suffered an emergency and required an operation. The significant delay was not acceptable to the donor family and they withdrew consent for donation.

Case study 2

There were multiple delays to the scheduled retrieval time for a renal only DCD donor. This was due to a number of factors, such as competing emergencies requiring theatre time and staffing changeover. The retrieving hospital was experiencing a busy theatre schedule and the surgical team had already experienced multiple delays that day, therefore they intended to defer retrieval until the next morning. The donor family was unwilling to wait and withdrew consent for donation.

Case study 3

Delays were experienced due to unavailability of a renal retrieval team for DCD referral because of increased donation and transplantation activity in the jurisdiction. The team had already delayed planned retrieval and a further period of delay was not supported by the family who withdrew consent.

Summary of key findings

- The retrieval system for solid organ donation is currently under pressure due to increased donation rates and limited national planning for future demand.
- There is an impending shortage of resources for retrieval resulting in inefficiencies, risks to quality and safety and the potential to decline retrieval due to logistical reasons.
- Aviation services contractual arrangements are negotiated locally in each transplantation unit – often without a standing contract. There is currently no national approach to the sourcing or procurement of aviation services for the organ retrieval process.
- There is international evidence that shows the benefits of 'de-coupling' retrieval teams from transplantation. Australia is currently utilising a hybrid system where 'de-coupling' retrieval services is more readily used for abdominal organ retrieval procedures. However, a 'de-coupled' model for all organ retrieval is not currently supported by all clinicians or the current funding model.
- There is no evidence of national oversight or a detailed nationally focused resource plan for the expansion of organ retrieval services to meet the likely increase in demand.
- The provision of cardiothoracic retrieval services in South Australia and the Northern Territory would be enhanced by the development of retrieval surgery skills within the cardiothoracic teams based in Adelaide.
- The provision of abdominal retrieval services in the Australian Capital Territory and Tasmania would be enhanced by the development of abdominal retrieval surgery skills in the surgical teams based in Canberra and Hobart respectively along the lines of the abdominal organ retrieval services currently operating in Darwin.

Recommendations

Recommendation	Description
Recommendation 38	The OTA should develop a national organ retrieval resource plan to more effectively manage and coordinate processes and training programs across Australia to meet the expected increase in organ retrieval demand.
Recommendation 39	The current organ retrieval tasking system should be retained; however, its adequacy should be reviewed in two years' time by the OTA to ascertain whether a national tasking system is required as demand increases.
Recommendation 40	Consideration should be given to the development of national sourcing of aviation services by the states and territories to support organ retrieval services in a more coordinated manner.

6.6.2 The use of ex vivo perfusion technologies to support transportation and enhancement of donated organ quality

Discussion of findings

As discussed in Section 4.8.4, ex vivo perfusion technology is an emerging technology currently only used in a small number of transplantation units across Australia. The technology is currently funded by the states and territories and various philanthropic sources and are well established in the heart and lung transplantation units in which it is currently operating. Its use was reported to enable improved transplantation outcomes on many occasions. However, the technology has not been introduced universally across all transplantation units or across all transplantation programs. Although there is international evidence to indicate that the technology may improve outcomes for liver and kidney transplantations, Australia has not trialled the technology in this capacity to date.

The Review found that the barriers to the introduction of the technology across transplantation units included funding and training of clinicians and support staff to successfully use the equipment. As stated in Section 4.8.4, the cost of perfusion machinery is considerable and its use is expensive, requiring approximately $30,000 AUD or more worth of consumables per use as well as additional staff and sometimes additional operating theatres. The Review found that funding for the procurement of the ex vivo perfusion technology was not always easily accessible from health services or jurisdictions, with one of the units receiving funding through a donation from a recipient.

As the technology is relatively new to Australia, accessing appropriate training for clinical staff is often limited, as training options are currently only available overseas. This was reported as a barrier to the introduction of the technology in Australia. International literature indicates that the cost effectiveness of the new technology is still being investigated and that this may be another factor of the delayed adoption and investment by health services and state and territory health departments.[165]

Summary of key findings

[165] Makdisi, G, et al, 2017, 'Ex vivo lung perfusion review of a revolutionary technology'. *Annals of Translational Medicine*, Vol. 5, No. 17, pp. 343.

- Ex vivo perfusion technology use is already well established in heart and lung transplantation and evidence is emerging in its role in liver and kidney transplantation.

Recommendations

Recommendation	Description
Recommendation 41	All Australian governments consider developing a national plan to optimise the use of perfusion technologies and ensure that best practice technology is available to transplantation units.

6.7 Element 7: Transplantation

Discussion of findings

The Review found that transplant procedures in Australia have some of the highest quality outcomes in the world. Since the implementation of the national reform program in 2009, the number of organ transplant recipients has increased by 75 per cent, from 799 recipients per annum in 2009 to 1,402 in 2017.[166] This increased rate of transplantation can be explained by the overall growth in donation rates, as well as the advancement of clinical expertise and a skilled workforce. Around 91 per cent of all organs retrieved in 2017 resulted in transplantation.[167] Hearts had the highest transplantation rates in 2017, with 94 per cent of retrievals resulting in transplantation.

In addition, Australia currently has one of the highest rates for successful renal transplantation, with graft survival rates exceeding 90 per cent within the first year of transplantation.[168] In 2016, the International Society for Heart and Lung Transplantation reported that the survival rate for lung transplantations at one year to be 82 per cent, and 69 per cent at three years and 59 per cent at five years. Australia is currently exceeding international standards with lung transplantation survival rates of 90 per cent at one year, 74 per cent at three years and 68 per cent at five years.[169] Clinicians identified that these outcomes are because of long-term management of patients, a highly skilled workforce, as well as effective public funding.

The Review found that one of the most prominent issues related to transplant surgery was resource coordination and management, including theatre scheduling and coordination of transplant teams. The Review found that variability in resources across the country had the largest impact on the ability to effectively manage and coordinate transplantation services. In particular, the availability of transplantation surgeons and clinical staff to perform transplantations within time-capped periods (particularly for DCD donors), the availability of theatres to perform transplantation procedures, and the availability of medical and supporting technology. The Review found that when there was variability in resources,

[166] The Australian Organ and Tissue Donation and Transplantation Authority, above n. 4.

[167] The Australia and New Zealand Dialysis and Transplant Registry, 2017 40th Annual ANZDATA Report Chapter 7: Australian Transplant Waiting list, viewed August 2018, < http://www.anzdata.org.au/v1/report_2017.html>.

[168] Kidney Health Australia, 2015, *Organ donation in Australia,* viewed November 2018, <https://kidney.org.au/your-kidneys/support/organ-donation/organ-donation-in-australia>.

[169] Paraskeva.M et al, Lung transplantation in Australia, 2018, '1986 - 2018; more than 30 years in the making', *The Medical Journal of Australia* Vol.208 No.10 viewed October 2018, <https://www.mja.com.au/system/files/issues/208_10/10.5694mja17.00909.pdf>.

there was a higher chance that the offer for transplantation would be declined and the offer would be passed on to another potential recipient. Transplantation procedures are inherently resource intensive and require careful coordination and sufficient time. The clinical advice throughout this Review was that transplantation is best performed during daylight hours. In order to effectively optimise transplantation procedure times, significant coordination is required. Some key stakeholders have suggested that jurisdictions should allocate greater resources to transplant coordination. The Review acknowledges that whilst this may be required; these issues demand local solutions, and these solutions are best developed by each state and territories and their hospital managers.

Nevertheless, the impact of resourcing on transplantation performance within each transplantation unit requires national monitoring and oversight to identify variability in performance across the country. This information can then be used to inform strategies to overcome resourcing challenges and improve transplantation rates nationally.

Summary of key findings

- The resource coordination and management of transplant surgery remains a challenge at every centre, however solutions to this challenging problem inherently lie in local resolution.
- National oversight is required to identify underperformance and resource inefficiencies to design strategies to improve overall performance in transplantation rates.

Recommendations

Recommendation	Description
Recommendation 42	The OTA should provide a national oversight role to identify opportunities for practice improvement in relation to the operational management of transplantation procedures.

