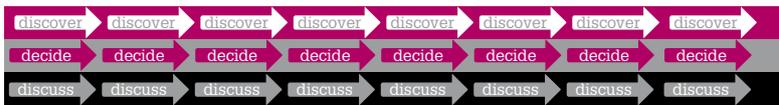




Australian Government
Organ and Tissue Authority

National Protocol for Donation after Cardiac Death

JULY 2010



This protocol was developed on behalf of the Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA) by the National Health and Medical Research Council (NHMRC). The protocol was prepared by Ms Shena Graham, Ms Alina Tooley, Ms Sue Huckson and Mr Luke Hurley from the NHMRC's National Institute of Clinical Studies (NICS).

We would like to thank the members of the Donation after Cardiac Death Working Party for their expert advice in the development of this protocol.

In addition, we acknowledge the professional writing services of Ampersand Health Science Writing in the development of this protocol.

©AOTDTA 2010
National Protocol for Donation after Cardiac Death.



Disclaimer

Health professionals are advised to use clinical discretion when applying information contained in this document. NHMRC and AOTDTA do not accept liability for any injury, loss or damage incurred by use of or reliance on the information. NHMRC and AOTDTA cannot guarantee and assume no legal liability or responsibility for the currency, completeness or accuracy of the information. The views and opinions expressed in this document do not necessarily represent those of the Australian Government.



Contents

Foreword	4
Introduction	5
1 Considerations before the protocol is applied	8
2 Protocol for donation after cardiac death	10
3 Key elements of donation after cardiac death in Australia	15
3.1 Medical suitability for donation after cardiac death	15
3.2 Determining the patient's wishes	16
3.3 Formal consents and authorisation to proceed with organ and tissue donation	18
3.4 Planning and preparation for DCD	20
3.5 Ante mortem interventions	20
3.6 Withdrawal of cardio-respiratory support	21
3.7 Management after withdrawal of cardio-respiratory support	21
3.8 Determination of death	22
3.9 Management after determination of death	23
3.10 Post mortem interventions	23
3.11 Retrieval surgery	24
3.12 Case review	24
Appendices	25
A Tools to support the donation after cardiac death process	25
B Legislative requirements associated with donation after cardiac death	29
C Ethical issues associated with donation after cardiac death	41
D Process of developing the protocol	43
E Abbreviations and acronyms	46
F Glossary	47
References	49



Foreword

The development of a National Protocol for Donation after Cardiac Death has been a collaborative process with a group of experienced clinicians and experts in medical law and ethics. The impetus for the protocol was a direction from the Commonwealth Government of Australia. During the establishment of a new national framework for the delivery of clinical services for organ and tissue donation across the country, there was a clear recognition of the need for an unambiguous and consistent protocol to enable the practice of donation after cardiac death in the Australian community.

Depending on the location of their practice, clinicians in Australia have sourced their information on donation after cardiac death (DCD) from three main publications: the ANZICS Statement on Death and Organ Donation (2008); the NSW Department of Health Organ Donation after Cardiac Death: NSW Guideline (2007); and the National Health and Medical Research Council (NHMRC) ethical guidelines Organ and Tissue Donation after Death, for Transplantation (2007). These documents are detailed, thoughtful and exhaustive, and as a consequence of their varying objectives provide their readership with different perspectives.

It has been the task of the committed working party established by the NHMRC to develop this clinical practice protocol for the delivery of DCD in Australian hospitals, which is consistent with the advice, perspectives and obligations outlined in the documents referred to above. This document is a protocol and not an evidence based guideline informed by a systematic literature review. The statements in this protocol have been drawn from the source documents and from expert opinion.

The current protocol provides this clinical pathway in an unambiguous and consistent way and I thank the group of experts who have worked so hard to produce it. The professional and public consultation process was an essential part of its development and resulted in the inclusion of broader expertise and perspectives.

As the clinical service and scientific evidence base of organ and tissue donation continues to evolve, in due course the protocol will require revision and refinement. I look forward to the natural changes and improvements that will occur in its future.

Dr Gerry O’Callaghan

Chair: National Health and Medical Research Council, Donation after Cardiac Death Working Party
National Medical Director, Australian Organ and Tissue Donation and Transplantation Authority



Introduction

Organ transplantation is an established and effective treatment that can be life saving or can dramatically improve quality of life. Transplantation relies upon the availability of organs donated by individuals; such donations are generally acts of generosity reflecting true altruism. Many Australians make the decision to be a donor, but relatively few die in circumstances that allow donation. At the time of death, facilitating organ donation is one way of respecting the wishes of potential donors.

Most commonly, organs for transplantation come from deceased donors where death has been determined using the 'brain function criterion' (donation after brain death or DBD). While DBD remains the preferred donation pathway because it results in the retrieval of more organs of better quality, donation after cardiac death (DCD)(also known as non-heart-beating donation or donation after cardio-circulatory death) provides an alternative pathway to donation for those patients for whom donation after brain death is not possible or appropriate.

Renewed interest in DCD in Australia has been driven in part by requests for organ donation from the family or next-of-kin of dying patients who do not meet the brain function criterion [1]. Potential benefits of DCD include respecting and facilitating an individual patient's wishes for organ donation [2], and an increase in the availability of organs and tissues for transplantation.

DCD is complex and raises significant ethical and logistical concerns. While determination of death after cessation of circulation is a very common event in medicine, DCD requires rapid organ retrieval after death occurs, because most organs are very sensitive to periods of ischaemia. This is most readily accomplished in the controlled situation of death following withdrawal of cardio-respiratory support. The decision to withdraw cardio-respiratory support is taken independently of any consideration of the potential for DCD. Though withdrawal of cardio-respiratory support is necessary for DCD, any discussion about DCD takes place as part of end-of-life management planning and only after the withdrawal of cardio-respiratory support has been discussed and agreed.

Ethical issues inherent to DCD include the potential for actual or perceived conflicts of interest and balancing the interests of potential donor patients, their families and potential organ recipients. Ethical concerns surrounding the withdrawal of cardio-respiratory support are not specific to DCD. There are practical and legal issues to be addressed concerning the determination of death in this context. There are also considerable logistical issues related to the relative urgency of organ protection and retrieval following death. There are also differences in State and Territory legislation and the interpretation of these statutes dictates some variation in the way that DCD is practised within Australia.

A national protocol for donation after cardiac death

The purpose of a national protocol for DCD is to outline an ethical process that respects the rights of the patient [3] and ensures clinical consistency, effectiveness and safety for both donors and recipients. This protocol provides a detailed framework for practice, which has a strong emphasis on communication and consistency and aspires to avoid any potential harm to patients, their families, recipients and the healthcare team. It seeks to be consistent in language and terminology with existing guidance on end-of-life care.

The protocol was developed by a working party convened by the National Institute of Clinical Studies (NICS) of the National Health and Medical Research Council (NHMRC). The working party included representation from the organ and tissue donation, transplantation and acute care sectors, consumers and experts in ethics and in law (see Appendix D).

The protocol differs from clinical practice guidelines in that it is based on review of existing documents in use in Australia and published overseas, rather than on a systematic review of the literature. Development of the protocol was informed primarily by the following three documents:

- ▶ NHMRC – Organ and Tissue Donation after Death, for Transplantation [4], which focuses on ethical principles involved in donation after death
- ▶ Australian and New Zealand Intensive Care Society (ANZICS) – Statement on Death and Organ Donation [1], which is based on comprehensive review of relevant literature, including comparable documents from other countries
- ▶ NSW Health – Organ Donation after Cardiac Death: NSW Guideline [5], which was informed by review of international and national literature and guidelines and widespread stakeholder consultation.

Significant international documents were also reviewed [6–8] as well as hospital guidelines from Victoria [9–11].

The development of the protocol was informed by a consensus stakeholder workshop held in March 2009, through which experts in the organ donation and transplantation sector were consulted. As well, a process of public and targeted consultation was undertaken from June to August 2009.

Appendix D provides more detailed discussion of the development of the protocol.

Scope

This protocol provides step-by-step statements on procedures used in the care of individual patients and families after a decision is made to withdraw cardio-respiratory support, and as such does not discuss the process of reaching that decision.

Given current State and Territory legislation, there will be differences in the way DCD is practised. Attempts have been made where possible to provide consistent guidance that complies with all jurisdictional legislation. The protocol identifies and summarises jurisdictional and legislative requirements with which local practice must comply.

This protocol applies to potential donors over the age of five years. Guidance for DCD by younger paediatric patients is currently being developed within the paediatric intensive care community.

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 [12].

Intended users

This protocol is intended for 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.

Requirement for data collection and audit

The collection of specific physiological information during the DCD process, from the withdrawal of cardio-respiratory support to the cessation of circulation, is important from a number of perspectives:

- ▶ Physiological measurements that reflect hypotension and hypoxemia clearly have an impact on the subsequent viability of the organ for transplantation. The rigorous collection of a defined set of physiological data provides transplant physicians with an opportunity to correlate the impact of cardiovascular death on subsequent graft viability during the lives of transplant recipients, and as such is an important obligation of individuals involved in the organ and tissue donation process.

- ▶ Such information will assist intensive care physicians and nurses to become more adept and discriminating in their capacity to predict those individuals who will die within an appropriate timeframe to make DCD possible.

Collection and analysis of this data will improve the capacity of clinical staff to advise Australian families during the decision making process.

The relevant points of measurement have been included in the checklist (Appendix A).

