

Australian
Healthcare
Associates

Organ and Tissue
Donation Reform
Package

Mid-Point Review Report
July 2011

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ABBREVIATIONS

ADAPT	Australasian Donor Awareness Programme
AHMAC	Australian Health Ministers Advisory Committee
AKX	Australian Paired Kidney Exchange
ANZOD	Australia and New Zealand Organ Donation Registry
ATCA	Australian Transplant Coordinator's Association
CEO	Chief Executive Officer
CNC	Clinical Nurse Consultant
CNS	Clinical Nurse Specialist
COAG	Council of Australian Governments
CTEPC	AHMAC's Clinical, Technical and Ethical Principal Committee
DBD	Donation after Brain Death
DCD	Donation after Cardiac Death
DFS	Donor Family Support
DFSIWG	Donor Family Support Implementation Working Group
DoHA	Department of Health and Ageing
dpmp	donors per million population
EC	Education Coordinator
ECN	Education Coordinators Network
ED	Emergency Department
EDR	Electronic Donor Record
ETWG	Eye and Tissue Working Group
EU	European Union
FMA Act	Financial Management and Accountability Act 1997
FTE	Full Time Equivalent
HMD	Hospital-based Medical Director
HSN	Hospital Senior Nurse
ICU	Intensive Care Units
JWG	Jurisdictional Working Group
NCIS	National Clinical Information System
NETN	National Eye and Tissue Donation and Transplantation Network
NHMRC	National Health and Medical Research Council
NODC	National Organ Donation Collaborative
NOK	Next Of Kin
ODC	Organ Donor Coordinators
ODHSF	Organ Donation Hospital Support Funds
ONT	Organización Nacional de Trasplantes (Spanish National Transplant Organisation)
OTA	Organ and Tissue Authority
OTDA	Organ and Tissue Donation Agency

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OTDC	Organ and Tissue Donor Coordinator
SMD	State Medical Director
SMD/JWG	State Medical Director/Jurisdictional Working Group
TRIP	Translating Research into Practice Fellowship
TSANZ	Transplantation Society of Australia and New Zealand

1 EXECUTIVE SUMMARY

The primary focus of this mid-point review is the examination of the progress on implementation of the reform package in 2010. This was the first full year of implementation of the reform measures. These findings need to be placed in context, so the report also incorporates relevant information about earlier work that was reported by stakeholders as having contributed to the achievements in 2010. Equally, given that the reform continues to evolve, commentary on activity by the Authority and the broader DonateLife Network since the end of 2010, is also included where appropriate, although a detailed review of the Authority's strategic priorities for 2011-12 was not in scope.

Overall, the reform package had achieved notable success by the end of 2010, though the progress in implementation of each of the nine measures of the reform package has varied.

Measures in which significant progress was achieved in 2010:

- The Authority and an enhanced network of jurisdictional organ and tissue donation agencies are 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 is now available in 77 hospitals nationally. These staff are evolving systems to support continued improvements in hospital donation performance
- New systems of funding hospitals' organ donation costs are operational
- A successful community awareness and education campaign has been delivered. The campaign has been well received. Importantly it has changed community awareness and behaviours related to potential for donation
- The Australian Paired Kidney Exchange (AKX) program commenced operation

Measures in which moderate progress was achieved in 2010:

- A framework for nationally consistent support for donor families was agreed
- A consensus was achieved regarding safe, equitable and transparent national transplantation processes
- A national protocol for Donation after Cardiac Death (DCD) was agreed

These policies and protocols are currently being implemented nationally.

Measures in which relatively little progress was achieved in 2010:

- There remains a need for a fit-for-purpose national education and training program to further develop capacity of the sectors healthcare professionals
- There remains a need to better define and develop the national eye and tissue donation and transplantation network

The mid-point implementation review canvassed the wide range of perspectives of stakeholders on implementation of the national reform package in organ and tissue donation. Stakeholder judgements on performance to date are determined in large part by their prior beliefs regarding the likely magnitude of the potential change and expectations regarding the likely rate of change in performance in the sector following the commencement of implementation of the reform package. Hence progress in

implementation of all reform measures has been variously described by stakeholders as being 'dismal or non-existent', 'excellent or outstanding' or at some point on the continuum between these extremes.

The conclusions regarding progress in implementation of reform in Australia's organ and tissue donation sectors are based upon prevailing majority viewpoints, available objective evidence and by comparing progress to date with that achieved by related international organ and tissue donation sector reform programs.

All national reform programs in healthcare are inherently difficult. The challenges facing those charged with implementing national reform of organ and tissue donation and transplantation sectors should not be underestimated. The structure of the reform package requires the Authority to lead reform by working with each of the eight jurisdictions to establish a jurisdictional, Organ and Tissue Donation Agency (OTDA) and the recruitment of hospital staff to form the DonateLife Network. It is also expected that the Authority will lead the introduction of consistent practices in all aspects of organ and tissue donation across all jurisdictions. The support of each jurisdiction will be required to achieve nationally consistent care. It is noted that the donation and transplantation arena also has a very large number of advocacy groups that believe they can and should play a role in implementation of national reform.

In addition to these inherent complexities, there were challenges and issues for the Authority in their first two years of operation. These are summarised within the body of the report. They relate to issues of staffing, operational style and strategic intent. These are perceived to have negatively impacted implementation of the reform measures. However all stakeholders describe these challenges and issues as being largely in the past. There is now a strong sense that the Authority and its leaders are 'on track'. In current interactions with the Authority the sector is experiencing better ways of working. There is a confidence across the sector that better outcomes will be achieved by the Authority in coming years. In 2011 the Authority appears well placed to lead the sector's ongoing efforts to enhance national deceased donation performance by enabling improved clinical care of potential deceased organ donors.

In 2008, the Australian Government announced the World's Best Practice National Reform Package for Organ and Tissue Donation for Transplantation which saw the commitment of \$151 million, including the establishment of a national authority. The package built on earlier Council of Australian Governments (COAG) commitments and work set in train through the national reform agenda launched in 2006. This has already delivered a significant increase in the key indicator of sector performance, Australia's deceased donor organ donation rate. The 309 deceased organ donors in 2010 was the highest number of donors on record. The rate at which the national number of deceased organ donors has increased, following the launch of the national reform, equals that seen in Spain, and exceeds that achieved by other nations at the same stage of related sector reforms.

The increase in our national deceased donor organ donation performance in 2010 can be largely attributed to a substantial increase in performance by a relatively small number of hospitals within two jurisdictions, New South Wales and Victoria. It is to be expected that early gains in the performance of national donation systems would derive from improved performance by relatively few hospitals. Early gains in performance of complex systems always come through the efforts of relatively small numbers of innovators or early adopters of change.

There is significant capacity to see continued growth in national deceased donor organ donation performance. National deceased donor rates of 23-25 dpmp are potentially achievable. Continued growth in national donor numbers, will require the reform to deliver a progressive increase in the

proportion of participating acute hospitals that become high performing donor hospitals over time. This would be assisted by better targeting of future investment on hospitals that are known to currently have a significant potential for deceased donation. Spain, which currently leads the world on deceased organ donation rates, makes decisions regarding donor support staffing based on an assessment of donation potential using Intensive Care Unit (ICU) throughput, casemix and mortality data.

The establishment of the DonateLife Network, including the hospital-based specialist staff in the 77 participating hospitals, provided an essential clinical practice improvement resource for the sector. Indications from a number of staff in high performing hospitals of 2010 and a number of OTDA staff suggest that work to deliver the increase in deceased donation performance built upon earlier initiatives of the 2006 national reform agenda, such as the National Organ Donation Collaborative. The hospitals demonstrating markedly increased donation performance have 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. We therefore conclude that these measures did directly contribute to the observed increase in national deceased donor performance in 2010.

It is likely that re-engineering hospital systems to support increased donation rates in an increased number of hospitals, will not occur simply through the addition of resources but will also require a concerted clinical practice improvement program with leadership provided at a national, jurisdictional and individual hospital level, with progress in terms of increasing deceased donor numbers, taking time.

Many of the reform measures would be anticipated to require significant lead-times before contributing to improvements in donation performance and some are not designed to impact directly on deceased donor organ donation rates. It would be premature to make definitive judgements on the potential utility of all of these measures at this early stage of their implementation.

In addition, attribution of any change in performance in healthcare systems to any particular initiative is always difficult. Nonetheless, we conclude that at this stage in implementation there is little evidence that the other reform measures (measures three to nine) made a direct contribution to the improved national donor performance seen in 2010.

All those consulted for the review endorsed the need for a national approach to organ donation and the structure that has been implemented. In the past two years there has been a progressive increase in commitment to the new national system and a growth in sector capacity. However the extent to which the DonateLife network is evident and operational as a cohesive national system still varies considerably across jurisdictions. This reflects differing levels of commitment and capacity within jurisdictions. The Authority needs to refine its guidance and support mechanisms for jurisdictions and participating hospitals to enable a progressive maturation of the network. Much of this network enhancement could be planned to occur within the context of implementing national frameworks for education and training of healthcare professionals and clinical practice improvement in deceased donation.

The Authority has opportunities to enhance its current governance and consultation arrangements. The Advisory Council requires revision of its membership and mode of operation. Most stakeholders agree that there should be a reduction in the size of the Advisory Council (to 9 members plus Chair). The Council should concentrate exclusively on provision of focused strategic advice and establish mechanisms for providing advice in addition to its quarterly face-to-face meetings.

There needs to be a review and refinement of the membership and terms of reference of all governance committees and subcommittees to ensure the Authority has regular access to all required inputs.

The current stakeholder forums should be reviewed and refined with a view to enhancing communication with its very broad stakeholder base. To date the support around key messages provided by a small number of the signatories to the Communications Charter with the Authority have not been consistent with the community messages promoted by the Authority.

There is a very real need to identify and articulate the roles, responsibilities and accountabilities of the Authority, the jurisdictions and the DonateLife Network hospital-based teams for:

- Monitoring current performance of deceased donation systems of care
- Designing and supporting delivery of improvements in the clinical care of potential deceased organ donors
- Educating, training and developing capacity of staff in the sector

This would best be achieved by the Authority establishing a formal *Clinical Governance framework* for the deceased organ donation and transplantation sector.

Nationally consistent approaches to performance monitoring (e.g. death audit, audits of clinical trigger tool use, organ utilisation and allocation data) would provide a foundation for national, jurisdictional and hospital-level interventions to drive overall improvements in national deceased organ donation performance. In recognition of this the Authority has established a Data and Audit Working Group and recently reached agreement with the SMD/JWG on a number of strategies to be implemented, towards achieving a nationally consistent approach to collection and review of this data.

Building national frameworks for *performance measurement, clinical practice improvement* and *professional education and development* for the DonateLife Network would require substantial clinical input. It could be achieved within existing resourcing provided the Authority devises mechanisms to better access and use the knowledge and experience of clinical staff of the DonateLife Network in establishing these national programs. This would see the Authority better leveraging the rich resource of clinical expertise available within the DonateLife network, while providing these staff with important networking and professional development opportunities.

The following summarises the opportunities for enhancing the DonateLife Network, identified by the review of 2010, although it should be noted that work has already commenced on some of these:

- Establish a relentless focus by the Authority on supporting and prioritising activities that deliver measurable changes in clinical care of potential donors in DonateLife Network hospitals
- Reallocate DonateLife Network resources
- Develop an active national clinical practice improvement program to optimise deceased donation
- Establish a national professional education program
- Increase the clinical inputs into the design of implementation strategies and programs
- Draw upon expertise within the Network
- Enhance communication across the DonateLife Network

- Reduce administrative complexity
- Formalise decision-making mechanisms for the DonateLife Network
- Improve media management

2 BACKGROUND

2.1 Organ donation rates

Organ transplantation is now the most cost-effective treatment for end-stage renal failure and the only available, life-saving treatment for end-stage failure of organs such as liver, lung and heart. The donation and transplantation of eye and tissue has the longest history and constitutes the largest donation and transplant sector in Australia, saving and improving the quality of life of countless Australians.

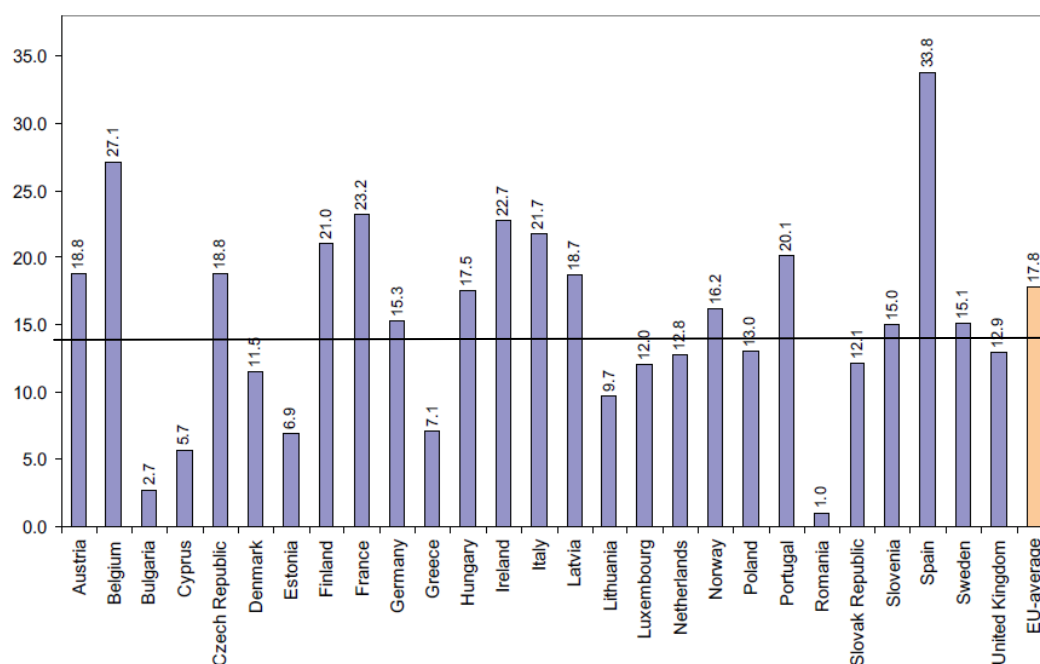
Australia has seen an ever increasing number of patients with organ failure or requiring treatments involving eye or tissue transplants on waiting lists over past decades. As Australia's population ages and the prevalence of chronic diseases such as diabetes increases, these waiting lists are likely to continue to grow. We are not alone in facing a shortfall in transplantable organs and tissues. Across the developed world the gap between the available supply and demand of organs and tissues for transplantation has led to the introduction of a variety of initiatives to improve nations' donor rates.

Australia has one of the world's best records in terms of clinical outcomes for organ and tissue transplantation. Eye donation rates in Australia are very good by international standards and all Australians requiring a corneal transplant will receive one. However Australia's rate of deceased organ donation and tissue donation has been relatively low in comparison with comparable healthcare systems.

During the early 1990's Australia's organ donation performance declined. The initial national donor rates of 14 to 15 donors per million population (dpmp) fell in the 1990's and became largely stable at around 10 dpmp from 1995.

While precise comparisons of Australia's organ donation performance in relation to the performance of other countries are difficult (due to a range of factors) 'donors per million population' is currently the only practical metric readily available for use in comparing health systems donation performance. Using this measure to compare Australia's organ donation performance against that of other countries (or indeed using any other of a range of suggested performance metrics) it can be seen that there is significant room for improvement in Australia's deceased donation performance (refer *Figure 2-1*). For example, in recent years the United Kingdom consistently achieved over 15 dpmp, the United States of America achieved 24 dpmp and Spain achieved a world-leading 35 dpmp. The average donor rate for European Union (EU) countries exceeds 17 dpmp.

Figure 2-1: European deceased donor rates (Australia's rate 14 dpmp)



These differences in donor rates between countries stem from a complex amalgam of demographic, cultural, social and historical factors in each country.

Ultimately a nation's organ donor rates are determined by community factors (the number of deaths occurring in which donation is possible and the willingness of family members to consent to donation) and healthcare system factors (in terms of both the organisation of donation systems of care and their performance in identifying and managing potential donors).

2.2 Approaches to increasing donation rates

The shortage of organs for donation has been seen as such an intractable problem in Australia that in recent years there has been a large number of reviews and inquiries of the sector. We have had several Parliamentary Select Committee Inquiries into organ donation, any number of National Forums and Summits on organ and tissue donation, several commissioned reviews and a national peak body for donation and transplantation (Australian Donate) and noticeable growth in the number of community groups actively advocating for sometimes quite radical changes in donation practices.

Many of these activities have generated a range of 'solutions' to perceived 'problems' in contemporary donation practices. These have often centred on proposing major policy shifts and legislative reforms in an attempt to redress the gap between supply and demand for donor organs and tissues. Such legislative changes have frequently included calls for the introduction of 'presumed consent' ('opt-out') for donation and even payment for the donation of organs and tissues.

In reality there is little evidence that such legislative policy changes, significantly influence national organ donation rates¹. There is however ample evidence that organisational changes and improvements that build a structured and systematic national approach to improving organ donation performance can lead to substantial increases in donation rates²⁻¹³.

In July 2006, Australia's Health Ministers recognised the importance of focusing on improving our national performance in organ and tissue donation. They agreed on the need for a new approach (a national reform agenda) to enable Australia to narrow the widening gap between the demand for and availability of organs and tissues for transplantation.

That year, three significant steps were taken:

- All governments signed a 10-point national reform agenda that had as its primary goal an increase in safe, effective and ethical organ and tissue donation for transplantation
- The Australian Government signalled its support for reform by committing \$28 million for national initiatives aimed at achieving this goal
- The National Clinical Taskforce on Organ and Tissue Donation was established in October 2006 to provide expert advice and consult widely with clinicians and other stakeholders in order to recommend practical initiatives for reform

One of the national initiatives funded in 2006 was a National Organ Donation Collaborative (NODC). This saw 28 Australian hospitals from most States and Territories (except Queensland and Tasmania) participating in a structured clinical practice improvement program from 2006 to 2008 to increase organ and tissue donation rates.

The key NODC strategies for improving organ donation in the hospital setting were improving the identification of potential organ donors within hospitals and increasing the rate at which families of potential donor were approached with a request for consent to donation. NODC had a heavy emphasis on education of key clinical staff in terms of both organ and tissue donation and how to implement systems improvement in the hospital setting. The aims were to build capacity of staff by enhancing their knowledge and skills and to help support local teams within hospitals to implement changes in their usual processes of care.

Over the life of the NODC, organ donation in Australia improved (from 10 dpmp to 12 dpmp), largely due to improved donor rates in several NODC hospitals. In 2009 and 2010 there has also been an increase in donation rate over and above the historical trend-line in hospitals that were not involved in these collaboratives, although NODC hospitals continue to demonstrate higher relative deceased donation performance (refer *Table 2-1*).

Table 2-1: Increase in deceased donation over baseline*

Participation in NODC	Increase in donation rate 2006-2008	Increase in donation rate 2009-2010
NODC Hospitals	19.4% ⁺	55.2% ⁺⁺
Non-NODC Hospitals	0.2% ⁺	21.9% ⁺⁺
All Hospitals	10.7%	40.1%

* Over baseline donor rate (average annual donor rate between 2001& 2005)

^{+/++}statistically significant difference between increase donor numbers NODC versus Non-NODC hospitals (p<0.0002)

The National Clinical Taskforce on Organ and Tissue Donation also commenced work on its review of the organ and tissue donation sectors and developed proposals for sector reform in 2006. The Taskforce worked from 2006 to 2007 to provide a final report to the Australian Government in February 2008. This report contained 51 recommendations on ways to improve Australia's donation and transplantation system and increase system performance.

In December 2007, following consideration of the draft final report of the Taskforce, Australian Health Ministers agreed to establish a governance structure to oversee the policy and program reforms recommended by the Taskforce.

2.3 World Best Practice Approach to Organ and Tissue Donation Reform Package

In July 2008, the Australian Government announced a Commonwealth funding package of \$151.1 million, including new funding of \$136.4 million over four years for measures to significantly improve Australians' access to lifesaving organ transplants. The proposed measures sought to establish Australia as a world leader in best practice organ donation for transplantation, through an integrated and comprehensive national reform package.

It was agreed at that time that the Commonwealth would lead implementation in partnership with states and territories and establishing the Australian Organ and Tissue Donation and Transplantation Authority (the Authority) to lead implementation of the reform.

The additional funding of \$151.1 million was allocated to implement various aspects of the reform package over four years.

The key features of the reform package include:

- \$67 million to fund dedicated organ donation specialist doctors and other staff in public and private hospitals
- \$46 million to establish the national authority (this amount includes funds held by the national authority for its administered programs)
- \$17 million in new funding for hospitals to meet additional costs associated with organ donation
- \$13.4 million to national public awareness and education
- \$1.9 million for counselling for potential donor families

Other significant elements, including enhanced professional education programs, consistent clinical protocols, clinical trigger checklists and data collection for organ transplants in hospitals.

2.3.1 Australian Organ and Tissue Authority

The Authority was officially established on 1 January 2009 through the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (the Act). The Authority is an independent statutory authority within the Australian Government Health and Ageing portfolio.

The Authority's role is to establish - in partnership with states, territories, clinicians, consumers and the community - a nationally coordinated approach to organ and tissue donation for transplantation.

The Authority is assisted in its drive for a new national approach to lifting Australia's organ and tissue donation and transplantation rates by a 15-member Advisory Council.

The Authority directly administers funds to non-government organisations to provide essential associated services, such as clinical data analysis and reporting, national organ matching services, and education and training for clinical staff. The Authority also funds community awareness activities.

The national reform program for Australia was built on international best practice and experience, together with the findings of the National Clinical Taskforce on Organ and Tissue Donation, the expertise and recommendations of key professional groups and a number of other stakeholders.

The Australian Government's objectives for the Authority are specified in the Act. Through the Authority the Government aims to:

- Improve community awareness of organ and tissue donation
- Increase the capability and capacity of the organ and tissue donation and transplantation sectors, in order to increase organ and tissue donation rates
- Optimise the allocation of organs and tissue to recipients.

The Authority assumed full responsibility for implementing the national reform package on 9 March 2009. In implementing the measures of the national reform package, the Authority's responsibilities include:

- Coordinating a national network of clinicians and other hospital staff dedicated to organ and tissue donation in hospitals across Australia
- Overseeing a new national network of state and territory organ and tissue donation agencies
- Formulating national policies and protocols relating to organ and tissue donation and transplantation matters, including close collaboration with peak clinical and professional organisations to develop consistent clinical practice protocols and standards
- Leading an ongoing community awareness and education program

2.3.2 Nine measures

The national reform package comprised nine measures that aimed to establish Australia as a world leader in best practice organ and tissue donation for transplantation. These are:

[Measure 1](#): A new national approach and system - a national authority and network of organ and tissue donation agencies

[Measure 2](#): Specialist hospital staff and systems dedicated to organ donation

[Measure 3](#): New funding for hospitals

[Measure 4](#): National professional education and awareness

[Measure 5](#): Coordinated, ongoing community awareness and education

[Measure 6](#): Support for donor families

[Measure 7](#): Safe, equitable and transparent national transplantation process

[Measure 8](#): National eye and tissue donation and transplantation network

[Measure 9](#): Additional national initiatives, including living donation programs

There are clear performance outcomes and targets attached to each objective.

These nine reform measures are all directly related to the National Strategy for sector reform as outlined below:

Strategic breakthrough issue: Improved capability and capacity in health system

The Authority establishes a new national network of specialist doctors and nurses dedicated to organ and tissue donation within 77 public and private hospitals in Australia and provide education, professional development and systems to support the new staff to increase organ and tissue donation rates. **Relates to Measures 1, 2, 3, 4 and 7**

The Authority provides new funding for public and private hospitals to ensure that costs are not a barrier to organ and tissue donation. **Relates to Measures 1 and 2**

The Authority works with state and territory governments and non-government organisations to integrate eye and tissue donation practices into the broader organ donation arrangements to ensure co-ordinated and collaborative national organ and tissue donation. **Relates to Measures 1, 2, 3, 4 and 8**

The Authority facilitates the development and implementation of nationally consistent, transparent and equitable donation and transplantation protocols including, for example, paired kidney exchange. **Relates to Measures 7 and 9**

Strategic breakthrough issue: Improve awareness and engagement of the Australian community, the non-government sector and others involved in increasing organ and tissue donation

The Authority establishes and supports a national network of donor family support co-ordinators that provide support for donor families. **Relates to Measure 6**

The Authority and NGOs deliver an integrated and coordinated public education and awareness program to increase Australians' engagement in improving organ donation rates. Professions, organisations and individuals in positions of influence such as political leaders, GPs, the media, sporting and other community groups, actively support the positive engagement of the Australian community. **Relates to Measure 5**

Strategic breakthrough issue: Improve the capacity and effectiveness of the Organ and Tissue Authority through people and business development

The Authority implements the Australian Public Service core values, Code of Conduct and performance framework and conducts its business in line with public sector best practice. The Authority develops the potential of staff against the Authority's mission and attracts and retains high quality people. The Authority effectively manages the transition and change required by the National Reform Agenda. The Authority effectively manages external partnerships. **Relates to all measures and specifically Measure 1**

2.3.3 Workforce for reform of organ and tissue donation performance

The workforce primarily responsible for implementation of reform of organ and tissue donation performance at the coal-face is the new hospital-based medical specialists and senior nurses with dedicated responsibility for organ and tissue donation.

Their roles and responsibilities reflect the content of the national reform package. They are required to work closely with the Authority and State and Territory Organ and Tissue Donation Agencies (OTDA's)

in a DonateLife network to ensure a nationally coordinated approach and consistency of clinical practice across all jurisdictions.

In their new roles Hospital-based Medical Directors (HMD's) have a primary focus on leadership at the local level, of programs that will drive the national effort to increase organ and tissue donation. The HMD's are responsible and accountable for developing and implementing local programs and processes to optimise organ and tissue donation for transplantation, including the education of hospital staff and improving the procedures used within their hospital for identifying and caring for potential donors, as well as obtaining consent for donation from the family of potential donors.

Specifically the HMD's are responsible for ensuring there are systems in place within their hospital so that all potential deceased donors are properly recognised and evaluated, and the opportunity for donation is available to all potential donors. The expectation is that there will be integrated management of the donation process to assure a uniformly high quality and national consistency of all protocols, processes and procedures from donor identification to donor family follow up and aftercare. Hospital Senior Nurses (HSN's) in Organ and Tissue Donation [either Clinical Nurse Consultants (CNC's) or Clinical Nurse Specialists (CNS's)] have also been employed in those major metropolitan and regional hospitals that were deemed to have the capacity for engaging in organ and tissue donation. The nature of these positions – including outreach to other smaller hospitals and after hours work involving assessment and management of potential donors, varies and reflects the needs of individual hospitals: population demographics and catchment; geographical location; capacity for organ and tissue donation activity; and hospital outreach activities.

The HSN's in Organ and Tissue Donation are responsible for raising awareness of, and providing educational services on organ and tissue donation for all local hospital and outreach medical, nursing and allied health staff that may come into contact with the donation process. They also facilitate, under the direction of the local HMD, organ and tissue donation episodes by working with hospital teams to help identify potential organ donors and convert such potential organ donors into actual donors.

The existing state and territory organ and tissue donation agencies formally became part of the DonateLife network on 1 July 2009, when they were re-established as a nationally integrated network to manage and deliver the organ donation process, according to national protocols and systems, in collaboration with their hospital based colleagues. There has been a significant increase in staffing of state and territory OTDA's, including the appointment of State Medical Directors (SMD's) of each agency. Each pre-existing jurisdictional agency has also undertaken a restructure, working towards having a consistent mix of professional competencies to support the provision of nationally consistent services.

The OTDA Network was completed with the establishment of a new OTDA in Tasmania in September 2009.

3 REVIEW METHODOLOGY

The Organ and Tissue Authority engaged Australian Healthcare Associates as the independent reviewer after a competitive tendering process. The review was performed by Australian Healthcare Associates between 19th May 2011 and 31st July 2011, and was overseen by a Reference Group (Membership: Appendix 1).

The review of the implementation of the National Reform Package (the package) entailed the following elements:

1. Provide advice on progress achieved in 2010 in implementing each of the nine measures, including the challenges and issues impacting the reform agenda (from both donation and transplantation perspectives);
2. Evaluate the increase in donation and transplantation rates achieved in 2010, having regard to the rate of increase compared to other countries;
3. Advise on the capacity to continue the growth trend in donation rates taking into consideration how each of the nine measures has contributed to the increase and whether they remain necessary to achieve continued improvement;
4. Consider the extent to which the DonateLife network is evident and operational as a national system and how it could be further enhanced and integrated in all states and territories; and
5. Consider the effectiveness of the current governance and consultation arrangements, including the role and membership of the Advisory Council as the peak committee providing advice to the Organ and Tissue Authority.

The review was informed by data, information, knowledge and wisdom drawn from:

- A detailed review of relevant national and international documents, reports and datasets related to the national reform or approaches to enhancing healthcare systems organ and tissue donation performance
- Structured interviews with key stakeholders within the organ and tissue donation sector within Australia (Stakeholder list: Appendix 2)
- Surveys of all staff actively engaged in implementation of the national reform package in State and Territory Donation Agencies and within hospitals with specialised medical and nursing resources (Results: Appendix 3)
- Structured interviews with national and international experts (from the USA, UK and Spain) on alternative approaches to and progress in reforming organ and tissue donation processes (Expert list: Appendix 2)

4 REVIEW FINDINGS

4.1 Measuring implementation of the nine reform measures

The Authority currently reports on progress in implementation of the reform measures against a set of Qualitative and Quantitative measures.

These performance indicators are a mixture of process measures and measures of outputs and outcomes. These initial performance indicators were determined by DoHA. They did not include any explicit targets or timeframes that could potentially have defined the anticipated trajectory for the implementation of the reform, against which progress could be mapped. Several stakeholders were highly critical of the failure to set explicit performance targets at the initiation of implementation of the reform. Given these concerns within the sector regarding early performance reporting using process measures by the Authority, it is encouraging to see the emergence of the more explicit outcome targets announced in 2010.

It is however very common for newly established organisations like the Authority to have a natural bias towards the reporting of process measures in early performance measure sets. This reflects the inevitable initial focus on establishment of staff and systems to support the eventual delivery of improved outcomes.

The addition of explicit targets and anticipated timelines for implementation by the Authority in the 2009-2010 annual report provides a more balanced and more outcomes focused performance indicator set. The inclusion of such explicit targets and timelines for achievement of specified goals will make it far easier for any future effort to track and report on progress of implementation of reform.

Since its inception the Authority has regularly reported to the community on the progress in implementation of the measures within the reform package. Such public reporting has included information provided in Annual Reports of (2008/2009 and 2009/2010), in a series of specific Project Updates and Report Cards.

During stakeholder consultation it became very apparent that there have often been quite marked differences in opinion within and outside of the sector regarding progress in implementation of the measures. The wide range of opinion regarding progress in implementation of the reform measures, relates in large part to the use by the Authority of a number of process measures in early performance reporting.

These discrepant opinions are by and large not based on stakeholders having access to different data and information sets. Rather these differences in opinion are almost exclusively due to very different interpretations by stakeholders of the exact same data and information sets. These judgements on performance to date are determined in large part by their prior beliefs regarding the likely magnitude of the potential change and expectations regarding the likely rate of change in performance in the sector following the commencement of implementation of the reform package.

Hence progress in implementation of all reform measures has been variously described by stakeholders as being *'dismal or non-existent'*, *'excellent or outstanding'* or at some point on the continuum between these extremes.

The mid-point implementation review canvassed the wide range of perspectives of stakeholders on implementation of our national reform package in organ and tissue donation. The conclusions

regarding progress in implementation of reform in Australia's organ and tissue donation sectors are based upon prevailing majority viewpoints, available objective evidence and by use of direct comparison of progress to date with that achieved by related international organ and tissue donation sector reform programs.

It is important to emphasise from the outset that all stakeholders agreed that the national initiative, including its national, jurisdictional and hospital-based levels of intervention are the way forward. No alternate approaches were canvassed. At issue is how to best deliver the desired outcomes using this new national approach.

4.2 Progress achieved in 2010

The 2009-2010 Annual Report by the Authority includes details of progress against the required qualitative and quantitative performance indicators. It also includes a narrative that enumerates a broad range of the activities undertaken by the Authority and the DonateLife network in delivering the reform package in 2009-2010.

This section summarises key stakeholder inputs on the progress in implementation of the reform in 2010, including discussion of some of the specific projects undertaken by the Authority to implement particular reform measures.

Measure 1	A new national approach and system - a national authority and network of organ and tissue donation agencies
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The DonateLife Network project

The purpose of the project is to establish a nationally coordinated approach to organ and tissue procurement based on world's best practice models, including the national standardisation of the care of potential donors. This standardisation includes establishment of a national donation infrastructure that would see the use of consistent protocols and procedures for the care of potential donors nationally.

The DonateLife Network is a national network involving jurisdictional Medical Directors, Organ and Tissue Donation Agencies (OTDA's), the specialist hospital medical directors and hospital based senior nurses for organ and tissue donation along with the staff of the Authority. This DonateLife Network therefore consists of the 36 staff in the Authority, the 8 jurisdictional Medical Directors, 72 staff in the nationally-coordinated network of state and territory OTDA's and 151 hospital-based specialist medical and nursing staff in 77 metropolitan and regional hospitals.

This Network grew progressively throughout 2009, with recruitment of increasing numbers of hospital-based specialist staff across that year and into the first quarter of 2010 and the rebranding of existing Organ Donor Agencies as 'DonateLife' OTDA's in July 2009. A new OTDA was established in Tasmania in September 2009. Structurally the new network was therefore substantially complete in early 2010.

Prior to the reform several jurisdictions already had identified medical and nursing positions within acute hospitals working in partnership with their jurisdictional OTDA to enhance deceased donation performance.

It is clear that a network of organ and tissue donation agencies and hospital-based specialist staff has been successfully established by the Authority. However there are widely divergent stakeholder opinions regarding the achievements by the Authority in implementation of this measure. Some describe the achievements as 'remarkable' or 'dramatic'; others describe progress as 'disappointing' although most stakeholders do not believe that the DonateLife Network is as yet operating as a nationally-coordinated and cohesive network.

To date there have been different levels of engagement by the jurisdictions with the new national approach and systems. Some have embraced the change enthusiastically and have worked actively to try and make it a success. Others have been less engaged to date and have been less willing to actively contribute to ensuring the successful implementation of a cohesive national DonateLife Network. It is unclear to what extent those jurisdictions with a reduced engagement in the establishment of this new national infrastructure for donation have been hampered by a lack of commitment or capacity for change.

A number of stakeholders wish to see the Authority assume a stronger leadership role in the sector. This includes establishing mechanisms that would enable the Authority to more effectively direct required changes in the management of the donation and transplantation across the entire continuum of care. A counter view was however expressed by some jurisdictional stakeholders. They see the leadership role for the Authority as limited because they view the Authority as having a very limited potential role in determining clinical care processes. They note that jurisdictional Health Departments currently have the authority and responsibility for care processes within their public hospital systems. They also assume the risk for the consequences of care. Given these circumstances, these jurisdictions regard final decisions about detailed processes of care of organ and tissue donors as logically residing with their Health Departments, not the Authority. This clearly is an area that requires clarification.

There were a range of levels of engagement in implementing reform in the organ donation sector in 2010 and this remains the case in 2011. On the one hand there are stakeholders who accept that there are significant opportunities to improve our national deceased organ donation performance and who wish to actively engage with the process of implementation of the national reform measures. On the other hand there are stakeholders who do not believe there to be significant scope for improving our national deceased organ donation performance, who either oppose or passively resist any efforts to implement the reform measures.

The first stakeholder cohort reports a level of frustration with the first 2 years of operation of the Authority because of perceived delays in implementation of the reform measures and an insufficient focus on changing clinical care processes. The second stakeholder cohort report a level of frustration with the requirement to be seen to participate in a program of work to fix a problem that they do not believe exists and therefore has no relevance in the environment in which they operate.

