Adopting an opt-out registration system for organ and tissue donation in Western Australia

A Discussion Paper

February 2011

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Introduction

This discussion paper considers the adoption of an opt-out organ and tissue donation registration system as an avenue to increasing the organ and tissue donation rate in Western Australia.

This paper considers an opt-out registration system which maintains the current practice of approaching the next of kin to confirm the wishes of their loved one to donate their organs. There are ethical and legal barriers to excluding the next of kin from the decision making process.

To implement an opt-out registration system, a change would be made to the WA Human and Tissue Act (1982). It would shift the onus of responsibility for action to register from the majority of West Australians who are supportive of donation to the minority who do not support donation. In this system all West Australians above 18 years of age would be considered to be in agreement with organ donation unless they register their objection. The right of families for consultation and participation in the consenting process at the time of donation would be preserved.

The paper will also cover the organ and tissue donation activity in Western Australia. An in-depth analysis of the real optimal organ donation rate in Western Australia and the potential impact of changes to the registration system towards this goal are provided.

Support for organ and tissue donation in the community is high with 77% of Australians generally willing to become organ and tissue donors[1]. This is not matched by the same level of registrations or discussions with family.

- 39.28% of the eligible West Australian population has registered a decision to donate or not to donate on the Australian Organ Donor Register[2] (AODR). This figure is in decline as annual population growth in Western Australia is marginally higher than the number of new registrants each year. It is important to note that in 2009, 1801 of 686,784 registrations were objections.

- As many as 40% of Australians do not know the donation wishes of their family members [3].Where the wishes of the deceased family member are known 93% of survey respondents in the Australian community will uphold those wishes [4]. This is reflected in practice where donation decisions of an individual are rarely overturned by the next of kin where they are known [5] [6] [7].

Therefore the key limiting factor is the ability to determine an individual's disposition towards organ and tissue donation after death in the context of less than optimum levels of registration on the AODR and less than optimum general community awareness about the donation wishes of their loved ones.

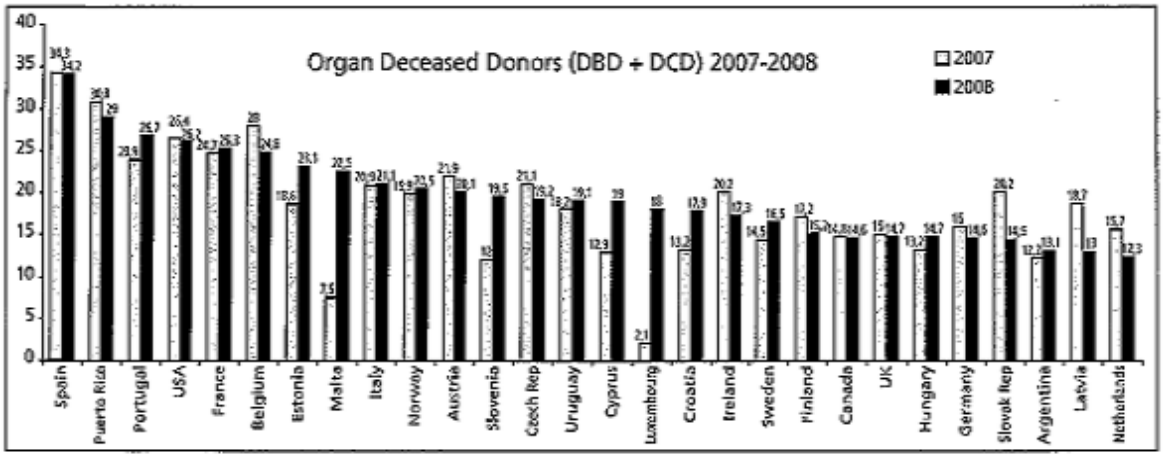
This is crucial in Western Australia where we will demonstrate that donation rates are limited by lower mortality and where it is therefore essential to make the most of every donation opportunity. Choosing between the introduction of opt-out or optimising the rate of registration by the implementation of a major advertising campaign such as Project Forward is the crucial decision that needs to be taken by the West Australian community.

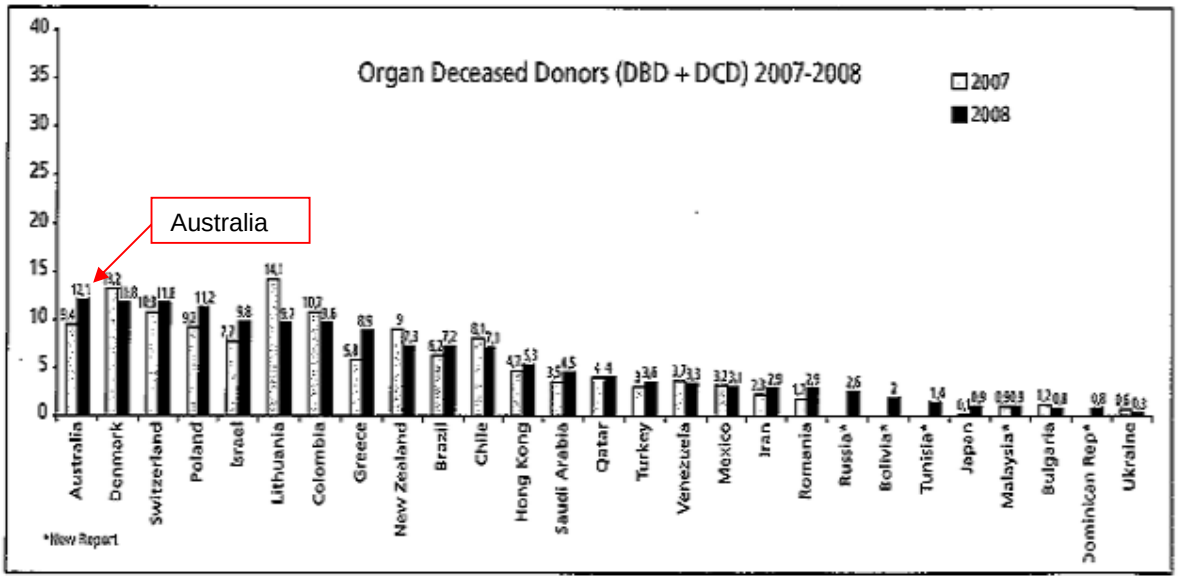
The Pathways to Donation

Background

Donors per million population (dpmp) is the crude international comparative measure for organ donation rates. Australia has one of the lowest dpmp organ donation rates worldwide with a rate of 11.3 per million in 2009.

Figure 1: Countries worldwide Organ Donation rate per million population in 2007 and 2008[8]





In Australia, the state with the highest rate of organ donation per million of population is South Australia. In 2009, South Australia reported 20 donors per million of the population, while Western Australia recorded the lowest donation rate of 9 per million of the population [9] [10].