Review

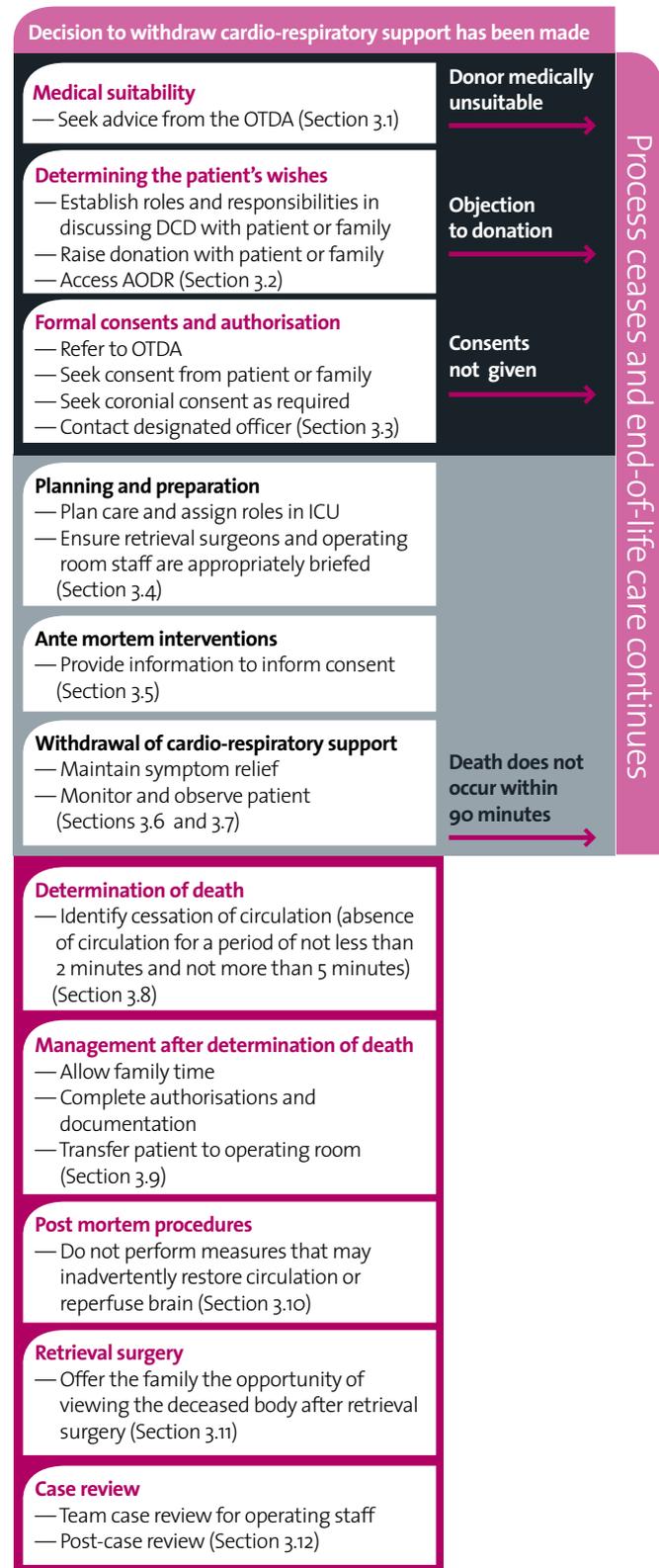
The Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA) will ensure that this protocol is reviewed and revised no more than five years after initial publication. Within this period, review of relevant sections will be undertaken if there are changes to State and Territory legislation, any major new evidence is published or any relevant major safety concerns emerge.

Structure of the protocol

The following flowchart identifies the key steps in the DCD process and the sections of the document in which they are discussed.

AODR=Australian Organ Donor Register
OTDA= Organ and Tissue Donation Agency

Diagram 1 Structure of the protocol



1 Considerations before the protocol is applied

DCD is complex and raises significant ethical and logistical concerns. Differences in State and Territory legislation add to the complexity of developing a nationally consistent protocol.

The following principles and prerequisites for DCD aim to ensure that the ethical issues that arise as a consequence of the clinical procedures associated with DCD are considered and addressed.

The NHMRC ethical guidelines [4] have been used to develop the following principles in relation to DCD.

- ▶ Donation of organs and tissues is an act of altruism and human solidarity that potentially benefits those in medical need and society as a whole.
- ▶ Obtaining organs and tissues for transplantation should always be undertaken with respect for all aspects of human dignity, including the worth, welfare, rights, beliefs and perceptions of all involved.
- ▶ Respect should be given to cultural heritage and to spiritual differences in the acceptance of organ and tissue donation and transplantation.
- ▶ The process of reaching and implementing a decision about the donation of organs and tissues for transplantation should respect the wishes, where known, of the deceased.
- ▶ In obtaining organs and tissues for transplantation, the needs of the potential donor and the family should take precedence over the interests of organ retrieval.
- ▶ Obtaining and transplanting organs and tissues should, as far as possible, be undertaken in a manner designed to protect recipients from harm.
- ▶ In the process of obtaining organs and tissues for transplantation, the needs of all those directly involved, including the donor, recipient, families, carers, friends and health professionals, should be recognised and accommodated as far as possible.
- ▶ The choice not to donate should be respected and the family shown understanding for the decision.

Caring for and respecting the dignity of the patient should be guided by patient interests and the needs of the family [6].

Prerequisites for donation after cardiac death

- ▶ **Withdrawal of cardio-respiratory support:** DCD may only be considered after an independent decision has been taken to withdraw cardio-respiratory support, generally in the situation where continuing treatment provides no prospect for recovery or is not considered to be in the patient's interests [1]. The medical decision should be undertaken in accordance with established principles and guidelines, and in consultation with the family.
- ▶ **Consent for DCD:** DCD may be possible following withdrawal of cardio-respiratory support if the family agrees to donation based upon their understanding of the patient's wishes. Donation should be explored only after the decision to withdraw cardio-respiratory support has been made.
- ▶ **Ante-mortem interventions:** If DCD is to proceed, a number of investigations, interventions and changes to patient care are necessary that would not otherwise be undertaken. These interventions take place before the death of the patient. As they are performed for the benefit of potential recipients rather than the donor patient, the ethical justification for such interventions relies on a broad interpretation of the patient's interests.
- ▶ **Timeframe for DCD:** For DCD to proceed, death must occur within a timeframe consistent with successful donation. The timeframes for organs being considered for donation are 30 minutes for liver and pancreas, 60 minutes for kidneys and 90 minutes for lungs. For the purposes of this protocol, a timeframe of 90 minutes has been specified.

It is essential that each step in the DCD process be based on respect for the rights and interests of all involved [6].

Due to the complexity of DCD, this protocol may not cover all aspects of every clinical situation involving DCD. Individual patient and 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 [12].

2 Protocol for donation after cardiac death

DCD may be considered only after an independent decision to withdraw cardio-respiratory support has been made.

Clinical considerations	Responsibility	Ethical, legal and logistical considerations	Reference
1 Medical suitability			
<p>DCD may be an option when, in the judgment of the treating intensivist, the patient meets the following criteria:</p> <ul style="list-style-type: none"> • no absolute contraindication to donation • the patient is likely to die within 90 minutes of withdrawal of cardio-respiratory support • the patient is not brain dead and is unlikely to progress to brain death. <p>An early discussion with the Organ and Tissue Donation Agency (OTDA) should occur to seek advice on the medical suitability of a potential donor.</p>	Intensivist	Information provided to the OTDA at this stage in the process includes age, relevant medical history and current physiological assessment (i.e. haemo-dynamics, lung, liver, renal function) but should not include identifying information.	Section 3.1
If potential donor is medically unsuitable, cease process and continue end-of-life care			
2 Determining the patient's wishes			
Before discussing donation with the patient (if competent) or family, careful consideration should be given to the appropriate roles and responsibilities of the individuals involved in the discussion of donation with the family.	ICU team	These discussions should include the treating intensivist, the ICU bedside nurse, the organ donor coordinator (if present) and may include a social worker.	Section 3.2.1
<p>In raising donation with the patient or family, appropriate information should be provided to support informed decision-making about DCD. (Note that if the family raises the matter before a decision to withdraw cardio-respiratory support is made, the approach should be acknowledged and documented, and the discussion deferred).</p> <p>The intention to access the Australian Organ Donor Register (AODR) to help the family make a decision on behalf of the patient should be shared with the family.</p> <p>Discussions should be documented in the patient's medical record.</p>	Intensivist	<p>Discussion of donation should be separate from that of withdrawal of cardio-respiratory support.</p> <p>Information provision should:</p> <ul style="list-style-type: none"> • take into consideration differences in culture, experiences and beliefs • include discussion of other possible outcomes (e.g. that donation may not be possible if death does not occur in required timeframes) • ensure 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. 	Section 3.2.1 Appendix C
After the family has raised or been approached about the possibility of donation, the AODR must be accessed .	Intensivist or organ donor coordinator	Information from the AODR should be provided to the family to assist in decision-making.	Section 3.2.2
If there is an objection to donation on the register or from the family, cease process and continue end-of-life care			

Clinical considerations	Responsibility	Ethical, legal and logistical considerations	Reference
3 Formal consents and authorisation			
Potential organ and tissue donors need to be referred to the State or Territory-based OTDA. The OTDA will require formal notification and information about the patient including name, date of birth, blood group, medical record number, requirement for coronial referral, and the information stated in point 1 above.	ICU team	Organ donor coordinators are responsible for conducting in-depth family interviews and clinical assessments.	Section 3.3.1
Formal written consent from the patient or family is required for retrieval of specific organs and tissues as well as blood, spleen, lymph nodes and blood vessels and for research. Any consents, including documentation of those provided verbally, should be included in the medical record.	Intensivist or organ donor coordinator	The family should be given clear information about the process of DCD to ensure that informed consent is possible. Where family consent is relied on, family members need to include the people specified to provide consent in State and Territory legislation. In discussing organ and tissue donation, family structures may need to be taken into account (e.g. involving Aboriginal and Torres Strait Islander Elders or other authority figures). Support for family members should be available from relevant hospital staff (e.g. religious advisers or social workers). The family may withdraw consent at any point. When this occurs, the process of DCD must cease and end-of-life care continues.	Section 3.3.2 Appendix B
Consent from the Coroner is necessary if the death is reportable. The specific requirements of individual coroners for notification after death vary and should be clarified. Consent should be documented in writing.	Intensivist or organ donor coordinator	Conditional consent from the Coroner must be obtained in these cases before withdrawal of cardio-respiratory support, if DCD is to proceed.	Section 3.3.3 Appendix B
The Designated Officer or officer holding an equivalent role must be contacted before withdrawal of cardio-respiratory support.	Intensivist or organ donor coordinator	The conduct of the Designated Officer or officer holding an equivalent role must comply with State and Territory legislation in all cases.	Section 3.3.4 Appendix B
If relevant consents and authority are not given, cease process and continue end-of-life care			

