Review of the implementation of the national reform agenda on organ and tissue donation and transplantation

Department of Health

August 2015

Building a better working world

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Acronyms and abbreviations

ACT	Australian Capital Territory
ADAPT	Australasian Donor Awareness Programme
AIHW	Australian Institute of Health and Welfare
AKX	Australian Kidney Exchange Programme
ANAO	Australian National Audit Office
ANZOD	Australia and New Zealand Organ Donation Registry
AODR	Australian Organ Donor Register
AOMS	Australian Organ Matching System
CALD	Culturally and Linguistically Diverse
CEO	Chief Executive Officer
CGF	Clinical Governance Framework
CHC	Council of Australian Governments Health Council
COAG	Council of Australian Governments
CPIP	Clinical Practice Improvement Programme
DBD	Donation after Brain Death
DCD	Donation after Circulatory Death
dpmp	Deceased donors per million population
EDR	Electronic Donor Record
FDC	Family Donation Conversation
ICU	Intensive Care Unit
IDAT	Introductory Donation Awareness Training
IHPA	Independent Hospital Pricing Authority
NOMS	National Organ Matching System
NSW	New South Wales
NT	Northern Territory
ODHSF	Organ Donation Hospital Support Funding
OTA	Organ and Tissue Authority
PEP	Professional Education Package
Qld.	Queensland
SA	South Australia
Tas.	Tasmania
Vic.	Victoria
WA	Western Australia
YTD	Year to date

Executive summary

On the 26 of May 2015, a review of the current Australian organ and tissue donation and transplantation programme (the 'Review') was announced by the Assistant Minister for Health. EY were appointed to undertake the Review in June 2015. The purpose of the Review was to examine the implementation of the national reform agenda on organ and tissue donation and transplantation, with reference to the role of the Australian Organ and Tissue Donation and Transplantation Authority (known as the 'Organ and Tissue Authority', OTA) and the wider health system's response. The Review comprised an extensive consultation process, which was supplemented by document and data review and the consideration of submissions provided by stakeholders.

Organ donation for transplantation in Australia and the national reform programme for organ and tissue donation for transplantation

The Australian organ and tissue donation system is based on an opt-in model, where individuals voluntarily record their consent or objection to becoming an organ and/or tissue donor on the Australian Organ Donor Register (AODR); however agreement from a donor's next of kin is also sought before donation proceeds.

On 2 July 2008, the Australian Government announced a national reform programme to implement a world's best practice approach to organ and tissue donation for transplantation; committing $151.1 million over four years (2008–2012) to improve access to transplants through a nationally coordinated approach to organ and tissue donation.

The Australian national reform programme aims to improve access to transplants for Australians through a sustained increase in the donation of organs and tissues. The two objectives of the national reform programme are to: (1) increase the capability and capacity within the health system to maximise donation rates; and (2) raise community awareness and stakeholder engagement across Australia to promote organ and tissue donation.

There are nine measures which form part of the national reform programme;[1] these activities are managed by the OTA through the DonateLife Network, in partnership with state and territory governments, eye and tissue banks, community organisations and the broader donation and transplantation clinical sectors.

The Organ and Tissue Authority and DonateLife Network

On 1 January 2009, the OTA was established to manage the implementation of the national reform programme. OTA has overall national responsibility for the implementation of the nine Council of Australian Governments (COAG) reform measures, working in collaboration with state and territory based DonateLife Agencies. The OTA has a three-tier committee structure in place to provide advice to OTA's Chief Executive Officer (CEO): (1) programme governance and advice, comprising the Advisory Council and Jurisdictional Advisory Group; (2) committees established by the CEO to provide sector specific advice and liaison, comprising the Clinical Governance Committee, Transplant Liaison Reference Group and DonateLife Partners Committee; and (3) purpose-specific working groups which are established by the CEO as required.

The DonateLife Network was also established in 2009 to provide a coordinated approach to organ and tissue donation for transplantation; it currently comprises a national network of DonateLife

[1] (1) Establish a new national approach and system for organ and tissue donation, including a national authority and network of organ and tissue donation agencies; (2) Establish specialist hospital staff and systems dedicated to organ donation; (3) Provide new funding for hospitals; (4) Provide national professional education and awareness; (5) Provide coordinated, ongoing community awareness and education; (6) Provide support for donor families; (7) Establish a safe, equitable and transparent donation and transplantation network; (8) National eye and tissue donation and transplantation; (9) Undertake additional national initiatives, including living donation programs.

Agencies and hospital-based medical and nursing staff across 77 hospitals[2] to work specifically on organ and tissue donation. The OTA provides Australian Government funding to each state and territory government to employ DonateLife staff through two-year funding agreements. This requires each jurisdiction to maintain a nationally consistent organ and tissue donation service delivery model and includes a performance and reporting framework enabling monitoring of progress in each jurisdiction.

Data is collected through the DonateLife Audit and is used to quantify state and national potential for organ donation, identify missed donation opportunities, and determine the consent rate for organ donation.[3] It also allows for individual hospital performance to be analysed. Data is also collected through the Australia and New Zealand Organ Donation (ANZOD) Registry which records and reports on organ donation within Australia and New Zealand on a monthly and annual basis.

Key findings and recommendations

Strategy

The strategy to increase organ donations, as detailed in the *Organ and tissue donation for transplantation in Australia: 2014-2018 Strategic plan* is sound; however there is still significant room for improvement of donation rates going forward. In order to see a substantial improvement in donation for transplantation rates, and to meet the national donation target (25 donors per million population, 'dpmp' by 2018)[4], there needs to be effective implementation and monitoring of the strategy nationally. Further improvement in performance can be achieved through implementation of the relevant May 2015 budget enhancements, the 2015-2016 strategic priorities and the strategic intention to progress towards allocation of donated organs on a national basis.

These strategies for improved performance must be underpinned by additional performance reporting. Including completion rates of Family Donation Conversation (FDC) training by Intensive Care Unit (ICU) staff and national public reporting by the DonateLife Network on the number of living kidney donations, both of which are required to ensure the complete picture of transplantation is published.

Recommendations are:

- Recommendation 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 in the Targeted Hospital Improvement Programme. In addition, the DonateLife Network should continue to implement the other 2015-2016 strategic priorities.
- Recommendation 2: The OTA, DonateLife Network and transplantation sector should continue to progress the allocation of donated organs on national basis, following the implementation of the Australian Organ Matching System (AOMS).
- Recommendation 3: The proportion of ICU specialists, staff and trainees who participate in the FDC Workshops should be monitored by the DonateLife Network by hospital.
- Recommendation 4: The number of living kidney donations should be reported and reviewed by the DonateLife Network and reported on the OTA's website.

Governance

Current governance arrangements for the OTA are advisory in nature only and do not provide any strategic oversight, performance monitoring, succession planning or mentoring of the CEO. The Review found that stakeholders were generally in support of the establishment of a Board of governance for the OTA who would be responsible for these functions (noting that legislative

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[2] 77 hospitals as at 31 March 2015

[3] Consent rate - Number of consents as a proportion of the number of requests made of potential donors.

[4] dpmp - 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.

amendments would be required). Some concerns were raised by a number of stakeholders over the observed 'defensiveness' of the OTA and tendency to limit debate about controversial issues; however, a Board of governance should foster a culture of debate within the DonateLife Network and the OTA.

Recommendations are:

- Recommendation 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.
- Recommendation 6: The Chair of the Board of governance should be an experienced leader of public hospital organisations, but need not be a clinician.
- Recommendation 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.
- Recommendation 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 Council of Australian Health Governments Health Council (CHC) members.
- Recommendation 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 governance operations.

Performance of the national reform programme

Prior to the implementation of the national reform programme, Australia's donor rate remained relatively constant at around 10 dpmp; it currently sits at 16.1 dpmp. Whilst Donation after Brain Death (DBD)[5] rates have declined in the last 18 months, Death after Circulatory Death (DCD)[6] rates, clinical tissue donation volumes and paired kidney exchange rates have continued to increase steadily.

The decline in DBD rates was evident in 2014 in NSW, WA and Qld. However, data for 2015 (through to end July 2015) indicates that five of eight jurisdictions have already improved on their 2014 performance.

The implementation of enhancements funded in the 2015 federal budget, along with continued implementation of a range of improvement strategies, should result in an improvement of donation rates; however, this is subject to effective implementation by the jurisdictions. Whilst performance data are distributed widely within the DonateLife Network, the Review found there is a need to publish performance data more prominently and in a more accessible form, this would help improve the understanding of the performance of the programme in the community.

Recommendations are:

- Recommendation 10: The OTA should prominently publish the following data on the performance of the Donate Life Network:
  - Donation rates by jurisdiction – quarterly for NSW, Qld., Vic., SA and WA and annually for Tas., ACT and NT
  - Numbers of people on the transplant 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

[5] DBD - Organ donation after brain death that has been determined on the basis of irreversible cessation of all brain function

[6] Organ donation after circulatory death that has been determined on the basis of irreversible cessation of blood circulation

(appropriately risk adjusted) by hospital.

- Recommendation 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.

Audit of donation practices

The DonateLife Audit is intended to provide a nationally consistent method of retrospectively auditing all deaths in DonateLife Network hospitals and is a management tool for driving performance improvement. The Review found that the national DonateLife Audit is comprehensive (with the planned inclusion of DCD donors) and allows a detailed assessment of donation practice at DonateLife Network participating hospitals; however, there is variability in the practice of audit. Clinicians also indicated that the audit could benefit from the inclusion of referrals for donation which would allow a more complete picture of intended and actual donors. The Review was not presented with any evidence that questioned the integrity of the data used in the audits.

Recommendations are:

- Recommendation 12: The DonateLife Network, led by the OTA, should define minimum standards for auditing of organ donation practices and seek the endorsement of CHC for these standards.
- Recommendation 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.

Funding policy

Organ Donation Hospital Support Funding, (ODHSF) provides a contribution towards the costs associated with organ donation activity using data provided by the Australia and New Zealand Organ Donation Registry (including the additional costs of Emergency Department and ICU beds for potential donors and costs related to donor clinical management and assessment of medical suitability such as pathology and imaging).The ODHSF provides a contribution towards the costs associated with organ donation activity. However, there are notable issues in the current funding arrangements, such as the cost of tissue typing and the surgical procedures for organ retrieval, transportation and transplantation activity which is currently borne by the states and territories.

Recommendations are:

- Recommendation 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.
- Recommendation 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 Independent Hospital Pricing Authority (IHPA) Pricing Framework as an in-scope public hospital service, noting that this is a proposal which is already being considered.

Awareness strategies, communication and donor family support

The national DonateLife Community Awareness and Education Programme aims to ensure a nationally consistent, evidence-based approach to communications about organ and tissue donation for transplantation. Awareness strategies are currently primarily focussed on local communication strategies, DonateLife week and the community grants programme; there has not been a national awareness campaign since 2010-2012. The Review received compelling and valued input from donor families, and while many of the individual donation experiences pre-dated the establishment of the OTA, the experiences remain relevant – including concern about the DonateLife logo and its similarity to recycling logos. The Review also noted that the impending improvement in the functionality of the AODR is an opportune time to promote the registry and that this would be a useful point for a national communication campaign.

Recommendations are:

- Recommendation 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.
- Recommendation 17: The proposed Board of governance should consider the DonateLife Community Awareness and Education Programme annually, including the Stakeholder Engagement Framework, to ensure a nationally consistent, evidence-based approach to communications about organ and tissue donation for transplantation.
- Recommendation 18: The OTA should consider revising 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.

Community Awareness Grants Programme

The Community Awareness Grants Programme forms part of the DonateLife Community Awareness and Education Programme; it provides funding for community-based awareness and education activities that contribute to increasing public understanding of, and support for, organ and tissue donation for transplantation. The Review found that the programme is an effective strategy to improve community awareness of the organ and tissue donation programme at the local level; but it was noted that the selection criteria for grant recipients had not been reviewed by the OTA Advisory Council prior to the call for applications.

Recommendations are:

- Recommendation 19: The proposed Board should consider the key criteria for selection of grant recipients prior to the commencement of the grant recipient selection process.

Australian Organ Donor Registry

The number of Australians who have voluntarily registered their intention to donate on the AODR is low (6,109,711), while the number of these individuals who have provided their consent is even lower (1,833,085).[7] The AODR provides a very useful platform for the consent conversation and results in higher consent rates among those registered than those who aren't registered. For example, when a donor has registered their wishes, there is a 90% consent rate.[8] The funded enhancement to the AODR will allow for a significant improvement in the consent process and is likely to result in a rapid improvement in enrolment numbers.

Recommendations are:

- Recommendation 20: Once the enhancement to the AODR is fully operational, a further campaign to increase enrolment should be undertaken as planned, noting there may be funding implications.

Electronic Donor Record

The Electronic Donor Record (EDR) was launched on 31 March 2014 following a two-year development and implementation period. It provides a national web-based information system to support the management and sharing of donor information required for organ and tissue referral and donation. The EDR implementation has been well received by the clinicians who use the record; however some further improvements will enhance the effectiveness and efficiency of the EDR, such as inclusion of referrals and improved access to information for clinical use.

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[7] As at 30 June 2015 and includes Intent Registrations of 16 and 17 year olds: http://www.humanservices.gov.au/corporate/statistical-information-and-data/australian-organ-donor-register-statistics/

[8] 2014 DonateLife Audit

Recommendations are:

- Recommendation 21: The EDR should be enhanced as planned to record all referrals to the Donate Life Network (not only those that proceed to donation) and the reasons for any decision not to proceed to donation.
- Recommendation 22: States and territories through the CHC 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.

New organ perfusion technologies

There are emerging ex vivo perfusion technologies that have the potential for organ resuscitation and reconditioning, potentially increasing the quality and number of organs available for transplantation. Currently there is variable use of these technologies in Australia; however it is an emerging technology and further evaluation of its effectiveness and benefits needs to be further explored.

Recommendations are:

- Recommendation 23: The effectiveness of organ perfusion technologies should be evaluated by AHMAC and the CHC and consideration given to their ongoing utilisation in the future, with costs reflected in the retrieval services IHPA price recommended at Recommendation 15.

Eye and tissue donation and transplantation

Currently, there are a variety of processes and models adopted by jurisdictions related to funding, administrative structures, donor selection, consent approaches and data management systems for retrieval, processing and storage, and distribution of eye and tissue products. There is opportunity for a national and standardised approach to the supply of tissue for donation through alignment of human tissue legislation across states and territories. An economic assessment of eye and tissue donation is soon to be undertaken by the OTA; allowing eye and tissue banks, jurisdictional health departments and other key stakeholders to respond to the financial, regulatory and efficiency challenges facing the sector.

Recommendations are:

- Recommendation 24: Following the completion of the Economic Analysis of the Eye and Tissue Sector, through the CHC, 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.

Conclusion

Since the implementation of the national reform programme in 2009, there has been an overall increase in the dpmp by 41% (11.4 dpmp in 2009 compared to 16.9 dpmp in 2014). While there has been some improvement as a result of the programme, the OTA and other stakeholders recognise there is a need for substantial improvement in performance if the goal of 25 dpmp by 2018 is to be achieved.

Despite a drop off in donation rates in 2014, performance in 2015 is looking stronger – with a number of jurisdictions having outperformed their July YTD 2014 outcomes. The challenge will be in maintaining and growing the current momentum in performance. The implementation of relevant enhancements funded in the 2015 federal budget, the priority areas outlined in the *Organ and tissue donation for transplantation in Australia 2014-2018 strategic plan*, along with continued implementation of a range of improvement strategies - should help facilitate further improvement of donation for transplantation rates.

However there also needs to be strong joint leadership from the OTA, the DonateLife Network and State and Territory Health Departments along with open and transparent dialogue – all of which is underpinned by further enhanced data collection, monitoring of performance and subsequent action. In addition, there are a range of improvements identified by the Review which would also facilitate the progress towards, and achievement of the national goals and targets.

1. Introduction and Terms of Reference

1.1 Review of the implementation of the national reform agenda on organ and tissue donation and transplantation

A review of the current organ and tissue donation and transplantation programme (the 'Review') was announced on 26 May 2015 by Assistant Minister for Health, the Hon Fiona Nash. The purpose of which was to review the implementation of the national reform agenda on organ and tissue donation and transplantation, with reference to the role of the Organ and Tissue Authority (OTA) and the wider health system's response.

EY were appointed to undertake the Review, led by Dr Tony Sherbon. The Review commenced in June 2015 and was completed on 31 July 2015. The review team undertook an extensive consultation process (see Appendix A for stakeholders consulted), which was supplemented by document and data review, and the review of submissions provided by stakeholders. Further detail on the Review approach is outlined in Section 1.3).

1.2 Terms of Reference for the Review

The Terms of Reference for the 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 programme has been:
        (a) led by *OTA*, particularly through:
            i. translating the national agenda into programmes;
            ii. communicating programme aims, and negotiating programme 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 Programme, 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 Programme 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.

1.3 Review approach

The Review comprised an extensive consultation process, which was supplemented by document and data review, and the review of submissions provided by stakeholders

Consultations were undertaken through a combination of face-to-face and telephone interviews, and included both group and individual consultations. Stakeholders for consultation were initially identified by the Australian Government Department of Health and the OTA, with some additional stakeholders identified by the review team. In addition, the review team was also contacted by stakeholders who wanted to participate in the process.

To facilitate the participation of the large number of stakeholders in the consultation process, group consultations were held across five states (NSW, Vic., Qld., ACT and SA) and included both clinician groups and group consultations with donor families, transplant recipients, those awaiting transplants and community organisations. Over 140 stakeholders were consulted as part of the consultation process.

Stakeholders who participated in the consultation process included:

- The OTA
- The OTA Advisory Council
- DonateLife Network – including Agencies, participating hospital staff
- Jurisdictional Health Departments
- Clinicians – including both donation and transplantation leadership
- Professional bodies
- Community organisations
- Donor families
- Transplant recipients and those awaiting transplants
- Donation/transplant outcome registries
- Eye and tissue banks.

A range of data and documents were reviewed, as well as submissions provided to the review team.

1.4 A guide to the report

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

- Section 2 – describes the background to the national reform programme, along with a summary of the findings of previous reviews
- Section 3 – describes the performance of the national reform programme
- Section 4 – describes the current strategy of the OTA for increasing donation rates
- Section 5 – describes the findings and recommendations of the Review
- Section 6 – describes the conclusion to the Review.

