

Discussion Paper:

**The use of ante mortem (before death)
interventions for organ donation in NSW**

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GLOSSARY

Ante mortem interventions	Treatments which may be administered before a patient's death, for the purpose of organ donation, which are of no medical benefit to the patient.
Anticoagulants	Blood thinning medications used to prevent formation of a clot, for example heparin.
Donation after Circulatory Death (DCD)	DCD is the process of organ donation following the death of a person whose heart has stopped beating (after cessation of circulation of their blood). The term "cardiac death" was previously used for this pathway to organ donation.
Donation after Brain Death (DBD)	DBD is the process of organ donation following the death of a person as a result of irreversible cessation of all function of their brain. The person dies because their brain is no longer receiving a blood supply (due to injury or disease such as stroke) and stops working.
Heparin	An anticoagulant medication
Hypotension	Abnormally low blood pressure.
Inotropes	Medications that improve circulation of the blood by affecting the force of muscular contractions in the heart or the diameter of blood vessels.
Non-therapeutic Interventions	Medical treatments, such as medications or procedures, which do not improve the patient's condition or stop it from deteriorating.
Person Responsible	The person identified by the hierarchy within the NSW <i>Guardianship Act 1987</i> who may give valid consent for medical treatment to a patient aged 16 years or over who lacks capacity.
Senior Available Next of Kin	The person, as defined in section 4 of the NSW <i>Human Tissue Act 1983</i> , who provides written consent to the removal of a person's organs and tissue after death.
Thrombolytic	Medication used to break up blood clots.
Vasodilator	Medication that causes widening of the blood vessels to reduce blood pressure.
Vasopressor	Medication that causes a narrowing of the blood vessels to increase blood pressure.

PURPOSE OF THE DISCUSSION PAPER

Access to organ donation and transplantation is an essential part of the provision of quality healthcare in NSW. Providing an organ transplant can be the difference between life and death for people whose own organ/s no longer work well enough to sustain life.

In NSW, consent for donation of organ/s after death is generally given by the patient before death - for example by registering their donation decision on the Australian Organ Donation Registry - and/or the patient's family after death.

However, if a patient is suitable to become an organ donor via the Donation after Circulatory Death (DCD) pathway, only the patient themselves is able to consent to treatments which may be administered before their death, for the purpose of organ donation, which are of no medical benefit to them. These treatments are called **ante mortem interventions**.

Unlike most other medical treatments given by a health professional, the purpose of ante mortem interventions is not for the medical benefit of the patient who will become an organ donor. Rather, it serves a public benefit in improving the function of the donated organs in order **to benefit the person or people who will receive the organs when they are transplanted**.

Some health professionals involved in organ donation and transplantation in NSW have proposed that changes be made to the law to permit the use of ante mortem interventions. The reasons these changes have been proposed are that:

- There is minimal risk to patient who is the potential organ donor
- It would align NSW with the procedures used in some other Australian States
- International experience and evidence shows that ante mortem interventions in DCD improve the function of organs after transplantation. This makes it more likely that the person who receives the organ will have a good outcome.
- The Transplantation Society of Australia and New Zealand (TSANZ) has produced evidence-based guidelines which could be endorsed as the basis for use of ante-mortem interventions.

For ante mortem interventions to occur in NSW, a major shift in policy and practice would be required to allow for treatment to be given to a patient where:

- that treatment is not for the therapeutic benefit to the patient and
- the patient is not consenting.

In this regard, it is noted that medical practitioners, and other health professionals, owe their primary duty to their individual patient. The Code of Conduct for Medical Practitioners states that:

Doctors have a duty to make the care of patients their first concern¹

¹ *Good Medical Practice: A code of conduct for doctors in Australia*; Medical Board of Australia; <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

The Code of Conduct also recognises that medical practitioners have a responsibility to protect the health of individuals and the community. While ante mortem interventions will not benefit an individual patient, they will bring a benefit to the community as a whole through improving the function of organs after transplantation.

Decisions about ante mortem interventions require a balance between a health professional's duty to their individual patient and the broader interests of the community as a whole. Balancing these interests requires careful consideration.

This paper has been prepared to canvass the complex issues relating to ante mortem treatment and allow for consultation with the community, health professionals, peak advocacy organisations and clinical expert groups.

The paper is seeking submissions on four key questions:

- 1. Should ante mortem interventions be permitted in NSW as part of DCD organ donation?**
- 2. If ante mortem interventions should be permitted in NSW as part of DCD organ donation, which of the following interventions should be permitted (see Table 2):**
 - a. Administration of medications to control blood pressure
 - b. Intravenous antibiotics
 - c. Intravenous anticoagulants, for example, heparin.
- 3. If ante mortem interventions were to be permitted in NSW, should the *Human Tissue Act 1983* be amended to allow the patient's senior available next of kin to act as a substitute decision maker for patients who lack capacity and consent to ante mortem interventions?**
- 4. What safeguards should be put in place to ensure that ante mortem interventions only occur in appropriate circumstances that do not harm the patient?**

This paper is set out in 6 parts:

- Part 1 provides background on organ donation and ante mortem interventions
- Part 2 examines the current law in respect of ante mortem interventions and organ donation
- Part 3 considers the question of whether ante mortem interventions should be permitted in NSW as part of DCD organ donation and which types of interventions should be permitted.
- Part 4 asks what would be the preferred way to allow these interventions in NSW
- Part 5 considers safeguards for ante mortem interventions
- Part 6 describes the consultation process and how to make a submission.

PART 1: BACKGROUND

1.1 What is organ donation?

Organ donation involves removing organs from someone who has died (a donor) and transplanting them into someone who, in many cases, is very ill or may die soon (a recipient). Organs that can be transplanted include the heart, lungs, liver, kidneys, intestine and pancreas.²

There are two pathways to organ donation after death (deceased organ donation). These are Donation after Brain Death (DBD) and Donation after Circulatory Death (DCD). In NSW, section 33 of the *Human Tissue Act 1983* provides³:

“For the purposes of the law of New South Wales, a person has died when there has occurred:
(a) irreversible cessation of all function of the person’s brain (brain death), or
(b) irreversible cessation of circulation of blood in the person’s body (circulatory death).”

1.2 Organ donation rates in NSW

Low rates of organ donation in NSW led to the development of *Increasing Organ Donation in NSW: Government Plan 2012*.⁴ The Plan sets out the approach for NSW to increase organ donation for transplantation and complements the Australian Government’s National Reform Programme.