Figure 2: Summary of Number of Donors by Year in Australia and New Zealand[11]

	QLD	NSW	ACT	VIC	TAS	SA	NT	WA	AUSTRALIA	NEW ZEALAND
1989	37	86	3	65	2	19	2	17	231	39
1990	38	74	5	45	2	27	1	11	203	40
1991	48	72	4	45	2	15	2	23	209	33
1992	66	70	0	42	4	20	0	14	216	53
1993	44	68	6	52	6	23	3	19	221	34
1994	38	71	2	26	6	23	1	16	183	35
1995	34	60	7	38	4	23	1	17	184	35
1996	35	63	6	49	1	25	3	12	194	36
1997	37	65	4	42	5	25	4	8	190	42
1998	40	63	2	40	0	35	3	13	196	46
1999	20	48	2	42	6	30	3	13	164	39
2000	37	55	5	44	1	30	2	22	196	41
2001	48	47	7	40	3	25	2	13	185	37
2002	44	55	6	47	6	31	2	15	206	38
2003	40	46	8	42	2	22	1	18	179	40
2004	39	63	6	45	2	39	1	23	218	40
2005	35	54	9	50	2	20	4	30	204	29
2006	36	50	4	45	8	36	2	21	202	25
2007	39	53	1	55	1	27	3	19	198	38
2008	48	57	5	67	8	43	3	28	259	31
2009	47	89	8	64	5	33	2	19	247	43
TOTAL	848	1289	100	985	76	571	45	371	4285	794

Organ Donation

In Australia, organ donors come from one of two pathways to donation:

1. *Donation After Brain Death:*

   This can only occur in an intensive care unit after declaration of brain death while on mechanical ventilation. Individuals presenting to a hospital with a catastrophic and unsalvageable insult to the head make up this cohort of total deaths that represent less than 0.5% of all deaths in Western Australia. The cause of mortality associated with these deaths is:

   - Trauma Road
   - Trauma-Non Road
   - CVA
   - Hypoxia (hanging, drowning)
   - Other

2. *Donation After Cardiac Death (DCD):*

   This can only occur in an intensive care unit after determination of futility of further treatment while on mechanical ventilation. Once again individuals presenting to a hospital with a catastrophic and unsalvageable insult to the head comprise this cohort of deaths. This group of individuals is unlikely to progress to brain death and a decision is made to withdraw futile treatment. In some circumstances where death is expected quickly after withdrawal of futile treatment and in discussion with the next of kin organ donation can be considered. The mortality associated with these deaths is the same as donation after brain death.

Tissue donation

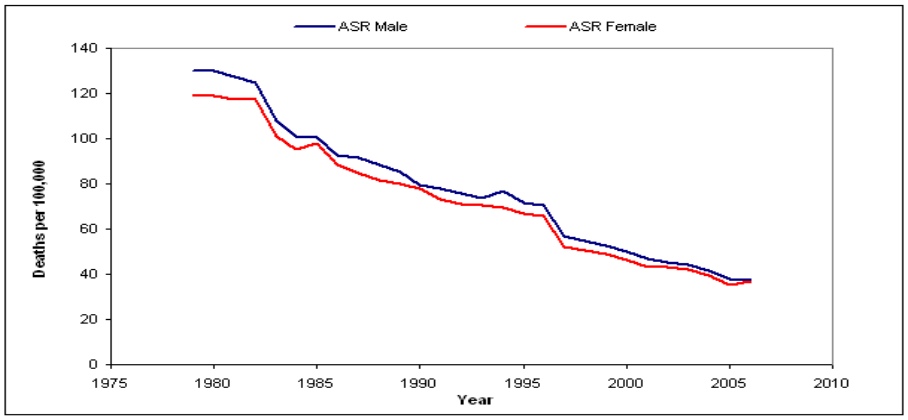
Tissue donation can occur within 24 hours of any death. Tissue donation is subject to much more stringent exclusion criteria than organ donation due to the life enhancing versus life saving nature of tissue donation. Medical suitability is the most significant influence on tissue donation rates.

What are the facts constraining organ donation in Western Australia?

Western Australia will not be able to consistently achieve a dpmp above 20 per million population for the reasons described below in order of descending importance:

- Western Australia's mortality from cerebral vascular accidents (CVA) in our elderly population is low and diminishing because of prevention of hypertension and public health campaigns to reduce smoking;

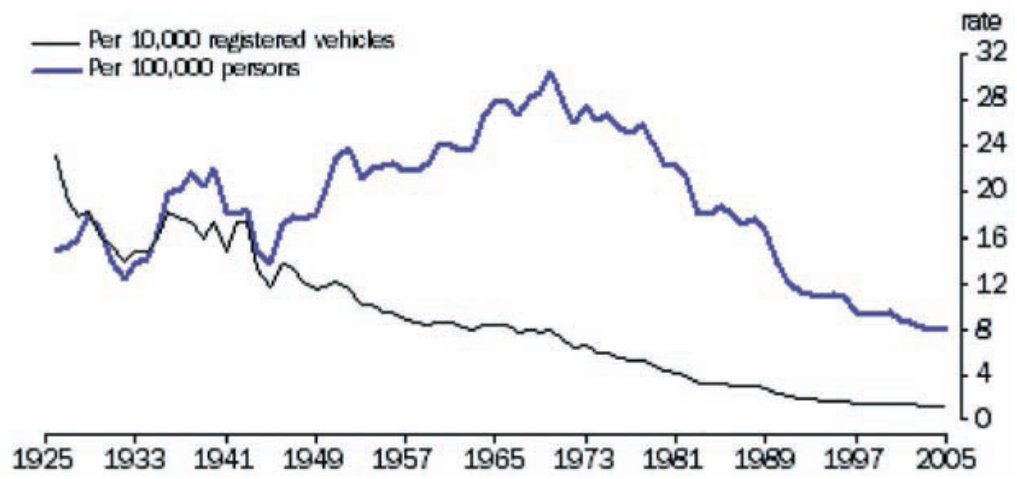
Figure 3: Trends in death rates for stroke in Australia, 1979 to 2006[12]



Note: Rates are age-standardised to the 2001 Australian population.

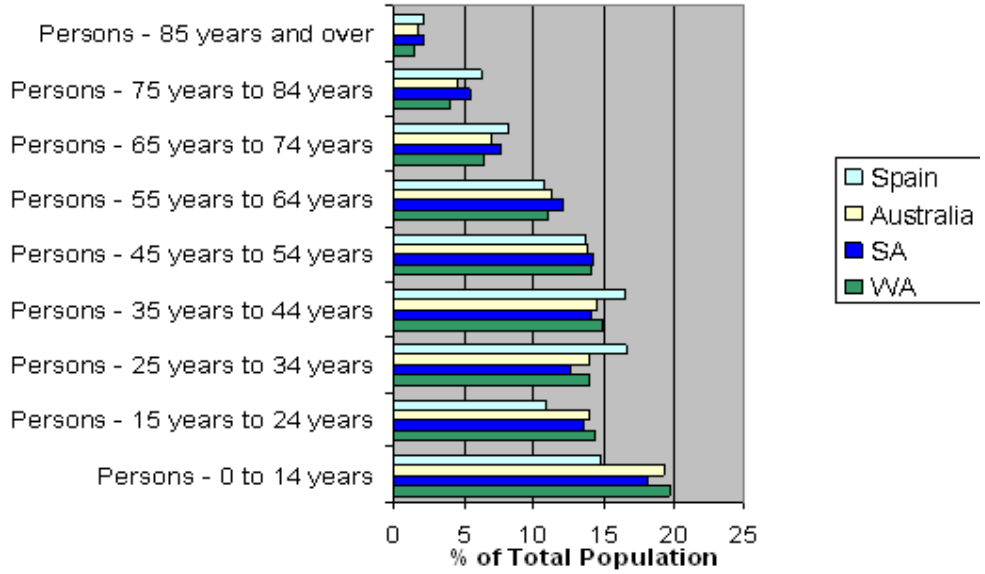
The West Australian rate of mortality from motor vehicle accidents (MVA) is too low;

Figure 4: Road Fatality rates 1926 – 2005[13]



- The demographics of Western Australia in comparison to Spain and South Australia are of a lower risk profile. The percentage of the West Australian population in the high risk for CVA (45-85 years) age range is lower than Spain and South Australia. The percentage of the West Australian population in the high risk MVA mortality (25 – 45 years) age range is lower than Spain. The mean population age in Spain is 40.1, South Australia 39.1 and Western Australia 36.3;