2. Background to the national reform programme and summary of previous reviews

2.1 Organ donation for transplantation in Australia

The Australian organ and tissue donation system is based on an 'informed consent' or opt-in model; requiring individuals to agree to donate their organs and tissue in the event of their death. Anyone over the age of 16 can choose to donate organs and tissues, after death for transplantation.

Few people die in a way that allows them to donate organs as organs for transplantation need to be removed soon after death. This can usually only happen when a person has died in hospital following a severe brain injury (e.g. from a stroke or car accident) or when a person is unable to survive severe injuries or other illnesses.

More people die in a way that means that tissues can be donated. This is because most tissues don't have to be taken from the body straight after death. Tissues can be donated whether or not the person dies in hospital. If they are medically suitable, they can be stored in tissue and eye banks for future use.

The Australian Organ Donor Register (AODR) enables individuals to record their consent or objection to becoming an organ and/or tissue donor. Regardless of whether an individual has provided consent for donation, the practice in Australia is to also seek agreement from a donor's next of kin before donation proceeds. As at 30 June 2015, there were 6,109,711 registrations on the AODR; however the total number of legally valid consent registrations is 1,833,085 (legally valid consent includes the provision of a signed registration form and includes intent registrations of 16 and 17 year olds who, as minors, cannot give their own consent).[9,10]

The number of deceased donors per million population (dpmp) is the most common measure used for international comparisons of performance in organ and tissue donation. Prior to the implementation of the national reform programme, Australia's donor rate remained relatively constant at around 10 dpmp; it currently sits at 16.1 dpmp (see Section 3) for further information on donation rates and performance).

2.2 The national reform programme on organ and tissue donation and transplantation

On 2 July 2008 the Australian Government announced a national reform programme to implement a world's best practice approach to organ and tissue donation for transplantation. This was endorsed by the Council of Australian Governments on 3 July 2008, committing $151.1 million (including $136.4 million in new Australian Government funding) over four years (2008–2012) to improve access to transplants through a nationally coordinated approach to organ and tissue donation. This investment recognised the importance of bridging the gap between the demand for transplantation and the availability of organs and tissues.

The Australian national reform programme aims to improve access to transplants for Australians through a sustained increase in the donation of organs and tissues by implementing a nationally

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[9] As at 30 June 2015: http://www.humanservices.gov.au/corporate/statistical-information-and-data/australian-organ-donor-register-statistics/

[10] Intent registration - occurs when people register their decision to donate through electronic avenues such as the online registration form. Legally valid consent registration - A legally valid consent registration occurs when someone provides a signed registration form to the Australian Organ Donor Register. People aged under 18 years of age can only register intent, in these cases legal consent from the families will still be required.

coordinated approach to organ and tissue donation. Evidence from comparable countries demonstrates that a coordinated national approach, focused on clinical practice reform, improves organ donation and transplantation rates.

The twin objectives of the national reform programme are 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

The nine key elements of the national reform programme, along with the allocation of the $151.1 million in funding across the programme, are described below:

- Measure 1: Establish a new national approach and system for organ and tissue donation - a national authority and network of organ and tissue donation agencies ($46.143m):
  - DonateLife Agencies in each jurisdiction ($20.137m)
  - The OTA ($24.106m operating, $1.9 capital)
- Measure 2: Establish specialist hospital staff and systems dedicated to organ donation ($66.965m)
- Measure 3: Provide new funding for hospitals ($17.129m)
- Measure 4: Provide national professional education and awareness ($0.720m)
- Measure 5: Provide coordinated, ongoing community awareness and education ($13.365m)
- Measure 6: Provide support for donor families ($1.854m)
- Measure 7: Establish a safe, equitable and transparent donation and transplantation network ($0.910m)
- Measure 8: National eye and tissue donation and transplantation ($3.149m)
- Measure 9: Undertake additional national initiatives, including living donation programs ($0.820m).

These activities are managed by the OTA through the DonateLife Network, in partnership with state and territory governments, eye and tissue banks, community organisations and the broader donation and transplantation clinical sectors.

2.3 The Australian Organ and Tissue Donation and Transplantation Authority

On 1 January 2009, the OTA was established to manage the implementation of the national reform programme. The OTA has overall national responsibility for the implementation of the nine COAG reform measures, working in collaboration with the state and territory based DonateLife Network (see Section 2.4 for further information on the DonateLife Network).

The OTA is an independent statutory agency within the Australian Government Health portfolio. It was established by the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*, which sets out the primary responsibilities for the OTA and the functions of the Chief Executive Officer. Within the legislation, the OTA is formally named as the Australian Organ and Tissue Donation and Transplantation Authority, however the Australian Organ and Tissue Donation and Transplantation Authority Regulations 2009 allow it to be also known as the Organ and Tissue Authority – as such, this is the title used in this Review.

The OTA is operated under the *Public Governance, Performance and Accountability Act 2013* and bound by legislated reporting obligations – with all responsibilities invested in the CEO, who reports directly to the Minister for Health (as per the Act). The Assistant Minister for Health has Portfolio responsibility for the OTA. Currently there is no Board of governance responsible for the overall

strategic performance of the organisation; rather there is the Organ and Tissue Authority Advisory Council (the 'Advisory Council') which provides advice to the CEO (see Section 2.3.1).

At 30 June 2015, the OTA employed 23.8 full-time equivalent staff; including a Chief Executive Officer and one Senior Executive Service officer. The governance arrangements for the OTA are outlined in Section 2.3.1. The OTA reports publicly on the implementation of the national reform programme, as well as broader measures associated with organ and tissue donation, through performance reports and its annual report.

The Australian Government announced on 13 May 2014 that OTA would merge with the National Blood Authority by 1 July 2015; this has not yet occurred and did not form part of the scope of the Review.

2.3.1 Governance arrangements for the Organ and Tissue Authority

There are several committees in place to provide advice to OTA's Chief Executive Officer (CEO) on relevant matters related to organ and tissue donation and transplantation in Australia. The OTA has a three-tier committee structure:

1. Programme governance and advice, comprising the:
    - Advisory Council: appointments have been managed by the then Parliamentary Secretary and their role is to provide advice to the OTA's CEO on matters relating to organ and tissue donation and transplantation.[11] The Advisory Council is comprised of individuals who bring a broad range of skills and experience and offer advice in a diverse range of areas.
    - Jurisdictional Advisory Group: is the peak governance committee for the DonateLife Network, chaired by the CEO and comprises State Medical Director and jurisdictional health department representatives. The group considers and makes recommendations to the CEO in respect of strategic priorities, clinical and data governance, planning and leadership of the DonateLife Network, and implementation of the reform programme on organ and tissue donation.
2. Committees established by the CEO to provide sector specific advice and liaison, comprising the:
    - Clinical Governance Committee: is the peak clinical committee for the DonateLife Network and pursues specific clinical issues. The committee is chaired by the National Medical Director and comprises the CEO, State and Territory Medical Directors and Agency/ Clinical/ Operational Managers from each State and Territory. The committee makes recommendations related to the clinical aspects of the national reform programme for consideration by the Jurisdictional Advisory Group.
    - Transplant Liaison Reference Group: provides advice to the CEO and facilitates engagement with the transplant sector on transplantation issues relevant to the national reform programme. Membership comprises the CEO, the National Medical Director and representatives from the Transplantation Society of Australia and New Zealand, Australasian Transplant Coordinators Association, Transplant Australia, Transplant Nurses Association, Australia and New Zealand Organ Donation Registry, and the Australia and New Zealand Intensive Care Society.
    - DonateLife Partners Committee: is the main mechanism for engagement with the non-government sector and comprises representatives from consumer groups as well as professional bodies involved in donation and transplantation.

[11] In August 2012, the second term of the Advisory Council was appointed

3. Purpose-specific working groups such are established by the CEO from time to time and disbanded once the assigned task is accomplished.[12]

2.4 The DonateLife Network

As part of the national reform agenda, state and territory governments agreed to the establishment of a national network of DonateLife Agencies and to employ hospital-based medical and nursing specialists in organ and tissue donation. As such, the DonateLife Network was first established in all jurisdictions in 2009.

The OTA provides Australian Government funding to each state government to employ the DonateLife staff. Funding to the states is provided through two-year funding agreements which require each jurisdiction to maintain an organ and tissue donation service delivery model that is consistent with the national reform approach and in accordance with relevant ethical guidelines and clinical protocols.[13] Funding agreements include an agreed performance and reporting framework to enable the OTA to monitor progress in each jurisdiction.

The National Roles and Responsibility Guidelines, developed by OTA in consultation with the state governments, inform the recruitment of DonateLife staff. At the end of March 2015, the DonateLife Network comprised 270 OTA-funded staff. This included:

- 180 hospital–based medical and nursing specialists for organ and tissue donation in 77 hospitals across Australia
- 90 staff in eight specialist DonateLife Agencies.

DonateLife State Medical Directors are in place in each state and territory, under the leadership of the OTA's National Medical Director. They are responsible for delivery of the national reform programme in their respective jurisdictions. They lead hospital-based staff (medical and nursing specialists in organ and tissue donation), along with DonateLife Agencies that specialise in organ donor coordination, donor family support, education coordination, communication activities and data and audit.

The Clinical Governance Framework (CGF) and Clinical Practice Improvement Programme (CPIP) were developed in consultation with the DonateLife Network, and provide the governance and accountability structure that supports effective implementation of a framework for clinical practice reform in all DonateLife hospitals across Australia. The CPIP provides a structure to support hospital-based doctors and nurses specialising in organ and tissue donation to achieve the objective of further developing clinical capacity and capability to increase organ and tissue donation in DonateLife Network hospitals across Australia. The CPIP provides guidance and key performance indicators for hospital-based organ and tissue donation activity, as well as a system for measuring and reporting on performance to inform ongoing, structured clinical change improvements. All DonateLife Network hospital-based teams have implemented annual local Hospital Activity Plans that address each of the components of the CPIP in their hospitals.

2.5 Registries and the collection of data

2.5.1 The DonateLife Hospital Performance Audit

Implemented in 2010, the DonateLife Audit is a nationally consistent method of retrospectively auditing all deaths in DonateLife Network hospitals. The data obtained from the audit is used to quantify national and jurisdictional potential for organ donation. It also identifies missed donation

[12] Including: the Eye and Tissue Advisory Committee, Data and Audit Working Group, Communications Reference Group, Communications Reference Group, Family Conversations Steering Group, Donor Family Support Implementation Group, and the Education Coordinators Network.

[13] Such as the NHMRC guidelines:
https://www.nhmrc.gov.au/guidelines/publications/subject/Organ%20Donation

opportunities and determines the request, consent and conversion rates[14] for organ donation in DonateLife Network hospitals. The audit data is also pivotal in helping to identify and develop new strategies to improve Australia's organ donation rate. DonateLife Audit data is reported on a quarterly and annual basis. The reports currently comprise data analysis based on DBD.[15] The OTA's Data and Audit Working Group manages the DonateLife Audit and reporting processes in DonateLife Network hospitals.

2.5.2 Registries

The OTA provides funding for the operation of a number of national donation and transplantation registries:

- Australia and New Zealand Organ Donation (ANZOD) Registry – further detail on this registry is provided below
- Australian Corneal Graft Registry
- Australia and New Zealand Cardiothoracic Organ and Transplant Registry
- Australian and New Zealand Dialysis and Transplant Registry
- Australia and New Zealand Liver Transplant Registry
- National Pancreas Transplant Registry

Australia and New Zealand Organ Donation Registry

The ANZOD Registry records and reports on organ donation within Australia New Zealand and was established in 1989 in Australia. The Registry reports monthly on the ANZOD website the numbers of deceased organ donors and the number of recipients benefiting from donation. An annual report is also produced on health outcomes of donation and how Australia and New Zealand compares to international outcomes in organ donation and transplantation. The data from ANZOD forms a core component of reporting on the national reform programme, in addition to the DonateLife Audit.

2.6 Training and education

Following the establishment of the OTA in 2009, there was a concerted effort to provide high quality education to health professionals around Australia on organ and tissue donation and sensitive and effective communication with families about donation. In 2009-2010 the OTA funded DonateLife agencies to employ an Education Coordinator to ensure delivery of education activities in each jurisdiction. On 1 July 2010, the OTA assumed responsibility for management of the General and Medical Australasian Donor Awareness Programme (ADAPT) workshops. The OTA undertook a review of the content of both ADAPT workshops over 2010-2011 to ensure that the information was useful and up to date. Additional initiatives implemented over 2010-2012 included development of a national suite of PowerPoint presentations for the use by DonateLife Network and supported jurisdictional education programs.

The OTA's Professional Education Package (PEP) was introduced in 2012 and provides education and training on supporting families in conversations about the opportunity for organ and tissue donation. It is designed to provide participants with the necessary knowledge and skills to

[14] Request rate - Number of requests of potential donors as a proportion of the total number of potential donors; Consent rate - Number of consents as a proportion of the number of requests made of potential donors; Conversion rate - Number of brain dead donors as a proportion of the number of potential donors with confirmed or probable brain death.

[15] Donation after Brain death (DBD): Organ donation after brain death that has been determined on the basis of irreversible cessation of all brain function

sensitively support grieving families to make an informed, proactive decision about donation. The PEP provides staged training and sequential learning through three units of training:

- ADAPT – includes an e-learning package
- FDC: Core Module – includes a two-day workshop and an e-learning package
- FDC: Practical Module – includes a one-day workshop and an e-learning package

More recently, a one-day workshop has been developed to provide education about organ donation to a multidisciplinary audience of clinicians, social workers and clergy. Introductory Donation Awareness Training (IDAT) has been piloted and will be delivered in the second half of 2015. IDAT will replace the ADAPT workshop and will be offered to professionals working in intensive care, emergency departments and the operating theatre – including medical, nursing, allied health and other support staff.

The OTA has also undertaken work to develop a national model for requesting consent. This has entailed a national pilot across 15 hospitals across 2013-15. A national evaluation of this pilot has been undertaken by an independent academic evaluator and provides data about the validity of using independent trained requestors as part of a collaborative requesting model.

2.7 Findings of previous reviews of the reform programme and performance of the OTA

Two previous reviews have been undertaken of the reform programme and the OTA:

- The organ and tissue donation reform package mid-point review, undertaken by Australian Healthcare Associates and completed in July 2011 (see Section 2.7.1 for further details)
- An audit of community awareness, professional education and family support, undertaken by the Australian National Audit Office (ANAO) and completed in April 2015 (see Section 2.7.2 for further details).

2.7.1 The organ and tissue donation reform package mid-point review[16]

The mid-point implementation review of the national reform package was completed in July 2011 to examine the progress of implementation in 2010; this was the first full year of implementation of the reform measures. The review revealed that the reform package had achieved notable success by the end of 2010, though there was variable progress on implementation of each of the nine measures of the reform agenda (see Table 1).

[16] Australian Healthcare Associates, *Organ and Tissue Donation Reform Package*, *Mid-Point Review Report*, July 2011.

Table 1: Progress achieved on the nine measures of the reform programme

Significant progress made	Moderate progress made	Little progress made
• The Authority and an enhanced network of jurisdictional organ and tissue donation agencies were well established, providing the infrastructure and human resources necessary to deliver a new national approach to donation. • Specialist hospital medical and nursing expertise dedicated to organ donation became available in 77 hospitals nationally • New systems of funding hospitals organ donation costs became operational • A successful community awareness and education campaign was delivered which was well received and changed community awareness and behaviours related to potential for donation • The Australian Paired Kidney Exchange (AKX) programme commenced operation	• Agreement on a framework for nationally consistent support for donor families • Consensus regarding safe, equitable and transparent national transplantation processes • Agreement on a national protocol DCD[17]	• A fit-for-purpose national education and training programme to further develop capacity of the sectors healthcare professionals • Defining and developing the national eye and tissue donation and transplantation network

The mid-point review also found that:

- There were challenges and issues for the OTA in the first two years of operation, relating to issues of staffing, operational style and strategic intent; these were perceived to have negatively impacted implementation of the reform measures.
- There was a significant increase in Australia's deceased donor organ donation rate, with the 309 deceased organ donors in 2010 being the highest number of donors on record. This was largely attributed to a substantial increase in performance by a small number of hospitals in NSW and Vic.
- The review noted that there was significant capacity to see continued growth in national deceased donor organ donation performance, with rates of 23-25 dpmp potentially being achievable. The review described that continued growth would require the reform to deliver a progressive increase in the proportion of high performing donor hospitals, which would be assisted by better targeting of future investment on hospitals that are known to currently have a significant potential for deceased donation.
- The hospitals demonstrating markedly increased donation performance had used the resources made available to them (through Measures One and Two of the 2008 Reform Package) to continue their local efforts to improve deceased donation performance.
- That re-engineering hospital systems to support increased donation rates in an increased number of hospitals, would not occur simply through the addition of resources - but would also require a concerted clinical practice improvement programme with leadership provided at a national, jurisdictional and individual hospital level, with progress in terms of increasing deceased donor numbers, taking time.
- Other areas of improvement identified included:
  - Revision of the membership and mode of operation of the Advisory Council, including a reduction in its size (to nine members and a Chair), a renewed focus on the provision of focused strategic advice, and establishment of mechanisms for providing advice in addition to its quarterly face-to-face meetings

[17] Donation after circulatory death (DCD): Organ donation after circulatory death that has been determined on the basis of irreversible cessation of blood circulation

- Review and refinement of the membership and terms of reference of all governance committees and subcommittees
- Stakeholder forums be reviewed and refined with a view to enhancing communication with the broad stakeholder base
- Identify and articulate the roles, responsibilities and accountabilities of the OTA, the jurisdictions and the DonateLife Network hospital-based teams through a Clinical Governance Framework
- Nationally consistent approaches to performance monitoring (e.g. death audit, audits of clinical trigger tool use, organ utilisation and allocation data) to provide a foundation for national, jurisdictional and hospital-level interventions to drive overall improvements in national deceased organ donation performance.

In response to the recommendations of the Mid-Point Implementation Review, the OTA has:

- Reviewed and refined the OTA and DonateLife Network governance structures including the Advisory Council and other governance committees
- Established agreed Roles and Responsibilities Guidelines for all DonateLife Network positions
- Established a Clinical Governance Framework and Clinical Practice Improvement Programme. In 2015-16 the programme moves into its second phase supported by new Commonwealth funding to include a targeted hospital improvement programme in those hospitals with the greatest potential to increase consent for donation;
- In addition they have embedded the DonateLife Audit, implemented the Clinical Practice Improvement Programme Survey, implemented the Electronic Donor Record, supported the Transplantation Society of Australia and New Zealand in revising the *Consensus Statement on Eligibility Criteria and Allocation Protocols*, and supported the Australian Transplant Coordinators Association in the revision of the Audit of Organ Allocation and Rotation, all of which have subsequently been used to inform interventions to improve national deceased organ donation performance.