Clinical considerations	Responsibility	Ethical, legal and logistical considerations	Reference
4 Planning and preparation			
The organ donor coordinator is responsible for the offer of organs and coordination of the retrieval surgery and retrieval teams	Organ donor coordinator	Logistical issues are considered including timeframe of retrieval (especially if interstate)	
It is recommended that a meeting be held in the ICU for planning care and assigning roles. At this meeting consideration should also be given to: <ul style="list-style-type: none"> the optimal place for withdrawal of cardio-respiratory support planning for end-of-life care should death not occur within 90 minutes of withdrawal of cardio-respiratory support. 	ICU team	Decision-making about the optimal place for withdrawal of cardio-respiratory support should involve consideration of family preferences, hospital logistics, retrieval surgery and relevant policy. <p>The timing of the withdrawal of cardio-respiratory support, the period of time to determine death and the timing for transfer to the operating room and opportunity for family to be present should be discussed with the family.</p>	Section 3.4
It is recommended that the organ donor coordinator, the operating room staff and the organ retrieval team meet to ensure that the retrieval surgeons and the operating room staff are appropriately briefed about the case, the proposed organ retrieval and the timing of withdrawal of cardio-respiratory support.	Organ donor coordinator	This meeting occurs after the donor coordinator has made all arrangements for organ and tissue donation, and just prior to withdrawal of cardio-respiratory support.	Section 3.4
5 Ante mortem interventions			
Specific ante mortem interventions and investigations to maintain organ viability, determine organ suitability and allow identification of suitable recipients are necessary for DCD to proceed. <p>Individual clinical judgement should take into account the context and clinical situation, what is known about the patient's wishes and the views of the family.</p> <p>In all cases, sufficient information to inform decision-making should be provided.</p> <p>The decision-making process and consents given for ante mortem interventions should be included in the medical record.</p>	Intensivist	Ante mortem interventions should be undertaken only if it is anticipated that they will not harm the patient and will not hasten or cause the death of or compromise the continuing care of the patient. <p>Measures should be taken to prevent any pain or discomfort associated with any ante mortem interventions administered.</p> <p>Costs for ante mortem interventions must not be charged to the family of the patient.</p> <p>Ante mortem interventions may only be performed in compliance with jurisdictional legislation, guidelines and/or institutional policy.</p>	Section 3.5 Appendix B Appendix C

Clinical considerations	Responsibility	Ethical, legal and logistical considerations	Reference
6 Withdrawal of cardio-respiratory support			
<p>The provision of end-of-life care and withdrawal of cardio-respiratory support is the responsibility of the primary treating team and should occur in accordance with jurisdictional and hospital policy.</p> <p>It is appropriate to maintain symptom relief in patients at the end of life, whether or not organ and tissue donation is planned.</p> <p>Withdrawal of cardio-respiratory support occurs at a planned location and at a prearranged time as discussed with family.</p>	Intensivist and ICU team	<p>The person responsible for withdrawal of cardio-respiratory support must act independently of the retrieval and transplantation teams.</p> <p>Prior to withdrawal of cardio-respiratory support all necessary arrangements for the donation process must be finalised. Regardless of the location of treatment withdrawal, the presence of the family should be encouraged and facilitated.</p>	Section 3.6
7 Management after withdrawal of cardio-respiratory support			
<p>Following withdrawal of cardio-respiratory support, monitoring of heart rate, oxygen saturation, respiratory rate and blood pressure and documenting of observations are required.</p> <p>A systolic blood pressure (SBP) ≤ 50mmHg is currently considered to be the most useful determinant of onset of 'warm ischaemic time'.</p>	Intensivist and organ donor coordinator	<p>Monitoring should be conducted in a way that is respectful to family and friends.</p> <p>The process should be timed on a single clock.</p>	Section 3.7
<p>If death does not occur within 90 minutes, the DCD process ceases and end-of-life care continues.</p>	Intensivist	<p>Eye and tissue donation may still proceed following the death of the patient.</p>	
8 Determination of death			
<p>Death should be determined on the basis of immobility, apnoea, absent skin perfusion and the absence of circulation for a period of not less than 2 minutes and not more than 5 minutes.</p> <p>The absence of circulation is ideally determined by clinical means supplemented with intra-arterial pressure monitoring if available.</p>	Intensivist	<p>Death must not be determined or certified by a member of the retrieval or transplant team.</p> <p>The Designated Officer (and Coroner if applicable) should be notified following determination of death.</p>	Section 3.8
9 Management after determination of death			
<p>This phase of clinical management may be used for family time, to transport the donor to the operating room and to confirm authorisations and complete documentation.</p>	Intensivist ICU team and organ donor coordinator	<p>If the family is unable to leave the bedside after the death of the patient, organ donation cannot proceed and normal post mortem procedures should be followed.</p> <p>When family members depart from the site of withdrawal they should be accompanied by a health professional designated to support them.</p> <p>In NSW there must be not less than 5 minutes between determination of death and commencement of retrieval surgery.</p>	Sections 3.9 and 3.3.4

Clinical considerations	Responsibility	Ethical, legal and logistical considerations	Reference
10 Post mortem procedures			
Once death has been determined, measures that may inadvertently restore circulation or reperfuse the brain are not permissible. It is permissible to re-intubate without ventilation, to prevent accidental aspiration of gastric contents.	Intensivist	If re-intubation without ventilation is required, it should not be performed by personnel who have been involved in the medical care of the patient, the withdrawal of cardio-respiratory support or determination of death	Section 3.10
11 Retrieval surgery			
The success of graft function post transplantation depends upon type of organ, pre mortem organ function and period of hypoperfusion and warm ischaemia.	Surgical retrieval team	If warm ischaemic time exceeds 30 minutes for liver and pancreas, 60 minutes for kidneys, and 90 minutes for lungs, organ donation may not proceed.	Section 3.11
Families should be offered the opportunity of viewing the deceased body after retrieval surgery.	Organ donor coordinator, bedside nurse, social worker	The family should be advised about the body's appearance before the viewing and offered support when they view the donor's body.	Section 3.11
12 Case review			
A team case review for operating room staff following retrieval surgery provides an opportunity to address issues related to the process.	Organ donor coordinator	This review also allows the opportunity to seek immediate emotional support if required.	Section 3.12
A post-case review meeting should be organised as soon as practicable following each organ donation case. This enables ICU and operating room medical and nursing staff; the organ donor coordinator and social worker involved, to discuss quality-related issues identified in terms of the process.	ICU team	This review also allows the opportunity to seek immediate emotional support if required.	Section 3.12

3 Key elements of donation after cardiac death in Australia

This section expands on the key elements of DCD raised in Section 2. Specific legal and ethical considerations are highlighted where relevant. Further discussion of legislative requirements and ethical issues, written by expert members of the working party, can be found in Appendices B and C respectively.

Donation after cardiac death may create a situation where there is the perception of a conflict of interest for individual clinicians in the treating team, between the interests of the patient and the potential recipients. For this reason, it is essential that there is a clear separation of discussions, decisions and roles, with the decision to withdrawal of cardio-respiratory support being taken independently of and before any approach to the family concerning organ and tissue donation.

The timing and sequences of DCD raise particular challenges as the patient or family must give consent for organ donation before the withdrawal of cardio-respiratory support and the death of the patient. In addition, after a decision to donate is made, the care of the patient is altered both before and after death (e.g. delayed withdrawal of cardio-respiratory support, extra investigations).

Guided by this protocol, it will be up to individual clinicians to decide how best to manage the rights of patients and the sensitivities of families in specific situations. Acting in the patient's best interests must always have primacy over other considerations when treatment decisions are being made, including any consideration of possible organ and tissue donation [1].

Overall considerations

- ▶ Family counselling and support must be offered throughout and following the DCD process, consistent with established State and Territory Organ and Tissue Donation Agency (OTDA) and local hospital policy and procedures.
- ▶ Meticulous planning of the care of the patient and family is important throughout the process of DCD. Several team meetings or discussions held at key time points in the process will help to ensure a coordinated and controlled sequence of events and environment for both the family and health professionals involved.
- ▶ A range of health professionals is likely to be involved in the process of determination of death, organ and tissue retrieval and transplantation. These professionals are obliged to preserve their own wellbeing and to pay attention to the impact of these events on their colleagues. Where health professionals recognise that they do not have the requisite knowledge, skills, experience for, or commitment to organ donation related activities, they have an obligation to inform their colleagues and facilitate the involvement of other appropriate health professionals.

3.1 Medical suitability for donation after cardiac death

Assessing medical suitability for DCD is a critical part of the process. An early discussion with the OTDA should take place to seek advice on the medical suitability of potential donors. No identifying information should be provided at this stage.

If a potential donor is medically suitable, the treating intensivist must make an assessment about the likely time of death after withdrawal of cardio-respiratory support. DCD can only proceed if the patient dies within an appropriate time after withdrawal of cardio-respiratory support.

Predicting the time of death can be difficult and requires considerable experience. Current research [13–17] indicates that it may be possible to provide at least some predictive accuracy based on the Glasgow Coma Scale (GCS), respiratory and haemodynamic parameters, inotropic requirements and the intensivist's clinical judgement. Further research and validation is required.

If specific 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.

3.2 Determining the patient's wishes

The serious illness and impending death of a person is a significant event for a family. Recognising the effects of this event and providing consideration and support for families is an essential element in the practice of DCD. The ANZICS Statement [1] recommends that a family meeting be held soon after the patient is admitted to the ICU, to establish the mutual trust and respect that are fundamentally important aspects of the relationship between the family and the health professionals involved. Such a meeting should take place within 12–24 hours of ICU admission and may be the first of several meetings in the hours and days that follow.

The family and other significant members of the patient's social network need to receive and understand much information in a short, and usually stressful, period of time. Families will differ in the amount of information and support they require. The pace of information provision should be determined by each family's needs and the particular situation.

Where possible, one health professional should be the main contact for the family throughout the process. Health professionals who have significant experience in this area or have undergone special training are best qualified to support the family. The assistance of a social worker, senior nurse, religious adviser, family doctor, psychiatrist, or psychologist should also be available [4].

Further information can be found in Sections 2.2 and 2.3 of the NHMRC guidelines for ethical practice, and Sections 3.5, 3.9 and 3.12 of the ANZICS Statement.

3.2.1 Raising organ and tissue donation with the family

A discussion among the ICU treating team members is useful to identify who should be present at the family meeting where organ and tissue donation is raised. This discussion should include the treating intensivist, the ICU bedside nurse, the organ donor coordinator (if present), the social worker and, where appropriate, Aboriginal Hospital Liaison Officers and/or Multicultural Liaison Workers [4].