There is clear evidence in some jurisdictions that a critical mass of clinicians (who are either innovators or early adopters of change) are driving local improvements in deceased donor organ donation in their own hospitals. These are the hospitals that are underpinning the recent increase in our national deceased donor donation rates. In other jurisdictions most stakeholders are content with the status quo and as yet there is no established tension for change in these jurisdictions, with a general acceptance that current donation performance levels are the best that can be realised.

The reform has had a major impact on the state and territory OTDA's. They have had a substantial increase in numbers of staff and experienced major changes to their staff mix. Prior to the reform, most

staff in the jurisdictional donor agencies were donor coordinators, with relatively few non-clinical positions. The reform has seen a substantial increase in the number of donor coordinators, with an even greater proportional increase in the number of non-clinical staff (managers, communications staff and administrative support staff) in OTDA's.

These changes to staff numbers and mix within pre-existing OTDA's have resulted in many OTDA staff experiencing changes in their roles, responsibilities and relationships over the past two years. There have been major changes in organ donor coordinators' roles in most jurisdictions, including revision of their role in the education of hospital-based staff and in the early identification and management of potential donors (with these responsibilities now often shared with the newly appointed hospital-based HMD's and HSN's). Some jurisdictions have also experienced a large increase in the number of organ donors over this time, with the consequent significant increase in the clinical case-load for donor coordinators.

These new working environments are viewed very positively by many staff in the OTDA's. However a substantial minority of this workforce have expressed significant dissatisfaction with the scope and nature of their workplace changes. Several stakeholders believe that insufficient attention was paid by the Authority to actively managing these changes in the OTDA's. Many believed that a nationally coordinated support program should have been established to assist OTDA staff in managing their transition into the new national network.

Despite the very major changes in identity, roles, responsibilities and relationships for jurisdictional OTDA's there have been few reported changes to the way clinical care is delivered by these agencies. Most are still operating using the exact same Standard Operating Procedures that were in use prior to their transition into the DonateLife Network. A number of stakeholders noted that in the past all jurisdictional OTDA's have operated differently and in large part these differences in modes of operating have continued under the DonateLife Network banner. This includes the extent to which each OTDA involves itself directly with eye and tissue donation (see commentary under Measure 8).

Therefore the extent to which the OTDA's of the Network can be said to be managing the organ and tissue donation processes in their jurisdiction *in accordance with nationally consistent policies set by the Authority* is currently quite limited. Most OTDA staff responding to the review survey did not believe the DonateLife Network is currently operating as a cohesive national entity.

Most OTDA and hospital staff report that there have been relatively few changes in everyday clinical practice since the advent of the DonateLife Network, with very few changes to clinical operating procedures and processes for organ donation and little or no change in their participation in the clinical care of eye and/or tissue donors.

All the DonateLife Network hospital-based specialist medical and nursing staff have faced the very real challenges of being in totally new positions, needing to establish their local roles and responsibilities and learning how to make these roles work within their local hospital environments. They report receiving no support in establishing these inaugural positions from the Authority and variable support from their SMD and/or OTDA. It is clear that there has been considerable variation across the nation in the detailed implementation of these new specialist roles within the participating DonateLife Network hospitals. This variation is related to the specific local circumstances of their hospital and jurisdiction; the interests, knowledge and experience of donation and clinical practice improvement of the incumbent specialist practitioners and their access to support from within and outside the DonateLife Network.

The extent to which these hospital-based staff report feeling part of a coordinated national network varied greatly across the nation. Many of these staff reported that communication between the Authority and their hospital and within the DonateLife Network has been relatively ineffective.

All hospitals consulted reported that they are largely working to locally developed protocols and procedures for most aspects of the care of potential organ and tissue donors. They see the progressive availability of an increasing range of nationally consistent protocols and procedures as an important means of supporting local implementation of future changes in clinical care.

The Authority Data Project

This project aimed to simplify the collection of relevant data to support performance monitoring and reporting and to allow relevant data to be used to help drive improvements in donation and transplantation performance. Several stakeholders noted the critical importance of significantly improving the clinical information systems in use in the sector. Many noted that there has been very little real progress made in this arena by the Authority to date.

The three major foci are:

1. *Death Audit*
2. *Integration of data sources*
3. *Electronic Donor Record*

1. Death Audit

Auditing of all deaths is occurring in hospitals with senior nurses employed as part of the reform program. The audit aims to measure and report on actual and potential donation activity and identify missed opportunities for donation. The audit data for 2010 has been distributed to the DonateLife Network.

A permanent web-based data capture and reporting solution is to be developed for the audit to collect transactional level data and report aggregated data at hospital, state and national levels. Whilst awaiting development of this web-based data capture and reporting solution an Excel based tool is being used to capture and record hospital based data according to the agreed national data set. The interim tool has been progressively refined to make it more user-friendly, provide greater guidance during data entry, and allow more in-depth data analysis. It is hoped to have the web-based data entry tool in everyday use in 2011.

There has been considerable criticism by some stakeholders of the lack of investment by the Authority in a national training program for all staff involved in the collection of national death audit data to ensure the reliability of data collection. Whilst there has undoubtedly been a progressive refining of data collection methods and tools over the past two years, individual jurisdictions have continued to determine how they approach the training of data collectors, resulting in potential differences in data capture and hence potential limitations in the comparability of data.

Organ Donor Coordinators and OTDA Managers had particular concerns regarding the extent of progress in the development of a nationally consistent death audit process. Until very recently the audit has been operating as a parallel series of jurisdictional audit processes rather than a genuinely national audit. Each jurisdiction has determined its own approach to the training of data collection staff and the mechanisms for data verification and clinical review of data. This makes comparisons between jurisdictions' reported performance in the audit potentially problematic. More importantly, the failure of some jurisdictions to engage senior clinicians in reviewing these data prevents the audit process from helping these clinicians identify barriers to improving donation. International best practice recommends

potential donor death audit programs should be operated on a national basis¹⁵. This ensures that there are national reference values for donation potential, areas for improvement and an assessment of the effectiveness of hospitals involved in donation. This information will identify high-performing 'benchmark' hospitals and prompt the identification of the care practices that underpin these high performing centres.

In recognition of these issues, the Authority has established a Death Audit Working Group, recently renamed as the Data and Audit Working Group, to progress nationally consistent approaches to implementation of the Death Audit. However these do not include an external audit process as yet.

2. Integration of data sources

In its inaugural year, the Authority outlined a proposal to map the current scope of outcomes data and its integration into a single database. This did not proceed in 2009-10. However, in 2011 this work will be undertaken by Australia and New Zealand Organ Donation Registry (ANZOD) to begin a process for reviewing and revising the structure and resourcing outcome data sets collation and analysis.

At present there are a number of national data collection systems that hold information about organ and tissue donation and transplantation. A single National Clinical Information System (NCIS) for donation and transplantation would see the integration of the many sources and types of information into an interactive, accessible, secure and easy to use system that will be available to a range of stakeholders.

Such a NCIS would be the central repository for all data related to donation and transplantation activities and would provide the Authority, and the DonateLife Network with significantly enhanced reporting and analytical capabilities to help drive improvements in donation and transplantation activities. This would assist in establishing Australia as a world leader in best practice organ donation for transplantation.

The initial priority identified by the NCIS Steering Committee was the mapping of existing registries, databases, information infrastructure and resources and other sources of data for collection, collation, reporting and analysis of outputs.

Stakeholders reported that this project has made especially slow progress. Several expressed their concerns that the delivery of a single functioning national data system is likely to be many years away. Many believe that there should be a significant increase in resourcing for the establishment of a functional NCIS for donation and transplantation. Such a system will be essential to identify opportunities for improving care of potential donors and track the impact of sector reform on health outcomes. Access to high quality data on outcomes would also help ensure that the current focus on increasing deceased donors is not negatively impacting on the quality of transplanted organs and transplant recipient outcomes.

3. Electronic Donor Record

The implementation of a national Electronic Donor Record (EDR) for offering organs for transplantation is intended to help streamline the organ offering processes by improving the efficiency of the collection and dissemination of accurate clinical information required by transplant specialists to determine the acceptance of organs for transplantation and their allocation to suitable recipients. It was not originally identified as a core component of the national reform agenda, and hence not included in the NRA measures, nor was funding allocated.

However a prototype system – DONORtrak has been developed by a team led by OTDA staff from South Australia in recent years. Ownership of the tool was transferred to the Authority and there were

plans to pilot the tool across several jurisdictions in 2010. These plans were subsequently shelved and the Authority researched the global market for a mature information system that would address EDR requirements. On the basis that there are a number of products that offer greater functionality it is now proposed to call for expressions of interest in tendering for provision of a suitable EDR.

Some stakeholders involved in this project expressed concerns about the management of this project by the Authority, including the transparency of decision-making and quality of communication regarding progress of the project. The OTA has sought to address these concerns by developing an EDR project plan for endorsement by the Advisory Council and the DonateLife leadership team (comprised of all SMDs and Jurisdictional Working Group representatives).

Measure 2	Specialist hospital staff and systems dedicated to organ donation
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Trained medical and nursing specialists dedicated to organ donation have been recruited at 77 hospitals to facilitate and coordinate organ and tissue donation activity and outcomes and support and educate hospital teams.

The introduction of these hospital-based specialist staff was universally acknowledged to represent a substantial achievement for the Authority. These staff are seen to be playing an important role in driving improved donation performance and are felt likely to play an increasingly important role in this respect in coming years.

The availability of these positions has raised the profile of organ and tissue donation within the DonateLife Network hospitals. The funding available for employment of these staff places the implementation of the reform measures on a financially sustainable foundation. The sector is no longer dependent on tapping into the goodwill of clinical staff to garner their support for donation improvement efforts, which previously were largely based upon the in-kind contributions of their time and expertise to these endeavours.

In a number of jurisdictions recruitment to these hospital-based DonateLife Network specialist positions initially proved difficult. As a consequence a number of hospitals effectively did not commence local implementation of many of the reform measures until the last quarter of 2009 or the first quarter of 2010. It is noted that recruitment of medical staff to the DonateLife HMD roles continues to be a significant issue in one jurisdiction. The Authority is currently working closely with this jurisdiction to support recruitment.

The specialist staff occupying these positions are acknowledged by all stakeholders to be essential in effecting the required changes within hospitals that will deliver optimal donation outcomes.

However there are very major differences in the beliefs of various stakeholder groups on *who* would take up these roles and precisely *what* these roles and responsibilities should be.

A small number of stakeholders expressed significant misgivings about the implementation of hospital-based clinical expertise to support improved donation performance. These stakeholders comprise a group of very interested advocates, which for the most part are external to the health system. They believe that the original vision for this reform measure has been lost in its implementation. These stakeholders expressed concerns about the move to employ staff on fractional appointments for hospital-based DonateLife Network medical specialist staff. They had advocated that the hospital

specialist staff roles should be fulltime medical appointments, held by eminent senior clinicians in various disciplines, (examples provided included several of specialists at/or nearing retirement) and focusing directly on engaging in the identification and management of all potential organ donors within their hospital (in effect substituting themselves for the usual care providers for all organ donation related aspects of care for patients who were potential organ donors). The same stakeholder group also opposed the appointment of nurses by DonateLife in relation to organ and donation work. The rationale for these views is a perception that this is the way that it is done in Spain (the country whose model the reform package has sought to emulate in large part).

However a review of the operations of the Organización Nacional de Trasplantes (ONT), the Spanish National Transplant Organisation, does not support this view. In reality the ONT largely employs part-time doctors (mainly Intensive Care specialists) to undertake organ and donation related work in its hospitals. Spain also routinely employs nurses to undertake organ and donation related work in participating hospitals. The ONT stress the critical importance of ensuring that the number of hospital-based staff and the exact composition of their hospital-based teams are allowed to vary over time and between selected hospitals, depending on the specific needs of each hospital. Further, the ONT devolves the responsibility for agreeing the final staffing of hospital-based teams to their regional coordinators and their hospital team. They argue that they are best placed to have a deep understanding of the possibilities and needs of each centre. Further information about donation systems in Spain is provided in Appendix 4.

Those from within the organ and tissue donation and transplantation sector have argued for part-time medical appointments of staff drawn from the pool of specialists currently engaged in the care of potential donors (i.e. intensive care specialists). Rather than inserting themselves into every donation-related care process and owning these processes, these specialists should provide clinical leadership for local programs seeking to optimise donation performance by their hospital. Part-time appointments also increase the likelihood of attracting appropriately skilled and experienced staff and help create a foundation for a local team to drive changes in clinical care processes in the local hospital setting.

At first the Authority persisted with the expectation, as was dictated by the terms of the original package, that the medical roles in particular should be filled by a fulltime specialist in the larger hospitals or a staff member with a substantial fractional appointment (0.5 FTE). This saw a number of jurisdictions struggle to fill the hospital positions. Progressively jurisdictions negotiated for increased flexibility in the fractionation of the medical and nursing specialist positions. Currently although there now are fulltime or substantive fractional positions in some jurisdictions, others have moved to larger numbers of smaller fractional appointments for their HMD positions.

All OTDA's and hospital staff consulted agreed there was a very real need to see greater flexibility in decision-making regarding the allocation of available hospital resources. Such flexibility would greatly improve the performance improvement capacity of participating hospitals. Most stakeholders believe whilst it is important to designate one medical specialist to be accountable for their hospital's organ and tissue donation performance, fractionation of the hospital-based medical and nursing specialist positions is typically the more effective recruitment and operational strategy. It facilitates appointment of appropriately skilled and experienced staff and provides the basis of a team to drive change in a single hospital setting. It also provides an increased 'round the clock' presence of organ and tissue donation expertise.

The hospital-based DonateLife Network specialist positions appear to have had most impact on actual clinical practices and donation performance when hospitals involve these staff in a team approach to clinical practice improvement for donation. Such hospitals typically have this team working together to

identify and resolve issues that negatively impact donation performance. This team may include the hospital-based DonateLife Network specialists and others from ICU; ED; Theatre; Executive management; Clinical Governance; Clinical Risk; Safety and Quality and/or other hospital departments.

Many of the hospitals that have demonstrated success in significantly increasing their donation rates have had donation practice improvement teams that were formed in 2006 for the NODC. Some of those reported that, though re-organised, these teams have provided the foundation for local improvements in donation performance.

Hospital-based DonateLife Network stakeholders continually stressed that high quality management of potential organ and tissue donors is part of good end-of-life care. This means it is the responsibility of all healthcare professionals involved in the care of the critically ill to play their role and ensure that the best possible care is delivered to patients approaching end-of-life, and this includes exploring the option of organ and tissue donation.

Some current HMD's believe their title 'Hospital Medical Director' is somewhat problematic. Rather than 'directing' colleagues, the DonateLife Network hospital-based staff report that they:

- Provide a locally accessible expertise with a special knowledge of donation
- Act as an advocate for best-practice in donation
- Act as a Clinical champion for improving donation performance
- Lead clinical practice improvement activities to help optimise donation performance
- Help guide the implementation of relevant clinical protocols and procedures to help optimise donation performance
- Ensure staff receive appropriate education regarding donation matters
- Help in establishing a culture within their hospitals where pursuit of the possibility of organ and tissue donation is part of usual end-of-life care
- Provide a single point of accountability for their hospitals' organ and tissue donation performance

These roles have delivered very substantial improvements in donation performance in several participating hospitals. Given this success it would be sensible to focus all available energies on successfully embedding these successful local leadership, advocacy and accountability models in all participating hospitals.

Whilst there is universal agreement that the investment in hospital specialist staff has raised the profile of donation and increased the level of endeavour to improve donation performance within hospitals, the extent to which performance has increased in proportion to the level of investment is disputed by some stakeholders.

There is still concern by some stakeholders about the perceived accountability of some DonateLife Network hospital-based staff. In some hospitals it appears difficult to reconcile the allocated medical specialist resource with the time apparently allocated to donation specific activities.

Clinical Triggers tool

The Clinical Triggers tool was the first attempt to introduce nationally consistent care for potential organ donors into our acute hospital system. The agreed tool was to be implemented into all emergency departments (EDs) and Intensive Care Units (ICUs) in public and private hospitals across Australia.

Initially it was planned to implement the protocol into those hospitals with Authority funded doctors and nurses (by January 2010) and then later rolled out to all other hospitals (by June 2010). The required tool has been available for some time. Many stakeholders noted that the processes of endorsement of the tool by relevant professional societies and associations took significantly longer than anticipated.

The initial performance targets (having a common tool in use in hospitals, providing nationally consistent protocols and criteria to identify potential donors, into all public & private hospitals by June 2010) proved to be overly ambitious. Whilst these tools were *circulated* to all hospitals, many stakeholders reported these tools are in routine use in all relevant clinical areas in relatively few hospitals. Many hospital staff consulted during the review reported that there were no plans for introduction of the tool in their particular hospital in the foreseeable future.

The Authority had indicated that monitoring the use of the clinical trigger tool in hospitals was to commence in April 2010. This monitoring has not yet commenced.

A number of stakeholders expressed the view that the Authority should have placed more emphasis on ensuring that the implementation of the Clinical Trigger tool had achieved changes in clinical practice. The success of implementation of the Clinical Trigger Tool should have been based upon audit of use, allowing the performance measure to be 'the proportion of hospitals routinely using the tool' or 'the number of potential donors identified through use of the tool in hospitals' rather than the process measure of 'distribution of the tool' to hospitals.

A number of stakeholders also noted the second attempt by the Authority to see nationally consistent care (i.e. having 'standardised referral protocols between emergency departments, intensive care units and operating theatres for care of potential donors' in place in 2009-2010) was similarly, overly ambitious. There is no evidence that this change in clinical care has been achieved in the majority of hospitals nationally.

The DonateLife portal

The DonateLife portal is essentially the NODC portal that was used to support hospital-based staff during the collaboratives. This transitioned from the National Health and Medical Research Council (NHMRC) to the Authority in late 2009. As part of this transition, the portal was renamed and rebranded as the DonateLife Portal.

The DonateLife Portal hosts a range of resources collected during the NODC's and also enabled data entry and reporting for hospitals. It also offers access to the latest international news and research related to organ and tissue donation and provides an online meeting point for the sharing of tools and resources. In its current configuration it is found to be of limited utility by most users, largely because it has not been updated regularly, there are difficulties navigating the portal and locating required information and technical limitations (such as an inability to copy much of the information available).

The Authority plans to implement a number of enhancements to improve the data capture and reporting capabilities of the portal and improve its overall functionality. The Authority has a current tender for a provider to implement *SharePoint 2010*, the Authority's new extranet that will replace the current cop.donatelife.gov.au Portal, re-engineer data entry input and help promote collaboration and the

sharing of information across the DonateLife Network through increased use of this Extranet by ODTA and hospital staff.

The proportion of surveyed ODTA and hospital based specialist staff who reported that they were likely to be regularly users of a revised portal was relatively modest.

Community of Practice

The Authority has committed to ensuring that there are strong relationships between the Authority, OTDA's and hospital-based clinical staff and that clinicians are updated and provided with the latest relevant information, data and evidence regarding organ and tissue donation.

The proportion of ODTA and hospital based stakeholders who reported that they currently felt actively engaged in information exchange within the DonateLife Network was modest. The DonateLife Network is not currently seen to be successfully sharing knowledge, experience and innovations across the sector by either OTDA staff or hospital-based staff.

Many hospital based specialists expressed dissatisfaction with the extent to which they have meaningful contacts with their national colleagues. Many called for an increased opportunity to interact with their peers using both technological solutions and more face-to-face contact.

A number of DonateLife Network stakeholders reported that 'cross-pollination' between hospitals and jurisdictions has diminished since the end of the NODC. Their perception is that the Authority has had little success to date in developing and implementing structures and programs that foster these important and productive peer interactions.

Measure 3	New funding for hospitals
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In late 2009, the Authority, SMDs and state and territory health department representatives, developed an activity-based funding model to provide Organ Donation Hospital Support Funds (ODHSF) to individual hospitals to address additional staffing, bed and other infrastructure costs associated with organ donation. The funding seeks to ensure that unmet costs are not a barrier to hospitals supporting organ donation.

There were a very wide range of opinions amongst stakeholders about the utility of this funding. Some believe it has been important to garner the goodwill and support of the broader hospital community; others see it as 'useful but not essential'; a final subset of stakeholders judges it to be 'a waste of time'. Initially funding was provided to assist with the costs of caring for a patient from the time they are identified as a potential donor based on actual organ donor numbers. Hospitals were then asked to maintain a record of donation-related activities using a specific data collection tool. The tool captures details, at the patient level, and aggregates the information to pre-populate de-identified, activity information in a claim form. Claims are acquitted retrospectively.

The model was introduced with an undertaking for a review with a proposed implementation of any revised model by 1 October 2010. The distribution of the ODHSF in 2010, on a percentage basis, is outlined by jurisdiction in *Table 4-1* below, based on data provided by OTA.

Table 4-1: Comparison between funding received and donation activity

Jurisdiction	Proportion of:		
	Organ donors in 2010 (%)	New funding for donation activity 2010 (%)	Funds for potential donor to funds for actual donor (%)
Queensland	16	13.5	46
New South Wales	29	30	73
Australian Capital Territory	3	2	27
Victoria	31	34	74
Tasmania	3	2	12
South Australia	10	7	27
Northern Territory	1	0.5	31
Western Australia	7	11	156
Australia	100 (n=309)	100	67

There are large variations in the funding provided for potential donor activities versus actual donor activities across jurisdictions. Relative funding provided for care of potential versus actual donor activities to individual hospitals, show even greater variations across the nation. These are difficult to explain on the basis of dramatically different approaches to the identification and care of potential donors across the nation. Stakeholders believe it more likely that the complexities of the invoicing mechanisms are responsible for these inequities in the distribution of payments from the ODHSF. Alternative funding mechanisms are noted to already be in place for the costs of ante-mortem care of patients who are potential organ donors. There were concerns by some stakeholders that any additional payments for care provided to potential donors could potentially be misinterpreted as 'financial inducements' for donation, in contrast to recompense for unfunded costs incurred by actual donation.

These ODHSF funds are widely regarded as 'useful' by hospital staff, for a variety of reasons. There was however little confidence amongst stakeholders that these new funds, as currently distributed, are materially impacting on hospitals' attitudes to donation, their levels of commitment to improving donation performance or their actual donation performance. Hospital-based specialists rated this measure as being of significantly less importance than the measures they perceived as high-impact changes (i.e. hospital-based specialist staff and the national community awareness and education campaign).

Jurisdictions have used different approaches to managing the payments of these funds. In some jurisdictions these funds are successfully being directed to identified cost centres (within ICU, ED or Theatre). Where there has been access to these funds some hospital specialists are then able to utilise them to support clinical practice improvement and/or education and professional development for clinical staff involved in donation.

In other jurisdictions these funds were not visible to hospital-based staff. Sometimes this was a conscious decision by the HMD's (to avoid any perceived conflict of interest attached to receipt of these funds). More often than not they were not flowing into ICU, ED and OR cost centres by choice, but rather were simply disappearing into their organisations operating budgets.

The established mechanisms for claiming these monies were regarded by most stakeholders as being unnecessarily complex and burdensome. In the absence of appropriate oversight and audit, it was

noted that there may be varying interpretation of some categories of activity and consequent inequities in allocation of funds.

A number of stakeholders had concerns that the definitions used for invoicing for these funds were not currently consistently applied across the nation. These inconsistencies create a potential for a lack of equity and unfair distribution of available funds.

In spite of the shortcomings all stakeholders believed it to be important to continue to reimburse hospitals for the reasonable cost of caring for potential donors. Current hospital payment mechanisms address the costs of end-of-life care for potential donors. These funds should target those costs specifically related to deceased donor organ donation.

A number of stakeholders expressed a preference that the payment process for future funding of donation activities be simplified. This could see payment of an agreed sum for actual donors, with this payment taking account of the known relationships between potential, intended and actual donors. It would be possible to determine these relationships from national average performance data within ANZOD or from hospital-specific performance data derived from the death audit.

Given these known and consistent relationships over time between potential, intended and actual donors many stakeholders supported that these funds being allocated to participating hospitals by direct payment to nominated HMD special purpose hospital accounts based on actual donor numbers. This was seen to avoid any requirement for invoicing and the risk of loss of 'visibility' of these funds to clinical staff within complex hospital accounting systems.

It is noted that these funds to hospitals for support of organ donation related activities represent a tiny fraction of the \$42 billion plus operational costs of all acute public hospitals. Even in major donor hospitals these funds represent only a relatively small fraction of their overall operating budgets. While these funds are fair and reasonable recompense for actual expenditures they have very little potential to act as a major motivator for hospitals to drive changes to clinical donation practices.

A revised system of funding should also ensure that all monies paid under this measure are accessible to those clinical areas within hospitals that perform the work that supports optimal organ and tissue donation performance.

Measure 4	National professional education and awareness
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The Authority is tasked with building system capacity to support optimal donation practices. This requires the development of suitable awareness and education programs that progressively enhance the skills, qualifications and professional standing of medical, nursing and allied health specialists who work in Australia's organ and tissue donation and transplantation sectors. Whilst the OTDA's are responsible for implementation of jurisdictional based education activities, the Authority has carriage of national training activities and the establishment of consistency in training across the DonateLife Network.

A National Education Strategy has been developed that identified 15 target groups for professional awareness and education. Initially priority has been given to the development of educational materials for the state and territory medical directors and senior nurses, the broader clinical community, designated officers and Australian Organ and Tissue Donation and Transplantation Authority staff.

In 2009/10 the Authority provided funding to DonateLife agencies to employ an Education Coordinator (EC) to ensure delivery of high quality education activities in each jurisdiction. The Authority then established the Education Coordinators Network (ECN), which held its first meeting in October 2010. This network serves as a forum between the Authority and all jurisdictions for sharing and planning of national education activities and strategies. The ECN provides input into the development and review of national education resources, and planning of education activities such as ADAPT and staff induction.

In October 2010, all State Medical Directors and representatives of each state and territory health department agreed that for 2010-2011 the Authority would concentrate on:

- Establishment of an Education Coordinators Network to facilitate national sharing and support
- Development of two family conversation training modules
- Training for State Medical Directors to include media and Australian Public Service training
- Dissemination and uptake in all jurisdictions of the Clinical trigger (GIVE) protocol
- Induction program as part of the DonateLife Forum in March 2011
- Organ Donation included in schools curricula for high school students
- Training for Organ Donor Coordinators

In planning their approach to the development of nationally consistent and targeted education programs for professional staff in the organ and tissue donation sector, the Authority has consulted widely with relevant professional groups. There are plans in place to build on existing education programs (such as ADAPT) and evolve new programs.

The Australasian Donor Awareness Programme (ADAPT) has provided nationally coordinated and consistent modular-based training and education to a range of clinical staff working in the organ and tissue donation sector since 1994. The educational needs of the medical and nursing staff in the sector previously met by this program are now being addressed by the Authority. The Authority has assumed responsibility for ADAPT. It has provided administrative oversight for program funding and delivery and has undertaken a content review. Since that time consultations have been conducted with professional bodies such as College of Intensive Care Medicine, Australian and New Zealand Intensive Care Society, Royal College of Nursing Australia and the Australasian College of Critical Care Nurses to secure their ongoing endorsement of the curriculum for the purpose of continuing education.

To support the increasing demand for ADAPT in Australia, the Authority is providing training to DonateLife staff members in all jurisdictions to deliver and support the grief components of workshops in their area. This training will provide staff with additional high level skills, and greatly improve the flexibility for jurisdictions to schedule the increased number of workshops. In 2011, the Authority has also provided funding for ADAPT directly to jurisdictions in order to support facilitation of workshop arrangements, resulting in the delivery of 10 medical and 32 general workshops. These workshops provided training for over 600 clinical staff in 2010. A total of 84 ADAPT workshops have been funded via the jurisdictional funding agreements and allocated across all jurisdictions for 2011. This is anticipated to provide continuing education for approximately 1000 health professionals.

In October 2010, the Authority conducted a Request for Tender (RFT) process to identify appropriate providers to develop two training modules on family conversations – one to be delivered as a

comprehensive one-day workshop, and one to be delivered as a concise module to be incorporated into the existing ADAPT program.

Following the close of the RFT, the Authority received no proposals for the development of the Family Conversation Training modules, and proceeded to conduct a direct course approach to the market. In February 2011, the Authority engaged SydneyLearning Pty Ltd (a commercial arm of the University of Sydney) to conduct a detailed stakeholder consultation and develop the Family Conversation Workshops, which will be piloted for commencement later in 2011.

A number of stakeholders expressed their concerns that the processes necessary to transition ADAPT to the Authority, perform the review of ADAPT and secure a suitable provider of these revised educational services have been far too slow.

A comprehensive package of PowerPoint presentations were finalised and distributed across the DonateLife Network in December 2010. The presentations are intended to provide nationally consistent messages and support local professional and community education. They focus on key issues such as discussing donation; pathways to donation; brain death; the donation process; eye and tissue donation; donor family support; DCD; retrieval surgery; and the national reform agenda. Presentations will be reviewed annually.

These educational programs have all taken significantly longer to develop than was anticipated by most stakeholders. Stakeholders were often very critical of the Authority's inability to progress the establishment of such programs. Many held concerns that devolution of responsibility for education to jurisdictions was perpetuating the cycle of duplication of effort and local reinvention that existed within the sector prior to the establishment of the Authority.

A national induction and orientation program for all hospital based and OTDA staff was developed by the Authority in partnership with several jurisdictional OTDA's. This focused on team building, change management, applied clinical practice and audit processes. This program was developed over the initial 2 years of operation of the Authority. Delivery of the program began in July 2009. The program was delivered in the larger jurisdictions as a three-day program. Staff who had attended these orientation and induction programs reported that the three day had been moderately well received. The program has recently been converted into a one day program.

In March 2011 the Authority held the second DonateLife National Induction Day, as part of the 2011 DonateLife Annual Forum. The day included sessions on the nine measures of the government reform agenda, the structure of the DonateLife Network, eye and tissue donation and transplantation, and data and audit processes. The day also included several workshops and provided an opportunity for new staff to meet, network and share experiences with others from around the country. Whilst the one-day induction was reported to be less successful by a number of those interviewed, the majority of feedback via survey from hospital staff indicated satisfaction. However the OTDA staff were less satisfied with just under 50% of agency staff expressing satisfaction,

Stakeholders believe the Authority should be holding more frequent national education, training and development forums for DonateLife Network staff, including engaging specialist interest subgroups of staff to meet nationally or at least cross-jurisdictionally.

It is noted that the Authority has recently partnered with the National Health and Medical Research Council to offer a research fellowship (NHMRC Translating Research into Practice (TRIP) Fellowship) for a health professional to undertake a practical project aimed at increasing donation rates in Australia.

The Australian Public Service Commission is developing SES training specifically for SMDs, to include media and Australian Public Service training. Training is scheduled for 12 August and 12 October 2011.

The Authority recently announced the new Janette Hall Scholarship, established in memory of a South Australian Organ Donor Coordinator who passed away in late 2010, to provide health professionals in the donation and transplantation sector with the opportunity to participate in international training and education programs. The inaugural round of the scholarship will be conducted from mid-2011.

The Authority is exploring options for the development of nationally-consistent advanced education and training for Organ Donor Coordinators and Transplant Recipient Coordinators. In May 2011 the Authority contracted to external evaluators to attend and assess the Organ Donor and Transplant Recipient Coordinators Advanced Course in South Australia, and provide the Authority with recommendations as to developing the program nationally.

Whilst the PowerPoint Presentations referred to above include material on eye and tissue donation, the eye and tissue stakeholders consulted noted that there had been no relevant materials developed by the Authority for staff in their sectors to date. The Authority has identified that they will work with the Australian Tissue Banking Forum to develop and provide a nationally consistent program for eye and tissue banking staff.

Overall there was some impatience expressed by most stakeholders with progress on the implementation of this measure. They see it as a critical component of building standardised approaches, strengthening the DonateLife Network and equipping hospital staff in change management processes.

They describe a clear sector need for:

- Access to suitable professional education materials and professional development programs
- A practical induction and orientation program for new staff
- Support programs for staff, including mentoring programs should be available to all new staff

In particular, materials and programs that are accessible online, or can be downloaded were seen to be sorely needed.

Measure 5	Coordinated, ongoing community awareness and education
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This measure seeks to increase public knowledge about organ and tissue donation and transplantation, build confidence in Australia's new donation system and increase family consent rates. This is being done through an ongoing, coordinated and evidence-based national community education and awareness program.

The national program aims to give Australians regular, clear, factual and relevant information about organ and tissue donation, and how they can make a difference. It is believed that greater knowledge within the community regarding organ and tissue donation and transplantation will over time lead to increased consent rates by donor families, and therefore more lives saved and improved through transplantation.

The intended outcomes for the National Community Awareness and Education Program are:

- More Australians are aware of the importance of organ and tissue donation and the lifesaving and life-transforming outcomes made possible through donation
- Australians are able to make an informed decision about their wishes in relation to organ and tissue donation
- More people, when asked about organ and tissue donation, will feel confident to uphold the wishes of the deceased and give consent for donation to proceed.

The National Community Awareness and Education Program aims to increase the family consent rate for organ and tissue donation in Australia. Currently the family consent rate to organ and tissue donation is less than 60%. The aim is to increase this rate to 70% by end June 2011, and 75% by end June 2012.

With few exceptions this measure has been seen to have been a great success by the overwhelming majority of stakeholders. It was deemed to have been of high quality, relevant and apparently effective. OTDA staff reported very high levels of satisfaction with programs initiated by the Authority. DonateLife Network Hospital-based staff also reported very high levels of satisfaction with these measures. There were a small number of stakeholders from within the community sector who took issue with some of the specific approaches taken with these programs (e.g. slogans, themes and style). These stakeholders believed that alternate service providers would have delivered a better suite of community communication programs at a lower cost.

A very small number of stakeholders regarded such community awareness and education programs to be a completely unnecessary waste of money. These stakeholders would prefer to see all available funds focused exclusively on measures to achieve rapid improvements in clinical care processes.

The programs have not only been well received, they have also been objectively successful. Research conducted before and after the launch of the DonateLife campaign shows impacts from the campaign. These include:

- The level of family discussion increased by 10% (from the benchmark of 48% to 58%)
- Awareness of family members' donation wishes increased by 7% (from the benchmark of 51% to 58%)
- Awareness that family consent is sought before donation can proceed increased by 9% (from the benchmark of 62% to 73%)

The relative shifts in survey response are the key measure of the success for these campaigns, and these are impressive, even if the absolute proportion of the population engaged in any particular belief or behaviour is possibly overestimated in these surveys.

The Authority now sets the directions, key messages and strategies for all national donation awareness programs, including the annual Awareness Week and donor recognition programs.

The Authority has also developed a national communications framework for organ and tissue donation that provides stakeholders with a nationally consistent, coordinated and evidence-based approach. There is a national communications charter that encourages all stakeholders in the sector to sign up to the principles of the national framework and express their commitment to conduct community

awareness activities in line with nationally consistent messages. A number of stakeholders who are signatories to the national charter noted that to date the charter has made little real difference to their approach to the development and delivery of their own organisation's communication strategies. Stakeholders did note that since the establishment of the DonateLife Network there are fewer competing logos, slogans and themes within the sector. Many noted that there are several organisations who are charter signatories that continue to promote a range of different slogans, messages and 'calls to action' to the broader community. This 'mixed messaging' is still seen to be a significant problem that is reducing the impact of the overall national awareness and education campaign by some stakeholders.

Some stakeholders believe that there has been too little emphasis by the Authority on community engagement programs (e.g. volunteer programs; school education and awareness programs; GP programs).

The public launch of DonateLife and the increased focus on organ and tissue donation for transplantation in Australia has generated, and can be expected to generate, higher levels of media interest in the effectiveness of the new national approach and the broader public debate on organ donation.

A nationally coordinated, effective approach to issues management is critical. A proactive national media management program has been an essential component of the Spanish model of sector reform¹¹ (Refer Appendix 4 for further information). A large number of stakeholders believe that the Authority's response to media management, in particular to issues management, was quite inadequate. In particular the Authority is reported to have been consistently too slow to respond to media requests for commentary to effectively deal with potentially adverse media coverage within the sector.