2.7.2 Australian National Audit Office report on Organ and Tissue Donation: Community Awareness, Professional Education and Family Support

The ANAO undertook an independent performance audit in early 2015 to assess the effectiveness of the OTAs' administration of: (1) professional education - Measure 4; (2) community awareness - Measure 5; and (3) donor family support activities - Measure 6.

The audit found that:

- The OTA made reasonable progress in implementing all three measures of the national reform programme, including the introduction of a Professional Education Package and National Donor Family Support Service
- The OTA also undertook a range of initiatives to raise community awareness and education about organ and tissue donation and transplant, including engaging with culturally and linguistically diverse (CALD) communities
- The OTA adopted an evidence-based approach to selecting the key message for its $13.8 million national advertising campaign conducted from 2010 to 2012. Tracking research indicated that Phase 1 of the campaign (at a cost of $9.2 million) achieved improved outcomes against the campaign benchmarks, while Phase 2 (at a cost of $4.6 million) delivered a more marginal return on investment, serving largely to help maintain the outcomes of Phase 1.
- The OTA's grants guidelines (for the Community Awareness Grants programme which distributes approximately $500 000 per annum to grant recipients for community awareness and education activities) do not fully outline its grants assessment process

- Since the implementation of the Professional Education Package there have been over 2000 training participants, with the audit noting that:
    - There would be benefit in the OTA continuing to monitor the ongoing effectiveness and reach of the Package by introducing relevant internal performance indicators
    - The OTA could also improve the consistency of the application of the FDC training by confirming which family consent request model should be adopted nationally, and promoting the application of this model through the FDC Workshops
- The absence of suitable performance indicators and related targets to help assess the effectiveness of initiatives across the three reform measures.

The three recommendations from the audit were that the OTA:

- More actively facilitate collaboration between Charter signatories through established forums, in order to further expand the capacity of the organ and tissue donation sector and the reach of community awareness and educational activities
- Review its grant administration to improve transparency and equity, with a particular focus on informing potential applicants of all available sources of grant funding and the assessment process applying to each source
- Improve services provided to donor families, including the families that provided consent but donation did not proceed, in particular:
    - Enhance the existing *Roles and Responsibilities Guidelines and National Organ and Tissue Donor Family Support Service Guidelines* to provide more information about the level of support families should be provided in the hospital setting
    - In consultation with the state and territory governments, introduce internal performance measures to assess the consistency and effectiveness of donor family support services.

The OTA agreed with all of the ANAO's Audit Report recommendations.

3. Performance of the reform programme

Section 2.5 describes the approach to the collection and reporting of data for the programme. This section outlines some of the key indicators of performance for the programme, including:

- Organ donation for transplantation performance, including:
  - deceased organ donation (Section 3.1.1)
  - living organ donation (Section 3.1.2)
  - Jurisdictional performance (Section 3.1.3)
  - International comparisons of performance (Section3.1.4)
- Solid organ transplantation waiting list performance (Section 3.2)
- A summary of key findings of the performance of the national reform programme (Section 3.3).

3.1 Organ donation for transplantation performance

Solid organs (as opposed to human tissue material) can be donated from either live donors (as in the case of kidneys) or deceased donors. Living donors can donate kidneys through either living donation or the Australian Paired Kidney Exchange programme. Donation from deceased donors is obtained after the donor is clinically declared brain dead (Donation after Brain Death, or DBD) or has suffered a circulatory death (Donation after Circulatory Death, or DCD).

3.1.1 National performance of the programme – deceased organ donation

The OTA has analysed Australia's potential deceased organ donor population in 2014, this indicates that:

- In 2014, the Australian population was 23,490,700 with an estimated 149,100 deaths occurring. Of these, approximately 74,400 deaths occurred in hospital, with around 700 potential donors identified – around 1% of hospital deaths
- Requests to families for donation were made in around 680 cases, with approximately 415 consenting to donation
- In just under 40 cases where family consent was given, donation did not proceed for a variety of reasons
- The resulting 378 deceased organ donors enabled 1,193 organs transplantation for 1,117 recipients.

Figure 1 shows the total number of organs transplanted from deceased organ donors (both the actual and trend) from 2009 to year-to-date (YTD) 2015. While there has been significant variation in the number of organs transplanted from deceased donors since 2009, it has been trending upwards overall.

Figure 1: Total organs transplanted from deceased organ donors 2009–YTD 2015 (Source: OTA)

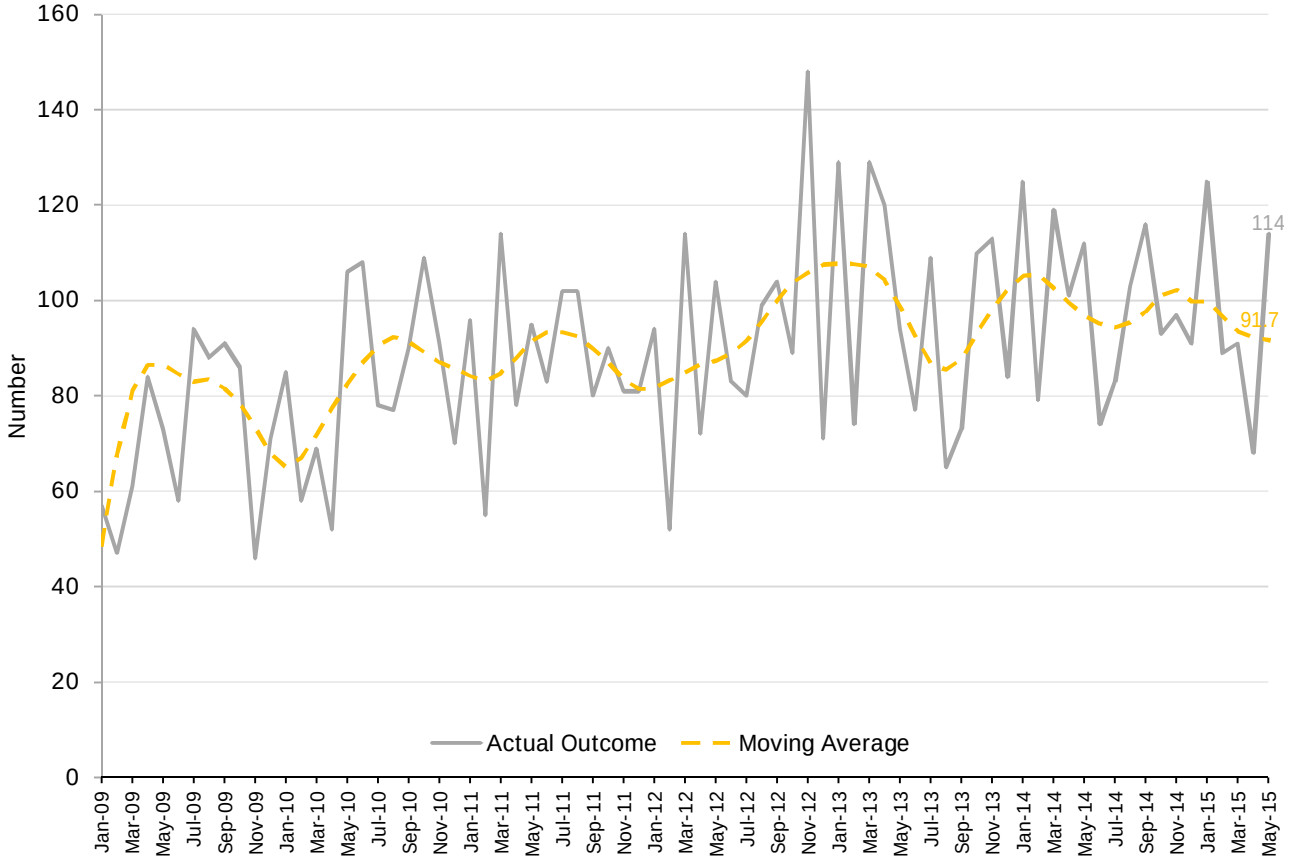


Figure 2 outlines the transplant recipients per million population from living and deceased organ donors, between 2003 and 2014. Overall, it shows that there was a 28% increase in transplant recipients per million population from deceased donors between 2009 and 2014, from 37.2 transplant recipients per million population to 47.6 transplant recipients per million population.

Figure 2 also shows that there has been a downward trend in the number of living donors since 2009, from 15.2 transplant recipients per million population to 11.4 transplant recipients per million population in 2014.

Figure 2: Transplant recipients per million population from living and deceased organ donors, 2003-2014 (Source: OTA)

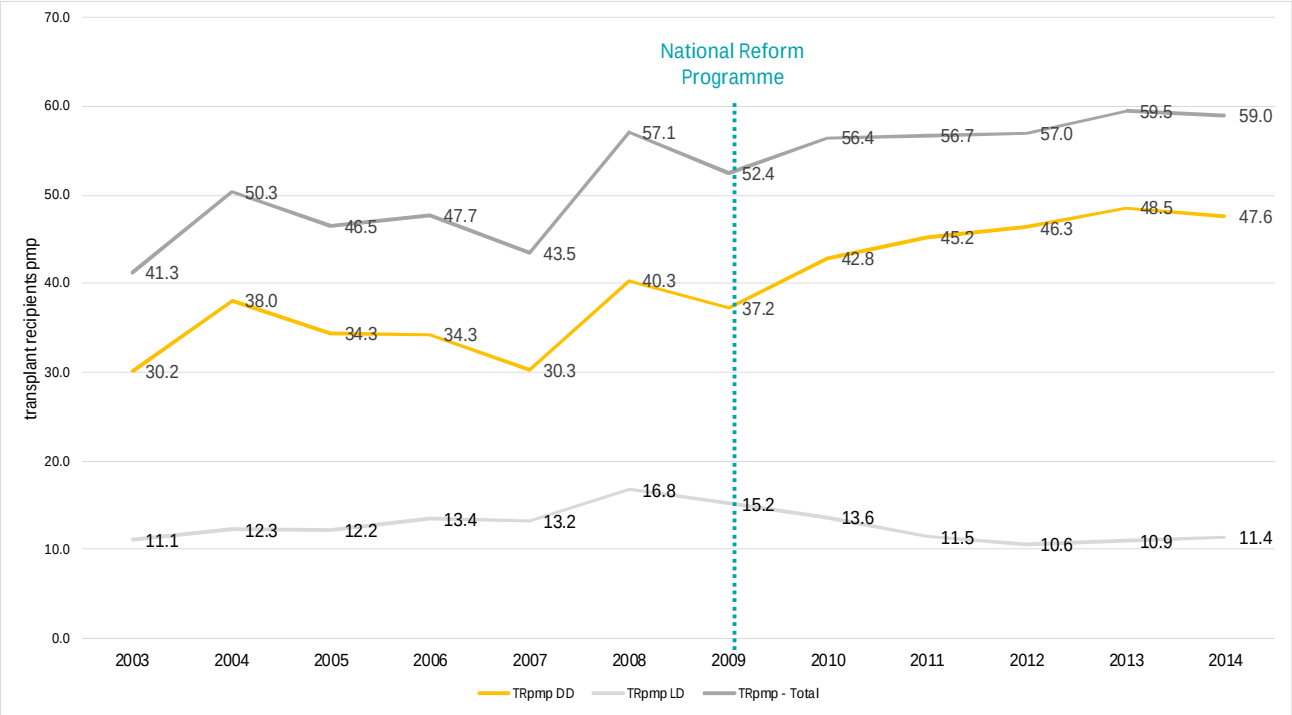
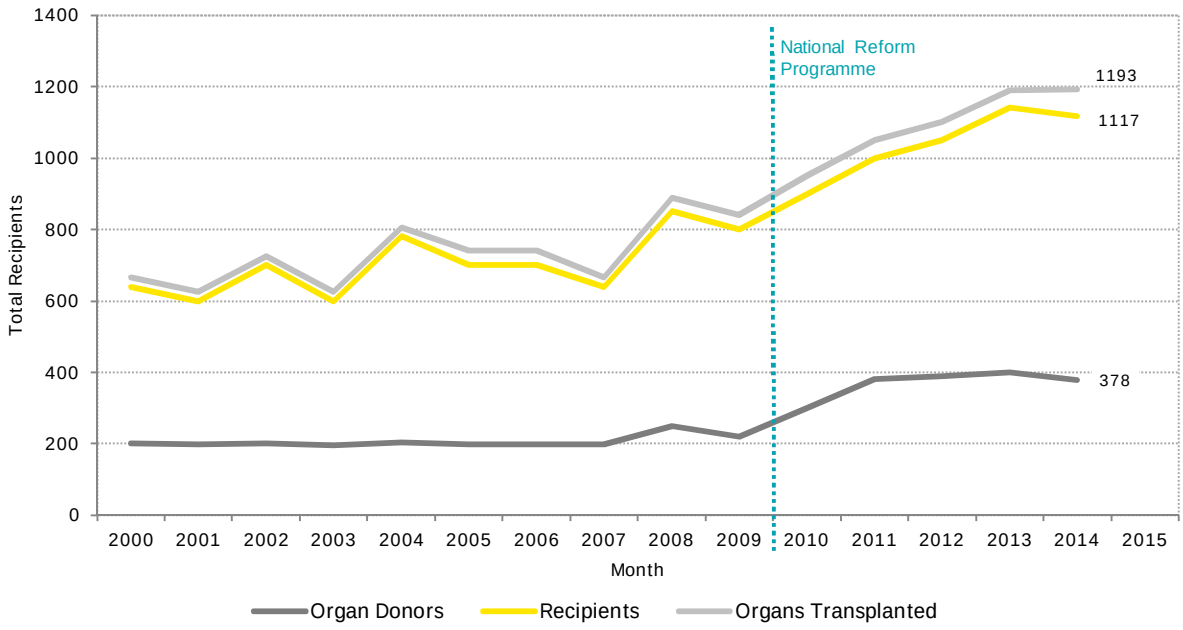


Figure 3 outlines the number of deceased organ donors, transplanted recipients and organs transplanted from deceased donors from 2000 to 2014 and shows that:

- The number of deceased donors decreased in 2009, which was the establishment year of the OTA and the DonateLife Network
- The number of deceased donors continued to grow until 2013 (with 391 deceased donors) and then declined in 2014, to 378 deceased donors[18]
- In 2014, 1193 organs were transplanted to 1117 recipients from 378 deceased organ donors
- Since 2009 there have been 534 additional donors with the majority of these donors being realised through the DBD pathway (60%); while 40% of the growth has been from the DCD pathway.

Figure 3: Deceased organ donors, recipients transplanted and organs transplanted from deceased donors 2000–2014 (Source: ANZOD)



[18] It should be noted that decreased donors does not necessary result in decreased organs transplanted.

Figure 4 shows the national deceased donation and transplant rates from 2008 to 2014. In 2014, Australia had a dpmp rate of 16.1; this result represents a 4.7% decrease compared with the 2013 outcomes (16.9 dpmp) and a 41% increase over 2009 outcomes (11.4 dpmp). It also shows that there was an initial drop-off in donors in 2009 when compared with 2008 (12.2 dpmp).

Figure 4 also shows that the number of transplant recipients per million population and organs transplanted per million population; both of which initially decreased in 2009 (compared to 2008) and decreased again in 2014. However, overall there has been some steady improvement.

Figure 4: National deceased donation and transplant rates (rates per million population) 2008-2014 (Source: OTA)

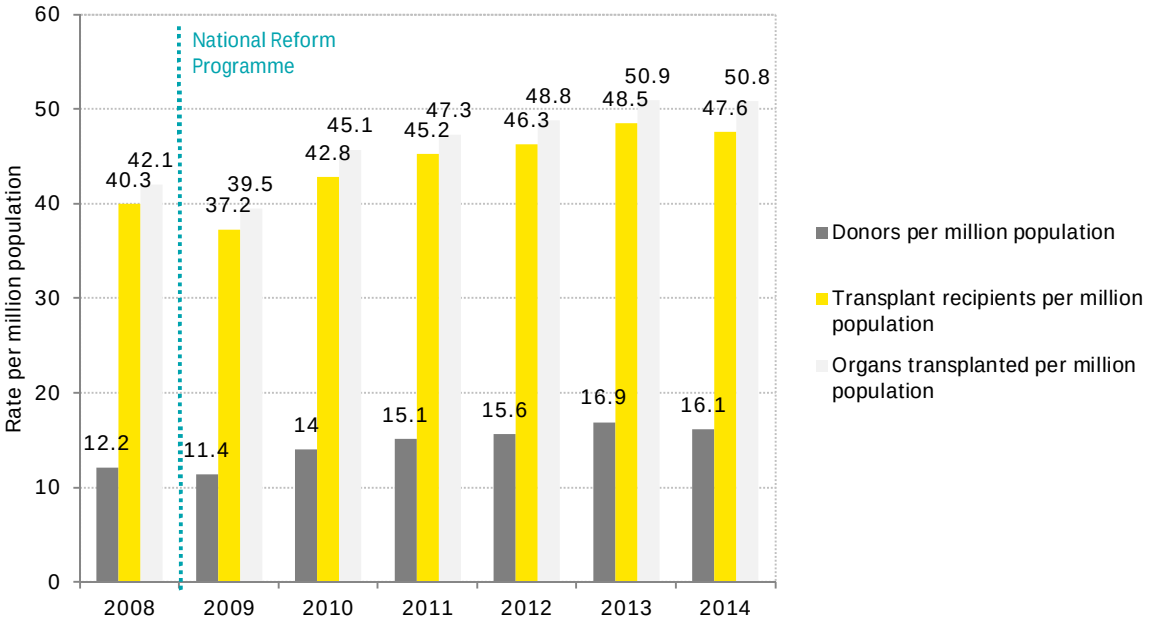


Figure 5 provides an overview of the solid organ transplants between 2000 and 2014, for each organ type. Results indicate that from the implementation of the national reform programme in 2009 to end 2014:

- Kidneys transplanted per million population have increased by 35% from 20.8 dpmp to 28.1 dpmp
- Livers transplanted per million population have increased by 18% from 8.5 dpmp to 10.1 dpmp
- Hearts transplanted per million population have increased by 24% from 2.7 dpmp to 3.4 dpmp
- Combined Heart-Lung transplants per million population have increase by 85% from 0.09 dpmp to 0.17 dpmp
- Lungs transplanted per million population have increased by 31% from 5.2 dpmp to 6.8 dpmp.
- Pancreas transplanted per million population have increased by 12% from 1.7 dpmp to 1.9 dpmp
- Pancreas islets transplanted per million population have decreased by 8% from 0.41 dpmp to 0.38 dpmp
- There has been no change in the intestine transplant rate.