Unless initiated by a family member, discussion of organ and tissue donation should be clearly separated from discussion of withdrawal of cardio-respiratory support. This may involve different individuals conducting the two discussions. Local institutional guidelines may provide further direction in this matter.

Once the decision has been made to withdraw cardio-respiratory support, it may be appropriate to discuss the ongoing maintenance of physiological support to provide time for consideration of the possibility of organ and tissue donation. During this time, care must be taken to provide family and friends with appropriate support and with effective communication related to any evolving plans concerning end-of-life management including organ and tissue donation.

In general, healthcare providers have an ethical obligation to respect the known wishes of patients. Offering DCD 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, by asking the family, consulting the AODR, or by other means (e.g. a patient's wishes may be expressed in an advance care directive). In most circumstances, family and friends will respect a patient's decision about donation; 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. However, organ and tissue donation should not proceed if it is considered that this would have a significant adverse impact upon the wellbeing of the surviving family members [1, 4].

Families, intensivists and circumstances vary considerably, such that there is no single 'right time' to raise the issue of organ and tissue donation [1]. However, organ and tissue donation should be considered as part of the provision of the care to the dying patient. Many families do not think of organ and tissue donation at this time and if they are not asked, the wishes of some patients may never be known. It is the responsibility of health professionals to ensure that everyone has the opportunity to have their wishes respected.

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 take place depending upon the clinical course of the patient.

Whatever the circumstances, the family, including the senior available next-of-kin, should be provided with information to make a considered decision about organ and tissue donation (see Section 3.3).

Families have a right to information that is relevant to their circumstances, given in a manner that is appropriate to their understanding and experience. The following should also be considered [4]:

- ▶ people may react in a variety of ways in emotionally charged situations
- ▶ differences in culture, experience and beliefs may have an impact on the way in which information is received and decisions are made
- ▶ death carries cultural and spiritual connotations that may differ between individuals and groups
- ▶ family structures need to be taken into account (e.g. Aboriginal and Torres Strait Islander Elders or other authority figures).

For Aboriginal and Torres Strait Islander families, the involvement of an Aboriginal Hospital Liaison Officer and/or Aboriginal Health Worker where available, will provide an additional level of support for the family and clinical team to ensure that communication and decision-making takes place in a culturally sensitive manner [4].

3.2.2 Accessing the Australian Organ Donor Register (AODR)

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

The AODR should only be accessed once a decision has been made to withdraw cardio-respiratory support, and after the family has raised or has been approached about the possibility of organ and tissue donation. At this point it is good practice to share the intention to access the AODR with the patient's family, as part of keeping them informed and involved, and in order to give them additional information to assist their decision-making.

Organ Donation cannot proceed if the patient has a registered objection on the AODR.

3.3 Formal consents and authorisation to proceed with organ and tissue donation

3.3.1 Referral to OTDA

As outlined in Section 3.1, early involvement of the organ donor coordinator can occur prior to seeking family consent for organ and tissue donation, to ascertain medical suitability of the potential donor. Once the patient's wishes have been determined, the patient is formally referred to the OTDA. The organ donor coordinator's role is integral to the remainder of the process.

- ▶ Once the family has been approached about organ and tissue donation and has given verbal consent to the treating intensivist, the organ donor coordinator will conduct an in-depth family interview. This is to explain in detail the process and requirements for DCD prior to seeking written consent.
- ▶ The organ donor coordinator is responsible for completing the Australasian Transplant Coordinators Association (ATCA) / Transplantation Society of Australia and New Zealand (TSANZ) Confidential Donor Referral Form, and performs a comprehensive clinical assessment including assessment of risk factors that would preclude donation or that may have an impact on recipients if donation proceeds.
- ▶ The organ donor coordinator liaises with the treating intensivist, the ICU team, operating room staff, retrieval teams and transplant coordinators throughout the donation process.

3.3.2 Patient/family consent

DCD is governed by law throughout Australia [1]. However, the details vary among jurisdictions. In some places, active consent is required, and in others absence of objection is sufficient. The relevant State and Territory legislation must be followed (links to relevant legislation in each State and Territory are given in Appendix B).

In most cases, the burden of consent falls upon the family, who are provided with what can be overwhelming amounts of information when considering DCD for their relative.

In limited circumstances, for example in patients with end-stage respiratory or cardiac disease or a high cervical spinal injury, the patients themselves will be competent to consent (see Maastricht Categories in Appendix F).

As outlined in the ANZICS Statement [1], the consent process should be preceded by a discussion that includes details of the process of withdrawal of cardio-respiratory support, including the available locations and ability for the family to be present until shortly after the time of death. The following points should also be covered [1]:

- ▶ organ retrieval needs to begin without delay after death in order to minimise the effect of warm ischaemia — this allows family members very little time with the patient after death
- ▶ staff will be available to support the family during this time
- ▶ care of the patient is not compromised by the need to preserve organs
- ▶ anxiolytics and analgesics will be given, as necessary, until the moment of death
- ▶ predicting the time from withdrawal of cardio-respiratory support to death can be difficult — if this interval is greater than the maximum that allows viable organ retrieval, organ donation will not be possible, although tissue donation may still occur if suitable and the family consents
- ▶ which organs may be suitable for transplantation and the effect on this of the time from withdrawal of cardio-respiratory support to death
- ▶ if organ donation is not possible, that care for the patient will be continued in the ICU or another suitable location

- ▶ consenting to donation will usually result in a significant delay in the withdrawal of cardio-respiratory support, due to the complex logistics associated with arranging donation and transplantation - the family must be prepared for and consent to this
- ▶ blood is taken for serology and tissue typing before withdrawal of cardio-respiratory support
- ▶ physiological support (e.g. inotropes, oxygen) may be necessary to stabilise the patient between consent for DCD and withdrawal of cardio-respiratory support
- ▶ if any procedures or administration of drugs to facilitate the transplantation process are considered appropriate, specific consent will be sought from the family (see Section 3.5)
- ▶ pre-operative assessment or factors identified in surgery may reveal medical reasons why donation may not proceed
- ▶ the circumstances of the death may need to be reported to the Coroner and a coronial post mortem examination may occur, which is independent of the donation process
- ▶ families may change their minds and withdraw consent at any time
- ▶ no financial burden to the family or the estate of the deceased will ensue as a result of consenting to organ and tissue donation.

3.3.3 Coroner's consent

Coronial legislation varies among the States and Territories. Any legal requirement for reporting of any death to the Coroner must be met. In the context of DCD, if the death is reportable to the Coroner, it will be necessary to discuss the withdrawal of cardio-respiratory support with the Coroner's representative before proceeding any further. A Statement of Identification should be completed, if the death is reportable to the Coroner.

3.3.4 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 the 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'. In this document the term 'Designated Officer' is used to encompass all of these terms.

The Designated Officer should be informed when there is a potential donor suitable for DCD and of the wishes, consent or lack of objection of the donor and/or the senior available next-of-kin or other next-of-kin. Arrangements may need to be made to contact the Designated Officer immediately after the determination of death for formal authorisation of donation.

Although the matters on which a Designated Officer must decide are specified in different ways in State and Territory legislation (see Appendix B), in all cases the role involves two elements

- ▶ authorisation of the removal of organs and tissue
- ▶ the legislation provides that a Designated Officer may authorise the removal of organs and tissue from a person "who has died"
- ▶ establishment of certain matters [18, 19]
- ▶ the deceased wished to consent to donation (ACT, NSW, NT, SA, Tas, Vic, WA) or had no objection to donation (Qld)
- ▶ that the deceased did not object and a senior available next-of-kin consents (NSW, Qld, Tas, Vic, WA) or has no objection (ACT, NT, SA) to donation
- ▶ the wishes or lack of objection of any other next-of-kin on the same or higher level (NSW, Tas)

- ▶ the inability to ascertain the existence or whereabouts of next-of-kin (NT, SA, VIC)
- ▶ the Coroner has consented to the removal of organs (all jurisdictions).

Most legislation states that authorisation for removal of organs and tissue must be in writing [1]. Accordingly, written consent is advised.

3.4 Planning and preparation for DCD

During the DCD coordination process it is suggested that there be two team meetings to plan care.

- ▶ An ICU meeting to assign roles and responsibilities during the withdrawal of cardio-respiratory support and DCD processes — This meeting should involve the intensivist, bedside nurse, the organ donor coordinator and social worker. If appropriate, the Designated Officer should attend this meeting. Consideration should be given to the optimal place for withdrawing cardio-respiratory support and plans made for end-of-life care in the event that death does not occur within an appropriate timeframe after withdrawal of cardio-respiratory support.
- ▶ A meeting that occurs after the organ donor coordinator has made all arrangements for organ and tissue donation, and just prior to the withdrawal of cardio-respiratory support — This meeting should involve the organ donor coordinator, the operating room staff and organ retrieval team. The purpose is to ensure that the retrieval surgeons and the operating room staff are appropriately briefed about the patient, the organs for retrieval, the roles and responsibilities of each person in the operating room and the timing of withdrawal of cardio-respiratory support. Preparation of the operating rooms and paperwork should be reviewed to ensure that all legal requirements have been met.

The outcomes of these meetings should be discussed with the family; for example, the timing of withdrawal of cardio-respiratory support and the opportunity for the family to be present, the period of time to determine death, and the timing for transfer to the operating room.

3.5 Ante mortem interventions

Organ donation cannot occur without the support of specific interventions and investigations to maintain organ viability, determine organ suitability and allow identification of suitable recipients. Unlike DBD, a number of these interventions must, by necessity, occur prior to death for DCD to proceed. These include:

- ▶ maintenance of physiology to support organ viability
- ▶ serological, tissue typing and other blood tests to determine organ suitability and allocation
- ▶ changes to the site and timing of withdrawal of cardio-respiratory support compared to other dying patients
- ▶ examination and screening of the potential donor to determine organ allocation.

There are a number of optional interventions that may be undertaken to either assist with assessing organ quality (e.g. bronchoscopy) or to improve organ viability (e.g. administration of heparin). There is no medical indication or current support for interventions such as femoral cannulation or administration of medications such as phentolamine, and these are not practiced in Australia.