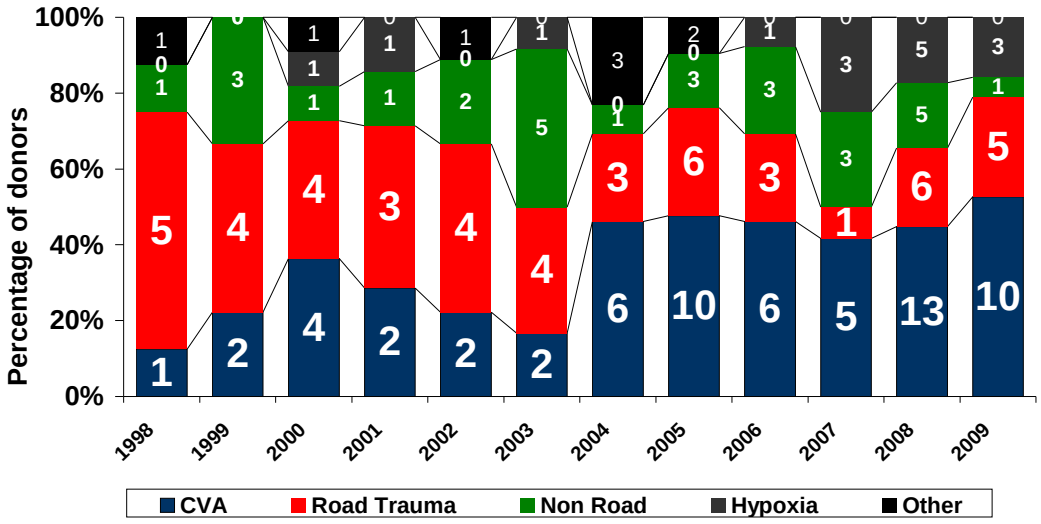
Figure 5: Population Age Profiles



- ICU beds per 100,000 population in Spain is 8.75, South Australia 6.78 and Western Australia 3.63 [14] [15];

- Perth has a single neurosurgical team practicing more and more decompressive craniectomy procedures (over 150 cases over 5 years). Interventional strategies to prevent brain death are aggressively implemented and contribute to an important shift in the distribution of the source of potential donors. Internationally CVA and MVA mortality account for approximately 80% of actual organ donors [16], in Western Australia CVA and MVA mortality account for only 55% of actual organ donors between 2005 to 2009.

Figure 6: Western Australia Organ Donors Cause of Death 1998-2009[5]



In conclusion Western Australia is drawing from a smaller pool of potential organ donors due to:

1. A younger population with a low mortality for CVA and MVA;

2. In the elderly population prevention of hypertension, and

3. Neurosurgical imaging and intervention will become more and more widespread with the support of increasing numbers of ICU beds.

Therefore personal and family consent for every organ donation opportunity is paramount.

Why do families say no when presented with a real opportunity to donate?

There are various reasons that families refuse donation[17] [18]. The decision to donation occurs in the midst of what is for most families, the most traumatic and unexpected event in their experience[19]. Families who are not prepared for the question are influenced by many factors including:

- Knowledge of the wishes of the deceased [20] [21];
- The timing of the approach and the skill of the requestor [22];
- The level of disagreement in the family generally [23];
- The time the patient has spent in hospital prior to declaration of death, cultural reasons and age of the deceased [24];
- The pathway to donation [25], and
- The perception that the organs may be going to someone who is not worthy [26].

The most significant predictor of the family's decision making process in this crucible of emotion and shock is a knowledge of the wishes of the family member for whom they have already begun to grieve [27]. This is reflected in the West Australian data where 95% of the time the family will support the decision of the deceased when it is known.

What is an achievable donation rate for Western Australia?

The following assumptions can be based on our current West Australian data on organ donation.

Over the last 5 years, each year there were 38-40 (19 to 20 dpmp) potential brain dead donors. Of these:

- 4-6 are known non-intents;

- 6-7 do not progress because the family do not consent where the deceased wish is unknown;

- 3 have their positive wish overturned by families. This can occur where;

1. The family is able to provide information that the deceased had verbalised an intention not to donate subsequent to registering an intention to donate on the AODR, or

2. Where information about the deceased wishes were not available at the time the family was asked to consider organ donation, the family have not given consent and information becomes available about the deceased wishes after the opportunity has passed.

- 22 become donors with family consent (accounting for 11 dpmp).

Because of the facts presented above it is crucial to understand that the pool of brain dead donors will further decrease over the next few years and that the increase in organ donation can only come from two sources:

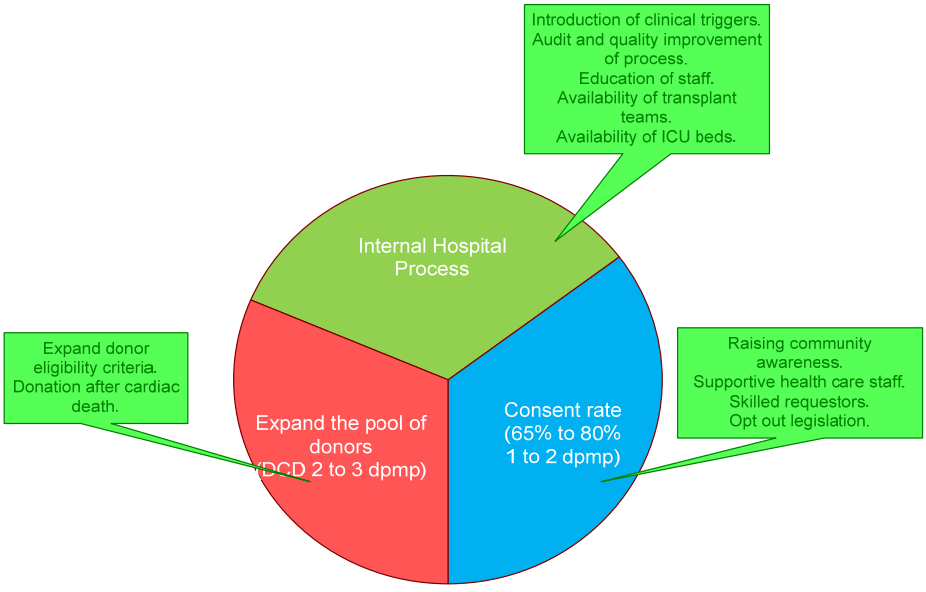
1. Improvement in the rate of consent from 65% - 80% - 1 to 2 dpmp (2 to 4 actual organ donors), and

2. Introduction of donation after cardiac death (DCD) as a pathway to donation 2 to 3 dpmp (2 to 6 actual organ donors). In time this rate will increase.

Therefore we estimate that a maximum achievable organ donation rate is 16 to 18 dpmp.

What are the strategies that Western Australia can implement to increase the donation rate?

Figure 7: Strategies in WA to increase organ donation rate



Three strategies can be implemented to improve the efficiency of the donation system and achieve an organ donation rate between 16 – 18 dpmp:

1. *Opt-out registration* - Focus on improving the rate of consent by families. In order to achieve this, a key issue is the ability to confirm the wish of the deceased regarding organ donation. A change in registration strategy to opt-out would target this. With the aim of increasing the current rate of consent when the next of kin are approached and

asked about organ donation after the death of their loved one. Currently in Western Australia the consent rate following a formal request for organ donation is 65%.

2. *Internal hospital processes* - This includes detection of potential donors, education of staff, a professional approach towards the family and ongoing support for next of kin. A discussion on these strategies is contained in a summary of the current system operating in Western Australia.

3. *New pathways to donation* - Expand the pool of potential donors by increasing the minimum acceptable criteria or introducing new pathways to donation such as donation after cardiac death.

It is clear that there are synergies between the strategies to improve donation and international comparisons have not determined a single clear avenue that will improve donation rates if introduced alone[28 29].

The synergy within a well implemented opt-out registration system includes sudden urgent need of family discussion about the organ donation question, realisation of current very low rates of organ donation, large media attention, change of the accepted civic attitude support by efficient intra-hospital organ donation and transplantation systems [30 31 32 33]. All these elements combine to impact on the donation rate.

