



Australian Government

**Australian Organ and Tissue Donation
and Transplantation Authority**

**National Health and
Medical Research Council**

National Protocol for Donation after Cardiac Death

~ DRAFT FOR PUBLIC CONSULTATION ~

2009

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Introduction

Donation after Cardiac Death, also known as non-heart beating donation, provides an additional pathway to organ and tissue donation for those patients who do not meet the criteria for brain death. Donation after Cardiac Death donors are certified dead using the criterion of irreversible cessation of circulation of blood in the body of the person.^[1] Determination of death after cessation of circulation is a very common event in medicine. However, Donation after Cardiac Death requires that organ removal takes place immediately after death, to minimise the effects of warm ischaemia on the organs that are to be transplanted.

In part, the re-emergence of Donation after Cardiac Death as an option in the end-of-life care of all patients has been driven by family or next-of-kin of severely brain injured, but not brain-dead patients who wish organ donation to be an option for their relative.^[1] Donation after Cardiac Death has continued to occur in countries where the concept of brain death is not recognised. Donation after Cardiac Death has two potential benefits. Firstly, Donation after Cardiac Death provides the opportunity to respect and facilitate an individual's wish for organ donation in circumstances other than brain death.^[2] Secondly, successful Donation after Cardiac Death increases the availability of organs and tissues for transplantation, with consequent improvements in the health and wellbeing of recipients. These benefits meet health care ethical imperatives of respecting patient autonomy and acting for the good of patients. For these reasons, the onus is on practitioners and institutions to develop the capacity to offer Donation after Cardiac Death to all suitable patients^[2] or make every reasonable attempt to fulfil the patient's wishes.

The logistically challenging and ethically complex process of Donation after Cardiac Death requires thoughtful deliberation to inform clinical practice. A detailed practice framework with a strong emphasis on communication and consistency has been developed which aspires to avoid any potential harm to patients, their families, recipients and the health care team.^[2] The recommendations within this protocol may not apply to every clinical situation. Individual patient, family or site characteristics need to be considered. This protocol should not be a substitute for a health care practitioner's informed clinical judgement with respect to treating the individual patient and/or family in an appropriate manner.^[3]

Background

At the National Summit on Organ Donation held in South Australia in July 2008, there was consensus agreement for the development of a national framework for Donation after Cardiac Death.

The Cognate Committee, which was formed in December 2007 to oversee policy and program reforms to Australia's organ and tissue donation and transplantation sectors, agreed to recommend to health ministers through the Australian Health Ministers Advisory Council (AHMAC) the development of a nationally consistent protocol and implementation plan for Donation after Cardiac Death for the Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA).^[4] AHMAC agreed that the National Health and Medical Research Council (NHMRC) provide guidance and oversight to the National Institute of Clinical Studies (NICS) to develop a protocol that could be implemented across all jurisdictions. The protocol was to be primarily informed by the recommendations described in the following documents:

NHMRC – Organ and tissue donation after death, for transplantation^[5]

These guidelines reviewed the following documents: AHMAC Recommendations for the Donation of Cadaveric Organs and Tissues for Transplantation (1996), and four discussion papers released by the Australian Health Ethics Committee (AHEC) in 1997. These guidelines focus on ethical principles for health professionals involved in donation after death and provide guidance on how these principles can be put into practice.

Australian and New Zealand Intensive Care Society (ANZICS) – Statement on death and organ donation^[1]

Development of the ANZICS Statement included a comprehensive review of relevant literature, including comparable documents from other countries. Conventional classification of levels of scientific evidence for the recommendations in the Statement were not used.

NSW Health – Organ Donation after Cardiac Death – NSW Guideline^[6]

The LifeGift Organ Donation Network NSW/ACT Donation after Cardiac Death Working Party was established under the auspice of the NSW Transplant Advisory Council (TAC) to develop the NSW jurisdictional guidelines for Donation after Cardiac Death. These guidelines were developed jointly by NSW Health and the NSW TAC. NSW Health undertook State and national stakeholder consultation on a consultation draft in 2006. A review of international and national literature and guidelines was undertaken to inform these guidelines.

Other significant international documents were reviewed as part of the document mapping phase such as the Canadian, New Zealand and United Kingdom Guidelines^[7-9] as well as State and hospital protocols from Queensland and Victoria.^[10-13] The document seeks to be consistent in language and terminology with guidelines on end of life.

Purpose

The purpose of developing a nationally consistent protocol for Donation after Cardiac Death is to support an ethically justifiable and auditable process that respects the rights of the patient^[14] and to make recommendations that are ethically, legally, and medically acceptable in the practice of Donation after Cardiac Death.

Intended users

This protocol is intended for clinicians and health care professionals involved in hospital-based organ and tissue donation processes. It also provides useful information for consumers and those responsible for the quality and safety of health care.

Scope of this protocol

This protocol begins with the consideration of a patient for potential organ and tissue donation following the decision to withdraw cardio-respiratory support, and does not include the process in arriving at that decision. However, general legal direction has been included addressing this issue in Section 11.

Methodology

This is a protocol and not a clinical practice guideline where a systematic literature review is required. It is a step-by-step statement of the procedures used in the care of individual patients and families to assure that the intended effect is reliably achieved. The recommendations in this protocol are based on the information contained in the existing documents previously referred to ^[1,5,6] and expert opinion.

This protocol is comprised of a series of clinical statements in the approximate sequence of events in which the Donation after Cardiac Death process occurs. These protocol statements, together with the protocol flowchart, are based on a review of international and national experience relating to Donation after Cardiac Death, and have been informed by the recommendations resulting from a Consensus Stakeholder Workshop held on 19 March 2009. Further, a Donation after Cardiac Death implementation tool in the form of a Checklist has also been developed (Appendix 1).

A supporting document follows the protocol, which provides further information related to the protocol statements, including the legislative requirements and ethical issues associated with Donation after Cardiac Death.

The steps undertaken to develop this protocol have included the employment of a project officer to support the development of a national protocol and implementation plan for Donation after Cardiac Death. A Donation after Cardiac Death Working Party was established (Appendix 2) which included an expert in law and an expert in ethics, to guide the process and development of the protocol. This working party had professional representation from organ and tissue donation, transplantation and acute care sectors as well as consumer representation.

Two meetings of the Donation after Cardiac Death Working Party were convened during the planning phase, with a joint meeting of the Donation after Cardiac Death working party and National Organ Donation Collaborative (NODC) Advisory Committee on 4 May 2009 to discuss and agree on the draft protocol, and to enable it to proceed to the public consultation phase.

The workshop on 19 March 2009 was attended by 62 delegates from the organ and tissue donation and transplantation sector (Appendix 3) and was followed by the NODC Learning Session on 20 March 2009, where hospital teams participating in the NODC were consulted on implementation issues relating to the national protocol for Donation after Cardiac Death.

Targeted and public consultation process

From June to July 2009 there will be a targeted consultation with relevant professional colleges and societies and a general public consultation period. The process for public consultation includes placing a notice in "The Australian" and placing the Draft Consultation Protocol on the NHMRC website with clear processes available for provision of comments. All comments submitted will be reviewed by the Donation after Cardiac Death Working Party, and where relevant, changes will be made to the protocol based on the stakeholder feedback.

The revised protocol will be submitted to the AOTDTA and once approved endorsement will be sought from each of the State and Territory chief medical health officers and the following professional colleges and societies:

Australian College of Critical Care Nurses
Australasian College for Emergency Medicine
Australian College of Emergency Nursing
Australian and New Zealand Intensive Care Society
Australasian Transplant Coordinators Association
Australian College of Operating Room Nurses
College of Emergency Nursing Australasia
Transplant Society of Australia and New Zealand

Scheduled review of this protocol

The AOTDTA will ensure that this protocol, once finalised, is reviewed and revised no more than five years after initial publication. The clinical evidence and possibly the legislation on which the protocol is based are likely to change.

A review of relevant sections of this protocol will be undertaken if any of the following occur within five years:

- changes to State and Territory legislation
- publication of any new major evidence, randomised controlled trials or systematic reviews that potentially have a bearing on the recommendations in this protocol
- emergence of any major safety concerns relevant to this protocol.

Funding

The development of this protocol was funded by the Department of Health and Ageing (DoHA) initially and subsequently by the AOTDTA.

Issues to be considered in using this protocol

Donation after Cardiac Death is a complex topic, and while other countries, such as the United Kingdom and New Zealand, have been able to develop national protocols, they do not have the same difficulties with differences in State and Territory legislation.

Achieving harmonisation of legislation and interpretation across all jurisdictions has been examined and the issues that arise as a result of those differences have been summarised in Section 11 of this document, which has been provided by Professor Colin Thomson. For the legislative issues to be resolved, Crown law advice from each jurisdiction will be required.

The current differences in jurisdictional legislation do not prohibit the practice of Donation after Cardiac Death in any State or Territory, but in the current legislative framework there will be differences in the way Donation after Cardiac Death is practised. All attempts have been made where possible to provide consistent guidance that complies with all jurisdictional legislative frameworks. Where this has not been possible the protocol states that practice must comply with local legislative requirements.

The concerns related to the ethics associated with Donation after Cardiac Death further add to the complexity of the development of a nationally consistent protocol. Section 12 of this document provides a summary of the ethical considerations by Professor Wendy Rogers.