Ante mortem interventions are performed for the benefit of potential recipients but must be consistent with the broader best interests of the patient, including respecting the patient's wishes to be an organ donor. Ante mortem interventions are ethical if they will contribute to the likely success of the transplantation and do not harm the patient. Therefore, carrying out ante mortem interventions requires a careful case-by-case assessment of each intervention and each patient. Individual clinical judgement should take into account the context and clinical situation, what is known about the patient's wishes and the views of the family. Costs for ante mortem interventions must not be charged to the family of the patient.

Measures should be taken to prevent any pain or discomfort associated with any ante mortem interventions administered. The decision-making process and consents gained for ante mortem interventions to facilitate DCD should be included in the medical record.

Laws relevant to consent for ante mortem interventions are not uniform in Australia. Clinicians must ensure that ante mortem interventions comply with jurisdictional legislation, guidelines and institutional protocols (see Appendix B).

3.6 Withdrawal of cardio-respiratory support

Withdrawal of cardio-respiratory support should be undertaken at an appropriate time and location, as agreed following discussion and planning (see Section 3.4). Prior to withdrawal of cardio-respiratory support for the purpose of DCD, all necessary arrangements for the donation process must be finalised and the identified location prepared.

The location of withdrawal of cardio-respiratory support will depend on a number of factors: the distance between the intensive care unit and the operating room; the ability to provide a quiet and private space; the details of where and how to continue palliative care if the patient does not die within 90 minutes; availability of staff familiar with and experienced in supporting the family and patient through the withdrawal process. Other considerations include hospital logistics and local policies and guidelines.

Irrespective of the location for withdrawal, families should be supported to be present if they wish while cardio-respiratory support is withdrawn and until the person's death.

Withdrawal of cardio-respiratory support, provision of best practice end-of-life care and all aspects of management of withdrawal of cardio-respiratory support are the responsibility of the treating intensivist and the intensive care team. Members of the retrieval or transplant team must not direct or coordinate end-of-life care.

The withdrawal of cardio-respiratory support should conform to jurisdictional legislation and institutional policy [4, 6, 20]. The person responsible for the withdrawal of cardio-respiratory support must function independently of the retrieval and transplantation teams [1, 6].

The palliative management of the withdrawal of cardio-respiratory support should be unaffected by the impending DCD. Maximisation of patient comfort and dignity and minimisation of adverse symptoms should be undertaken [9, 20, 21]. It is especially inappropriate to withhold any medication related to comfort or dignity that would normally be offered if DCD were not a consideration.

3.7 Management after withdrawal of cardio-respiratory support

Clinical observations that should be recorded following withdrawal of cardio-respiratory support include heart rate, oxygen saturation, respiratory rate and blood pressure. The most useful determinant of the onset of warm ischaemia is currently considered to be the time at which systolic blood pressure (SBP) falls to 50mmHg or below. Monitoring should be undertaken in a way that is respectful to the family.

A single clock must be used to time all events relating to DCD, to ensure that an accurate and consistent record of the sequence of events is maintained.

If cessation of circulation does not occur within a timeframe consistent with successful donation, DCD cannot proceed and the patient should be given continuing end-of-life care [4] in the place and manner previously discussed with the family (see Section 3.4).

3.8 Determination of death

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

Death is legally defined as the irreversible cessation of the circulation. In the context of DCD, irreversible has been taken to mean that: [4]

- ▶ sufficient time has elapsed to eliminate the possibility of auto-resuscitation so that, in the absence of resuscitative attempts, cessation is irreversible
- ▶ resuscitative attempts are either contraindicated on medical grounds, given that it has been determined that meaningful recovery of the patient is unlikely, or the patient (or the person with legal authority to make his or her medical decisions) has decided that resuscitative measures would be unduly burdensome.

A period of observation after cessation of the circulation and before determination of death is necessary to establish that auto-resuscitation will not occur [13]. In circumstances other than donation, clinical examination alone is 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]. In the context of DCD the same standard is applied but the need to recognise and minimise the period of warm ischaemia makes it desirable to supplement usual clinical examination with invasive arterial pressure monitoring when this is available.

The ANZICS statement [1] recommends that death be determined to have occurred when all the following features are present: immobility, apnoea, absent skin perfusion and absence of circulation, evidenced by absent arterial pulsatility for a **minimum** of two minutes, as measured by the pulse or preferably by monitoring the intra-arterial pressure.

In international practice, there is a range of recommendations for the period of observation of absent circulation for the determination of death of between 2 and 5 minutes [6–8, 13, 22–24]. We recommend that the period of observation should be not less than 2 minutes and not more than 5 minutes.

Determination of death is legally required before organ retrieval can proceed. The time and date of death should be documented [1]. The death should be certified by an intensivist or other nominated doctor who is not a member of the organ retrieval or transplantation teams.



3.9 Management after determination of death

Following the determination of death, a short period of time will elapse before the retrieval surgery can commence. This time is needed to complete the requisite documentation and to support the family and friends as they farewell the deceased patient. It is also affords recognition of the nature and significance of the death and impending donation process. This can be used for transportation to the operating room and surgical preparation. It is important that this brief phase is planned in advanced to minimise unnecessary delays. Clinical and family circumstances and local physical and organisational arrangements will influence this. In NSW (but in no other jurisdiction) this period must not be shorter than 5 minutes.

There may be a tension between the family's needs and the requirements for successful donation [25]. 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, 25].

The needs of the potential donor and the family must take precedence over the interests of organ retrieval. If the family requires prolonged time with the deceased, then donation may not proceed. The family should be supported by a health professional through this process.

3.10 Post mortem interventions

Following death, the retrieval team may re-intubate to prevent aspiration and ensuing pulmonary damage. Insufflation with 100% oxygen is permissible. Other interventions such as administering heparin and performing intercostal cannulation, vascular cannulation and bronchoscopy may occur.

Procedures that may inadvertently restore cerebral circulation, myocardial perfusion or oxygenation, such as cardiac compressions and mechanical ventilation, are to be avoided until after the commencement of organ retrieval surgery.

3.11 Retrieval surgery

As discussed in Section 3.4, organ donor coordinators are responsible for the offer of organs and tissues and coordination of the retrieval surgery and retrieval teams. They liaise with the operating room staff, notifying them of the potential DCD 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.

Once death has been determined, the retrieval surgery should commence as soon as possible. However, there are logistical processes that must take place first, including re-intubation if lung donation is being considered, transfer of the potential donor on to the operating table and prepping and draping of the skin.

The principle of organ retrieval surgery in the context of DCD is rapid and effective organ perfusion with minimisation of risk of organ injury. The nature of the surgical process is dependent on whether single or multi-organ retrieval is to be performed [5]. The organs that can be retrieved will depend in part on the warm ischaemic time. The success of graft function after transplantation is dependent upon the type of organ, pre-mortem organ function and the period of hypoperfusion and warm ischaemia. Donors are screened for organ function, and reasonable attempts are made to minimise warm ischaemia. Currently, if this time exceeds 30 minutes for liver and pancreas, 60 minutes for kidneys, and 90 minutes for lungs, organ donation may not proceed.

The family of the deceased should be given the opportunity to view the body after organ and tissue donation. The family should be advised about the body's appearance before the viewing and offered support during the post mortem viewing. Ideally, this support should be provided by the health professional who has been the family's main contact. If this is not possible, then another appropriately trained health professional such as a social worker or bereavement counsellor should become involved [4].

Care for the family does not stop with the death of the patient or with retrieval of organs and tissues if donation proceeds. This care should be provided by ICU staff immediately after death and after organ retrieval and, later, by the OTDA.

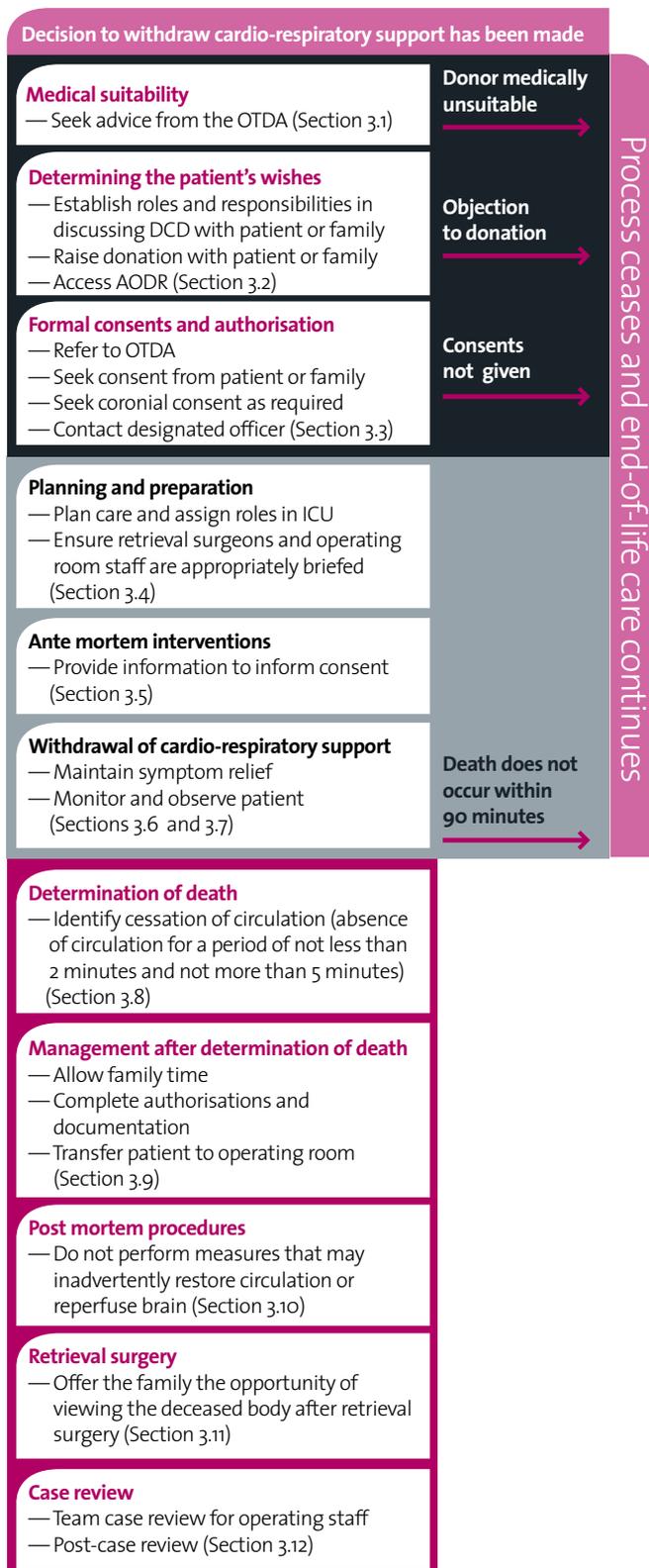
3.12 Case review

Case review meetings are useful for addressing issues related to the process and allow the opportunity for those involved to seek immediate emotional support if required.