There has been a continuing upward trend in organ and tissue donation from deceased donors over the last 10 years. In 2015 there were 127 deceased organ donors in NSW, a significant increase from 92 deceased donors in 2014 (*Table 1*).

	2009	2010	2011	2012	2013	2014	2015
Total organ donors	69	87	77	88	102	92	127
Donation after Brain death	54	63	59	69	86	65	87
Donation after Circulatory Death	15	24	18	19	16	27	40

Table 1: Total Number of NSW organ donors 2009 – 2015

In both Australia and overseas, Donation after Circulatory Death (DCD) has been an important way to increase the number of organs available to be transplanted (*Figure 1*).

² www.donatelife.gov.au/discover/about-donation

³ S33 NSW Human Tissue Act 1983

⁴ http://www0.health.nsw.gov.au/pubs/2012/pdf/organ_donation.pdf

In 2015, 31% (40 of 127) of all organ donors in NSW were DCD donors (Figure 2), which is a small increase on the proportion of DCD donors in 2014 (29%). By comparison, in Victoria in 2015 approximately 37% and in 2014 approximately 40% of deceased donors were from the DCD pathway.

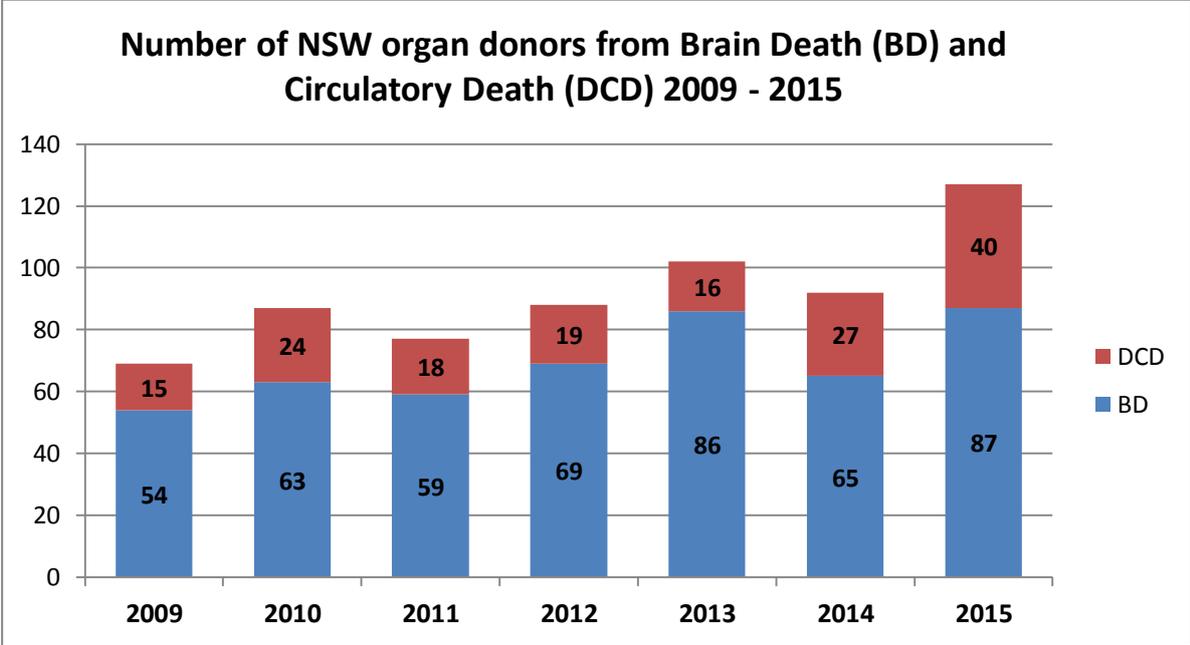


Figure 1: Number of deceased donors- NSW - by donation pathway 2009–2015

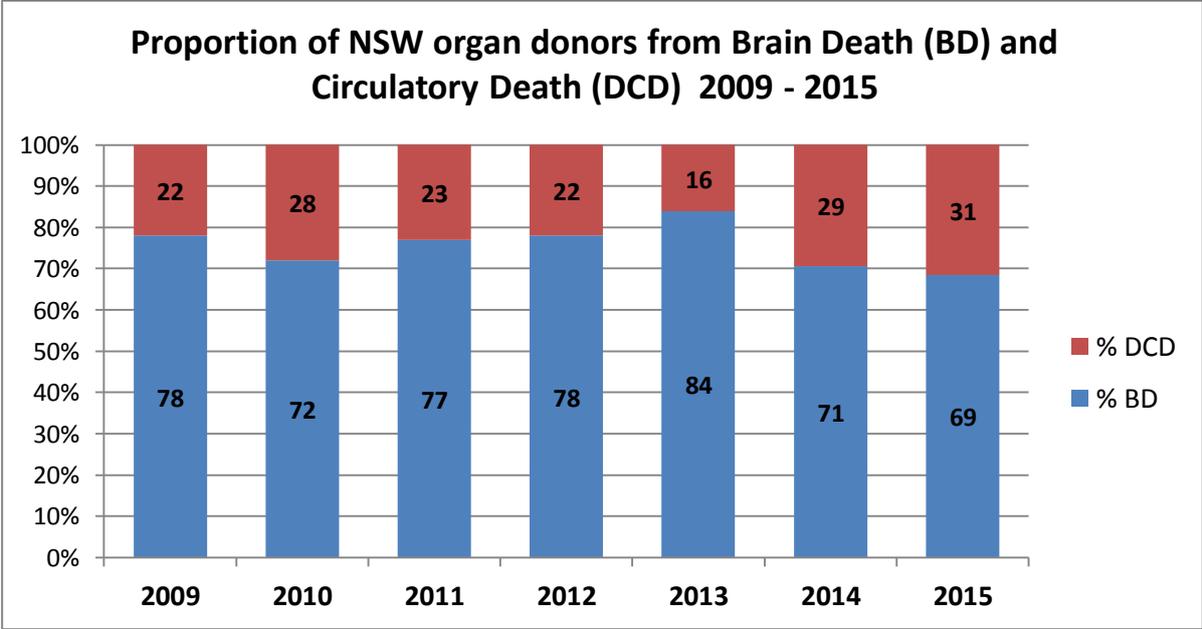


Figure 2: Proportion of organ donors – NSW - by donation pathway 2009 - 2015

Nationally, 28% of all deceased donors were from the DCD pathway in 2014 and 2015.⁵