Another important aspect of the donation system is that it is essential to dispel myths which exist regarding organ donation such as; a person not being dead, doctors making less effort to keep someone who is a known donor alive, the same doctor in hospital is responsible for the care of the patient and the transplantation process and organs of young people are the only organs wanted for transplants [34]. The support of the West Australian community is integral to the donation and transplantation system and any changes being considered.

The relationships between strategies are multi-faceted and subsequent discussion looks at the current system as it is operating in WA and considers the implications of an opt-out registration process.

What is the current progress and results from the national reform agenda; "World's Best Practice Approach to Organ and Tissue Donation For Australia"?

In 2008, the Commonwealth government committed $136.4 million of new funding over four years to reform organ and tissue donation for transplantation in Australia by introducing legislation to create the Australian Organ and Tissue Authority to lead the reform agenda.

This is based upon a 9 measure plan:[35]

- 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

Western Australia has committed to the COAG process until June 2012.

In Western Australia the introduction of DonateLife has increased the presence of organ donation staff in hospitals engaged in improving the systems of identification and management of potential donors in the public and private health care settings from 8.1 to 19.2 FTE. The salient results so far are:

1. A clinical trigger for donation has been introduced in all West Australian ICU's and metropolitan Emergency Departments to help identify potential donors. An audit of hospital deaths with the appropriate mortality is being conducted in metropolitan hospitals with Emergency Department's or ICU's.

2. Expanding the pool of potential donors through the introduction of the donation after cardiac death pathway. This pathway has just been introduced at Royal Perth Hospital and Fremantle Health Service with Sir Charles Gairdner Hospital to follow in 2011. These hospitals have the appropriate acuity and infrastructure to support the donation after cardiac death pathway capability. In the medium term, Princess Margaret Hospital will also be considered for the program.

This national approach is only in its infancy but early indications are that the donation rates in Australia are trending upwards from an average of 10 dpmp to 11.3 dpmp in 2009 to a projected 13.5 dpmp in 2010.

So far the results are not as marked in Western Australia as in some of the eastern states. This is due to the fact that DCD has been introduced earlier by the other states because of legal issues requiring resolution in Western Australia (Acts Amendment Act - *Consent to Medical treatment Act 2008)*. Western Australia's intra-hospital performance was already excellent due to the dedication of the ICU staff and the prevailing mortality rate in Western Australia. Two West Australian hospitals are consistently in the top ten organ donating hospitals in Australia and six of the nine ICU's in the metropolitan area have previously participated in solid organ donation. This participation is appropriate in context of patient acuity at the ICU's.

Therefore DonateLife WA has put in place the foundations for increase of the donation rate through the development of the DCD program from which Western Australia can expect an additional 2 to 3 dpmp.

Despite strategies to improve the consent rate above the prevailing 65% there has been no improvement in the willingness of the West Australian community to agree to organ donation at the time of formal approach. This issue needs to be the focus of the future improvement strategies.

The choice will be between:

1. Developing the community's awareness through a major media campaign focusing on improvement in the rate of registration such as Project Forward, or

2. Changing the system of registration from opt in to opt-out.

What is the current organ and tissue donation system in Western Australia and why is it flawed?

Western Australia has an 'opt-in' organ donation policy, where citizens can indicate their preference to be an organ donor by registering online or via a form available from Medicare Australia who administer the Australian Organ Donor Register (AODR). If a person does not 'opt-in' it is assumed either they were not aware of how to register, they were not motivated enough to register or they do not wish to consent to be an organ donor.

At the time of death, the next of kin of the deceased is required to consent to organ and tissue donation.

Tissues and organs will not be removed if it is known the deceased had voiced objections to organ donation during their lifetime.

Each state has their own relevant legislation. In Western Australia this is effected by the *WA Human Tissue and Transplant Act (1982)*.

The AODR was established in January 2005. It is the only national registry for organ donation. Registration via driving license was abandoned in most states apart from New South Wales. NSW retains a Road Traffic Authority Donor Registry and utilises both the AODR and the RTA Registry to determine the most current consent status of the donor.

The majority of state based registries linked to driving licences were abandoned because:

- Not everyone has a driver's license;

- The wish of the person should not be visible on a portable document so that there is no perception that they are not treated for their best interest because they are registered donors;

- The AODR provided improved information security whereby only an authorised health practitioner is entitled to access the register once the patient has been declared brain dead and only for the purposes of considering transplantation. In Western Australia the authorised health practitioner is the Donor Coordinator;

- State based registries had inherent access difficulties when the deceased was registered in another state.

The flaw of the AODR is despite 77% of the population willing to be an organ or tissue donor only 39.28% of the eligible population has registered.

WA Registrations on the AODR		
Total WA Population on AODR as at:-	08/2010	**686,784**
% of WA Population on AODR		
WA Population (ABS)		2,171,197
> 16 Years old		1,743,344
% of WA Population on AODR		31.54%
% of WA Population over 16 years on AODR		**39.28%**
Total Objections at 2009		**1801**

Why will a change of legislation to improve registration into the Organ Donation Register reduce the objection rate by families?

There are various organ and tissue consent processes. The two main aspects integral to organ donation policies worldwide are:

1. Type of registration active around the world

    a. *Opt in (expressed consent):* People are required to provide consent or intent to be an organ/tissue donor through some form of action such as expressing the wish to family members or registering on some form of Organ and Tissue Donation Register.

    b. *Opt-out (presumed consent)*: People are presumed to be pro organ donation, unless they have registered to 'opt-out' or refuse to be a donor.

2. Influence of family and next of kin

    a. *No influence or consultation*: only the register is consulted by the doctors and coordinators before the decision.

    This paper does not consider an opt-out registration system that excludes the next of kin from the decision making process at the time of donation. There are insurmountable challenges to this concept in an Australian context with regard to:

    - Potential for complication to the grieving process of families of donors [36] [37];
    - Ethics of the model [38] [39] [40];
    - Potential for legal challenge [41] [42];
    - Introduction of increased clinical risk [43] [44];
    - The risk to marginalised societal groups and adults that lack decision making capacity [45];
    - The impact on health care professionals [46] [47] [48].

b. *Family and Next of Kin are consulted and have the power of veto*: The doctor considers the family's wishes and then decides.

In Australia, the current system is "opting in" with family power of veto. In Belgium, it is "opt-out" with family power of veto. In practice, healthcare professionals seek family consent in a range of opt-out systems although it is not compulsory to do so [49]. The implications of this difference is significant.

The practical problem of the "opting in" is simple:

- 77% of the population is pro-organ donation.
- Less than 40% of West Australians register an opinion.
- 60% advise their next of kin but may or may not register the decision on the AODR.
- 40% of Australians do not know the wishes of their loved one regarding donation.

There is 35% objection rate in Western Australia. From year to year there is capacity for 15% to 20% improvement in the rate of consent through a system that positively and simply records the wishes of the population more effectively.

A 15 to 20% increase in the consent rate would result in an additional 2 to 4 life saving organ donors per year. Improvements in the consent rate would synergise greater gains from improvements in other areas of the donation system.

The solution offered by a well implemented "opt-out" is:

- 77% of the population is generally pro-organ donation.
- 15% - 20% of the population registers its objection after a prolonged campaign encouraging them to do so.
- Healthcare professionals are able reframe the discussion with family members with improved confidence in the knowledge of the deceased wishes, in all cases the family will know that the person has not 'opted out'
- The family objection rates drops significantly thereby increasing the organ donation rate.

Currently in the absence of information contained on the AODR the dialogue between the Coordinator or Intensive Care physician and the family is in 60% cases:

Your family member is now a potential organ donor but we do not know his intentions about it.

35% of families refuse organ donation

Once an opt-out system is implemented it becomes :

Your family member is a potential donor and we know that he has not recorded any objection to become a donor.

Only an estimated 20% of families refuse organ donation

The fact that a health care professional can in nearly all cases give a clear indication on the wish of the patient is crucial in assisting the family's decision making.