Figure 5: Solid organ transplants (per million population), 2000 – 2014, Australia (Source: ANZOD)

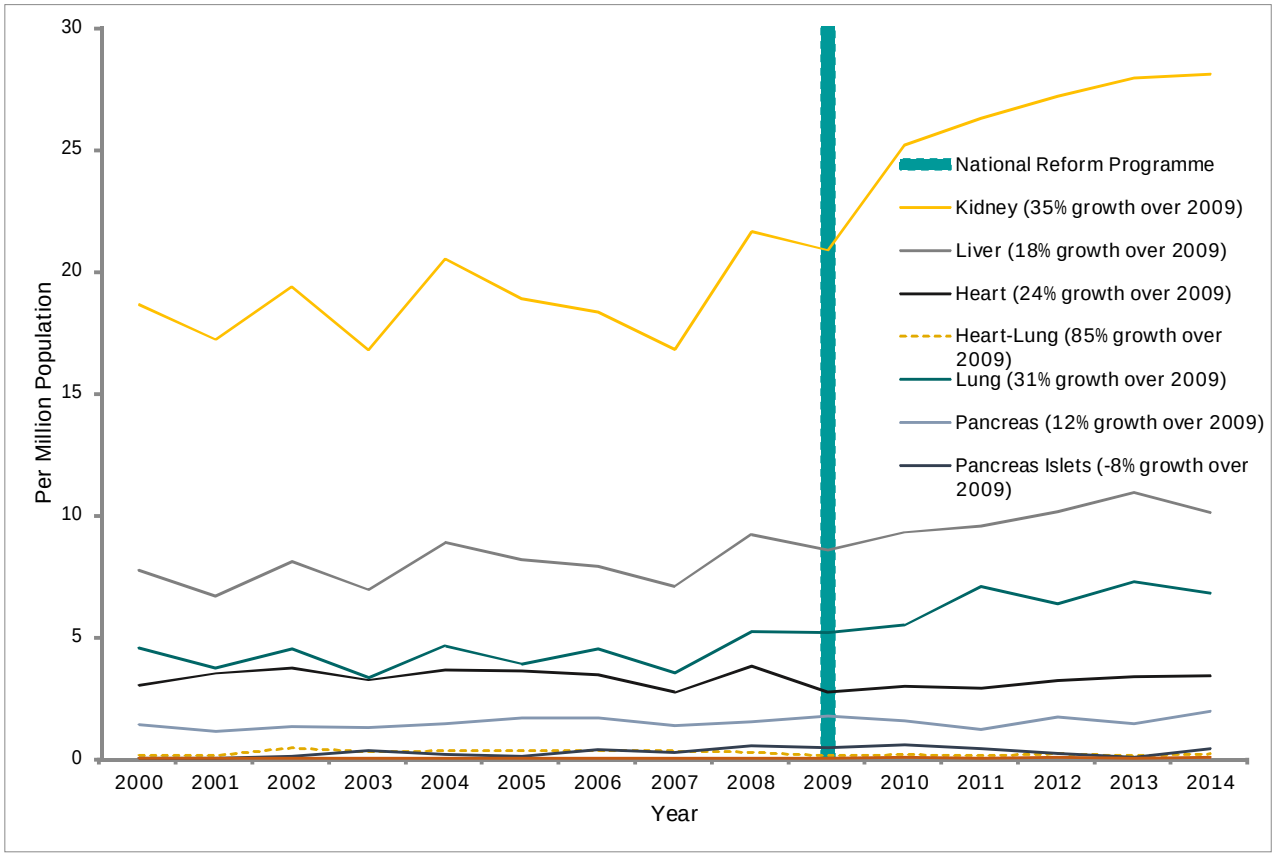


Figure 6 shows the number of organs transplanted from deceased donors – including kidney, liver, heart, lung, pancreas (including islets) from 2008 to 2014, including:

- Kidneys are the predominant organ donated and transplanted. In 2014, 659 kidneys were transplanted from deceased organ donors; this was 2% higher than the 2013 outcome (n=645), and 46% higher than the 2009 outcome (n=452).
- 79 hearts were transplanted in 2014; this was 3% higher than the 2013 outcome (n=77) and 34% higher than the 2009 outcome (n=59)
- 159 lungs were transplanted in 2014; this was 5% lower than the outcome in 2013 (n=167) and 42% higher than the 2009 outcome (n=112)
- 237 livers were transplanted in 2014; this was 6% lower than the outcome in 2013 (n=252) and 28% higher than the 2009 outcome (n=185).

Figure 6: Organs transplanted from deceased donors - Kidney, liver, heart, lung, pancreas (including islets) 2008–2014 (Source: ANZOD)

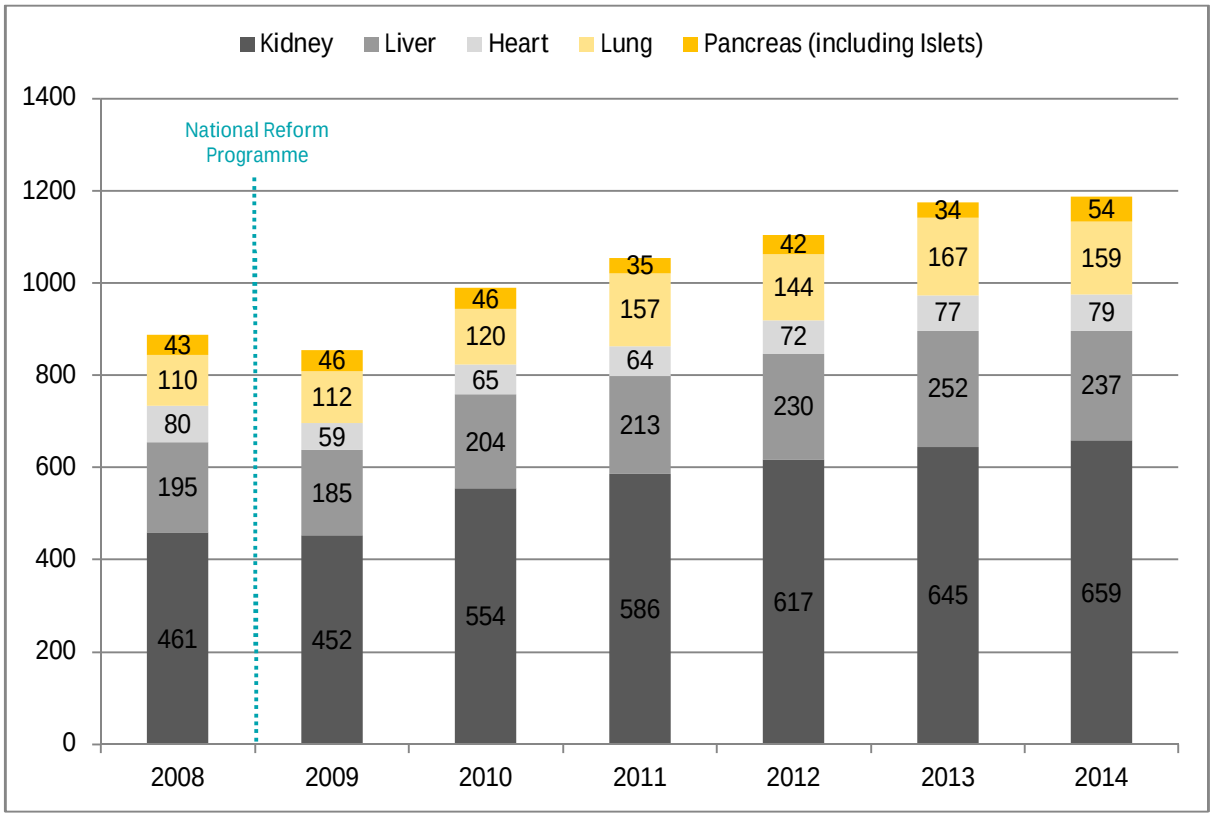


Figure 7 shows the number of deceased donors, by donation pathway, from 1998 to 2014:

- In 2014, 72% (n=271) of deceased donors were realised from the DBD pathway and the remaining 28% (n=107) from the DCD pathway
- There was a notable decrease in DBD pathway donations between 2008 (n=236) and 2009 (n=205)
- Compared to 2013, there was an 11% decrease in donations realised from the DBD pathway and a 24% increase in donations form the DCD pathway in 2014
- Compared to 2009, there were 66 additional donors (50% growth) realised from the DBD pathway and 65 additional donors (50% growth) from the DCD pathway in 2014.

Figure 7: Deceased donors by donation pathway 1998–2014 (Source: ANZOD)

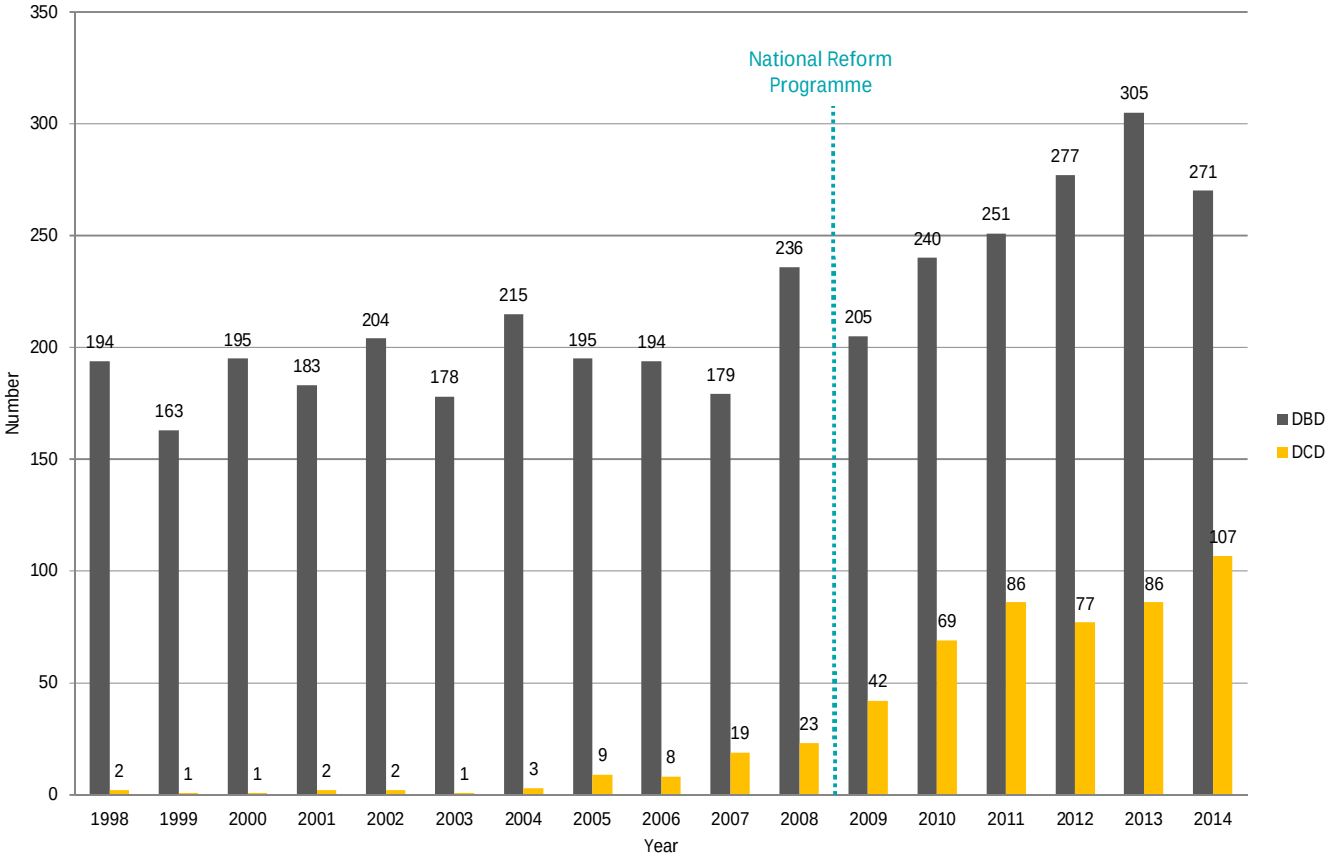
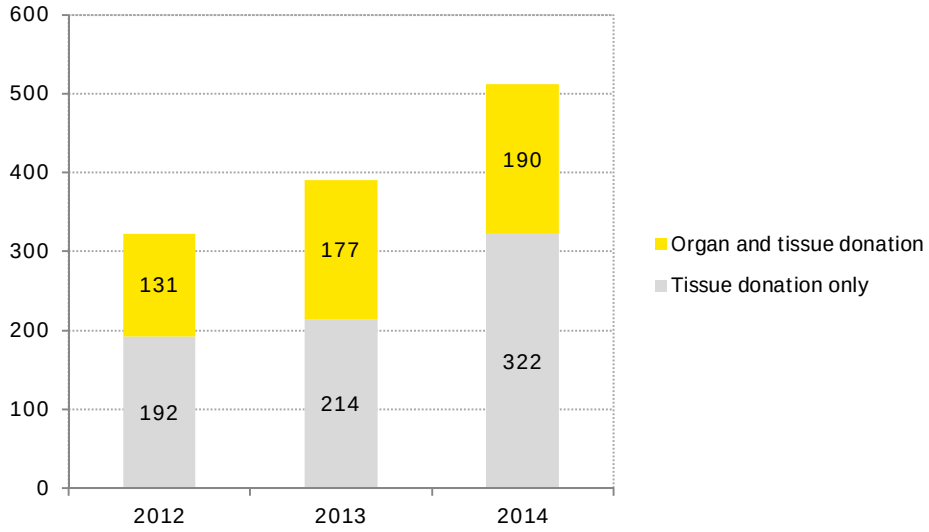


Figure 8 shows the number of deceased tissue donations from 2012 to 2014. In 2014, 512 tissue donations were made, representing a 31% increase compared to 2013 and a 59% increase compared to 2012.

Figure 8: Deceased tissue donation 2012 – 2014 (Source: ANZOD, OTA)



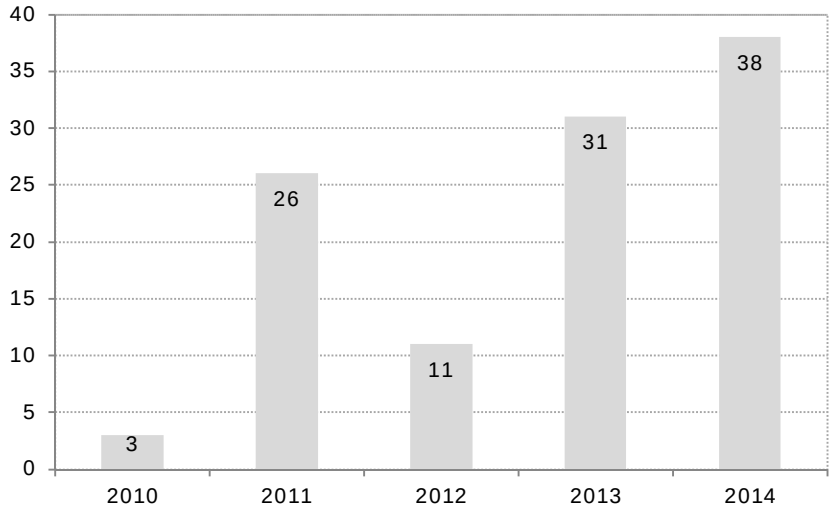
3.1.2 National performance of the programme - living organ donation

Living organ donation of kidneys can be obtained through living donor kidney transplantation or through the Australian Paired Kidney Exchange Programme (AKX) - which the OTA has direct responsibility for.

In 2014, there were 267 living donor kidney transplantations performed nationally.[19]

Figure 9 outlines the number of transplants undertaken through the AKX programme between 2010 and 2014. It shows that in 2014, the AKX programme facilitated 38 live donor kidney transplants (increasing from 31 in 2013), bringing the total number of transplants conducted under the programme to 109 since its commencement in August 2010.

Figure 9: Australian Paired Kidney Exchange Programme 2010-2014 (Source: OTA)



[19] Organs donated and transplanted in Australia and New Zealand by transplanting region, January – December 2014

Table 2 shows the number of living tissue donations between 2012 and 2014. In 2014, there were 3,713 tissue donations from living tissue donors. This outcome represents a 2% decrease compared to 2013 and 2% increase compared to 2012.

Table 2: Living tissue donations 2012-2014 (Source: ANZOD)

	2012	2013	2014
Musculoskeletal	3652	3784	3696
Cardiovascular	0	20	17
Total	3652	3804	3713

3.1.3 Jurisdictional performance in the programme

Table 3 and Figure 10 outline the jurisdictional donation rates from 2009 to 2014 and show that:

- All jurisdictions have increased their dpmp rate since the start of the national reform programme in 2009, with SA seeing the least improvement – however this only reflects their considerably higher dpmp rate at the outset of the programme
- In 2014, Vic., SA, Tas. and the ACT jointly accounted for a 3% increase in the national dpmp
- NSW, Qld. and WA together accounted for a 7.7% decline in 2014
- The jurisdictional variation in outcomes resulted in a net decrease of 4.7% in the national dpmp (0.8 dpmp) in 2014.