Many stakeholders believe that the Authority needs to implement a much more proactive approach to media management, including the appointment of appropriate spokesperson(s) that could provide consistent, trusted messages regarding donation matters to our community. It is noted that the Authority is currently redeveloping its media strategies.

There were concerns raised by some community sector stakeholders regarding the extent to which the Authority have engaged with those within this sector in a collaborative and cooperative way over the first two years of its operations. Most of these stakeholders report that the frequency and quality of their informal interactions with Authority staff have improved significantly since the appointment of the new Chief Executive Officer (CEO) in early 2011. However a number of these stakeholders continue to be dissatisfied to some degree with their access to a formal communication channel for their interactions with the Authority.

A consistent theme from a number of community sector stakeholders was that they were offered too little opportunity to provide meaningful input to the community awareness and education programs lead by the Authority. They felt that they were often simply being asked to ratify decisions that had already been finalised (described by one stakeholder as 'post-hoc pseudo-consultation').

A small number of organisations believe that their working relationships with the Authority would be enhanced if they had formal representation within the Authority's Governance structure (e.g. on the Advisory Council).

Many community sector stakeholders appeared to have a very limited knowledge and understanding of progress on the implementation of the nine reform measures. This included being simply unaware of

progress with implementation of a particular measure and holding incorrect beliefs regarding the progress of implementation.

Measure 6	Support for donor families
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The Authority developed a framework for a nationally consistent approach to support for donor families. A Donor Family Support (DFS) Working Group was formed in August 2009. Working group members considered the recommendations from the Care and Support of Donor Families Project Report and developed the framework to move towards implementation of consistent care. In addition the Authority provided funding as of 2010 for Donor Family Support Coordinators in each Organ and Tissue Donation Agency to provide ongoing support to donor families.

It was initially anticipated that a national program would be available by December 2009. In reality The National Donor Family Support Service Framework did not become available until December 2010 and it has yet to be fully operationalised. A number of stakeholders were critical of these delays. Several stakeholders who participated in an early workshop on donor family support were completely unaware of the progress that has occurred in implementation of this measure since that workshop.

The framework for the national donor Family Support Program released in December 2010 includes guidelines for use by staff in providing a donor family support program, education, training, and resources for donor family support staff and for family members. There are national guidelines for counselling, thanksgiving and remembrance services for donor families. The framework document is seen as being a valuable step to securing nationally consistent, high quality bereavement services for donor families by OTDA staff.

The Authority has established a Donor Family Support Implementation Working Group (DFSIWG). The DFSIWG have revised the Resources and the Authority engaged an external professional organisation to focus test the revised Resources to ensure that they met the needs of potential donor families. The Authority, in conjunction with the DFSIWG have further revised the Resources based on the recommendations from the focus group testing and following another round of focus testing will release and launch the final set of resources in the second half of 2011.

Measure 7	Safe, equitable and transparent national transplantation process
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The Transplantation Society of Australia and New Zealand (TSANZ) were initially engaged by DoHA to develop nationally consistent, safe, equitable and transparent processes for the management of transplantation waiting lists and the allocation of donated organs across Australia prior to the establishment of the Authority. The Authority subsequently assumed responsibility for oversight of this work.

A first draft of the national protocols (the Consensus Statement) was published on the Transplant Society of Australia and New Zealand (TSANZ) website for public access and review in August 2009. TSANZ members and key stakeholder groups to provide written submissions and public consultation and commentary invited.

A consultation forum was held in September 2009 in Sydney. This consultation forum covered the key issues relating to organ allocation and waiting lists including some of the non-clinical aspects such as ethical considerations. A large number of groups were represented at the consultation forum including government departments and health jurisdictions, consumer and community groups, professional organisations and clinical bodies.

The consultation process resulted in a second draft of the Consensus Statement that was released for further consultation in March 2010. The final Consensus Statement was delivered to the Authority in June 2010. The Authority is currently overseeing the process of implementation of this guidance document into everyday clinical practice nationally.

All stakeholders acknowledged the value of both the guideline development processes and its final product, the Consensus Statement on *Eligibility Criteria and Allocation Protocols*.

In finalising the current version of the Consensus Statement, TSANZ identified a number of outstanding policy issues which require clarification in future versions of the Statement. These relate to issues such as:

- adopting a clear governance mechanism to ensure that the clinical currency of the Consensus Statement can be maintained
- progressing work on: whether 'likelihood of survival' should be considered as an eligibility criterion for waiting lists; separate criteria for alternate listing and re-transplantation; equity of allocation and access for rural and regional patients; and consideration of appeals mechanisms
- the scope for closer engagement with the NHMRC in development and endorsement of future versions of the Consensus Statement

The Authority and TSANZ have already reached agreement on the process for maintaining the clinical currency of the current Consensus Statement. The Authority has provided funding for TSANZ to strengthen secretariat support for each TSANZ Standing Committee and has agreed a protocol for initiation and approval by the TSANZ Council of refinements and additions to the Consensus Statement so that changes in clinical practice can be reflected in the Statement as a living document. The OTA National Medical Director will be closely involved in this process as an observer, when appropriate, on the TSANZ Council and as a member of the Donor Surgeons and Coordinators Standing Committee. Maintenance of the Consensus Statement will flow through to all subsidiary documents including the Australasian Transplant Coordinators Association (ATCA) Guidelines and Standard Operating Procedures. The additional secretariat support for TSANZ will include professional secretariat support for ATCA to update and distribute complementary professional documents.

Over 2011-12, the OTA and TSANZ will clarify the process for development of the next version of the Consensus Statement, including the mechanism for resolving the outstanding policy issues and options for closer engagement of the NHMRC in this process.

Stakeholders note that an audit reporting mechanism is yet to be developed. Such an audit is felt to be essential by stakeholders. It would allow the reporting of actual practice against the uniform eligibility criteria for acceptance onto the organ waiting list and nationally uniform allocation criteria for donated organs.

Once these audit processes have been developed, most stakeholders expressed the view that the Authority would be the logical owner of such a national audit process. They felt that the Authority

should assume responsibility for ensuring that the required audits were performed and for public reporting of these audit outcomes.

Measure 8	National eye and tissue donation and transplantation network
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The Authority originally planned to establish a national network to manage eye and tissue donation, retrieval, processing, storage and transplantation. This network would introduce systems that will deliver a coordinated, accountable, national tissue transplantation service for patients across Australia. While the National Reform Package references a *National Eye and Tissue Donation and Transplantation Network (NETN)*, having a separate eye and tissue network would represent an approach that lacks the integration, accountability and effectiveness that the national reforms are premised on. Instead the Authority is working with stakeholders to deliver closer coordination of the eye and tissue sectors and ensure improved access to eye and tissue transplants for Australians.

A NETN would:

- raise community awareness and promoting education
- develop automated real time donor notification systems
- establish family contact and consent to ensure a single coordinated point of contact
- deliver enhanced training for requesters, collectors and eye and tissue bank scientists
- establish a national eye and tissue donor database
- develop national eye and tissue allocation protocols
- develop national eye and tissue outcome data registries
- develop a national approach for the collection and analysis of demand, supply and utilisation of eye and tissue data

The development of a NETN has been seen to be a key measure for achieving a world's best practice approach to tissue donation for Australia. Many stakeholders believed that this measure was given a relatively low priority by the Authority in 2009 and 2010. They are encouraged by a renewed focus on the NETN that is apparent under the new CEO in 2011. Others however felt that the focus for the Authority in the early stages, needed to be on solid organ donation.

A scoping paper, investigating this initiative, has been completed and has been reviewed by the Authority. The Authority is considering the report's recommendations in consultation with key stakeholders including the commonwealth, state and territory governments.

The scoping paper provided a range of recommendations, including recommendations that were within the remit of the Authority and some that were not. In May 2010, the Authority wrote to the Australian Health Ministers Advisory Committee's Clinical, Technical and Ethical Principal Committee (CTEPC) seeking advice on those recommendations that the Authority did not have the policy remit or funding to address. The Authority subsequently advised CTEPC in September 2010 of the progress in integration of the eye and tissue sectors into the DonatLife Network.

Several stakeholders were of the opinion that the scoping paper contains significant factual errors. Several believe that it failed to materially advance the concept for the NETN and were disappointed that

there was no apparent pathway for progressing implementation of a NETN. The report also canvasses many options for the Eye and Tissue Network that a number of stakeholders do not believe to be practically achievable.

In 20 October 2010, CTEPC asked that the State Medical Directors (SMD) and Jurisdictional Working Group (JWG) develop options for more effective eye and tissue retrieval, processing and storage (more effective' can be considered to equate to improved clinical outcomes, increased donations and administrative efficiency).

Once developed, these options will be considered by the Authority's CEO, the SMD and JWG committee before being provided to CTEPC, Australian Health Ministers' Advisory Council (AHMAC) and Australian Health Ministers' Conference (AHMC).

The NETN was planned to be operational in the first half of 2010. A number of stakeholders were critical of the apparent lack of progress in the establishment of a NETN. Others felt that the proposed network will offer only marginal improvements on existing sector arrangements and hence were less concerned by the relatively slow progress in implementation of this measure. It was very apparent that stakeholders across the existing eye and tissue sectors do not share a common view on the structure, purpose, proposed activities and potential operational models for a NETN.

If progress is to be made in developing the NETN stakeholders believe that more resources will need to be made available for implementation of this measure. It may even be necessary to establish an Eye and Tissue specific staffing within the Authority, including a national Medical Director for the Eye and Tissue sectors.

A number of jurisdictions have been prompted by discussions around a potential NETN to review their provision of eye and tissue donation services. The appetite and potential for national reform in this sector varies greatly across the nation. Some jurisdictions have already restructured their eye and tissue donation services to formally integrate them into their jurisdictional OTDA's. Some are currently considering some level of restructure of eye and tissue donation services. Others see their current service arrangements as effective, efficient and financially sustainable and are not convinced that there would be any material value in integration of these distinctively different services into a single jurisdictional OTDA and have no current plans to alter the status quo. OTDA staff expressed a wide range of opinions on the desirability and utility of integrating eye and tissue donation into their existing organ donor agencies.

Stakeholders representing the eye and tissue sectors consulted during the review frequently saw few (or no) advantages in such integration. Many expressed their concerns that 'integration for integration's sake' would potentially erode the effectiveness and quality of services provided by the current eye and tissue sectors. A few stakeholders candidly acknowledged that they had no desire whatsoever to integrate their services with other sector providers.

Several stakeholders argued that a business case for reform of the eye and tissue sectors and establishment of a NETN needs to be developed by the Authority presented to AHMAC and these sectors before any further discussions occur regarding the future of a NETN. They consistently argued that there were significant differences between the organ, eye and tissue donation sectors. It was felt that merging organ, eye and tissue donation organisations would achieve nothing that could not be achieved through collaboration between independently operated peer organisations.

Sector stakeholders reported that there appears to be a greater awareness of eye and tissue donation in hospitals and improved opportunities for installing referral protocols in hospitals with DonateLife Network specialist staff. These staff are seen as a valuable asset for the eye and tissue sectors in assisting with educating hospital staff and raising awareness of eye and tissue donation matters. In jurisdictions with a significant increase in deceased organ donors there has been a consequent noticeable increase in eye donation. The eye and tissue sector stakeholders report that the OTDA's have traditionally had strong relationships with their jurisdictional eye and tissue donation services. These relationships do vary somewhat across jurisdictions, but they have largely been strengthened by implementation of the reform package.

All stakeholders were of the opinion that there remains a lack of clarity regarding the strategic intent of this measure. The confusion amongst key stakeholders on the structure and function of this proposed network extends to members of the relevant Authority Reference Group (the Eye and Tissue Working Group/ ETWG).

The ETWG are tasked with drafting advice for the CEO in response to the CTEPC request. The options will be considered by the CEO provision of formal advice to CTEPC, AHMAC and the Australian Health Ministers' Conference (AHMC) seeking their consideration in the second half of 2011. There are clear advantages in use of a broad 'network' label. There are virtually endless potential national models that could not unreasonably fit this descriptor.

Collaboration between the eye and tissue sector already exists to varying degrees in a number of jurisdictions, with a range of models used for eye and tissue banking in Australia. Models for the future include separately managed and funded organisations that undertake their own processes (including seeking consent for donation) to more 'integrated' models that undertake eye and tissue banking under the auspices of state government and/or in close cooperation with the DonateLife Network. Several stakeholders noted that existing national professional 'networks' for Eye donation and transplantation and Tissue donation and transplantation already provide sufficient connectivity for their sectors. They remained sceptical about the ability of an additional NETN auspiced by the Authority to add material value to the eye and tissue donation and transplantation sectors.

Discussions have commenced between the Authority and the eye and tissue sectors regarding the impact of the introduction of the Biologicals Framework which is an amendment to the Therapeutic Goods Regulations 1990.

Measure 9	Additional national initiatives, including living donation programs
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Australian paired kidney exchange

This initiative aims to increase live kidney donor transplants by identifying matches for incompatible donor-recipient pairs.

The Authority has overseen the development of a user manual for the AKX program, which was endorsed by the Renal Transplant Advisory Committee, TSANZ, and the Transplant Nurses Association, the Australasian Transplant Coordinators Association and most state and territory Health Departments. National implementation of the program and enrolment of donor and recipient pairs have begun.

This initiative was welcomed by several stakeholders, although a number commented on the very slow evolution of the program under the aegis of the Authority.

Several stakeholders expressed concerns about the current governance arrangements for this national program. They believe that although required to authorise exchanges, that jurisdictional staff largely concerned with deceased donation would not necessarily be seen to have the required expertise for this role. It was suggested that it would be preferable to task the Renal Transplant Advisory Committee with the responsibility for governance of the AKX program.

While occasional stakeholders felt that the Authority had no remit in live donor programs, most stakeholders were of the opinion that in coming years the Authority will be required to take a more active role in oversight of live donation nationally. These stakeholders however noted that this is probably not a suitable current focus for the Authority, giving the perceived need to address deceased organ donation as its initial priority. Indeed all stakeholders canvassed identified optimising deceased organ donation as the obvious initial (and current) priority for the Authority.

National Protocol for Donation after Cardiac Death

The national protocol outlines an ethically sound set of processes that respect the rights of the patient and ensures clinical consistency, effectiveness and safety for both donors and recipients. The national Donation after Cardiac Death protocol was prepared by the National Health and Medical Research Council (NHMRC) on behalf of the Authority. The Authority's National Medical Director chaired the group that developed the protocol. In July 2010, the Authority assumed responsibility for national implementation of the National Protocol. They developed a national implementation plan that assists jurisdictions in implementing the DCD Protocol within their jurisdictions.

The Authority has worked collaboratively within the DonateLife Network and with appropriate professional bodies, state and territory Health Departments, clinicians and the community to ensure successful implementation and application of DCD practices in as many hospitals as possible across Australia. This has been an important step forward in the establishment of a national approach to increasing organ donation numbers.

However progress in establishing functioning multi-organ DCD programs within Australian hospitals has been relatively slow. Most hospitals with DCD programs had established these programs prior to the release of the national DCD protocol. They have not needed to alter their DCD clinical care processes in response to the national protocol.

The first multi-organ DCD donation episode occurred in South Australia in 2006. In 2010 hospitals in Victoria, New South Wales, Queensland, South Australia and Australian Capital Territory had DCD deceased donations. Several additional hospitals had DCD protocols in place and have subsequently had DCD donations or are awaiting a suitable potential donor. Other hospitals are at present considering the introduction of DCD.

Hospital-staff reported that the availability of a national DCD protocol has helped encourage hospital to consider local adoption of DCD deceased donation within their own organisation, but thus far this has had only a very minor impact in terms of the number of hospitals nationally who are operating a DCD deceased donation program.

The impact of DCD on total organ donor numbers has been significant, as is discussed in greater detail in *section 4.2.2* of this report.

4.2.1 Challenges and issues impacting the reform agenda

For the purposes of this review stakeholder inputs on the overarching challenges and issues impacting the reform agenda are presented as relating to:

- Staff issues
- Style
- Strategic intent

Staff issues

The key initial challenge for the DonateLife Network was the slow initial rates of recruitment to the SMD and hospital based medical and nursing positions that were critically important to the successful implementation of the reform package.

Although the rate of recruitment increased throughout 2009, at the end of October 2009 (the target date for completion of recruitment) only 2/3rds of the required positions were occupied by staff (62 of 91FTE). It was not until 6 months later (March 2010) that the majority of these hospital-based positions and the new positions in the organ and tissue donation agencies were reported to have been successfully filled.

The slow recruitment was attributed by stakeholders to several issues including:

- An absolute national shortage of critical care medical and nursing staff
- A very small pool of trained staff with suitable prior knowledge and skill in organ and tissue donation
- A relatively low priority of organ donation as a sub-speciality career interest amongst suitable clinical staff
- The novelty of the inaugural positions, including a perceived lack of clarity regarding possible role definition and the sustainability of the posts
- An initial insistence that positions be effectively full-time (later to be reduced to 0.5 minimum FTE appointments)

A number of stakeholders commented on the very diverse range of experience of the hospital-based staff recruited to fill the DonateLife Network specialist positions. Some hospitals have appointed very experienced leaders to these new roles, while others have appointed much more junior staff into these positions. Some stakeholders expressed concern that as a direct consequence of these differences in seniority there will be stark differences across participating DonateLife Network hospitals in their capacity for hospital-based teams to initiate, lead and leverage local changes in the care of potential donors.

There was also considerable commentary by some stakeholders on the very varied roles of these newly appointed staff in hospitals, both within jurisdictions and between jurisdictions.

It appears that the desire to implement a single model (of staffing, roles and day-to-day activity) for these hospital-based experts in organ and tissue donation has been thwarted by the application of widely divergent approaches to staffing, roles and work practices in implementation of this measure in funded DonateLife Network hospitals. On occasions the perceived pressure to fill the staff positions resulted in appointing staff without ensuring that there was a shared understanding regarding the

proposed roles, responsibilities and accountabilities of the positions. While position descriptions existed they had very little relationship to actual work practices.

It will be important that the Authority establishes mechanisms to examine which of the various models used by hospitals with their specialist donation medical and nursing expertise delivers the desired outcomes. This should include an analysis of the relative cost-effectiveness of these various approaches to implementation of these new roles. Perhaps the clinical team review currently underway in one jurisdiction might inform the development of a methodology for these reviews.

A number of the current DonateLife Network HMD appointments appear to include a component of a 'notional' payment. In some cases it would be very difficult to reconcile the time regularly spent working on activities specific to organ and tissue donation with the funding/ FTE currently allocated to that position by the Authority. A number of HMD's have a range of other roles within (and beyond) their hospital. On occasion the nature of these commitments would make it virtually impossible for them to consistently devote the time to donation systems improvement efforts stipulated in their position descriptions and employment contracts.

The specific resource allocation to a designated role was a decision made in large part by the Authority and the jurisdiction, not the hospital or the incumbent. It is likely that pressures applied within the sector to fill as many of the nominated hospital-based roles during the establishment of the Authority led to some hospital staff being given the responsibility for improving donation performance that included a FTE allocation that was to some greater or lesser extent notional.

This responsibility was sometimes layered on top of existing workloads. Some staff were not relieved of sufficient of their other responsibilities to allow them to free up time stipulated to be available to work on improving organ and tissue donation performance across their hospital. As the time available for some appointed staff to devote to donation-related activities is not directly correlated with current funding allocations across the system as a whole, the Authority is not obtaining full value from its current investment in hospital-based medical specialists. In some hospitals with considerable potential for improving donation performance, progress is greatly hampered if the FTE allocated to improving donation performance is not routinely available because of such competing priorities in the workplace.

Stakeholders also noted that on occasions the scope for donation-specific activities in some hospitals is so low that it would have proven difficult for the appointed hospital-based staff to productively commit the FTE allocated to improving donation performance to practical and useful endeavours.

Many clinician stakeholders suggested that the current allocation model for hospital-based resources across the DonateLife Network must be revisited. There must be an attempt to try and better align the available resource with the potential for improving donation performance.

Mechanisms also need to be established to ensure that all DonateLife Network hospitals realistically align the time allocated by staff to improving donation performance with the funding provided. Negotiations between jurisdictions and hospitals regarding the most effective use of available resources were felt likely to be the best mechanism to determine the ultimate use of available funds. A number of stakeholders also noted that given the varied experience levels of the current hospital-based staff, it will be critically important to ensure that they receive suitably tailored education and professional development support. There will be the need to increase their knowledge and skill in donation specific issues, and to assist them to acquire the knowledge and skills needed to design and implement clinical practice improvement within their hospitals.

SMD positions initially proved difficult to fill in some jurisdictions. This required use of interim appointments by some jurisdictions. The transitioning from these interim posts to definitive positions was felt by several stakeholders to have negatively impacted the implementation of the reform measures in these jurisdictions. All SMDs reported a significant personal 'learning curve' in these new roles across 2009 and 2010. These roles continue to evolve as the reform program is implemented

The reform has had a major impact on the jurisdictional OTDA's. It has taken considerable time for the Organ Donor Coordinators (ODC's)¹ to accommodate to the very major changes in their roles and to adapt to the new management and accountability models. While some jurisdictions have responded to these challenges by introducing a structured change management process within their OTDA, a number of stakeholders noted that there has been no attempt to ensure a nationally consistent approach to the support of OTDA staff through this major change program.

The implementation of the new HSN roles proved to be particularly problematic for some OTDA's and their staff. These new DonateLife Network hospital-based roles have subsumed several roles previously fulfilled by ODC's within the sector and valued by them as important contributors to their job satisfaction. This role displacement has at times created tensions in the relationships between OTDA-based ODC's and the DonateLife Network HSN's. Stakeholders advise that these issues have been progressively resolved in most jurisdictions over the past 12 months and are now considered to be less problematic. However these stakeholders felt that these issues should have been anticipated by the Authority and a suitable change management program should have been required in all OTDA's.

There was a high staff turnover at all levels of the Authority. Very few staff had any prior experience of the sector, even fewer has relevant clinical experience. These all slowed organisational learning, hampered management of projects and reduced effectiveness and efficiency. Many stakeholders commented adversely on the high turnover of staff at the Authority since its inception. This is widely seen to have been a major constraint on the rate at which the Authority has been able to progress implementation of the reform package. The turnover of senior staff was also believed by many stakeholders to be responsible for frequent changes in focus and direction by the Authority in its first two years of operation ('they all too often switched horses mid-race'), which saw projects stall, change direction or disappear from the agenda altogether.

The ability to recruit capable staff and train and retain them within the sector was seen to be fundamental to helping ensure that the Authority operates more effectively into the future. The introduction of a staff retention performance indicator in 2010 is noted.

A small number of stakeholders believe that the national office for the Authority has too many staff and that these numbers should be substantially reduced.

All stakeholders noted that there has been an improvement in staff in the Authority over the past 6 months or so, both in terms of their perceived quality and capacity and in staff retention. There appears to be more coherence in operations and a shift in the style of their interactions with the sector. There have also been improvements in the quality of communications between the Authority and the rest of the sector and the perceived level of trust between the Authority and jurisdictions in this time.

¹ <http://www.atca.org.au/files/ATCA%20-%20National%20Guidelines%20for%20Organ%20&%20Tissue%20Donation.pdf> for further information about ODCs.

It has been noted by several stakeholders that in comparison with other international donation programs, the initial reform implementation model in Australia had remarkably few clinicians with significant amounts of their time dedicated to helping to drive implementation of the national reform agenda. In addition an issue identified by many stakeholders was the very limited use of experienced clinician input into the everyday work of the Authority's national office, apart from the position of National Medical Director. The Authority has sought to bolster their clinical input through the establishment of more regular meetings of SMDs, with monthly meetings in the process of being established.

To achieve success, implementation of most of the reform measures will require substantial clinician input if we are to see the design of fit-for-purpose programs that support implementation of the reform measures and the ongoing monitoring and improvement of sector performance.

Style issues

There have been a number of issues impacting the initial implementation of the reform agenda identified by a large number of stakeholders during the review.

Rather than providing sector leadership and enabling clinical practice improvement in deceased donation, the Authority was seen in its first year of operation as operating as a policy and funding agency for the sector. There was of course a need to focus on these areas during the establishment phase, however stakeholders were looking for more. Relationships within the sector were often perceived to be more akin to those between a purchaser of services and providers of services than between colleagues or peers. There was also a perceived lack of trust in key relationships and an apparent disregard by the Authority of established nodes of obvious expertise within the sector.

There was seen to be a very high burden associated with the complex administrative arrangements demanded by the Authority. Often stakeholders reported that achieving compliance with the demands of the bureaucracy consumed much of the available time and energy in the sector, yet appeared to be of little relevance to the stated aim of the reform. All too often procedural correctness seemed to be more important than functional outcomes.

Many expressed concerns that the approach to implementation of the reform measures taken by the Authority was too prescriptive. Many stakeholders commented on an almost complete lack of flexibility in the approach to implementation of the reform blueprint initially required of them by the Authority. It is noted that the blueprint being implemented by the Authority was endorsed by COAG for implementation across all jurisdictions.

All stakeholders have noted that there has been a progressive realisation by the Authority of the need for some jurisdictional flexibility regarding implementation issues and an increased scope for local adaptation and tailoring of approaches to implementation. There is however still a common view that the Authority still lacks flexibility and this hampers the effectiveness and efficiency of jurisdictional implementation. The Authority also reports being hampered by the inflexibility of the funding for the Reform Package and the inability to move funding between individual measures.

A number of jurisdictional stakeholders asserted that the early rigidity in the approach to implementation by the Authority significantly compromised the outcomes of their attempts to implement the reform measures locally within both their OTDA and their DonateLife Network hospitals.

The first issue regarding the Authority's approach to implementation was the strong initial preference for the recruitment of full-time staff to fill the jurisdictional SMD positions and the hospital-based HMD/ HSN

positions. All jurisdictional stakeholders were of the opinion that it was neither desirable nor pragmatic to require full-time commitments from staff to these posts. The Authority notes that the position descriptions set out in the 2010-12 Funding Agreements for SMDs and HMDs, now states that SMD appointments should be a minimum of 0.8 FTE and HMD appointments should be a minimum of 0.5 FTE.

Stakeholders felt that it would have been preferable to have focused on offering flexibility in the terms of employment for all these newly created positions. They suggested that the best candidates would have been more quickly secured if part-time positions, job-sharing options and/or fixed-term secondments had been allowed to be featured in the initial round of job offers.

This would have helped attract the most suitable candidates to these positions, by providing those considering these positions the option of retaining currency with other relevant desired roles (be they clinical, academic and/or managerial). It also would have allowed jurisdictions and hospitals to tailor their employment solution to their specific clinical workforce and donation performance improvement needs.

As time passed it became increasingly apparent to many that it would be necessary to stop emphasising the preference for full-time appointments if positions were to be filled. Stakeholders report that there were considerable jurisdictional differences in the approaches taken to secure the required hospital-based DonateLife Network specialist staff. Several stakeholders held concerns that the Authority allowed such variable approaches to recruitment across jurisdictions.

A number of stakeholders report that the employment of several individuals at one hospital to fill the designated FTE allocation brought many advantages. These include: the effective creation of the basis of a local clinical practice improvement team; an increase in the range of skills available for use in these teams; an increase in the proportion of time that hospitals have a local donation expert readily available in-house (specialist coverage); helping ensure that donation specialist advocates remain grounded in the everyday workplace in which reforms are to be implemented; and the smoothing of succession planning processes. It is noted that the Spanish ONT recommend that their hospital-based medical staff be part-time appointments¹⁶.

Another issue regarding the reform identified by many stakeholders was the need to work within the federated model of governance of the acute care sector to implement reform. Federation requires that the Authority manage the implementation of all of the substantive reform measures in large part by negotiation with the state and territory Health Departments. These Health departments in turn negotiate with their jurisdictional OTDA's and the participating DonateLife Network hospitals within their own jurisdictional acute health governance frameworks.

The layering of responsibility, authority and accountability within this federated governance model are very familiar to all those who work in policy development and management of acute healthcare in Australia. It is a complex environment. It is notoriously difficult to enact any nationally consistent changes to acute care, and even more difficult to make changes quickly.

The implementation of any national policy in acute health through the requisite jurisdictional Health Department and hospital system governance structures often results in quite variable final outcomes both within and between hospitals. Whilst no stakeholder saw any alternative governance model for this sector as practical in the Australian context, most stressed that the encumbrances inherent to this governance model be taken into account when judging the achievements of the Authority in this mid-point implementation review. All stakeholders readily acknowledged that the federated governance

structure of our acute health sector does not assist the Authority in implementation of the national reform agenda. This is especially so if there is the potential for resistance to change at some level within the sector to an aspect of a proposed implementation of change.

The Authority has ensured that there are explicit contracts in place that provide clear guidance on the roles, responsibilities and accountabilities of all parties. But change management through contract management is difficult.

The current contracts with jurisdictions are widely seen by the jurisdictions as being very demanding to manage. In particular they note that the contract requires excessively detailed and frequent reporting. Both jurisdictional and OTDA stakeholders felt that current reporting requirements are too onerous and are not materially contributing to improving donation performance.

Several stakeholders commented that the human resource requirements for current reporting are compromising staff availability for use in more productive activities. Current reporting involves duplication of reported data elements and includes measures deemed of dubious relevance by many stakeholders. All stakeholders report that reporting requirements have progressively increased over the life of the Authority.

Several stakeholders from across the sector expressed concern that the Authority at times has appeared to lack independence from DoHA. There is a perception of a 'risk-averse culture' within the Authority that has stymied decision-making and slowed the progress of implementation of a number of reform measures.

There were also frequent criticisms by stakeholders that there was an over dependence by the Authority on the use of competitive tendering processes. A large number of stakeholders expressed the view that targeted procurement via a request for assistance to individuals or groups within the sector with known expertise was likely to deliver better outcomes at lower cost in a more timely fashion. Stakeholders were of the opinion that such an approach would not only be more effective and efficient it would also see the Authority acknowledging that pockets of special skill and knowledge do exist within the sector. This was felt likely to contribute to a strengthening of the culture of collaboration and cooperation across the DonateLife Network.

Several stakeholders have raised concerns about the approach to governance of projects managed by the Authority. Too many projects have either not been delivered, have substantially changed focus and/or have been delivered later than ideal. It is noted though that the Organ and Tissue Authority is an Australian Government Financial Management and Accountability Act 1997 (FMA Act) Agency. As an FMA Act Agency, the Organ and Tissue Authority must abide by the Commonwealth Procurement Guidelines which require competitive tendering processes in defined circumstances.

Strategic Intent issues

Many stakeholders believe that there was insufficient attention by the Authority on prioritising strategies that would directly support changes in clinical care processes in participating hospitals. There was no Clinical Governance framework, insufficient focus on national approaches to measuring clinical performance and little in the way of practical support for the required clinical practice improvement programs to improve care for potential donors nationally.

A second issue identified with the approach taken to implementation of the reform measures was the resource allocation model used for Measure 2 (Specialist hospital staff and systems dedicated to organ

donation). These resourcing decisions ultimately determined the hospitals participating in the reform and their level of specialist staff.

The overall resource allocation to each component of the reform was defined at the time of announcing the reform. The underpinning rationale for these resourcing decisions were unclear to most stakeholders consulted. These early resourcing decisions determined jurisdictional resourcing. The final allocations of resources to individual hospitals by jurisdictions were apparently based on a variety of local factors, but these staff allocations were not based on objective criteria indicative of the donation potential of hospitals.

Consequently some hospitals with historically low donor numbers, who would also be anticipated to have a relatively low donor potential (on the basis of known factors such as case-mix, through-put and mortality) received relatively significant resourcing in comparison with other hospitals with a much larger current donor rates and apparent potential for donation.

A number of stakeholders suggested that both the relative resource allocation across the various reform measures and the distribution of funding within any individual measures should be revisited by the Authority. In doing so, the Authority should seek to arrive at a more evidence-based formula for the allocating available funding to activities which have the highest probability of returning an increase in donation performance. In the specific case of funding for Measure 2 (Specialist hospital staff and systems dedicated to organ donation) all stakeholders believe that the Authority could arrive at a more evidence-based allocation formula by focusing on funding staff in hospitals with the highest probability of returning an increase in donation activity. This would mean profiling of each hospital's potential for deceased donation, taking account of the size, casemix and specialty referral patterns should underpin future decisions on both resourcing and the establishment of performance targets. The process of identifying and targeting those hospitals with the greatest potential for improving donation performance is used in Spain by Organización Nacional de Trasplantes (ONT), where hospitals are categorised into three categories on the basis of the presence or not of key organ donation related facilities, as follows:

- **TYPE 1 Hospitals:** Big reference centres with all medical facilities 24 hours per day, including neurosurgery and solid organ transplantation services.
- **TYPE 2 Hospitals:** Centres with neurosurgery but without transplantation facilities.
- **TYPE 3 Hospitals:** Centres neither with transplant nor neurosurgery services.

Most ONT staff are then focused within Type 1 and 2 hospitals.

It was also advocated by jurisdictional and agency stakeholders that more scope should be given to jurisdictions and participating DonateLife Network hospitals to make final decisions regarding their preferred staff profile for expenditures of funds available for specialist hospital staff and systems dedicated to organ donation, rather than remaining reliant on centralised decision-making by the Authority on these matters.

In regard to performance targets, care needs to be taken with applying blanket expectations across all hospitals. It would be quite unreasonable, for example, to demand a nominated fixed increase in donation performance of a hospital that has no unrealised deceased donors and exceeds benchmark performance in potential donor conversion rates.

The need for reconsideration of the approach taken to implementation of reform in smaller jurisdictions was also raised by some stakeholders. A number believe that the smaller jurisdictions would benefit from a formal partnership with a larger jurisdiction. This was felt to maximise opportunities to drive

improved donation performance in the longer term while increasing the cost-effectiveness of implementation of reform in these smaller jurisdictions.

A number of stakeholders believe that there has been too little focus by the Authority to date on achieving practical changes in the clinical care processes and protocols that have major impacts on the performance of our donation system. It was frequently felt that the Authority has received too little advice on implementation and other inputs from clinicians with practical experience of either donation systems or approaches to improving health system performance.

In theory the Authority's National Medical Director could be argued to have a very large workforce within the DonateLife Network to draw upon for relevant clinician inputs. In practice this potential workforce has not yet been harnessed effectively to help drive national implementation. Several of the SMD's and hospital-based staff have made substantial contributions to national endeavours. However others have as yet been given less opportunity or have been less well positioned to contribute substantively to national implementation efforts.

The Authority needs to improve its mechanisms for accessing the pool of clinicians with the necessary knowledge, skills and time available to commit to the national implementation agenda to progress implementation of a number of programs and projects that undoubtedly exist within the DonateLife network. It is noted that the Authority is establishing regular meetings of the SMDs and for some time have had reference groups and working parties, which incorporate hospital based staff in their work program.

However many stakeholders believe that there still could be a greater emphasis across the DonateLife Network on clearly delineating those tasks that need to be led nationally, those that require jurisdictional leadership and those that are best led locally in participating hospitals.

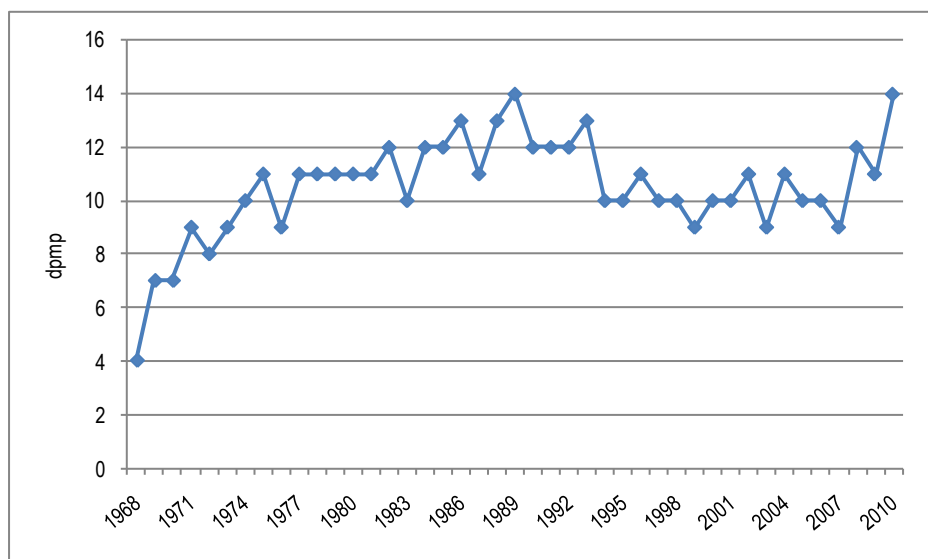
Similar concerns were raised regarding better identifying the appropriate level within the new system for reporting of particular datasets. Measurement and performance reporting should be to support management. Most stakeholders believe that currently there is far too much data (and too much detailed information) being transmitted to the national office. Stakeholders believe that much of the data and information required in current national reporting should be viewed and managed at hospital and/or jurisdictional levels.