- ▶ A team case review for operating room staff following retrieval surgery provides an opportunity to review all aspects of the retrieval.
- ▶ All staff involved in the case should be strongly encouraged to attend a post-case review meeting. This forum provides staff with an opportunity to discuss any quality issues in relation to the DCD process.

Appendices

A Tools to support the donation after cardiac death process



Note: This flowchart should be used in conjunction with the following checklist.

Checklist for donation after cardiac death

Consideration of DCD is contingent upon the decision to withdraw cardio-respiratory support and should only occur after that decision has been made. The family may withdraw consent at any point. Where this occurs, the process of DCD ceases and end-of-life care continues.

Most of the points of measurement included here are collected routinely by organ donor coordinators and recorded on the observation chart (P18 of the ATCA/TSANZ Confidential Donor Referral Form 2009)

Clinical considerations	Notes and measurement points
1 Medical suitability	
<input type="checkbox"/> Patient meets criteria for DCD	Note: No absolute contraindication to donation Likely to die within 90 minutes of withdrawal of cardio-respiratory support Not brain dead and unlikely to progress to brain death
<input type="checkbox"/> Advice on medical suitability sought from the ODTA	If potential donor is medically unsuitable, cease process and continue end-of-life care
2 Determining the patient's wishes	
<input type="checkbox"/> Roles and responsibilities of the individuals involved in the discussion of donation with the family determined	
<input type="checkbox"/> Information to support informed decision-making about DCD provided to family	
<input type="checkbox"/> Family notified of intention to access the AODR	
<input type="checkbox"/> AODR accessed and information conveyed to family	If there is an objection to donation on a register or from the family, cease process and continue end-of-life care
<input type="checkbox"/> Discussions documented in patient's medical record	
3 Formal consents and authorisation	
<input type="checkbox"/> Potential donor referred to ODTA	
<input type="checkbox"/> Formal consent to organ donation provided by patient or family and documented in the medical record	
<input type="checkbox"/> Staff member identified to consider and take responsibility for family needs	
<input type="checkbox"/> Requirement for Coroner's consent identified and, where applicable, documented	
<input type="checkbox"/> Designated officer or equivalent contacted and statutory responsibilities identified	If relevant consents are not given, cease process and continue end-of-life care

Clinical considerations	Notes and measurement points
4 Planning and preparation	
<input type="checkbox"/> Meeting held in ICU for planning care and assigning roles	Note: The outcomes of these meetings should be discussed with the family; for example, the timing of withdrawal of cardio-respiratory support and the opportunity for the family to be present, the period of time to determine death, and the timing for transfer to the operating room
<input type="checkbox"/> Site of proposed withdrawal of cardio-respiratory support determined	Measurement 1 Location of WCERS: ICU or OR
<input type="checkbox"/> Plans made for end-of-life care should death not occur within 90 minutes of withdrawal of cardio-respiratory support and discussed with family	
<input type="checkbox"/> Organ donor coordinator, operating room staff and the organ retrieval team briefed	
5 Ante mortem interventions	
<input type="checkbox"/> Necessary ante mortem interventions identified and discussed with family and patient (if competent) and relevant consents documented	Note: Ante mortem interventions may only be performed in compliance with jurisdictional legislation, guidelines and institutional protocol
6 Withdrawal of cardio-respiratory support	
<input type="checkbox"/> Person responsible for withdrawal of cardio-respiratory support and determining death is not a member of the retrieval or transplant team	
<input type="checkbox"/> Measures taken to conduct monitoring in a way that is respectful to family and friends	
<input type="checkbox"/> Symptom relief maintained	
<input type="checkbox"/> Cardio-respiratory support withdrawn	Measurement 2 Time of withdrawal of cardio-respiratory support: hrs If death does not occur within 90 minutes, cease process and continue end-of-life care
7 Management after withdrawal of cardio-respiratory support	
<input type="checkbox"/> Heart rate, oxygen saturation, respiratory rate and blood pressure monitored and observations documented by organ donor coordinator	Note: Process timed by organ donor coordinator on a single clock Measurements 3 & 4 Onset of SBP \leq 50mmHg:hrs O² saturation \leq 50%: hrs

Clinical considerations	Notes and measurement points
8 Determination of death	
<input type="checkbox"/> Cessation of circulation is determined	Note: Absence of a palpable central pulse, preferably in combination with the observation of a zero pulse pressure, measured by arterial pressure monitoring. Measurement 5 Cessation of circulation: hrs
<input type="checkbox"/> Period of observation after cessation of circulation	Note: No less than 2 mins and not more than 5 mins
<input type="checkbox"/> Death is determined to have occurred	Measurements 6 & 7 Time observed: ... mins Time and date of death:hrs, / /
9 Management after determination of death	
<input type="checkbox"/> Phase of family care and clinical and logistical planning, essential notifications and family support occur	Note: In NSW after death is determined, there must be a period of at least 5 minutes before surgical retrieval can commence
<input type="checkbox"/> Designated Officer (and Coroner as applicable) notified of determination of death and provides authorisation	
<input type="checkbox"/> Family has time with deceased and then departs	Note: The family is supported during this time. If the family is unable to leave the patient following death, organ retrieval may not proceed — normal post mortem procedures are followed
<input type="checkbox"/> Transfer of the donor to the operating room	
10 Post mortem procedures	
<input type="checkbox"/> Post mortem procedures discussed and planned	Note: Measures that may inadvertently restore circulation or reperfuse the brain are not performed. Post mortem interventions are performed by the retrieval team
11 Retrieval surgery	
<input type="checkbox"/> Organ retrieval surgery commences	Measurements 8 & 9 Surgical incision: hrs Commencement of cold perfusion:hrs
<input type="checkbox"/> Family offered the opportunity of viewing the prepared body after retrieval surgery	
<input type="checkbox"/> Family advised about the donor's appearance and offered support when they view the body	
12 Case review	
<input type="checkbox"/> Team case review for operating room staff conducted	
<input type="checkbox"/> Post-case review meeting conducted	

B Legislative requirements associated with donation after cardiac death

Donation and transplantation of organs and 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 DCD 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 ACT, Qld and Tas are explicit that the authority of such representatives includes the withdrawal of cardio-respiratory support. Laws in the NT, SA, Vic and WA are not explicit on this matter, and law in NSW has been interpreted in different ways in two recent decisions [26, 27], 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.

In the DCD 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
- 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.



Consent to organ and tissue donation

This consent can be given by the patient, if competent and sufficiently informed or by a senior available next-of-kin, as provided by State and Territory transplantation laws (see below). A practical difficulty may arise if the relevant State or Territory legislation does not recognise the legal capacity of substitute decision-makers (such as Power of Attorney or Appointed Guardian) after death. Health care staff may be required to discuss withdrawal of cardio-respiratory support and / or ante mortem interventions with a substitute decision maker prior to death but will be required to discuss consent to organ donation with a senior available next-of-kin defined by the Human Tissue legislation in their State or Territory.

Advance Care Directives

The patient's wishes expressed in an advance care directive would be considered sufficient evidence of a donor's consent or objection to donation and transplantation.

The various definitions of advance care directives, the powers of substitute decision-makers and their relationship to the legislation regulating human tissue transplantation across Australia cannot be accurately and conveniently summarised. For this reason, it is recommended that the reader refer to State and Territory guardianship legislation for the relevant guide to the powers of substitute decision-makers in their jurisdiction. Refer to the table that outlines guardianship legislation at the end of this appendix.

Authorisation by the Designated Officer or officer holding an equivalent role

This section outlines State and Territory legislation regarding authorisation by the Designated Officer. A summary of the legislation is given in the table at the end of this appendix.

Timing of Designated Officer decisions and authorisation

All State and Territory legislation provides that a Designated Officer may authorise the removal of organs and tissue from a person "who has died", having made inquiries about the matters listed in the next paragraph. Although the Designated Officer's authorisation is to be made after the person's death, the laws appear to permit the necessary inquiries to be made before the person dies.

There are differences among State and Territory laws that set out the requirements for the Designated Officer's authorisation. The legislation differs in relation to whether inquiries about the deceased's wishes must be made first, whether the deceased's decision is one of consent or no objection, the standard for the Designated Officer's authorisation, the identity of the senior available next-of-kin, the nature of the senior available next-of-kin's decision and coronial consent. The provisions of each State and Territory's legislation on these matters are summarised below.



ACT

What are the conditions for the Designated Officer's authorisation?

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 a senior available next-of-kin. The legislation makes the first set of inquiries (about the deceased wishes) a condition to be met before the second set (about the senior available next-of-kin's views) can be undertaken. In most other jurisdictions, this condition is not applied.

What is the standard for the Designated Officer's authorisation?

That it appears to the Designated Officer that the requirements have been met.

What is the basis of the deceased's decision?

A wish for or consent to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

For any other dead person:

- ▶ if in domestic partnership immediately before death, domestic partner
- ▶ adult son or daughter
- ▶ if not in domestic partnership immediately before death, adult son or daughter
- ▶ the parent
- ▶ an adult brother or sister.

What is required of the senior available next-of-kin?

That the senior available next-of-kin has not expressed an objection to removal of organs or tissue.

What is meant by coronial consent?

The Designated Officer cannot authorise removal of tissue unless Coroner has given consent. Coroner authorised to give direction that consent not required.



NSW

What are the conditions for the Designated Officer's authorisation?

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 senior available next-of-kin. The legislation makes the first set of inquiries (about the deceased wishes) a condition to be met before the second set (about the senior available next-of-kin's views) can be undertaken. In most other jurisdictions, this condition is not applied.

What is the standard for the Designated Officer's authorisation?

That the Designated Officer is satisfied that the requirements have been met.

What is the basis of the deceased's decision?

A consent to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

Please note however that where the child is in the care of the State, the Principal Officer of the Care Agency is the consenting authority for organ and tissue donation.