6.8 Element 8: Post transplantation care

For element 8, the findings of the Review relate to:

- General comments (Section 6.8.1)
- Renal post transplantation care (Section 6.8.2)
- Non-renal post transplantation care (Section 6.8.3)
- Post transplantation care for young adults (Section 6.8.4)
- Renal post transplantation care for Aboriginal and Torres Strait Islander people (Section 6.8.5)
- The experience of recipients post transplantation (Section 6.8.6).

6.8.1 General comments

Discussion of findings

As discussed in Section 4.10, post transplantation care is complex and requires extensive monitoring following surgery. In most cases, monitoring is required for the rest of the recipient's life or for as long as the donated organ remains functioning. However, post transplantation care varies depending on the complexity of the transplant surgery, the organ and the recipient's overall condition.

Nevertheless, as discussed in Section 6.7, Australia continues to achieve some of the highest

survival rates post transplantation in the world. This is due to the care provided following transplantation.

6.8.2 Renal post transplantation care

The Review found that renal transplantation programs have well established post transplantation care clinics following discharge from hospital. The Review found that in areas where there are well established local networks available for post transplantation care, patients were usually able to return to their place of residence for ongoing care in the community setting. The Review found that where this option was available, local physicians were reported to be well trained in post transplantation care and had strong connections with transplantation programs to enable continuing professional development in new practices (such as antibody testing and post transplantation medication) and shared care.

However, not all renal transplantation programs across Australia have well networked access to care in the community for recipients post transplantation. This was found to increase pressure on recipients – in terms of cost and risked the overall outcomes – increasing the inequity experienced by recipients.

Advances in post transplantation care

There are multiple areas of active research that are predicted to deliver change in the clinical practice of post transplantation care within the next ten years.

Clinicians reported that transplantation units are combining cellular therapies with organ transplantation for the treatment of drug resistant viral and fungal infections in organ and bone marrow transplant recipients. This new technique is likely to become common therapy and the standard of care for some clinical situations. The ability to detect transplant rejections reliably from a blood or urine test is also within reach using gene testing approaches.

With the utilisation of home monitoring and point of care testing, patients will no longer be required to relocate or travel to centralised facilities for post transplantation care, optimising care options for patients living in rural and remote Australia. The expanding use of technologies such as telehealth will also bring a multitude of benefits. Treating clinicians will be able to virtually maintain continuity of care after the patient is discharged from hospital, and patients will be able to receive efficient and convenient follow-up care minimising transportation costs.

The Review found that post-operative medications are expensive, with an estimated cost of $2,800 AUD for the first three months of maintenance. This price is not inclusive of the immunosuppressant drugs required. 80 per cent of patients are administered Basiliximab, a new drug recently released to the market, costing approximately $6,666 AUD per course. The remaining 20 per cent will require Anti-Thymocyte Globulin, costing approximately $10,000 AUD in the first year.

New drugs are predicted to be released into the market within the next ten years. Its introduction will improve outcomes, aiming to prevent or treat fibrosis, resolve infectious risks and prevent antibody medicated drugs. However, this will inevitably increase the financial burden of post-operative care. The appropriate economic drivers must be set in place to accommodate for these costs as well as encourage the adoption of new developments to improve patient outcomes.

6.8.3 Non-renal post transplantation care

Heart, liver and lung transplantation programs generally maintain their patients at clinics within the program post transplantation. The Review found that this approach was preferred by clinicians as it ensured that patients maintained continuity of care and were monitored effectively according to their needs. It was also found that options for post transplantation care in community settings for heart, lung and liver transplant recipients

were limited due to availability of appropriately trained physicians.

Although the current post transplantation care model in heart, lung and liver transplantation has enabled high quality patient outcomes for transplant recipients, the sustainability of the model will become problematic into the future as the number of transplantations continues to increase. Further, the current model places a high burden on transplant recipients having to travel to the transplantation clinics regularly, particularly for those recipients living in rural and remote regions as well as those from low socio-economic backgrounds.

Given the expected increase in the volume of transplants in the coming years, the Review found that non-renal post transplantation care should be shared with specialised local clinicians. This would ensure that post transplantation clinics in transplantation units remain sustainable and patients continue to access appropriate care post transplantation, with less impact both socially and economically.

To effectively implement a shared care model for non-renal post transplantation care, shared care protocols are required between local clinicians and transplantation units. Further, information technology solutions are required to enable shared patient records. Training programs, resources and infrastructure are required to ensure that local clinicians are effectively skilled and resourced to manage patients locally. In addition, current MBS funding requires review in order to enable the delivery of services in the local setting. This is discussed further in Section 7.2.2.

6.8.4 Post transplantation care for young adults

The Review found that there are profound differences and specialised requirements for care of children transitioning into adulthood. Teenagers and young adults were reported to have the worst outcomes after a kidney transplant of any age under 70 years, with approximately one third of kidney transplants failing within five years.[170] This particular demographic of patients, aged between 16 and 24 often require specialised attention as they transition to adulthood, and often struggle with the shift from paediatric care to an adult care setting. The Review found that not all transplantation programs have specialised clinicians or multidisciplinary teams to provide targeted care to this cohort. As a result, this cohort is often at risk of experiencing sub-optimal outcomes.

Kidney Health Australia has received funding from the Australian Government to develop a program that supports young adults living with advanced kidney disease. The program will aim to empower and equip young Australians living with kidney disease with the necessary support to maintain independence, pursue study and employment and ultimately increase successful transplantation rates for young adults.[171]

[170] Kidney Health Australia, 2018, *Kidney Health Australia to develop pioneering youth program*, Media release, viewed September 2018 < https://kidney.org.au/cms_uploads/docs/media-release-kha-youth-program-funding-grant-2018.pdf>.

[171] Ibid.

6.8.5 Post transplantation outcomes for Aboriginal and Torres Strait Islander people

As discussed by Khanal et al 2018, the outcomes after kidney transplantation, in terms of both graft function and patient survival, are considerably poorer for Aboriginal and Torres Strait Islander patients, particularly for those from remote areas.[172] Although it has been established that Aboriginal and Torres Strait Islander people are more likely to require transplantation due to higher rates of end-stage kidney disease than non-Indigenous people, it is important that the potential benefits for patients are balanced against the risks when making decisions about treatment.

Clinicians reported the view that unless strategies are developed to improve transplantation outcomes for Aboriginal and Torres Strait Islander people, improving access to transplantation alone, will pose a high risk of creating a problem which is worse than the current experience. The Review found that it was important to identify the issues affecting graft and patient survival among Aboriginal and Torres Strait Islander people to develop holistic strategies for improving both access to transplantation and transplantation outcomes. The project to be undertaken by the TSANZ, *Improving access to and outcomes of kidney transplantation for Aboriginal and Torres Strait Islander people* will likely explore this concern further. It is important that the TSANZ project consider the findings from the consultations to be undertaken by Kidney Health Australia with Aboriginal and Torres Strait Islander people to develop the *Caring for Australasians with Renal Impairment Indigenous Guidelines*.[173]

6.8.6 The experience of recipients post transplantation

The Review found that the recipient experience post transplantation was generally positive as patients were provided with a life-saving gift that dramatically improved quality of life. However, the Review found that there was variability in the experience of recipients due to factors such as accessibility of post transplantation clinical care, point of care testing, post transplantation psychosocial support and post transplantation complications, and the management of those complications. Although groups such as Transplant Australia provide extensive psychosocial, employment and social participation support to transplant recipients, the Review found that there is variability in access to support across Australia.

The Review found that there currently is not a national method to capture the experience of recipients post transplantation. Unlike donation, resources have not been dedicated to the implementation of patient experience data collection as a means of identifying issues or under performance in the system and designing strategies for improvement. Lack of patient input into transplantation policy, combined with a lack of evidence around the nature of patient preferences, has added potentially unnecessary controversy to the formulation of policy in the transplantation system. The Review found that the introduction of mechanisms to capture recipient experience may have a dramatic influence in improving the effectiveness transplantation policy and outcomes.

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[172] Khanal N, 2018, above n. 9.

[173] The Hon Ken Wyatt AM, MP, 2018, *First Nations People to Guide a Healthier Renal Future*, Australian Government Department of Health: Canberra, viewed October 2018 <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2018-wyatt152.htm>.