The impact of implementing an opt-out policy draws upon other major aspects:

- The fact that the topic suddenly becomes important in the society debate and the crucial family discussion about the organ donation question takes place;
- The publication of organ donation rate and the reality of current very low rates of organ donor enable families and individuals to understand the situation. The true level of objection encourages the acceptance that action is required;
- Parliament is involved and the profile of organ donation becomes prominent;
- Media participation of the reform provides opportunity of education and dialogue;
- A culture shift happens with change of the accepted civic attitude;
- A multiplier effect of increasing organ donation takes place. Organ donation and transplantation becomes a true success story and success creates further progress and confidence in the system.;
- A civic pride to achieve the most generous system in the world increasingly reinforces the perception that the right attitude is to donate.

The impact of these aspects is difficult to quantify or extract from the literature. Discussions with staff and persons living in opt-out countries show that over time, the choice of the opt-out system gains acceptance and engenders civic pride[50].

It is important to note that analysis of the effect of an opt-out system on its own does not support a direct positive effect on the rate of donation [51] [52] [53] [54] [55]. Rather it is the cumulative effect of increased awareness around organ and tissue donation and the systems that support donation that generate positive movement in the donation rates.

Why did Belgium adopt an opt-out system?

After the introduction of Cyclosporine A a potent immunosuppressant in 1984, transplantation of all organs became very successful. The problem of the poor organ donation became very acute. For two years, a very intensive public debate took place in order to promote a better system of registration of the wish of all Belgian residents. The two key arguments for its introduction were:

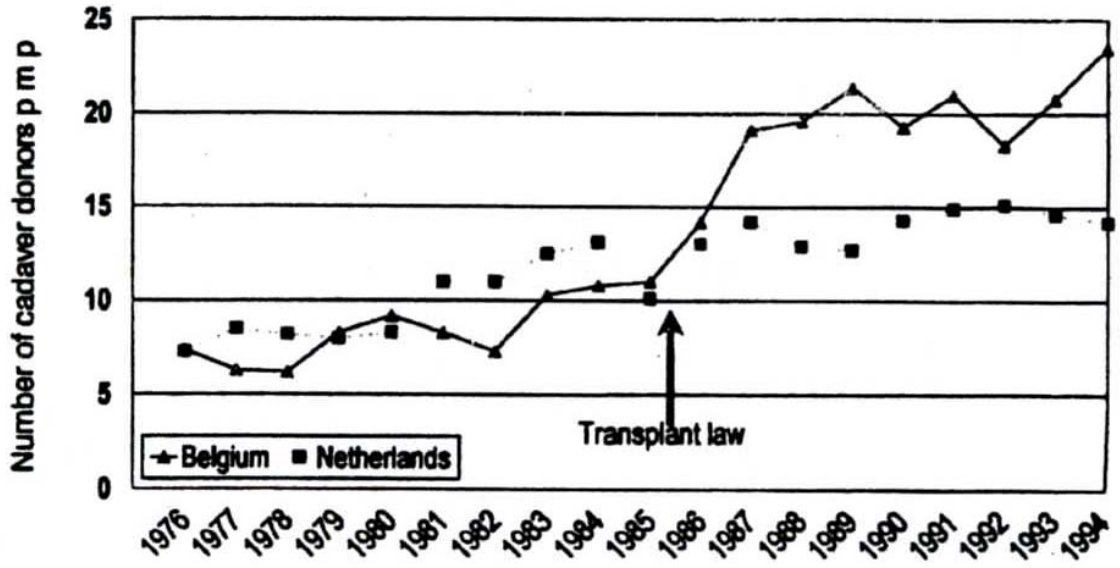
1) Statistics showing that over 95% of the population were in favour of donation. Therefore the onus was placed on the minority to register their 'No' [56].

2) Common sense that family acceptance would come out of a clear system capturing all the population.

What was the impact of the adoption?

Within 3 years of implementation, the organ donation rate had doubled from 11 pmp (current rate in Western Australia) to 22 pmp and has remained stable ever since.

Figure 8: Number of donors (dpmp) in Belgium and the Netherlands



Were experiences in other countries consistent?

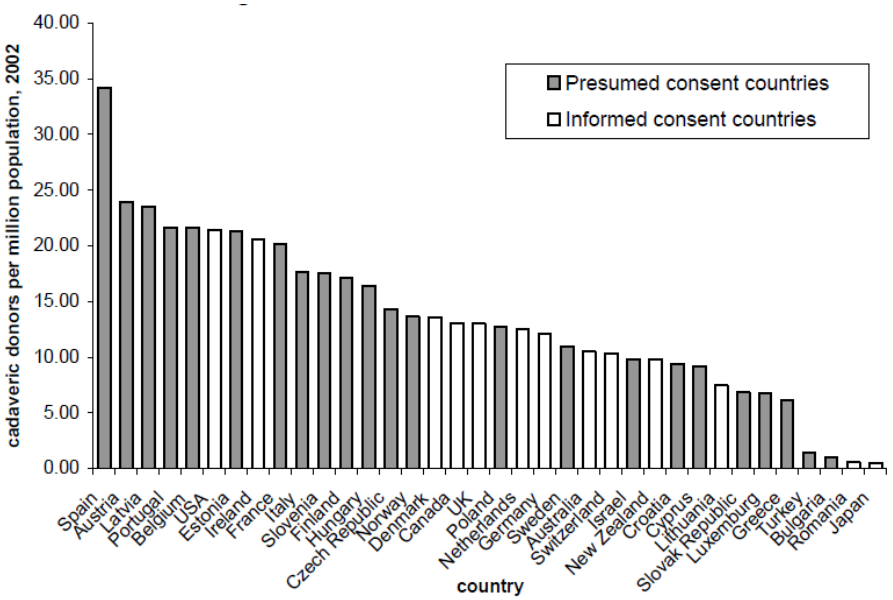
The effect of the introduction of an opt-out system is not always immediate and positive as evidenced by the 10 year lag between the introduction of the opt-out system in Spain in 1979 and the increase in organ donation rates from 1989 [57]. In Brazil the introduction of an opt-out system was troubled by a lack of understanding within the community and increased distrust in the medical system leading to a decline in the donation rates that has yet to completely recover [58]. The opt-out system was introduced in 1997 and repealed in 1998 [59].

More recent analysis suggests that the system of registration considered on its own has no discernable effect on donation rates [60] [61] [62]. Alternately participants working in opt-out systems see the value of the system in its creation of a society that values organ donation as the morally right thing to do [63].

A vast array of research papers and reports have analysed the difference between the two consent processes and whether this in fact affects the donation rate, with some reporting presumed consent organ donation programs increase the donation rate by 25% to 30% [64] [65]. Other papers suggest that there is no net effect attributable directly to system of consent [66] [67] [68] [69] [70]. Additionally there are success stories, Belgium and failures, Brazil.

Rithalia et al (2009) in a comparative review of five European countries before and after introduction of opt-out attributed an estimated 25% of the increase in dpmp was associated with opt-out legislation. This review also concluded that presumed consent alone did not explain the difference between a country's dpmp. Rather it was a combination of legislation, availability of donors, organisation and infrastructure of the transplant service, wealth and investment in healthcare, public attitudes and awareness. The paper cautioned that the relative importance of various elements to the organ donation and transplant systems represented an unknown for the purposes of planning and predicting effects.

Figure 9: Type of consent, by Number of Donors (dpmp) in 2002 Worldwide[71]



It is clear that in 2002 most countries with opt-out legislation have higher organ donation rates than most countries with opting in legislation.

However exceptions exist in both directions and there has been significant movement since 2002 in the performance of countries that do not appear to be dependent on the system of consent.

The USA and Ireland have the same organ donation rate as Belgium despite an opting in system. These two countries have newly reinforced organ donation agencies and strong cultural vision of community generosity.