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DONATION AFTER CARDIAC DEATH PROTOCOL

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Donation after Cardiac Death Protocol

1. Withdrawal of cardio-respiratory support is a pre-requisite to Donation after Cardiac Death and is a well established practice in the Intensive Care Unit (ICU). This protocol offers no recommendations for the process involved in that medical decision. However, it is anticipated that the decision to withdraw cardio-respiratory support is undertaken in accordance with established principles and guidelines. The conduct of a discussion regarding the withdrawal of cardio-respiratory support held with the family is likely to have a significant impact on decision-making related to organ and tissue donation.
2. Donation after Cardiac Death is not appropriate if, in the judgment of the treating intensivist, it is anticipated that a patient is likely to survive for longer than 90 minutes after withdrawal of cardio-respiratory support.
3. Consideration for Donation after Cardiac Death involves a formal assessment of medical suitability. An early informal discussion with the Organ and Tissue Donation Agency (OTDA) may also be helpful in establishing clear exclusions.
4. The unique nature of Donation after Cardiac Death dictates that careful consideration is given to the determination of appropriate roles and responsibilities for the organ donation discussion with the family.
5. As directed by Australian Government policy, the Australian Organ Donor Register (AODR) should be accessed in relation to all medically suitable patients when considering organ and tissue donation. When the AODR is accessed, the information should be conveyed to the family, especially if it might assist them with decision-making (Appendix 5).
6. The senior available next-of-kin and other family members require a range of information to make a considered decision about organ and tissue donation. All discussions with the family and senior available next-of-kin concerning organ and tissue donation should be documented in the medical record. Families may feel overwhelmed. It is important to acknowledge this and offer appropriate, ongoing communication and support.
7. When the case is referred to the OTDA the following information is required: patient demographics; diagnosis; past medical and social history; current clinical data, and requirement for Coronial referral. The organ donor coordinators are responsible for conducting in-depth family interviews and clinical assessments.
8. Formal consent for Donation after Cardiac Death should specify the organs and tissues to be donated. It may be appropriate to obtain conditional consent at the same time for the specific organs and tissues to be donated in the event of brain death if there is a realistic possibility of this eventuality.
9. Consent from the Coroner is necessary for Donation after Cardiac Death, if the death is reportable. At least conditional consent from the Coroner must be obtained in these cases prior to withdrawal of cardio-respiratory support if Donation after Cardiac Death is to proceed. The specific requirements of individual Coroners for notification after death must be clarified. Throughout the process, all consents and authorisations, including those provided verbally, should be documented in the medical record.

Donation after Cardiac Death Protocol (cont.)

10. The role of the Designated Officer (and Delegated Officer in Western Australia or “the person in charge of the hospital” in the Northern Territory) is to:
 - a. ensure that documentation of death has been completed correctly
 - b. ensure that all relevant consents from the deceased patient, the senior next-of-kin and the Coroner have been obtained, and
 - c. authorise removal of tissue according to legislative requirements.

The Designated Officer or officer holding an equivalent role must be contacted before withdrawal of cardio-respiratory support, and in some jurisdictions will likely be present as death is certified.

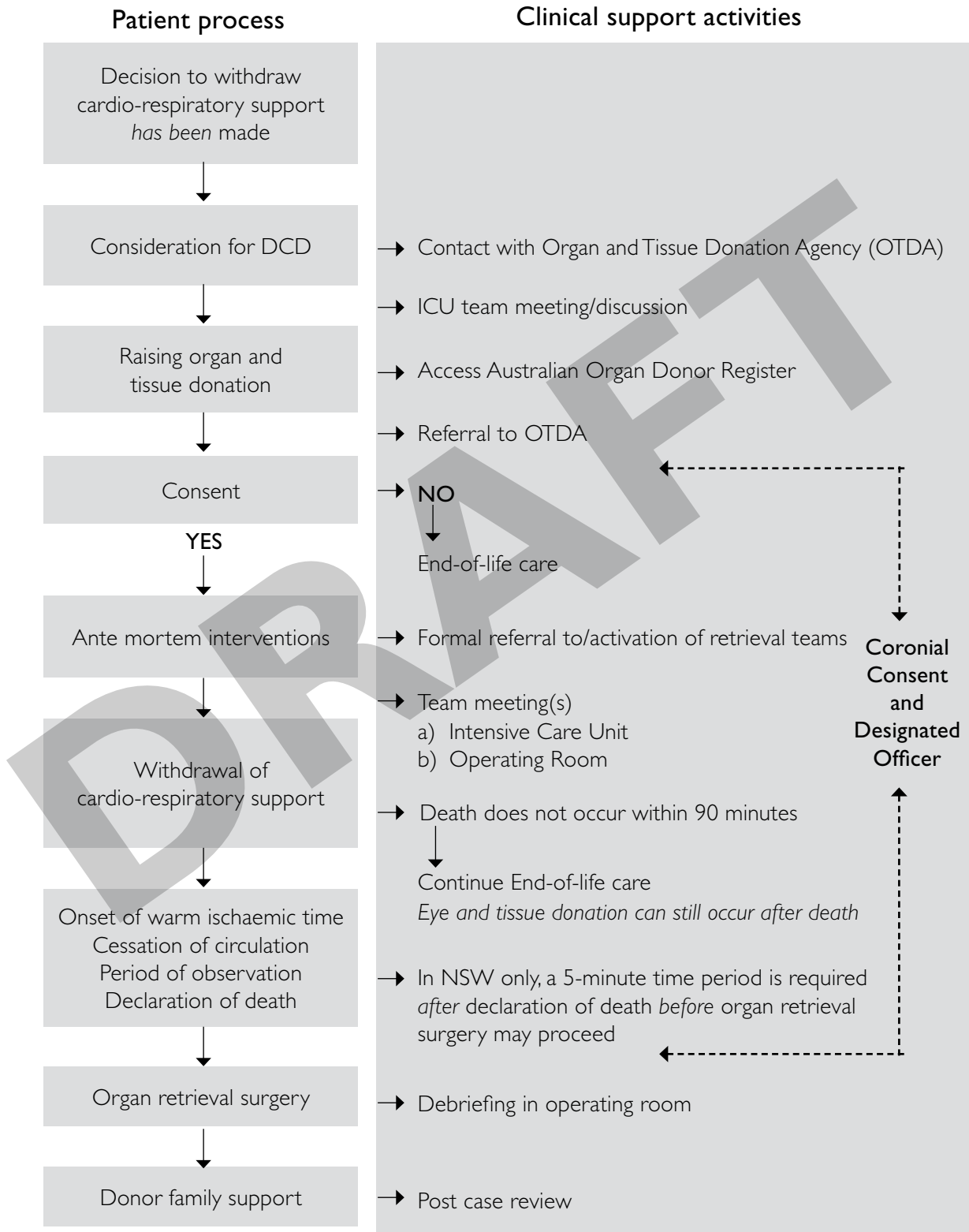
11. Referral of the potential organ and tissue donor to, and activation of, retrieval teams is usually the responsibility of the organ donor coordinator.
12. Ante mortem interventions can only occur if the patient is competent and consents or the senior available next-of-kin has given consent. The administration of ante mortem interventions must comply with jurisdictional legislation or guidelines and institutional protocol.
13. It is considered important that both the ICU team and the operating room team meet to plan care during the Donation after Cardiac Death process:
 - a. The ICU meeting should include the intensivist and bedside nurse, other members of the ICU team, organ donor coordinator and allied health professionals, and serves to assign roles and responsibilities during the withdrawal of cardio-respiratory support and later the Donation after Cardiac Death process.
 - b. In the operating room the organ donor coordinator, the operating room staff and the organ retrieval team meet to assign roles and responsibilities for the retrieval surgery. This operating room meeting should occur following the consent for organ and tissue donation but prior to the withdrawal of cardio-respiratory support.
14. The provision of end-of-life care and withdrawal of cardio-respiratory support is the responsibility of the primary treating team (usually the ICU team) and should be provided in accordance with jurisdictional or hospital policy. While it is illegal to administer treatments aimed at hastening death, there is no justification for withholding or limiting symptom relief in patients at the end of life, whether or not organ and tissue donation is to proceed.
15. If death does not occur within 90 minutes of withdrawal of cardio-respiratory support then the Donation after Cardiac Death process will cease. End-of-life care will continue, however this possibility will need to have been considered and planned for before withdrawal of cardio-respiratory support is undertaken. If consented, eye and tissue donation can still proceed upon the subsequent death of the patient.
16. Careful clinical observation during the period following withdrawal of cardio-respiratory support is essential. Monitoring of heart rate, oxygen saturation and blood pressure are all required. It is critical that the onset of ‘warm ischaemic time’ (WIT) is recognised with the onset of a systolic blood pressure \leq 50mmHg.

Donation after Cardiac Death Protocol (cont.)

17. Cessation of circulation is considered to be the absence of a palpable central pulse with the observation of a zero pulse pressure, measured on invasive arterial pressure monitoring.
18. A period of observation of the absence of pulsatile circulation of not less than two minutes is recommended as the minimum requirement to establish irreversibility. However, this period of observation should not exceed five minutes.
19. Certification of death should be undertaken by a senior medical practitioner based on 'irreversible cessation of circulation' following the period of observation in an immobile and apnoeic patient. Death must not be certified by a member of the organ retrieval or transplant team.
20. A five-minute time period *after* declaration of death is required in NSW *before* organ retrieval surgery can proceed. This period is not routinely offered in other jurisdictions unless negotiated with the family, who are made aware of the risk of reduction of graft viability that this entails. If opted for, this time period may be used to transfer the patient to the operating room to limit WIT.
21. Following death, the donor is transferred to the prepared operating room and retrieval surgery commences.
22. A team debrief in the operating room following organ retrieval surgery is highly recommended to address any issues relating to the process.
23. Families should be offered the opportunity of viewing the deceased body after retrieval surgery. Depending on local hospital policy, the body may be viewed in an area adjacent to the operating suite, in the ICU or in the hospital mortuary.
24. A post-case review meeting should be organised as soon as practicable following each Donation after Cardiac Death case. This forum enables staff involved to debrief and to discuss any quality-related issues identified in terms of the Donation after Cardiac Death process.

Donation after Cardiac Death Flowchart

This flowchart illustrates the process of care for the potential Donation after Cardiac Death (DCD) donor and the related clinical support activities as outlined in the protocol statements.