Summary of key findings

- Kidney transplantation programs generally have well established networks for returning transplantation patients to their home community including handover of ongoing care (with support) provided by a local specialist in most cases.
- The heart, liver and lung transplantation programs do not generally have post transplantation care networks developed with the relevant specialists close to where the patient resides. Whilst this model has served these programs well in the past it is unsustainable in the future given the projected increase in the population of post transplantation patients.
- The transition from paediatric care to early adult care is problematic for many transplant recipients and must be specifically managed and resourced in all paediatric transplantation programs.
- Post transplantation outcomes experienced among Aboriginal and Torres Strait Islander people are currently much worse than those experienced by non-Indigenous Australians. Further work is required to identify issues affecting graft and patient survival and design strategies as part of the TSANZ project.
- Patient experience data post transplantation is not currently collected consistently within the system. The introduction of mechanism to measure experience may greatly benefit the effectiveness of policy and outcomes in transplantation.

Recommendations

Recommendation	Description
Recommendation 43	The heart, lung and liver transplantation programs develop post transplantation models of care that includes shared care with an appropriate locally based clinical team after the initial period of post transplantation stabilisation, particularly in the case of rural and regional patients.
Recommendation 44	Each paediatric organ transplantation program, and its affiliated adult transplantation program, develop explicit pathways for transition to adult care if these pathways are not already in place.
Recommendation 45	Each transplantation unit should provide comprehensive rehabilitation for patients post transplantation with a focus on employment and social participation.
Recommendation 46	Patient reported outcome measures be added to all organ transplant outcome registries.

7. Key findings and recommendations: Supporting elements of the system

This section describes the findings and recommendations for the Review relating to the supporting elements of the Australian organ donation, retrieval and transplantation system.

For the supporting elements, the findings of the Review relate to:

- Supporting element 1: Data and information management (Section 7.1)
- Supporting element 2: Financing arrangements for the system (Section 7.2)
- Supporting element 3: Research for the organ donation, retrieval and transplantation system (Section 7.3).

7.1 Supporting element 1: Data and information management

7.1.1 Accessibility, usability and integration of data and information

Discussion of findings

As discussed in Section 4.11.1, a substantial amount of data is collected and reported through the OTA and DonateLife Network, national organ transplant outcome registries, and states and territories. The collection of this data has assisted in driving the reform agenda, particularly for donation. However, the Review found that the current system for accessing and sharing data created barriers to understanding the performance of the whole system and driving improvement.

The Review found that access to state and territory inpatient data held by the OTA cannot be distributed without the consent of states and territories. The accessibility of this data limits the management of the organ transplantation programs, as performance data cannot be readily accessed for benchmarking and identification of performance issues.

The outcome registries which are maintained and updated by transplantation programs within each state and territory are considered by many stakeholders to be comprehensive, well managed and close to world class. However, a number of gaps still remain in the registries maintained for kidney, liver, heart and lung outcomes. In particular, the Review found that the current registries lack published information or granularity on the reasons for organ decline by the transplantation unit, the number and characteristics of patients waiting for transplantation (with the exception of kidneys), patient reported outcomes and the use and outcomes of organs from extended criteria organ donors. The Review also found that there was limited utilisation of the heart and lung registry data among lung transplantation clinicians across Australia and contributed more readily to the international registry instead. The Review found that the comprehensive capture of data across all registries was important in order to inform safety and quality outcomes and best practice in organ transplantation as well as better enabling benchmarking across Australian and internationally.

The Review notes that the entry of patient data into the outcome registries is laborious and consumes a lot of time and resources from clinical staff. Although the registries are partly funded by the Australian Government, the Review found that the distribution of funding

across these registries vary, with the heart and lung registry receiving approximately $130,000 AUD in funding each year and the liver registry receiving approximately $450,000 each year.[174] As a result, the maintenance of these registries, particularly for heart and lung, rely heavily on the voluntary contribution of clinical staff in each transplantation unit. Nevertheless, key stakeholders recognised the registry as close to world class but the reliance on voluntary contributions may not be able to be maintained in the long term as activity increases. As a result, all key clinical stakeholders highlighted the importance of adopting a more sustainable model for maintaining the registry.

As noted in Section 4.11.1, the OTA are currently working with all jurisdictions to develop and implement an overarching data governance framework to ensure nationally consistent data collection and management. *The OTA Data Governance Framework* ('the Framework') includes a set of agreed principles which cover data governance, privacy, confidentiality and security. These provide guidance on how to manage data assets to ensure consistent provision of trusted, high-quality data to inform decision making and drive improvement in organ and tissue donation outcomes.

The Review found that the current dispersed nature of the outcome registries could be improved through consolidation into one central system. Key stakeholders consulted in the Review expressed that benefits could be realised through this approach, however cautioned the expense required to undertake such a project.

The OTA Data Governance Framework

A significant amount of data and information exists within the organ donation retrieval and transplantation sector. However, the extent to which this information is available to the parties that need it varies widely. To address this, the OTA in recognising the importance of evidence-based decisions, has proposed The OTA Data Governance Framework. The Framework outlines the arrangements for the collective responsibility of managing data assets within the sector.

The Framework is underpinned by a set of Data Governance and Privacy Principles which will provide guidance on how to manage data assets to ensure consistent provision of trusted, high-quality data to inform decision making and drive improvement. The Framework further prescribes that a Data Governance Committee be established to promote compliance and oversee operational aspects of the Data Governance and Privacy Principles. These principles are intended to apply to all data collected and managed in online shared data sets. The included data assets are:

- DonateLife Audit
- Australia and New Zealand Intensive Care Society (ANZICS) Adult Patient Database
- ANZDATA
- The NOMS / OrganMatch
- Australia and New Zealand Liver Transplant Register (ANZLTR)
- Australia and New Zealand Cardiothoracic Organ Transplant Register (ANZCOTR)
- Australia and New Zealand Islets and Pancreas Transplant Register (ANZIPTR)
- Electronic Donor Record (EDR)
- Australia and New Zealand Organ Donation Registry (ANZOD)

[174] The Australian Organ and Tissue Donation and Transplantation Authority, "Financing Agreements 2018 – 2020" (received December 2018).

Summary of key findings

- Access to data held by the OTA which is not currently distributed to all government representatives is only granted with the consent of all nine government representatives. This impairs the management of the organ transplantation programs.
- Comprehensive and robust national patient outcome registries exist for kidney, heart, lung and liver transplantation. However, all registries could be enhanced by the addition of more information on reasons organs have been declined by the transplantation unit, the number and characteristics of patients waiting for kidney transplantation, patient reported outcomes, and the use and outcomes of organs donated from extended criteria donors.
- The entry of patient data into the outcome registries is laborious and consumes a lot of time and resources from clinical staff and is often completed on a voluntary basis.
- The OTA is currently working with states and territories to develop a Data Governance Framework with the aim to improve data management and access.

Recommendations

Recommendation	Description
Recommendation 47	The states and territories should facilitate access to and sharing of nationally agreed de-identified datasets among jurisdictions through continued support to the OTA to develop and implement its data governance framework.
Recommendation 48	National patient outcome registries for heart and lung transplantation should be formally and comprehensively supported by the OTA and funded to reflect their purpose.
Recommendation 49	Consideration should be given to the consolidation of all transplantation registries into one central system.
Recommendation 50	Consideration be given by the states and territories to the automation of data submission to the organ transplant outcome registries via the electronic medical records operating in most transplantation units.
Recommendation 51	Measures of access to the kidney transplantation programs and data relating to the profile and numbers of patients on the kidney transplantation waiting list as well as outcomes from the use of organs from extended criteria organ donors should be considered by the ANZDATA for inclusion in the data set that is collected and reported.

7.2 Supporting element 2: Financing arrangements for the system

For Supporting Element 2, the findings of the Review relate to:

- The inpatient phase of care (Section 7.2.1)
- The outpatient assessment and outpatient post operative care process (Section 7.2.2)
- Funding of new advances in the organ donation, retrieval and transplantation system (Section 7.2.3).