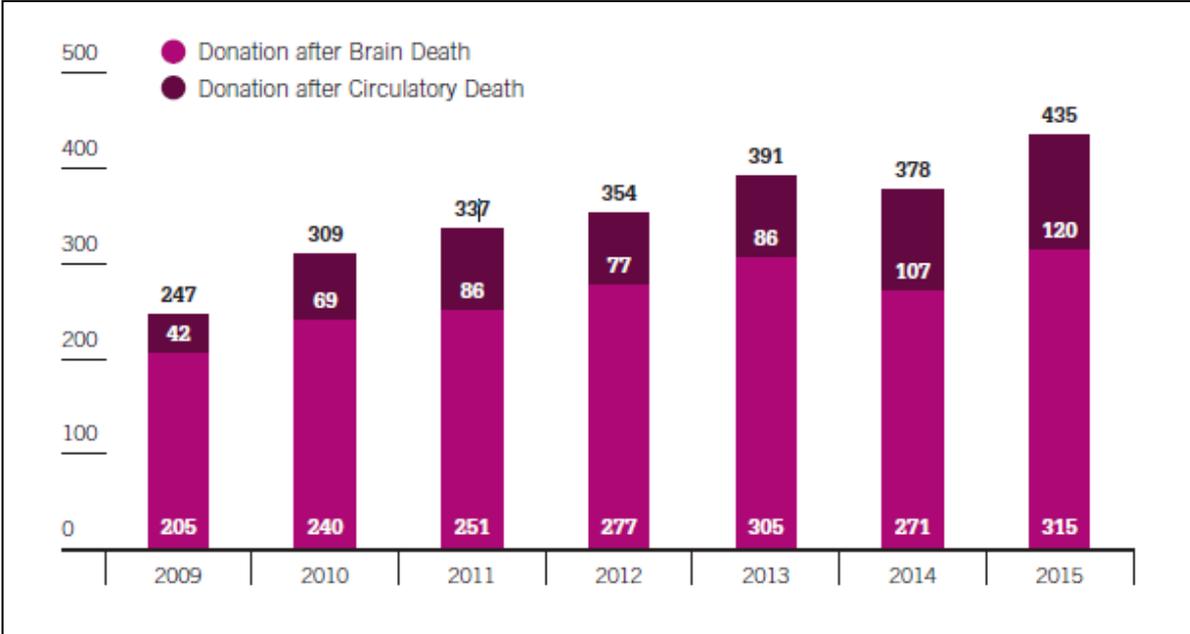


Figure 3: Number of deceased donors- Australia - by donation pathway 2009–2015

1.3 What is DCD organ donation?

Very few people are suitable to be considered for DCD. These people are patients in an intensive care unit who are so sick that their doctors agree they will not live without life sustaining measures (often referred to as life support). Usually these are patients with very severe brain injury from which they cannot recover. In rare circumstances, patients with other unsurvivable injuries or illnesses may be considered.

Only when the treating doctors and family have agreed that it is not in the patient’s best interest to continue using life sustaining measures and that these measures should be withdrawn, will DCD be considered. At this point, patients who are considered for DCD organ donation are generally unable to make their own decisions.

DCD is discussed with the family after the decision has been made to withdraw life sustaining measures.

DCD only goes ahead if the person wanted to donate their organs after death and/or the family consent to the person’s organs being donated after death and all of the requirements of the Human Tissue Act have been met.

⁵ <http://www.anzdata.org.au/anzod/v1/HistoricalInterimSummaries.html>

Further, patients will only be considered for DCD if it is expected that they will die from their injury or disease within 60 to 90 minutes of life support measures being withdrawn.

1.4 What are the steps in DCD organ donation?⁶

1. After a decision is made that a patient will be withdrawn from life sustaining treatment, the possibility for organ donation is discussed with the family.
2. After the family has indicated that they will consent to organ donation, arrangements are made for the patient's life sustaining treatment (*cardio respiratory support / life support*) to be withdrawn. This happens in the operating theatre or intensive care unit.
3. The patient is kept as comfortable as possible with good end of life care before and after life support is withdrawn, until death occurs. Good end of life care includes managing any associated pain or distressing symptoms with analgesia and sedation. During the dying process the patient's blood pressure drops. Long periods of low blood pressure can damage organs due to lack of blood flow and oxygen. For this reason, organ donation can only go ahead if the patient dies within 90 minutes of withdrawal of life support.
4. After the heart and circulation stop, two minutes must elapse in order to establish that the patient's circulation has permanently stopped before death can be declared.
5. The consent for organ donation is not valid and is not acted on until after the patient has died.
6. After death (and after the family has consented to organ donation) essential documents related to death certification are completed. Families have a short time to say goodbye and the deceased person is transferred to operating theatre (if they died in the intensive care unit).
7. The deceased person is placed onto the operating table and surgery commences. It is important that all these activities happen as quickly as possible (within a few minutes), to minimise damage to the organs due to lack of blood flow.

The treatment given to patients who are potential DCD donors may be slightly different from the treatment of patients who are dying but are not going to be DCD organ donors. These differences do not harm the patient and are essential for organ donation to occur. Examples of these differences include:

- Delaying withdrawal of life sustaining treatment (*cardio respiratory support / life support*) to allow time to organise the organ donation operation

⁶ This is a general summary of the steps in DCD organ donation. Different procedures may apply depending on the circumstances. For example, if a death is referable to the Coroner, the Coroner's consent for organ donation is required.

- Taking blood samples to ensure the organs are suitable for donation and to match the organs to potential recipients
- Possibly moving the patient to a place that is more suitable for the process of DCD, such as the operating theatre or a room close to the operating theatre. This is to shorten the delay before organ donation surgery after death.

1.5 What are ante mortem interventions for DCD organ donation?

Ante mortem interventions for DCD are treatments that are given to a patient **before their death** where the patient is reasonably expected to be organ donor after death.

This type of treatment is not for the benefit of the patient's health. The purpose of the ante mortem treatment is to improve the function of the donated organ/s when transplanted into a recipient.

Ante mortem interventions are not intended to hasten or cause the death of the patient. They are only given where it is expected they will not have a negative impact on the patient and where the risk is minimal. For example, if a patient has a known allergy to a medication such as an antibiotic, the antibiotic would not be given.

Giving ante mortem interventions to a patient who is a potential DCD donor is currently allowed in NSW only in the very rare cases where the patient specifically consents to these interventions before their death. However, in most cases, the patient is unable to consent to such interventions and therefore any consent to treatment must be given in accordance with the *Guardianship Act 1987*.