For any other dead person:

- ▶ a spouse immediately before death
- ▶ adult son or daughter
- ▶ a parent
- ▶ an adult brother or sister.

What is required of the senior available next-of-kin?

That the senior available next-of-kin has consented to removal of organs or tissue and the wishes or lack of objection of any other next-of-kin on the same or higher level are not different.

What is meant by coronial consent?

The Designated Officer cannot authorise removal of tissue unless Coroner has given consent.



NT

What are the conditions for the Designated Officer's authorisation?

The Designated Officer can conduct inquiries about the deceased's wishes and/or those of a senior available next-of-kin.

What is the standard for the Designated Officer's authorisation?

That the Designated Officer has reason to believe that the requirements have been met.

What is the basis of the deceased's decision?

A wish for or consent to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

For any other dead person:

- ▶ a spouse or de facto partner
- ▶ adult son or daughter
- ▶ a parent
- ▶ an adult brother or sister.

The authorisation can proceed if inquiries are unable to ascertain the existence or whereabouts of next-of-kin.

What is required of the senior available next-of-kin?

That the senior available next-of-kin has not expressed an objection to removal of organs or tissue.

What is meant by coronial consent?

If Designated Officer has reason to believe that the death of a person may be a reportable death, cannot authorise removal unless the Coroner has consented. Coroner authorised to give direction that consent not required.



QLD

What are the conditions for the Designated Officer's authorisation?

The Designated Officer can conduct inquiries about the deceased's wishes and/or those of a senior available next-of-kin.

What is the standard for the Designated Officer's authorisation?

That it appears to the Designated Officer that the requirements have been met.

What is the basis of the deceased's decision?

A lack of objection to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ spouse
- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

For any other dead person:

- ▶ spouse
- ▶ adult son or daughter
- ▶ the parent
- ▶ an adult brother or sister.

What is required of the senior available next-of-kin?

That the senior available next-of-kin has consented or objected to the removal of organs or tissue.

What is meant by coronial consent?

The Designated Officer cannot authorise removal of tissue unless Coroner has given consent. Coroner authorised to give direction that consent not required.



SA

What are the conditions for the Designated Officer's authorisation?

The Designated Officer can conduct inquiries about the deceased's wishes and/or those of a senior available next-of-kin.

What is the standard for the Designated Officer authorisation?

That the Designated Officer has reason to believe that the requirements have been met.

What is the basis of the deceased's decision?

A wish for or consent to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

For any other dead person:

- ▶ the spouse or domestic partner
- ▶ adult son or daughter
- ▶ a parent
- ▶ an adult brother or sister.

The authorisation can proceed if inquiries are unable to ascertain the existence or whereabouts of next-of-kin.

What is required of the senior available next-of-kin's decision?

That the senior available next-of-kin has not expressed an objection to removal of organs or tissue.

What is meant by coronial consent?

If the Designated Officer has reason to believe that the circumstances are such that an inquest may be held in relation to the deceased's death, cannot authorise removal unless the Coroner has consented. Coroner authorised to give direction that consent not required.



TAS

What are the conditions for the Designated Officer's authorisation?

The Designated Officer can conduct inquiries about the deceased's wishes and/or those of a senior available next-of-kin.

What is the standard for the Designated Officer's authorisation?

That it appears to the Designated Officer that the requirements have been met.

What is the basis of the deceased's decision?

A wish for or consent to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

For any other dead person:

- ▶ if in domestic partnership immediately before death, domestic partner
- ▶ adult son or daughter
- ▶ if not in domestic partnership immediately before death, adult son or daughter
- ▶ the parent
- ▶ an adult brother or sister.

What is required of the senior available next-of-kin's decision?

That the senior available next-of-kin has not expressed an objection to removal of organs or tissue and the wishes or lack of objection of any other next-of-kin on the same or higher level are not different.

What is meant by coronial consent?

The Designated Officer cannot authorise removal of tissue unless Coroner has given consent. Coroner authorised to give direction that consent not required.



VIC

What are the conditions for the Designated Officer's authorisation?

The Designated Officer can conduct inquiries about the deceased's wishes and/or those of a senior available next-of-kin.

What is the standard for the Designated Officer's authorisation?

That the Designated Office has reason to believe that the requirements have been met.

What is the basis of the deceased's decision?

A wish for or consent to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

For any other dead person:

- ▶ spouse or domestic partner
- ▶ adult son or daughter
- ▶ a parent
- ▶ an adult brother or sister.

The authorisation can proceed if inquiries are unable to ascertain the existence or whereabouts of next-of-kin.

What is required of the senior available next-of-kin?

That the senior available next-of-kin has not expressed an objection to removal of organs or tissue.

What is meant by coronial consent?

If Designated Officer has reason to believe that the circumstances are such that an inquest may be held in relation to the deceased's death, cannot authorise removal unless the Coroner has consented. Coroner authorised to give direction that consent not required.



WA

What are the conditions for the Designated Officer's authorisation?

The Designated Officer can conduct inquiries about the deceased's wishes and/or those of a senior available next-of-kin.

What is the standard for the Designated Officer's authorisation?

That the Designated Officer is satisfied that the requirements have been met.

What is the basis of the deceased's decision?

A wish for or consent to donation.

Who can be a senior available next-of-kin?

For a dead child:

- ▶ if the child has a spouse or domestic partner over 18, that spouse or de facto partner
- ▶ a parent
- ▶ an adult brother or sister
- ▶ guardian immediately before death.

For any other dead person:

- ▶ if person has spouse and de facto partner, the spouse or de facto partner
- ▶ adult son or daughter
- ▶ if not in domestic partnership immediately before death, adult son or daughter
- ▶ the parent
- ▶ an adult brother or sister.

What is required of the senior available next-of-kin?

That the senior available next-of-kin has consented and that the wishes or lack of objection of any other next-of-kin are not different.

What is meant by coronial consent?

If the Designated Officer has reason to believe that the death of a person may be a reportable death, cannot authorise removal unless the Coroner has consented. Coroner is authorised to give direction that consent not required.

Links to State and Territory legislation:

Human Tissue legislation

ACT	www.legislation.act.gov.au/a/1978-44/default.asp
NSW	www.legislation.nsw.gov.au/maintop/view/inforce/act+164+1983+cd+o+N
NT	notes.nt.gov.au/dcm/legislat/legislat.nsf/d989974724db65b1482561cfoo17cbd2/76ae960e1e6cd7b7692571f10009d36d?OpenDocument
QLD	www.legislation.qld.gov.au/LEGISLTN/CURRENT/T/TransplAAnatA79.pdf
SA	www.legislation.sa.gov.au/LZ/C/A/TRANSPLANTATION%20AND%20ANATOMY%20ACT%201983.aspx
TAS	www.thelaw.tas.gov.au/tocview/index.w3p;cond=ALL;doc_id=118%2B%2B1985%2BAT%40EN%2B20091102210000;histon=;prompt=;rec=;term=Human%20Tissue
VIC	www.legislation.vic.gov.au/Domino%5CWeb_Notes%5CLDMS%5CPubLawToday.nsf
WA	www.slp.wa.gov.au/pco/prod/FileStore.nsf/Documents/MRDocument:12950P/\$FILE/HumntissueAndTransplantAct1982_02-co-00.pdf?OpenElement

Guardianship legislation

ACT	www.legislation.act.gov.au/a/1991-62/default.asp
NSW	www.legislation.nsw.gov.au/viewtop/inforce/act+257+1987+cd+o+N/?autoquery=(Content%3D((%22Guardianship%22))%20AND%20((Type%3D%22act%22%20AND%20Repealed%3D%22N%22)%20OR%20(Type%3D%22subordleg%22%20AND%20Repealed%3D%22N%22))&dq=Document%20Types%3D%22Acts,%20Regs%22,%20Exact%20Phrase%3D%22Guardianship%22,%20Search%20In%3D%22Text%22&fullquery=((%22Guardianship%22)))
NT	http://notes.nt.gov.au/dcm/legislat/legislat.nsf/d989974724db65b1482561cfoo17cbd2/f235f66c0dcb420b692575dd00186287?OpenDocument&Highlight=o,guardianship
QLD	www.legislation.qld.gov.au/Search/?IW_FIELD_WEB_STYLE=Guardianship&IW_DATABASE=Acts+SL+as+in+force+%28current%29&Submit1=search+
SA	www.legislation.sa.gov.au/LZ/C/R/GUARDIANSHIP%20AND%20ADMINISTRATION%20REGULATIONS%201995.aspx
TAS	www.thelaw.tas.gov.au/tocview/index.w3p;cond=ALL;doc_id=44%2B%2B1995%2BAT%40EN%2B20100312140000;histon=;prompt=;rec=;term=Guardianship
VIC	www.legislation.vic.gov.au/Domino%5CWeb_Notes%5CLDMS%5CPubLawToday.nsf
WA	www.slp.wa.gov.au/pco/prod/FileStore.nsf/Documents/MRDocument:17611P/\$FILE/GuardianshipAndAdminAct1990_05-a0-00.pdf?OpenElement

Summary of relevant State and Territory legislative differences

1. What are the conditions for the Designated Officer's authorisation?	
ACT, 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 a senior available next-of-kin. The legislation makes the first set of inquiries (about the deceased wishes) a condition to be met before the second set (about the senior available next-of-kin's views) can be undertaken. In most other jurisdictions, this condition is not applied.
NT, QLD, SA, TAS, VIC, WA	The Designated Officer can conduct inquiries about the deceased's wishes and/or those of a senior available next-of-kin.
2. What is the standard for the Designated Officer's authorisation?	
ACT, QLD, TAS	That it appears to the Designated Officer that the requirements have been met.
NSW, WA	That the Designated Officer is satisfied that the requirements have been met.
NT, SA, VIC	That the Designated Officer has reason to believe that the requirements have been met.
3. What is the basis for the deceased decision?	
ACT, NT, SA, TAS, VIC, WA	A wish for or consent to donation.
NSW	A consent to donation.
QLD	A lack of objection to donation.
4. Who can be a senior available next-of-kin?	
	See specific jurisdictional requirements as outlined in Appendix B.
5. What is required the senior available next-of-kin?	
ACT, NT, SA, VIC	That the senior available next-of-kin has not expressed an objection to removal of organs or tissue.
NSW	That the senior available next-of-kin has consented to removal of organs or tissue and the wishes or lack of objection of any other next-of-kin on the same or higher level are not different.
QLD	That the senior available next-of-kin has consented or objected to the removal of organs or tissue.
TAS	That the senior available next-of-kin has not expressed an objection to removal of organs or tissue and the wishes or lack of objection of any other next-of-kin on the same or higher level are not different.
WA	That the senior available next-of-kin has consented and that the wishes or lack of objection of any other next-of-kin are not different.
6. What is meant by coronial consent?	
ACT, QLD, TAS	The Designated Officer cannot authorise removal of tissue unless Coroner has given consent. Coroner authorised to give direction that consent not required.
NT, WA	If Designated Officer has reason to believe that the death of a person may be a reportable death, cannot authorise removal unless the Coroner has consented. Coroner authorised to give direction that consent not required.
SA, VIC	If the Designated Officer has reason to believe that the circumstances are such that an inquest may be held in relation to the deceased's death, cannot authorise removal unless the Coroner has consented. Coroner authorised to give direction that consent not required.
NSW	The Designated Officer cannot authorise removal of tissue unless Coroner has given consent.