7.2.1 The inpatient phases of care

Discussion of findings

Contribution of state and territory funding for transplantation

The Review found that funding for organ donation, retrieval and transplantation is complex and multi-layered. As illustrated in Figure 27 and Table 24, total transplantation inpatient expenditure in Australia has increased by at least $13 million since 2015 and is projected to increase by another $30 million by 2022.[175]

Figure 27: Actual national expenditure 2015 - 2017 and projected expenditure to 2022 (AUD), SOURCE: IHPA (projections by EY)

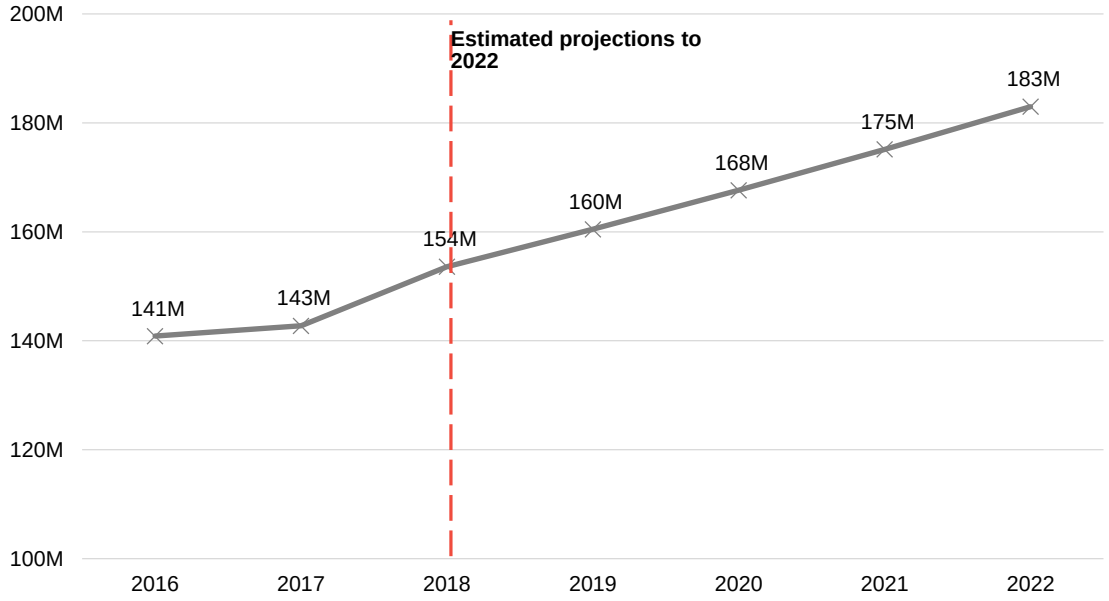

Table 24: Actual national inpatient expenditure 2015 - 2017 and projected expenditure to 2022 (AUD), SOURCE: IHPA (projections by EY)[176]

Year	Total separations	Total NWAU[177]	Actual NEP	National expenditure
2016	1,621	28333.13	$4,971	$140,843,989.23
2017	1,701	29233.22	$4,883	$142,745,813.26
2018	1,694	31280.49	$4,910	$153,587,205.90
2019	-	-	-	$160,457,161.62*
2020	-	-	-	$167,634,410.46*
2021	-	-	-	$175,132,697.64*
2022	-	-	-	$182,966,383.20*

*Projected national expenditure based on average YOY growth of 4.47 per cent from 2015 – 2018

[175] The Independent Hospital Pricing Authority, "Number of separations and NWAUs 2015 – 2018 per organ by state" (received November 2018); Note: These projections are calculated based on average national expenditure growth from FY2016 – FY2018. More detailed modelling is required to accurately account for forecasted number of transplants, NWAU and NEP each year.

[176] Ibid.

[177] The cost of each transplantation can be calculated by multiplying the annual National Efficient Price (NEP) and the NWAU). The NWAU and NEP will be updated annually by the Independent Hospital Pricing Authority.

The figures above reflect the total state and territory and Commonwealth contributions to funding inpatient transplantation care in Australia. Governments have continued to increase their contribution as activity in transplantation volumes have continued to grow. Their continued commitment is required in order to effectively meet demand for transplantation in the future and achieve the strategic objectives of the national reform agenda.

Funding of retrieval and transplantation services

As discussed in Section 4.11.2, to the point of the commencement of the retrieval procedure for organ donation, funding is supported by an Australian Government block payment per patient to the hospital that is treating the donor, as well as state and territory funding for donation service delivery. All recipient costs (including retrieval, transplantation and inpatient post transplantation care) are funded by state and territory activity based funding systems.

As discussed in earlier sections, organ retrieval and inpatient care have evolved substantially over the past decade, even more so since the introduction of the reform program. As such the Review found that the NWAU for transplantation has increased for kidney, heart and liver since 2015. In 2018, the average kidney transplantation is measured at 9.6 NWAU (increased by 0.3 NWAU since 2017), heart transplantation is 33.3 NWAU (increased by 2 NWAU since 2017) and liver transplantation is 29 NWAU (increased by 1 NWAU since 2017).[178] This can be attributed to the increase in costs in the sector, the introduction of new technology (such as ex vivo organ perfusion technologies), new practices (such as extended length of stay incurred with DCD organ transplantation) and new medication treatments (such as new immunosuppressant medication) which have all contributed to improved retrieval and patient care outcomes.

The Review found that the current Australian Revised Diagnosis Related Groups classification arrangements for organ retrieval and transplantation do not currently accurately reflect the potential complexity of current practices. Further, retrieval and transplantation are currently classified within the one Australian Revised Diagnosis Related Groups making it difficult to accurately ascertain costs. As a result, current practices cannot be appropriately accounted for and accurate planning cannot be undertaken to manage funding into the future. Furthermore, in the circumstance where retrieval is undertaken (and a cost is incurred) and transplantation does not eventuate, the transplantation unit is not reimbursed for the cost of the retrieval because the current model allocates retrieval costs to the recipient. The Review found that it would be more appropriate for retrieval costing to be attached to the donor activity and funding or ‘de-coupled’ to counteract this issue.

Further, the Review found that Australian Government block funding provided to hospitals for donation has not been effectively indexed. Currently the Australian Government, through the OTA provide a capped payment of $10,000 AUD to each hospital per donation patient. This funding is to assist with intensive care unit sustainment of potential organ donors and theatre access for donation. The Review found that the payments that reaches the hospitals have not been indexed since inception in 2009 and does not adequately reflect the needs of hospitals undertaking the organ donation.

[178] The Independent Hospital Pricing Authority, above n. 194.

Clinicians consulted through the Review reported that the costs of undertaking the donation, retrieval and transplantation process for DCD donated organs and organs from extended criteria donors were higher than DBD organs and this is not currently reflected in the funding for these procedures. The Review finds that this reported concern should be clarified through a costing study of these variables.

Summary of key findings

- The current national Activity Based Funding model does not adequately cover costs in the circumstance where retrieval is undertaken (and a cost is incurred) and transplantation does not eventuate. The current model allocates retrieval costs to the recipient; however, if the transplant does not occur, the transplantation unit is not reimbursed for the cost of the retrieval.
- There is anecdotal evidence that the costs of the retrieval and inpatient phase of care have increased substantially in recent years. This is due to factors such as the introduction of ex vivo perfusion technologies, new immunosuppressant medication as well as the extended length of stay incurred with rising rates of DCD donated organ transplantation. This appears to be reflected in the national Activity Based Funding model through increasing price weights.
- The current Australian Revised Diagnosis Related Groups classification arrangements for organ transplantation are not sufficiently refined to accurately price the difference in costs between DCD and DBD donated organ transplantation.
- The Australian Government funding contribution to hospitals to support organ donation has not been indexed since its inception.

Recommendations

Recommendation	Description
Recommendation 52	The IHPA conduct a costing study and classification review for the classification of organ donation, retrieval and transplantation to take into account the cost impact of the use of DCD donated organs and organs from extended criteria donors and to appropriately attribute retrieval costs.
Recommendation 53	Consideration be given by the Australian Government to applying indexation to the Organ Donation Hospital Support Funding (ODHSF) at the same rate as the indexation of the National Efficient Price as determined by the IHPA annually.

7.2.2 The outpatient assessment and outpatient post operative care process

Discussion of findings

As described in Section 4.3.3, the types of assessments required for transplantation have expanded greatly and some of the treatments require new and emerging medications. As a result, the Review found that the current Tier 2 classification in the national Activity Based Funding system as defined by the IHPA is not sufficiently refined to allow differential pricing of the wide spectrum of pre transplantation assessment.