The *Guardianship Act 1987* sets out the circumstances in which a substitute decision maker can consent to medical treatment on behalf of a person who lacks capacity. The *Guardianship Act* only allows a substitute decision maker to consent to treatment where that treatment is carried out for the purpose of promoting and maintaining the health and well-being of the patient⁷. As ante-mortem interventions are not generally aimed at promoting or maintaining the health and well-being of the patient, a substituted decision maker cannot generally consent to such treatment in NSW.

The ante mortem interventions that are being generally considered as part of this Discussion Paper may include treatments that are similar to or in addition to the treatments that the patient may have already received as part of their care in hospital.

In NSW it is proposed that the use of antibiotics, anticoagulants (for example heparin) and medications to control blood pressure would be permissible.

Table 2 lists the ante mortem interventions that are being considered for use in NSW for potential DCD donors already being cared for in an intensive care unit or emergency department.

⁷ Guardianship Act 1987 (NSW) – see sections 32 and 46

A. INTERVENTIONS TO MAINTAIN STABILITY OF THE POTENTIAL DONOR BEFORE WITHDRAWAL OF LIFE SUSTAINING TREATMENT		
Intervention	How invasive / risks?	Benefits for organ transplantation
Administration of medications to control blood pressure: Inotropes, vasoconstrictors and vasodilators.	Administered intravenously via existing IV lines. Low / Small risk of wide fluctuations in blood pressure. Not reasonably expected to prolong suffering of the patient.	These medications help to maintain a person's blood pressure and the circulation of blood and oxygen throughout their body. This is vital, to ensure physiological stability and maintenance of organ function.
B. INTERVENTIONS TO OPTIMISE ORGAN SUITABILITY FOR TRANSPLANTATION		
Intervention	How invasive / risks?	Benefits for organ transplantation
Intravenous antibiotics	Administered intravenously via existing IV lines Low / Small risk of anaphylactic reaction (allergic response) if patient's allergy is not known previously.	Antibiotics minimise the risk of infection in the transplant recipient. Infection is a major risk for the success of transplantation surgery.
Intravenous anticoagulants, for example heparin	Administered intravenously via existing IV lines. Low / Risk is promotion of bleeding. In some patients, this medication may lead to unusual bleeding and potentially hasten death. For potential DCD donors, the treating doctor has already determined that they are so ill they will not survive their injury or illness and the decision has been made to withdraw life sustaining treatment.	This medication reduces the possibility of blood clots forming after the patient dies and blood circulation around the body stops, including to the organs for transplantation. Heparin has been shown to improve quality of organs for transplantation if administered shortly before withdrawal of life sustaining measures in potential DCD patients. ⁸

Table 2: Ante mortem interventions for patients already being cared for in hospital that may be used for DCD organ donation in NSW

⁸ Yiming, C, Shahrestani S, Hong CC et al. Donation after Circulatory Death for Liver Transplantation: A Meta-Analysis on The Location Of Life Support Withdrawal Affecting Outcomes. *Transplantation*. 2016

1.6 Why do some specialists in organ donation and transplantation want to use ante mortem interventions for organ donation after circulatory death (DCD)?

During the dying process circulation of blood slows and eventually stops when the person's heart stops. Due to falling blood pressure and falling oxygen levels during this process, damage to organs can occur. There is also an increased chance of blood clots forming which can damage organs. This damage can affect the functioning of organs to be used in transplantation after death.

Some specialists would like to use ante mortem interventions to reduce the risk that organs from DCD donors will be damaged, and to increase the number and suitability of organs which are available for transplantation.

Reducing the risk of organ damage may lead to better outcomes for transplant recipients. Increasing the number of organs available may decrease the waiting time for people in need of an organ transplant.

PART 2: SUMMARY OF THE CURRENT NSW LAW IN RESPECT OF ANTE MORTEM INTERVENTIONS

Part 5 of the *Guardianship Act 1987* governs how medical and treatment decisions are made on behalf of a person over 16 who does not have the capacity to make their own decision. The *Guardianship Act 1987* is administered by the NSW Department of Justice.

Deceased organ donation is governed by the NSW *Human Tissue Act 1983* which is administered by the NSW Ministry of Health.

2.1 NSW Guardianship Act 1987

The *Guardianship Act* applies when a patient over 16 lacks capacity to consent to medical treatment. The Act is intended to ensure that patients lacking capacity are not denied treatment and that treatment is given for the purposes of promoting the health and wellbeing of patients.⁹

The *Guardianship Act* establishes a substitute consent hierarchy where the patient's 'person responsible' (usually the patient's spouse/partner or family member, but not always) or the NSW Civil and Administrative Tribunal can consent on the patient's behalf. However, generally the person responsible can only give consent for treatment if the treatment is for the purpose of promoting and maintaining the patient's health and wellbeing.

Consent cannot generally be given under the *Guardianship Act* for non-therapeutic treatment (treatment that does not improve the patient's condition or stop it from deteriorating). However, in limited cases the *Guardianship Act* allows consent to be given for treatment has a non-therapeutic purposes, or potentially a non-therapeutic purpose, being in relation to clinical trials¹⁰.

As ante mortem intervention for DCD organ donation is not for the therapeutic benefit of the patient, the patient's person responsible cannot consent to such treatment. This is the case even where the patient has consented to be an organ donor.

2.2 NSW Human Tissue Act 1983

The *Human Tissue Act 1983* deals with the donation, removal and use of organs and tissues, including from deceased persons.

The *Human Tissue Act 1983* requires that consent to the removal of tissue from a deceased person for the purposes of transplantation is given in writing, either by the individual prior to their death, or by the deceased's senior available next of kin after death (in certain cases, the consent of the Coroner is also required). The senior available next of kin may consent to the donation either in writing or by "other prescribed means", which is usually an audio recording of their consent.

In all cases, consent can only be given after death.

⁹ See Part 5 of the *Guardianship Act*

¹⁰ See Division 4A of Part 5 of the *Guardianship Act*

Senior available next of kin have no decision making authority under the *Human Tissue Act 1983* until after the donor's death. They are not able to consent to ante mortem (before death) interventions for patients who are potential DCD donors. As noted above, consent cannot be given under the *Guardianship Act 1987* for treatment that is not for a therapeutic benefit of the patient.