Table 3: Jurisdictional donation rate 2009-2014 (Source: OTA)

	2009	2010	2011	2012	2013	2014
NSW	9.9	12.6	11.0	12.4	14.2	12.6
VIC	12.1	17.9	19.3	16.3	19.2	20.0
QLD	10.9	11.1	15.0	17.1	16.6	15.0
SA	20.5	19.0	21.3	17.5	20.4	21.4
WA	8.5	9.6	14.0	13.1	18.7	13.6
TAS	9.9	19.7	11.7	29.3	15.6	17.5
NT	8.8	8.7	17.3	33.9	28.9	28.6
ACT	14.1	17.4	13.7	20.2	10.0	18.1
Australia	11.4	14.0	15.1	15.6	16.9	16.1

Figure 10: Jurisdictional donation rate 2009-2014 (Source: OTA)

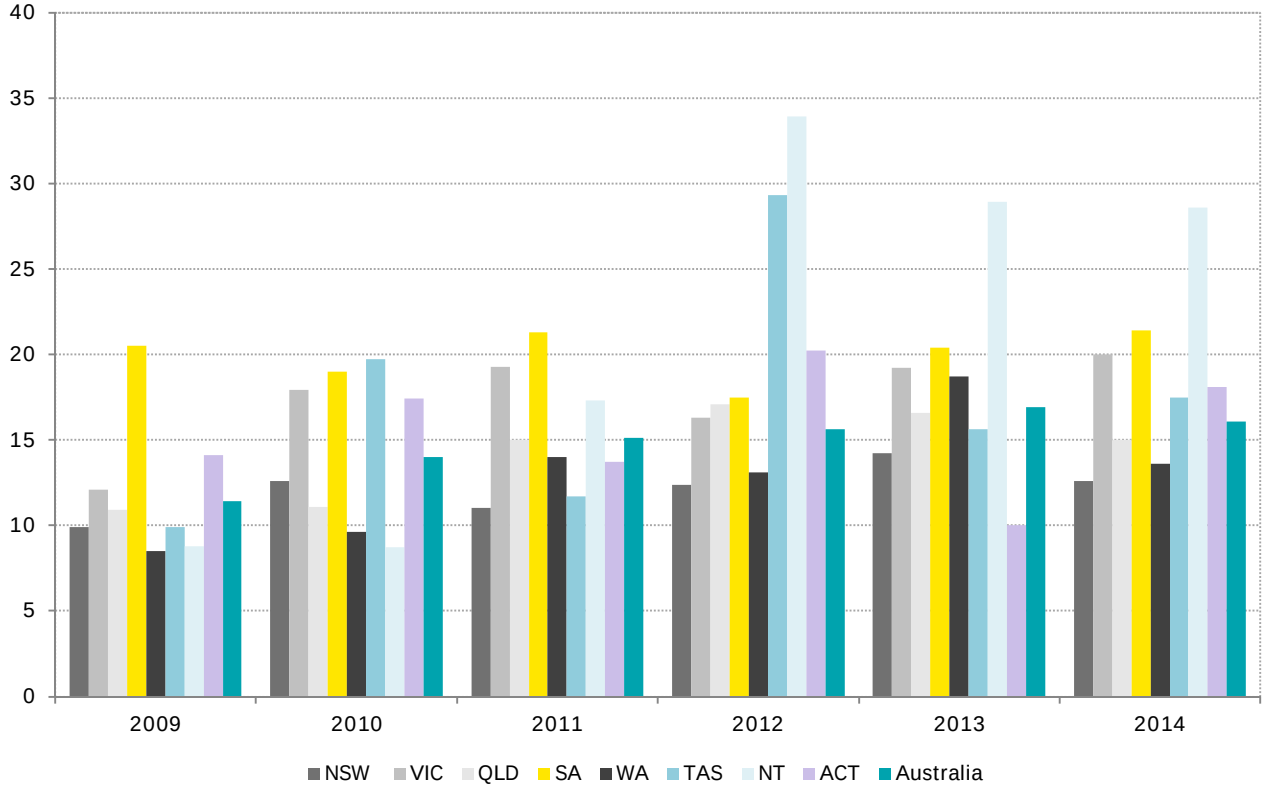


Table 4 outlines the jurisdictional monthly and YTD deceased organ donors against 2014 YTD outcomes and 2015 indicative targets.[20] In March 2015, the Australian Health Ministers Advisory Council agreed the national and jurisdictional indicative targets to achieve 25 dpmp by 2018.[21] The national indicative organ donation target for 2015 is 18.2 dpmp, which equates to 435 deceased organ donors.

Table 4 shows that:

- The YTD outcome at end July 2015 was 227 deceased organ donors, against an indicative target of 254 donors – compared with an outcome of 216 in 2014
- In comparison to their 2014 outcomes, NSW, Vic., QLD, WA and ACT have made good progress in 2015; with their 2015 YTD outcomes surpassing their 2014 July YTD outcomes.

[20] Noting that monthly variations in outcomes naturally occur and can be substantial

[21] This decision was subsequently noted by Australian health ministers at the CHC meeting in April 2015 - *May 2015 Organ Donation and Transplantation Performance Statistics*, June 2015

Table 4: Jurisdictional monthly and YTD deceased organ donors against 2014 outcomes and 2015 indicative targets (Source: OTA/ANZOD)

	2015							2014	2014-2015
	March outcome	April outcome	May outcome	June outcome	July outcome	YTD outcome	YTD indicative target	July YTD outcome	YTD Change
NSW	5	7	17	8	10	64	68	55	16%
VIC	9	3	12	8	7	66	74	64	3%
QLD	6	8	4	6	10	43	49	42	2%
SA	2	1	0	7	5	20	22	21	-5%
WA	3	1	5	1	4	21	25	20	5%
TAS	0	0	0	0	1	1	6	6	-83%
NT	0	0	1	0	0	1	3	3	-67%
ACT	4	0	1	1	1	11	7	5	120%
Australia	29	20	40	31	38	227	254	216	5%

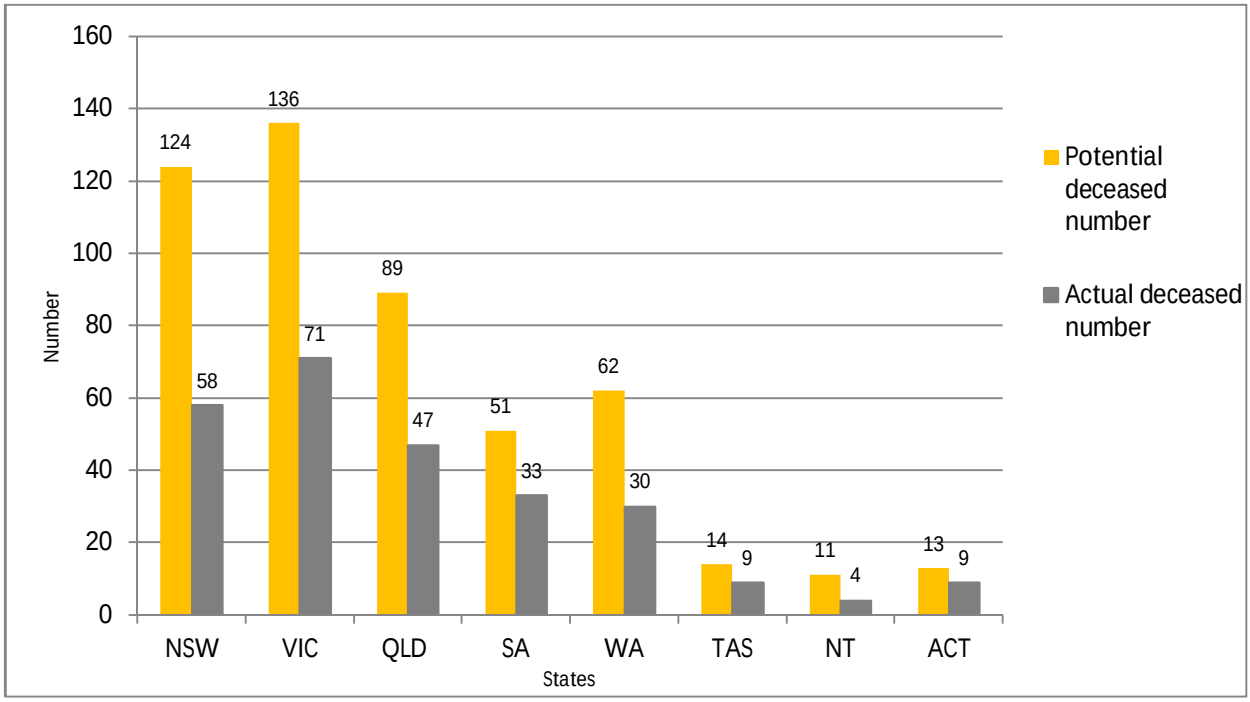
Figure 11 shows the potential and actual donors, by jurisdiction in 2014. In 2014, there were 500 potential DBD donors nationally, of which 261 became actual donors. It should be noted that some donations do not proceed due to medical reasons associated with the donor. Treating clinician led discussions remained the predominant request model (72%) in 2014 and more than half of the families with whom donation was discussed knew their loved ones wishes regarding donation (52%); however family knowledge of donation decision decreased by 2% compared with 2013.

Some of the main reasons why families decline requests for donation included:[22]

- The most common reason donation was declined (29.3%, n=83) was because the family believed patient would not want to donate
- The next most common reasons for declined donation were cultural and religious reasons (19.8%, n=56)
- While 14.5% of declines were due to the family not liking the idea of organ donation (n=41).

[22] National DonateLife Audit Report, 2014.

Figure 11: Potential donors and actual donors by jurisdiction, 2014 (Source: National DonateLife Audit Report)



The DonateLife Network closely monitors key performance indicators for DBD donors that measure the completion of the consent process. These key performance indicators include:

- Request rate – the number of requests as a percentage of all potential donors (98% in 2014)
- Consent rate – the number of consents as a percentage of all requests to potential donors (59% in 2014)
- Conversion rate – the number of DBD as a percentage of all potential donors with confirmed or probable brain death (52% in 2014).

Table 5 outlines the jurisdictional KPI comparisons for request rate, consent rate and conversion rate between 2010 and 2014. It shows that:

- The national consent rate and conversion rate declined in 2014 compared with 2013.
- Over the period between 2010 to 2014:
  - The national request rate increased by 6%
  - The national consent rate increased by 4%
  - The national conversion rate increased by 8%.

Table 5: Jurisdictional KPI Comparison 2010 – 2014 (Source: National DonateLife Audit Report)

	Request Rate						Consent Rate						Conversion Rate					
	% 2010	% 2011	% 2012	% 2013	% 2014	% Var	% 2010	% 2011	% 2012	% 2013	% 2014	% Var	% 2010	% 2011	% 2012	% 2013	% 2014	% Var
NSW	89	93	89	94	98	9	52	51	59	62	55	3	41	42	50	52	47	6
VIC	94	95	91	98	99	5	52	64	57	55	60	8	40	55	45	50	52	12
QLD	89	91	94	93	98	9	56	58	65	62	56	0	44	46	58	50	53	9
SA	100	97	97	100	100	0	66	81	79	77	67	1	59	73	74	73	65	6
WA	93	100	96	99	94	1	49	57	50	63	57	8	37	43	42	55	48	11
TAS	87	100	100	91	100	13	77	64	79	60	79	2	67	55	79	46	64	-3
NT	75	73	80	89	100	25	67	27	58	63	45	-22	50	20	47	56	36	-14
ACT	100	100	82	90	92	-8	70	56	64	67	83	13	70	56	53	60	69	-1
Australia	92	94	92	96	98	6	55	59	61	62	59	4	44	49	51	54	52	8

3.1.4 International comparisons

Figure 12 shows international comparisons of dpmp across Australia, Portugal, Spain, UK and Croatia. It is difficult to draw direct comparisons between countries in terms of progress in organ donation reform due to difference in health care systems, population size, culture, community attitude, clinical practice and the relative baseline for national organ and tissue donation reform. However, the trends from leading organ donation countries show incremental progress taking time over several years. Other observations include:

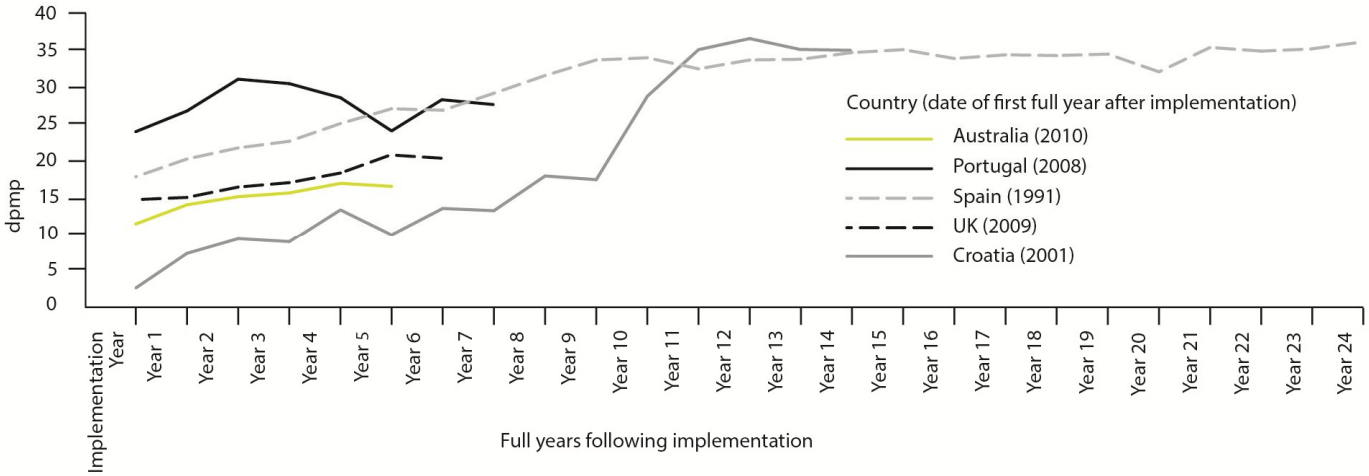
- International experience from leading organ donation countries has shown that variation in donation and transplantation outcomes has occurred annually, with rates continuing to trend upwards over time. This is apparent in Portugal and Croatia where performance declined in their fifth year of organ and tissue donation reform. While in Spain, deceased donor organ donation increased only 2.4% from 33.6 dpmp to 34.4 dpmp between 1999 and 2009.
- Spain is often cited as the world-leader in organ donation, with a deceased organ donation rate of 36 dpmp. However, there are currently a number of significant differences in the Spanish model when compared to Australia, including:
    - The Spanish model of donation uses presumed consent; whereby organs can be used for transplantation after death unless individuals have objected during their lifetime (an opt-out system). The Spanish model uses a "soft" presumed consent approach, where doctors take active measures to ascertain the consent of the next of kin
    - There has been a rapid growth in the acceptance of older transplant donors in Spain, for example between 1999 and 2009 the number of donors older than 70 years increased from 3.8 to 8.8 dpmp (a 132% increase). 2014 data indicates that donors over 60 years of age constitute 54% of deceased organ donors and donors over 70 years now constitute 30% of deceased organ donors[23]
    - Over the same decade, the number of younger donors (15-30 years old) decreased from 6.6 to 2.5 dpmp (a 62% decrease) in Spain
    - In Spain, the effective donation rate in 2009 was 29.9 donors dpmp (reflecting where at least 1 organ has been used for transplantation), compared to the overall organ donation rate of 34.4 donors dpmp (reflecting where at least at least 1 organ has been procured)
    - It is also apparent from the Spanish literature that the percentage of unsuccessful donors is rising because the age of the donor population has risen.[24]
- DonateLife clinicians reported to the Review that the average length of hospital stay prior to donation in Spain (e.g. five days) is also well above that in Australia (e.g. three days).
- DonateLife clinicians also reported to the Review that organs from marginal donors are obtained more readily, due to wider acceptance criteria, in Spain than Australia.

A range of transplant clinicians noted that the Transplantation Society of Australia and New Zealand was currently revising its guidelines (*Organ Transplantation from Deceased Donors: Consensus Statement on Eligibility Criteria and Allocation Protocols*) which will include a revision of the acceptability of donated organs across Australia. Transplant clinicians also cautioned that organ donation rates should only be interpreted in conjunction with transplant outcome data which is not readily available in Spain.

[23] Memoria de Actividad ONT 2014

[24] Halldorson J and Roberts JP, Decadal Analysis of Deceased Organ Donation in Spain and the United States Linking an Increased Donation Rate and the Utilization of Older Donors, Liver Transplantation 19:981–986, 2013

Figure 12: International comparison – Australia, Portugal, Spain, UK and Croatia (Source: ANZOD, International Registry on Organ Donation and Transplantation, OTA)



3.2 Solid organ transplantation waiting list performance

Table 6 outlines Australia's deceased donor kidney waiting list from 2008 to 2013. It should be noted that some people on the deceased donor waiting list receive kidneys from living donors. However, most people who receive living donor kidneys are not on the deceased donor waiting list. The table shows that:

- While kidneys are the most predominant organs being donated and transplanted, there are still a substantial number of people active[25] on the waiting list (n=1333 in 2008 and n=1073 in 2013).
- The number of people who died while on the waiting list has also decreased from 2008 (n=12) to 2013 (n=3)
- Kidney transplants are predominantly from deceased donors, with the number of living donors declining since 2008 (n=122, compared to 54 in 2013).

[25] "Active" wait list means people who would be transplanted immediately if an organ were available on the date reported. It does not reflect the transitions on or off the waitlist over the period since data was last reported to the Registry, nor does it include the outcomes of those not transplanted.

Table 6: Australia's deceased donor kidney waiting list (number and flow totals), 2008-2013 (Source: ANZOD)

		National Reform Programme				
Event	2008	2009	2010	2011	2012	2013
Active start of year	1333	1251	1264	1183	1087	1073
Made active	653	670	630	707	736	762
Taken off list	182	178	149	197	153	140
Deceased donor transplant	417	401	499	533	554	581
Living donor transplant	122	64	58	62	45	54
Transplants abroad	2	4	1	2	0	1
Died on list	12	10	4	9	6	3
Died within 12 months of removal from list	18	22	14	16	16	17
Active end of year	1251	1264	1183	1087	1065	1056
Deceased donor transplant off list	42	45	51	37	53	49
Living donor transplant off list	232	263	238	193	193	198

Table 7 outlines the waiting list data for deceased liver donors in Australia and New Zealand from 2008 to 2013. Data on liver transplants performed abroad, and those who died within 12 months of removal from the list, is not collected by the Australia and New Zealand Liver Transplant Registry. The table shows that:

- The number of deceased donor transplants for livers has incrementally increased from 2008 (n=229) to 2013 (n=279)
- The number of people active at end of the year on the waiting list has been variable, peaking in 2010 (n=194) was at its lowest in 2013 (n=164)
- The number of people who died while on the waiting list has been variable, with the highest number in 2008 (n=48) and the lowest in 2010 (n=12)

Table 7: Australia and New Zealand deceased liver donor waiting list (number and flow totals), 2008-2013 (Source: Australia and New Zealand Liver Transplant Registry Annual Report, ANZOD)

		National Reform Programme				
Event	2008	2009	2010	2011	2012	2013
Active start of year	199	169	175	194	192	186
Made active	290	335	335	336	347	358
Taken off list	48	69	46	68	60	72
Deceased donor transplant	229	228	248	253	268	279
Died on list	48	32	12	17	29	29
Active end of year	169	175	194	192	182	164

Table 8 outlines the waiting list data for heart transplantation in Australia and New Zealand from 2008 to 2013. Data on cardiothoracic transplants performed abroad is not collected by the Registry. The table shows that:

- The number of deceased donor transplants decreased between 2008 (n=90) and 2013 (n=86)
- The number of people active at end of the year on the waiting list for hearts remained static between 2008 and 2010, increasing considerably in 2011 and 2012, and decreasing again in 2013
- In 2013, 15 people died on the waiting list, which was notably higher than the number of people who died on the waiting list between 2008 and 2012.