Further, the Review found the *General Explanatory Note 13.33 of the Medicare Benefits*

Schedule[179] stipulates that current regulations preclude the payment of Medicare benefits to patients who have undergone a non-renal organ transplant for a period of six weeks post transplantation.

These restrictions on claiming MBS for post transplantation care inhibit any proposed shared care models because the transplant recipient would not be able to claim for the services provided outside of the transplantation unit.

Complexities with MBS claiming for outpatient assessments

General Explanatory Note.13.33 of the Medicare Benefits Schedule

Current regulations preclude the payment of Medicare benefits for professional services rendered in relation to or in association with:

(e) the transplantation of a thoracic or abdominal organ, other than a kidney, or of a part of an organ of that kind; or the transplantation of a kidney in conjunction with the transplantation of a thoracic or other abdominal organ or part of an organ of that kind;

(f) The removal from a cadaver of kidneys for transplantation.

Section 3(5), Health Insurance Act 1973 (Cth)

(5) Unless the Minister otherwise directs, a professional service, not being a service specified in an item in the general medical services table that is expressed to relate to a professional attendance by a medical practitioner (however described)…shall be deemed to include all professional attendances necessary for the purposes of post-operative treatment of the person to whom the professional service is rendered.

Summary of findings

- The current Tier 2 classification is not sufficiently refined to allow differential pricing of the wide spectrum of pre-transplantation assessment.
- The current *General Explanatory Note.13.33 of the Medicare Benefits Schedule* proscribes claiming for post transplantation care, with the exception of kidney transplantation.

Recommendations

Recommendation	Description
Recommendation 54	The IHPA conduct a costing study and classification review for the classification of non-admitted pre and post organ transplantation care.
Recommendation 55	Consideration should be given by the Australian Government for the proscription of access to the MBS for the recipients of organ transplantation other than kidney transplantation be removed from the next version of the General Explanatory Notes 13.33 of the *Medicare Benefits Schedule*.

[179] The Australian Government Department of Health, 2018, General Explanatory Notes 13.33; Medicare Benefits Schedule, Canberra, viewed November 2018 <http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/04AA67013FD6E6C0CA25834700038565/$File/201812-MBS.pdf>.

7.2.3 Funding of new advances in the donation, retrieval and transplantation system

As discussed in earlier sections of the report, a review is to be conducted by the TSANZ into the kidney algorithm and findings from this are to be incorporated into OrganMatch when it is implemented (planned for April 2019). The Review found that the modelling of the potential outcomes of the algorithm review is being undertaken in-kind. Further, the Review found that funding for the OrganMatch project is currently accounted for until it goes live on 2 April 2019, plus an additional year of funding for managed support, infrastructure and licensing. This funding only takes into consideration the implementation of OrganMatch with limited functionality. There is currently no commitment of funding beyond 2020 or any additional commitment to enhance the functionality of OrganMatch to enable efficiencies in organ allocation, offer and acceptance (as described earlier in this report).

The Review found that OrganMatch has the potential to streamline the management of waiting lists and allocation for both renal and non-renal organs. However, current funding arrangements reflect the limited functionality of OrganMatch. In order to optimise the use of OrganMatch and improve the efficiency and effectiveness of waiting list and allocation management, a review of the funding for OrganMatch and the resources required to undertake the review of the kidney allocation is needed.

Summary findings

- Current funding arrangements for the review of the kidney algorithm is not comprehensively funded.
- The OrganMatch project is currently funded up until it goes live on 2 April 2019 and includes an additional year of funding to April 2020 for managed support, infrastructure and licensing. It does not include budget for any application system enhancements.

Recommendations

Recommendation	Description
Recommendation 56	The funding allocated to the implementation of OrganMatch should be reviewed by the Australian Government to take into account the need to model the potential outcomes of any altered algorithms that will be utilised within the new system

7.3 Supporting element 3: Research for the organ donation, retrieval and transplantation system

7.3.1 Research opportunities and priorities

Discussion of findings

The Review found that there are a multitude of research bodies that currently inform and drive the evolution of the organ donation, retrieval and transplantation system in Australia. Research is a valuable part of innovation and improving practices to maximise patient outcomes. The Review found that there are a number of research projects taking place in the system that may provide great value to the system yet there is currently no national system to provide oversight or coordination over these research projects. Without this,

there is a high risk that research may be taking place in areas outside the view of the reform agenda. This may also increase the possibility of duplication and inefficient use of funding.

The Review also found that further research is required in certain areas of the donation and transplantation space, particularly in the area of transplantation and post transplantation (see Recommendation 58). This additional research will be essential to informing the development of an adequate long term strategy.

Summary of key findings

- A range of research activities have been identified during the Review which are not currently coordinated through a national system aligned to the national strategy.
- There are a number of research activities taking place that should be considered in future research strategies.

Recommendations

Recommendation	Description
Recommendation 57	The OTA should provide national oversight and coordination of research activities after consultation with the TSANZ and other clinical advisers and consider the following research opportunities and priorities: • The place of ex vivo perfusion technologies in kidney and liver transplantation. • Point of care testing for kidney transplant recipients in remote Australian communities. • The possible use of monthly administration of immunosuppressant medications in remote communities following organ transplantation. • Alternative donor matching technologies. • Organ donation patterns in minority and marginalised communities within Australia. • The reasons why families change their mind after agreeing to organ donation. • The overall demand for organ transplantation in Australia (see Recommendations 17 and 18).

8. Conclusion

Since the implementation of the national reform program in 2009, Australia has made significant progress towards establishing a world's best practice organ donation, retrieval and transplantation system. Since 2009, deceased organ donation and transplantation has improved significantly, with a 106 per cent growth in the number of organ donations and a 75 per cent increase in the number of transplantations. The progress in the system can be attributed to the sustained and joint commitment of all Australian governments.

Whilst acknowledging the improvements to date, increased activity has created downstream pressure on the capability and capacity of the health system to support every organ donation opportunity and optimise transplantation outcomes for recipients. Further, variable practices and performances across Australian jurisdictions has led to inequity of access and outcomes for some Australians. Specifically, the Review found that both Aboriginal and Torres Strait Islander Australians and Australians who live in rural and remote locations often experience significant barriers to transplantation. Even though these populations often have a greater need for transplantation due to a higher incidence of end-stage organ disease.

As continued growth in organ donation and transplantation activity is projected, the Review found that the current system requires enhancement in order to sustain and continue to drive optimal outcomes for all Australians. This Review has provided 57 evidence-based recommendations to inform the development of a future long-term strategy for Australia's retrieval and transplantation sector for deceased donation, including three key priorities for action:

1. An organised, nationally driven strategy is required to meet the increase in organ transplantation volumes.
2. Governance to optimise future growth and sustainability of the donation, retrieval and transplantation system.
3. A nationally driven approach to improve organ donation and transplantation rates among Aboriginal and Torres Strait Islander Australians and Australians who live in rural and remote locations.