In some rare circumstances, a patient who is a potential DCD donor may consent to ante mortem interventions immediately before death. This may occur when a patient with capacity elects to cease treatment in ICU and requests to become an organ donor after their death. These patients have an opportunity to be given information about ante mortem interventions and to choose to consent to these interventions before the withdrawal of their life sustaining therapy.

However, in most cases in NSW where there is a potential DCD donor, ante mortem interventions cannot be provided as there is no person able to consent to the giving of such interventions.

2.3 Current laws regarding ante mortem interventions in other Australian states

In some Australian states, the relevant legislation allows consent for ante mortem interventions to be sought from either the equivalent of the person responsible or the senior available next of kin.

As noted above, in NSW consent can be obtained in rare circumstances to authorise ante mortem interventions. While DCD can and does occur in NSW, there is concern that transplant outcomes from DCD donors may not be the best they could be because of the current restriction on ante mortem interventions.

PART 3

A: SHOULD ANTE MORTEM INTERVENTIONS BE PERMITTED IN NSW AS PART OF DCD ORGAN DONATION?

As noted in Part 1, ante mortem interventions do not improve the potential donor's condition or stop it from deteriorating and are not for the therapeutic benefit of the patient. For DCD, these medical treatments are given in the period immediately before death help to improve the function and number of organs to be donated.

To answer the question whether ante mortem interventions should be permitted in NSW as part of DCD organ donation, it is necessary to consider the following:

- arguments against use of ante mortem interventions
- arguments in support of ante mortem interventions
- risks to patients
- benefits for people who want to be organ donors
- benefits to the community
- national consistency of organ donation practice.

Each of these is addressed below.

3.1 Arguments against use of ante mortem interventions in DCD organ donation

The fundamental duty of a medical practitioner is to his or her patient, and the care of the patient should be the practitioner's primary concern¹¹. As such, allowing a medical practitioner, or other health professional, to be involved in the giving of ante mortem interventions to their patient would arguably be inconsistent with a practitioner's duty to their patient.

However, it is recognised that practitioners also owe a duty to protect the health of the community as a whole. There are cases, such as clinical trials, where a medical practitioner may recommend that a patient undertake certain treatment even though the patient may not receive a therapeutic benefit. Clinical trials may or may not benefit an individual patient but they are essential to the health of the community.

Following on from the point above, there is also a risk that allowing medical practitioners to be involved in ante mortem treatments may damage the therapeutic relationship between health practitioners and patients. Patients have a general right to expect that health practitioners will only recommend and provide treatment where there is a benefit to the patient in doing so.

If patients cease to trust that medical or health practitioners will only act in their therapeutic interests, patients may be less inclined to trust their practitioner. Trust is essential for a strong relationship between a practitioner and their patient and benefits both the individual and community as a whole. In the case of organ donation,

¹¹ *Good Medical Practice: A code of conduct for doctors in Australia*; Medical Board of Australia; <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

if patients and their families cease to trust that health practitioners will act in the interests of patients, there is a risk that community support for organ donation will be eroded.

In order to protect a person who lacks capacity, persons responsible are generally required to only consent to treatment when it is in the patient's best interest, not in the interest of other people. This helps ensure that people who lack capacity are not disadvantaged in relation to receiving medical treatment. If a person responsible was able to consent to ante mortem treatments that did not benefit the patient, there is also a concern that giving them such a role would be inconsistent with general principles that apply to persons responsible.

However, as noted earlier, there are limited circumstances in which a person responsible can consent to treatment that the patient may not benefit from, being clinical trials. It could therefore be argued that the community benefits derived from permitting ante mortem treatments for DCD – reducing organ damage and increasing the numbers of organs available for transplantation - would justify allowing such treatment to be given to patients who lack capacity.

3.2 Arguments in support of the use of ante mortem interventions in DCD

The Australian and New Zealand Intensive Care Society's (ANZICS) *Statement on Death and Organ Donation* supports ante mortem interventions on the basis that "available scientific evidence confirms their utility in improving organ viability"¹².

International experience and evidence emerging from the UK, the USA and Canada, as well as Australia, indicates that the use of ante mortem interventions in DCD improves the function of organs after transplantation, thereby increasing the chances of a good outcome for the recipient. For example:

- US^{13,14} and Canadian¹⁵ DCD guidelines now consider administration of heparin at the time of withdrawal of life sustaining treatment as standard care. Ante mortem use of vasodilators to improve organ perfusion is also widespread in those countries.
- Evidence from the US supports the use of heparin to enhance lung transplantation outcomes¹⁶

¹² Australian and New Zealand Intensive Care Society. *The ANZICS Statement on Death and Organ Donation (Edition 3.2)*. Melbourne: ANZICS, 2013.

¹³ Bernat et al (2006), 'Report of a National Conference on Donation after Cardiac Death' *American Journal of Transplantation* vol 6 issue 2, February 2006 ,p 283 :DOI: 10.1111/j.1600-6143.2005.01194.

¹⁴ American Thoracic Society Health Policy Committee 'An Official American Thoracic Society/International Society for Heart and Lung Transplantation/Society of Critical Care Medicine/Association of Organ and Procurement Organizations/United Network of Organ Sharing Statement: Ethical and Policy Considerations in Organ Donation after Circulatory Determination of Death', *American Journal of Respiratory Critical Care Medicine*, vol 188;1, July 2013 ,pp 103–109 DOI:10.1164/rccm.201304-0714ST

¹⁵ Canadian Council for Donation and Transplantation, *Donation After Cardiocirculatory Death: A Canadian Forum, Report and Recommendations*; Canadian Council for Donation and Transplantation, 2005

¹⁶ Sanchez P et al Ex-Vivo Lung Evaluation of Pre-arrest Heparinization in Donation After Cardiac Death: *Annals of Surgery* 2013 Vol 257 No 3,pp 534-541: doi 10.1097/SLA.0b013e318273bef1 and Levvey B Jet al Excellent Clinical Outcomes From a National Donation-After-Determination-of-Cardiac-Death Lung Transplant Collaborative , *American Journal of Transplant* Vol12 No 9, Sept 2012 pp2406-2413:doi: 10.1111/j.1600-6143.2012.04193.