4.2.2 Evaluation of the increase in donation and transplantation rates in 2010

The raft of measures implemented since the announcement of the reform agenda for the organ and tissue donation sector by Health Ministers in 2006 and substantially bolstered in 2008 through the release of the reform package, has undoubtedly driven improvements in donation performance in Australia.

In 2010 there were a record number of solid organ donors in Australia (309 donors), reflecting a return to a national donor rate of 14 dpmp (refer *Figure 4-1*). There were a commensurate record number of transplants (931) and a reduction in the numbers of Australians on transplant waiting lists.

Figure 4-1: Australian donation rates (dpmp)



Source: Australian and New Zealand Organ Donation Registry and DonateLife website
(NB: rounded to whole numbers)

Three principal factors are known to determine organ donation rates.

- The number of persons dying in hospital in circumstances in which organ donation is feasible
- The ability of hospital staff to identify potential donors, refer these patients for consideration of donation and manage these patients until organ retrieval can be facilitated
- The proportion of potential donors in whom consent for donation is obtained

The greatest barrier to improving current organ donation performance in Australia is not a lack of suitable deceased donors but the failure at an individual hospital level to identify potential donors and 'convert' these potential into actual donors.

It is known that improvements in the complex set of processes that occur from donor identification to the transplantation of an organ can have a large impact on organ donation rates.

However even given optimal healthcare systems performance it is unlikely that the number of organs from donors who have been declared brain dead would ever meet our national demand.

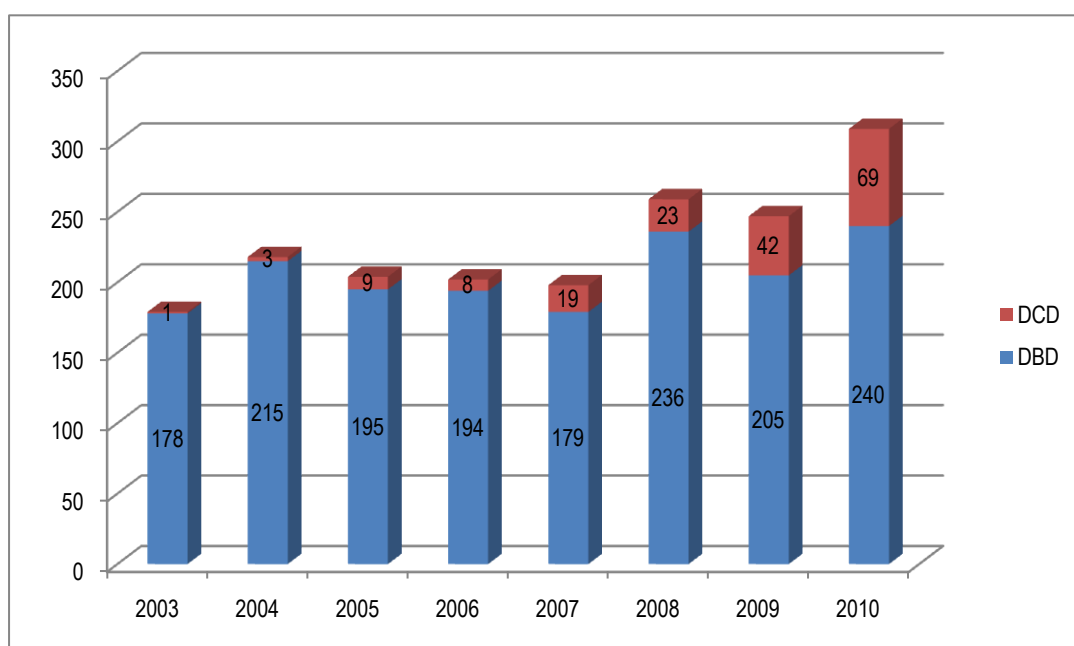
Internationally there is a trend towards fewer potential brain dead donors, probably reflecting the reduction in the prevalence of trauma (and in particular road trauma) and the progressive aging of our populations (with the consequent reduction in the proportion of deaths in the population who are medically suitable for organ donation).

The introduction of Donation after Cardiac Death (DCD) programs that is, the retrieval of organs from patients who have suffered a cardiac arrest, is one means of significantly increasing organ deceased donor numbers. DCD was the usual mode of kidney donation when these transplant programs began in the 1970's. In Australia this mode of donation was largely replaced by deceased donation from patients in whom death was determined by 'irreversible cessation of brainstem function' over 30 years ago, although occasional DCD donation of kidneys did continue to occur in some jurisdictions.

The 2006, NODC encouraged participating hospitals to consider relaunching DCD programs as part of its 'change package' of reforms. That year saw the first multi-organ DCD donor episode in South Australia. From 2006 onwards a small number of hospitals nationally, subsequently commenced DCD multi-organ donor programs. Now in 2011, DCD has occurred in every jurisdiction except for Tasmania and the Northern Territory (where a lack of a transplant program and logistics make DCD difficult).

It is noted that a substantial proportion of the increase in organ donation in the past few years in Australia can be attributed to the rapid growth in DCD donors (refer *Figure 4-2*), with 69 such donors reported amongst the 309 donors (22%) in 2010. Without access to the option of DCD donation in the past 4 years the sector would have seen a much more modest increase in organ donor numbers.

Figure 4-2: National deceased donation figures – Donation after DCD and DBD (2003 -2010)



The keys to all successful hospital donation performance improvement programs are better identification, referral and management of potential donors and improved consenting processes within acute hospitals.

Optimising the donation performance in any health system requires the routine incorporation of the consideration of the potential for organ and tissue donation into normal end-of-life care in all hospital that care for critically ill patients.

This 'normalisation' of donation sees all clinical staff responsible for the care of patients who may be potential organ and tissue donors regarding exploration of the possibility of donation as an integral part of everyday end-of-life care. In this setting these staff ensure that the option of donation is explored in all suitable circumstances.

Achieving this 'normalisation' requires hospitals to have a relentless focus on optimising donation performance, maximising the likelihood that all potential donors are identified and referred and ensuring the greatest possible proportion of these potential donors are converted into actual donors.

A review of organ donation performance in Australia over the past 14 years (refer Figure 4-3) indicates that there was a significant change in national organ donor numbers and donation rates in the years following the announcement of the 2006 national reform agenda and then again in 2010, the first full year of implementation of the 2008 reform package.

Figure 4-3: National deceased donation trends (1997-2010)

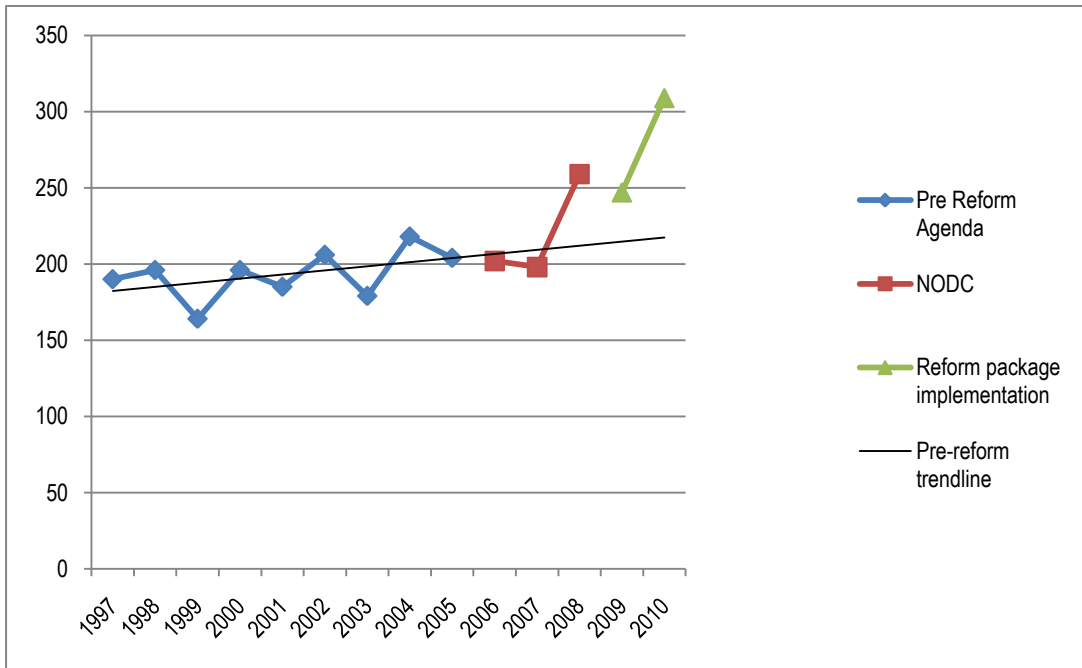
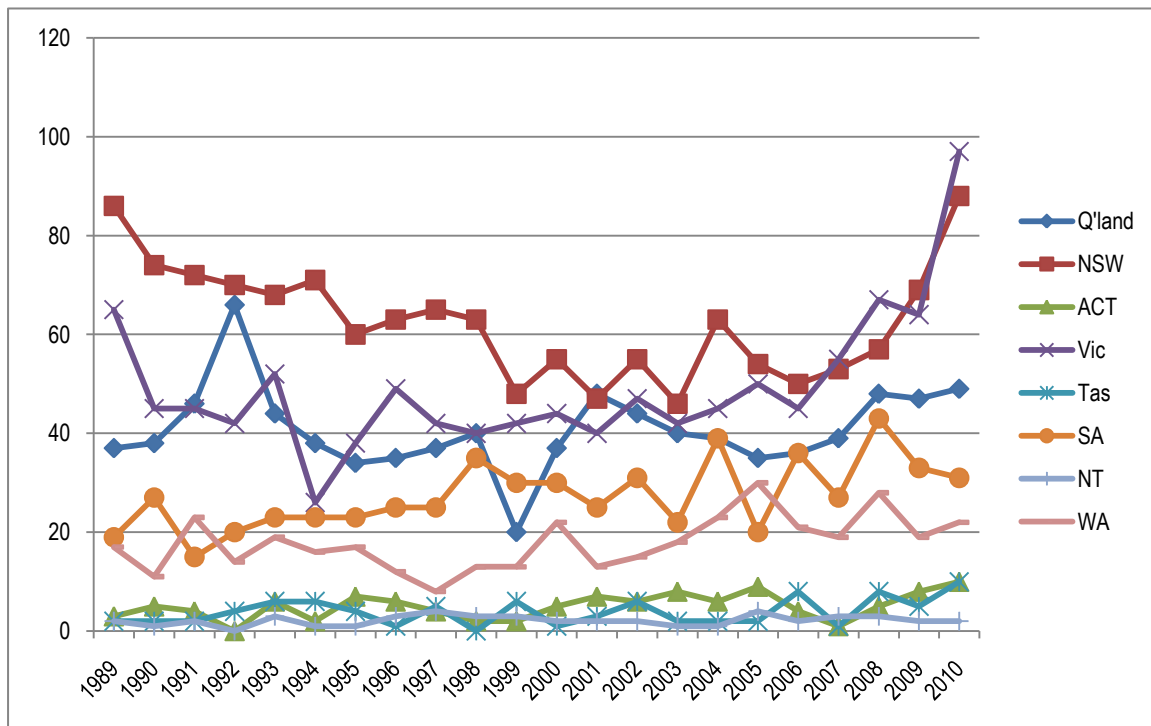


Figure 4-4: Jurisdictional deceased donation trends



As is apparent from *Figure 4-4*, it is noted that the increase in national deceased donation performance seen in 2010 was largely attributable to very major increases in donor numbers in Victoria and NSW. The increases in fact occurred in a relatively small number of hospitals. A number of stakeholders proposed that the increases in their hospitals built on the earlier work they had done as part of the NODC. This would suggest that the lead times and the reform that must be undertaken for attaining increases should not be underestimated.

The national increase in donor numbers has been entirely attributable to better identification, referral and management of potential deceased donors, rather than any change in the rate of consent for donation.

The overall consent rate for donation in Australia remains unchanged (below 60%). This is relatively low by international best-practice standards as is apparent from *Table 4-2*.

Table 4-2: International consent rates

Country	Family consent rate for deceased donation of organs (%)
Bulgaria	77
Estonia	79
France	70
Greece	54
Hungary	91
Iceland	75
Italy	71
Latvia	80
Norway	76
Poland	91
Portugal	94
Romania	79
Slovak Republic	83
Slovenia	78
Spain	83
United Kingdom	62
United States of America	61

It is recognised that rates of family consent for donation vary appreciably between and within countries. These variations presumably are explained by the differences in cultural and social factors that influence the acceptance of donation, including the commonly perceived value and importance of donation in a society and variability of healthcare provider processes and procedures for obtaining consent.

Within Australia deceased organ donors are predominantly (95%) Caucasoid. There is a significant under-representation of all minority groups on a proportion of population basis.

4.3 The capacity to continue the growth trend in organ and tissue donation rates

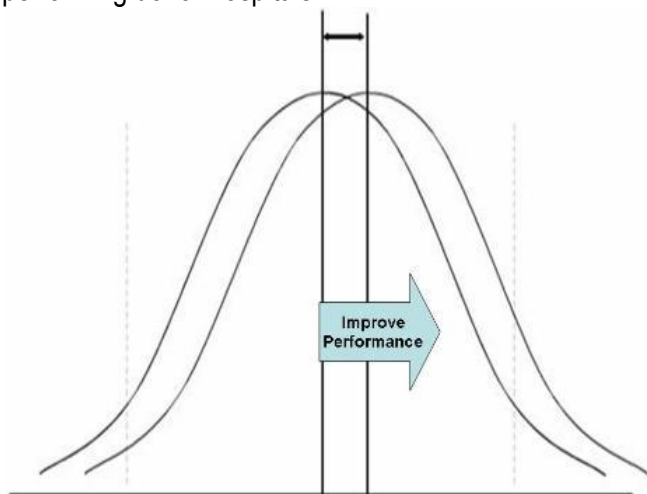
Comprehensive data for analysis for the mid-point implementation review was available only for organ donation. There was insufficient data on relative eye and tissue donation activities in 2010 and prior years to draw any conclusions regarding the trends in donation rates for these sectors.

The improved deceased organ donor performance in 2010 demonstrates that our healthcare system can implement changes in the way we care for potential donors within acute hospitals and deliver increases in deceased organ donor numbers.

As reported in the previous section, in 2010 a relatively small numbers of hospitals were driving this improvement in national organ donation performance. These 'early adopters' of change demonstrate that as a community we can move well beyond the 10 or 11dmpm that had become the 'norm' until the introduction of the national reform agenda.

There is every reason to believe that these high-performing donor hospitals can either maintain their current levels of performance or even continue to improve their overall donation performance producing further improvements in national donation performance. However we cannot expect the sustained efforts of these few hospitals to deliver optimal national donation performance.

To continue the national growth trend in organ donation and eventually achieve our deceased donor potential we will need to spread the system changes and improved performance into a progressively increasing number of hospitals across all jurisdictions. The rate of growth in donor numbers nationally will be largely determined by how quickly we increase the proportion of all hospitals that become high performing donor hospitals.



High performing donation systems are not characterised by uniform high performance across all hospitals within that healthcare system. All high performing deceased donor countries demonstrate marked regional and hospital variations in relative performance. Their success in improving overall systems performance reflects a relentless focus on progressively increasing the proportion of high performance hospitals and regions, thereby shifting their overall countries performance towards optimal levels of performance.

It is very encouraging that as a national donation system we have succeeded in beginning this journey. However we will not have unlocked our national deceased donor potential until all acute care hospitals

across all jurisdictions have succeeded in changing their care processes and are effectively operating as high performing deceased donor hospitals.

As 'high-performing' deceased donor organ donation hospitals these would ensure:

- Every person dying in that acute hospital who is medically suitable* to donate organs after their death is provided with the opportunity to donate as one part of high quality end-of-life care for that person
- Their family response to the approach of the appropriately skilled healthcare professionals requesting consent for donation is informed by their prior knowledge of the wishes of their loved one regarding donation

*In this context 'medically suitable' means that there is an acceptable likelihood of good health outcomes in the proposed recipients of transplants of organs donated by this person

4.3.1 The contribution of each of the nine measures to the increase in donation rates in 2010

In the complex world of healthcare it is often difficult to attribute any observed change to a single intervention with any degree of confidence. This is certainly so in our national organ and tissue donation sector.

Given the timing of significant changes in deceased donor care (e.g. the introduction of DCD programs), recent trends in deceased donor organ donation rates and the donation rate in 2010 it seems more reasonable to attribute the increase in donation rates in 2010 to the complex set of interventions in the sector since the launch of the national reform agenda since 2006, rather than seeking to attribute this increase solely to implementation of the nine reform measures.

While all stakeholders within the transplantation sector were very pleased by the increase in national deceased donation rates in 2010, there were few who were confident that this increase could be directly attributed to the establishment of the Authority and the implementation of the reform package. When seeking to attribute observed changes in donation performance to the implementation of any particular measure (or indeed the set of nine measures) it must be remembered that the increase in donation in 2010 was due to the improved performance in a small subset of donor hospitals, not because of a system-wide change in performance. In many donor hospitals (and several jurisdictions) donation performance has continued to follow the historical trend-line.

This variation in performance across the sector must be able to be accounted for in any attempt to attribute the increase in donation rates in 2010 to any of the nine reform measures. It is also important to emphasise that an inability to confirm attribution of the increase in the 2010 donation performance to implementation of any particular measure does not imply that this measure is not contributing to enhanced donation performance (or will not contribute to enhanced donation performance in future years).

All change programs require time to deliver their potential. Clinical practice improvement programs require sufficient time to recruit, orient and train staff, establish functional hospital-based clinical practice improvement teams, perform process analyses, develop strategies to improve the processes of care, and fully implement these improvement strategies. 2010 was effectively the first full year of operations for the new DonateLife Network.

It is very likely that this was too early in the national implementation of the reform measures to realistically expect to be in a position to attribute a change in donation performance directly to the reform measures, either individually or collectively.

Given these caveats, this midpoint we make the following observations regarding the potential contribution of each of the nine measures to the increase in deceased donor organ donation rates in 2010:

Measure 1: A new national approach and system - a national authority and network of organ and tissue donation agencies.

Whilst the new national approach began in January 2009 (and was further enhanced with the integration of OTDA's in July 2009) in reality all stakeholders reported that this new national approach and associated systems is still in evolution.

At the beginning of the 2010 calendar year the Network was substantially established structurally, but functionally was very much still a 'work in progress'. There had been relatively few changes in actual clinical systems and care processes in either OTDA's or participating DonateLife Network hospitals that could realistically be attributed to the implementation of DonateLife Network by the Authority.

It is however likely that the overall direction being set by the Authority and the environment for change created by the progressive establishment of a functional DonateLife Network did significantly assist hospitals that had already commenced their journey to improve donation performance.

Generally it was these hospitals with prior knowledge and experience of improving local donation performance that proved able to leverage the opportunities provided during the establishment of the DonateLife Network and continue with their efforts to systematically enhance their care processes and donation outcomes in 2010.

There is ample evidence from stakeholders that the emerging DonateLife Network provided essential supports to those hospitals that had proven to be *early adopters* of change with regard to organ and tissue donation performance. As such the emerging DonateLife Network did help them to achieve significantly improved donation performance within their hospitals.

However the establishment of a DonateLife Network was in itself not sufficient to prompt all participating hospitals to embrace a program of change and improve their own donation performance. Thus it could be said that the new national approach, the DonateLife Network, proved to be a '*necessary but not sufficient*' measure for delivering a change in donation performance in 2010.

Measure 2: Specialist hospital staff and systems dedicated to organ donation

These staff have undoubtedly been critically important in guiding the improved donation performance in the subset of hospitals that improved their donation performance in 2010. However in 2010 the majority of the DonateLife Network hospital-based staff were working within hospitals that did not record an improvement in donation performance.

All available evidence suggests that the availability of such staff is critically important. They provide leadership and direction for local donation performance improvement activities. However the simple act of employing nominated specialist staff specialising in organ and tissue donation within a hospital is not in itself sufficient to ensure that hospital improves their donation performance.

Once again it could be said that implementation of this measure, specialist hospital staff and systems dedicated to organ donation, proved to be a *'necessary but not sufficient'* measure for delivering a change in donation performance in 2010.

Measure 3: New funding for hospitals

It is very difficult to draw any conclusion regarding the correlation between the observed changes in donation performance in 2010 and this new funding. It is noted that similar funding for hospitals for organ donation activities was available to hospitals in Victoria for many years prior to the implementation of this reform. Victoria demonstrated the greatest jurisdictional improvement in donation performance in 2010. This indicates that the introduction of these hospital funding mechanisms are not absolutely necessary to drive improved donation performance.

In addition these funds were made available to all hospitals. Very many hospitals received these funds in 2010; relatively few demonstrated improved donation performance in 2010.

The payment to hospitals is undoubtedly a reasonable sum in terms of compensating hospitals for donation-related expenditures. These funds are likely to be potentially useful in supporting extant local clinical practice improvement efforts within hospitals. However it is unlikely that such modest payments would act as a significant driver for the initiation of clinical practice improvements in most hospitals. This is especially so in those hospitals where ODHSF payments are not visible to those being asked to engage in the clinical practice improvement processes, as is currently the case in a number of participating DonateLife Network hospitals.

Measure 4: National professional education and awareness

It would be very difficult to suggest that there was any link between the observed changes in donation performance in 2010 and these programs.

Development of these programs has been very slow. There is no correlation between participation in the education and awareness activities auspiced by the Authority and observed improvements in donation performance.

Together these factors suggest that these programs were not major contributors to the observed changes in donation performance in 2010. This measure does however have the potential to contribute to future improvements in deceased donation performance.

Measure 5: Coordinated, ongoing community awareness and education

These programs ultimately seek to deliver an improvement in the rate of next-of-kin consent for donation. This will be a consequence of building community support for donation and transplantation. In particular it is hoped that a better understanding by our community of the need to know the intent of their loved ones regarding their willingness to donate will lead to improvements in the rate of next-of-kin consent for donation.

There was no change in the observed national consent rate for donation in 2010. This suggests that this measure did not contribute to the observed increase in donation performance in 2010. This measure does however have the potential to contribute to future improvements in deceased donation performance.

Measure 6: Support for donor families

There had been little substantial implementation of the proposed changes to donor family support in 2010. This measure therefore cannot be said to have contributed to the observed increase in donation performance in 2010.

Negative donor family experiences have the potential to negatively impact national donation performance. This measure does therefore have the potential to contribute to future improvements in deceased donation performance.

Measure 7: Safe, equitable and transparent national transplantation process

There had been little substantial implementation of proposed changes to these processes in 2010. This measure therefore cannot be said to have contributed to the observed increase in donation performance in 2010.

Community concerns regarding allocation processes have the potential to negatively impact national donation performance. This measure does therefore have the potential to contribute to future improvements in deceased donation performance.

Measure 8: National eye and tissue donation and transplantation network

There had been little substantial implementation of proposed changes to eye and tissue donation in 2010.

This measure is anticipated to impact eye and tissue donation, not organ donation. This measure therefore cannot be said to have contributed to the observed increase in donation performance in 2010 and cannot ever be expected to impact deceased donor organ donation rates.

Measure 9: Additional national initiatives, including living donation programs

There had been no substantial implementation of AKX program in 2010. This program is not designed to impact deceased donation rates, hence this program cannot be said to have contributed to the observed increase in donation performance in 2010 and cannot ever be expected to impact on deceased donor organ donation rates.

DCD deceased donors made a very substantive contribution to the increased donation performance observed in 2010. These DCD donors came almost exclusively from hospitals who had implemented their DCD programs prior to the release of the national DCD protocol (July 2010).

The evolution of these hospital-based DCD programs was undoubtedly influenced by the discussions that occurred across the sector regarding DCD during the NODC and subsequently throughout the development of the national DCD protocol.

Whilst DCD deceased donors were responsible for a large part of the observed increase in national deceased organ donor numbers in 2010, the observed increase in donation performance in 2010 cannot be attributed to the availability of the National Protocol for Donation after Cardiac Death.

It is inevitable that the availability of the national DCD protocol will help individual hospitals engage in DCD donation in the future. This measure does therefore have the potential to contribute to future improvements in deceased donation performance.

4.3.2 The potential for continued growth in deceased donation of organs in Australia

Deceased donation activity currently is primarily (80%) based on donation after brain death. Around 20% of total deceased donation episodes are currently based on donation after cardiac death.

Demographic trends in most developed countries over the past decade have resulted in either stable numbers of potential brain stem dead donors or a gradual reduction in the relative numbers of potential brain stem death deceased donors. In contrast the re-establishment of DCD donor programs and the move to multi-organ DCD donation has resulted in a marked increase in the numbers of potential deceased organ donors.

When discussing the potential for growth in deceased donation it is important to remember that relatively few people die in circumstances where deceased donation of organs is possible. The potential deceased donor pool is finite and quite small.

It is estimated that organ donation is a possibility in no more than 1% of all deaths and in fewer than 3% of in-hospital deaths.

Potential organ donors constitute a very small subset of the critically ill (amongst the 130,000 plus patients admitted to Intensive Care Units across Australia each year there are perhaps 500-600 potential organ donors) and an even smaller subset of acutely ill patients presenting to Australian hospitals (amongst the 7 million plus patients presenting to Emergency Departments across Australia each year there are those same 500-600 potential organ donors).

Given the number of potential deceased organ donors is both finite and relatively limited, it is vital that every possible deceased organ donation opportunity is recognised and every possible step taken to convert each potential donor into an actual donor. This is sometimes referred to as 'aggressive pursuit of every donation opportunity'.

Organ donation and procurement is acknowledged to be complex. These complexities include social, ethical, legal, emotional, technical and logistical issues and challenges.

Successful donation and transplantation of deceased donor organs and tissues requires the cooperation of many players, with very high levels of knowledge and skill and the timely execution of a myriad of sequential and parallel tasks.

It is a concerted focus on making improvements to each and every aspect of the complex process from potential donor identification through to the transplantation of donated organs and tissues that has been repeatedly shown to have the most significant positive impacts on a nation's organ donation rates.

These steps are:

1. *Donor identification*
2. *Donor screening*
3. *Donor maintenance*
4. *Consent/authorisation*
5. *Organ retrieval*
6. *Organ allocation*
7. *Organ transplantation*

1. Donor identification

All potential donors need to be identified at the earliest possible stage. This early identification facilitates donor screening for suitability for donation and allows the optimising of care of the donor to ensure maintenance of best possible organ function.

In all healthcare systems many potential organ and tissue donors are currently not realised as actual donors due to lack of staff awareness of donation potential, inadequate evaluation, lack of referral for consideration of donation or because the option of donation is not presented to relatives.

Whilst there remains scope to improve the identification of potential brain stem dead (BSD) deceased donors, recent trends in donation performance suggest that there is likely to be an even greater potential for growth in donor numbers by improving the identification of potential DCD donors.

Training those involved in the care of the critically ill to recognise every patient with a potential to become an organ donor after their death is a very important step in optimising organ donation rates. Experience clearly indicates that the establishment of efficient systems for identifying potential organ donors is a key element in any effort to increase the donation rate.

The presence of healthcare professionals at each hospital with a significant potential for organ donation, who are responsible for ensuring an effective proactive donor detection programme, is a very important element of a system-wide program to optimise organ donation and improving donor detection rates.

2. Donor screening

The risk of transmission of disease from the donor to the recipient through organ transplantation needs to be minimized, while balancing the imperative not to needlessly discard potentially transplantable organs and tissues.

Although the use of donors who are not ideal because of a history that indicates a higher disease transmission risk ("high-risk donors"), can be considered under certain circumstances, as another means of expanding the availability of organs for transplantation. The potential contribution of this pool of potential donors to increasing donation rates is numerically quite small.

The use of organs with less-than-optimal function (variously described as 'extended criteria donors' or 'marginal donors' i.e. donors with characteristics such as advanced donor age or a history of hypertension and diabetes) can be considered under certain circumstances as another means of expanding the availability of organs for transplantation. This represents a potentially quite large pool of potential donors.

It must be remembered that use of such marginal donors may negatively impact transplant outcomes. There is an inevitable tension between the relentless pursuit of larger *numbers* of donated organs and tissues by use of marginal donors and achieving the best possible *health outcomes* for those awaiting transplantation. During the review many stakeholders strongly emphasised the absolute need for the Authority and the reform measures to focus on strategies that achieve the best possible health outcomes for those requiring transplantation.

It is widely accepted that there will be an increased use of marginal donors over time. This must be accompanied by stringent informed consent procedures to guarantee that the person receiving these organs is fully aware of the potential for less than optimal health outcomes and programs. In addition,

programs that carefully analyse comparative transplant outcomes in the recipients of these donated organs and the transparency of decision-making will be necessary.

3. *Donor maintenance*

It is essential that organs procured are kept in the best possible condition prior to retrieval. The maintenance of the potential donor's physiological state while in intensive care both prior to and during organ retrieval, minimises the risk that donation is unable to proceed because of 'failed physiological support' and also makes a major difference to the condition of donated organs and the outcomes of transplantation.

4. *Consent/authorisation*

Appropriate consent or authorisation must be obtained both from next-of-kin (or surrogate decision-makers) and from relevant other individuals (e.g. Coroner; Designated Officer; Public Advocate) before organs can be removed.

The consent rate achieved reflects the knowledge, attitudes and beliefs of the community (in particular, the next-of-kin approached for consent) and the performance of the healthcare system (in particular, the skill and experience of the staff engaged in the approach).

The key determinant of the likelihood of the next-of-kin agreeing to donation is known to be their prior knowledge of the wishes of the potential donor regarding deceased donor organ and tissue donation.

There is a need for action on two fronts to increase the likelihood of the next-of-kin agreeing to donation. The first is improving community awareness and support and the second is the provision of specific training and experience in the request for consent to healthcare professionals.

5. *Organ retrieval*

The surgical technique for removing organs from the body and the way those organs are subsequently handled and preserved prior to and during transportation are critical to the successful outcome of the transplant. Organs may be damaged during removal and/or transportation. Some can be repaired, but a few will have to be discarded. Effective, timely coordination of retrieval activities is necessary to guarantee the success of the process.

It is vital that appropriately trained and resourced retrieval teams are available in a timely fashion when the potential for donation exists. Mechanisms must exist to either bring such a team to the donor hospital or transfer the potential donor to a retrieval-capable hospital. There needs to be appropriate resourcing and management of the retrieval process. Several stakeholders noted that an increase in deceased donor numbers will inevitably prompt a revision of current retrieval services. This would require an increase in resourcing (financial and human) and an increased national coordination of retrieval services to ensure the capacity of the national donation system to cope with the increased supply of donor organs. This must include contingencies for surge capacity.

Occasional stakeholders noted the need to have a discussion regarding the economics and logistics of organ retrieval. They believed that at some point these costs will preclude proceeding with an intended donor resulting in loss of these organs from the pool available for transplantation.

6. *Organ allocation*

The best long-term outcomes of transplantation for some organs depend in part on ensuring the best possible tissue matching between donor and recipient.

A well-organised system for allocating and transporting donated organs in the most adequate way is important. In some cases, optimum allocation will require exchange of organs between jurisdictions and on occasions between countries.

A number of stakeholders commented on the potential inequities inherent in the current jurisdiction-specific approaches to organ allocation and suggested that a national allocation system for all deceased donor organs would be both more equitable and efficient.

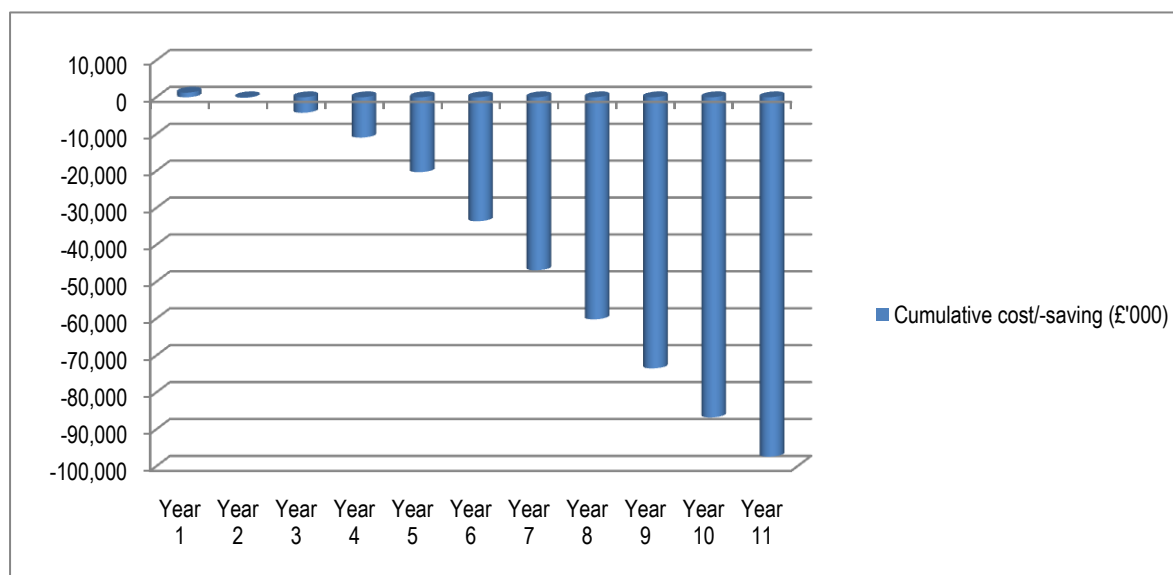
7. Organ transplantation

Transplantation teams require the staff, training and financial and physical resources to ensure that all potentially transplantable organs are utilised to deliver the maximal positive health outcomes for our community from each donor. There needs to be appropriate planning of the resourcing and management of transplantation services to ensure that they are able to effectively use all potentially transplantable organs.

Given the cost-effectiveness of renal transplantation it is unlikely that there will be a long-term need for an overall increase in financial resourcing of the transplant sector. However there is a necessity for resource planning on the transplant to occur across each jurisdiction, to optimally manage a progressive growth in deceased donor organ donation.

Formal economic modelling of the overall health system impacts of increasing deceased donor performance have recently been performed in the UK¹⁷. These show very major long-term savings for health systems through increasing deceased donor organ donation and transplantation activities, as indicated in *Figure 4-5*.

Figure 4-5: Savings for overall health system through increased donation performance (UK)



While there may be a potential need for some short term increases in investment by some jurisdictions, to ensure there is sufficient transplant centre and ICU bed capacity to allow transplantation of all currently available deceased donor organs, in the long-term there should be no concerns that improving deceased donation performance will drive up overall healthcare costs, either nationally or within any individual jurisdiction.

What the increase in transplantation of deceased donor organs does require is specific forward planning for the delivery of national transplantation services. This must aim to ensure a sufficient national capacity to manage the current number of donated organs and the anticipated future increases in activity.

This planning must include identification of strategies and mechanisms locally, at the jurisdictional level and nationally to manage surge capacity.*

* Surge capacity is a health care system's ability to manage a sudden or rapidly progressive influx of patients within the currently available resources at a given point in time

Unlocking the deceased donation potential within any healthcare system requires structured performance improvement programs in organ and tissue donation, operating at national and regional levels and within every hospital where there is a significant potential for organ donation. Such programs seek to continually and rigorously evaluate the whole process of organ and tissue donation, whilst taking account of the specific circumstances and characteristics of each hospital and health system. They make it possible to compare processes and results, to identify areas for potential improvement and to take action and implement improvement to care processes.