Table 8: Australia and New Zealand deceased donor heart waiting list 2008-2013 (Source: Australia and New Zealand Cardiothoracic Organ Transplant Registry, ANZOD)

		National Reform Programme				
Event	2008	2009	2010	2011	2012	2013
Active start of year	61	52	51	53	78	78
Made active	113	110	103	117	108	105
Taken off list	24	33	17	7	15	19
Deceased donor transplant	90	71	76	76	85	86
Died on list	8	7	8	9	8	15
Active end of year	52	51	53	78	78	58

Table 9 outlines the waiting list data for deceased lungs in Australian and New Zealand from 2007 to 2013. The table shows that:

- The number of deceased donor transplants for lungs has increased between 2008 (n=129) and 2013 (n=188).
- The number of people active at end of the year on waiting list and number of people who died while waiting on the list has remained fairly static since 2008.

Table 9: Australia and New Zealand deceased donor lung waiting list (number and flow totals), 2008-2013 (Source: Australia and New Zealand Cardiothoracic Organ transplant Registry, ANZOD)

		National Reform Programme				
Event	2008	2009	2010	2011	2012	2013
Active start of year	111	105	109	124	112	107
Made active	165	155	181	189	186	227
Taken off list	26	15	15	22	16	14
Deceased donor transplant	129	130	136	172	161	188
Died on list	16	6	17	13	14	14
Active end of year	105	109	124	112	107	108

Table 10 outlines the waiting list data for deceased pancreas donors between 2012 and 2013 in Australia only. This data includes both people waiting a combined kidney-pancreas transplant (majority) and those waiting a pancreases transplant (following a previous kidney transplant). It does not include people waiting for pancreas islet cell transplants. The table shows that:

- The number of deceased donor transplants for pancreas decreased from 2012 (n=37) to 2013 (n=33)
- The number of people active on waiting list increased substantially from 2012 to 2013, both at the start and end of the year.

Table 10: Australia deceased donor pancreas waiting list (number and flow totals), 2012-2013 (Source: National Pancreas Transplant Registry, ANZOD)

Year	Active at start of year	Made active	Taken off list	Transplanted deceased donor	Died on list	Active at end of year
2012	43	60	16	37	2	48
2013	85	48	26	33	2	72

3.3 Summary of the performance of the national reform programme

The key findings of the national reform programme are:

- In 2014, 1,193 organs were transplanted to 1,117 recipients from 378 deceased organ donors.
- In 2014, Australia had a dpmp rate of 16.1 dpmp, this result represents a:
  - 32% increase over 2008 dpmp outcomes (12.2 dpmp)
  - 41% increase over 2009 dpmp outcomes (11.4 dpmp)
  - 4.7% decrease compared with the 2013 dpmp outcomes (16.9 dpmp).
- At a Jurisdictional level, NSW, Qld. and WA together accounted for a 7.7% decline in donation rates in 2014 – this variation in outcomes resulted in a net decrease of 4.7% in the national dpmp.
- Between 2008 and 2014, donations via the DBD pathway have varied:
  - There was a notable decrease in DBD pathway donations between 2008 (n=236) and 2009 (n=205)
  - Between 2009 and 2014 there has been an increase in donations via the DBD pathway, from 205 to 271
  - However there was a notable decline in donations from 2013 to 2014, due to a decline in donations in Qld., WA and NSW.
- Between 2008 and 2014, there has been an overall increase in donations via the DCD donation pathway – from 23 in 2008, to 42 in 2009, to 107 in 2014.
- The AKX programme has seen an increase from three paired kidney exchanges donations in 2010 to 38 in 2014.
- There has been steady and sizable increase evident in deceased human tissue donated between 2012 and 2014 (59% increase), with a small increase in living tissue donation over the same time period (2% increase).

- Kidneys are the most predominant organs being donated and transplanted with the number of people active[26] on the waiting list declining between 2007 and 2013 (n=1333 in 2008 and n=1073 in 2013). In addition, kidneys are predominantly transplanted from deceased donors, with the number of living donors declining since 2008 (n=122, compared to 54 in 2013).
- 2015 YTD outcomes (as at end July) for the number of deceased organ donors are higher than the 2014 outcome (227 compared to 216).

[26] "Active" wait list means people who would be transplanted immediately if an organ were available on the date reported. It does not reflect the transitions on or off the waitlist over the period since data was last reported to the Registry, nor does it include the outcomes of those not transplanted.

4. Current strategy of the OTA to increase organ donation for transplantation rates

The OTA strategic plan aims to ensure that organ and tissue donation is delivered on a collaborative basis with a view to increase organ donation outcomes to 25 dpmp by 2018 – which is the target endorsed by all Australian health ministers in April 2015.

The DonateLife 2014-2108 strategic plan was developed with input from the Advisory Council and the Jurisdictional Advisory Group over the last 18 months. The strategic plan was endorsed by the Jurisdictional Advisory Group and Advisory Council and published on the OTA website in June 2015. The plan will be reviewed and updated annually to ensure it remains current reflects the strategic priorities for the next year. The plan identifies the following key objectives:[27]

- To increase the number of potential organ and tissue donors
- To improve organ and tissue donor conversion rates
- To enhance systems to support organ and tissue donation and transplantation.

Twenty-two strategies were developed to achieve these objectives, with a set of actions to support achievement of each strategy. During 2015-16, the OTA will focus their efforts on the following five priority areas, which are specifically focused on building on initiatives implemented in previous years and improving donation performance:

1. Implement the second phase of the Clinical Governance Framework and Clinical Practice Improvement Programme including a Targeted Hospital Improvement Programme: in partnership with State and Territory Governments. This will build the cross-border peer relationships between the like hospitals to enhance local organ and tissue donation practice through exposure to alternate systems and approaches.
2. Continuing to deliver specialist education to health professionals involved in conversations with families about the opportunity for donation: the education opportunities for health professionals involved in family donation conversations will continue to be developed and delivered to provide clinicians and donation specialists with increased knowledge and skill to support families in making donation decisions. This work will contribute to increasing the donation consent rate.
3. Developing a national vigilance and surveillance framework for organ donation and transplantation: including endorsement of the framework to further support safety and quality in organ donation for transplantation. Including the investigation, resolution and learning from adverse outcomes related to organ donation and transplantation. A Vigilance and Surveillance Expert Advisory Committee will also be established.
4. Commencing the development of the AOMS: which will replace the current National Organ Matching System (NOMS). This will allow for optimal matching of transplant recipients through the application of best practice algorithms to further maximise the equality of access and clinical outcomes of transplants in Australia.
5. Conducting community awareness and education activities on organ and tissue donation: The Department of Human Services, which administers the AODR, will be introducing the functionality for electronic signatures to register legal consent registrations on the AODR. This will remove the current barriers in the process, as well as providing greater certainty of an individual's donation decision for clinicians and families at the family donation conversation. The electronic registration process will be supported by the OTA through the implementation of a national online donor registration campaign and revising the Professional Education Programme to incorporate AODR changes.

[27] http://www.donatelife.gov.au/strategic-plan

In order to reach the national target of 25 dpmp, the Review has noted that the DonateLife Network will need to achieve the following:

- Increase the DBD rate, through improving hospital performance and expanding the clinical acceptance criteria for the donation of organs for transplantation
- Identify opportunities and develop strategies to increase the DCD rate
- Improve the conversion rate to 70% (from the current rates of 52%[28]) through better community and clinical education.

[28] 2014 data. DonateLife Audit, January-December 2014 Report: Brain Death Donors

5. Key findings and recommendations

This Section outlines the key findings and recommendations of the Review across the following key areas:

- Strategy – see Section 5.1
- Governance of the OTA – see Section 5.2
- Performance – see Section 5.3
- Audit of donation practices – see Section 5.4
- Funding policy – see Section 5.5
- Awareness strategies, communication and donor family support – see Section 5.6
- Community Awareness Grants Programme – see Section 5.7
- Australian Organ Donor Registry – see Section 5.8
- Electronic Donor Record – see Section 5.9
- New organ perfusion technologies – see Section 5.10
- Eye and tissue donation and transplantation – see Section 5.11
- Issues outside the scope of the Review – see Section 5.12.

5.1 Strategy

5.1.1 Discussion of findings: Strategy

The *Organ and tissue donation for transplantation in Australia: 2014-2018 Strategic plan*[29] identifies the objectives, strategies and actions for the next four years, along with a range of performance and outcome measures for monitoring and reporting progress. The plan identifies the five strategic priorities for 2015-16 aimed at continued and sustained increases in organ and tissue donation for transplantation (see Section 4). This is further enhanced by the commitment of an additional $10.2 million by the Australian government over the next two years for a new measure focused on accelerating growth in organ and tissue donation for transplantation. $8.1 million of this will be provided to the OTA to fund four targeted initiatives, three of which will focus on delivery of the OTA's strategic priorities (see Section 4).

The Review noted some assumptions held by some interviewees that the focus of implementation of one of these initiatives – the Targeted Hospital Improvement Programme – would be limited to intra-jurisdictional hospital support in contrast to the need to build peer support networks nationally. Any restriction of this programme in this manner would represent a wasted opportunity for shared learning.

One of the strategic priorities includes the development of the AOMS, which will allow for more optimal matching of organs to transplant recipients on a national basis. The Review received evidence that there are currently instances of organs being turned down by some jurisdictions, which would have been accepted by other jurisdictions. An improved ability to match and distribute organs on a national basis, facilitated through the AOMS, should minimise the wastage of organs (particularly kidneys) and expand the potential pool of donor organs, while ensuring that organs are matched and used most effectively.

[29] http://www.donatelife.gov.au/strategic-plan

Another strategic priority is the continued development and delivery of specialist education to health professionals through the Professional Education Package (PEP). Currently, this training is focussed on upskilling health professionals in family donation conversations (through the FDC Workshops), with Advanced FDC workshops to be developed to provide treating clinicians and donation specialists with increased knowledge and skills to support families in making donation decisions. Eye and tissue FDC workshops, tailored to telephone-based family consent for eye and tissue donation outside the hospital setting, are also to be developed. Currently there is no monitoring or reporting across the DonateLife Network of the number or proportion of ICU staff that have completed the training.

While the strategy and strategic priorities are sound, there is still significant room for improvement of donation rates going forward. As such, there needs to be strong execution and monitoring of the implementation of the strategy nationally, with particular focus across NSW, Qld. and WA in order to see a substantial and sustained improvement in donation rates in these jurisdictions, along with a reversal of the reduction in their donation rates as seen in 2014.

The Review did receive some evidence (particularly in relation to the management of donated kidneys) that there is currently a heavy emphasis on the intra-jurisdictional allocation of the organs in the algorithm that facilitates organ allocation within NOMS. It was somewhat concerning to note some instances where kidneys were rejected in one jurisdiction - where following review of these cases by another jurisdiction, it was evident that the kidneys may well have been accepted.[30] While the review was not in a position to investigate these instances, and transplant matters lie outside the Terms of Reference for the Review (see Section 0) - it is apparent that the development of the enhanced AOMS represents an opportunity to ensure organs are appropriately distributed nationally, taking into account logistical, organ survival and recipient matching issues.

Currently donation rates are expressed in terms of the number of donors per million of population (dpmp) and is a measure of activity for comparative purposes. The *Organ and Tissue Donation Reform Package, Mid-Point Review Report* outlined, based on a sound methodology, that national deceased donor rates of 23-25 dpmp are achievable, assuming 100% detection of all potential deceased donors and a 75% consent rate. The *Organ and tissue donation for transplantation in Australia: 2014-2018 Strategic plan* was developed as a means of increasing current organ donation outcomes to 25 dpmp by 2018.

The Review found that there is no reporting of living kidney donations (outside of the AKX programme) by the DonateLife Network. While the AKX programme aims to increase the options for living kidney donation, the current level of living kidney donations is not readily available within the Network. It is important to understand the trend in living kidney donation rates in order to obtain the full picture of organ transplant rates across Australia. The Review did receive some evidence that some possible living kidney donations are currently deferred whilst a cadaveric donation is awaited. Therefore it will be important to monitor the number of living kidney donations performed at a national level to ensure that the overall donation rate has not decreased.

5.1.2 Summary of findings: Strategy

The key findings were:

- The strategy to increase organ donations, as detailed in the *Organ and tissue donation for transplantation in Australia: 2014-2018 Strategic plan* is sound, although continued improvement in performance is required to meet the national donation target – particularly in NSW, Qld. and WA
- The implementation of the relevant May 2015 budget enhancements and the 2015-2016 strategic priorities represent a significant opportunity to improve organ donation rates in the mid-term

[30] QLD clinicians consultation, 7 July 2015

- Implementation of a strategic intention to progress towards allocation of donated organs on a national basis would likely result in a further improvement of the performance of the programme
- Improved reporting is required in relation to completion of FDC training by ICU staff
- National reporting on the number of living kidney donations is required
- The methodology used to derive the national target organ donation rate of 25 dpmp was sound and the target is appropriate for Australia and achievable.

5.1.3 Recommendations: Strategy

Recommendation 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 in the Targeted Hospital Improvement Programme. In addition, the DonateLife Network should continue to implement the other 2015-2016 strategic priorities.

Recommendation 2: The OTA, DonateLife Network and transplantation sector should continue to progress the allocation of donated organs on national basis, following the implementation of the AOMS.

Recommendation 3: The proportion of ICU specialists, staff and trainees who participate in the FDC Workshops should be monitored by the DonateLife Network by hospital.

Recommendation 4: The number of living kidney donations should be reported and reviewed by the DonateLife Network and reported on the OTA's website.

5.2 Governance of the OTA

5.2.1 Discussion of findings: Governance of the OTA

The OTA is a statutory authority established by the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* which sets out the primary responsibilities for the OTA and the functions of the CEO. The CEO is appointed pursuant to Section 14 of the Act and is appointed by the Minister by written instrument. The instrument of appointment provides for the Minister to assess the CEO's performance.

The CEO is supported through a three-tier committee structure, as described in Section 2.3.1, comprising:

1. Programme governance and advice, by the Advisory Council and Jurisdictional Advisory Group – the Advisory Council has the role of advising the CEO about organ and tissue donation and transplantation matters, while the Jurisdictional Advisory Group considers and makes recommendations about strategic priorities, clinical and data governance, and programme planning
2. Committees established by the CEO to provide sector specific advice and liaison, including the Clinical Governance Committee, the Transplant Liaison Reference Group and the DonateLife Partners Committee
3. Purpose-specific working groups which are established by the CEO and disbanded once the assigned task is accomplished.

As such, current governance arrangements are advisory in nature and do not provide any strategic oversight, performance monitoring, succession planning or mentoring of the CEO. The Review found that stakeholders were generally in support of the establishment of a Board of governance for the OTA, noting that legislative amendments would be required. Given that the agenda of the OTA will become more complex going forward; a Board would provide additional support to the CEO in governing the implementation of strategy and the achievement of outcomes. The proposed Board

chair may also provide a national spokesperson for the DonateLife programme. States and Territories will need to be involved in the selection of Board members with the Board being skills-based, not representational. The Board should not include current serving Commonwealth or state and territory officials to ensure that the Board does not become representational in nature.

The OTA is currently a non-corporate Commonwealth entity under the Public Governance, Performance and Accountability Act 2013 (PGPA Act). Changes to the governance structure may require Finance Minister Approval and would require legislative changes.

The Review notes that the establishment of a Board will incur about $200k[31] in additional costs (largely Board member payments), but considers this to represent a reasonable investment for the benefit expected. It would be a matter for the Board to decide whether the OTA Advisory Council would remain in addition to the Board.

Some concerns were raised by a number of stakeholders over the observed 'defensiveness' of the OTA and tendency to limit debate about controversial issues. A Board of governance should foster a culture of debate within the DonateLife Network and the OTA.

It was noted by some jurisdictions that OTA presents matters for the consideration of health ministers directly to AHMAC rather than through the relevant committees that support the Council. It would likely assist jurisdictions in considering these matters if the relevant committees had an opportunity to review the matters prior to AHMAC.

5.2.2 Summary of findings: Governance of the OTA

The key findings were:

- The strategic oversight of the DonateLife Network, as well as the performance monitoring, succession planning and mentoring of the OTA CEO, will be improved by the introduction of a Board of governance for the OTA and will be responsible for these functions.

5.2.3 Recommendations: Governance of the OTA

Recommendation 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.

Recommendation 6: The Chair of the Board of governance should be an experienced leader of public hospital organisations, but need not be a clinician.

Recommendation 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.

Recommendation 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 CHC members.

Recommendation 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 governance operations.

[31] Note: this is an estimate only

5.3 Performance

5.3.1 Discussion of findings: Performance

As described in Section 3, the performance of the national reform programme has been variable since its commencement, particularly performance by jurisdiction. Overall key findings in relation to performance include:

- Between 2009 and 2014 there has been an increase in donations via the DBD pathway, from 205 to 271 donors
- However there was a decline in donations from 2013 to 2014 – due to a decline in donation outcomes in Qld., WA and NSW
- Between 2009 and 2014, there was an increase in the DCD donation pathway from 42 donors to 107, with a small decrease in donations between 2011 and 2012
- The AKX programme has seen an increase from three live kidney donations in 2010 to 38 in 2014
- There has been steady and sizable increase evident in deceased human tissue donated through the programme between 2012 and 2014 (59% increase), with a small increase in living tissue donation over the same time period (2% increase)
- Performance against national key performance indicators for 2014 includes 98% for requests (against a target of 100%), 59% for consent (against a target of 75%), and 52% for conversion (against a target of 70%).