Countries with opt-out legislation can do less well than Australia but may not have comparable standards of healthcare (e.g. Croatia, Cyprus and Turkey).

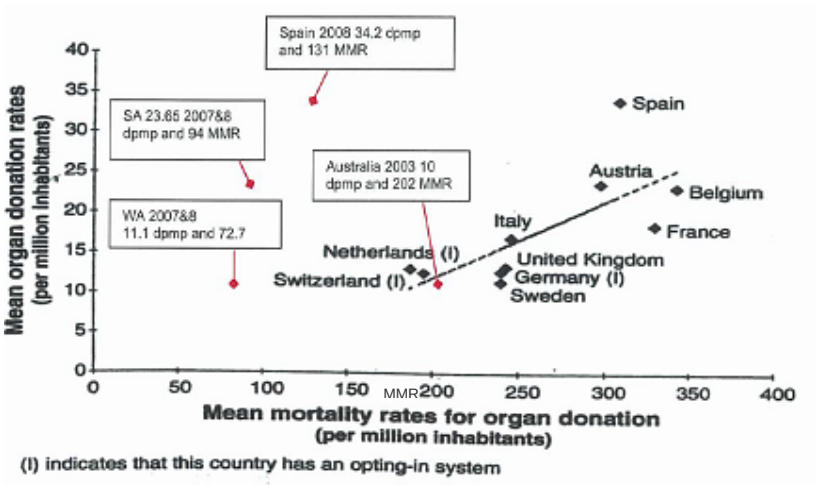
Will the opt-out system definitely improve organ and tissue donation in Western Australia?

Some studies have reported that a change from informed to presumed consent does not guarantee increasing the donation rate [72] [73] [74]. They attribute the success of the donation system to a combination of elements including the fact that the countries having opt-out legislation also happen to be those with a high rate of mortality from traffic accident and cerebral bleeds. Other studies are more direct in their assessment of the link between donation rates and mortality rates [75] [76] [77].

In order to assist with the current decision to be taken we have attempted to apply the same method used by Coppen et al [78] to determine the benefits that could be expected.

The data is not used as common international comparison like dpmp because it is difficult to produce. From our best analysis of the mortality data updated rates have been plotted on the graph below.

Figure 10: Relevant mortality rate and average donation rate per million of the population[79]



In Figure 10, the Australian, West Australian and Spanish data has been added to indicate relative performance. Five year average dpmp rates have been used to remove fluctuations in the Australian data. The mean mortality rate (MMR) data was averaged over two years for the Australian date. The method utilises total deaths within the population in the groupings of motor vehicle accidents (MVA) and cerebrovascular accidents (CVA) in the population under 65 years old standardised to a MMR of deaths per million population. This data is also presented in the table on the following page.

The relatively low MMR for Western Australia is consistent with the lower mean West Australian population age as CVA mortality exponential increases with increasing population age.

From this we can conclude although introducing opt-out may have an effect but it will not be as dramatic as the Belgium results.

International and jurisdictional Comparison Using Coppen et al 2005 method	Males	Females	Persons Total	Spain adjusted deaths per million Per Million Population (38,440,252) <65 y.o. at 2001]*	Australia adjusted deaths per million Per Million Population (17,296,905) <65 y.o. at 2003]**	Australia adjusted deaths per million Per Million Population (18,773,537) <65 y.o. at 2007]**	West Australia adjusted deaths per million Per Million Population (1,853,479) <65 y.o. at 2007]**	*South Australia adjusted deaths per million* *Per Million Population (1,343,581) <65 y.o. at 2007]***	Australia adjusted deaths per million Per Million Population (19,035,206) <65 y.o. at 2008]**	West Australia adjusted deaths per million Per Million Population (1,912,776) <65 y.o. at 2008]**	*South Australia adjusted deaths per million* *Per Million Population (1,359,900) <65 y.o. at 2008]***	Spain adjusted deaths per million Per Million Population (39,124,889) <65 y.o. at 2008]**
CVA Spain 2005#	4,267	2,593	6,860	178								
MVA Spain 2005#	3,216	776	3,992	104								
CVA/MVA total Spain 2005#	7,483	3,369	10,852	282								
CVA Deaths Australia 2003#	1,197	930	2,127		123							
MVA Death Australia 2003#	1,020	353	1,373		79							
CVA MVA Total Australia 2003#	2,217	1,283	3,500		202							
CVA Deaths Aus 2007##	438	319	757			40						
MVA Deaths Aus 2007##	448	139	587			31						
CVA MVA Total Aus 2007##	886	458	1,344			72						
Combined Totals Intentional Self Harm and Assaults##			1415			75						
Total CVA, MVA, Self Harm, Assaults			2,759			147						
CVA Deaths WA 2007##	30	24	54				29					
MVA Deaths WA 2007##	85	27	112				60					
CVA MVA Total WA 2007##	115	51	166				90					
Combined Totals Intentional Self Harm and Assaults##			203				110					
Total CVA, MVA, Self Harm, Assaults			369				199					
CVA South Australia 2007##	37	24	61					45				
MVA South Australia 2007##	57	19	76					57				
CVA/MVA total South Australia 2007##	94	43	137					102				
Combined Totals Intentional Self Harm and Assaults##			144					107				
Total CVA, MVA, Self Harm, Assaults			281					209				

International and jurisdictional Comparison Using Coppen et al 2005 method				**Spain adjusted deaths per million**	**Australia adjusted deaths per million**	**Australia adjusted deaths per million**	**West Australia adjusted deaths per million**	***South Australia adjusted deaths per million***	**Australia adjusted deaths per million**	**West Australia adjusted deaths per million**	***South Australia adjusted deaths per million***	**Spain adjusted deaths per million**
	Males	**Females**	**Persons Total**	**Per Million Population (38,440,252) <65 y.o. at 2001]***	**Per Million Population (17,296,905) <65 y.o. at 2003]****	**Per Million Population (18,773,537) <65 y.o. at 2007]****	**Per Million Population (1,853,479) <65 y.o. at 2007]****	***Per Million Population (1,343,581) <65 y.o. at 2007]****	**Per Million Population (19,035,206) <65 y.o. at 2008]****	**Per Million Population (1,912,776) <65 y.o. at 2008]****	***Per Million Population (1,359,900) <65 y.o. at 2008]****	**Per Million Population (39,124,889) <65 y.o. at 2008]****
CVA Deaths Aus 2008##	464	347	811						43			
MVA Deaths Aus 2008##	465	140	605						32			
CVA MVA Total Aus 2008##	929	487	1,416						**74**			
Combined Totals Intentional Self Harm and Assaults##			1,724						91			
Total CVA, MVA, Self Harm, Assaults			3,140						165			
CVA Deaths WA 2008##	47	31	78							40.78		
MVA Deaths WA 2008##	32	0	32							16.73		
CVA MVA Total WA 2008##	79	31	110							**57.51**		
Combined Totals Intentional Self Harm and Assaults##			235							122.86		
Total CVA, MVA, Self Harm, Assaults			345							180.37		
CVA South Australia 2008##	37	29	66								*49*	
MVA South Australia 2008##	41	10	51								*38*	
CVA/MVA total South Australia 2008##	78	39	117								***86***	
Combined Totals Intentional Self Harm and Assaults##			147								*108*	
Total CVA, MVA, Self Harm, Assaults			264								*194*	
CVA Spain 2008**	1,548	842	2,390									61
MVA Spain 2008**	2,201	539	2,740									70
CVA/MVA total Spain 2008**	3,749	1,381	5,130									**131**
Combined Totals Intentional Self Harm and Assaults**			3,283									84
Total CVA, MVA, Self Harm, Assaults			8,413									215

* Population statistics derived from the Institution National de Estadistica data www.ine.es

Mortality rates derived from the World Health Organisation Mortality Database www.who.int the most recent complete dataset for each country was used.