A suitably skilled workforce underpins delivery of optimal organ and tissue donation outcomes for our community. Improving a hospital's donation performance requires healthcare professionals involved in the routine care of potential donors to have appropriate donation-specific knowledge and skills and those leading the changes to clinical care processes to have the ability to design and implement a successful clinical practice improvement programs.

Therefore it is critically important that high quality, effective, accessible training programs are available and used by all healthcare professionals involved in the care of potential donors.

4.3.3 The potential national capacity for deceased donor organ donation

There are three different approaches taken to generate an estimate of a nation's potential capacity for deceased organ donation.

The first approach looks at international best-practice 'benchmark' performance (i.e. that achieved in Spain), assumes that this level of performance (35 dpmp) can be achieved in the nation under consideration and uses available information regarding the local demography to estimate donation capacity. Despite its recognised limitations¹⁴ this approach has been widely applied within the Australian context by any number of pundits. These limitations relate to the metric itself (dpmp) [which is derived using different definitions of 'organ donor' in different countries] - and major differences in nations' demographics and mortality distributions [and hence substantially different potential deceased donor pools]. If we had been operating at Spain's level of performance nationally there would have been 790 deceased donors in 2010 (35 dpmp).

The second approach seeks to identify local 'benchmark' donation performance (i.e. the highest performing region within the country of interest; in the Australian context it is South Australia's 20-23 dpmp) and assume that the whole country can match that level of performance given implementation of appropriate governance and clinical practice improvement systems. If we had been operating at this

level of performance nationally there would have been around 520 deceased donors in 2010 (23 dpmp).

The third (and preferred) approach bases its projected estimates for the likely capacity for organ donation on the most recent available potential deceased organ donor / death audits. This approach also provides the unique opportunity to identify areas in the donation process where improvements in care may be possible. Typically such audits of potential organ donors internationally in recent years have revealed:

- 80 -90% of potential brain dead donors are currently detected
- 50% of potential DCD donors are currently detected
- 10% of consented donors (intended donors) do not proceed to actually donate

Using this approach and the available data from the death audit data nationally we can derive an estimate for the 2010 capacity for organ donation based on the given 309 actual donors (14 dpmp).

For the purposes of this forecast it is assumed an optimal deceased donor program would achieve a 100% detection of all potential deceased donors and a 75% consent rate. If we had been operating at this level of performance nationally, the 762 potential deceased donors in 2010 would have resulted in up to 572 actual donors (25 dpmp) if there was no loss of intended donors, and 515 actual donors (23 dpmp) if there continued to be a 10% loss of intended donors.

These data all suggest that there remains a significant opportunity to continue growth in the numbers of deceased organ donors in Australia.

4.4 The DonateLife Network as a national system

The staff and administrative frameworks for the operation of the DonateLife Network were progressively established through 2009 and early 2010. The DonateLife Network is now structurally complete. It has a very clear purpose and well articulated goals. However, as would be expected of any new national healthcare organisation, it is still evolving in terms of its detailed form and function.

4.4.1 The extent to which the DonateLife Network is evident and operational as a national system

The DonateLife Network was assembled using a mix of existing structures and personnel (the existing OTDA's and their staff, the NODC legacy systems and the relatively small numbers of hospital-based staff within our hospital systems who were engaged to address some aspects of donation performance) and new structures and personnel (the Authority, the rebadged and expanded OTDA's and the overwhelming majority of the DonateLife Network hospital-based specialist staff).

In seeking to build and coordinate a cohesive national network the Authority has therefore faced the dual challenges of needing to manage issues that arise with a major change for the staff of extant organisations whilst simultaneously trying to help orient and motivate a large cohort of new staff working in new roles within a network of public and private hospitals across metropolitan and regional Australia.

By and large stakeholders have reported that the increased staffing of OTDA's has now resulted in improved service delivery nationally and better working conditions and support systems for OTDA staff.

Many transplantation sector stakeholders were unsure of the extent to which there has been effective functional integration of the OTDA's into a genuine national network. They questioned the authority of the the Authority to direct changes in clinical care, noting that effective control of these agencies appears to still reside with jurisdictional Health departments.

Several stakeholders from the transplantation sector also noted the significant friction that was evident between OTDA staff and DonateLife Network hospital-based staff in several jurisdictions during the first two years of implementation of the reform.

Whilst the majority of issues underpinning these conflicts appear to have been largely resolved, it was often noted that the process of integration of the new staff into the sector should have been better managed by the Authority

The Authority has been required to operate within the federated governance model that operates for all acute hospital healthcare service delivery within Australia. The challenge of enacting national change in healthcare delivery under federalism was commonly commented upon by stakeholders. While the Authority now funds almost all activity occurring in the sector, it has direct operational control over very few activities. The Authority is largely dependent on the cooperation of jurisdictions for the implementation of nationally consistent approaches to the care of potential organ and tissue donors and the creation of models of clinical practice improvement that will optimise donation performance. If there were to be any hurdles or barriers to implementation of proposed changes identified in either the OTDA or participating hospital environments the Authority paradoxically often has no authority to act to overcome these barriers. Rather it must work to resolve issues through negotiations with jurisdictions and seek to obtain a consensus decision on a way forward. This undoubtedly slows the pace of the change process.

Although there were some exceptions, the majority of stakeholders within the DonateLife Network report a much stronger allegiance and sense of relationship to their jurisdictional structures and processes than to the national Network.

For many stakeholders a large part of the reform has been seen as 'rebranding' of pre-existing clinical networks.

There have been relatively few national activities involving staff within the DonateLife Network to date, with most staff reporting that almost all of their current interactions within the DonateLife Network occur within intra-jurisdictional forums. A number of stakeholders they would like to see a greater sense of national cohesion in the donation sector as promoted during the NODC.

Stakeholders frequently noted that the scope of the proposed reform was always very ambitious. The reform measures sought to cover a broad range of issues simultaneously. These include deceased and living organ donation issues; the structure and operations of the deceased organ donation sector; eye and tissue donation issues; the structure and operations of the eye and tissue donation sectors; transplantation issues; professional and public awareness and education issues and bereavement support issues.

Some of these matters are clearly inter-related; involve working with a relatively small set of stakeholders and quite specific knowledge sets. Others are quite distantly related, involve engaging with very different stakeholder groups and constituencies and require very different knowledge sets and sector experience.

The breadth of the reform agenda has proven a significant challenge for the Authority. This undoubtedly accounts for the relatively slow progress of implementation of several of the reform measures. Many stakeholders commented on the lack of substantive outputs from many projects initiated by the Authority. Even when projects were clearly very important to the Authority's ability to progress the reform agenda they still frequently languished.

The Authority was established with very few staff with any prior knowledge and experience of the relevant organ, eye and tissue donation and transplantation sectors. In particular the Authority has had very little access to clinically trained staff to help lead the design of clinical practice change programs and strategies to support implementation of the reform measures in hospital practice.

In its first two years of operation there was a relatively high staff turn-over at all levels of the Authority. These human factors slowed the growth in relevant intellectual capital and social capital within the Authority. These workforce capacity issues inevitably hampered implementation of some the reform measures.

4.4.2 Opportunities to further enhance and integrate the Network

The review has identified a number of opportunities to further enhance and integrate the network on the basis of stakeholder feedback about progress in 2010, though it is noted that work in relation to some of these has already commenced. These are detailed in the following table.

Table 4-3: Potential opportunities for enhancing the Network

Opportunity for Network enhancement	Strategies
<i>Establish a relentless focus by the Authority on supporting and prioritising activities that deliver measurable changes in clinical care of potential donors in DonateLife Network hospitals</i>	Establish a nationally consistent death audit program and use this as the foundation stone for a national performance monitoring and clinical practice improvement program within a formal national clinical governance framework. Develop specific national guidance documents for all key clinical care processes.
<i>Reallocate DonateLife Network resources</i>	Revisit the relative allocation of available funds for the implementation of reform between measures and within measures to try and deliver the most cost-effective outcomes. Allow the Authority to be accountable for determining annual funding allocations and priorities given available overall resources. Better target the available human resources in jurisdictions and to hospitals with a realistic potential for significant donation activity, based on an analysis of throughput and casemix. Retain a single point of accountability for OTDAs and hospitals, but allow both flexibility in how they staff the agency and hospitals within their part of the DonateLife Network. Develop a support framework for jurisdictional clinical practice improvement programs and common resources for hospital based

Opportunity for Network enhancement	Strategies
	clinical practice improvement programs.
<i>Develop an active national clinical practice improvement program to optimise deceased donation</i>	<p>Design and introduce a national, structured clinical practice improvement program to support jurisdictions and participating hospitals improve deceased donation by better identification and management of potential donors.</p> <p>Focus this program on helping hospitals learn practical ways of changing clinical practice.</p> <p>Ensure all DonateLife Network hospitals have functioning teams working to improve donation performance.</p> <p>Ensure all DonateLife Network hospital teams report on their progress in enhancing their hospitals donation performance within their local clinical governance frameworks and into relevant national specialist societies.</p>
<i>Establish a national professional education program</i>	<p>Establish specialised educational programs for all clinician groups within the DonateLife Network.</p> <p>Leverage the available international resources to build this program.</p> <p>Establish a remotely accessible national induction and orientation program for new staff.</p>
<i>Increase the clinical inputs into the design of implementation strategies and programs</i>	<p>Recognise the need to increase the access of the national office to substantive inputs of experienced clinicians.</p> <p>Develop formal mechanisms to structure the inputs of SMD's and OTDA and hospital-based staff to the national agenda to ensure that all provide similar substantial inputs to national implementation strategies and programs.</p> <p>Develop formal mechanisms to obtain inputs into the national implementation planning from DonateLife Network hospital-based medical and nursing staff.</p>
<i>Draw upon expertise in the sector</i>	<p>Develop more tailored procurement processes consistent with Commonwealth Procurement Guidelines that include use of panels of preferred providers and select tender processes or direct procurement of services from other Commonwealth, State, Territory or Local Government entities where no commercial market exists and where specific expertise is required.</p>
<i>Enhance communication across the DonateLife Network</i>	<p>Implement an effective national Community of Practice for all clinical disciplines (how-so-ever titled).</p> <p>Require regular jurisdictional Network clinician forums with some common agenda items (within the national clinical practice improvement program).</p> <p>Program regular national forums for DonateLife Network staff that</p>

Opportunity for Network enhancement	Strategies
	focus on sharing knowledge and approaches to improving a specific clinical practice or canvassing a particular clinical issue. Ensure all DonateLife Network staff regularly interact with peers outside their immediate, everyday work environments.
<i>Reduce administrative complexity</i>	Reduce the reporting burden both in terms of content and frequency. Simplify payment systems for the HDSF by payment of an agreed recompense for actual donors.
<i>Formalise decision-making mechanisms for the DonateLife Network</i>	Adopt AHMAC consensus decision-making guidelines and establish criteria for referral to CTEPC.
<i>Improve media management</i>	Develop and implement a proactive media management plan for the Authority. Establish a more effective national issues management plan for the DonateLife Network.

4.5 The effectiveness of the current governance and consultation arrangements of the Organ and Tissue Authority

4.5.1 Governance

Under the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*, the Minister for Health and Ageing appointed the Chair and members of the Advisory Council for three-year terms on 24 February 2009. A minimum of 9 and maximum of 15 (currently 13) non-governing members plus the Chair provide advice to the Chief Executive Officer on organ or tissue donation and transplantation matters. The Advisory Council is required to meet at least four times a year.

The Advisory Council appears to have been functioning more as a communication vehicle for briefing Advisory Council members on issues and progress with the reform rather than as a means of systematically obtaining required advice for the operations of the Authority. A number of the Advisory Council members feel that Council members have had relatively little opportunity to provide substantive advice. Several commented that the Council sometimes appears to be trying to act as a governing Board rather than an advisory body.

The quarterly Council meetings are relatively brief. Most of the available meeting time has been taken up with the presentation of detailed updates on the progress in implementation of the reform package, rather than in active consideration of initiatives or issues. Many members of the Council felt they had been given too little time to provide meaningful input into the Authority.

There has been relatively little accessing of the skills of the Advisory Council members between these scheduled face-to-face quarterly meetings. Most Council members believed they had been 'under utilised'. They believe that there could be many opportunities for improving the effectiveness of the

Council's operations. A number highlighted that better use of communication technologies would secure the Authority better access to advice from Council members.

Within the sector more broadly, many stakeholders questioned the makeup of the current Advisory Council. While most believed that the membership should include individual appointees, occasional stakeholders argued for the inclusion of representative appointees from key stakeholder organisations.

Most stakeholders expressed concern regarding the extent to which the Advisory Council as currently constituted, was in the position to be able to provide the necessary expert inputs that would be of value to the CEO and the operations of the Authority.

Many stakeholders believe that the current Council is too large and unwieldy and does not work effectively. They felt that a 6-8 member group with targeted expertise would be more effective than the current group. They should meet regularly with CEO with a strict focus on strategic issues – not financial, operational or management issues. Further they suggested that such a stream-lined Advisory Council should include a mix of experienced and emerging leaders. Their skills should encompass: organ donation, media management, transplantation, state/commonwealth functions and interactions, consumer advocacy and legal/ethical expertise. On the basis of the convergence of feedback, it is suggested that the Advisory Council be reduced to 9 members plus Chair (as indicated previously this is the minimum number allowed under the Act).

Regular stakeholder forums should be used to communicate with and canvass issues with the broader sector.

In addition to this Advisory Council the Authority has established additional Governance committees:

- State Medical Director- Jurisdictional Working Group (SMD/JWG) Committee;
- Audit Committee.

A SMD Clinical Reference Group is to begin meeting in the near future.

Occasional stakeholders identified perceived deficiencies in governance of the Authority in the first 1-2 years of operation. They suggested that at times there appeared to be a relative lack of insight by the Authority of the potential policy, legislative, financial and operational impacts of decisions regarding implementation of the reform on jurisdictions.

Several stakeholders expressed concern that there appears to be too little regard given to the likely return on investment in the decision-making processes within the Authority.

The effectiveness and procedural efficiency of the SMD/JWG Committee was described in very different terms by different stakeholders. Some felt it to be working well, providing their jurisdiction with good opportunities for input into the decision-making processes of the authority. Others expressed the view that at times this Committee had not followed the appropriate guidelines for achieving consensus decisions during its meetings and had provided too little opportunities for genuine contributions by their jurisdiction into the directions taken by the Authority.

Several felt workings of this Committee has been insufficiently collegiate in the past, with some describing their role as more that of a compliant observer rather than a peer member. Some even described the working relationships within this Committee as being more adversarial than collegiate.

All stakeholders interviewed were optimistic about the substantial improvements to both the culture and operating procedures of the important governance groups of the Authority under the direction of the new CEO. Relationships across the DonateLife Network are now seen in a very positive light. There appears to be a substantial change in leadership style and a renewed spirit of goodwill and cooperation across the Network.

Several stakeholders were of the view that the SMD/JWG Committee required an ability to use appropriately and proportionate escalation on issues of importance or when consensus decision-making proves impossible. Several stakeholders believe that the Authority CEO should be required to refer such matters to the Clinical, Technical and Ethical Principal Committee (CTEPC) of AHMAC. This should enable a process that ensures there is joint Commonwealth, State and Territory commitment to oversight delivery through the CTEPC (and its Chief Medical Officer members) or AHMAC of national targets, priorities and outcomes under the National Reform Agenda.

It is noted that to date the Authority has not established an explicit Clinical Governance Framework² for its operations. Such a framework would provide a vehicle for clarifying roles across the different DonateLife layers as well as performance targets and measurement activities.

The governance of the OTDA's and DonateLife Network hospital-based staff varies between jurisdictions. Some jurisdictions have very clear reporting and accountability processes in place between their Health Departments and their OTDA and the hospital-based DonateLife Network staff, with regular interactions between relevant managers and a shared responsibility for reporting progress in implementation to the Authority. In other jurisdictions the Health Departments act as a conduit for transferral of funds to the OTDA and Network hospital-based staff, but have less frequent and in-depth interactions between DonateLife Network staff and the Authority.

Some jurisdictional OTDA's have formal advisory committee structures; others operate within a less structured governance framework.

Responsibility for reporting on progress with implementation also varies between jurisdictions. In all OTDA's, participating hospitals and the Health Department contribute to reporting, but the primary responsibility for reporting to the Authority rests with the ODTA's in some jurisdictions and with the Health Department in others.

Employment models for the DonateLife network hospital-based staff also vary across jurisdictions. Typically these staff are directly employed by their hospitals. However some jurisdictions have the jurisdictional OTDA directly employ the HSN's.

² Examples of clinical governance frameworks may be downloaded using the following links:

http://www.health.vic.gov.au/clinrisk/downloads/clin_gov_pol_framework.pdf

[http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/C774AE55079AFD23CA2577370000783C/\\$File/32296-Australian-SandQ-Framework.PDF](http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/C774AE55079AFD23CA2577370000783C/$File/32296-Australian-SandQ-Framework.PDF)

http://www.safetyandquality.health.wa.gov.au/docs/clinical_gov/Introduction_to_Clinical_Governance.pdf

4.5.2 Consultation

Under the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*, the Chief Executive Officer appoints expert advisory committees to ensure that the national reform agenda is implemented and that relevant stakeholders are consulted.

These are Sub Committees that focus on particular aspects of the Authorities activities and refer matters to a relevant governance committee for endorsement as required. These are currently:

- SMD Clinical Reference Group
- Agency Managers Reference Group
- Education Working Reference Group
- Donor Family Support Reference Group
- Eye and Tissue Working Group
- Data and Audit Reference Group
- Communications Reference Group

There have also previously been:

- The Principal Committee: a committee of senior jurisdictional representatives that provided advice on policy, legislative and administrative issues relevant to the Australian Government's national reform package and other organ or tissue donation and transplantation matters, as well as advice on wider health sector issues and emerging trends that are identified as having implications for the implementation of the national reform package and organ or tissue donation and transplantation matters more broadly. It was wound up in late 2009.
- Transplant Liaison Expert Advisory Committee to advise the CEO about organ and/or tissue donation and transplantation matters referred to it by the CEO. This has not convened for some considerable time.
- The DonateLife Expert Advisory Committee to advise the CEO on matters of mutual relevance to the donation and transplantation sectors. This was wound up in 2010.

The joint State Medical Director- Jurisdictional Working Group (SMD/JWG) Committee and the State Medical Directors' Clinical Reference Group (when established) would appear to be the prime sources of advice and guidance for the Authority in 2011.

The Jurisdictional Working Group supports the Authority to progress operational issues associated with implementing the reform package measures from Commonwealth, State and Territory Government perspectives. The group provides advice to and works directly with the Authority to implement policy, legislative and administrative matters.

It is proposed that the State Medical Directors' Clinical Reference Group consider and make recommendations to the Authority in respect of the strategic priorities, clinical and data governance, planning and leadership of the DonateLife Network, and the implementation at a state-based level of the World's Best Practice Approach National Reform Package on Organ and Tissue Donation for Transplantation.

The Authority also convenes a number of forums with identified stakeholders that seek to improve communications within the sector. The community sector organisations consulted often reported that

despite these forums they were unhappy with their communications with the Authority. They expressed concerns that they were given very limited opportunity to provide meaningful inputs on proposed initiatives. Often they failed to receive any notice (or inadequate notice) of initiatives announced in the media, resulting in their organisation being either 'blind-sided' by these announcements or having inadequate forewarning to effectively engage and link in to these initiatives.

Several stakeholders were of the opinion that the Authority has had little success in articulating its vision and mission in the acute health sector. These stakeholders perceive a failure by the Authority to assert ownership of donation and transplantation.

5 CONCLUSION

The major structural elements of the Reform Package have been established. There is now a national DonateLife Network under a single Authority and the recruitment of hospital based staff to the Network, has occurred. This has been achieved in spite of significant challenges at all levels.

The number of organ donations across Australia in 2010 was the highest ever and early indications are that donor numbers in 2011 are likely to be higher still. It needs to be noted that these results have been driven through the significant achievements of a handful of hospitals across New South Wales and Victoria. Of the increase in donor numbers from 2009 to 2010, a significant proportion (43.5%) was from DCD, with the remainder being DBD.

Overall, when compared with international jurisdictions that have implemented major reforms, Australia is tracking at levels equivalent to or better, given the stage of implementation.

The breadth and scale of the agenda set for the Authority by the nine measures within the Reform Package, is substantial. Work has occurred to varying degrees across each of these measures. There is nothing to suggest at the mid-point that these measures should be changed, although the movement by the Authority to articulate priorities for the current financial year would appear to be appropriate, given the scale of the reform they have been asked to achieve.

There remains a healthy impatience for further progress of reform that was conveyed by many stakeholders, particularly by those actively working within the sector. A number of these stakeholders were critical of the pace of delivery by the Authority on the fundamental supports for effective reform, such as national education and training programs and clinical protocols to drive national consistency. Further they stress that the DonateLife Network is not yet functioning as a cohesive national system. They are particularly looking for support with establishing and evolving clinical improvement programs in their hospitals. They are calling for more jurisdictional, inter-jurisdictional and national opportunities to come together as DonateLife network members, as well as guidance on how to drive hospital level changes in clinical care. This development of a national framework (eg clinical practice improvement model) that includes training for network staff in change management at the hospital level in deceased donation warrants prioritisation and does not appear to be adequately targeted in the current priorities set by the Authority.

The governance of the reform continues to evolve. There is a plan to strengthen clinical input to the initiative through the establishment of a clinical reference group comprised of the SMDs, which seems highly appropriate given the clinical focus of the reform package. This is in addition to the SMD/JWG Committee that currently meets. There were calls by many stakeholders to streamline the membership of the Advisory Council to nine members plus the Chair, clarify the role and review the skillsets that are required. The challenges that can occur when a national initiative is rolled out across the eight jurisdictions have and continue to occur, though to a lesser degree now. We suggest that the development of a formal clinical governance framework would be an important step towards clarifying roles at all levels in relation to the reform.

In summary the Reform is well under way. There remain opportunities to better enable staff within the DonateLife network and build the momentum for changes in deceased organ donation performance across more hospitals nationally. The Authority has transitioned through a difficult period and is now well established although many stakeholders believe that it is time for the Authority to assume a greater leadership role within the sector. They call for the Authority to actively work in partnership with

jurisdictions, the DonatLife network and relevant professional and community stakeholder groups, so that continuing improvements in our national organ and tissue donation performance can be delivered.

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This report has made extensive use of data regarding Australian deceased donation that was obtained from ANZOD Registry Reports. The report draws on data in the published reports from 1997 to 2010. The ANZOD Registry Reports are published by the Australia and New Zealand Organ Donation Registry, Adelaide, South Australia. Editors (2011): Leonie Excell, Kathy Hee, Graeme Russ.

The data reported here have been supplied by the Australia and New Zealand Organ Donation Registry. The interpretation and reporting of these data are the responsibility of the Authors and in no way should be seen as an official policy or interpretation of the Australia and New Zealand Organ Donation Registry.



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Appendix 1

Appendix 1: Membership of Reference Group

The membership of the reference group was

- Ms Mary McDonald, First Assistant Secretary, Regulatory Policy and Governance Division, Department of Health and Ageing or suitable nominee;
- Mr Joe Castellino, Assistant Secretary, Health Programs, Ageing and Sport, Department of Prime Minister and Cabinet, or suitable nominee;
- Ms Kaye Pulsford, Executive Director Governance and Capability, Office of the Chief Health Officer, Queensland Health or suitable nominee;
- Ms Roslyn Elmes, Executive Director Public Health and Ambulatory Care, Northern Metropolitan Health Service, WA Health or suitable nominee;
- Dr Sally Tideman, State Medical Director, South Australia;
- Dr Jonathan Gillis, State Medical Director, New South Wales;
- Professor Jeremy Chapman, Director of Acute Interventional Medicine (SWAHS) and Renal Services, Westmead Hospital and Advisory Council member
- Dr Marisa Herson, Head, Donor Tissue Bank of Victoria and Organ and Tissue Advisory Council member.



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Appendix 2

Appendix 2: Stakeholder consultation list

Name	Interest in Review
The Hon. Catherine King	Parliamentary Secretary for Health and Ageing
<i>Organ and Tissue Donation and Transplantation Authority Advisory Council</i>	
Mr Sam Chisholm	Chairman
Dr David Boadle	Member (TAS)
A/Prof Dianne Stephens	Member and NT Medical Director
Prof Don Chalmers	Member (TAS)
Prof Geoff Dobb	Member and Chair, Australia and New Zealand Intensive Care Society (ANZICS) Death and Organ Donation Committee
Prof Jeremy Chapman	Member and Director of Acute Interventional Medicine (SWAHS) and Renal Services, Westmead Hospital
Prof John Horvath	Member (NSW)
Dr Marisa Herson	Member and proposed M-PIR Reference Group member (VIC)
Ms Rachael Martin	Member (NSW)
Prof Russell Strong	Member (QLD)
Ms Anne Cahill-Lambert	Member (ACT)
<i>State Medical Directors</i>	
Dr Andrew Turner	TAS
Dr Helen Opdam	VIC
Dr Imogen Mitchell	ACT
Dr Jonathan Gillis	NSW
Dr Kevin Yuen	WA
Dr Philip Sargent	QLD
Dr Sally Tideman	SA
<i>Hospital Based Staff</i>	
Dr Sally Tideman	DLN South Australia
Dr David Cook	Intensive Care Unit - Princess Alexandra Hospital
Dr David Pilcher	Hospital Based Medical Director, Alfred Hospital Victoria
Dr Anders Aneman	Hospital Medical Director, Liverpool Hospital Sydney
<i>Department of Health Representatives</i>	
Ms Donna Burton	Commonwealth Department of Health and Ageing
Ms Mary McDonald	Department of Health and Ageing
Ms Roslyn Elmes	WA Health
Ms Karen Botting	VIC

Dr Kerry Chant	NSW
Ms Sue Ireland	SA
<i>Charter Signatories</i>	
Ms Francesca Rourke	President, Australasian Transplant Coordinators Association (ATCA)
Prof Peter MacDonald	Chair, Standing Committees, Transplantation Society of Australia and New Zealand (TSANZ)
Dr Sally McCarthy	Chair, Australasian College for Emergency Medicine (ACEM)
Mr David O'Leary	Gift of Life Inc.
Ms Anne Wilson	Kidney Health Australia
Dr Graeme Pollock	Chair, Eye Bank Association of Australia and New Zealand and Lions Eye Donation Service
Ms Anne Cowie	Chair, Australian Tissue Banking Forum and Perth Bone & Tissue Bank Inc.
Ms Robyn Hookes	The David Hookes Foundation
Mr Chris Thomas	Transplant Australia
<i>International</i>	
Mr Howard Nathan	Philadelphia Gift of Life Inc
Ms Sally Johnson	Director of Organ Donation and Transplantation, National Health Service Blood and Transplant (UK)
Dr Raphael Matasanz	National Transplant Organisation (ONT, Spain)
Dr Teresa Beigay	Director, Special Donation Initiatives, Health Resources and Services Administration, Department of Health and Human Services (USA)
<i>Other</i>	
Prof Josette Eris	Chair, Transplant Liaison EAC
Mr Marvin Weinmann	ShareLife



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Appendix 3

Appendix 3: Survey results

Some lessons from the surveys

- Very considerable pent-up frustration within OTDA's, with perception that they have too little input to the agenda of the Authority (as evidenced by content of free-text commentary and the relative volume of free-text entries; words per returned survey)
- Strong senses in OTDA that their expertise is not valued by the Authority
- Considerably higher overall dissatisfaction within OTDA's than within hospitals
- Good response rates achieved in both groups
- Considerable ambiguity amongst OTDA staff. Recorded Satisfaction levels at or below neutral point for many domains e.g.
 - Managers re communication
 - ODC re communication
 - ODC re Death audit
 - Managers re COP
 - ODC re COP
 - SMD re COP
 - Admin re Portal
 - Managers re donor family support
 - Managers re orientation & induction
 - Managers re network cohesion
 - ODC re network cohesion
 - Communications staff re training
 - ODC re training
 - Managers re 2010 increase in donor number link with reform
- About half OTDA staff employed since reform implementation began
- Hospital staff are largely very experienced professionals
- Hospital staff largely positive about most domains

Variations in satisfaction in responses to common issues

Levels of satisfaction regarding the following	OTDA Strongly agree or Agree	Hospitals Strongly agree or Agree	P value
Effective Communication	30/65	56/101	NS
Progress in implementation of reform measures	42/65	93/101	<0.002
Progress with death audit	31/65	93/101	<0.002
Community of practice	16/65	63/101	<0.002
DCD	45/65	62/101	NS
Improved OTDA and hospitals working relationships	41/65	68/101	
National initiatives helped us improve	37/65	71/101	NS
Orientation & induction	31/65	67/101	<0.02

Final Report: Mid-point Implementation Review of the National reform package - *A World's Best Practice Approach to Organ and Tissue Donation*

Professional Education & Training	26/65	72/101	<0.002
DonateLife Network cohesive & delivering consistent care	22/65	58/101	<0.002
Increased donor numbers due to national reform measures	32/65	53/101	NS
Community awareness campaign	48/65	63/1101	NS
Changed role in organ donation	18/65	45/101	<0.03
Changed role in eye & tissue donation	11/65	39/101	<0.03

- Hospital staff report measures two and five as the most important
- Hospital staff see three, seven, eight and nine as significantly less important

Measure	Very Important (n)	Fairly Important (n)	Very + Fairly (n)
1	49	36	85
2	64	29	93
3	54	29	83
4	61	27	88
5	68	25	93
6	57	28	85
7	50	27	77
8	42	26	68
9	55	27	82



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Appendix 4

Appendix 4: Synopsis of donation related reforms in five international jurisdictions

1 THE UNITED KINGDOM

Like Australia, the UK has a long tradition of reviewing and modifying its approach to organ and tissue donation and transplantation sectors. Some of these key national initiatives include:

- In 1968 a National Tissue Typing and Reference Laboratory (NTTRL) established at Southmead Hospital, Bristol.
- In 1972 the National Organ Matching and Distribution Service (NOMDS) founded.
- In 1979 NTTRL and NOMDS merged to become UK Transplant Service.
- 1991 UK Transplant Service becomes a Special Health Authority and is renamed United Kingdom Transplant Support Service Authority (UKTSSA). The UK Transplant Support Service Authority (UKTSSA) was specifically tasked with improving donation performance nationally.
- In July 2000, UK Transplant was reformed with a new, extended remit to increase organ donation rates.
- In October 2005 UK Transplant merged with the National Blood Service and Bio Products Laboratory to form NHS Blood and Transplant, an NHS Special Health Authority responsible for optimising the supply of blood, organs, plasma and tissues and raising the quality, effectiveness and efficiency of blood and transplant services.

NHS Blood and Transplant (NHSBT) are responsible for ensuring the safe and secure supply of blood, stem cells, tissues, solid organs and plasma products to the NHS; and for promoting and raising awareness of donation. They supply blood to hospitals in England and North Wales; tissues and organs across the UK; and fractionated plasma products to the NHS and the world market.

The UK Organ Donation Taskforce have made a series of recommendations to improve the national organ donation performance in 2008

These have been progressively implemented by the ODT Directorate of NHSBT

Deceased donation performance in the UK has improved in recent years and is on track to meet their national performance targets

The increase in donation performance in the UK has been due to better identification of potential donors and the growth of DCD donor programs

The UK has very strong national staff education and training programs and a strong national death audit program that play important roles in underpinning the success of their reforms

Amongst their core responsibilities they manage the National Blood Service and are responsible for the NHS Organ Donor Register, the British Bone Marrow Registry and the NHS Cord Blood Bank.

In 2008 NHSBT was reorganised into three operational Directorates and UK Transplant was renamed Directorate of Organ Donation and Transplantation within NHSBT, which is responsible for Organ Donation and Transplantation across the UK.

The Organ Donation and Transplantation Directorate (ODT) have responsibility, with partners in the Department of Health and the devolved administrations for delivering the recommendations of the Organ Donation Taskforce.

The UK Organ Donation Taskforce recommendations sought to deliver a 50% increase in deceased organ donation numbers and a 73% increase in the numbers of deceased organs donated in the UK within the first five years of operations of NHSBT.

Following upon the recommendations of the Taskforce the NHSBT Organ Donation and Transplantation Directorate has set about a reorganisation of a number of aspects of organ and tissue donation services. These have included:

- Established a network of Clinical Leads and non-clinical Donation Champions and Organ Donation Committees in donating hospitals
- Transferring all the Specialist Nurses working for many different NHS Trusts on Organ Donation into NHSBT employment, and the employment of extra organ donation specific nursing staff. As a result, there are now over 200 specialist organ donation nurses working within NHS Trusts to increase organ donation. This change was designed to deliver consistency in ways of working and a clear emphasis on organ donation for all NHS Trusts
- Implemented regional Donor Transplant Co-ordinator (DTC) networks across the UK accountable to NHSBT and doubled the total number of DTCs
- Worked with the NHS to ensure the appointment of over 175 Clinical Leads for Organ Donation, the establishment of over 140 Donation Committees within NHS Trusts and have provided these hospital-based teams with tools needed to optimise donation performance via an innovative Professional Development Programme
- Commissioned 13 organ retrieval teams across the UK working to agreed specifications and standards providing a network of organ donor retrieval teams (transplant surgeons, nurses and anaesthetists) to ensure timely high-quality organ removal
- Completed the roll-out of an Electronic Offering System (EOS) to most transplant centres to speed up donor registration and organ offering
- Further developed the electronic Potential Donor Audit
- Established a new clinical governance system within their ODT directorate and a new Transplant Policy Review Committee was established to oversee policies and standards
- Commissioned an on-line survey to measure public attitudes towards the Organ Donor Register (ODR) and barriers to joining it. Concerns about the level of respect given to a deceased person's body and whether doctors make every effort to help a patient if they are

identified as a potential organ donor topped the list of reasons given for not joining the ODR

- Launched the first ever UK-wide organ donation public awareness campaigns
- Appointed Professor James Neuberger as Associate Medical Director, Organ Donation and Transplantation, Dr Paul Murphy as Clinical Lead in Organ Donation and Mr David Mayer as Clinical Lead in Organ Retrieval. These appointments are seen to be key in supporting NHSBT's role in ensuring the successful implementation of the Organ Donation Taskforce recommendations.

To increase the number of deceased organ donors in line with target, they have performed detailed mapping of the organ donation pathway and used information from this mapping to guide prioritisation in improving donation performance.

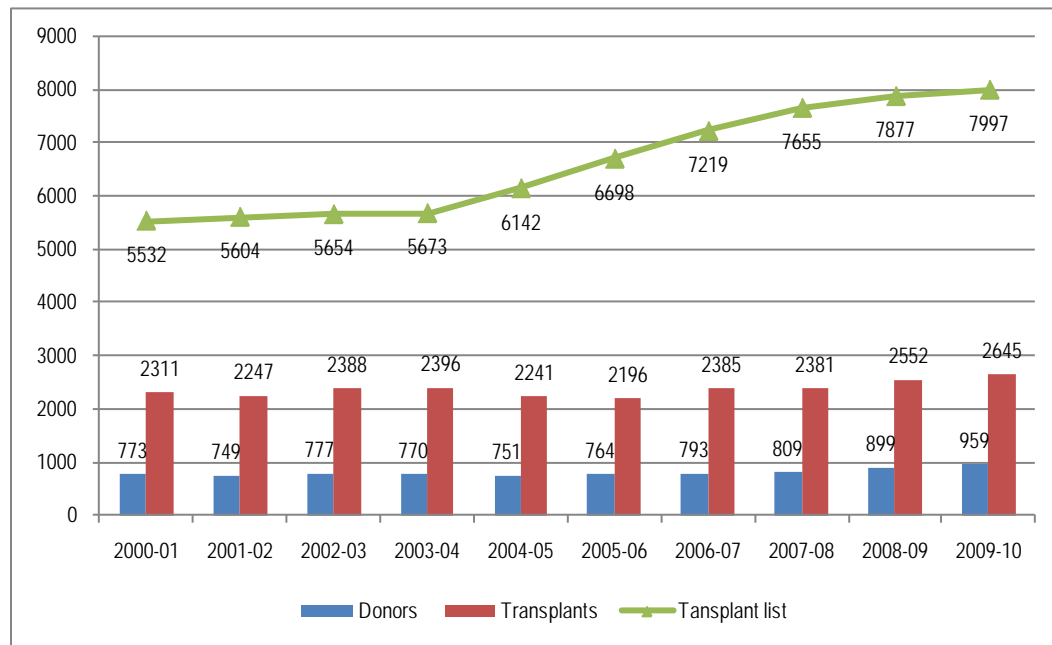
They also set out to lead, manage, motivate and develop the Donor Transplant Coordination (DTC) workforce and in particular focused on ensuring that the Donor Transplant Coordination workforce has the capacity, capability and resilience to meet the growing number of deceased donors, including the commissioning of external training as required.