The Review found that there is the capacity for further enhancing the reporting of performance data by the OTA; this was noted by all stakeholder groups. Particular gaps in performance reporting noted by stakeholders included the need for more accessible information on transplant waiting list status (including the total number waiting and waiting time) and the number of deaths on the waiting list.

While some of this data is currently available on the ANZOD website, this is not well known and can be difficult to find. Improved publication and provision of readily available data by the OTA will help to drive performance improvement within the Network, in particular, encouraging jurisdictional and hospital managers to take action and improve performance at clinical and hospital executive levels.

The Review also found that the publication of donation performance (appropriately risk adjusted) by hospital deserves further consideration by the OTA. Stakeholders identified that they felt that this would be best introduced progressively after publication of regular jurisdictional donation performance data.

Guidelines are in place for the roles and responsibilities of positions within the DonateLife Network, including the key performance outcomes and measures which articulate the expected areas of focus and outcomes for the positions. The roles and responsibilities were previously included in State and Territory Funding Agreements. However, a separate document (*DonateLife Network Roles and Responsibilities Guidelines, Version 2 – September 2014*) has been created to enhance access and utilisation to the information. The Review found that there is variability in performance of staff across the DonateLife Network, indicating that there is room for improved implementation and monitoring of key performance outcomes and measures, such as staff turnover within the Network, by states and territories.

The Review also noted some variability in the clarity of who is responsible for the implementation of the DonateLife Network within each jurisdiction. Whilst in most jurisdictions it was clear who is responsible, it was not clear who was responsible in NSW and WA.

The Review was not presented with any evidence that led the Review to question the integrity of the performance data published by ANZOD or the OTA. However, a number of stakeholders consulted suggested that annual publication of donation performance statistics by the Australian Institute of Health and Welfare (AIHW) would strengthen the acceptance of the data. The Review

noted that AIHW already publishes some organ donation data in its biennial publication 'Australia's Health'.

The Review was presented with claims that differences in neurosurgical intervention rates between jurisdictions accounted for the variability in brain death diagnosis and DBD rates. This claim could be readily tested by comparing neurosurgical intervention rates between jurisdictions.

5.3.2 Summary of findings: Performance

The key findings were:

- Whilst DBD rates have declined in the last 18 months, DCD rates, tissue donation volumes and paired kidney exchange rates have continued to increase steadily.
- The decline in donation outcomes was evident in 2014 in NSW, WA and Queensland only
- The implementation of enhancements funded in the 2015 federal budget, along with continued implementation of the *Organ and tissue donation for transplantation in Australia: 2014-2018 Strategic Plan*, should result in an improvement in donation rates to return to, and exceed, recent levels; however this is subject to effective state and territory implementation
- Whilst performance data is distributed widely within the DonateLife Network, there is a need to publish performance data more prominently and in a more accessible form to improve the understanding of the performance of the programme in the community.

5.3.3 Recommendations: Performance

Recommendation 10: The OTA should prominently publish the following data on the performance of the Donate Life Network:

- Donation rates by jurisdiction – quarterly for NSW, Qld., Vic., SA and WA and annually for Tas., ACT and NT
- Numbers of people on the transplant 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.

Recommendation 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.

5.4 Audit of donation practices

5.4.1 Discussion of findings: Audit of donation practices

The DonateLife Audit is intended to provide a nationally consistent method of retrospectively auditing all deaths in DonateLife Network hospitals and as a management tool for driving performance improvement.

The DonateLife Audit is a web-based tool used in all DonateLife Network hospitals to collect key performance and clinical data, which is used to quantify national and jurisdictional potential for organ donation. The Audit identifies missed donation opportunities, and also determines the request, consent and conversion rates for organ donation and is based on the DBD pathway only. There are plans for the Audit to report on the two donation pathways (both DBD and DCD) in 2016.

The DonateLife Audit data is analysed and reported on a quarterly basis to the Jurisdictional Advisory Group and the OTA Advisory Council. The quarterly reports are also circulated to the jurisdictional DonateLife Medical Directors, who are responsible for providing feedback on the audit outcomes to their hospitals, with a view to drive improvement. These reports are not publically available.

The Data and Audit Working Group, established by the OTA, manages the DonateLife Audit and reporting processes in DonateLife Network hospitals and is intended to utilise this data to drive clinical performance improvement. The Data and Audit Working Group comprises jurisdictional data and audit officers, along with representatives with relevant clinical and technical expertise.

The Review found that overall the national DonateLife Audit system is comprehensive and allows a detailed assessment of donation practice at DonateLife Network participating hospitals; however there is variability in the practice of audit between jurisdictions, and in some cases within jurisdictions. Clinicians also indicated that the audit could benefit from the inclusion of referrals for donation which would allow a more complete picture of intended and actual donors.

The Review was not presented with any evidence that questioned the integrity of the data used in the audits.

5.4.2 Summary of findings: Audit of donation practices

The key findings were:

- There is evidence of some variability in the practice of organ donation audit
- There is the opportunity for the Audit to capture donation referrals to better understand intended and actual donors.

5.4.3 Recommendations: Audit of donation practices

Recommendation 12: The DonateLife Network, led by the OTA, should define minimum standards for auditing of organ donation practices and seek the endorsement of CHC for these standards.

Recommendation 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.

5.5 Funding policy

5.5.1 Discussion of findings: Funding policy

There are two types of funding agreements entered into between the Commonwealth and each state and territory health department: (1) Organ Donation Hospital Support Funding (ODHSF); and (2) DonateLife Network - State and Territory Funding.

Funding for DonateLife Network hospitals is allocated through the ODHSF which was endorsed by AHMAC in November 2009. This is an activity-based funding programme which provides hospitals with a funding contribution towards the additional costs associated with organ donation activity to ensure that cost is not a barrier to donation for transplantation.

In 2012, a simplified ODHSF was agreed which 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 ACT and the Hospital and Health Services in Qld.

The OTA enters into funding agreements with the State and Territory Health Departments to implement the organ donation service delivery model, consistent with the national organ and tissue donation reform agenda in the public hospital sector and, where mutually agreed, in the private hospital sector. The funding formula for distribution of DonateLife funds between jurisdictions was based on a modified population-based formula commonly used in national health programmes. The most recent funding agreements were negotiated in 2012.

The funding committed to each jurisdiction through these State and Territory Funding Agreements meets the definition of a grant under the Commonwealth Grant Rules and Guidelines (CGRGs). The CGRGs require agencies to publically report the details (e.g. value, term, recipient) of all grants awarded within 14 days of agreement execution. The OTA reports all grants on the DonateLife website.32

Some jurisdictions expressed concern that they were not receiving their fair share of the State and Territory funding. The Review noted that this State and Territory funding was allocated on the basis of long standing arrangements between the Commonwealth, states and territories in 2014/15 but it is difficult to ascertain this from the mandatory reports published on the OTA web site. It would assist all states and territories to understand the fairness of the allocation of the State and Territory Funding if it was clearly published on the OTA web site as a consolidated table indicating the funding share by jurisdiction including the 2015/16 allocation.

The Review found that stakeholders considered that while the donation side is well funded, there is greater clarity required for the funding of tissue typing and the surgical procedures for organ retrieval, transportation and transplantation activity. States and territories currently bear the cost of organ retrieval and transplantation, beyond the commencement of the organ retrieval procedure, and this cost is not recognised by the Independent Hospital Pricing Authority in its current Pricing Framework. This is important because under the current health funding agreement between the Commonwealth, states and territories (the National Health Reform Agreement) IHPA determines what is a public hospital service and, therefore, is eligible for Commonwealth funding under the National Health Reform Agreement. However, it is understood that IHPA is currently consulting stakeholders on the inclusion of these services within its scope of public hospital services.

5.5.2 Summary of findings: Funding policy

The key findings were:

- ODHSF provides a contribution towards the costs associated with organ donation activity using data provided by ANZOD (including the additional costs of Emergency Department and ICU beds for potential donors and costs related to donor clinical management and assessment of medical suitability such as pathology and imaging).
- ODHSF provides a contribution towards the costs associated with organ donation activity; however there are notable issues in the current funding arrangements, such as the cost of tissue typing and the surgical procedures for organ retrieval, transportation and transplantation which is currently borne by the states and territories.

5.5.3 Recommendations: Funding policy

Recommendation 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.

[32] http://www.donatelife.gov.au/accountability-and-reporting

Recommendation 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.

5.6 Awareness strategies, communication and donor family support

5.6.1 Discussion of findings: Awareness strategies, communication and donor family support

The national DonateLife Community Awareness and Education Programme aims to ensure a nationally consistent, evidence-based approach to communications about organ and tissue donation for transplantation. It comprises DonateLife Week, Community Awareness Grants, media and public relations, community education and outreach, social media, and printed and online public information. The OTA also provides funding for Social Marketing and Communications Officers in the DonateLife Agencies in each jurisdiction to manage the community education and awareness programmes. The Review found that the success of local communication strategies was often driven by the goodwill of volunteers who were proactive in setting up opportunities to speak about DonateLife.

Between 2010 and 2012, a national advertising campaign was undertaken at a cost of $13.8 million. The primary target audience for the campaign was families, with a focus on discussing donation wishes. There has been no national campaign since then.

The Review was presented with evidence that extensive organ donation promotion campaigns have improved community awareness and promoted discussion amongst family members.[33]

The DonateLife Stakeholder Engagement Framework was updated in July 2014 to reflect the evolution of the national reform programme and stakeholder engagement with the national DonateLife Community Awareness and Education Programme. All members are signatories to what was previously known as the DonateLife National Communications Framework and Charter. From 1 July 2014, these two documents were consolidated into the DonateLife Partnership Agreement (the Agreement), with three tiers of partnership:

- DonateLife Partners - consisting of non-government organisations in the organ and tissue donation or transplantation sectors
- DonateLife Corporate Partners
- DonateLife Community Partners.

As at January 2015, OTA had 52 DonateLife Partners, 20 DonateLife Community Partners and five Corporate Partnerships. The Review noted that OTA has recently committed to meeting with key community partners twice per year.

The Review noted that the impending improvement in the functionality of the AODR (see Section 5.8.1) is an opportune time to promote the registry and that this would be a useful point for a national communication campaign.

OTA has engaged the Australian Curriculum Studies Association to develop a suite of school education resources for Year 5-6 school students, in addition to the existing Year 8 and Year 9 school education resources produced in 2013. The Review noted that the community members consulted were very supportive of this.

[33] Woolcott Research Tracking Survey, 2011-2012

The Review received compelling and valued input from donor families who recounted their profound experiences with courage and candour. While most of the individual donation experiences pre-dated the establishment of the OTA, the experiences remain relevant. Donor family recognition is crucial to the success of the DonateLife Network and organ donation in Australia. Donor families reported an appreciation of the donor-recipient letter exchange programme and the remembrance services, and also noted the crucial importance of counselling following donation. Donor families long for community recognition of donation, although attempts to establish memorials have received varied receptions. Nevertheless, ongoing consultations with donor families over donor memorials would be valued by donor families,

In November 2009, OTA launched the DonateLife brand and website and the DonateLife logo became the official symbol for organ and tissue donation in Australia. The Review found that donor families in particular were concerned about the DonateLife logo and its similarity to recycling logos. While this logo had been designed with the best of intention, and may have been well received at the time, donor families now feel that it too closely resembles logos associated with recycling. A version of the logo with an emphasis on the theme of 'a gift' was suggested by a number of donor families.

5.6.2 Summary of findings: Awareness strategies, communication and donor family support

The key findings were:

- Awareness strategies are currently primarily focussed on local communication strategies, DonateLife week and the community grants programme
- There has not been a national awareness campaign since 2010 -2012
- Donor families have expressed concern about the OTA logo and its similarity to recycling logos
- There is an opportunity to substantially improve awareness of the AODR when it is enhanced in 2016 and that this is likely to improve registrations and subsequent donation.

5.6.3 Recommendations: Awareness strategies, communication and donor family support

Recommendation 16: The Australian government considers 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.

Recommendation 17: The proposed Board of governance should consider the DonateLife Community Awareness and Education Programme annually, including the Stakeholder Engagement Framework, to ensure a nationally consistent, evidence-based approach to communications about organ and tissue donation for transplantation.

Recommendation 18: The OTA should consider revising 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.

5.7 Community Awareness Grants Programme

5.7.1 Discussion of findings: Community Awareness Grants Programme

The OTA has administered a Community Awareness Grants Programme since 2009 based on extensive community research; with eight Community Awareness Grant rounds, totalling close to $2.9 million. The total funding provided to recipients for the eighth round was $463,000.

The Community Awareness Grants Programme forms part of the DonateLife Community Awareness and Education Programme; it provides funding for community-based awareness and education activities that contribute to increasing public understanding of, and support for, organ and tissue donation for transplantation. Those eligible to be grants recipients include non-government organisations and professional bodies, including community-based not for profit organisations or local government associations.

The focus of the grant rounds has differed over time – including DonateLife Week events, activities and events targeted at CALD communities, and activities that improve community awareness and education. Grant rounds have been promoted through OTA's website, a national media release, social media and in *The Australian* newspaper.

The Community Awareness Grants guidelines are designed to assist applicants in assessing the appropriateness of their proposed project against the suitability criteria for a grant under the Community Awareness Grants Programme. The ANAO audit found that the grants guidelines do not fully outline its grants assessment process and recommended that the OTA review its grant administration to improve transparency and equity, with a particular focus on informing potential applicants of all available sources of grant funding and the assessment process applying to each source.

Most stakeholders consulted by the Review noted the effectiveness of the grants programme, including its alignment with the OTA strategy; but it was noted that the selection criteria for grant recipients had not been reviewed by the OTA Advisory Council prior to the call for applications.

5.7.2 Summary of findings: Community Awareness Grants Programme

The key findings were:

- The Community Awareness Grants programme is an effective strategy to improve community awareness of the organ and tissue donation programme at the local level.

5.7.3 Recommendations: Community Awareness Grants Programme

Recommendation 19: The proposed Board should consider the key criteria for selection of grant recipients prior to the commencement of the grant recipient selection process.

5.8 Australian Organ Donor Registry

5.8.1 Discussion of findings: Australian Organ Donor Registry

The Australian Organ Donor Registry (AODR) is the only national register for people to record their decision about becoming an organ and tissue donor for transplantation after death. It is a voluntary register administered by the Department of Human Services on behalf of the Australian government. The clinical decisions that follow from the notation of the registration of consent at the time of donation are made under the provisions of the relevant state and territory human tissue legislation.

Registering is voluntary and family consent is still obtained by clinicians before donation can go ahead; only people aged 18 years and over can register their legally valid consent or objection on AODR. Those aged 16 and 17 can register their intention to donate.

Total number of registrations as at 30 June 2015 on the AODR is 6,109,711. While the total number of legally valid consent registrations (including intent registrations of 16 and 17 year olds) is 1,833,085.

The Review found that the process for the provision of legally valid consent registrations is a barrier as it currently requires the provision of a hard copy signature. In addition, NSW and SA are the only states in Australia that have a system for registration of consent for organ donation via an individual's drivers licence. In NSW it was found that the process of drivers licence renewal was not an ideal process for this kind of decision as it provided minimal opportunity to either give detailed information about deceased donation or to prompt discussion of individual's wishes with their family. In addition, having a two tiered system of registering consent in NSW was confusing for clinicians at the time of decision-making in hospitals and for family members. As such, a decision was made by NSW in 2012 to streamline to a single national register, and is currently phasing out the registration of consent for organ donation via the drivers licence, in order to simplify the process. In SA, the registry is linked to the AODR; however these registrations can only be classified as 'intent' to donate.

The Review found that clinicians are very supportive of the AODR given it provides a platform for family donation conversations. It also provides a higher consent rate for donation with those who have registered as the family is aware of the preference of the individual, compared to those who have not registered their intent. For example, the 2014 DonateLife Audit data shows that when the donor has registered their wishes, there is a 90% consent rate.

One of the OTA's strategic priorities for 2015-2016 is focused on increasing the proportion of legal consent registration on the AODR through the introduction of the functionality for electronic signatures. This will aim to remove the current barriers in the process, as well as providing greater certainty of an individual's donation decision for clinicians and families during family donation conversations. OTA will also support this process through a national online donor registration campaign and revising the Professional Education Programme to incorporate AODR changes.

The alignment of state and territory human tissue legislation proposed in Section 5.11 should allow greater clarity in supporting the AODR as the single register of consent for organ donation in Australia.

5.8.2 Summary of findings: Australian Organ Donor Registry

The key findings were:

- The number of Australians who have registered their intention to donate on the AODR is low (6,109,711)[34] while the number of these individuals who have provided their consent is even lower (1,833,085).[35]
- The funded enhancement to the AODR will allow for a significant improvement in the consent process and is likely to result in a rapid improvement in enrolment numbers.
- The AODR provides a very useful platform for the consent conversation and results in higher

[34] As at 30 June 2015: http://www.humanservices.gov.au/corporate/statistical-information-and-data/australian-organ-donor-register-statistics/

[35] As at 30 June 2015 and includes Intent Registrations of 16 and 17 year olds: http://www.humanservices.gov.au/corporate/statistical-information-and-data/australian-organ-donor-register-statistics/

consent rates among those registered compared to those who are not registered

- The use of driver licence designation in many states was well intentioned but confused the family donation conversations in many instances, so the phase out of this system should be completed in NSW.

5.8.3 Recommendations: Australian Organ Donor Registry

Recommendation 20: Once the enhancement to the AODR is fully operational, a further campaign to increase enrolment should be undertaken as planned

5.9 Electronic Donor Record

5.9.1 Discussion of findings: Electronic Donor Record

The Electronic Donor Record (EDR) was launched on 31 March 2014, following a two-year development and implementation period. It provides a national web-based information system which supports the management and sharing of donor information required for organ and tissue referral and donation processes.

To ensure that appropriate governance processes were in place for the exchange of information through the EDR between jurisdictions and the Commonwealth, a multilateral data sharing agreement was put into place. The agreement describes the agreed governance and responsibilities of each jurisdiction and the OTA in the management of data collected, how it can be accessed and how it can be used. It aims to address the Commonwealth privacy legislation, as well as state and territory legislation, which determines how health information can be stored and utilised.