Appendices

Appendix A: Glossary of Terms

Terms	Description
Accessibility and Remoteness Index of Australia (ARIA+)	The Index used by the Australian Statistical Geography Standard to define 5 classes of relative remoteness across Australia. ARIA+ is derived by measuring the road distance from a point to the nearest Urban Centres and Localities in five separate population ranges. The Australian Statistical Geography Standard Statistical Area Level 1 (SA1) boundaries are overlayed onto the ARIA+ grid and an average score is calculated based upon the grid points that are contained within each SA1. The resulting average score determines which remoteness category is allocated to each SA1
Activity Based Funding (ABF)	Model for funding of hospitals whereby hospitals get paid for the number and mix of patients that are treated
Australian Refined Diagnosis Related Groups	The Australian admitted patient classification system which provides a clinically meaningful way of relating then number and type of patients treated in a hospital to the resources required by the hospital.
Deceased donors per million population (dpmp)	The number of deceased donors per million population. The number of deceased organ donors in a given year divided by the estimated population of the country in that period and multiplied by 1,000,000
DonateLife Agency	An agency established in each state and territory which provides oversight of donation and transplantation services within that state and territory
DonateLife Network	The Commonwealth Government funded organ and tissue service in Australia, comprising of medical, nursing and administrative staff who work in the public hospital sector and where agreed, private hospitals in each state and territory
Donation after Brain death (DBD)	Organ donation after brain death that has been determined on the basis of irreversible cessation of all brain function
Donation after circulatory death (DCD)	Organ donation after circulatory death that has been determined on the basis of irreversible cessation of blood circulation
Family Donation Conversation Trained Specialist	A donation specialist role that provides additional expertise in supporting and informing families in end-of-life decision making related to organ and tissue donation
Inner Regional Australia	SA1 Average ARIA+ Value Range: greater than 0.2 and less than or equal to 2.4
Major cities of Australia	SA1 Average ARIA+ Value Range: 0 to 0.2
Medicare Benefits Schedule (MBS)	A listing of the Medicare services subsidised by the Australian Government
National Efficient Price (NEP)	Published annually by the Independent Hospital Pricing Authority, the NEP determines the amount of Commonwealth Government funding for each public hospital services, and provides a price signal or benchmark about the efficient cost of providing public hospital services. The NEP multiplied by the NWAU provides the total cost of a hospital service.
National Health Reform Agreement	Agreement entered into in August 2011 that sets out the shared intention of the Commonwealth, and state and territory governments to work in partnership to improve health outcomes for all Australians and ensure the sustainability of the Australian health system.
National Weighted Activity Unit (NWAU)	The unit of measure for the Activity Based Funding (ABF) system
Non-nationals	Citizens of other countries that are not permanent residents of Australia

Terms	Description
Non-renal organ	For the purposes of this Report, non-renal organs are heart, lung, liver, and intestine, pancreas and pancreas islets. The Report focuses on heart, liver and lungs
Outer Regional Australia	SA1 Average ARIA+ Value Range: greater than 2.4 and less than or equal to 5.92
Pharmaceutical Benefits Scheme (PBS)	Program of the Australian Government that provides subsidised prescription drugs to residents of Australia
Remote Australia	SA1 Average ARIA+ Value Range: greater than 5.92 and less than or equal to 10.53
Renal organ	Kidneys
Rural and remote	Areas in Australia that are classified as either Outer Regional, Remote Australia or Very Remote Australia according to the Australian Statistical Geography Standard
Very Remote Australia	SA1 Average ARIA+ Value Range: greater than 10.53

Appendix B: List of stakeholders consulted

A number of donor families, transplant recipients and patients awaiting transplantation were consulted as part of the Review.

Last Name	First Name	Organisation/s
Alexander	Stephen	TSANZ Children's Hospital Westmead
Alexander	Kate	NACCHO
Allen	Richard	Westmead Clinical School, University of Sydney Transplant Australia
Baker	Janet	Queensland Health
Barry	Lucinda	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Bateman	Katherine	Transplant Nurses Association
Bell	Amanda	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Bergin	Peter	Alfred Hospital
Boan	Peter	Royal Perth Hospital
Botting	Karen	Victorian Department of Health and Human Services
Boudville	Neil	St John of God Mt Lawley Hospital
Bowles	Tom	Western Australia Country Health Service
Bryson	Greg	Queensland Health
Burgess	Anna	Victorian Department of Health and Human Services
Burkolter	Nadia	DonateLife ACT
Burley	Robyn	The Royal Australasian College of Physicians
Bushby	Sharon	Aboriginal Health Council of Western Australia
Campbell	Scott	Brisbane Private Hospital
Campbell	Kirsty	Royal Darwin Hospital

Last Name	First Name	Organisation/s
Cantwell	Linda	Victorian Transplantation and Immunogenetics Services Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Carroll	Robert	Royal Adelaide Hospital
Cavazzoni	Elena	Children's Hospital at Westmead NSW Organ and Tissue Donation Service
Celcer	Juliana	NSW Organ and Tissue Donation Service
Chadban	Steven	Transplant Liaison Reference Group Royal Prince Alfred Hospital
Chan	Elaine	Westmead Hospital
Chant	Kerry	NSW Ministry of Health
Chapman	Jeremy	Westmead Hospital
Chen	John	Flinders Hospital
Chesneau	Stuart	Australian Red Cross Blood Services
Chow	Kevin	Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Clayton	Philip	Australia and New Zealand Dialysis and Transplantation Registry (ANZDATA) Royal Adelaide Hospital
Coates	Toby	Transplantation Society of Australia and New Zealand (TSANZ) Royal Adelaide Hospital
Coco	Tina	DonateLife Queensland
Connellan	Mark	St Vincent's Hospital Sydney
Crawford	Michael	Royal Prince Alfred Hospital
Crouch	Julie	Donatelife WA
Daniels	Sandra	Queensland Health
D'Costa	Rohit	DonateLife VIC The Royal Melbourne Hospital & NorthWestern Mental Health Victorian and Tasmanian Renal Transplant Advisory Committee (VTRTAC)

Last Name	First Name	Organisation/s
De Santis	Dianne	PathWest
Dennis	Kathy	ACT Health
Derrington	Petra	Pathology Queensland
Dhittal	Kumud	St Vincent's Hospital Sydney
Diviney	Mary	Australian Red Cross Blood Service Victorian Transplantation and Immunogenetics Services (VTIS) Victorian and Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Doherty	Richard	The Royal Australasian College of Physicians
Dole	Kerry	NT Department of Health, Royal Darwin Hospital
D'Onise	Katina	SA Health
D'Orsogna	Lloyd	Pathwest Laboratory Medicine WA
Downes	Kylie	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Downie	James	Independent Hospital Pricing Authority
Evans	David	Royal Adelaide Hospital
Evenden	David	Department of Human Services
Fagan	Jo	Western Australia Department of Health
Fawcett	Jonathan	Greenslopes Private Hospital
Fenny-Walch	Belinda	Tasmanian Population Health Services
Fink	Michael	The Austin Hospital, Warringal Private Hospital
Fisher	Charles	North Shore Private Hospital
Fisher	Danielle	NSW Organ and Tissue Donation Service

Last Name	First Name	Organisation/s
Flarey	Malynda	NSW Ministry of Health
Francis	Ross	Princess Alexandra Hospital
Furey	Michael	Victorian Department of Health and Human Services
Garred	Anna	Queensland Health
Gillis	David	Australian Society of Clinical Immunology and Allergy (ASCIA), Sunshine Coast University Hospital
Glanville	Allan	ShareLife, St Vincents Hospital Sydney
Goodman	David	St Vincent's Private Hospital Melbourne, Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Goodwin	Melissa	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Gopan	Basu	The Alfred Hospital, Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Gould	Andree	DonateLife WA, Royal Perth Hospital
Gow	Paul	The Austin Hospital, Warringal Medical Centre
Granger	Emily	St Vincent’s Hospital Sydney
Greenfield	Joanne	Queensland Health
Griffin	Anthony	Princess Alexandra Hospital
Griffiths	Emma	Kimberly Aboriginal Medical Services
Hardstaff	Ruth	John Hunter Hospital
Harkness	Michelle	St Vincent’s Health Network
Harper	Emily	ACT Health
Harrison	Judy	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Hartley-Jones	Julie	Department for Health and Ageing, South Australia

Last Name	First Name	Organisation/s
Hawes	Ellen	Queensland Health
Heaney	Mairead	Princess Margaret Hospital
Hebson	Naomi	Queensland Health
Hempstalk	Matty	Transplant Australia
Hodak	Alison	DonateLife SA
Holdsworth	Rhonda	Australian Red Cross Blood Services
Holmes-Liew	Chien-Li	Royal Adelaide Hospital
Holt	Steve	Royal Melbourne Hospital
Hudson	Fiona	Australian Red Cross Blood Service, Victorian Transplantation and Immunogenetics Services (VTIS), Victorian and Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Hughes	Peter	Royal Melbourne Hospital
Humphreys	Ian	Australian Red Cross Blood Services
Ireland	Susan	Department for Health and Ageing, South Australia
Iris	Ashley	Fiona Stanley Hospital
Isaacs	Kim	Kimberly Aboriginal Medical Services
Jamieson	Andrew	Western Australia Country Health Service
Jansz	Paul	St Vincent's Hospital Sydney
Jaques	Bryon	Sir Charles Gairdner Hospital
Javorsky	George	The Prince Charles Hospital
Jeffrey	Gary	Sir Charles Gairdner Hospital Liver Foundation of Western Australia
Jesudason	Shilpa	Royal Adelaide Hospital Women's and Childrens Hospital Adelaide Kidney Health Australia