- Experience with DCD lung retrieval at The Alfred Hospital in Melbourne also indicates that using ante mortem heparin provides advantages in assessing the suitability of lungs for potential transplantation¹⁷
- Data from Victoria on 16 liver transplants from DCD donors showed that there was a significantly increased risk of early graft loss by not giving ante mortem heparin¹⁸
- The 2006 US *Report of a National Conference on Donation after Cardiac Death* noted, “An emerging body of subclinical/molecular evidence supports the use of pre-procurement treatments for their preserving effect on the vascular endothelium of the transplanted organ. The administration of pharmacologic agents may minimize ischemia/reperfusion injury and improve organ function after DCD transplantation”¹⁹
- The results of a recent meta-analysis on DCD and liver transplantation.²⁰

There is no evidence that the use of ante mortem interventions, in accordance with recognised clinical guidelines, compromises the care or treatment of the patient, provided that there are no other reasons for not providing the treatment e.g if the person was allergic to a medication.

Further, there is evidence that the use of ante mortem interventions can lead to better outcomes for recipients of organ donations. This assists in ensuring that the decision of individuals who consent to organ donation is appropriately respected by ensuring organs are transplanted in an optimal condition, and is beneficial to the community as a whole.

3.3 Risks to the patient

There are concerns about risk of harm to patients associated with ante mortem interventions. These include hastening death; increasing suffering of the dying patient; and causing distress to the families of donors either in the event that additional treatments are provided, or because treatments are being administered which are not for the direct benefit of the potential donor.

The Australian National Protocol for Donation after Cardiac Death²¹ states that “Ante mortem interventions are performed for the benefit of potential recipients but must be consistent with the broader best interests of the patient, including respecting the patient’s wishes to be an organ donor. Ante mortem interventions are ethical if they will contribute to the likely success of the transplantation and do not harm the patient”.

¹⁷ Snell, GI., Levvey, BJ., Oto, T., McEgan, R., Pilcher, D., Davies, A., Marasco, S. and Rosenfeldt, F. Early Lung Transplantation Success Utilizing Controlled Donation After Cardiac Death Donors, *American Journal of Transplantation*, Vol 8 No 6, June 2008 ,pp1282–1289 :doi:10.1111/j.1600-6143.2008.02231.

¹⁸ Riddiough G, et al , Predictors of early graft loss in donation after circulatory death liver transplantation: paper presented at International Society for Organ Donation & Procurement 12th International Congress , Sydney 2013

¹⁹ Bernat, JL et al *op cit* p 283

²⁰ Yiming, C, Shahrestani S, Hong CC et al. Donation after Circulatory Death for Liver Transplantation: A Meta-Analysis On The Location Of Life Support Withdrawal Affecting Outcomes. *Transplantation*. 2016

²¹ National Health and Medical Research Council & Australian Organ and Tissue Authority *National Protocol for Donation after Cardiac Death in Australia*, Australian Organ and Tissue Authority 2010

Avoidance of additional risk to the dying patient (and potential donor) is a necessary condition in most arguments that support ante mortem interventions in DCD. The *Australian National Protocol for Donation after Cardiac Death* states that “Ante mortem interventions should be undertaken only if it is anticipated that they will not harm the patient and will not hasten or cause the death of or compromise the continuing care of the patient.”²²

This principle is also incorporated in operational protocols of sites which routinely use ante mortem interventions for DCD donors. For example, most American and Canadian centres that use ante mortem heparin as standard care for patients who are potential DCD donors have protocols that include guidance to avoid the use of heparin in patients with a known risk of bleeding.

The risks of heparin given to a patient who is a potential DCD donor who does not proceed to organ donation are thought to be minimal. Heparin is an anticoagulant which prevents blood clotting in arteries, veins and organs. Heparin does not dissolve existing clots the way other thrombolytic drugs do. Therefore, it is considered unlikely, for example, for heparin to cause bleeding in a head-injured patient who is not actively bleeding. However, as noted above there may be small or theoretical risks with regard to administration of heparin in selected patients, such as those who have a pre-existing bleeding disorder (e.g. haemophilia). The effects of heparin typically last from 2 to 6 hours.²³

Theoretical concerns have been raised that vasodilators may cause hypotension (low blood pressure) in the potential donor, possibly hastening their death.²⁴

Similarly the risks to a dying patient from ante mortem administration of antibiotics are likely to be minimal, provided the patient does not have an allergy to the antibiotic used.²⁵

The *Australian National Protocol for Donation after Cardiac Death* states that, along with good end of life care, “Measures should be taken to prevent any pain or discomfort associated with any ante mortem interventions administered.”²⁶ Care of a patient who is being considered for DCD with potential use of ante mortem interventions would include administration of analgesia and sedation, to minimise or prevent any pain or discomfort that may be associated with any proposed interventions.

There may also be disruptions for the families of potential donors if they have to leave the patient while an ante mortem procedure is performed, particularly for invasive procedures.

²² *National Protocol for Donation after Cardiac Death in Australia, op cit*

²³ DuBois J, Delmonico F, D'Alessandro A : When Organ Donors Are Still Patients: Is Premortem Use of Heparin Ethically Acceptable?, *Am J Crit Care*. 2007;16(4):396-400.

²⁴ Bernat JL et al, *op cit* p283

²⁵ Richards, B and Rogers, WA. Organ donation after cardiac death: legal and ethical justifications for antemortem interventions. *MJA* 2007; 187:168-170

²⁶ *National Protocol for Donation after Cardiac Death in Australia, op cit*

3.4 Benefits for people who want to be organ donors

When a person has given their consent to be an organ donor, it can be argued that ensuring the organs they donate are in the best possible condition for transplantation is a way to honour that person's donation decision.

In 2011, the UK Donation Ethics Committee of the Academy of Medical Royal Colleges stated that "In planning end of life care for a patient for whom life-sustaining treatment is no longer appropriate, if the patient wished to become an organ donor, then care that facilitates successful donation is likely to be highly compatible with a best interests approach."²⁷

In addition to good care of the patient who is a potential organ and tissue donor in intensive care, use of ante mortem interventions that do not cause or place the patient at significant risk of harm or distress, is an effective way of ensuring donated organs can be successfully transplanted.

However, many organ donors do not consent for organ donation before their death. Instead their families consent on their behalf. Therefore, arguments about the assumptions people make about organ donations will not always apply.

When people consent to be an organ donor after death, it could also be argued that the patient has only considered, and consented to, what happens to their organs after death, not what treatment is provided before death. In NSW, it is particularly noted that especially for DCD, ante mortem interventions are not yet permissible and it is unlikely that people considering consenting to organ donation are also contemplating what ante mortem interventions may be given to them in the event they become an organ donor.