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SUMMARY OF CONSENSUS STAKEHOLDER WORKSHOP
DISCUSSIONS AND RECOMMENDATIONS

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Summary of consensus stakeholder workshop discussions and recommendations

The aim of the Consensus Stakeholder Workshop on Donation after Cardiac Death was to consult with experts in the organ donation and transplantation sector, review available national and international guidelines on Donation after Cardiac Death, and to make recommendations on the key elements of a consistent approach to Donation after Cardiac Death for Australia.

The participants were allocated to specific groups and asked to explore key issues and related questions identified by the Donation after Cardiac Death Working Party. Issues included: organisation of care; potential organ donor screening and predictors of death; family discussion and disclosure, consent, and accessing the Australian Organ Donor Registry (AODR); the role of ante mortem interventions; declaration of death (including onset of warm ischaemia and period of observation) and the minimum requirements for a facility to be able to undertake Donation after Cardiac Death.

The groups were asked to reach a consensus position on these items and report back to the wider group. The recommendations resulting from the workshop were used to inform the development of the protocol.

1. Organisation of care

Following a decision to withdraw cardio-respiratory support, Donation after Cardiac Death may be considered. It is recommended that the Organ and Tissue Donation Agency (OTDA) is contacted to determine suitability prior to raising organ donation with the family. As part of the Donation after Cardiac Death process, meticulous planning of the care of the patient and family is important. It is recommended that roles and responsibilities are assigned at these discussions/meetings.

A discussion amongst the ICU treating team to identify who should be present at the family meeting where organ and tissue donation is raised is beneficial. This discussion should include the treating intensivist, the ICU bedside nurse, the organ donor coordinator (if present) and other allied health professionals.

The AODR and other jurisdictional registers must be accessed to determine if there is a registration of the patient's wishes.

During the Donation after Cardiac Death coordination process it is suggested that there be further team meetings to plan care:

- a. An ICU meeting to assign roles and responsibilities during the Donation after Cardiac Death and withdrawal of cardio-respiratory support process. This meeting should involve the intensivist, bedside nurse, the organ donor coordinator, and allied health professionals. The Designated Officer or officer holding an equivalent role may or may not attend this meeting.
- b. A meeting in the operating room that occurs following consent but prior to the withdrawal of cardio-respiratory support, where roles and responsibilities are allocated. This includes preparation of the operating room and a review of paperwork to ensure that all legal requirements have been met. This meeting should involve the liaison consultant anaesthetist, peri-operative and peri-anaesthetic teams allocated for retrieval surgery including auxiliary staff members, the retrieval team including transplant surgeons, and the organ donor coordinator. A representative of the ICU team and the Designated Officer may or may not attend this meeting.

It is of benefit to all staff involved in the case to attend a post-case review meeting. This forum provides staff with an opportunity to debrief and for any quality issues in relation to the Donation after Cardiac Death process to be discussed.

Consensus stakeholder workshop recommendation

It is recommended that several team meetings or discussions are held, at key time points in the Donation after Cardiac Death process, to ensure a coordinated and controlled sequence of events and environment for both the family and health professionals involved.

2. The decision to withdraw cardio-respiratory support

Donation after Cardiac Death is possible in ICU patients following withdrawal of cardio-respiratory support if the family agrees to donation, if continuing treatment provides no prospect for recovery or is not in the patient's best interest.^[1]

Withdrawal of cardio-respiratory support is a pre-requisite to Donation after Cardiac Death and is a well-established practice in the ICU.^[1] This protocol does not offer recommendations for the process involved in that medical decision. However, it is anticipated that the decision to withdraw cardio-respiratory support is undertaken in accordance with established principles and guidelines.^[15, 16] The conduct of the discussion with the family regarding the withdrawal of cardio-respiratory support is likely to have a significant impact on the decision-making related to organ and tissue donation.

Caring for and respecting the dignity of the patient should be guided by patient interests and the needs of the family.^[7] It is important that the family understands that the care of the patient is not compromised by the need to preserve organs and that counselling and support are provided.^[5]

When determining the optimal place for the withdrawal of cardio-respiratory support, family preferences, hospital logistics, retrieval surgery and any relevant policy should be considered.

Consensus stakeholder workshop recommendations

- The decision to withdraw cardio-respiratory support, such as mechanical ventilation and/or inotropes and vasopressors should be made prior to, and independent of, any consideration of Donation after Cardiac Death.^[6]
- End-of-life care should be provided for all patients.
- Families should be offered care and support, ensuring effective communication about the plans for withdrawal of cardio-respiratory support.
- No member of the transplant or retrieval team should be involved in the end-of-life care, the withdrawal of cardio-respiratory support, or the declaration of death.

Refer to Section 12: Ethical issues

3. Medical suitability for Donation after Cardiac Death

Consideration for Donation after Cardiac Death

Once the decision to withdraw cardio-respiratory support has been made, the option of Donation after Cardiac Death needs to be considered by the treating intensivist. The option of Donation after Cardiac Death is possible when, in the judgment of the treating intensivist, the patient meets the following criteria:

- Maastricht Category 3 and 4 (Appendix 4)
- there is no absolute contraindication to donation
- the patient is likely to die within 90 minutes following the withdrawal of cardio-respiratory support.

An informal discussion with the OTDA regarding the medical suitability of the patient should occur at this time.

Predictors of death

It may be difficult to predict the likelihood that circulatory arrest will occur within 90 minutes of withdrawal of cardio-respiratory support. Several tools^[17-20] have been developed to predict death, however none of the tools has been adequately validated.

Australian experience^[21] using a modified University of Wisconsin assessment tool showed no statistical association with the time from withdrawal of cardio-respiratory support to death. The adapted United Network for Organ Sharing (UNOS) tool, systolic blood pressure, APACHE II score, ventilatory dependence, oxygen disruption, Glasgow Coma Scale (GCS) score and intensivist's opinion all showed a statistically significant association for predicting time from withdrawal of cardio-respiratory support to death.^[21]

It is possible to predict the time from withdrawal of cardio-respiratory support to death using GCS; respiratory and haemodynamic parameters; inotropes^[17] and the intensivist's clinical judgement. However, this requires validation in a large multicentre study.^[21]

If predictive tests are deemed necessary, the treating intensivist should document in the medical record any conversations held with and consents given by the family regarding these tests.

Consensus stakeholder workshop recommendation

Donation after Cardiac Death is contraindicated if the treating intensivist judges that the patient is likely to survive for longer than 90 minutes after withdrawal of cardio-respiratory support.

Raising organ and tissue donation with the family

The discussion addressing withdrawal of cardio-respiratory support must be clearly separated from the organ and tissue donation discussion. This is important to minimise distress to families and avoid any potential or perception of conflict of interest on the part of any persons involved in the care of the patient or the patient's family.^[9]

In some circumstances, where in the judgement of the intensivist the family has a clear understanding and acceptance of the patient's prognosis, it may be appropriate to raise the potential for organ and tissue donation sequentially to the decision to withdraw cardio-respiratory support in the same family discussion.

Some families may independently raise the possibility of organ and tissue donation, prior to the decision to withdraw cardio-respiratory support. If this occurs, the issue should be documented in the medical record and the family advised that further discussions will occur depending upon the clinical course of the patient.

Consensus stakeholder workshop recommendations

- Organ and tissue donation, including Donation after Cardiac Death, should be offered as a normal part of quality end-of-life care, and therefore should be raised with all potentially suitable patients.
- The use of a separate health professional to discuss Donation after Cardiac Death, other than the individual who conducted the discussion about treatment withdrawal, may be appropriate.^[1,6] Local institutional protocols should provide further direction in this matter.
- After agreeing to organ and tissue donation, the discussion with the family should include full disclosure of issues relating to the Donation after Cardiac Death process.
- The family, including the senior available next-of-kin, should be provided with information to make a considered decision about organ and tissue donation.

Accessing the Australian Organ Donor Register (AODR)

Australian Government policy requires consulting the AODR to ascertain the potential donor's registration status and any recorded wishes, and that the potential donor's family or senior next-of-kin should be informed of these (Appendix 5). The AODR should be accessed by authorised clinical personnel, predominantly organ donor coordinators and authorised doctors.^[1]

In NSW, the Road Traffic Authority (RTA) register may also be accessed to ascertain an individual's wishes.

Consensus stakeholder workshop recommendations

- The AODR should be accessed after the decision to withdraw cardio-respiratory support has been made, in all medically suitable patients who may be potential organ and tissue donors, to identify any registered consents or refusals to organ donation.
- The AODR may be accessed at any point from the end-of-life discussions, the decision to withdraw cardio-respiratory support, up to and including the consent by the family for organ and tissue donation.
- The family or senior available next-of-kin should be informed of the information recorded on the AODR in relation to the potential donor's wishes.

Contact the Organ and Tissue Donation Agency (OTDA)

All potential organ and tissue donors need to be referred to the State or Territory based OTDA.

The organ donor coordinator will attend the hospital and conduct an in-depth family interview, explaining in detail the process and requirements for Donation after Cardiac Death. Where verbal consent to organ and tissue donation has been obtained from the family by the treating intensivist, the organ donor coordinator will discuss all matters relating to the Donation after Cardiac Death process prior to obtaining written consent.

The organ donor coordinator is responsible for completing the Transplantation Society of Australia and New Zealand (TSANZ) / Australasian Transplant Coordinators Association (ATCA) confidential referral form, and performing a comprehensive clinical assessment including assessment of risk factors that would preclude donation.

The organ donor coordinator will liaise with the treating intensivist, the ICU team, operating room staff, retrieval teams and transplant coordinators throughout the donation process.

Consensus stakeholder workshop recommendations

Early contact with the OTDA can occur prior to seeking family consent for organ and tissue donation, to confirm medical suitability.