There has been a strong emphasis on ensuring that DTC's are embedded in UK hospitals with a focus on building productive working relationships with critical and emergency care staff and to lead the development of clinical networks for donation across all UK hospitals.

They aim to ensure that hospital clinical leads for donation, non-clinical donor champions and hospital donation committees have the skills, information and necessary supports to increase deceased donation.

There are currently 17.7million people - 29% of the UK population - on the NHS ODR, with just fewer than one million names added in the last year. There has been a steady increase in the number of transplants in this country over the past seven years, with 3,708 transplants recorded in 2009-10, a 7% increase on the previous year. Figure 1 below shows the number of deceased and living donors for 2000 to 2010.

Figure 1: Number of deceased donors and transplants in the UK, 1 April 2000 – 31 March 2010, and patients on the active transplant lists at 31 March



The number of deceased organ donors in the UK continued to fall over a number of years but following the implementation of the Organ Donation Taskforce recommendations, the numbers are increasing. The number of donors after brain death (DBD) has increased by 2% over the last three years, reversing the trend which had seen a 17% decrease between 2000/01 and 2007/08. The number of donors after cardiac death (DCD) has been increasing year-on-year as an effort to bridge the gap between the number of deceased donor organs available for transplant and the number of patients waiting for a transplant. In particular the number of these donors has increased by 68% since 2007/08. Living donors also continue to increase.

Progress on organ donation over the last three years, since the creation of ODT Directorate within NHSBT, has also been very encouraging. As at December 2010 deceased organ donation had increased by 26% over the 2007-08 baseline year (following publication of the Organ Donation Taskforce report). It is on course to deliver the 50% increase by 2012-13 targeted by the ODTF report.

The number of organ transplants carried out across the UK in 2009-2010 rose for the fifth year in succession, reaching a record high of 3,706. At the same time, there was the highest ever number of deceased organ donors in the UK – 959, a 7% increase compared with the previous 12 months.

Table 1: Donor Update for the UK (1st April 2009 to 31st March 2011)

Organ Donors	April 2010-March 2011	April 2009-March 2010	% change
Deceased Brain Death Donors	637	624	2
Deceased DCD donors	373	335	11
Total Deceased Donors	1010	959	5

Donation rates have improved, but UK donor rates remain significantly below those of their European counterparts, such as Portugal and Spain.

In the UK the deceased donor pool is also changing as a result of the increasing age profile and relative body mass index of donors. This adversely impacts the number and quality of organs that can be retrieved from these donors. Hence the growth in transplantation across the UK is proportionately lower than the growth in donation.

As a consequence delivering the targets set by the ODTF and being able to sustain further increases beyond the time period set becomes even more challenging.

In addition to saving and improving lives there is a strong economic case for organ transplantation in the UK. The existing transplantation programme realises gross annual savings in excess of £300m versus alternative medical treatments.

The impact of increasing the number of organs available by 50% for transplant by 2013 would increase the savings to the NHS by an additional £200m p.a. (refer report by the Specialised Commissioning Team, West Midlands - October 2010).

NHSBT ODT Directorate Action Plans

NHSBT's ODT Directorate's current action plans include:

- Promoting more widely the economic case for organ donation and transplantation
- Deriving the benefits from the deployment and ongoing development of the 12 Regional Specialist Nurse (Organ Donation) Teams and the Clinical Leads for Organ Donation (CLOD) now in place, and building on the CLOD Professional Development Programme
- Creating and sustaining regional collaboratives that bring together clinicians from all parts of the donation and transplantation pathway, with identifiable, accountable Regional Clinical Leads in each Region. Part of this is the creation and roll-out of supportive, visible performance improvement systems on a quarterly basis
- Driving performance improvement through reporting a balanced scorecard of performance data that measures national, regional and team performance at each stage of the pathway

- Continued development and optimisation of the commissioning of organ retrieval and supporting processes. Begin exploring options for integrating the commissioning/funding of retrieval and transplantation across the UK
- Review of the current ODR infrastructure, following publication of the Duff report, leading to the development and implementation of a modern, fit for purpose ODR
- developing a strategy for data collection and processing and the development of supporting IT systems
- Continued development of the EOS system for the offering of donor organs and review of the collection and analysis of PDA data
- Developing strategies and processes aimed at increasing the representation of BME communities within the ODR and assisting the donation process
- Implementation of a research and development framework and approval process, leading to development of an agreed programme, and reflecting our intent to work with hospital partners to assess novel methods for improving the quality and number of organs available for transplant
- Subject to Cabinet Office approval, marketing plans to sustain and further develop the public awareness campaign that was launched in November 2009
- Optimising transplant activity from living donors in order to enable further expansion in live donation. Optimising pre-emptive living donor kidney transplantation. Optimising transplant activity from non-directed altruistic donation. Facilitating appropriate expansion in other forms of living donation. Encouraging paired pooled live donation and facilitating development of ABO incompatible and antibody incompatible transplants.

Strategic Targets for 2011 - 2014

The targets (refer Table 2) for improving the rate of organ donation and transplant are a shared objective of all stakeholders within the DH, the other UK Health Services and partners across Government. They have been incorporated into the Terms of Reference of the DH Program Delivery Board, and reflected in the strategic targets of NHSBT.

Table 2: UK Strategic Targets 2011-14

Strategic Targets – Organ Donation and Transplantation	2010-11 Plan	2010-11 Actual	2011-12 Plan	2012-13 Plan	2013-14 Plan
Number of Deceased Organ Donors	1,104	1,000	1,095	1,214	1,297
Cumulative percentage increase in deceased organ donation from 2007-08 baseline	36%	26%	35%	50%	60%
Number of people registered on the Organ Donor Register (ODR)	20.0m	17.9m	18.9m	20.3m	21.6m

Strategic Targets – Organ Donation and Transplantation	2010-11 Plan	2010-11 Actual	2011-12 Plan	2012-13 Plan	2013-14 Plan
Number of Living Organ Donors	1,100	996	1,050	1,1081	1,112
Number of Organ Transplants	4,308	3,754	4,108	4,488	4,843

Note: 2010-11 actual based on November 2010 data with %variance projected to full year.

The current NHSBT Strategic Plans aim to:

- Increase deceased organ donation and sustain and improve thereafter
- To achieve self sufficiency in donation and transplantation across the UK, taking into account the changing donor pool
- To change public behaviour with regard to organ donation, especially amongst minority communities

The strategy for organ donation and transplantation that was developed in 2007-08 was originally constructed around the recommendations of the Organ Donation Task Force (ODTF). These largely focused on creating the infrastructure identified as being critical to improving the rates of organ donation in the UK.

Much of that work is now complete and the focus is now on NHSBT developing into the UK Organ Donation Organisation that was envisaged by the ODTF and building on the infrastructure now in place to improve performance.

Seven strategic themes have thus been identified in support of the strategic objective for Organ Donation and Transplantation:

Enable NHSBT to fulfil its role as the UK Organ Donor Organisation

Enable NHSBT to fulfil its role as the UK Organ Donor Organisation ensuring compliance with EU directives, implementation of an integrated quality and governance system and development of modern IT systems to support donor registration and organ allocation.

Development support for organ donation throughout the wider NHS

Remove the obstacles to organ donation and effectively performance manage the identification and referral of potential donors.

Maximise conversion of potential organ donors into actual donors

Maximise the conversion of potential donors into actual donors by developing and implementing a robust, sustainable donor co-ordination service and further developing the network and effectiveness of clinical leads and donation committees.

Ensure organ retrieval services are sustained through a period of change

Ensure organ retrieval services are sustained through a period of change in commissioning across England, and potentially the other UK health services, and are able to respond in a constrained financial environment.

Change public behaviour with regard to organ donation

Change public behaviour with regard to organ donation through social marketing strategies to promote organ donation as 'expected behaviour' amongst UK citizens. Although 90% of the UK general public approve of organ donation, only 28% have registered on the organ donor register.

Develop living organ donation

Develop and implement a strategy for increasing Living Donation.

Sustainable cornea donation

Develop and implement a robust, sustainable cornea donation service

In 2010 the Health Secretary announced new 'aspirational' objectives for increasing numbers on the Organ Donation Register to 25 million by 2013, and to increase the number of organs donated by 73%.

These objectives have been incorporated into the Terms of Reference of the Department of Health Programme Delivery Board chaired by Chris Rudge, National Clinical Director Transplantation for the Department of Health.

In contrast with Spain's, donation after cardiac death has increased steadily in the UK. In 2009 it comprised almost a third of deceased donors (4.7 per million of population, almost entirely from patients with anticipated cardiac arrest after withdrawal of cardio-respiratory support, usually in intensive care units).

In 2010 the ODT Directorate increased the number of nurses specialising in organ donation, together with the appointment of a new network of doctors working as clinical leads for organ donation. They see these changes as being fundamental to their success.

Other developments recommended by the Taskforce are also now helping to deliver the stepped change in culture and professional practice throughout the donation and transplant community that will help the Directorate deliver on the original promise of a 50% increase in donation by 2013.

All the improvements in UK donation performance have occurred with no change in the consent rate for organ donation, which remains at around 60%. [The overall DBD consent rate was 61% and the 95% confidence limits for this percentage range from 57% to 65%. For DCD, the overall consent rate was 58% and the 95% confidence limits range from 54% to 62%].

Consent rates vary across the UK. It is stressed that caution should be applied when interpreting these consent rates as no adjustment has been made for the mix of patients in terms of age, sex and ethnicity. The DBD consent rates range from 48% in Northern Ireland to 79% in the East of

England SHA. DCD consent rates range from 28% in Wales to 68% in the South West of England SHA].

On average in the UK, 3.9 organs were retrieved per DBD and 2.6 per DCD in 2009-2010. Organ donor rates per million population (pmp) show variation in the actual number of DBD and DCD across the UK, as indicated in Table 3 below. There are 10.1 DBD pmp for the UK as a whole, but across the English Strategic Health Authorities this ranges between 5.7 and 14.8 dpmp. For DCD the UK rate is 5.4 dpmp, ranging from 0 to 5.9 across countries of the UK and from 2.8 to 9.6 in the English Strategic Health Authorities. Northern Ireland is alone in not having a programme for donors after cardiac death in this time period. The numbers of potential DBD and potential DCD (dpmp) also varies across the UK.

Table 3: Organ donation rates (dpmp) in the UK, 1 April 2009 - 31 March 2010, by country and English Strategic Health Authority

Country of donation/ Strategic Health Authority	DBD		DCD		TOTAL		Living	
	N	(pmp)	N	(pmp)	N	(pmp)	N	(pmp)
North East	33	(12.8)	19	(7.4)	52	(20.2)	43	(16.7)
North West	76	(11.0)	44	(6.4)	120	(17.4)	103	(14.9)
Yorkshire and The Humber	50	(9.6)	30	(5.8)	80	(15.4)	70	(13.4)
East Midlands	25	(5.7)	7	(1.6)	32	(7.3)	58	(13.2)
West Midlands	59	(10.9)	21	(3.9)	80	(14.8)	115	(21.3)
East of England	40	(7.0)	55	(9.6)	95	(16.6)	43	(7.5)
London	113	(14.8)	61	(8.0)	174	(22.8)	386	(50.7)
South East Coast	34	(7.9)	12	(2.8)	46	(10.7)	2	(0.5)
South Central	48	(11.8)	15	(3.7)	63	(15.5)	71	(17.4)
South West	47	(9.0)	41	(7.9)	88	(16.9)	61	(11.7)
England	525	(10.2)	305	(5.9)	830	(16.1)	952	(18.5)
Isle of Man	0	(0)	1	(12.5)	1	(12.5)	0	(0)
Channel Islands	5	(33.3)	1	(6.7)	6	(40.0)	0	(0)
Wales	28	(9.4)	13	(4.3)	41	(13.7)	39	(13.0)
Scotland	47	(9.1)	16	(3.1)	63	(12.1)	50	(9.6)
Northern Ireland	18	(9.7)	0	(0)	18	(9.7)	20	(10.8)
TOTAL	623	(10.1)	336	(5.4)	959	(15.5)	1061	(17.2)

While the number of donors overall is increasing, it is important to be aware that there are changes over time with regard to donor characteristics.

- *Donors are older:* In 2009-10, 26% of deceased donors were aged 60 years or more compared with 14% in 2000-01. In particular the proportion of these donors aged at least

70 years has increased from 2% to 8% over the same time period. The trend was similar for both DBD and DCD

- *Donors are more likely to be obese:* The proportion of clinically obese donors (Body Mass Index (BMI) of 30 or higher) has increased from 13% to 24% in deceased donors in the last 10 years and the trend was similar for both DBD and DCD
- *Fewer donors are victims of trauma:* In addition, the proportion of all deceased donors after a trauma death has decreased from 20% to 11% over the same time period

All of these changes may have an adverse impact on the quality of the organs and the subsequent transplant outcome for the recipient.

Across the UK, 5% of donors are from ethnic minority groups. By contrast, ethnic minority groups represent 8% of the UK population and these groups form 25% of the kidney transplant waiting list. People of Asian or African–Caribbean descent are three to four times more likely than white people to develop end-stage renal failure and to need a kidney transplant. People from these populations are also much less likely to give consent for organ donation when asked.

The UK national Potential Donor Audit (PDA) comprise all patient deaths in UK Intensive Care Units (ICUs), excluding cardiothoracic ICUs and patients aged over 75 years. The number of potential donors and rates per million population (pdpmp) ranged from 7.9 pdpmp in the East of England SHA to 21.4 pdpmp in the North East SHA. Potential DCD ranged from 7.0 pdpmp in Northern Ireland to 40.7 pdpmp in Yorkshire and The Humber SHA. Overall, there were 789 potential DBD (12.8 pdpmp) and 1218 potential DCD (19.7 pdpmp) in the UK.

Table 4: Rates for different death types

	DBD	DCD
Potential donors	789	1,218
Referral rate	88%	48%
Approach rate	93%	87%
Consent rate	61%	58%
Conversion rate	49%	15%

In the UK National Institute for Health and Clinical Excellence (NICE) has this year published draft guidelines on improving donor identification and consent rates for deceased organ donation. NICE recommends that organ donation should be discussed by all families of potential donors (and where appropriate with patients). The draft guideline recommends that parents, families, or guardians should only be approached for consent when it is clearly established that they understand the inevitability of the death.

Each hospital should have a policy and protocol for identifying potential organ donors and managing the consent process. The pathway for organ donation (from identification to consent)

should be coordinated by a multidisciplinary team, led by an identifiable consultant working in close collaboration with the specialist nurse for organ donation and faith representatives, where relevant.

The draft guideline recommends that all patients who are potential suitable donors should be identified as early as possible, based on either of the following criteria:

- Defined clinical trigger factors in patients who have had a catastrophic brain injury and who have had death confirmed against neurological criteria
- The intention to withdraw treatment in patients with a life-threatening or life-limiting condition after cardiac death

If a patient has the capacity to make their own decisions, their views on organ donation should be obtained. If the patient is close to death and does not have the capability to make their own decisions, the draft guideline recommends that the healthcare clinical team caring for the patient should refer to and act in accordance with any earlier directives made by the individual, if available. The team should also establish if the individual has registered and recorded their decisions on the NHS ODR, and explore if the patient had any expressed views, with those close to the individual.

The draft guideline also makes recommendations about what information parents, families, or guardians of potential donors should be provided with. For all potential donors this should include assurance that the primary focus is on the care and dignity of the patient (whether the donation occurs or not) and that the parents', family's, or guardians' wishes will be respected. There should be explicit confirmation and reassurance that the standard of care received will be the same whether consent for organ donation is given or not. The rationale behind the decision to withdraw or withhold life-sustaining treatment and how the timing will be coordinated to support organ donation should also be explained.

NICE has not yet issued final guidance to the NHS; these recommendations may change after consultation. Final guidance is likely to be published in August 2011. The guideline development process included an extensive review of relevant literature and evidence-based assessment of recommended changes that provides a valuable international resource for the sector.

The programme is designed for the growing number of Clinical Leads for Organ Donation and the Donation Committee Chairs who work alongside them. These people have been appointed to key roles in hospitals to implement recommendations made by the Organ Donation Taskforce and help increase donation rates by 50% over a five-year period.

Presently 170 clinical leads throughout the UK dedicate time every week to working with colleagues in intensive care units and emergency medicine departments to encourage organ donation to be viewed as part of normal, everyday practice in hospitals.

There are also currently 100 donation committees in place with responsibility to champion organ donation in general within hospitals. Eventually there will be a total of 194 Clinical Leads and 184 donation committees based in acute hospitals across the UK. It is estimated that there are 286 acute hospitals in the UK that have the potential for deceased donation.

Leadership within frontline NHS services was identified by the Taskforce as a major catalyst in making organ donation usual rather than unusual. The programme has been developed in collaboration with the medical colleges and is supported by UK Government Health Departments. This new development is seen to be an exciting, innovative programme that will improve skills to increase organ donation in hospitals.

As all the international evidence points towards the need to support and train those who care for potential organ donors, this programme has a strong focus on providing support and training for those involved in organ donation in the NHS. It seeks to expand the numbers of clinical leaders in this vital field. It seeks to take participants' knowledge of organ donation to an advanced level, and just as importantly, offers the developmental opportunities that are necessary for staff to become effective leaders in their hospitals and implement the real change that is needed to continue to raise rates of organ donation in the UK.

The programme also establishes a network of regional donation collaboratives in which clinicians involved in donation and transplantation will come together to share experience and best practice. The twelve month programme involves face to face workshops, self-study and regional events aimed at building leadership and change management skills, and to advance clinical expertise and capability.

The Clinical Leads, who are mainly intensive care consultants, are supported in their work by Donor Transplant Co-ordinators in hospitals. Together they work to streamline the referral of potential donors to help make sure that more people have their decision to donate fulfilled and more lives are saved through transplantation.

The initiatives of the last two years have delivered results. They highlight the value of having clinical leads, specialist nurses and Organ Donation committees in hospitals, promoting organ donation and removing barriers to make sure it becomes normal everyday practice. The ODT Directorate have worked closely with frontline NHS services to make organ donation a usual rather than unusual event.

Dr Paul Murphy, an Intensive Care Consultant in Leeds and NHSBT's National Clinical Lead for Organ Donation notes that all the evidence points towards increasing donation rates through support and training for those who care for potential organ donors and their families. NHSBT's work, supported by the UK Governments' Health Departments, has been vital in increasing donation.

Clinical Leads, who are mainly intensive care consultants, work collaboratively with Specialist Nurses in Organ Donation, most of who are resident in hospitals. They work alongside hospital donation committees to champion donation and streamline the pathways of potential donors. This helps make sure that more people have their decision to donate fulfilled and more lives are saved through transplantation.

2 THE UNITED STATES OF AMERICA

The Organ Procurement and Transplantation Network (OPTN) is the unified transplant network established by the United States Congress under the National Organ Transplant Act of 1984. The network is operated by a private, non-profit organization under federal contract.

The United Network for Organ Sharing (UNOS) was awarded the initial OPTN contract on September 30, 1986, and has continued to administer the OPTN more than 16 years.

The OPTN is a unique public-private partnership that links all of the professionals involved in the donation and transplantation system. The primary goals of the OPTN are to:

- Increase the effectiveness and efficiency of organ sharing and equity in the national system of organ allocation, and to
- Increase the supply of donated organs available for transplantation.

The UNOS is based in Richmond, Virginia, and administers the OPTN under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

The OPTN helps ensure the success and efficiency of the US organ transplant system. OPTN responsibilities include:

- facilitating the organ matching and placement process through the use of the computer system and a fully staffed Organ Centre operating 24 hours a day
- developing consensus based policies and procedures for organ recovery, distribution (allocation), and transportation
- collecting and managing scientific data about organ donation and transplantation
- providing data to the government, the public,

The US reform initiative was built around a series of nationally managed clinical practice improvement programs (The Breakthrough Collaboratives) in deceased donation

Deceased donation performance improved following these Collaboratives

The improvements in deceased donation performance ceased after a few years, but the new higher donation level has since been substantially maintained

The national strategy for improving deceased donation performance is still based on a set of nationally managed clinical practice improvement programs.

There has been no structural reform of the donation sector in the USA as part of sector reform

There has been a major increase in DCD donations and a reduction in BSD donations over recent years

The USA has achieved a substantial increase in minority donation rates over the past decade

- students, researchers, and the Transplant Registry, for use in the ongoing quest for improvement in the field of solid organ allocation and transplantation
- developing (1999) and maintaining a secure Web-based computer system, which maintains the nation's organ transplant waiting list and recipient/donor organ characteristics
 - providing professional and public education about donation and transplantation, the activities of the OPTN and the critical need for donation

Under federal law, all US transplant centres and organ procurement organisations must be members of the OPTN to receive any funds through Medicare. Other members of the OPTN include independent histocompatibility laboratories involved in organ transplantation; relevant medical, scientific, and professional organizations; relevant voluntary health and patient advocacy organizations; and members of the general public with a particular interest in donation and/or transplantation.

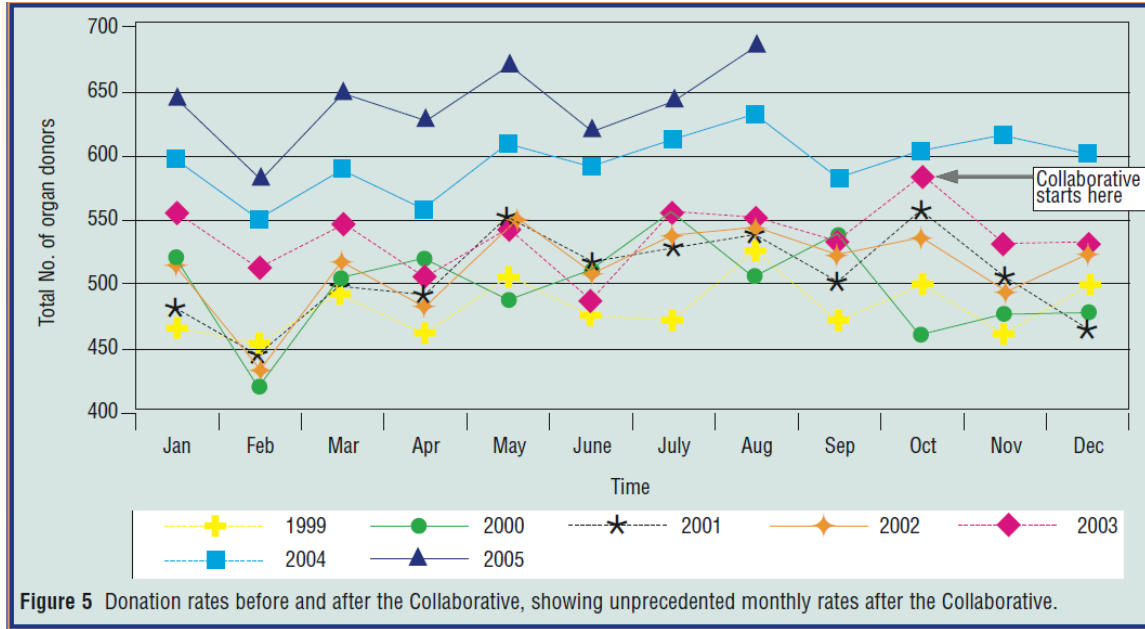
A driving force of OPTN activities is achieving dramatic annual increases in the number of deceased donors, the average number of organs transplanted from deceased donors and the total number of deceased donor organs transplanted.

In 2004, the organ transplantation program participated in a systematic assessment of its performance as part of an overall effort to push the network toward more transparency in its plans and results, and toward better performance in meeting its goals.

A set of program performance goals are developed for their national organ transplantation program by US Department of Health and Human Services and Office of Management and Budget. A major strategy to assist in meeting these goals was the Breakthrough Collaborative Series. The, Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Transplantation working in partnership with the Institute for Healthcare Improvement, Quality Reality Checks Inc. and teams of Organ Procurement Organizations (OPOs) and their hospital and transplant centre partners from across the country have participated in a series of Organ Donation Breakthrough Collaboratives.

These Collaboratives ran between 2003 and 2008 as components of the US Department of Health and Human Services Gift of Life Donation Initiative. The aim of these Collaboratives was to dramatically increase the availability of transplantable organs.

Since 2003, participant OPOs and their partnering large hospitals, and now transplant centres (Transplant Centre Growth and Management Collaborative), have been working to achieve a significantly higher conversion rate and increase the number of organs transplanted per donor, results that will drive the future success of organ procurement.

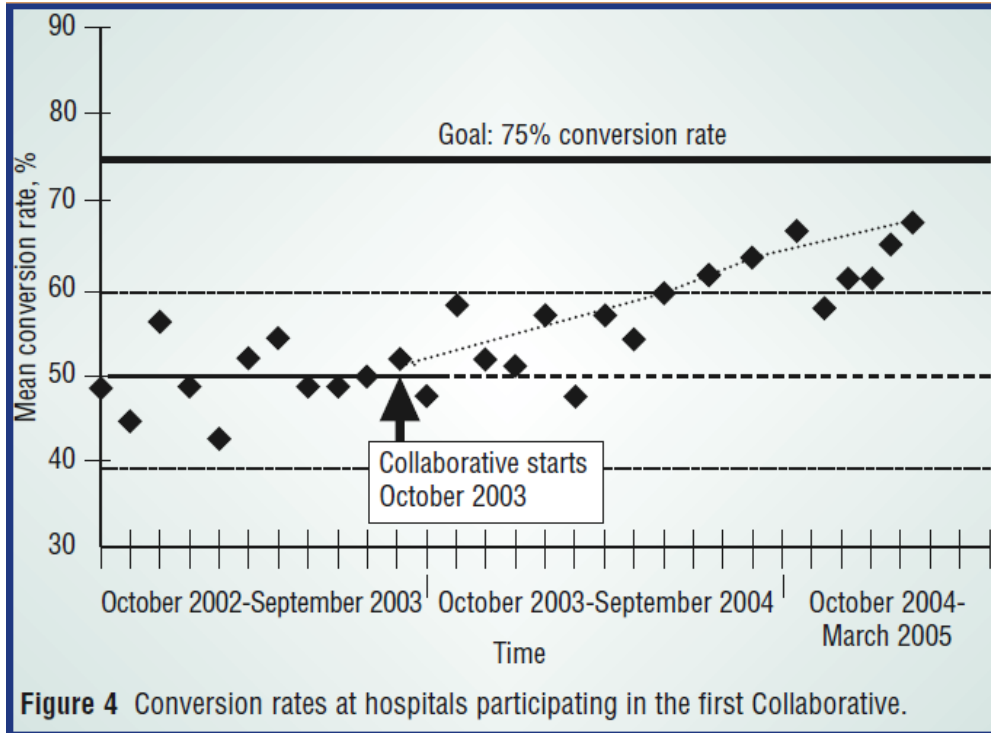


The learning and knowledge that result from these Collaboratives continues to be disseminated to the larger audience of organ transplant organizations, hospitals, and transplant centres for adoption and replication through the work of the Donation and Transplantation Community of Practice established by HRSA as the sustainability strategy following the Collaborative cycles.

These Collaborative series were:

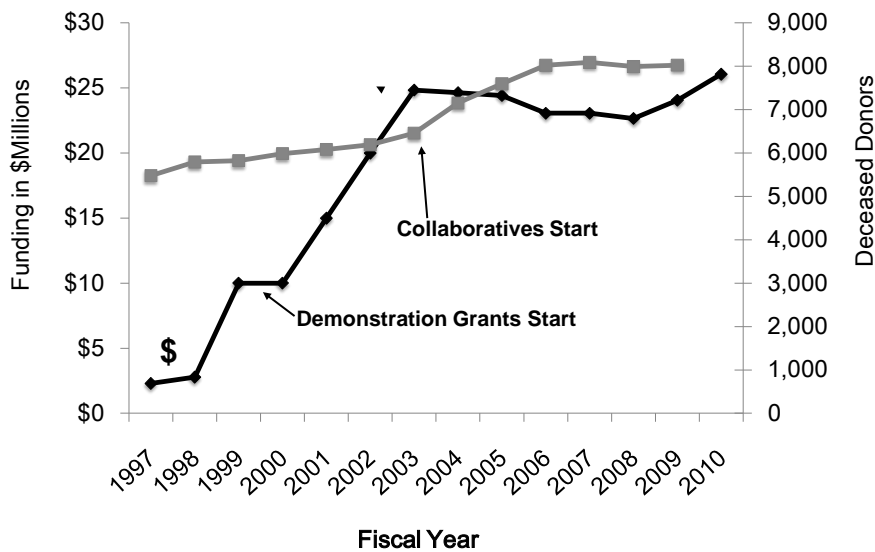
- Organ Donation Breakthrough Collaborative
- Organ Transplantation Breakthrough Collaborative
- Organ Donation and Transplantation Collaborative
- Transplantation Growth and Management Collaborative

These resulted in a measurable improvement in national donation performance.



Due in large part to the efforts of these Collaboratives, organ donation rates increased in the first year of this national effort (by 10.8% in 2004 compared with 2003). The number of deceased organ donors continued to increase through until 2006. The national deceased donor organ donation performance has since stabilised at the new national 'norm' in recent years.

Organ Transplantation Funding History and number of Deceased Donors



The sustained increases in deceased donor numbers have created a need for transplant centres to adjust to a new level of organ availability and prepare for additional growth. To assist transplant centres in meeting this challenge, HRSA created the Transplant Growth and Management Collaborative, which sought to identify and spread best practices among centres committed to effectively growing their transplant programs.

Following these collaboratives a concentrated effort led by representatives of many organizations in the donation and transplant community has succeeded in creating a vehicle that ensures a continued national commitment to improved donation performance. In January 2006, a Steering Committee was formed to bring this dream into reality. In June 2006, the Organ Donation and Transplantation Alliance was officially incorporated for the specific purpose of conducting educational activities related to, and accelerating the success of the organ donation and transplantation collaboratives.

The Alliance leadership comes from those organizations critical to the organ donation and transplant process. As an independent organization, the Alliance can effectively and efficiently partner with professional organizations and the U.S. government to achieve their shared vision. This Alliance uses 5 strategies to enhance donation performance across the donation continuum – from designation through long-term patient and graft survival:

STRATEGY 1: Refine the national performance measures and renew executive and front-line commitment to performance improvement.

STRATEGY 2: Partner to develop a national education and training system to support organ donation and transplantation professionals.

STRATEGY 3: Create a federal financial and regulatory climate for OPOs and transplant programs to increase the number of successful transplants in the U.S.

STRATEGY 4: Promote the use of donation intentions as advanced directives through collaboration among donor designation organizations, OPOs, tissue and eye banks and research organizations at the national and DSA level.

STRATEGY 5: Identify appropriate opportunities and methods for the Alliance to advocate for improvements in living donation.

They utilize Local, Regional, and National initiatives, including forums, summits and learning congresses to strengthen the Communities of Practice and improve hospital performance in organ and tissue donation.

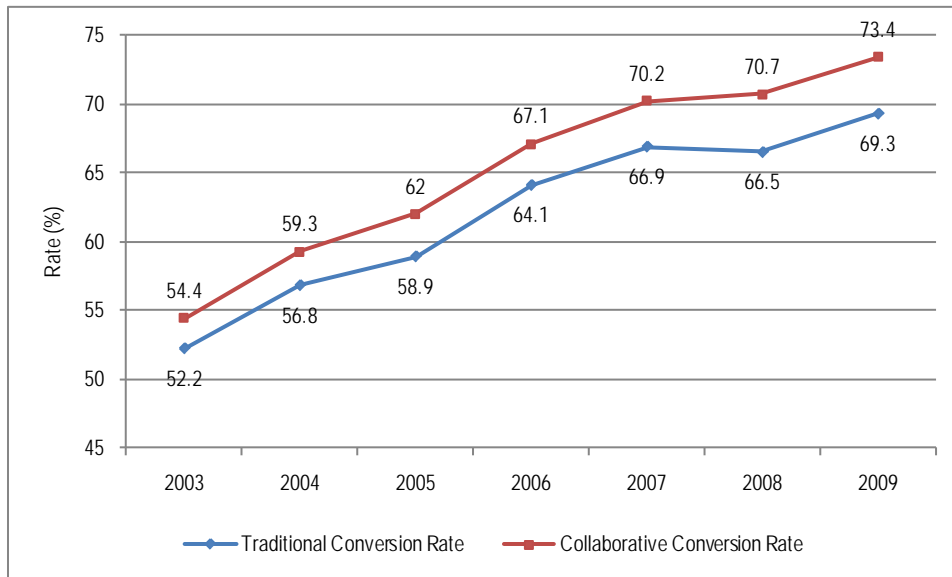
Their membership includes:

- Donor hospitals
- Transplant centers
- OPOs
- Donor designation professionals
- Tissue and eye banks

- Healthcare organizations
- Community organizations
- Government

Current US thinking regards organ donation capacity as being reached when all donation service areas produces 75% conversion rates; 3.75 organs transplanted per brain-death donor and 10% DCD (with 2.75 OTPD) within a system that has sufficient resources to transplant the resulting organ supply.

Figure 2: Performance against 75% Conversion Rate goal (USA)



They are currently meeting their national targets for conversion and the proportion of DCD donors, but not meeting targets for organs per donor in either donor category.

They have noted a national fall in 'eligible deaths', which they believe is the principle cause of the decline in donor numbers seen in the US in recent years. This may relate to changing demographics, particularly the aging of their population.

Figure 3: Performance against the 3.75 OTPD goal (USA)

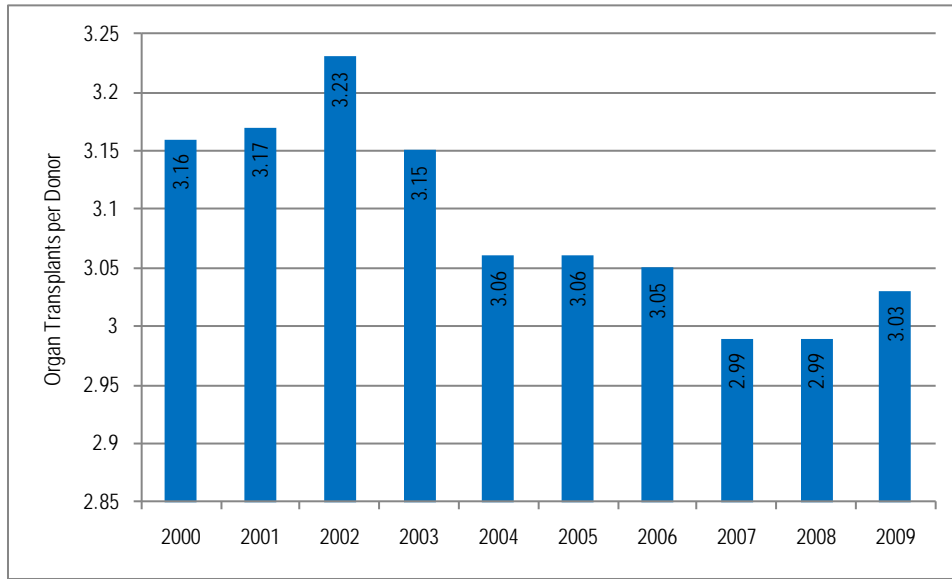
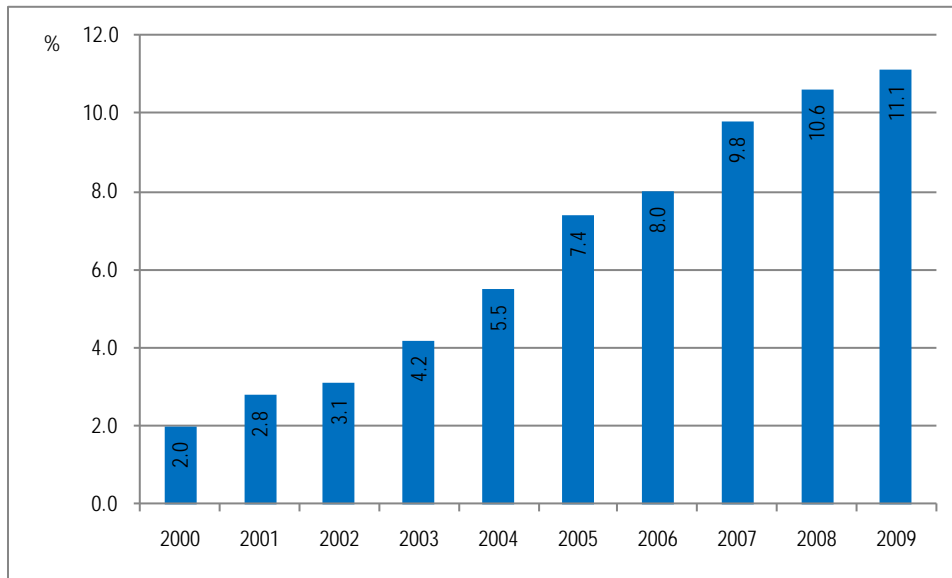


Figure 4: Performance against the 10% DCD goal



Since 2010 their work nationally has been informed by National Taskforces for Donor Management and Transplant Centre issues and a Quality Improvement Taskforce has provided inputs to aid implementation of improved care processes.