Last Name	First Name	Organisation/s
Jones	Sarah	DonateLife NT Royal Darwin Hospital
Jones	Robert	The Austin Hospital
Kanellis	John	Monash Health Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Kausman	Joshua	The Royal Children's Hospital Melbourne Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Kawanishi	Yujiro	St Vincent's Hospital Sydney
Kirkland	Geoff	Royal Hobart Hospital
Knighton	Michael	Australian Government Department of Human Services
Kusic	Rada	NSW Ministry of Health
Lamberton	Tim	Aussie Transplant Mates
Larbalestier	Robert	Fiona Stanley Hospital, Royal Perth Hospital
Larkins	Nicholas	Princess Margaret Hospital Perth Children's Hospital
Laver	Heylen	DonateLife SA
Lawton	Paul	Menzies Institute for Medical Research
Lee	Darren	Epworth Eastern Hospital Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Levin	Adeera	International Society of Nephrology
Levvey	Bronwyn	The Alfred Hospital
Lewton	Andrew	Unknown at this time
Lim	Wai	Sir Charles Gairdiner Hospital
Ludlow	Marie	Kidney Health Australia
Lusis	Nadia	Victorian Aboriginal Community Controlled Health Organisation (VACCHO)

Last Name	First Name	Organisation/s
Luxton	Grant	NSW Organ and Tissue Donation Service
Lynch	Stephen	Princess Alexandra Hospital
Lyon	Louise	Victorian Aboriginal Community Controlled Health Organisation (VACCHO)
MacDonald	James	NACCHO
Majoni	William	Royal Darwin Hospital Menzies School of Health Research
Malouf	Monique	St Vincent's Hospital Sydney
McCaughan	Geoff	ShareLife, Royal Prince Alfred Hospital
McDonald	Stephen	Royal Adelaide Hospital Australia and New Zealand Dialysis and Transplantation Registry (ANZDATA)
McDonald	Mark	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
McDonald	Kelli	QIMR Berghofer Medical Research Institute
McDowell	Bruce	Donor Families Australia
McEvoy	Leanne	DonateLife VIC, Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
McGiffin	David	The Alfred Hospital
McGinn	Stella	Royal North Shore Hospital
Mendal	Joy	Tasmanian Department of Health and Services
Michell	Ian	St Vincent's Hospital Melbourne Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Mitchell	Amanda	Aboriginal Health Council of South Australia
Moodie	Stewart	DonateLife SA
Murphy	Lisa	Kidney Health Australia
Myerson	Brian	ShareLife
Nesbitt	Amanda	Department for Health and Ageing, South Australia
Neville	Sarah	Independent Hospital Pricing Authority
Northam	Holly	Donor Families Australia, DonateLife ACT
Nowrojee	Sharon	North Metropolitan Health Service WA, Western Australia Department of Health
Nunnink	Leo	DonateLife Queensland
O'Connell	Philip	Westmead Hospital
O'Leary	Michael	Royal Prince Alfred Hospital NSW Organ and Tissue Donation Service

Last Name	First Name	Organisation/s
Opdam	Helen	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Paizis	Kathy	Austin Health, Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Palk	Nigel	SA Health, Australasian Transplant Coordinators Association
Park	Shelly	Australian Red Cross Blood Services
Perry	Greg	Royal Perth Hospital
Peter	MacDonald	St Vincent's Hospital Sydney
Pilcher	David	The Alfred Hospital
Pollock	Carol	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Powell	Bruce	Donatelife WA
Price	Terri	Queensland Health
Pussell	Bruce	ShareLife, Prince of Wales Hospital Sydney
Radford	Sam	DonateLife VIC Austin and Warringal Private hospitals
Ray	Soumya	Royal Perth Hospital, DonateLife WA
Richards	Gregory	Queensland Health
Robins	Anthony	Western Australia Country Health Service
Russ	Graeme	Royal Adelaide Hospital
Saunder	Alan	St John of God Berwick Hospital
Shackel	Nicholas	Liverpool Hospital
Shun	Albert	Children’s Hospital Westmead
Silvester	William	Australian and New Zealand Intensive Care Society, DonateLife VIC
Smith	Melissa	Donatelife WA
Snell	Greg	The Alfred Hospital
Spurrier	Nicholas	Department for Health and Ageing, South Australia
Stacey	James	Kimberly Aboriginal Medical Services
Stacey	Sharon	Princess Margaret Hospital
Starkey	Graham	The Austin Hospital
Steele	Nick	Queensland Health
Storman	Michael	Children’s Hospital Westmead
Taylor	Eileen	Queensland Health
Tesar	Peter	St Andrew's War Memorial Hospital Brisbane

Last Name	First Name	Organisation/s
Thomas	Gordon	The Children's Hospital at Westmead
Thomas	Chris	Transplant Australia
Thornton	Lisa	Unknown at this time
Thwaites	Stephen	Monash Health
Tobin	Patrick	The Royal Australasian College of Physicians
Towns	Susan	DonateLife TAS
Trotter	Michael	Metro North Hospital and Health Service
Turner	Andrew	DonateLife TAS Royal Hobart Hospital
Vago	Angela	Austin Hospital
van Hardeveld	Emma	The Royal Melbourne Hospital, Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
van Haren	Frank	DonateLife ACT Canberra Hospital
Verran	Deborah	Royal Prince Alfred Hospital
Warrillow	Stephen	Austin Health, Australia and New Zealand Intensive Care Society
Washer	Mal	Australian Organ and Tissue Donation and Transplantation Authority (OTA)
Weinman	Marvin	ShareLife
Westall	Glen	The Alfred Hospital
White	Lisa	Australian Government Department of Human Services
Whitlam	John	Austin Health Victorian & Tasmanian Renal Transplant Advisory Committee (VTRTAC)
Whyman	Nola	Department for Health and Ageing, South Australia
Williamson	Geoffrey	Western Australia Country Health Service
Wilson	Kate	Australian Red Cross Blood Services
Wilson	Gabrielle	Victorian Department of Health and Human Services
Wood	Lee	DonateLife NT
Wright	Kerr	Kimberly Aboriginal Medical Services
Wyburn	Kate	Royal Prince Alfred Hospital

Appendix C: List of documents, data and literature reviewed

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Appendix D: Guidelines, standard operating procedures and governance structure for each element of donation retrieval and transplantation

	Element 1 Initial assessment and waitlist management (potential recipient)	Element 2 Deceased donation (potential donor)	Element 3 Organ allocation	Element 4 Organ offer	Element 5 Organ acceptance	Element 6 Retrieval (donor)	Element 7 Transplantation (recipient)	Element 8 Post Transplant-ation (recipient)
Guidelines and Standard Operating Procedures	• NHMRC, 2016, *'Ethical Guidelines for Organ Transplantation from Deceased Donors'*, 2016 Version 1.0 • TSANZ, 2017, *'Clinical Guidelines for Organ Transplantation from Deceased Donors'*, May 2017 Version 1.1	• NHMRC, 2016, *'Ethical Guidelines for Organ Transplantation from Deceased Donors'*, 2016 Version 1.0 • TSANZ, 2017, *'Clinical Guidelines for Organ Transplantation from Deceased Donors'*, May 2017 Version 1.1 • ANZICS, 2013, *'ANZICS Statement on Death and Organ Donation'*, Edition 3.2, 2013 • ANZICS, XXXX, *'Statement on Brain Death Determination'*, XXXX • ANZICS, XXXX, *'Statement on Circulatory Death Determination' XXXX* • ANZICS, 2014, *'Statement on Care and Decision Making at the End of Life for the Critically Ill'*, 2014 • OTA, 2010, *'National Protocol for Donation after Cardiac Death'*, July 2010 • OTA, 2017, *'Best Practice Guideline for Offering Organ and Tissue Donation in Australia'*, June 2017 • TSANZ, 2017, *'Clinical Guidelines for Organ Transplantation from Deceased Donors'*, May 2017 Version 1.1 • OTA, 2016, 'Australian *Vigilance and Surveillance Framework for Program Donation for Transplantation,'* September 2016, Version 1.0ATCA Guidelines 4th Edition 2008	• TSANZ, 2017, *'Clinical Guidelines for Organ Transplantation from Deceased Donors'*, May 2017 Version 1.1 (Appendices - algorithms payback) • ATCA, 2017, *'National Standard Operating Procedures – Organ Allocation, Organ Rotation, Urgent Listing, Auditing Process'*, Version 2.1 ATCA-TSANZ SOP 001/2017	• NHMRC, 2016, *'Ethical Guidelines for Organ Transplantation from Deceased Donors'*, 2016 Version 1.0 • ATCA, 2017, *'National Standard Operating Procedures – Organ Allocation, Organ Rotation, Urgent Listing, Auditing Process'*, Version 2.1 ATCA-TSANZ SOP 001/2017	• ATCA, 2017, *'National Standard Operating Procedures – Organ Allocation, Organ Rotation, Urgent Listing, Auditing Process'*, Version 2.1 ATCA-TSANZ SOP 001/2017	• TSANZ, 2017,*'Guidelines for Hospitals to Assist Credentialing of Transplant Surgeons in Australia and New Zealand,'* Version 1.01.0,May 2017 • ATCA, 2016, *'National Standard Operating Procedures – Packaging, Labelling, Storage and Documentation of Deceased Vessels,'* Version 2.0, 2016 ATCA-TSANZ SOP 003/2016 • ATCA Guidelines 4th Edition 2008	• ATCA, 2016, *'National Standard Operating Procedures – Packaging, Labelling, Storage and Documentation of Deceased Vessels,'* Version 2.0, 2016 ATCA-TSANZ SOP 003/2016 • ATCA Guidelines 4th Edition 2008TSANZ, 2017,*'Guidelines for Hospitals to Assist Credentialing of Transplant Surgeons in Australia and New Zealand,'* Version 1.0, May 2017	-