4. Consent and authorisation to proceed with organ and tissue donation

Patient/family consent

The laws that govern organ and tissue donation after brain death throughout Australia also govern Donation after Cardiac Death.^[1] However, in some jurisdictions consent is required, and in others absence of objection is sufficient. The relevant State and Territory legislation must be followed.

In relation to the patient or family:

- a. Written consent is required for specific organs and tissues as well as blood, spleen, lymph nodes and blood vessels, and for research. The written consents may also include the additional organs suitable for donation in the event that the patient progresses to brain death.
- b. Any discussions held with and consents obtained from the family and the senior available next-of-kin must be documented in the medical record.

No financial burden to the family or the estate of the deceased should ensue as a result of consenting to organ and tissue donation.^[1]

Consensus stakeholder workshop recommendations

- Clinicians should note the statement by the Australian Health Ministers' Conference (AHMC) Organ Donation Working Party (Appendix 5) that a sincerely held objection by the family should be respected even if it is in conflict with the known intention of the potential donor.^[1,5]
- It may be appropriate to obtain written consent for organ and tissue donation for both cardiac and brain death donation in the same discussion with the family.
- Information about Donation after Cardiac Death should be provided in the public domain for access by interested individuals.^[22]

Designated officer authorisation

All jurisdictions recognise the specific role within a hospital of an officer responsible for authorising the removal of organs and tissue for the purpose of transplantation, and other therapeutic, medical or scientific purposes.^[1] In all State and Territory legislation except NT, the person given the role is referred to as the Designated Officer. In WA there are both Designated and Delegated Officers. Under NT legislation the reference is to 'the person in charge of the hospital'.

State and Territory legislation regarding the responsibilities of the Designated Officer or officer holding an equivalent role must be adhered to in all cases.

The Designated Officer or officer holding an equivalent role should be informed when there is a potential donor suitable for Donation after Cardiac Death donation and what the wishes, consent or lack of objection of the donor and/or the senior available next-of-kin or other next-of-kin are. At that time, arrangements need to be made to contact the Designated Officer or officer holding an equivalent role immediately after the declaration of death so the authorisation can be given to donation proceeding.

Although the matters on which a Designated Officer or officer holding an equivalent role must decide are specified in different ways in State and Territory legislation (see Section 11, p.24-25), it can be said that the role of the Designated Officer or officer holding an equivalent role involves two elements: (1) authorising the removal of organs and tissue and (2) establishing that certain *matters* exist:

As to (1), the legislation provides that a Designated Officer or officer holding an equivalent role may authorise the removal of organs and tissue from a person “who has died” and appear to require the authorisation to be made after the person’s death.

As to (2), the legislation requires that the Designated Officer or officer holding an equivalent role establish the following *matters*:

- the wishes of, consent to, or lack of objection to, donation of the deceased
- the current consent or lack of objection to donation by the senior available next-of-kin
- the wishes or lack of objection of any other next-of-kin on the same or higher level
- the inability to ascertain the existence or whereabouts of next-of-kin, and
- that the Coroner has consented to the removal of organs.^[23,24]

Most (but not all) legislation states that authorisation for removal of organs and tissue must be in writing.^[1]

Consensus stakeholder workshop recommendations

- Appropriate processes must exist in hospitals to enable the Designated Officer or officer holding an equivalent role to authorise removal of organs and tissue for transplantation.^[1]
- The Designated Officer or officer holding an equivalent role may be responsible for determining if a death is reportable.
- Designated Officers or officers holding an equivalent role in the hospital should receive specific training regarding the Donation after Cardiac Death process and their responsibilities.

Coroner’s consent

If the death is reportable, consent for retrieval of organs and tissue for donation and transplantation is required from the Coroner. Legislation in all States and Territories provides that donation in this context cannot proceed without the Coroner’s consent.^[6]

The Coroner can be informed that there is a potential donor suitable for Donation after Cardiac Death and of the circumstances in which death will be determined and declared. In those jurisdictions in which the Coroner is authorised to give a direction before the person has died (see Section 11, p.25), that direction should be sought. In the remaining jurisdictions, if the Coroner is satisfied on the information provided that an autopsy will not be required, arrangements need to be made to contact the Coroner immediately after the declaration of death to secure consent to donation proceeding.

In some jurisdictions the Coroner may wish to withhold consent until circulatory arrest, although conditional approval will have been given before withdrawal of cardio-respiratory support.^[1]

Local policy and procedure may require additional permission from the respective forensic pathologist to undertake organ and tissue retrieval.^[25]

Consensus stakeholder workshop recommendation

In anticipation of death, appropriate hospital processes must exist where the death is reportable, to seek permission from the Coroner^[1] for organ and tissue donation.

Refer to Section 11: Legislative requirements
12: Ethical issues

5. Ante mortem interventions

Ante mortem interventions are only permitted (except in NSW and Qld^[6,10]) when the patient, if competent, or the senior available next-of-kin has given consent. This is consistent with international practice.^[1,8,12]

ANZICS supports such interventions only if available scientific evidence confirms their utility in improving organ viability.^[1] The evidence for at least some ante mortem interventions is variable and inconclusive. Ante mortem cannulation appears to result in no better outcomes than cannulation after cardiac arrest.^[26] There is some evidence in favour of anticoagulants and thrombolytic agents^[27,28] but it is not clear whether anticoagulation before cardiac arrest is superior to anticoagulation after cardiac arrest. Ante mortem anticoagulants may be administered at the discretion of the intensivist, provided he/she does not think it will influence the process of dying,^[8] and if agreed to by the family.

Ante mortem interventions that need to be routinely provided to support organ and tissue donation include tests to determine donor compatibility; the delaying of withdrawal of cardio-respiratory support; manipulation of inotropic or ventilatory parameters to maintain physiological stability, and vascular access procedures.

As Donation after Cardiac Death has not been directly addressed in existing law, consent for ante mortem interventions must be examined on a jurisdiction-by-jurisdiction basis.^[1,7] Health professionals are required to follow the legislation of the State or Territory in which they practise.^[5,6,10] Ante mortem interventions are not permitted in NSW and Queensland by their respective guidelines.^[6,10]

Consensus stakeholder workshop recommendations

- Ante mortem interventions including those recommended by the transplant team can be implemented at the discretion of the treating intensivist until more definitive evidence on their efficacy is available, provided there is no legal impediment and the consent of the family has been obtained.
- The decision-making process and consents gained for ante mortem interventions to facilitate the Donation after Cardiac Death process should be clearly documented in the medical record.
- Legal requirements concerning ante mortem interventions vary between jurisdictions. Health professionals are required to follow the legislation of the State or Territory in which they are practising.^[5]

Refer to Section 11: Legislative requirements
12: Ethical issues

6. Management after withdrawal of cardio-respiratory support

For Donation after Cardiac Death, intensivists are likely to be the senior medical practitioners caring for patients up until death.^[5] The medical and ethical framework for the withdrawal of cardio-respiratory support, provision of best practice end-of-life care and all aspects of management of withdrawal of cardio-respiratory support is the responsibility of the treating intensivist and the intensive care team.

The withdrawal of cardio-respiratory support should occur according to jurisdictional legislation and institutional protocol.^[5,7,15] The person responsible for the withdrawal of cardio-respiratory support should be independent of the retrieval or transplantation teams.^[7]

The location of withdrawal of cardio-respiratory support will occur according to local hospital logistics, policy and family preferences. This can occur either in the ICU, peri-operative area or the operating suite. It is appropriate to allow the family to be present if they so wish while cardio-respiratory support is withdrawn and until the person's death, irrespective of the location for withdrawal.

The timing of withdrawal of cardio-respiratory support for the purpose of Donation after Cardiac Death is undertaken at a time that is appropriate following discussion between the family, the ICU team, organ donor coordinator, operating room staff and transplant teams.

While no medication should be administered with the intent of hastening death, all the usual measures to control pain, discomfort, suffering and anxiety should be administered to ensure a death with dignity.^[11,15,16]

Consensus stakeholder workshop recommendations

- There is no justification for withholding or reducing pain relief in patients who wish to become organ and tissue donors.
- Medical practitioners must not administer treatments aimed at hastening death.

7. Declaration of death

Given the importance of achieving uniformity in clinical practice across jurisdictions, death after cessation of circulation (in the context of Donation after Cardiac Death) should be determined according to the procedures outlined in the ANZICS Statement on Death and Organ Donation.^[1]

The legal standard on which the certification of cardiac death relies is the irreversible cessation of circulation of blood in the body of the person. A period of observation is necessary to determine that circulation will not recur spontaneously (auto resuscitation).^[17] Cessation may then be declared irreversible because cardiopulmonary function *will not resume spontaneously* (auto resuscitation), and there is no legal or ethical basis for attempting resuscitation.^[17]

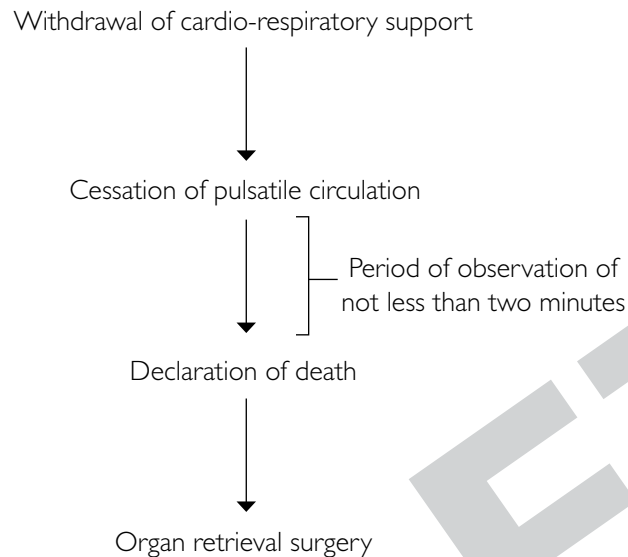
In circumstances other than donation, clinical examination alone is generally sufficient to determine cessation of circulation, and death is confirmed by clinical examination revealing the absence of responsiveness, heart sounds, pulse and respiratory effort.^[1] However, the urgent time constraints of Donation after Cardiac Death require rapid and definitive proof of cessation of circulation by use of monitoring and/or confirmatory tests.^[6] Where possible, intra-arterial monitoring should be utilised to determine cessation of circulation for a period of not less than two minutes to assure the family and staff that the patient is dead. However this period of observation should not exceed five minutes. Clinical observations that should be recorded following withdrawal of cardio-respiratory support include heart rate, arterial blood pressure, respiratory rate and oxygen saturation.