Mortality data derived from Australian Bureau of Statistics data www.abs.gov.au

** Mortality data derived from Instituto Nacional de Estadistica data www.ini.es

Why did recent review in Australia, the United Kingdom, Queensland and Tasmania investigate but so far postpone the introduction of an opt-out registration system?

Under the drive of Prime Minister Gordon Brown, the UK Government had introduced a bill for opt-out to be discussed by Parliament in 2004. The introduction of this bill was supported by the British Transplant Society and the Medical Council.

Parliament asked for special taskforce to report on the issue. The report of the taskforce was published in 2008. After extensive research the UK Organ Donation Taskforce recommended the UK should not move to an 'opt-out' program and more investment should be focused on implementation of the 14 recommendations in improving management and awareness of organ donation. They recommended that if organ donation rates have not increased by 50% in five years the notion of 'opt-out' would be revisited for consideration[80].

The Queensland and Tasmanian Government published in 2008 large review papers reviewing the same issues and coming to a similar conclusion in relation to the Australian National Reform Agenda following widespread consultation it was determined that the recently introduced reforms should be given time to have an impact before opt-out should be considered.

With careful consultation with the community, health and legal forums to consider and support the proposal we do not believe that these reviews should be considered as a barrier to Western Australia.

It is essential on this matter to understand that people opposing organ donation are a small but very vocal group. Their ability to steal the debate from a law that would suit the majority of the population has to be perceived and made relative. We should strive to develop a true Western Australian community vision of participating in life giving, life enhancing activities. This initiative should be to build and strengthen our community values.

All Western Australians to some extent will be affected if changes are made to the organ donation policy from simply registering a choice; to being a family member making a decision regarding donating organs of a loved one; to being a donor oneself.

What are the risks and benefits of introducing opt-out legislation in Western Australia and how to control them?

There are several risks that are present in the proposal. They fall into two categories defined by Western Australia's ability to influence the outcomes.

Risks over which Western Australia has a higher level of control include:

Risk	Mitigation Strategy	Consequence
The potential for higher than expected registration of objections to donation on the AODR.	Active positioning strategy as responding to our community's aspiration and not as a governmental requirement of citizens to participate. Continued education and marketing around organ and tissue donation to allow people to reconsider a decision not to donate at any point during their life time.	It will not be possible to actively approach the families of individuals who have registered a decision not to donate. The result could be anywhere between 15 to 35% based on WA and NSW data. At last review WA has approximately 1801 registered objections.

Risk	Mitigation Strategy	Consequence
Minority and disadvantaged groups are adversely effected by the change to an opt-out registration system.	Recognise early the concerns and objections of minorities and address them factually and seriously. Next of kin approach and authorisation remains integral to the model.	Negative media and confused messaging around the opt-out registration system.
Itinerant workforce, recent migrants to the state and tourists are disadvantaged by the opt-out registration system.	Next of kin approach and authorisation remains integral to the model. People living in WA for over 6 months should be made aware of the needs to register their objection if they have never expressed their wish for organ donation. The mechanisms for them to be made aware of this necessity needs discussion.	N/A
Lower levels of participation among health care professionals as a result of ethical concerns with the system.	Clear factual messaging around the reasons for the change. Next of kin approach and authorisation remains integral to the model.	Lower donation rate.
Lower levels of trust in the public health system in relation to organ tissue donation. Trust is important to the acceptance of organ donation. Trust refers to multiple aspects of the organ donation process including; the manner in which consent is recorded and stored, the medical practitioner performing transplantation and government coordination. Without trust, people will 'opt-out' of organ donation or family members may not authorise the organ donation process to occur.	Clear factual messaging around the reasons for the change. Media campaign and factual information over an appropriate period will generate trust in this new approach. Common sense is the strongest advocate for the case of opt-out. Emphasis to be given to the community's overwhelming support of organ and tissue donation. Encourage and respect choice. Promotion of life giving choices.	Lower donation rate.

Risk	Mitigation Strategy	Consequence
The debate is shifted away from the impact of opt-out legislation to one of individual rights to autonomy.	Individual or patient autonomy is integral to the organ donation process. Not only does it ensure the correct decision is made regarding organ donation, it also relieves any burden of decision making from family and medical practitioners. In all instances, the ideal system for organ donation is one which ensures the patient's wishes are respected. Messaging to emphasise that a well implemented opt-out system respects individual autonomy as each person can register their decision not to be an organ and tissue donor.	Confused messaging and potentially higher registration of no consents.

Risks over which Western Australia has a lower level of control include;

Risk	Mitigation Strategy	Consequence
The Commonwealth does not provide agreement to amend the messaging around the AODR for West Australians.	Limited. Creation of an alternate system of registration.	Confusion in the messaging around multiple systems of consent. No single system to capture all West Australians in place. Establishment costs and access difficulties. Data migration costs.
The Commonwealth withdraws funding for Western Australia's component of the organ and tissue reform agenda as a result of a breach of the funding agreement.	Work with the Commonwealth to ensure proceeding with an opt-out system will not impact on the reform agenda by delaying the introduction until after 30 June 2012.	Loss of approximately $5.5 million in funding over 2 years.
Minority and disadvantaged groups are adversely effected by the change to an opt-out registration system.	Recognise early the concerns and objections of minorities and address them factually and seriously. Specific messages will need to be developed for the implications of opt-out for these groups. NOK approach remains integral to the model.	Negative media and confused messaging around the opt-out registration system.

Benefits

An increase of the Western Australian donation rate and the continuation of Western Australia's live kidney donation programme would:

- Allow each transplant programme to cover annually the needs of the West Australian population;
- Reduce to less than 5% the rate of death on waiting lists in renal and liver transplantation;
- It would reduce dramatically the need to place patients on extremely expensive ventricular assisting device whilst on the waitlist;
- Progressively reduce the number of patients on waiting list.

The public knowledge of these achievements would be the most important factor to justify the bold decision taken.

What are practicalities of implementing opt-out?

Once an Act of Parliament has been proclaimed, a six month period should be allocated so that people can register their objection if they so wish. The best mechanism is for it to be registered as an objection to donation on the AODR. The AODR is a consent/intent based registry operated by Medicare under the auspice of the Health Insurance Commission Amendment Bill 2002.

1. It is an established and safe national registry;
2. The forms are readily available;
3. The website is existing and function, and
4. It is an established policy for secure and privileged access

Distribution of brochures occurs through Medicare offices, DonateLife WA and the WA Department of Transport via direct mail with license renewal notices. Agreement would need to be sought from the Commonwealth to utilise the AODR, Medicare offices, DonateLife WA to distribute the forms with different associated messaging for West Australians.

Presently Western Australia is committed through the Council of Australian Governments process to the 9 measures of the National Reform Agenda for Organ and Tissue Donation Reform until 30 June 2012.

By using the AODR, no new tools, form, website or registry needs to be created. The same registry is used but populated with a different emphasis.

The media campaign would need to be significant so that people know and trust the new system.