The Review found that users of the EDR were generally satisfied with the system and its implementation; allowing for data entry management and sharing of donor information, overall improving the safety and transparency of the donation process. However, they noted that currently the EDR only captures the critical information of donations which proceed to transplantation, and not referral for donation. As such, the EDR currently does not capture the full audit trail for donations (both those that proceed and do not proceed to donation).

The review found the users of the EDR would like to see this functionality incorporated. The Review acknowledges that action is currently underway within the OTA to progress this issue. Additional improvements of the EDR identified by users included the ability to search the EDR and improved access for clinical use, which is currently restricted due to EDR data being sent to transplant teams as a PDF. Such functionality would require states and territories to align health record privacy legislation (where it exists) in order to remove any impediments to access to the full EDR by transplant clinicians and other DonateLife network members, such as those involved in the organ allocation and retrieval decisions.

Transplant clinicians also commented that the EDR can be an extensive electronic record and the addition of a summary would assist in their assessment of the donor.

The OTA also suggested that the data held in the EDR represents an important opportunity for research into organ transplantation issues. This was not raised by other stakeholders, but it would seem evident that research into organ donation patterns is an important activity that will substantially contribute to a better understanding of organ donation and should be facilitated.

5.9.2 Summary of findings: Electronic Donor Record

The key findings were:

- The EDR implementation has been well received by the clinicians who use the record; they feel that it has made a substantial improvement to the donation process
- Some further improvements will enhance the effectiveness and efficiency of the EDR, such as inclusion of referrals and improved access to information for clinical use.

5.9.3 Recommendations: Electronic Donor Record

Recommendation 21: The EDR should be enhanced as planned to record all referrals to the Donate Life Network (not only those that proceed to donation) and the reasons for any decision not to proceed to donation.

Recommendation 22: States and territories through the CHC 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.

5.10 New organ perfusion technologies

5.10.1 Discussion of findings: New organ perfusion technologies

Organs begin lacking oxygen as soon as they are removed from the donor and tissues may have been damaged by the time a transplant takes place. Current practice is for donor organs to be kept in 'cold static preservation' at less than ideal temperatures and levels of oxygenation during transport and when preparing for transportation.

There are emerging ex vivo perfusion technologies that have the potential for organ resuscitation and reconditioning, potentially increasing the quality and number of organs available for transplantation.

These technologies are designed to preserve donor organs by providing oxygenation throughout the entire organ-preservation process before transplantation. Research shows that the technology could preserve more donor organs, reduce mortality among those on the waiting list and provide them with better post-transplant outcomes.[36]

Currently there is variable use of these technologies in Australia; however it is an emerging technology and further evaluation of its effectiveness and benefits needs to be further explored.

5.10.2 Summary of findings: New organ perfusion technologies

The key findings were:

- New organ perfusion technologies may improve the availability and viability of donated organs.

5.10.3 Recommendations: New organ perfusion technologies

Recommendation 23: The effectiveness of organ perfusion technologies should be evaluated by AHMAC and the CHC and consideration given to their ongoing utilisation in the future, with costs reflected in the retrieval services IHPA price recommended at Recommendation 15.

[36] Templeton. D. (2015). *New technology preserves organs during transplant process*. American Journal of Transplantation. US. Viewed 15 July 2015 http://medicalxpress.com/news/2015-01-technology-transplant.html

5.11 Eye and tissue donation and transplantation

5.11.1 Discussion of findings: Eye and tissue donation and transplantation

Currently, there are a variety of processes and models adopted by jurisdictions related to funding, administrative structures, donor selection, consent approaches and data management systems for retrieval, processing and storage and distribution of eye and tissue products.

The collection of tissue for donation is regulated by human tissue legislation within each of the states and territories and there is some variation in the provisions of the legislation between jurisdictions. This variation and a lack of information sharing between some tissue banks impairs the national supply of tissue for donation and impacts equity of access; however through an alignment of human tissue legislation, there is the opportunity to facilitate the national allocation of donated tissue through consistency and standardisation of approach. It is acknowledged that a change in legislation will take time; however more complicated processes of alignment of state and territory legislation have been achieved previously (such as the health professional legislation reforms of 2007-2009).

An economic assessment of eye and tissue donation is soon to be undertaken by the OTA to allow eye and tissue banks, jurisdictional health departments and other key stakeholders to respond to the financial, regulatory and efficiency challenges facing the sector.

In addition, there is now an agreed national eye and tissue donation data set, allowing for eye and tissue donation and transplantation outcomes to be publically reported. As such, the data shows that since 2012, there has been a steady increase in deceased tissue donation (59%), with a slight increase in living tissue donation (2%). However, the Review found that there is variability in the utilisation of these tissues by jurisdiction.

5.11.2 Summary of findings: Eye and tissue donation and transplantation

The key findings were:

- The Economic Analysis of the Eye and Tissue Sector provides an opportunity for a national and standardised approach to the supply of tissue for donation
- There is a steady increase evident since 2012 in deceased tissue donated through the programme; there still exists extensive variability in process and models adopted by jurisdictions and by eye and tissue banks within jurisdictions.

5.11.3 Recommendations: Eye and tissue donation and transplantation

Recommendation 24: Following the completion of the Economic Analysis of the Eye and Tissue Sector, through the CHC, 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.

5.12 Issues outside the scope of the Review

The Review was informed of a number of issues that are better explored through a more focussed review on transplantation issues, including:

- Variability in application of acceptance criteria for organs between transplant units; although as noted in Section 5.1, the Transplantation Society of Australia and New Zealand is currently revisiting the *Organ Transplantation from Deceased Donors: Consensus Statement on Eligibility Criteria and Allocation Protocols*
- Potential exhaustion of transplant retrieval teams
- Some anecdotal evidence of the loss of opportunities to retrieve donated organs through the lack of available retrieval teams
- The efficiency of the deployment of travelling retrieval teams to Adelaide and Canberra when local teams could well be trained to retrieve organs.

It would seem opportune for these matters to be considered by AHMAC in the near future.

6. Conclusion

Since the implementation of the national reform programme in 2009, there has been an overall increase in the dpmp by 41% (11.4 dpmp in 2009 compared to 16.9 dpmp in 2014). While there has been some improvement as a result of the programme, the OTA and other stakeholders recognise there is a need for substantial improvement in performance if the goal of 25 dpmp by 2018 is to be achieved.

Despite a drop off in donation rates in 2014, performance in 2015 is looking stronger – with a number of jurisdictions having outperformed their July YTD 2014 outcomes. The challenge will be in maintaining and growing the current momentum in performance. The implementation of relevant enhancements funded in the 2015 federal budget, the priority areas outlined in the *Organ and tissue donation for transplantation in Australia 2014-2018 strategic plan*, along with continued implementation of a range of improvement strategies - should help facilitate further improvement of donation for transplantation rates.

However there also needs to be strong joint leadership from the OTA, the DonateLife Network and State and Territory Health Departments along with open and transparent dialogue – all of which is underpinned by further enhanced data collection, monitoring of performance and subsequent action. In addition, there are a range of improvements identified by the Review which would also facilitate the progress towards, and achievement of the national goals and targets.

Appendices

Appendix A Stakeholders consulted

Name		Position	Organisation
Adair	Michele	Executive Officer	Cystic Fibrosis NSW
Anderson	Teresa	Chief Executive	Sydney Local Health District
Arya	Dinesh	Chief Medical Officer	Department of Health, NT
Aspinall	Diana	-	Consumer representative
Balderson	Glenda	Scientific Director, Liver Transplant Unit, Princess Alexandra Hospital	Australia and New Zealand Liver Transplant Registry
Baldwin	Mary	-	Transplant recipient
Bastian	Louise	-	Cancer Voices SA
Benson	Tim	Chair	NMHS Community Advisory Council
Boyd	Carolyn	-	Transplant recipient
Brieva	Jorge	Donation Specialist Medical, John Hunter Hospital, Newcastle	DonateLife NSW
Buckland	Lisa	Director	Lions Eye Bank WA
Cahill Lambert	Anne	-	OTA Advisory Council (former)
Campbell	Leanne	-	Donor family
Caris	Sharon	Executive Director	Haemophilia Foundation Australia
Cass	Yael	Chief Executive Officer	OTA
Cavazzoni	Elena	State Medical Director	DonateLife NSW
Celcer	Juliana	Clinical Manager	DonateLife NSW
Chadban	Steve	President	Transplantation Society of Australia and New Zealand
Chant	Kerry	Chief Health Officer and Deputy Secretary, Population and Public Health	NSW Ministry of Health
Chapman	Julie	-	Transplant recipient family
Chapman	Jeremy	Westmead Hospital renal physician	OTA Advisory Council
Chapman	Will	-	Transplant recipient
Coco	Tina	Agency Manager	DonateLife QLD
Colquhoun	Janelle	-	Transplant recipient
Cook	David	Donation Specialist Medical, Princess Alexandra Hospital	DonateLife QLD
Corke	Charlie	Chair (past)	College of Intensive Care Medicine of Australia and New Zealand
Cowie	Anne	Managing Director	PlusLife WA
Cross	Martin	-	ShareLife
Davis	Leanne	Executive Officer	Cystic Fibrosis SA
D'Costa	Rohit	State Medical Director	DonateLife VIC
Delriviere	Luc	Head of liver transplant and hepato-biliary surgery	Sir Charles Gardiner Hospital

Name		Position	Organisation
Diver	Frances	Deputy Secretary, Health Service, Performance & Program	Department of Health, VIC
Dobb	Geoffrey	Director of Critical Care at Royal Perth Hospital and Head of Intensive Care	OTA Advisory Council
Downes	Kylie	Agency Manager	DonateLife ACT
Dykes	Nicola	WSLHD Organ & Tissue Donor Coordinator	DonateLife NSW
Eccles	Ashley	Director, Projects	OTA
Ellis	Christine	National President	Transplant Nurses Association
Elmes	Ros	Executive Director, Public Health & Ambulatory Care, North Metro Area Health Service	Department of Health, WA
Eris	Josette	Chair, Transplant Liaison Reference Group; Nephrologist	Royal Prince Alfred Hospital
Farrugia	Twanny	-	Transplant recipient
Ferrari	Paolo	Director, Australian Paired Kidney Exchange Program; Nephrologist	Prince of Wales Hospital
Fisher	Danielle	General Manager	DonateLife NSW
Furey	Michael	Manager, Blood, Pharmaceutical, Organ and Tissue Donation	Department of Health, VIC
Gauthier	Nicole	Donation Specialist Coordinator	DonateLife VIC
Glanville	Allan	Board Member	Outcomes Australia
Gomez	Maria	CEO	Outcomes Australia
Green	Kevin	-	Donor family
Hall	Bruce	Professor of Medicine	University of NSW
Harper	Emily	Manager, Office of the Chief Health Officer	ACT Health
Harrison	Graham	-	Donor Family
Harrison	Judy	Chief Financial Officer	OTA
Hart	Phil	Chief Executive Officer	College of Intensive Care Medicine of Australia and New Zealand
Hawes	Ellen	Director, Blood Tissue and Organ Team	Queensland Health
Herson	Marisa	Eye and Tissue sector representative	OTA Advisory Council
Hobson	Jamie	Transplant Liaison Nurse	Australasian Transplant Coordinators Association
Hodak	Alison	Donation Specialist Coordinator	Australian College of Critical Care Nurses / DonateLife SA
Hodgkinson	Suzanne	Neurologist	Liverpool hospital and UNSW
Horvath	John	-	OTA Advisory Council
Hughes	Peter	Nephrologist	Royal Melbourne Hospital
Ireland	Sue	Manager Blood Organ & Tissue Programs	Department for Health and Ageing, SA
Jacobs	Genevieve	Vice-president	Gift of Life Incorporated
Johnston	Adam	-	Consumer representative
Jones	Philippa	Donation Specialist Nursing Coordinator	DonateLife SA
Jones	Bob	Liver Transplant Unit Director	Austin Hospital

Name		Position	Organisation
Kanellis	John	Chair	Transplantation Society of Australia and New Zealand
Kay	Tom	Director	St Vincent's Institute
Koch	David	Chair (past)	OTA Advisory Council
Lancione	Gloria	-	Cystic Fibrosis consumer
Laver	Heylen	Agency Manager	DonateLife SA
Lee	Jessica	-	ShareLife
Little	Robert	-	Consumer representative
Lynch	Mary	Donation Specialist Nursing, Sir Charles Gairdner Hospital	DonateLife WA
MacDonald	Peter	Cardiologist	St Vincent's Hospital, Sydney
Madson	Greg	President	People with Disabilities WA
Maher	Judith	-	Consumer representative
Manning	Linda	-	Perth Hospital Heart Valve Bank
Mc Ardle	Martina	Committee member	The Heart and Lung Transplant Trust (Victoria) Inc. Committee
McCaughan	Geoff	Board Member	Outcomes Australia
McDonald	Stephen	Executive Officer	Australia and New Zealand Dialysis and Transplant Registry
McDowell	Bruce	-	Donor Families Australia
McKenzie	Anne	-	Consumer representative
McWaters	Kim	-	Donor family
McWaters	Sharon	-	Donor family
Moodie	Stewart	Donation Specialist Medical, Queen Elizabeth Hospital	DonateLife SA
Myerson	Brian	Board Member	ShareLife
Northam	Holly	Assistant Professor in Critical Care Nursing	Donor Families Australia
Nunnink	Leo	State Medical Director	DonateLife QLD
Nuttall	Nichalas	Director	Queensland Tissue Banks
O'Connell	Philip	President	The Transplant Society (International)
O'Leary	David	President, Gift of Life Incorporated	OTA Advisory Council
Opdam	Helen	National Medical Director	OTA
Palk	Nigel	President	Australasian Transplant Coordinators Association
Parker	Cath	Executive Officer	Cystic Fibrosis QLD
Parker	David	Council/committee member	Kidney Health Australia Council and Renal Transplant Advisory Committee Consumer representative
Pavlovic	Julie	TNA executive	Transplant Nurses Association
Pengilley	Andrew	Deputy Chief Health Officer	ACT Health
Phillips	Paddy	Chief Medical Officer	Department for Health and Ageing, SA
Phillips	Ron	Chair, Sydney Local Health District Board	Sydney Local Health District

Name		Position	Organisation
Pleass	Henry	Surgical rep	Transplantation Society of Australia and New Zealand
Pollock	Graeme	A/Chair and Treasurer	Eye Bank Association of Australia and New Zealand
Poniatowski	Stefan	Head	Donor Tissue Bank of Victoria
Powell	Bruce	State Medical Director	DonateLife WA
Radford	Sam	Donation Specialist Medical, Austin Hospital	DonateLife VIC
Randall	John	Board Member	ShareLife
Rischbieth	Amanda	Chief Executive	Heart Foundation
Rogerson	Kelly	Operations Manager	DonateLife VIC
Rourke	Francesca	DonateLife Network Donation Specialist Coordinator	OTA Advisory Council
Russ	Graeme	Chair	Australia and New Zealand Organ Donation Registry
Ryan	Jason	Chairman	Transplant Australia
Sampson	Brett	Donation Specialist Medical, Flinders Medical Centre	DonateLife SA
Shackel	Nick	RPAH hepatologist	NSW Transplant Advisory Committee
Silvester	Bill	Chair	Australian and New Zealand Intensive Care Society - Committee on Death and Donation
Skinner	Michelle	Donor Family Support Coordinator	DonateLife VIC
Smith	Melissa	Agency Manager	DonateLife WA
Snell	Greg	Medical Director, Lung Transplant Service	Alfred Hospital
Snell	Gregory	-	Transplantation Society of Australia and New Zealand
Stephens	Dianne	State Medical Director	DonateLife NT
Stewart	Kim	Director, Office of the Chief Health Officer	NSW Ministry of Health
Stitt	Nicola	Donation Specialist Nursing Coordinator Intensive Care Unit	Australian College of Critical Care Nurses
Swan	David	Chief Executive	Department for Health and Ageing, SA
Thomas	Chris	Chief Executive Officer	Transplant Australia
Tideman	Sally	Immediate Past State Medical Director	DonateLife SA
Torzillo	Paul	Director, Clinical Services	Royal Prince Alfred Hospital
Turner	Allan	CEO	Zaidees Rainbow Foundation
Turner	Andrew	President	Australian and New Zealand Intensive Care Society / DonateLife Tas.
Tyson	Amy	Advocacy Manager	St Vincent's Health Australia
Van der Meer	Gavin		Geelong bone bank
Van Haren	Frank	State Medical Director	DonateLife ACT
Verran	Deborah	Transplant Surgeon	Royal Prince Alfred Hospital
Vohra	Mehak	Policy Officer	Consumers Health Forum
Vortman	Sarah	Principal Policy and Planning Officer Blood, Tissue and Organ Team	Queensland Health

Name		Position	Organisation
Waldron	Philippa	-	Donor Family
Watchirs	Helen	Donor family	OTA Advisory Council
Webster	Angela	Westmead nephrologist	NSW Transplant Advisory Committee
Weinman	Marvin	Chairman	ShareLife
Williams	Jennifer	CEO	Australian Red Cross Blood Service
Williams	John	-	Consumer representative
Williams	Keryn	-	Australian Corneal Graft Registry
Wilson	Anne	Chief Executive Officer & Managing Director	Kidney Health Australia
Winter	Joyleen	President	Biotherapeutics Association of Australia
Wiseman	Laurie	-	Donor Family
Wyburn	Kate	Chair, Staff Specialist Nephrologist Royal Prince Alfred Hospital	NSW Transplant Advisory Committee

Appendix B Glossary of terms

Active end of year: This data refers to the count of patients on an active deceased donor waiting list at the end of the calendar year of reporting.

Active start of year: This data refers to the count of patients on an active deceased donor waiting list at the start of the calendar year of reporting. The active deceased donor waiting list comprises people who would be transplanted immediately if an organ were available.

Consent rate: Number of consents as a proportion of the number of requests made of potential donors.

Conversion rate: Number of brain dead donors as a proportion of the number of potential donors with confirmed or probable brain death.

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.

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.

Intent registration: Intent registrations occur when people register their decision about becoming an organ and tissue donor on the Australian Organ Donor Register, but have not yet provided a signed registration form.

Legally valid consent registration: A legally valid consent registration requires a record of the hard copy signature by each applicant to record their decision about becoming an organ and tissue donor on the Australian Organ Donor Register. People aged under 18 years of age can only register intent, in these cases legal consent from the families will still be required.

Request rate: Number of requests of potential donors as a proportion of the total number of potential donors

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