	Element 1 Initial Assessment & Waitlist Management (Potential Recipient)	Element 2 Deceased Donation (Potential Donor)	Element 3 Organ Allocation	Element 4 Organ Offer	Element 5 Organ Acceptance	Element 6 Donated cadaveric organ retrieval (Donor)	Element 7 Transplantation (Recipient)	Element 8 Post Transplantation (Recipient)

Oversight and Governance	• Transplant Society Australia & New Zealand (TSANZ) Council
	• Society of Nephrologists (ANZSN)
	• Transplant Liaison Reference Group (TLRG)
	• Transplant Society Australia & New Zealand (TSANZ) Council
	• Cardiac AC
	• Liver & Intestinal AC
	• Lung AC
	• Paed AC
	• Pancreas & Islet AC
	• Renal Transplantation Advisory Committee (RTAC)
		• OTA JAG
		• OTA Vigilance & Surveillance Expert Advisory Committee
		• Australian and NZ Intensive Care Society (ANZICS)
		• College of Intensive Care Medicine of Australia and NZ (CICM)
			• Australasian Transplant Coordinators Association (ATCA)
			• State based transplant Advisory Committees
			• Transplant Liaison Reference Group (TLRG)
			• Transplant Society Australia & New Zealand (TSANZ) Council –
			• Cardiac AC
			• Liver & Intestinal AC
			• Lung AC
			• Paed AC
			• Pancreas & Islet AC
			• Renal Transplantation Advisory Committee (RTAC)
				• Australasian Transplant Coordinators Association (ATCA)
				• State based transplant Advisory Committees
				• Transplant Liaison Reference Group (TLRG)
				• Transplant Society Australia & New Zealand (TSANZ) Council –
				• Cardiac AC
				• Liver & Intestinal AC
				• Lung AC
				• Paed AC
				• Pancreas & Islet AC
				• Renal Transplantation Advisory Committee (RTAC)
					• Australasian Transplant Coordinators Association (ATCA)
					• Advisory Committees
					• Transplant Liaison Reference Group (TLRG)
					• Transplant Society Australia & New Zealand (TSANZ) Council –
					• Cardiac AC
					• Liver & Intestinal AC
					• Lung AC
					• Paed AC
					• Pancreas & Islet AC
					• Renal Transplantation Advisory Committee (RTAC)
						• Australian College of Perioperative Nurses (ACORN)
						• Australasian Transplant Coordinators Association (ATCA)
						• Royal Australian College of Surgeons (RACS)
						• Transplant Nurses' Association (TNA)
						• Transplant Society Australia & New Zealand (TSANZ) Council –
						• Donor Surgeons/ Donor Coordinator Advisory Committee(DSDCC)
						• Cardiac AC
						• Liver & Intestinal AC
						• Lung AC
						• Paed AC
						• Pancreas & Islet AC
						• Renal Transplantation Advisory Committee (RTAC)
							• Australian College of Perioperative Nurses (ACORN)
							• Royal Australian College of Surgeons (RACS)
							• State based transplant Advisory Committees
							• Transplant Liaison Reference Group (TLRG)
							• Transplant Nurses' Association (TNA)
							• Transplant Society Australia & New Zealand (TSANZ) Council
							• Donor Surgeons/ Donor Coordinator Advisory Committee(DSDCC)
							• Cardiac AC
							• Liver & Intestinal AC
							• Lung AC
							• Paed AC
							• Pancreas & Islet AC
							• Renal Transplantation Advisory Committee (RTAC)
								• Australia & NZ Organ Donation Registry (ANZOD) and Organ Specific Registries
								  • Dialysis and Transplant Registry (ANZDATA)
								  • Islet and Pancreas Transplant Registry (ANZIPTR),
								  • Australia and New Zealand Liver Transplant Registry (ANZLTR)
								  • Society of Nephrologists (ANZSN)
								  • Cardiothoracic Organ Transplant Registry (ANZCOTR)
								• Community groups
								  • Transplant Australia
								  • Kidney Health Australia
								• Transplant Liaison Reference Group (TLRG)
								• Transplant Nurses' Association (TNA)
								• Transplant Society Australia & New Zealand (TSANZ) Council
								• Donor Surgeons/ Donor Coordinator Advisory Committee(DSDCC)
								• Cardiac AC
								• Liver & Intestinal AC
								• Lung AC
								• Paed AC
								• Pancreas & Islet AC
								• Renal Transplantation Advisory Committee (RTAC)
								• Vigilance & Surveillance Expert Advisory Committee

Appendix E: Terms of Reference

The Terms of Reference for the 2015 Review were as follows:

A. Having regard for the objectives and elements that were agreed by COAG when endorsing the national reform agenda in 2008 (see below), and the goals that governments subsequently endorsed, the review will investigate and report on:

1. How effectively the program has been:

(a) led by the OTA, particularly through:

i. translating the national agenda into programs;

ii. communicating program aims, and negotiating program methods with states and territories and other relevant stakeholders; and

iii. monitoring and reporting on performance.

(b) translated into policy and practice by state health authorities and DonateLife agencies

(c) delivered by hospitals and DonateLife and other staff directly involved in the donation or transplantation of organs.

2. The key factors that have influenced the pace and extent of the achievements to date.

3. The relevance and utility/value of: the performance and progress reports issued about the Program, and; the measures used to assess and report on performance, progress and achievement against targets.

B. In light of findings in relation to (A), the review will make recommendations on any changes in the design, administration, delivery, monitoring, reporting, or other aspect of the Program that would improve:

1. progress towards, and achievement of, the national goals and targets; and/or

2. value for money.

C. The review will have regard to:

1. Australian Healthcare Associates, Organ and Tissue Donation Reform Package, Mid-Point Review Report, July 2011.

2. Australian Government, Response to the Mid-Point Implementation Review of the National Reform Agenda – a World's Best Practice Approach to Organ and Tissue Donation in Australia.

3. Australian National Audit Office, Report No.33, 2014–15, Performance Audit Organ and Tissue Donation: Community Awareness, Professional Education and Family Support, Australian Organ and Tissue Donation and Transplantation Authority, April 2015.

D. In addition to reviewing relevant data and written information, the reviewers will consult with:

1. The Chief Executive Officer and the Chair and members of the Advisory Council of the OTA

2. Relevant executives in State and Territory Departments and Ministries of Health

3. Relevant executives in Local Hospital Networks and public hospitals

4. Relevant lead clinicians in participating public hospitals

5. Other key stakeholders as identified by the reviewers.

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