Declaration of death by a medical practitioner is required by law before organ retrieval can proceed. After declaring death, there is no impediment to proceeding with activities directed towards organ retrieval. The intensivist responsible for determining death should document the time and date of death.^[1] The patient must be declared dead by an intensivist or other designated doctor who is not a member of the organ retrieval or transplantation team. Once death has been declared, measures that may restore circulation must not be undertaken. Reintubation without ventilation to prevent aspiration and ensuing pulmonary damage is permissible.^[1]

If irreversible cessation of circulation after withdrawal of cardio-respiratory support does not occur within a timeframe consistent with successful donation (as designated by State, Territory or local policy), the patient must be returned to a prearranged area for continuing end-of-life care.^[5] This possibility will need to have been considered and planned before withdrawal of cardio-respiratory support.

Figure 1: Declaration of Death Time Intervals

A nationally harmonised approach to illustrate the time intervals between withdrawal of cardio-respiratory support, declaration of death and progress to surgery.



NOTE: The NSW Donation after Cardiac Death guideline requires a five-minute time period *after* the Declaration of Death, *before* organ retrieval surgery may proceed. This is considered mandatory in NSW only.^[6] This time period is **not** routinely required outside NSW and need not be offered unless negotiated by the family, aware of the risk of reduction of graft viability that this entails.

Consensus stakeholder workshop recommendations

- Cessation of circulation as evidenced by absent palpable central pulse and a pulse pressure of zero, measured by intra-arterial catheter, followed by a period of observation of at least two minutes to exclude auto-resuscitation, is required to declare death.
- ECG monitoring is not required, as electrical activity may persist for many minutes following the cessation of circulation, which is the basis for the declaration of death.^[1]
- Data should be collected in a nationally consistent manner. Heart rate, blood pressure and oxygen saturation should be measured following withdrawal of cardio-respiratory support. Clinical data is documented in the medical record or Donation after Cardiac Death record maintained by the organ donor coordinator.
- A single clock must be used to time all events relating to Donation after Cardiac Death, to ensure that an accurate record of the sequence of events is maintained.^[1]
- The most useful determinant of the onset of warm ischaemic time is a systolic blood pressure (SBP) ≤ 50 mmHg and needs to be accurately recorded.
- Death is declared by a senior medical practitioner.

Refer to Section 12: Ethical issues

8. Organ retrieval surgery

The organ donor coordinator is responsible for the offer of organs and coordination of the retrieval surgery and retrieval teams. They will liaise with the operating room staff and the liaison consultant anaesthetist, notifying them of the potential Donation after Cardiac Death donor. This enables the operating room staff to negotiate staff requirements and theatre availability.

All necessary preparations in the operating room should be completed and the retrieval teams and operating room staff should be ready prior to withdrawal of cardio-respiratory support, to ensure that warm ischaemic time is kept to a minimum.

Consensus stakeholder workshop recommendation

Once death has been declared the retrieval surgery must commence as soon as possible. The nature of the surgical process is dependent on whether single or multi-organ retrieval is to be performed.^[6]

9. Donor family support

Family counselling and support must be offered throughout and following the Donation after Cardiac Death process, consistent with established State and Territory OTDA and local hospital policy and procedures.

Consensus stakeholder workshop recommendation

Families should be offered care and support, ensuring effective communication throughout the Donation after Cardiac Death process, including the ongoing care of the patient following the withdrawal of cardio-respiratory support, declaration of death, retrieval surgery and post-mortem viewing of the deceased.

10. Minimum requirement for a facility to be able to undertake Donation after Cardiac Death

There was recognition that there needed to be recommendations related to the system and infrastructure required for the implementation of a national Donation after Cardiac Death protocol.

The implementation of a Donation after Cardiac Death protocol in a hospital requires support and endorsement from all staff involved within the organisation. It should not be undertaken until the relevant staff members have been educated.^[1]

A hospital requires the following organisational and clinical features to undertake Donation after Cardiac Death:

- institutional commitment from the hospital management to support Donation after Cardiac Death in the short and long term
- clinical leadership for the program and defined responsibility and accountability mechanisms
- relevant clinical expertise and resources including ICU, Emergency Department and Operating Room capacity, Radiology, and access to an approved laboratory and diagnostic services
- access to a Designated Officer or officer holding an equivalent role and the Coroner, and
- access to a bereavement program such as the services provided by a State- or Territory-based OTDA.

Consensus stakeholder workshop recommendations

- A national protocol should be developed that defines the key requirements for a hospital to implement a Donation after Cardiac Death program, outlining a framework for hospitals to develop local Donation after Cardiac Death operational policies and procedures which can be used for certification.
- The national protocol will need to be underpinned by a tiered training system able to provide initial training and support during the roll-out of a hospital Donation after Cardiac Death program as well as support for ongoing certification and professional development requirements.
- The option of developing an inter and intra jurisdictional referral and transfer system to move donors or staff expertise between hospitals should also be explored to ensure there is equity of access to Donation after Cardiac Death.

11. Legislative requirements associated with Donation after Cardiac Death

Donation and transplantation of organs or tissues is conducted in the context of laws that govern the provision of health care generally, and are substantially uniform in Australia. These laws, both statutes and common law, establish the necessity for, and the conditions of, effective consent to health care, requirements for competence to make health care decisions, and the standards of conduct of health professionals. However, other laws that are relevant are not uniform, for example, those that determine the identity and authority of those who can make health care decisions for people who lack that capacity.

The difficulties that these differences present for a national protocol for the decisions that are necessary for donation of organs and tissues after cardiac death are identified below.

Deciding to withdraw cardio-respiratory support

This is an essential stage in Donation after Cardiac Death and is made as part of regular intensive care practice and on established criteria.

Where the practice involves discussion with representatives of the patient, establishing authority can be important. Laws in the Australian Capital Territory (ACT), Queensland (Qld) and Tasmania (Tas) are explicit that the authority of such representatives includes the withdrawal of cardio-respiratory support. Laws in the Northern Territory (NT), South Australia (SA), Victoria (Vic) and Western Australia (WA) are not explicit on this matter, and law in New South Wales (NSW) has been interpreted in different ways in two recent decisions^[29,30] leaving it unclear whether they have this authority.

Deciding about ante mortem interventions

Although the practice of ante mortem interventions is not uniform in Australia, it is important to establish the conditions in which they are lawful. If the patient is competent to decide about ante mortem interventions, the legal issue is whether sufficient information has been provided to inform that decision.

If the patient is incompetent to decide, some uncertainties arise about whether an authorised decision-maker has authority to make this decision. Laws in jurisdictions other than NSW are not explicit on such a decision but commonly require the decision-maker to reach a decision that is in the best interests of the person concerned and to take their wishes into account. Guidelines in

NSW and Qld prohibit these decision-makers from approving ante mortem interventions (see below).

In the Donation after Cardiac Death context, the decision of an authorised decision-maker to consent to interventions and the decision of the senior available next-of-kin to consent to organ and tissue donation need to be made in a short timeframe. There may be advantages in identifying one person who has authority to make these decisions and is also the appropriate family member with whom to discuss the decision to withdraw cardio-respiratory support.

In NSW, because the decision-maker is required to have regard to the objects of the relevant part of the Act, which are:

- “a) to ensure that people are not deprived of necessary medical or dental treatment merely because they lack the capacity to consent to the carrying out of such treatment, and
- b) to ensure that any medical or dental treatment that is carried out on such people is carried out for the purpose of promoting and maintaining their health and well-being”

the view has been taken that, as these interventions would not meet those objectives, the decision-maker cannot authorise them.

The point being made in the NSW guidelines is that because both paragraphs (a) and (b) must be taken into account by a decision-maker, that person cannot consent to ante mortem interventions.

In Qld, guidelines provide that “the administration of treatments in order to optimise organ function for the benefit of the recipients, in the period after withdrawal of LST (life sustaining therapies) *before* the patient’s death, is not permissible in Queensland”.^[10]

Consent to organ and tissue donation

If this consent has been given by the patient, the legal issue is whether sufficient information has been provided to inform that decision. If the decision is to be made by the senior available next-of-kin, as provided by State and Territory transplantation laws, the practical difficulty, noted above, may arise if differences among relevant State and Territory laws preclude the same person qualifying to be the decision-maker for the decisions about ante mortem interventions and about donation, as well as the appropriate person with whom to discuss withdrawal of cardio-respiratory support.

Authorisation by the Designated Officer or officer holding an equivalent role

Differences among State and Territory laws that set out the conditions for the Designated Officer’s authorisation may present difficulties. The legislation differs in relation to the conditions for Designated Officer authorisation, the standard for that authorisation, and the nature of the senior available next-of-kin’s decision.

Conditions for Designated Officer authorisation

In the ACT and NSW, the Designated Officer is first required to make inquiries to establish whether the deceased had expressed a wish for, or consented to, donation and can authorise removal of organs and tissue where this is established. *Only if this is not established*, can the Designated Officer proceed to make inquiries about the absence of objection (ACT) or consent (NSW) of the senior available next-of-kin, and authorise removal of organs and tissue if this is established. The legislation makes the first set of inquiries (about the deceased’s wishes) a condition to be met before the second set (about the senior available next-of-kin’s views) can be undertaken. In all other jurisdictions, this condition is not applied.