3.5 Benefits to the community

Where someone has agreed to donate organs and tissues after death, it is acknowledged that some people propose there is public benefit in retrieving and maintaining those organs in the best possible condition for transplantation.

Allowing use of ante mortem interventions in DCD, where appropriate and safe, could ensure that the number and quality of donated organs for transplantation is increased, more transplants are able to be performed and transplantation outcomes should be improved.

This situation is similar to clinical trials of new treatments. Clinical trials are conducted to test new treatments and/or to compare different treatments. The aim is to see if they improve health outcomes so that the treatments can be introduced more broadly. Clinical trial participants may obtain a benefit if they receive a treatment which improves their health condition rather than placebo or a treatment that either does not improve their health or causes a side effect. However, ultimately, the benefit is for the community as a whole.

²⁷ UK Donation Ethics Committee, *An Ethical Framework For Controlled Donation After Circulatory Death Consultation*, Academy of Medical Royal Colleges, January 2011.

3.6 National consistency of organ donation practice

There are nationally agreed procedures for allocating donated organs.²⁸ This is to ensure that people with the most urgent need for transplantation are provided with the best matched organs for them regardless of where they live. In general however, organs are transplanted to a patient who lives in the state where the donor is being cared for.

As previously discussed, in some Australian states it is possible to use ante mortem interventions in DCD with the consent of a person responsible (or similar). While DCD can and does occur in NSW, organs may be allocated for transplantation in another state. The number of organs able to be offered for transplantation and transplant outcomes from NSW DCD donors may not be the best they could be because of the restriction on ante mortem interventions.

B: WHICH ANTE MORTEM INTERVENTIONS MIGHT BE PERMITTED IN NSW?

If ante mortem interventions were to be generally permitted in NSW, consideration of which ante mortem interventions might be permitted should occur.

See Table 2: Ante mortem interventions for patients already being cared for in hospital that may be used for organ donation in NSW.

Whilst acknowledging that a range of ante mortem interventions are in use in other States in Australia and internationally, it is proposed to limit consideration of the use of ante mortem interventions in DCD in NSW to patients who are already being cared for in hospital, and who are already intubated and ventilated (as part of the treatment given to try to save that person's life) at the time that it is determined that ongoing active treatment is not in their best interests.

The rationale for this proposal is that, in addition to being intubated and ventilated, these patients are likely to already be receiving other interventions such as intravenous (IV) lines and to being treated with one or more medications to maintain their blood pressure and organ function as part of the treatment to save their lives.

The Transplantation Society of Australia and New Zealand (TSANZ) has developed clinical guidelines on organ transplantation and allocation of organs to patients.²⁹ TSANZ also promotes best practice guidelines regarding care of donors to maximise transplantation benefits.

If the use of ante mortem interventions were to be permitted in NSW, additional evidence-based interventions may be considered for use in the future.

Given the evidence regarding the benefits of ante mortem heparin in liver transplantation in particular, and the existence of protocols which are routinely used in international settings, the TSANZ could be invited to collaborate with NSW Health

²⁸ [TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors April 2016](#)

²⁹ [TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors April 2016](#)

on a protocol for use of ante mortem heparin in DCD in NSW. A similar approach could be adopted for use of antibiotics and other medications which may be of benefit in ensuring that donated organs are clinically suitable for transplantation.

Question 1:

Should ante mortem (before death) interventions be permitted in NSW as part of DCD organ donation?

Question 2:

If ante mortem interventions should be permitted in NSW as part of DCD organ donation which of the following interventions should be permitted?

- a. Administration of medications to control blood pressure**
- b. Intravenous antibiotics**
- c. Intravenous anticoagulants, for example heparin.**

PART 4: IF ANTE MORTEM INTERVENTIONS ARE ALLOWED, WHAT IS THE PREFERRED WAY TO PERMIT ANTE MORTEM INTERVENTIONS FOR DCD IN NSW?

This part of the paper considers the options available to permit ante mortem interventions for DCD in NSW, should ante mortem interventions be allowed in NSW.

Where a patient lacks capacity, legislation in NSW currently prohibits a person responsible or a senior next of kin consenting to ante mortem interventions on behalf of a dying patient. To allow ante mortem interventions would require legislative change. Two options are set out regarding what changes could occur to allow ante mortem interventions.

Option 1: Registering a decision to be a donor is taken to imply consent to ante-mortem interventions in DCD

One option for allowing ante mortem interventions in DCD in NSW would be to amend the *Human Tissue Act 1983* to provide that consent for ante mortem interventions is taken to be given if a person consents to organ donation.

The basis for this option is that it could be argued that it is reasonable to assume that a person who has consented to organ donation wants their donated organs to be suitable for transplantation, and so it can be implied they have also consented to interventions to make this possible.³⁰ Enabling the donor's decision to donate respects their autonomous decision and may, in turn, confer benefit in their dying.

The difficulty with this option is that consent to treatment, either by the patient or on the patient's behalf, should be based on informed consent. However, information that is in the public domain about DCD and ante mortem interventions is limited. It would be difficult to say that there is enough general information available and understood by the public that an argument of informed presumed consent can be made.

There are some limited statements available in Australian publications which mention ante mortem interventions. For example, the National Health and Medical Research Council's (NHMRC) *Making A Decision About Organ And Tissue Donation After Death* includes the statement "If the family agrees, the patient may be moved to an operating theatre before death and measures taken to prepare for donation after death".³¹ It is questionable whether the public would readily access NHMRC publications to obtain information when making a decision regarding organ donation.

Even if there was information in the public domain, informed consent generally requires a patient to understand the individual risks and benefits of a particular treatment, which would almost never occur when information only comes from the public domain.

30 Richards B, Rogers W. 'Organ Donation after Cardiac Death: Legal and Ethical Justifications for Ante-mortem Interventions' *Medical Journal of Australia*, vol188, No 3, February 2008, p188

31 National Health and Medical Research Council *Making A Decision About Organ And Tissue Donation After Death*: Australian Government 2007

This option will not assist in cases where the patient has not recorded their consent to organ donation. Approximately half of all donation opportunities currently rely on the senior available next of kin to provide consent after the patient's death in the absence of a registered donation decision by that person. Option 1 would not allow the person responsible to consent to ante mortem interventions at the same time as the senior available next of kin consented to organ donation.

In addition, relying on presumed/implied consent for ante mortem interventions may also be ethically challenging as the consent would only be acted upon when the patient is dying and quite likely unconscious and unable to be offered the opportunity to retract their consent. Having a presumed consent process where there is not a realistic prospect of consent being revoked is not considered appropriate.