They have also recently commissioned a 'potential donor' study to provide a basis for evidence-based goal setting, using rigorous methods and both demographic and epidemiological approaches to measure variables having impact on potential donation performance.

Figure 5: Performance against Non-DCD Donation goal

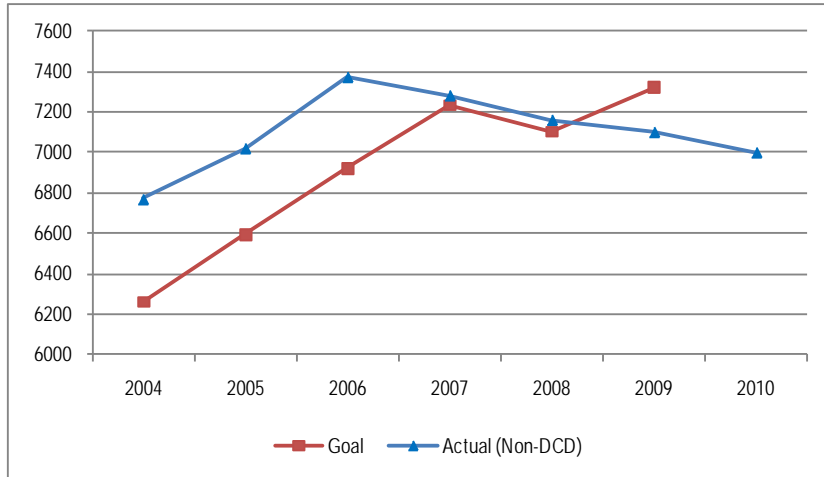


Figure 6: Performance against DCD donation goal

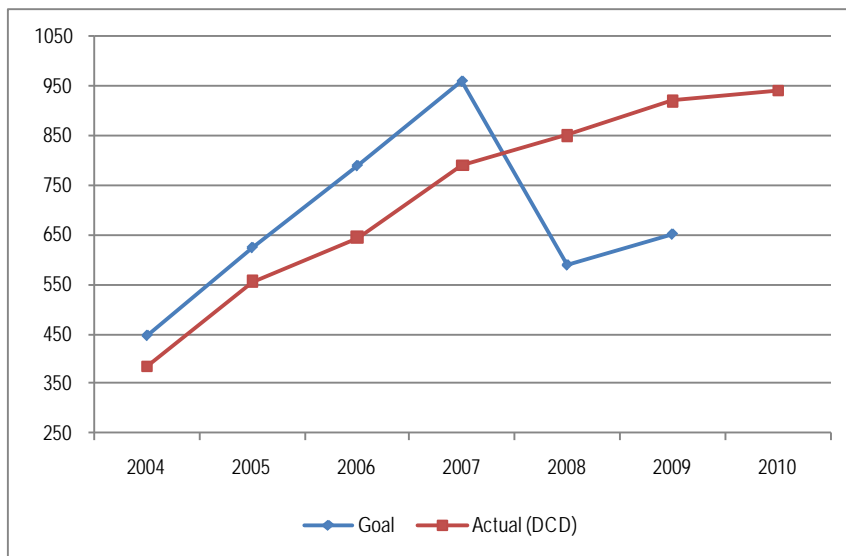
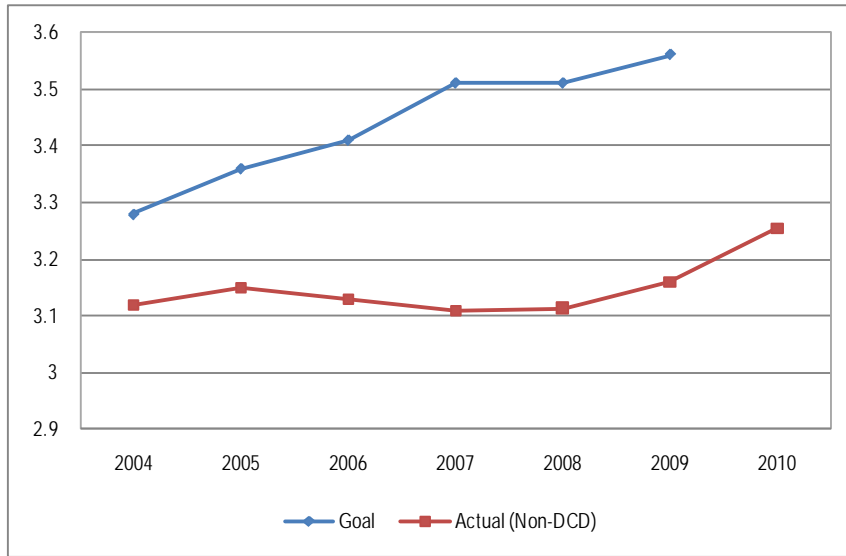


Figure 7: Performance against Non-DCD organs transplanted per donor



Since the beginning of organ transplantation in the United States in 1954, the number of donated organs has been considerably lower than the number of patients waiting for organs (potential recipients). This lack of donated organs has been significantly pronounced within the African American population.

In 1978, in Washington, DC, an awareness of the scarcity of minority donors became evident especially among African Americans. From 1978 until now – 2009, four decades later, an in-depth grass roots movement emphasizing community education and empowerment combined with the use of mass media has successfully increased minority donation rates exponentially. This program was initiated with a \$500 grant from Howard University and subsequently funded by the National Institutes of Health grants and other funding totalling more than \$10 million between 1993 and 2008.

A complex set of interventions has been undertaken over the past decade. Between 1990 and 2008, minority donations percentages have doubled (15%-30%). African American organ donors per million population (odm) have quadrupled from 22.4 odm - 53 odm between 1982 and 2008. Minorities now donate in Proportion to their Population Distribution.

Table 5: Minorities' donation rates in proportion population distribution

Ethnicity	Populaton rate %	Donation rate %
White	71.7	72.1
African American	12.7	12.6
Hispanic	10.9	12.2

Asian	3.8	2
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UNOS/OPTN Data of April 4, 2003 Population information based upon Census

Table 6: Cadaveric Donors per 1,000 evaluable deaths and number of donors by ethnicity and OPOs, 1995-1998

Ethnicity	Donation rate %	Donors	Donation rate %	Donors	P Value*
White, Non Hispanic	59.3	4,928	59.2%	11,279	0.02
White, Hispanic	105.9	1,055	47.4	886	<.01
African American	43.4	1,263	32.9	1,286	<.01
Other	50.7	228	42.4	272	<.01

Source International Scientific Registry

*National Minority Organ Tissue Transplant Education Program (MOTTEP) versus Non National MOTTEP

Table 7: Increase in Minority Donation Rates (organ donors per million and percentages)

Ethnicity	No. of donors		Organ donors per million		Donation rate, %	
	1990	2008	1990	2008	2000	2008
African American	659	2007	22.4	53	11.2	14
Hispanic/Latino	518	1957	22.9	50	11.2	14
Asian	73	4,24	10.3	35.3	2.7	2.9
Total minority donors	1,250	4,988	22.6	138.3	25.1	30.9

Source:UNOSOPTN Database – January 2009.

It is noted that the USA reforms have largely relied on national coordination of support systems to promote a relentless focus on deceased organ donation. These external national and regional support systems encouraged existing staff hospital to pursue every opportunity to optimise their hospital's deceased donation outcomes. These programs frequently included temporary project staff within hospitals to help achieve changes in care.

There have been no permanent structural reforms within their hospitals system to sustain improved deceased donation performance. Their ongoing national programs continue to use established

adult education and performance improvement techniques to try and motivate hospitals to commit to prioritising deceased donation activities within their hospital systems.

It may be that such systems of education and exhortation are less capable of delivering sustained and progressive improvements in donation performance in the complex acute care hospital environment than can be achieved by combining these education and exhortation programs with structural ('hard wired') reform by permanently changing hospital staffing structures and clinical governance processes.

3 SPAIN

The Spanish model is widely acknowledged as an outstanding example of how organisational changes in the transplantation system can increase the number of organs available from deceased donors.

The Organización Nacional de Trasplantes (ONT) was created in 1989 as a result of the wish of health professionals and patient advocacy associations to find solutions to a chronic shortage of organs and tissues for transplantation.

Based on the premise that the greatest barrier to increasing organ transplantation was the failure to identify and 'convert potential into real donors', the Spanish government, through the National Transplant Organisation have set up a nationwide system to monitor potential organ donors and optimise deceased donation performance.

Since 1989 the ONT has coordinated and facilitated the donation, extraction, preservation, distribution, exchange and transplantation of organs and tissues for the Spanish health system. The agency is attached to the Ministry of Health. Each Autonomous Community, however, has sovereignty over the issuing of accreditations for the extraction and transplantation of organs and tissues.

The reorganization of the Spanish organ procurement and donation system in 1989 has been associated with an increase in donation rates of more than 130 per cent over the initial ten years of its operations.

In 1989, 14.3 dpmp were donated; as early as in 1999 33.6 dpmp were donated. Donation rates have since stabilised at or above this rate.

Spain remains the benchmark for success in reform of deceased donation programs

Spain has achieved durable changes in culture and clinical care of potential deceased organ donors over the past two decades

Deceased organ donation is an established component of end-of-life care in Spain

Spain has a strong focus on national education for healthcare professionals

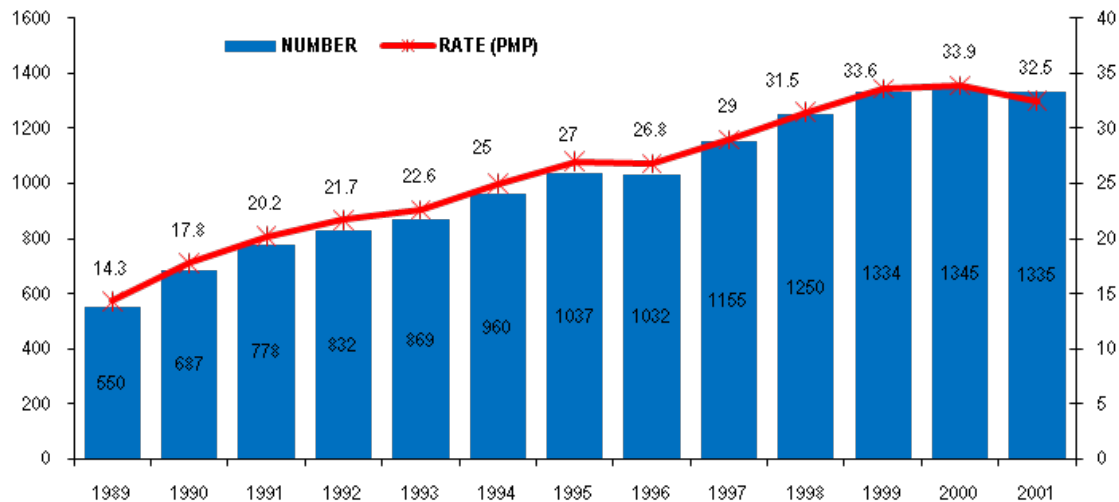
Spain uses its national death audit program to drive its clinical practice improvement programs in participating hospitals

The national ONT provide very visible, strong and effective leadership of the sector. They educate, audit, develop clinical practice improvement programs and perform research

The national and regional offices of ONT support teams of clinicians to progressively improve their deceased donation performance

There are many myths concerning the 'Spanish Model'. More emphasis should be placed on studying their

Figure 8: Organ donors in Spain - absolute number and annual rate (dpmp)



Main elements of the Spanish Model of Organ Donation and Transplantation

- Donation coordination at three levels:
 - National
 - Regional
 - Hospital
- Specialist hospital donation coordinators
 - Medical specialists, mainly critical care physicians
 - Supported by nurses
 - Part-time dedication to donation coordination activities
 - Independence from the transplant teams
 - Appointed by and reporting to the hospital medical director
 - Main objective is deceased donation
 - Progressively more involved in: promotion, training and education, relation with the mass media, management of resources, research
- Central Office (ONT) as a support agency
- Quality Assurance Death Audit Program in the deceased donation process
 - Continuous clinical chart review of deaths at critical care units of procurement hospitals
 - Two phases: internal and external audit
- Great effort in medical training through different type of courses
 - Targets: transplant coordinators, intensive care physicians and nurses, emergency and urgency physicians and nurses, other health care professionals
- Close attention to the mass media with a special communication policy
- Hospital reimbursement for deceased donation activities

The responsibilities and activities of the ONT include the following:

- Maintain and manage waiting lists of patients for organ transplant
- Coordinate transplant processes
- Produce statistical data on organ and tissue transplants
- Promote continuing education, training and research in the field of organ donation and transplant (including training for healthcare professionals on all aspects of organ transplants, such as approaching grieving families, drawing up registries of potential donors, donor maintenance, and so forth)
- Provide information to all stakeholders involved in organ donation and transplant
- Provide a 24-hour, 7-day-a-week phone service for public enquiries
- Collaborate with relevant national and international organisations with the aim of promoting organ donation and transplants

In recent years Spain has consistently recorded a national deceased donation rate of around 35 dpmp annually. These increases in deceased donation rates have largely been the result of changes in the clinical care of potential donors.

The success of the Spanish approach to organ donation is commonly attributed to five interlinked elements of the Spanish system that have a strong focus on identifying and redressing problems with clinical care of potential donors:

1. *Hospital Coordinators and coordinating teams*
2. *Funding hospitals for organ transplant activity*
3. *Quality Assurance process using Death Audit*
4. *Training of all staff involved in care of potential donors*
5. *Pro-active management of the mass media*

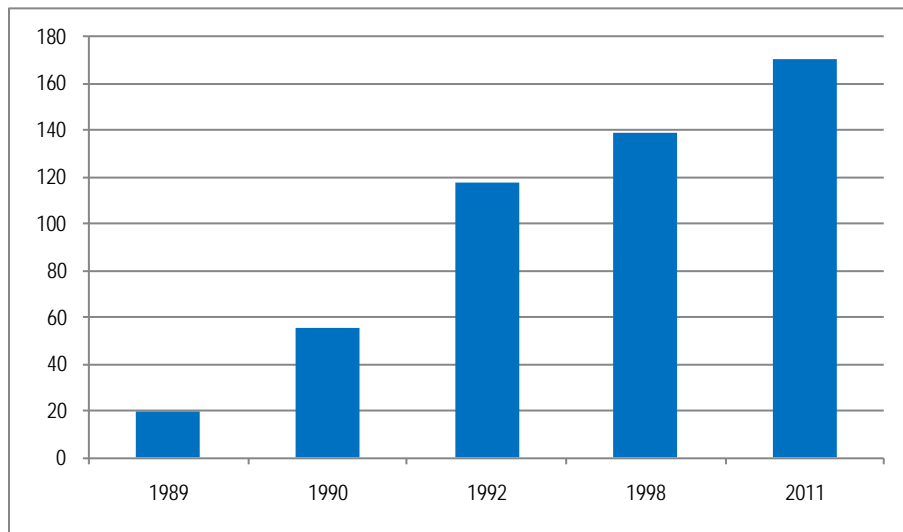
1. *Hospital Coordinators and coordinating teams*

The presence of hospital co-coordinators and coordinating teams in hospitals is one of the most salient features of the system (larger hospitals may have several part-time staff while smaller hospitals may have only one or two healthcare professionals involved in transplant management).

This 'grass roots' approach to the hospital-level management of potential donors ensures that hospitals are actively involved in improving donation performance and are accountable for their own performance within the system.

From 1989 the number of Spanish hospitals with donation coordination teams rose from twenty to 118 by 1992 and over 170 in 2011. This sees staff in all hospitals in Spain with a recognized potential for deceased donation.

Figure 9: Number of participating Spanish hospitals



2. Funding hospitals for organ transplant activity

The second crucial feature of the Spanish model is the system of funding and reimbursement to hospitals for organ transplant activity. Small hospitals which are not able to finance the entire transplant operation are reimbursed by the relevant authorities. This financial support, and the operational support provided to smaller hospitals by the national and regional donation authorities, enables these smaller hospitals to be involved in the donation process.

3. Quality Assurance process using Death Audit

The third element is a comprehensive quality assurance system based on a death audit. The ONT developed a national quality assurance system for deceased organ and tissue donation and transplantation in 1998. This aims to identify any deficiencies in the processes of clinical care of potential deceased donors and developing ways to make improvements to care processes that would maximize the potential for organ donation and transplantation.

It consists of death audit evaluations in every participant hospital, which are conducted in two phases. The first phase is an internal evaluation carried out by the transplant coordinating team in each hospital. The team reviews all clinical histories of deaths within the hospital and provides the ONT with a description of the circumstances, including any reasons why a patient did not become a donor. This evaluation must be conducted at least every three months.

In the second phase, an external evaluation is conducted by a coordinating team from another region, in which the data collected are verified, the efficiency of the process of organ donation and extraction is assessed, and areas for improvement are identified.

4. Training of all staff involved in care of potential donors

Adequate training of all staff involved in the care of potential organ donors is essential. This has been identified as a key success factor in Spain. All aspects of care are improved by having well trained staff. Even family refusals, which are a common reason why potential donors do not

become actual donors, can be shown to be substantially reduced when staff are well trained to respond adequately to and support the relatives of potential deceased donors.

5. Pro-active management of the mass media

The final important element in the Spanish model is the proactive management of mass media. Much attention has been given by the ONT to informing the media, and to the provision of systematic and comprehensive information to both healthcare professionals and the lay public about organ donation and transplantation through media outlets.

Many have argued that the use of mass media in Spain on the issue of organ donation has greatly influenced the creation of a positive social atmosphere around organ donation and transplantation.

It is noted that the Spanish have never invested heavily in public awareness campaigns or similar measures. This is due to shortage of funds, not in-principle opposition to such campaigns.

The ONT acts as a service agency for the whole National Health System. It provides leadership and direction to a coordinated program of work that seeks to achieve a continuing increase in the availability of organs and tissues for transplantation whilst guaranteeing their most appropriate distribution in accordance with the ethical principles of equity which should prevail in the transplant activity. Its principal aim is the promotion of deceased donation for the increase of tissues and organs available for transplantation.

As indicated, ONT manages the national donation of organs and tissues using three levels of co-ordination (National, Regional and Hospital). It has created a dynamic functional network whose activities and successes has made it an exemplar management model when consideration is being given to national reform of the organisation of organ and tissue donation systems.

National Coordination

The national coordination operates from a Central Office with headquarters in Madrid. It consists of the National coordinator, a Health Professional team (Doctors and Nurses) and support staff that perform the following functions:

- Co-ordination of donation and transplantation process
- Maintenance and updating of the solid organ transplant waiting lists
- Ensuring appropriate application of the agreed Allocation Criteria
- Production of guidelines, regulations and reports
- Production of Consensus documents regarding clinical care processes
- Promotion and co-ordination of multi-centre studies and research projects related to donation and transplantation
- Spreading of information about donation and transplantation to healthcare professionals and the general population
- Statistical data analysis on donation and transplantation activities

- Development, participation in and promotion of continuing education, training courses and staff development forums for the nation

Regional Coordination

There are 17 Autonomous Communities (or regions). Each has a representative in the Organ and Tissue Transplant Standing Commission of the National Health System. Any subject related with transplantation that affects more than one Autonomous Community is discussed in this forum.

This Commission has at its disposal a Committee of Conflict and another one of Transparency that are entrusted with ensuring the complete honesty of the co-ordination system.

The Regional Coordinator has the same powers and functions at a regional level as the National Coordinator at the state level. That is, they act as a link between different Health and non-Health bodies, the health authorities, professionals and the general public.

In some Autonomous Communities that have taken on the management of all health services, these coordinators are also responsible for the coordination of resources, tasks relating to information, circulation and promotion.

Hospital Coordination

Currently comprises over 170 teams distributed in selected hospitals across the nation. In smaller centres this coordination may be undertaken by only one person. In larger centres the coordination role is undertaken by a team of doctors and nurses. Their task is to ensure that systems are in place in that hospital to turn all potential organ donors in their hospital into actual donors and to participate as needed in management of the Donation Process. They are responsible for guaranteeing the integrity of the entire process of deceased donor organ and tissue donation.

They report to the hospital medical director and CEO. In most cases this work is combined with other professional roles, usually as ICU specialists. Over 95% of doctors in coordination roles are part-time and approximately 60% of nurses in coordination roles are part-time. These coordinators thus maintain contact with everyday hospital life. The presence of multiple trained professionals within each major participating hospital also creates a local support network and helps with succession planning.

As the coordinators are involved in donation activities only on a part-time basis, it is feasible to create such appointments even at hospitals with low deceased donor potential. A majority of coordinators are critical care physicians, with some from Emergency medicine and Anaesthesia backgrounds.

Hospitals in Spain are classified in three categories depending on the existence of specific facilities:

- **TYPE 1 Hospitals:** Big reference centres with all medical facilities 24 hours per day, including neurosurgery and solid organ transplantation services
- **TYPE 2 Hospitals:** Centres with neurosurgery but without transplantation facilities

- **TYPE 3 Hospitals:** Centres neither with transplant nor neurosurgery services

Most ONT staff are focused within Type 1 and 2 hospitals. Decisions regarding staffing are based on an assessment of donation potential using ICU throughput, casemix and mortality data.

The Spanish Quality Assurance Death Audit Program in Deceased Donation is seen as essential to their success. The program includes an internal audit performed within their hospitals and an external audit carried out by experts belonging to another region. External audits are performed at the request of the regional organisation.

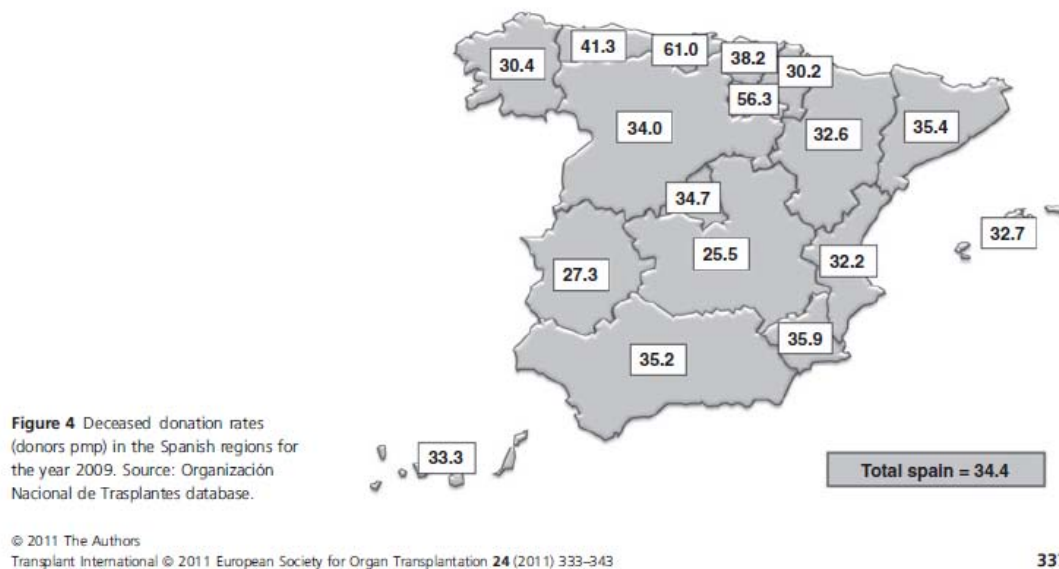
Training of all healthcare professionals involved in care of potential deceased organ donors is another essential component of the model. Regular courses focus on the entire process of deceased donation and on some of its particular phases have been aimed at all directly or indirectly involved professionals. Since 1991, over 11,000 professionals have been trained through these courses.

The communication policy of ONT and its network is based on four basic principles:

- A 24-h telephone line available for consultation
- Easy and permanent access to the media
- Connection with journalists built through dedicated meetings aimed at learning about mutual needs
- Delivery of messages with no intermediaries.

These measures have led the media to consistently handle information about donation and transplantation in an appropriate fashion.

Finally, as with all other activities performed within the public health care system, hospitals are reimbursed for their donation and transplantation activities.



As with all healthcare systems there is considerable variation across the 17 health regions in Spain with donation rates ranging from 24 to 48 dpmp. The top 20 per cent of health regions have organ donation rates ranging from 42 to 48dpmp

ONT Quality Assurance Program

The improvement in donation performance witnessed in the organ donation program in Spain has been a direct result of ongoing efforts to identify and overcome system problems such as undetected donors, errors in donor management, inadequacies in the approach to donor families and organisational and logistical aspects of organ retrieval.

These improvement activities are the collective responsibility of all professionals involved in the donation and transplantation process, with the main responsibility falling on the hospital coordination teams. The ONT is responsible for ensuring that no potential donor is lost due to lack of evaluation, lack of referral and that every potential donor family is approached with a request for donation.

The process of organ donation and transplantation is a long and complex one that needs continuous evaluation in order to detect where, when and why donors are lost and in order to draw up the most appropriate solutions. It is necessary to identify areas of deficiency in processes where efforts should be directed.

The one and only aim of this continuous system evaluation is the generation of continued improvement in national organ donation performance.

The ONT Quality Assurance Program has three specific objectives:

- To define the theoretical capacity of organ procurement at each participating hospital depending on the characteristics of the hospital
- To detect any deficiencies or gaps in the existing processes for organ donation and procurement and to analyse the causes of all potential donor losses, as a means of identifying areas for improvement
- The description of hospital care processes having impact on the outcomes of the donation and transplantation process

The evaluation of the process of organ donation and retrieval is carried out in two phases. First the hospital coordinating team continuously performs an internal death audit. The second phase consists in an external death audit carried out by a Co-ordination team from other hospitals. The external evaluation seeks to verify that the internal medical record review has been properly done (including validation of data collection) and to evaluate the efficacy of the performance improvement program in the particular hospital with a view to identifying areas for improvement in the donation and transplantation process.

The ONT has designed a software program which automatically generates an evaluation report, after entry of the required death audit data. This report is sent to the Hospital Co-ordination Team, to their Managers and to the Regional and National Co-ordination teams of the ONT.

Spain has the highest rate of organ donation in the world. This is often mistakenly cited as a successful example of 'presumed consent' legislation. However, the country does not have an opt-out register, nor is public awareness of the 1979 legislation promoted. Consent for donation is always sought from next-of-kin (NOK) and donation does not proceed in the absence of NOK consent.

Rafael Matesanz and others within Spain strongly believe that the presumed consent legislation issue is in fact irrelevant. Spain in fact demonstrates that it is possible to have the highest rates of organ donation without recourse to presumed consent.

A recent community survey in Spain analysed the population's disposition towards organ donation after death. Of the participants, 8.1% were declared donors, 59.3% were likely to donate, 14.5% were against donating and 18.1% did not know or did not respond; 87.3% would donate relative's organs if the deceased favoured donation, 50.2% if the deceased's wishes were unknown and 13.1% even if the deceased opposed donation.

Among people who were favourable towards donation, the main motives expressed were the will to save other people's lives, solidarity and knowing they might someday need a donation. The most important motives for not donating among participants who were against it was the fear of premature organ extraction, of premature pronouncement of death and of mutilation. Reticence to donate is associated with low socio-economic and cultural level, advanced age and high religious commitment; it is also associated with a low perception of transplant efficacy, not directly knowing any transplanted people and the lack of qualified information.

The vast majority of Spain's deceased donors are heart beating donors diagnosed as brain stem dead in intensive care units (32 per million of population). Spain has a low rate for both live organ donation (five per million of population) and for non heart beating donation (also known as donation after cardiac death, or DCD) (2.3 per million of population, largely uncontrolled DCD donors, where cardiac arrest has occurred unexpectedly outside hospital or in emergency departments).

As indicated previously, although Spain has shown the highest national rate of deceased donor organ recovery in the world, there has always been quite marked regional variation in donor performance. For example in 2007 there were 7 of 17 regions with greater than 40 dpmp and still a marked regional variability. ONT has therefore launched a strategy to achieve a substantial improvement in national donation and transplantation in Spain in the coming years: The 40 dpmp Plan.



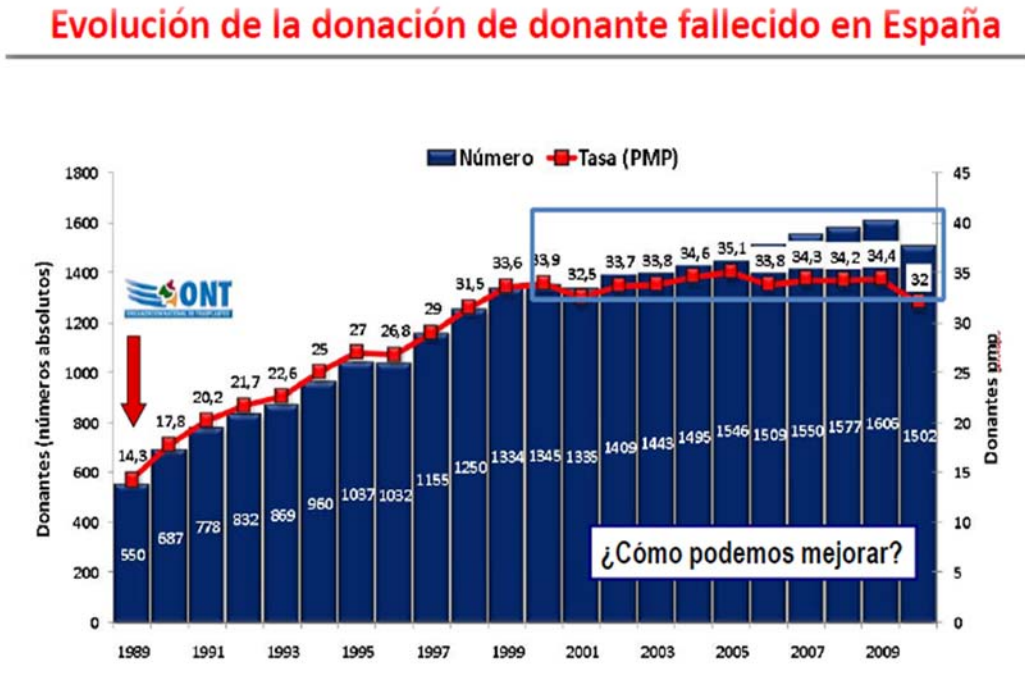
The overall objective is to increase the average rate of deceased donors to 40 dpmp between 2008 and 2010 by:

- Improving the detection and management of brain-dead donors by:
 - Improving access to intensive care resources
 - New forms of hospital management
 - Targeting ethnic minorities and
 - Improved evaluation/maintenance of thoracic organ donors
- Increased use of expanded criteria donors (older donors, donors with positive tests to certain viral diseases, and donors with rare diseases)
- Donation after cardiac death

The international benchmark 'Spanish Model' has certain structural elements. It has also had been characterised by an unwavering determination to provide the leadership and support systems for an ongoing national clinical practice improvement program that continues to seek to identify and remove all clinical systems of care issues that potentially act as barriers to optimal deceased

donation performance. The main reason for their success is well summarised in a slide (see Figure 10) shown to staff in Madrid early in 2011.

Figure 10: Organ donation performance slide (Spain)



Whilst most of the content of slide is self-explanatory, the most critical part of the slide that encapsulates the rationale for their enduring success is the phrase “*Como podemos mejorar?*” which means “*How can we improve?*”.

4 CANADA

During the past decade the number of organ donors in Canada has increased but living donors have accounted for over two thirds of this increase. The average annual increase in deceased donors during the past decade was less than 2%.

The ten organ procurement organizations (OPOs) in Canada submit data to the Canadian Organ Replacement Registry (CORR) regarding the number and characteristics of deceased organ donors, the number and types of organs removed for the purposes of transplantation and the number of organs transplanted from each deceased donor. Donors are attributed to the region where the donor was identified, irrespective of where the organs are transplanted.

In this report, deceased organ donors are reported from four regions: Western Canada (British Columbia, Alberta, Manitoba and Saskatchewan), Ontario, Quebec and Atlantic Canada (New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland and Labrador). Deceased donors in Canada's northern territories are currently identified by OPOs in British Columbia and Alberta and are attributed to Western Canada in this report.

A deceased organ donor is identified in CORR when at least one organ is transplanted from a deceased person. Most of the increase in deceased donation in Canada over the past decade has resulted from accepting more potential donors age 60 and older.

Most deceased donors in Canada are still neurologically determined death donors. The first donation after cardiac death in the modern era occurred in 2006, and this mode of deceased donation is slowly growing to now represent around 10% of all deceased donors. Programs offering donation after cardiac death are growing in number, with four provinces now engaged. All cardiac death donors were younger than age 55, and the vast majority (around 70%) are from a single province (Ontario).

Canada have had a number of attempts at reforming its organ donation sector over the past two decades

Most of these have involved the creation of advisory organisations, forums, committees and groups that did not have strategies to directly change the care of potential donors

Canada ran a national Breakthrough Collaborative in Organ donation in 2006. There was a minor increase in deceased donation following the collaborative

There were no structures put in place across Canada to spread and sustain the work of the Breakthrough Collaborative. Deceased donor rates have since returned to baseline values

Since 2008 Canada has been planning its next reform. This is very similar in content to the reforms introduced in Australia

This proposed reform agenda awaits ratification and implementation by the Parliaments of Canada (excluding Quebec)

Regional variation in the deceased donation performance is very evident in Canada. The deceased donor rate per million (dpmp) has remained relatively unchanged during the past decade, 13.8 dpmp in 1999 and 14.7 dpmp in 2008. The only increase in the rate was among persons aged 60 and older.

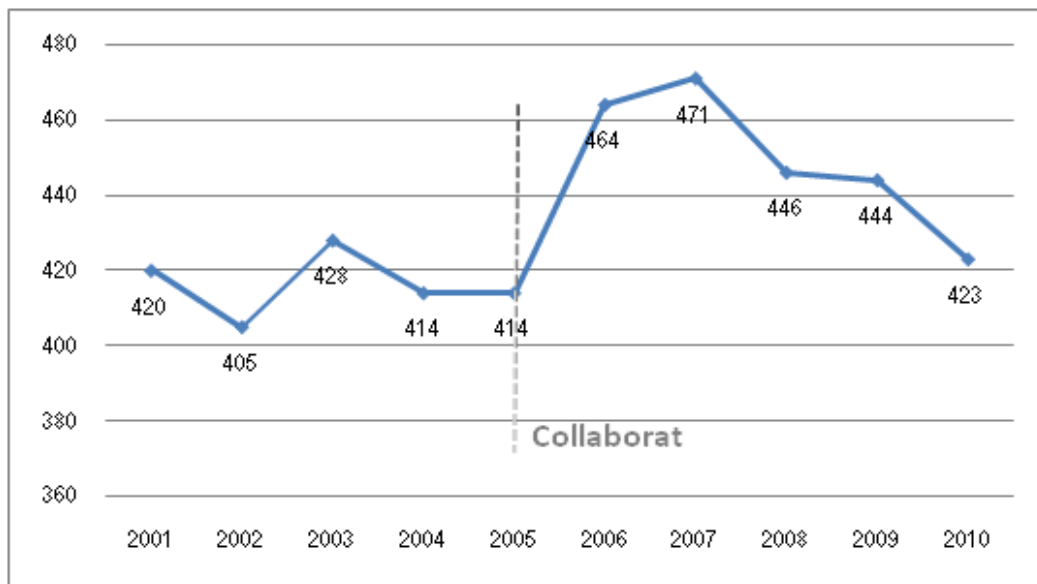
Over the last decade, there was an annual average increase in the number of deceased donors of less than 2%. There was some variation in growth of deceased donation between regions: the average annual increase in Ontario was 3.6% per year, compared to 1.8% in Quebec and less than 1% in Western and Atlantic Canada.