Standards for Designated Officer authorisation

In ACT and Tas, the standard of decision for the Designated Officer is that the necessary matters “appear” to exist. In NSW, the Designated Officer is required to be “satisfied” that the necessary matters exist while in the remaining jurisdictions, the Designated Officer must have “reason to believe” that those matters exist (or no reason to believe that they do not).

Nature of senior available next-of-kin’s decision

In NSW, Qld, Tas, Vic and WA, the Designated Officer or officer holding an equivalent role is required to establish that the senior available next-of-kin has consented, while in ACT, NT and SA, the Designated Officer or officer holding an equivalent role is to establish that the senior available next-of-kin has no objection.

Because the time period for these decisions will be compressed in the Donation after Cardiac Death context, identifying these differences and establishing processes that conform will be important.

Timing of Designated Officer decisions and authorisation

State and Territory legislation provides that a Designated Officer or officer holding an equivalent role may authorise the removal of organs and tissue from a person “who has died” and appear to require the authorisation to be made after the person’s death.

The legislation also requires the Designated Officer or officer holding an equivalent role to decide (according to the varying standards listed above) that *certain matters* exist in relation to that person, namely:

- the wishes of, consent to, or lack of objection to, donation of the deceased
- the current consent or lack of objection to donation by the senior available next-of-kin
- the wishes or lack of objection of any other next-of-kin on the same or higher level
- the inability to ascertain the existence or whereabouts of next-of-kin
- that the Coroner has consented to the removal of organs.^[23,24]

The laws appear not to prevent the Designated Officer or officer holding an equivalent role making inquiries and reaching decisions on these matters before the person dies.

Coronial consent

In cases of Donation after Cardiac Death where the death is reportable to the Coroner, consent is necessary for the retrieval of organ and tissue. Because the timing of that consent could be critical to the success of Donation after Cardiac Death, differences among State and Territory laws could create difficulties for a national protocol.

In NT, SA, Vic and WA, the relevant legislation places an onus on the Designated Officer or officer holding an equivalent role to decide whether or not the death is one that attracts the jurisdiction of the Coroner, while in ACT, NSW, Qld and Tas, the legislation only requires that the Coroner’s consent be obtained.

In Qld, SA, Tas and WA, legislation authorises a Coroner to give a direction before the death of the person that the Coroner’s consent to removal of organs and tissue is not required.

12. Ethical issues associated with Donation after Cardiac Death

Donation after Cardiac Death raises a number of ethical issues that require thoughtful deliberation and sensitive practice to avoid any potential harm to patients, their families, recipients and the health care team.

End-of-life care

All dying patients deserve the best possible end-of-life care. This includes compassionate and respectful care at all times, adequate pain relief and other comfort measures, and consideration of the needs of family/friends. There are no inherent barriers to providing good end-of-life care to patients who wish to become organ and tissue donors. In particular, there is no justification for withholding or reducing pain relief in patients who wish to become organ and tissue donors.^[2,22]

Medical practitioners must not administer treatments aimed at hastening death.

Participation in Donation after Cardiac Death affects the timing of withdrawal of cardio-respiratory support; in most cases treatment is continued for longer than might otherwise occur. Disruption or distress to family and friends should be minimised as much as possible by maintaining care and support and ensuring effective communication about the plans for withdrawal.^[2]

Respecting patient autonomy

In general, health care providers have an ethical obligation to respect the known wishes of patients. Offering Donation after Cardiac Death to patients who wish to become organ and tissue donors is a way of respecting their autonomy. Practitioners have a well recognised obligation to ascertain and facilitate their patient's wishes about donation, through consultation with the AODR, from conversations with the family, or by other means. The currency of the patient's decision should be investigated, especially if considerable time has elapsed since registration of the decision.^[2]

In most circumstances, family and friends will respect a patient's own decision about donation, particularly if this has been discussed at some time; their role is then one of affirmation or confirmation of the patient's wishes. It is rare that relatives will go against a known wish to donate, even if they were unaware of that decision. Should this occur it creates a conflict for practitioners between respecting the patient's choice, and providing care and support to the family. All attempts to understand the reticence of the family should be made and reassurance given regarding any misconceptions related to organ and tissue donation. However, organ and tissue donation should be abandoned if it is considered that this would have a significant adverse impact upon the wellbeing of the surviving family members.^[1,5] It may be justifiable to override the patient's decision to donate if the family is unable to support that decision, on the grounds that the patient may have withdrawn consent if they had understood the distress that this would cause to their loved ones.^[2]

Consent

Consent to medical interventions should be informed and voluntary. Unlike other medical interventions, decisions about consent for organ and tissue donation have traditionally been made by the individual alone, without a face to face meeting with a health care professional or a detailed description of organ retrieval and the associated processes. This has been justified on the grounds that the intervention (retrieval) takes place after the death of the person. After death, the person no longer has physical interests susceptible to harm. In a sense, the details matter less as there is no range of options to choose from; the critical decision is to either be or not be a donor (although if choosing donation, individuals may indicate which organs or tissues they wish to donate). Other

reasons why donation decisions may be based on limited information include the fact that thinking about donation can be difficult as this requires facing one's own mortality, and that it may be distressing to consider the details of the operation.

This generally low level of understanding about organ and tissue donation is in marked contrast to the situation once a person is a potential organ and tissue donor. The burden then falls upon the family, who are provided with what can be overwhelming amounts of information when consenting to donation for a Donation after Cardiac Death patient. Thus there is a tension between the level of information we regard as adequate to make a considered decision to donate, and the level provided (usually to the family) once donation is a reality. This tension applies to donation after death diagnosed by the brain function criteria as well as Donation after Cardiac Death. Resolving this tension is beyond the scope of this protocol^[2], but we recommend increased provision of appropriate public information.

Ante mortem interventions

Preparing a patient for organ and tissue donation requires a number of interventions, such as taking blood for screening and tissue typing and other physical investigations.^[2,22] In addition to these procedures, which are routine for all donors, there are a number of interventions that are specific to potential Donation after Cardiac Death donors, such as administering heparin and other drugs or cannulating femoral vessels. Unlike donors after brain death, all of these interventions take place prior to death in Donation after Cardiac Death patients. Performing these interventions raises issues of beneficence, non-maleficence^[2,22] and consent. Health care practitioners are obliged to act for the good of their patients and to avoid harming them.

Ante mortem interventions are performed for the health of potential recipients, rather than the health of the donor patient. Therefore the ethical justification for ante mortem interventions must be grounded in a broad understanding of the patient's interests. At this point in time when the patient is dying, he or she has very limited physical interests to promote.^[2,22] However, such patients have an interest in having their decisions executed. It is reasonable to assume that if a person wishes to be an organ and tissue donor, this includes performing the donation in a way that will maximise its likely success, consistent with not harming the patient. Ante mortem interventions are ethical if they will contribute to the likely success of the transplantations and do not harm the patient, therefore their administration requires a careful case by case assessment of each intervention and each patient. As with other aspects of organ and tissue donation, most potential donors are unaware of the details of ante mortem interventions when they make their decision to donate. This means that the onus for authorising ante mortem interventions falls upon the patient's relatives or legal decision maker, based upon the best interests of the donor patient.^[2,22]

In addition to these issues, the use of ante mortem interventions raises the concern that the donor patient may be treated in an instrumental way, as a means to an end, rather than as a person in their own right. Addressing this concern relies upon the high quality and patient-centered clinical care offered to the patient by their practitioners.^[2]

Declaration of death

For successful transplantation, organs must be retrieved from the deceased person as soon as possible after death has occurred. In diagnosing death, it is important to satisfy the need for certainty so that practitioners and the family can be confident that the patient is indeed dead. The legal requirement for certifying death relies upon the irreversible cessation of circulation^[1]; how this is diagnosed is a clinical matter and the legislation offers no further guidance on determining irreversible cessation of the circulation.

Death occurs once the circulation ceases. In order to meet the irreversibility requirement, death cannot be declared until the possibility of auto resuscitation has been excluded, hence the minimum of a two minute period between circulation ceasing and death being declared.^[1,2]

At this point there may be a tension between the family's needs and those of proceeding to donation.^[22] Each case requires sensitive handling and good communication with the family prior to the moment of death in order to prepare them for the sequence of events.^[2,22] The family must be fully informed regarding the necessity for the prompt transfer of the patient to the operating room following declaration of death in order to fulfill their loved one's wishes and ensure the best outcome for transplantation.

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Definitions

Designated Officer (or officer holding an equivalent role):

A person responsible for scrutinising the process and authorising the removal of organs and tissues from a deceased person for transplantation.

Donation after Cardiac Death (DCD):

Also known as Non-Heart Beating Donation, refers to donation after death has been determined to have occurred, on the basis of the absence of circulation (and of other vital signs).

End-of-life care:

Care provided to the dying individual and their surviving loved ones.^[31]

Family:

In this document, family means those closest to the person in knowledge, care and affection, including the immediate biological family; the family of acquisition (related by marriage or contract); and the family of choice and friends (not related biologically or by marriage or contract).^[1]

Family meeting:

A structured meeting between the members of the family of an intensive care patient and staff involved in the care of the patient; sometimes also called family conference.^[31]

Intensivist:

In this document, intensivist means an intensive care specialist or other specialist with rostered responsibility for patients in the ICU.^[1]

Period of observation:

The period of time immediately after circulation ceases, during which time the person is observed to confirm that the cessation of circulation is irreversible (determined by loss of pulsatile activity on the intra-arterial wave-form) up to the declaration of death. The minimum length of time for observation is two minutes.

Senior available next-of-kin:

The senior available next-of-kin, of a deceased adult, is the person who is available and highest in the hierarchy:

- the spouse of the person
- son or daughter, over the age of 18, of the person
- a parent of the person, or
- a brother or sister, over the age of 18, of the person.