Accordingly, Option 1 is not supported by the Ministry of Health at this time.

Option 2: Allowing the potential donor's senior available next of kin to provide substitute consent for ante mortem interventions

A deceased person's senior available next of kin can consent to organ donation if the deceased had not, while alive, given their written consent and had not objected to organ donation prior to their death. In practice, the senior available next of kin is involved in the discussions relating to organ donation, even where the donor has given their written consent. The senior available next of kin is generally involved in all decisions relating to organ donation.

If ante mortem interventions were to be allowed in NSW, one option is to amend the *Human Tissue Act 1983* to allow the potential donor's senior available next of kin to consent to these treatments. The senior next of kin would then operate as a substitute decision maker for the potential organ donor who lacks capacity. It is noted that this role would be limited to the issue of ante mortem interventions and is not intended to more generally replace the role of the person responsible under the *Guardianship Act*.

Allowing the senior available next of kin to act as a substitute decision maker and consent to ante mortem interventions would ensure that ante mortem interventions only occurred on a case by case basis, where both the clinicians and the senior available next of kin agreed that the ante mortem intervention(s) should be given to the potential donor. It would also enable the obtaining of relevant medical information from them to minimise any negative effects on the potential donor, such as an allergy to a drug. Allowing the senior available next of kin to consent would be consistent with the framework for authorising organ donation.

It is important to note that not every potential donor has a senior available next of kin who is contactable at the time of their death. If a senior available next of kin cannot be contacted, donation only proceeds if there is evidence that the patient had previously consented to it, for example, either on an organ donor register or in an Advance Care Directive.

If Option 2 was supported and the *Human Tissue Act 1983* was amended to allow ante mortem interventions to be given with the consent of the senior available next of kin, there would still be instances where they could not be used.

In principle, the Ministry of Health supports the use of ante mortem interventions proposed in this paper – heparin, antibiotics and medications to control blood pressure. There is strong evidence that use of heparin in particular contributes to improved function of the donated organs that have been transplanted. These interventions are non-invasive and carry a low risk to the patient, and cause minimal, if any, discomfort.

If it were decided that ante mortem interventions can take place in NSW, Option 2 is the in principle preferred option of the Ministry to permit the use of ante mortem interventions in DCD. This option most closely replicates the current framework for consent to organ donation, ensures discussion and agreement takes place with the potential donor's family and will ensure that ante mortem interventions are considered on a case by case basis where clinicians and the family agree that it is appropriate.

Persons who registered an objection to organ donation, or have otherwise indicated an objection to ante-mortem interventions, for example in an advance care directive

If a process to allow ante mortem interventions were to be permitted in NSW, there is no intention that this process would override a person's previously expressed wishes against either organ donation or ante mortem interventions.

As such, if a person has a current registered objection to organ donation, or organ donation would otherwise not be lawful under the *Human Tissue Act 1983*, a senior next of kin (or other substitute decision maker) would not be able to consent to ante mortem interventions.

Likewise, if a person had made an advanced care directive, or otherwise indicated an objection to ante mortem interventions (regardless of whether or not the person registered a consent to be an organ donor), the senior next of kin (or other substitute decision maker) would not be able to consent to ante mortem interventions.

Question 3:

If ante mortem interventions were to be permitted in NSW, should the *Human Tissue Act 1983* be amended to allow the patient's senior available next of kin to act as a substitute decision maker for patients who lack capacity and consent to ante mortem interventions?

PART 5: ADDITIONAL SAFEGUARDS FOR ANTE MORTEM INTERVENTIONS

Were ante mortem interventions to be allowed in NSW, consideration should also be given to appropriate safeguards.

Such safeguards could include the development of agreed standard procedures and protocols which ensure that:

- the substitute decision maker has access to all relevant information before consenting to the use of ante mortem interventions
- an appropriate consent framework is in place to enable a substitute decision maker to consent to the interventions
- ante mortem interventions are only used appropriately and in a way that would not cause harm to the potential donor or hasten death
- good end of life care is not compromised.

For example, if a patient has a known allergy to a medication it would not be given as an ante mortem intervention.

Accordingly, submissions are sought on whether the proposed safeguards are appropriate and practical or whether there are alternative safeguards that can be put in place.

Another issue on which the Ministry would like to hear submissions is whether the patient's treating medical practitioner should be involved in this process or whether the practitioner that assesses the patient for ante mortem interventions should be independent from the treating team. Having an independent medical practitioner may provide a degree of oversight. However, on the other hand, the treating practitioner may be in a better position to properly assess the patient and make a determination as to the patient's condition and possible effects on the patient.

Question 4:

What safeguards should be put in place to ensure that ante mortem interventions only occur in appropriate circumstances that do not harm the patient?

PART 6: CONSULTATION

This discussion paper will be on placed on public display on the NSW Health Website and the Your Say website for a period of six weeks (42 days) to allow individuals to make submissions. The Ministry will also provide a copy of the paper to key stakeholders.

The Ministry of Health is seeking submissions on four key questions:

- 1. Should ante mortem interventions be permitted in NSW as part of DCD organ donation?**
- 2. If ante mortem interventions should be permitted in NSW as part of DCD organ donation, which of the following interventions should be permitted?**
 - a. Administration of medications to control blood pressure
 - b. Intravenous antibiotics
 - c. Intravenous anticoagulants, for example heparin.
- 3. If ante mortem interventions were to be permitted in NSW, should the *Human Tissue Act 1983* be amended to allow the patient's senior available next of kin to act as a substitute decision maker for patients who lack capacity and consent to ante mortem interventions?**
- 4. What safeguards should be put in place to ensure that ante mortem interventions only occur in appropriate circumstances that do not harm the patient?**

Submissions on the use of ante mortem interventions for organ donation in NSW should be made to:

Ante mortem interventions for organ donation in NSW
Office of the Chief Health Officer
NSW Ministry of Health
Locked Mail Bag 961
NORTH SYDNEY NSW 2059

Submissions may also be made via email to organ@doh.health.nsw.gov.au and marked "Ante mortem interventions for organ donation in NSW" as the subject title.

Submissions must be received by **Monday 30th January 2017**.

Individuals and organisations should be aware that generally any submissions received may be made publically available under the Government Information (Public Access) Act 2009. The Ministry of Health, in considering the submissions received may also circulate submissions for further comment to other interested parties or publish all, or parts, of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.