The number of organs transplanted per deceased donor has been unchanged over the last decade. While utilization of kidneys and livers for transplantation is least influenced by the donor's age, utilization of hearts and lungs for transplantation varies considerably with the donor's age. There was a notable increase in utilization of lungs for transplantation in all donor age groups. Deceased donors aged 55 and older account for most (71%) of the growth in deceased donors in Canada.

Canada is one of the only countries in the western world without a national, coordinated system for organ and tissue donation and transplantation. The system as it stands today is at capacity, and is struggling to cope with current needs and projected future demand.

A whole of government review in 1999 resulted in the development of a comprehensive national strategy to reform organ and tissue donation. This included the establishment of a national Canadian Council for Donation and Transplantation (CCDT) in 2000. The CCDT acted as an advisory body to Canada's Health Ministers. Whilst having a broad mandate the CCDT focused almost exclusively on the development of clinical guidance documents and clinical standards.

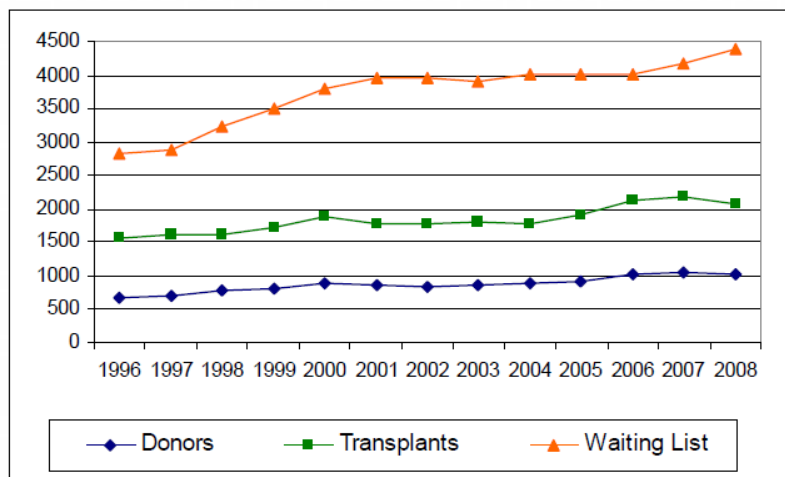
Figure 11: Deceased Organ Donors (Canada)



The CCDT also supported a Canadian Breakthrough Collaborative in Organ Donation in 2006. This was associated with a transient 10% increase in deceased donation rates over the following few years.

Concerns resurfaced within the Canadian system about the donation sector as deceased donor rates again returned to a level of 14 dpmp.

Figure 12: System Performance Gaps – Organs (Canada)



Source: Canadian Organ Replacement Register, Canadian Institute for Health Information (2008)

In August 2008, Canadian Blood Services was given a mandate by the Federal, Provincial and Territorial Deputy Ministers of Health (excluding Quebec) to develop - in consultation with stakeholders, the public, and the medical community - a recommendation for a new national system for Organ and Tissue Donation and Transplantation (OTDT).

Canadian Blood Services' experience operating a nationally-integrated delivery system, its existing infrastructure and expertise, and the trust earned with Canadians across the country, were key factors in the assignment of this new mandate.

Canadian Blood Services is receiving \$35 million over five years from the federal, provincial and territorial governments to enhance organ and tissue donation and transplantation in Canada. This mandate included assuming the activities of the former Canadian Council for Donation and Transplantation (CCDT), as well as setting up registries for living donor paired exchange, urgent status and highly sensitized patients. Canadian Blood Services was also given the responsibility to develop a plan for an integrated OTDT system, in collaboration with the OTDT community, in order to improve system performance in Canada.

CBS were tasked with:

- Continuing work developing policies and knowledge translation for: leading practices, guideline developments, performance measurement, accreditation, public engagement and awareness
- Developing national registries for living donor paired exchanges, urgent status patients and highly sensitized patients and intent to donate
- Designing a new national system for OTDT in Canada in collaboration with the OTDT community

Expectations and challenges identified by CBS included:

- The sector has complex problems require complex solutions for organs and for tissues, yet many stakeholders want immediate action. It needs to be recognised that the problems in the sector will not be solved quickly
- Stakeholders are tired of being consulted, but further consultations and information needed
- Need to balance requirements for tissue programs which are often under estimated
- High and divergent stakeholder expectations
- Roles of OPO's in future national structure contentious
- Role of Canadian Blood Services in future national structure contentious
- Different opinions regarding priorities

CBS goals were:

- To design a Canadian system that defines clear roles & responsibilities, and clear accountabilities to improve organ donor rates, and patient access and outcomes in all jurisdictions
- To present a practical, fundable plan, that is supported by the OTDT community, to the Deputy Ministers of Health

CBS are committed to working in partnership with national societies and organizations involved in organ and tissue donation and transplantation services. In September 2008, an initial stakeholder consultation was held to discuss the situation. Representatives from transplant, donation, administration, Intensive Care Units, Emergency Room, tissue banks, Organ Procurement Organizations, patients, donor families, living donors, government and ethical/legal organizations were brought together.

It was recommended that OTDT could best be served by a nationally coordinated system, but there were differences in opinion on roles, responsibilities and technical details of how the system should operate.

In May 2009, three committees were struck, a Steering Committee made up of 12 prominent experts in public healthcare policy, and two expert committees, one focused on organs and the

other on tissues. These committees met throughout 2009-2010 and will lead the development of the formal system recommendation. The participation and input of the public and stakeholders have been part of this process.

The Steering Committee was made up of prominent individuals to guide the development of the strategy for a national system for OTDT in Canada. Members of the Steering Committee represented a variety of regional perspectives, and include notable leaders in the areas of healthcare, government and industry - as well as experts on the subject of organs and tissues. They provided overall direction on strategic priorities in the design of this new national system.

Strategic partnerships such as the one with Accreditation Canada have also resulted in system change. This year new hospital accreditation standards for donation and transplantation were launched, including three new sets of standards for donation and transplantation as well as enhancements to the critical care standards and emergency room standards. Implementation of these standards and associated measures in hospitals will further improve the identification and referral for donation and transplantation of organs and tissues in Canada.

System Design

To develop recommendations for an integrated OTDT system, Canadian Blood Services drew upon its own expertise in performance management. The methodology used by Canadian Blood Services for the blood system was adapted to meet the needs of OTDT community and involved the following four phases:

- Assessment of the current state
- Establishment of strategic direction
- Defining goals and how progress will be measured
- Development of an implementation approach

In addition to having a defined process and broad stakeholder consultation, another guiding design principle was to build on what already works well in the system—to complement existing processes and functions that are performing well and to avoid duplicating efforts already underway in various jurisdictions. It was recognized that previous efforts have been made by provincial programs and organizations to improve donation performance and that there were pockets of excellence throughout the country.

To that end, the process focused on fixing the most critical problems in the system, and on developing solutions that would raise the performance of all provinces without negatively impacting today's stronger performers.

The premise was that not only are organ donation and transplantation programs in Canada not able to cope with the current demand for organs, they are unable to plan, in a coordinated, integrated manner, for future demand.

The Organ Donation and Transplant community acknowledged that:

- Canada is failing to realize its potential for organ donation
- The Canadian organ and tissue system is neither sufficiently equitable nor transparent
- There are system inefficiencies associated with patient assessment and organ allocation that can impact patient wait times and health
- The current system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvements

As well, tissue banking in Canada currently takes place in 23 independent tissue banks (excluding Quebec) that recover, process, store and distribute tissue allografts with a focus on hospital, regional and local needs.

The Tissue Donation and Transplant community believed that:

- The safety and quality of tissue product in Canada cannot be assured
- Current Canadian tissue practices do not ensure security of supply
- Independent and uncoordinated Canadian tissue banks result in inefficient tissue collection, processing and distribution
- Lack of measurement and accountability fail to drive consistent, system-wide improvements

With these change imperatives in mind, Canadian Blood Services designed a process that aligned broad stakeholder engagement with specialised policy development such that the current state analysis, strategic direction, goals identification, outcomes measurement and implementation are informed and validated at each stage by expert stakeholders and community members.

Although CBS sought to keep the government of Quebec informed they opted not to participate in system design at this time. However, it should be noted that the Quebec clinical community is supportive of initiatives that will increase donation rates in Canada and improve access for patients. An example of this is Quebec's decision to become a formal participant in the Living Donor Paired Exchange Registry.

Proposed Solutions – Organs

Proposed solutions have been developed based on the result of over a year of investigation and analysis by the Committees and input from the broader stakeholder community. In general, the proposed solutions for organ donation and transplantation are organized around three priority areas: accountability, increased organ donation and improved access to transplantation, though some of the proposals are related to infrastructure and some of the solutions address more than one priority.

Final detailed recommendations, including costing and implementation considerations, were presented to the provinces and territories as part of the final report in early 2011.

Accountability:

- Development of an inter-provincial accountability framework and clinical governance model, to ensure compliance and significant, sustained performance improvements
- Mandatory data collection and reporting of organ donation and transplantation data to a central agency, to improve transparency

Increased Organ Donation:

- Professionalization of donation services, through the implementation of Donation Physician Specialists in some hospitals
- Continued support for development and implementation of leading practices, health care professional education and public awareness

Improved Access to Transplantation:

- Increase the functionality of registries to include allocation of all organs for all patients, according to agreed to local and inter-provincial sharing rules, to improve processes, data and accountability within the system
- Development and implementation of common policies for patient referral and listing, and allocation, to ensure consistency and fairness across the country

Proposed Solutions – Tissues

In general, the proposed solutions are organized around three priority areas: quality and safety, efficient and secure supply, and responsive and forward looking system, though some of the proposals are related to infrastructure and some of the solutions address more than one priority. Final detailed recommendations, including costing and implementation plans, were presented to the provinces and territories as part of the final report in early 2011.

Quality and Safety:

- Improve the quality and safety of tissue and ensure complete traceability of product, through implementation of a standard quality program and leading practices

Efficient and Secure Supply:

- Develop a single, inter-provincial tissue supply plan, aligning supply with demand, through both domestic and imported products, to ensure the needs of Canadian patients are met
- Increase the number of tissue donors to close tissue supply gaps, with an initial focus on corneas, tendons, paediatric heart valves, and an emergency skin supply
- Coordinate tissue referral and recovery, to align with the supply plan

Responsive and Forward Looking System:

- Consolidate tissue processing into centres of excellence in purpose-built facilities, to increase quality and achieve efficiencies

- Develop a single tissue inventory that moves the right tissue to the right location when it is needed

Organ Registries Update

Canadian Blood Services have developed three national patient registries to increase transplant opportunities for Canadians:

- Living Donor Paired Exchange (LDPE) Registry
- National Organ Waitlist (NOW)
- Highly Sensitized Patient (HSP) Registry

Phase I: LDPE ... Operational

The first registry, the Living Donor Paired Exchange (LDPE), was delivered in January 2009, and has contributed significantly to facilitating living kidney transplants across the country.

Phase II: NOW and HSP ... Project Underway

With Phase I complete and operational, the Organ Registries team at Canadian Blood Services is developing the second phase which includes bringing the National Organ Waitlist (NOW) online to achieve the benefits of a real-time, web-based system, as well as the Highly Sensitized Patient (HSP) Registry for kidney patients with increased antibodies. Once Phase II is complete, these three registries will be integrated and accessible through one web-based portal.

A recent Ipsos Reid public opinion poll showed that the majority of Canadians have either made the decision to donate, or are open to donation, however few have taken action to register their consent.

Key poll findings include:

- Canadians agree that improving access to organ and tissue donation is a top health-care priority, and that increased education and awareness about donation options for both the public and medical communities is key. They also believe that a physician or medical professional should approach families at the appropriate time to discuss donation options
- While Canadians are united in the need for an improved OTDT system, their opinions differ on potential remedies; for instance:
 - 88 per cent believe the wishes of a deceased person who has signed a donor card or registered their intent should be followed – regardless of the wishes of next-of-kin
 - However, only 54 per cent of Canadians favour “presumed consent,” in which organs and tissues are considered public goods unless one “opts out.” Meanwhile, 45 per cent are decidedly opposed to a system that assumes consent without prior consultation
- Most Canadians list inter-provincial collaboration as the top priority for developing an integrated system, to ensure wait times are consistent across the country and that patients have a fair chance of receiving a transplant, regardless of where they live

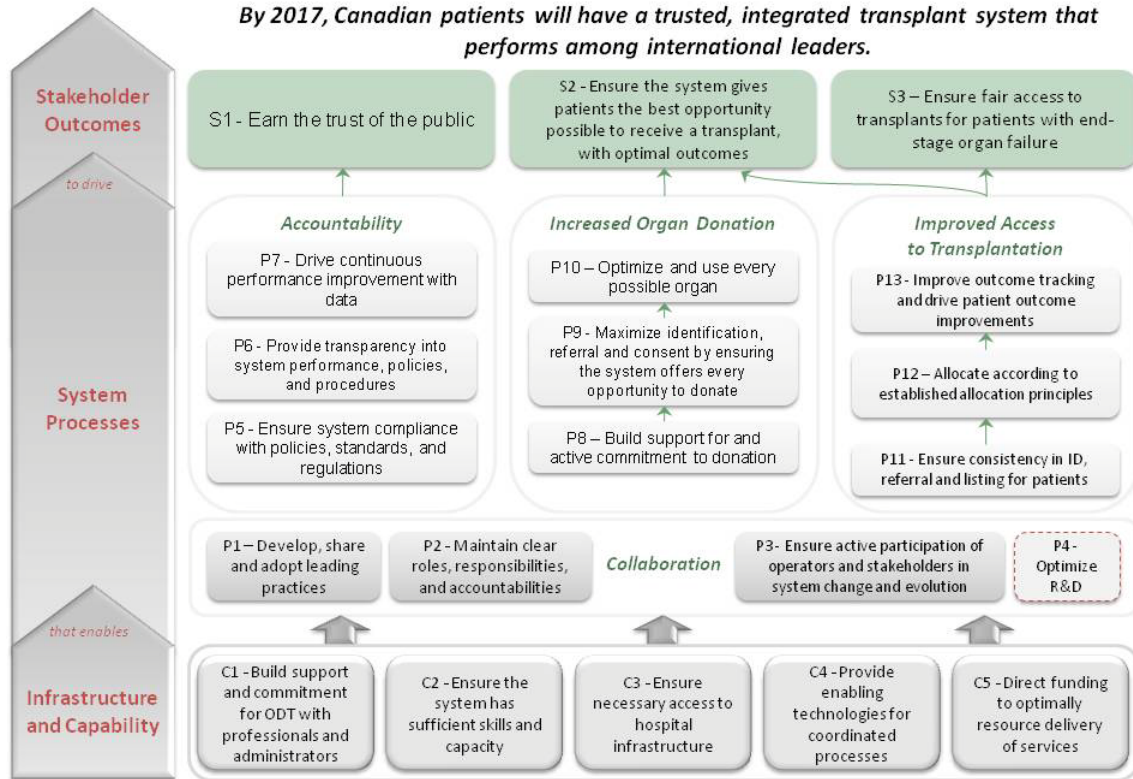
This polling information supports data that Canadian Blood Services collected during a series of nine public dialogue consultations held across the country in recent months. In particular, public dialogue participants expressed surprise that wait times for organs vary widely across the country. Similar to Ipsos' data, consultation participants placed a high premium on equality and fairness; and improved collaboration nationwide.

Canadians are very supportive of organ and tissue donation and transplantation (OTDT), but not enough of them act on that support. As a result, Canada's donation rate is about half that of the best performing countries and has been relatively flat for the last decade.

The Federal, Provincial and Territorial governments mandated Canadian Blood Services to design a system to improve the performance of OTDT in Canada and MedicAlert® and almost a dozen key national patient organisations, representing more than 15 million Canadians have come together to play an important role in bringing the patient perspective to the design of a new system.

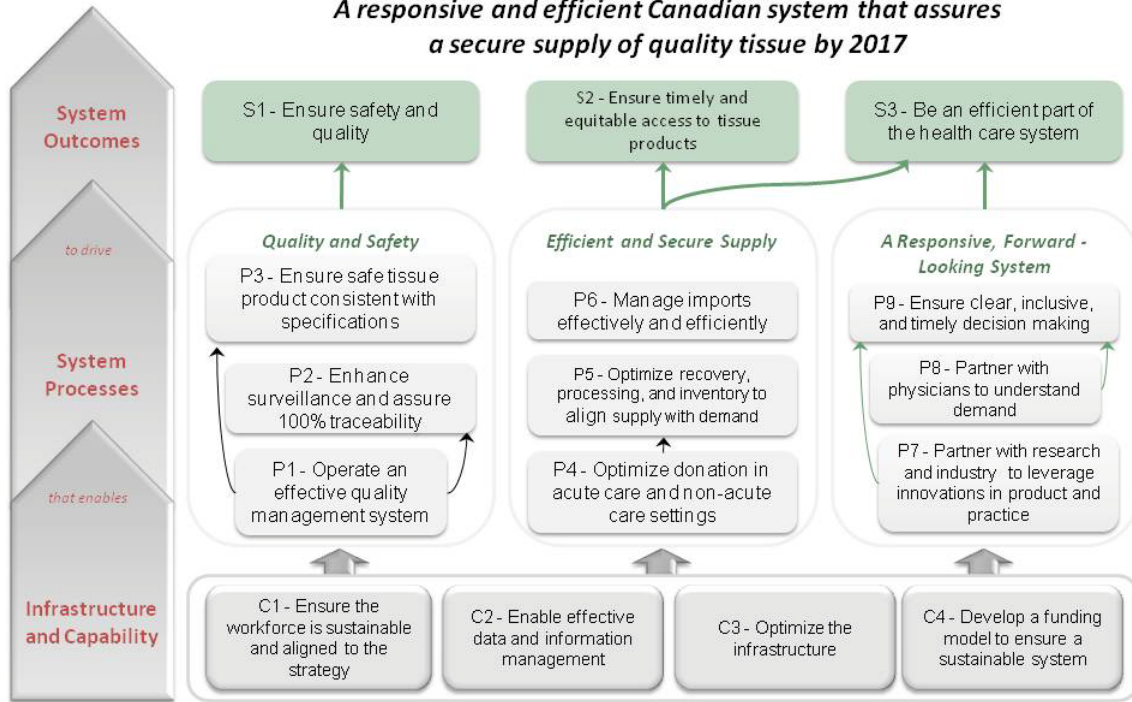
Organ System Strategy Map

By 2017, Canadian patients will have a trusted, integrated transplant system that performs among international leaders.



TISSUE SYSTEM STRATEGY MAP

A responsive and efficient Canadian system that assures a secure supply of quality tissue by 2017



5 ITALY

In Italy the network that co-ordinates donation and transplant activities was established in 1999. It is articulated on four levels: local, regional, inter-regional and national.

Local co-ordination; experienced hospital physicians with knowledge of organ donation issues communicate with the regional donation centre regarding potential donors, maintain contact with families of potential donors, organise awareness and education campaigns in partnership with their regional donation centre, and ensure that staff follow all the relevant procedures with regard to deceased organ donation.

Regional co-ordination is provided by regional donation reference centres. These regional centres manage: organ donations and relations with ICUs, waiting lists and relations with external centres, organ and tissue retrievals, transplants, relations with transplant centres, relations with the Inter-regional centre;

Inter-regional co-ordination; currently three inter-regional organisations provide coverage for Italy. The three organisations are:

AIRT (Inter-regional Transplant Association) covers Piedmont, Valle d'Aosta, Tuscany, Puglia and Emilia-Romagna and the Autonomous Province of Bolzano;

NITp (Nord Italia Transplant program) covers Friuli, Liguria, Lombardy, Marche, Veneto and the Autonomous Province of Trento;

OCST (Southern-Central Organisation for Transplants) covers Abruzzo, Basilicata, Calabria, Campania, Lazio, Molise, Sardinia, Sicily and Umbria.

The inter-regional centres manage relations with regional centres in their jurisdictional area. They coordinate reporting on potential donors and allocations of organs, urgencies, organ given as advance, return of organs, contacts with other Inter-regional Centres and with the National Transplant Centre.

Italy introduced a reform package in 1999 built around both legislative reform and structural reform

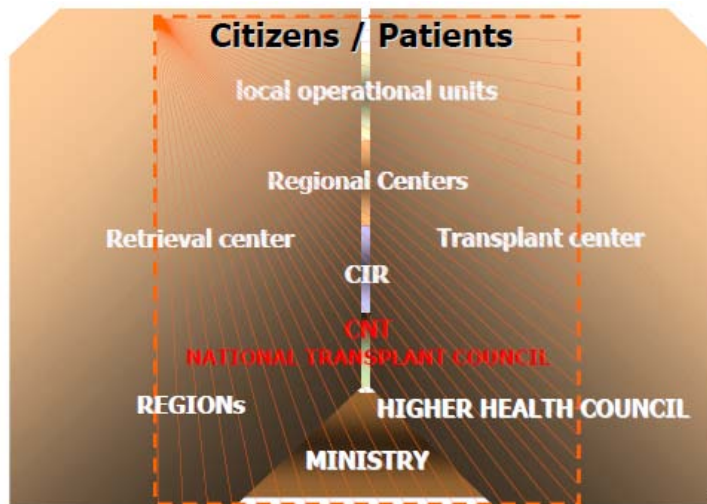
Deceased donation rates increased initially through the improved performance of a few regions. Donor rates then stabilised (or fell)

The national donor agency in Italy is an effective administrative body.

The national donor agency in Italy has been less active in healthcare professional education and provision of leadership of nation clinical practice improvement than other national organisations

Over time many regions in Italy have shown no improvement in donation performance, whilst others have greatly improved performance. Donation rates per region vary more than 5 fold across Italy

They also update registries of retrievals carried out over the national territory, of transplanted organs, of follow-up and organs exchanged with other co-ordination organisations.



The National Transplant Centre

The National Transplant Centre (CNT) is a technical body of the Italian Ministry of Health, established under Law 91, dated April 1 1999, in order to promote, coordinate and manage organ and tissue donation and transplantation in Italy.

The Centre, located in the Italian National Institute of Health (ISS), is chaired by the President of ISS, and is composed by the General Director, nominated and appointed by the Health Minister, and by representatives of the Inter-regional or Regional Centre, nominated by State-Regions Conference.

The Centre is supported by the Transplant Standing Technical Council, which prepares the technical-operational guidelines for carrying out retrieval and transplant activities, giving advisory opinions to CNT. The CNT also avails itself of experts from the Biomedical Engineering and Immunology Laboratories of the National Institute of Health.

A number of Italy's national strategies to improve organ donation are implemented via use of legislative reform.

These laws include Law 91 (art. 8) that establishes the following functions of CNT:

- Controlling, through information systems, collected data on donations, transplants and waiting lists
- Setting criteria for preparation of operating protocols, as rules for allocation of organs and tissues, currently carried out by regional and inter-regional centres
- Issuing guidelines on regional and inter-regional centres activities
- Allocating organs in urgent situations

- Establishing homogeneous criteria to evaluate the quality of structures involved in transplant activities
- Promoting and co-ordinating relations with European Organ Exchange Organizations
- Managing National Programmes regulated by shared rules (i.e. paediatric and liver urgencies) and programmes not regulated by ad hoc guidelines but generally accepted (i.e. pancreas, bowels, HIV, lung, kidney and liver).

In addition to these important tasks, CNT is responsible for the promotion of community information campaigns on organ donation, retrieval and transplantation, the management of the transplant information system (SIT) and leading the organisation and management of the Italian transplant system.

CNT coordinates national information campaigns launched through mass media, to stress out the importance of organ and tissue donation. Information is provided to citizens also through the web site of the Ministry of Health and through a toll-free number for transplantation, where a staff of experts answers more frequently asked questions, and through a newsletter, directed to all professionals in the field, that is published every two weeks.

The CNT is involved in several national programmes and coordinates or participates in national projects or research programmes.

There are also national projects managed by CNT. The main current projects include:

- Assessment, selection and use of kidney marginal donors
- Innovative Strategies for Liver Transplant
- Surveillance of the national transplant kidney programme for the Difficult patients
- Management of national heart emergencies
- Biological national repository for safety of transplant network
- Clinical protocols for surveillance of calculated risk transplants
- Italian Gate to Europe (organ export program)
- Outcomes in transplants carried out
- National certification of Coordinators
- Comparative study protocol for the evaluation of artificial substitute in liver insufficiency
- Protocol on management of bowel and multi-visceral transplant programme
- Document on regional standards for transplant organs centres authorizations
- Implementation of a regional quality programme on the process of organs and tissues retrieval
- Epidemiological data collection and evaluation for donations and transplantation of hematopoietic stem cells

- Clinical application of the PCR diagnostic test to determine the tissue from which the cancer has been developed

The Information System (SIT) of the Italian National Transplant Centre has the following functions:

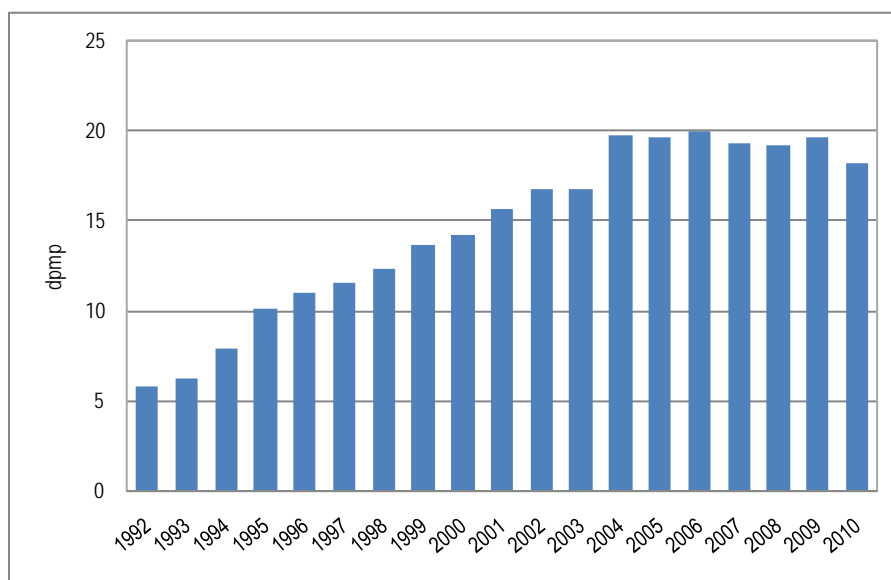
- Registration and collection of citizens wishes regarding organ and tissue donation
- Automatic information collection of data on retrieval and transplant activities carried out nationally;
- Allocation audit
- Allowing information sharing among sector

CNT controls and evaluates the quality of donation and transplant programs by auditing their activities against specific guidelines for recommended care.

In 2010 the number of transplants carried out in Italy totalled 2874, decreasing compared to 3163 of 2009 (-9.1%).

The main cause of the downturn in transplantation was the aging deceased donor population. An increase in the average age of donors significantly reduces the number of organs suitable for transplant.

Figure 13: National organ donation rates, dpmp (Italy)



SOURCE: E' quanto si legge in 2010 Report on organ donation and transplantation available by national transplant centre

Italy continues to demonstrate very wide ranges in donation performance across its regions, with five-fold differences between the highest donation regions (>45 dpmp) and their lowest donor regions (9 dpmp). There have been little improvements in donation performance since

implementation of the reform in several regions, with much of the national increase in deceased donation attributable to marked improvements in performance of a small number of regions.

There was also a decrease in the number of potential donors (i.e. in 2010 there were 2289 potential donors versus 2326 potential donors in 2009). NOK consent rates were stable (and in line with European patterns of consent) with families refusing consent in 31.5% of potential donors (against 30.4% in 2009).

Figure 14: Comparison in donation rates between regions (Italy)

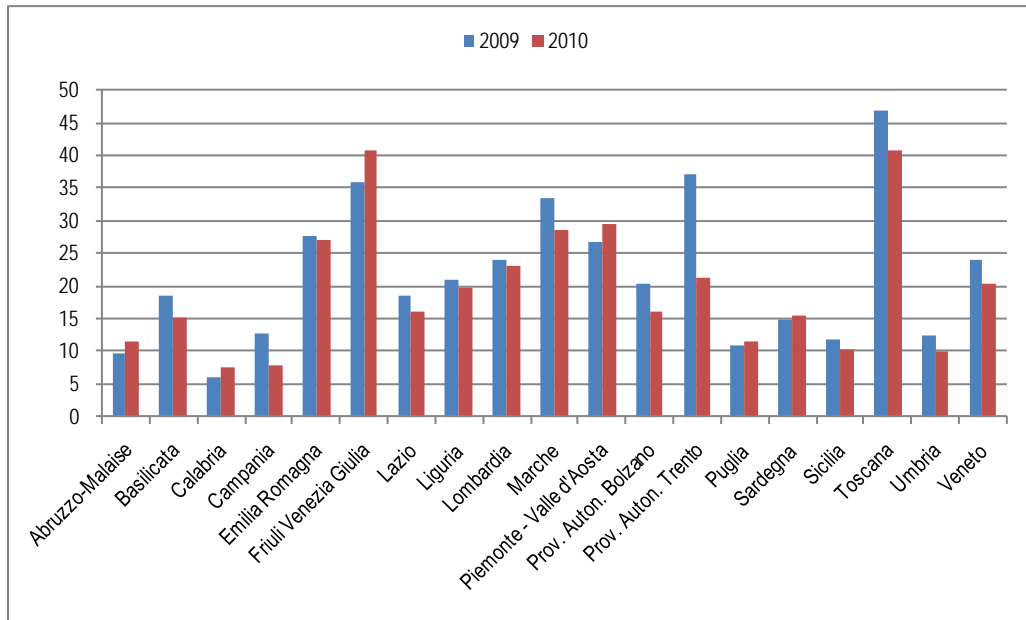
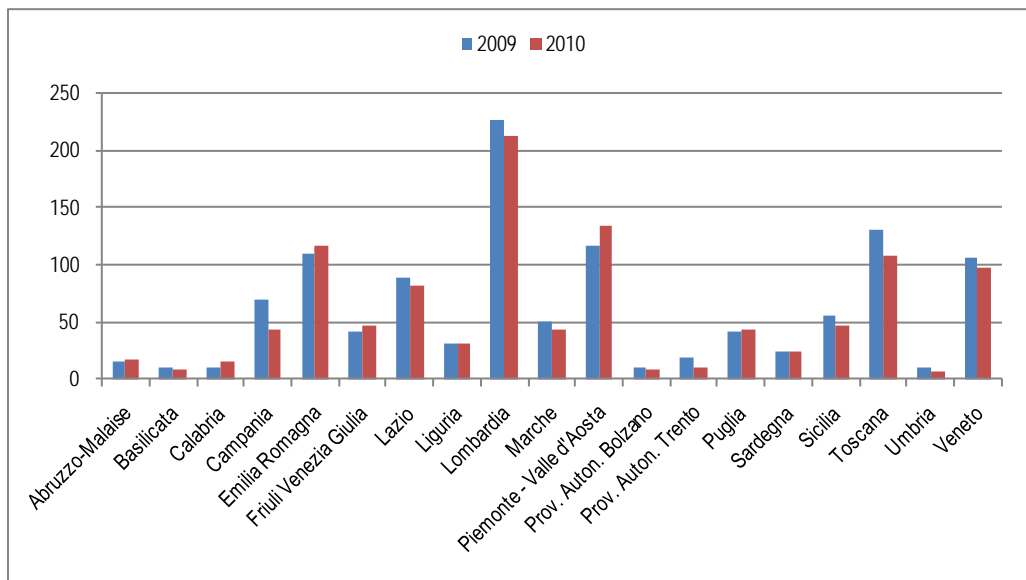


Figure 15: Comparison in donated organ utilisation rates between regions (Italy)



6 LESSONS FOR AUSTRALIA

At this early point in implementation of our national organ and tissue reform agenda, Australia is performing as well as any other healthcare system in terms of the observed increase in numbers of deceased organ donors. Indeed it is currently performing better than many other nations.

Table 8: Summary of key reform elements by country

Key Element	Spain	UK	USA	Canada	Italy
National Infrastructure supporting improved donation performance	✓	✓			✓
National framework to drive organ donation performance improvement within hospitals	✓	✓	✓	✓	
Specialist hospital staff supporting donation performance improvement teams in hospitals	✓	✓			✓
A national deceased donation quality assurance program, with two stages of evaluation	✓	✓			✓
Nationally coordinated training for all healthcare personnel involved in organ donation	✓	✓			✓
Reimbursement of hospitals to recover procurement costs	✓		✓		
Public awareness and Education campaigns		✓	✓	✓	✓
Proactive management of mass media opportunities	✓	✓			✓

In 2011 we still have much to learn from the Spanish experience. This is particularly the case if we focus on learning from what they have actually implemented in practice, rather than endless discussions about the perceived merit of supposed reform measures that are in fact myths, rather than any part of the actual 'Spanish Model'. Of particular value is their intense focus on staff education and training and their use of detailed profiling of high performing hospitals to continue to identify potential system wide changes in care for potential donors that could drive improved system performance.

We also have much to learn from the UK's structured national approach to training, educating and developing their staff specialising in optimising organ donation performance.

Key lessons for Australia from the experiences of our international colleagues in implementing reform in the organ and tissue donation sectors include:

1. Focus on changing clinical care processes within hospitals

- Long term successful impact of reforms requires a major focus of national reforms efforts on changing clinical care processes within donor hospitals. There need to be multiple complimentary strategies that drive these changes in clinical care of potential donors within all participating hospitals
- Reforms that do not include the establishment of specific structures and strategies to continuously drive changes in clinical care of potential donors within hospitals do not deliver long term success
- Successful national programs have in place very active programs at a national level that support clinical practice improvement within participating hospitals. These include major national professional education, training and development programs and objective measurement of deceased donation system performance (through use of national death audits of care of potential deceased donors that seek to identify problem with donor care systems)
- Successful reform programs have a range of specific activities that support desired changes in clinical care of potential donors within participating hospitals occurring in a coordinated fashion at national, regional and hospital levels
- Successful programs tailor their interventions to ensure that they are fit for purpose in their intended environment

2. Nationally developed education and training

- Nationally developed education and training for professionals involved in improving donation performance must focus on building staff capability in both donation specific issues and their capacity to lead a change management program within their own hospital systems
- Education and training for professionals must include remotely accessible educational materials and formal structured meetings/forums that encourage face-to-face exchanges of knowledge and experience between the professional working in the donation sector

3. National Death Audit

- The national death audit needs both internal and external audit components. The external audit is particularly important to help the development of a better shared understanding amongst clinicians about the true potential for deceased donation (particularly in the circumstance of high risk and/or marginal/extended criteria potential donors)

4. Expanding the application of successful care practices

- Early success in national reform is usually due to a relatively small number of hospitals or regions demonstrating significant improvements in their deceased donation performance. Unless an increasing proportion of hospitals and regions follow in time and also increase their relative performance there is soon a levelling off of national deceased donor organ donation performance (albeit at a higher level than pre-reform).
- Long term success for national reform of deceased donor organ and tissue donation sectors requires national programs that progressively increase the proportion of high performing hospitals and regions by identifying better care practices and transferring these across an ever increasing proportion of participating hospitals