The senior available next-of-kin, of a deceased child, is the person who is available and highest in the hierarchy:

- a parent of the child
- a brother or sister, over the age of 18, of the child
- a guardian of the child.

Warm Ischaemic Time (WIT):

The onset of warm ischaemic time is a systolic blood pressure ≤ 50 mmHg. Warm ischaemic time is the loss of normal or adequate blood flow to an organ to the start of cold perfusion. The concept of warm ischaemic time is relevant to transplantation, with the period of a systolic blood pressure ≤ 50 mmHg to cold perfusion flush deemed most critical as organ integrity is compromised.

Withdrawal of cardio-respiratory support:

Withdrawal of cardio-respiratory support is defined as the cessation of inotropic and ventilatory support. This term replaces “withdrawal of care”, “withdrawal of life-sustaining therapy” and “withdrawal of life support”.

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Appendix I: Donation after Cardiac Death Protocol Checklist

The following is an approximate sequence of events

Process	Person(s) responsible	Good practice point
1. The decision to withdraw cardio-respiratory support (withdrawal of cardio-respiratory support) has been made with the family	Intensivist	Withdrawal of cardio-respiratory support is a pre-requisite for Donation after Cardiac Death. This protocol offers no recommendations for the process involved in that medical decision. It is anticipated however, that the decision to withdraw cardio-respiratory support is undertaken in accordance with established principles and guidelines.
2. Does the patient meet the criteria for Donation after Cardiac Death?	Intensivist	Donation after Cardiac Death is not appropriate if, in the judgement of the treating intensivist, it is anticipated that a patient is likely to survive for longer than 90 minutes after withdrawal of cardio-respiratory support.
3. First contact with the Organ and Tissue Donation Agency (OTDA)	Intensivist	Consideration for Donation after Cardiac Death involves a formal assessment of medical suitability. An earlier discussion with the OTDA may also be helpful in establishing clear exclusions. Cease process if potential donor is unsuitable.
4. ICU team meeting/ discussion	Intensivist	Careful consideration should be given to determining the appropriate roles and responsibilities for the organ donation discussion with the family.
5. Access the Australian Organ Donor Register (AODR)	Intensivist or organ donor coordinator	The AODR (and other jurisdictional registers) should be accessed in all medically suitable patients, during end-of-life discussions when considering organ and tissue donation as per Australian Government policy. When the AODR is accessed, the information should be conveyed to the family (Appendix 5). AODR accessed <input type="checkbox"/>
6. Organ donation is raised with the family	Intensivist	Organ donation may have already been raised by the family. The senior available next-of-kin and other family members require appropriate information to make a considered decision about Donation after Cardiac Death.
7. Referral to the OTDA	Intensivist	The OTDA will require formal notification and will require the following referral information: patient demographics; diagnosis; past medical and social history; current clinical data, and requirement for Coronial referral.
8. Obtain written consent for organ donation from the family	Intensivist or organ donor coordinator	Formal written consent is required for specific organs and tissues as well as blood, spleen, lymph nodes and blood vessels and for research. It may be appropriate to obtain conditional consent at the same time for the specific organs and tissues to be donated in the event of brain death, if there is a realistic possibility of this eventuality.
9. Obtain Coronial consent (if reportable death)	Intensivist or organ donor coordinator	Consent from the Coroner is necessary for Donation after Cardiac Death if the death is reportable, and should be documented in writing.
10. Authorisation of Designated Officer is required	Intensivist or organ donor coordinator	To ensure that: 1) documentation of death has been completed correctly 2) all relevant consents from the deceased patient, the senior available next-of-kin and the coroner have been obtained 3) authority to remove organs and tissue according to legislative requirements has been provided.
11. Referral of potential organ donor to, and activation of, retrieval teams	Organ donor coordinator	The organ donor coordinator is responsible for the offer of organs and coordination of the retrieval surgery and retrieval teams.
12. Administration of ante mortem interventions	Intensivist	Ante mortem interventions can only occur if the patient is competent and consents or the senior available next-of-kin has given consent. The administration of ante mortem interventions must comply with jurisdictional legislation or guidelines and institutional protocol.

Appendix I: Donation after Cardiac Death Protocol Checklist (cont.)

Process	Person(s) responsible	Good practice point
13. Meeting(s) to plan care 1) ICU team 2) Operating room	1) ICU team 2) Organ donor coordinator	1) A meeting is held in the ICU for planning care and assigning roles, and to clarify the process of withdrawal of cardio-respiratory support and later the Donation after Cardiac Death process. 2) In the operating room, the organ donor coordinator, the operating room staff and organ retrieval team meet to assign roles and responsibilities for the retrieval surgery. This meeting occurs after consent for organ and tissue donation, but prior to withdrawal of cardio-respiratory support.
14. Withdrawal of cardio-respiratory support	Intensivist	The provision of end-of-life care and withdrawal of cardio-respiratory support is the responsibility of the primary treating team (usually in the ICU) and should be provided in accordance with jurisdictional or hospital policy.
15. In the event that the patient does not die within the specified timeframe, end-of-life care continues	Intensivist	If death does not occur within the 90 minute timeframe, then the Donation after Cardiac Death process will cease. End-of-life care will continue. This possibility will need to have been considered and planned for prior to withdrawal of cardio-respiratory support. If consented, eye donation and tissue donation can still proceed upon the subsequent death of the patient. Cease Donation after Cardiac Death process.
16. Onset of warm ischaemic time	Intensivist and organ donor coordinator	1) Careful clinical observation during the period following withdrawal of cardio-respiratory support is essential to recognise the onset of 'warm ischaemic time' recognised by a systolic blood pressure \leq 50mmHg. 2) It is important to time the process on a single clock.
17. Cessation of circulation	Intensivist	Cessation of circulation is considered to be the absence of a palpable central pulse with the observation of a zero pulse pressure, measured on invasive arterial pressure monitoring.
18. The period of observation	Intensivist	A period of observation of the absence of pulsatile circulation of not less than two minutes is recommended as the minimum requirement to establish irreversibility. However this period of observation should not exceed five minutes.
19. Declaration of death	Intensivist	Certification of death is undertaken by a senior medical practitioner, based on 'irreversible cessation' following the period of observation in an immobile apnoeic patient.
20. NSW State Guideline requires a five minute time period after the declaration of death, before organ retrieval surgery may proceed.	Intensivist	Not offered outside NSW. Not routinely required in other jurisdictions unless negotiated by family, aware of the risk of reduction of graft viability that this entails.
21. Transfer of deceased donor to operating room (if site of withdrawal is other than operating room)	ICU, organ donor coordinator and ancillary staff	The donor is transferred directly into a prepared operating room and retrieval surgery commences.
22. Debriefing for operating room staff	Organ donor coordinator	A team debriefing in the operating room following organ retrieval surgery provides an opportunity to address issues related to the process.
23. Opportunity for family to spend time with the deceased.	Organ donor coordinator, bedside nurse, social worker	Families should be offered the opportunity of viewing the deceased body after retrieval surgery.
24. Post-case review	ICU team	A post-case review meeting should be organised as soon as practicable. It enables staff involved to debrief and discuss quality-related issues identified in terms of the Donation after Cardiac Death process.

Appendix 2: Donation after Cardiac Death Working Party

NAME	RELEVANT AFFILIATIONS	POSITION
Gerry O'Callaghan Chair	Chair: National Organ Donation Collaborative (NODC) Advisory Committee, Australian and New Zealand Intensive Care Society (ANZICS)	Intensivist, Flinders Medical Centre, SA
Deanne Crosbie	NODC Advisory Committee, Australasian College for Emergency Medicine (ACEM)	Emergency Department Physician, Townsville Hospital, QLD
Nicola Dykes	NODC Advisory Committee	Organ and Tissue Donor Coordinator, Westmead Hospital, NSW
Kathy Hee	NODC Advisory Committee, Australian Transplant Co-ordinators Association (ATCA)	Manager, South Australian Organ Donation Agency (SAODA)
Ray Raper	NODC Advisory Committee, ANZICS	Head of Intensive Care, Royal North Shore Hospital, NSW
Bill Silvester	NODC Advisory Committee (proxy for Dr Helen Opdam), ANZICS Organ Donation Committee	Intensivist, The Austin Hospital, VIC
Alison Barnwell	LifeGift NSW	Coordinator of Bereavement Services, Lifegift NSW
David Cook	Queensland Health, Queenslanders Donate/ ANZICS	Intensivist, Princess Alexandra Hospital, QLD
Michael Fink	Transplant Society of Australia and New Zealand (TSANZ)	Transplant Surgeon, The Austin Hospital, VIC
Catherine Hannan	Australian College of Critical Care Nurses (ACCCN)	Organ Donor Coordinator, SAODA
Ella Meek	Australian College of Operating Room Nurses (ACORN)	Theatre Nurse, Westmead Hospital, NSW
David Pilcher	ANZICS	Intensivist, The Alfred, VIC
Graeme Pollock	Lions Eye Donation Service (representing Tissue Sector)	Director, Lions Eye Donation Service, VIC
Wendy Rogers	Deputy Chair: NHMRC Organ Donation Guideline Working Group	Professor of Clinical Ethics, Macquarie University, NSW
Francesca Rourke	Queenslanders Donate	Organ Donor Coordinator, QLD
Colin Thomson	Chair: Australian Health Ethics Committee	Professorial Fellow, University of Wollongong and Adjunct Professor, Macquarie University, NSW
Julie Vomero	Consumer whose husband was a DCD donor	Consumer, VIC
Sue Huckson	National Health and Medical Research Council (NHMRC), National Institute of Clinical Studies (NICS)	Director: Effective Practice Program, NODC Project Manager
Alina Tooley	NHMRC NICS	NODC Transition Manager
Shena Graham	NHMRC NICS	Donation after Cardiac Death Project Officer