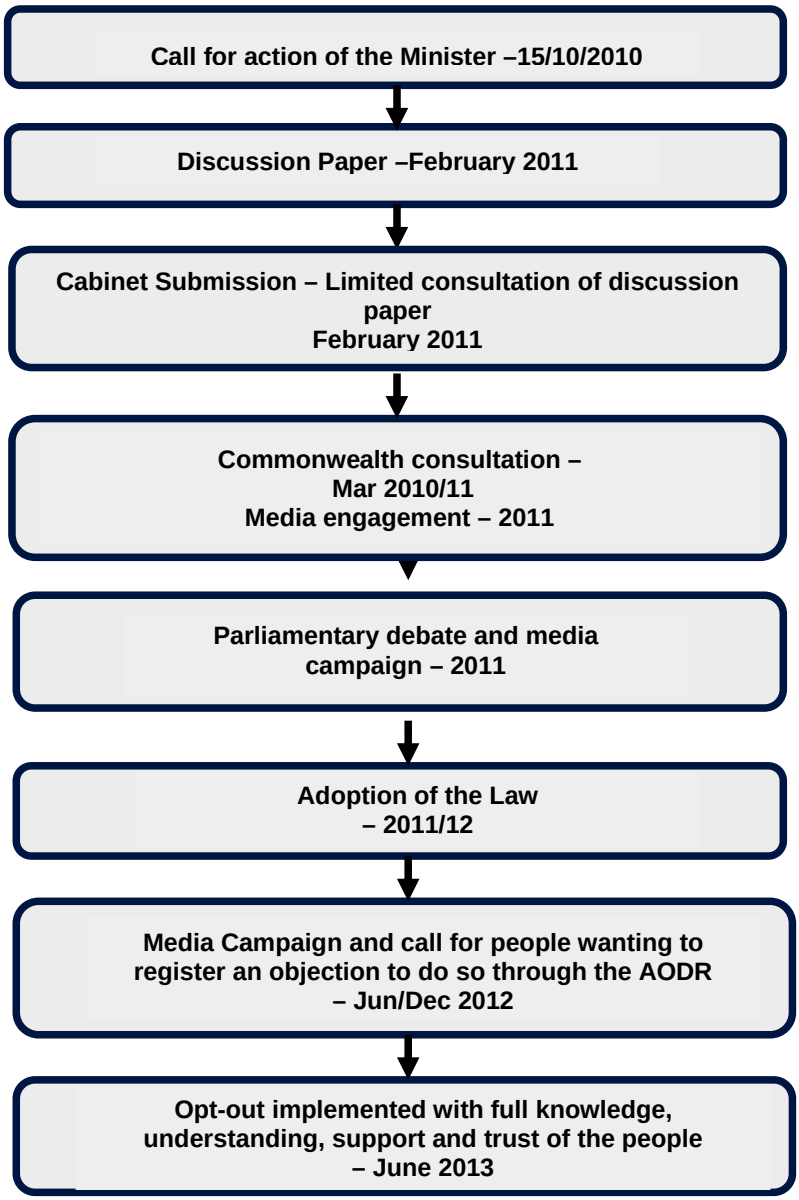
The cost of this reform will be predominately advertising on a large scale during the first year and subsequent smaller campaigns to ensure ongoing awareness of the requirement to opt-out in subsequent years. An estimated budget of $3 to 5 million should be considered for the implementation strategy.

In the event that agreement with the Commonwealth was not forthcoming on the use of the AODR with alternate messaging the establishment of an independent register for Western Australia would need to costed and will have an impact on the timeframe for an introduction of an opt-out system. Movement away from a single national registry would be a backward step for Western Australia in light of the investment over the five years since the introduction of the AODR.

How long will it take to shift from opting in to opt-out?

The process would take up to 2 to 3 years. It is essential to develop clear strategies to consider the roles, rights and impact on various groups within the West Australian community including:

- The donor, family and friends;
- Children (16 years and younger);
- Medical practitioners and allied health staff;
- Cultural and religious groups;
- People with disabilities;
- Non-residents, and
- Hard to reach groups/remote groups.



Is now the right time to commence moving to opt-out?

Western Australia has committed through the COAG process to the 9 measures until 30 June 2012. This commitment has been executed through the signing of funding agreements for staffing until 30 June 2012 and a communication charter and framework. The communication charter and framework commits Western Australia to stay on message with a primary emphasis on the "Discover Decide Discuss" campaign.

Discussion is the primary and registration is the secondary message within the communication strategy.

In the context of current commitments between Western Australia and the Commonwealth on the organ and tissue reform agenda, the 2010/11 and 2011/12 financial years do not represent clear opportunities for Western Australia to commence moving to opt-out without jeopardising funding and legitimacy within the COAG arena.

What would the law look like?

The draft of the 2004 UK law is a very clear template for the law envisaged in Western Australia. It is suggested that the terminology in the UK draft example on the following page should be amended from "consent to donation" to "agreement to donation" in a Western Australian bill. The effect of this suggestion would be to separate in the mind of the community the potential donor's agreement to donation from the consent required from the family at the time of donation.

Organ Donation (Presumed Consent and Safeguards) Bill

A Bill to provide for the removal of organs for transplantation purposes, after death has been confirmed in a person aged 16 or over, except where a potential donor previously registered an objection or where a close relative objects.

Be it enacted by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows: -

1. Presumption of consent for donation of organs

(1) Where a person has not during his lifetime registered an objection to his body, or any specified part of his body, being donated for transplantation after his death it shall be presumed that he consented to such donation –

(a) except where the designated person is satisfied, on the basis of information provided by a person's spouse or partner (or, where there is no spouse or partner, by a parent or child of the deceased),
that the person had expressed an objection to donation that had not been registered; or

(b) to proceed with the donation would cause distress to the person's spouse or partner (or, where there is no spouse or partner, to a parent or child of the deceased).

(2) In the case of a child aged 16 years or under there shall be no presumption of consent, and donation may proceed only if the designated person is satisfied that such donation is in accordance with the wishes of the child,
or with the consent of the child's parents or other primary carer.

2. Register of objection to transplantation of organs

(1) There shall be register of those persons who object to their organs being used for transplantation.

(2) Where it is intended to remove any organ of a deceased person for the purposes of transplantation, the register established under subsection (1) must be consulted to determine whether the person had registered an objection.

(3) Regulations shall make provision relating to the register established under:

Subsection (1) and in particular in connection with –

(a) the manner in which a person is able to register an objection;
(b) the manner in which the register must be consulted before the removal of organs for transplantation.

(4) Regulations under subsection (3) shall be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

3. Death of person donating organs

No organs may be removed from a person whose organs are intended to be used for transplantation unless two registered medical practitioners, independent of the medical practitioners who would be responsible for transplanting the organs, have satisfied themselves that the person is dead.

(1) This Act extends to England and Wales only.

Conclusions

- Implement an opt-out policy for registration on the AODR in Western Australia. From the data available it may have an impact on the objection rate from families and therefore increase organ donation. The best case scenario would be a projected net increase of between 1 to 2 dpmp (2 and 4 actual organ donors) per year.

- 16-18 dpmp represents the maximum achievable rate in Western Australia subject to improving the consent rate to 80%. The community's goodwill needs however to be assisted by introducing opt-out or optimising the current opt-in system. It is the Western Australian community and their support that will enable this next level of improvement to the consent rate.

- Intra-hospital improvements made under the National Authority program are having an impact including detection for potential donors and education of staff.

- Expand the pool of potential donors by increasing the minimum acceptable criteria or introducing new pathways to donation such as donation after cardiac death being implemented by the National Authority program. There is potential to increase the organ donation rate in Western Australia from 11 dpmp to between 14 to 16 dpmp with the current introduction of donation after cardiac death.

- Western Australia's organ donation rate is limited by very low mortality rates in comparison to international rates and Australia as a whole. Therefore the consent of donors and donor's families is paramount to the Western Australian organ donation system as it is an essential limiting factor.

- The media campaign necessary to inform and create such a shift in culture around this sensitive issue is essential to the success of this venture. Without bi-partisan support in parliament and the community this project should not be attempted.

- Prior to proceeding with an opt-out registration system, agreement should be sought from the Commonwealth regarding the security of the funding and the capacity to introduce this initiative in parallel to the current reform program. An alternate option of sequencing the opt-out initiative to follow the current reform agenda after 30 June 2012 can be explored if this agreement is not forthcoming.

- If the opt-out system is judged by the Executive and the Parliament to be a strategy whose time has not come or whose impact is too uncertain or small compared to the resource and political investment required, the current system of opting in should be pushed to its full potential by the use of community awareness raising media strategy such as those proposed in the Project Forward project.

- Whichever option is chosen, it is clear that Western Australia cannot accept a system where the generosity of its people is not fully realised.

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