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Appendix 3: Consensus stakeholder workshop participants

NAME	RELEVANT AFFILIATIONS
Claire Baker	TSANZ Standing Committee, Transplant Coordinator (Living Donor Transplant Coordinator)
Alison Barnwell	DCD Working Party / Bereavement Counsellor, LifeGift NSW
Deepak Bhonagiri	State Medical Coordinator NSW / ANZICS Organ Donation Committee
Margaret Bramwell	Senior Social Worker, Royal North Shore Hospital
Jorge Brieva	Intensivist, John Hunter Hospital
Robbie Brown	Area Organ and Tissue Donor Coordinator, Royal North Shore Hospital
Bettina Clark	LifeGift VIC
Tina Coco	Queenslanders Donate
Nicole Coleman	NODC Advisory Committee
David Cook	DCD Working Party
Michael Crawford	TSANZ Standing Committee – Liver Transplant
Deanne Crosbie	NODC Advisory Committee / DCD Working Party / ACEM
Amy Davis	LifeGift NSW/ACT
Pam Dipplesman	ACCCN, Organ and Tissue Donation and Transplantation Advisory Panel
Geoff Dobb	NODC Advisory Committee / Chair ANZICS Organ Donation Committee
Jo Duflou	Forensic Pathologist, Department Of Forensic Medicine, University of NSW
Nicola Dykes	NODC Advisory Committee / DCD Working Party
Michael Fink	DCD Working Party / TSANZ Liver Rep
Jonathan Gillis	Paediatric Intensivist, Westmead Hospital
Jennifer Gillott	Australasian Donor Awareness Program
Shena Graham	Donation after Cardiac Death Project Officer, NHMRC NICS
Kelvin Grove	LifeGift NSW/ACT
Catherine Hannan	DCD Working Group / ACCCN / ATCA
Kathy Hee	NODC Advisory Committee / DCD Working Group / ATCA / Manager: SAODA
Robert Herkes	NODC Advisory Committee
Kaye Hewson	Queensland Health Policy Branch
Sarah Hoy	CENA
Sue Huckson	Director, Effective Practice Program, NHMRC NICS
Graham Kyd	TSANZ Standing Committee, Transplant Coordinator (Living Donor Transplant Coordinator)
Gordon Laurie	Intensivist, Princess Alexandra Hospital
Julie Letts	Principal Policy Analyst, Clinical Ethics, Department of Health, NSW
Kate Leutert-Gibson	ACCCN, Chair: Organ & Tissue Donation & Transplantation Advisory Panel

Appendix 3: Consensus stakeholder workshop participants (cont.)

NAME	RELEVANT AFFILIATIONS
Bronwyn Lewvey	TSANZ Standing Committee – Lung
Mary Lynch	NODC Advisory Committee / ACCCN
Jennie Martin	ACEM
Ella Meek	DCD Working Party / ACORN
Johnny Millar	ANZICS Organ Donation Committee / Paediatric Intensivist
Stewart Moodie	Intensivist, Royal Adelaide Hospital / The Queen Elizabeth Hospital
Paul Murphy	National Clinical Lead for Organ Donation, National Health Service, UK
Jean Murray	SA Health
Holly Northam	NODC Advisory Committee
Fran O'Brien	ACORN
Gerry O'Callaghan	NODC Advisory Committee / DCD Working Party / ANZICS Organ Donation Committee / National Medical Director, AOTDTA
David Pilcher	DCD Working Party / ANZICS
Graeme Pollock	DCD Working Party / Lions Eye Donation Services representing Tissue
Treena Quarin	NODC Advisory Committee / ACEM
Raymond Raper	NODC Advisory Committee / DCD Working Party / ANZICS
Wendy Rogers	DCD Working Party / Deputy Chair: NHMRC Organ Donation Guideline Working Group – Ethics
Francesca Rourke	DCD Working Party / Queenslanders Donate
Phil Sargent	Paediatric Intensivist, Mater Children's Hospital
Nicola Seifert	LifeGift NSW/ACT
Siva Senthuran	Intensivist, Townsville Hospital
Bill Silvester	NODC Advisory Committee / DCD Working Party / ANZICS Organ Donation Committee
Linda Sims	ACEN
Melissa Smith	DonateWest, WA
Stephen Streat	Clinical Director, Organ Donation New Zealand / ANZICS Organ Donation Committee
Colin Thomson	DCD Working Party / Chair: AHEC
Alina Tooley	Transition Manager, NHMRC NICS
Elizabeth Treasure	ACCCN – Organ and Tissue Donation and Transplantation Advisory Panel / ATCA
Julie Vomero	DCD Working Party / Consumer, Victoria
Neil Widdicombe	Intensivist, Royal Brisbane & Women's Hospital
Lee Wood	LifeNet, NT

Appendix 4: Maastricht categories

1995 Maastricht International Conference, Nederland defined four categories of non-heart-beating donation (NHBD).^[32,33] These categories were developed to categorise potential organ donors on a clinical basis and are widely accepted internationally.^[17,34] Category 5 has recently been suggested as an addition to the other four categories.^[9]

In Australian practice Categories 1, 2 and 5 are considered ‘uncontrolled’ and due to the ethical and logistic difficulty in protecting organs while obtaining consent from a grieving family **are not considered** to be potential organ donors in Australia at present.^[1,6]

Category 3 is the most likely scenario in which **DCD is likely to occur**. Patients which fall in this category will predominantly be those with severe brain injury who do not meet brain death criteria.^[1,5,6] Less commonly patients with other conditions such as end-stage respiratory failure or high cervical injuries may be considered.

Category 4, although a rare occurrence, **are a realistic consideration** where a family has already consented to organ and tissue donation.^[1,5,6]

Maastricht Categories

Category 1: Dead on arrival – unknown warm ischaemic time. ‘*Uncontrolled*’.^[1,5,6]

Category 2: Unsuccessful resuscitation – known ischaemic time ‘*Uncontrolled*’.^[1,5,6]

Category 3: Awaiting cardiac arrest after planned treatment withdrawal. Known and limited warm ischaemic time. ‘*Controlled*’.^[1,5,6]

Category 4: Cardiac arrest after confirmation of brain death^[33], but prior to organ retrieval. Ischaemic time known and potentially limited. ‘*Uncontrolled*’.^[1,6]

Category 5: Unexpected cardiac arrest in a critically ill patient. Ischaemic time known and potentially limited. ‘*Uncontrolled*’.^[5,35]

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Appendix 5: Ministerial policy statement on organ and tissue donation

Australian Health Ministers' Conference – April 2004

Ministerial policy statement on organ and tissue donation

In April 2004 a national meeting of Health Ministers agreed that in all States and Territories the expressed wishes of a deceased person regarding organ and tissue donation should be respected and given effect. The Ministers directed the establishment of an expert working group to advise on the implementation of this decision.

The law in each State and Territory requires that if the circumstances allow, organ and tissue donation can proceed in the following situations:

- if the deceased person consented to organ and tissue donation in their lifetime
- or when there is no record of the deceased's consent or objection, if the family agrees to organ and tissue donation.

The law upholds the right of the deceased person to become an organ donor if they have expressed such an intention, but it is normal practice for families to be asked about their knowledge of what the deceased person would have wanted. Although it is very rare for families to go against the wishes of their deceased relative, a sincerely held objection to organ donation by the family will be respected.

During 2004, the Australian Government reviewed the Australian Organ Donor Register (AODR) and is significantly upgrading it. Australia now has a single national register of organ and tissue donors, the AODR.

The AODR will be established as a register of consent to organ and tissue donation, rather than an expression of a wish to be a donor. For legal reasons, for Australians aged 16 and 17 years, the AODR remains a register of intent rather than of consent, which means that family consent will still be required for minors to become donors. Registrations will not be accepted from people under the age of 16.

It is important that people registering on the AODR discuss their intention to record their consent or objection to organ and tissue donation with family and close friends.

It is a decision of Federal, State and Territory Health Ministers that:

- the Australian Organ Donor Register should be routinely consulted whenever a medically suitable donor is identified
- if the deceased has enlisted on the Register, the family should be informed of the deceased's consent or objection
- advice should be sought from the family and/or close friends about whether the deceased had changed their decision since registering
- families should always be kept informed and involved in discussions about organ donation as it proceeds
- all States and Territories will ensure these decisions are incorporated into local hospital processes.^[36]

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Appendix 6: Abbreviations and Acronyms

ACCCN: Australian College of Critical Care Nurses

ACEM: Australasian College for Emergency Medicine

ACEN: Australian College of Emergency Nursing

ACORN: Australian College of Operating Room Nurses

ACT: Australian Capital Territory

ADAPT: Australasian Donor Awareness Programme

AHEC: Australian Health Ethics Committee

AHMAC: Australian Health Ministers Advisory Council

AHMC: Australian Health Ministers' Conference

ANZCA / JFICM: Australian and New Zealand College of Anaesthetists/
Joint Faculty of Intensive Care Medicine

ANZICS: Australian and New Zealand Intensive Care Society

AOTDTA: Australian Organ and Tissue Donation and Transplantation Authority

ATCA: Australasian Transplant Co-ordinators Association

CENA: College of Emergency Nursing Australasia

DCD: Donation after Cardiac Death

DoHA: Department of Health and Ageing

ICU: Intensive Care Unit

NHMRC: National Health and Medical Research Council

NICS: National Institute of Clinical Studies

NSW: New South Wales

NT: Northern Territory

NODC: National Organ Donation Collaborative

OTDA: Organ and Tissue Donation Agency

QLD: Queensland

SA: South Australia

SAODA: South Australian Organ Donation Agency

TAS: Tasmania

TSANZ: Transplantation Society of Australia and New Zealand

VIC: Victoria

WA: Western Australia