C Ethical issues associated with donation after cardiac death

DCD 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, 25].

Medical practitioners must not administer treatments aimed at hastening death.

Participation in DCD 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 DCD 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 [2, 4]. 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 his or her family [2].

Consent

Consent to medical interventions should be informed and voluntary. Unlike other medical interventions, decisions about consent for organ and tissue donation, and the recording of this choice on the AODR, 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 public 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 DCD for their relative. 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 DCD. Resolving this tension is beyond the scope of this protocol [2].

Ante mortem interventions

Preparing a patient for organ and tissue donation requires a number of interventions, such as taking blood for viral screening and tissue typing and other physical investigations [2, 25]. In addition to these interventions, which are necessary for all donors, there are a number of interventions that are specific to potential DCD donors, such as administering heparin and other drugs. Unlike in DBD donors, most of these interventions take place prior to death in DCD patients. Performing these interventions raises issues of beneficence, non-maleficence [2, 25] and consent [28]. 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 the time when the patient is dying, he or she has very limited physical interests to promote [2, 25]. However, such patients have an interest in having their recorded or expressed choices 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 what is in the best interests of the donor patient [2, 25].

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].

Determination of death

For successful transplantation, organs must be retrieved from the deceased person as soon as possible after death has occurred. In recognising and determining 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, 29]; 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 has ceased irreversibly. In order to meet the irreversibility requirement, death cannot be determined until the possibility of auto-resuscitation has been excluded, hence the **minimum** of a two-minute period between circulation ceasing and death being determined [1, 2].

At this point there may be a tension between the family's needs and those of proceeding to donation [25]. 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, 25]. The family must be fully informed regarding the necessity for the prompt transfer of the patient to the operating room following determination of death in order to fulfill the patient's wishes and ensure the best outcome for transplantation.

D Process of developing the protocol

Donation after Cardiac Death Working Party

Name	Relevant Affiliations	Position
Dr Gerry O'Callaghan Chair	Chair: National Organ and Donation Collaborative (NODC) Advisory Committee Australian and New Zealand Intensive Care Society (ANZICS)	National Medical Director, AOTDTA
Ms Alison Barnwell	DonateLife NSW	Coordinator of Bereavement Services, DonateLife NSW (2009); State Coordinator – Bereavement Services.
Dr David Cook	Queensland Health DonateLife Queensland ANZICS	Intensivist, Princess Alexandra Hospital QLD
Dr Deanne Crosbie	NODC Advisory Committee Australasian College for Emergency Medicine (ACEM)	Emergency Department Physician, Townsville Hospital, QLD
Mr Graham Douglas-Meyer (September 2009)	AHEC Consumer Member	Chair of the Australian Federation of Disability Organisations (AFDO)
Ms Nicola Dykes	NODC Advisory Committee	Organ and Tissue Donor Coordinator, Westmead Hospital, NSW
Dr Michael Fink	Transplant Society of Australia and New Zealand (TSANZ)	Transplant Surgeon, The Austin Hospital, VIC
Ms Shena Graham	DCD Protocol Development Project Officer, seconded position	Hospital Senior Nurse, Organ Tissue Donation, The Alfred, VIC
Ms Catherine Hannan	Australian College of Critical Care Nurses (ACCCN)	Organ Donor Coordinator, DonateLife South Australia
Ms Kathy Hee	NODC Advisory Committee Australian Transplant Co-ordinators Association (ATCA)	Manager, DonateLife South Australia
Ms Sue Huckson	NHMRC NICS	Director: Effective Practice Program
Ms Ella Meek	Australian College of Operating Room Nurses (ACORN)	Theatre Nurse, Westmead Hospital, NSW
Dr David Pilcher	ANZICS	Intensivist, The Alfred, VIC
Dr Graeme Pollock	Lions Eye Donation Service (representing Tissue Sector)	Director, Lions Eye Donation Service, VIC
Dr Ray Raper	NODC Advisory Committee ANZICS	Head of Intensive Care, Royal North Shore Hospital, NSW
Prof Wendy Rogers	Deputy Chair: NHMRC Organ Donation Guideline Working Group	Professor of Clinical Ethics, Macquarie University, NSW
Ms Francesca Rourke	President ATCA	Organ Donor Coordinator, QLD
A/Prof Bill Silvester	NODC Advisory Committee (proxy for Dr Helen Opdam) ANZICS Death and Organ Donation Committee Medical ADAPT Steering Committee	Intensivist, Austin Hospital, VIC Medical consultant, DonateLife Victoria
Mr John Stubbs (September 2009)	AHEC Consumer Member	Executive Officer of Cancer Voices Australia
Prof Colin Thomson	Chair: Australian Health Ethics Committee (2006-2009)	Professor of Law and Ethics Professorial Fellow, University of Wollongong and Adjunct Professor, Macquarie University, NSW
Ms Alina Tooley	NHMRC NICS (2009) AOTDTA	NODC Transition Manager (2009) Director, Community of Practice, AOTDTA
Ms Julie Vomero	Consumer	VIC

Development process

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

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 DCD for the AOTDTA [30]. AHMAC agreed that the NHMRC provide guidance and oversight to 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 [4]

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. They were developed after extensive public consultation and review of key documents including: 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.

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 [5]

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 DCD. 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 [6–8] as well as hospital guidelines from Victoria [9–11]. The document seeks to be consistent in language and terminology with guidelines on end-of-life care.

DCD Working Party

The steps undertaken to develop this protocol included the employment of a project officer and the establishment of a DCD Working Party, which included an expert in law and an expert in ethics. This working party also had professional representation from the organ and tissue donation, transplantation and acute care sectors as well as consumer representation.

A total of five meetings of the DCD Working Party were convened during the development phase, including a joint meeting of the DCD Working Party and National Organ Donation Collaborative (NODC) Advisory Committee was held on 4 May 2009 to discuss and agree on the draft protocol and to enable it to proceed to the public consultation phase. The final meeting was held on 21 January 2010. Subsequently the protocol was submitted to AHEC for advice to NHMRC Council to recommend that the Chief Executive Officer of the NHMRC approve and release the National Protocol for DCD to the AOTDTA for publication.

The protocol was developed under the auspices of AHEC whose advice was critical to its development.

DCD Consensus Stakeholder Workshop

The Consensus Stakeholder Workshop on Donation after Cardiac Death on 19 March 2009 was attended by 62 delegates from the organ and tissue donation and transplantation sector 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 process of DCD.

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 DCD, and to make recommendations on the key elements of a consistent approach to DCD for Australia. The recommendations resulting from the workshop were used to inform the development of the protocol.

Targeted and Public Consultation Process

NHMRC Council approved the initial draft protocol for DCD for public consultation on 10 June 2009. From June to August 2009 a targeted consultation with relevant professional colleges and societies and a general public consultation were undertaken. The process for public consultation included placing a notice in “The Australian” and placing the draft consultation protocol on the NHMRC website with clear processes available for providing comments. Forty-two submissions were received, with representation from professional colleges and societies; individual clinicians; consumer organisations; religious groups; ethics-based organisations and government agencies. All submitted comments were reviewed by the Donation after Cardiac Death Working Party and considered in developing the final version of the protocol.

A revised draft informed by the public consultation process was approved in principle by the AHEC committee on 28 October 2009, with recommendations for revisions.

On 23 November 2009, a submission regarding the draft National Protocol for Donation after Cardiac Death was reviewed by the Aboriginal and Torres Strait Islander Health Advisory Committee (ATSIHAC), who recommended further consultation, be undertaken with specific Aboriginal and Torres Strait Islander peak bodies prior to publication. Advice was sought from the Australian Indigenous Doctors’ Association (AIDA) with reference to matters related to discussing organ and tissue donation with family members in a culturally sensitive manner and in obtaining consent. No further changes were requested.

In response to consumer feedback additional work was undertaken with the assistance of the AHEC Consumer members on the DCD Working Party to develop a plain language statement to accompany the DCD protocol.

Endorsement process

Following NHMRC approval of the protocol further endorsement was sought from 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
- ▶ Australian Transplant Coordinators Association
- ▶ Australian College of Operating Room Nurses
- ▶ College of Emergency Nursing Australasia
- ▶ College of Intensive Care Medicine
- ▶ Royal Australasian College of Surgeons
- ▶ Transplantation Society of Australia and New Zealand.

E Abbreviations and acronyms

ACCCN	Australian College of Critical Care Nurses
ACEM	Australasian College for Emergency Medicine
ACORN	Australian College of Operating Room Nurses
ADAPT	Australian Donor Awareness Programme
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers Advisory Council
AHMC	Australian Health Ministers' Conference
ANZICS	Australian and New Zealand Intensive Care Society
AODR	Australian Organ Donor Register
ATCA	Australasian Transplant Co-ordinators Association
CICM	College of Intensive Care Medicine
DBD	Donation after brain death
DCD	Donation after cardiac death
ICU	Intensive Care Unit
NHBD	Non-heart beating donation
NHMRC	National Health and Medical Research Council
NICS	National Institute of Clinical Studies
NODC	National Organ Donation Collaborative
OTDA	Organ and Tissue Donation Agency
SBP	systolic blood pressure
SA Health	South Australia Health
TSANZ	Transplantation Society of Australia and New Zealand

F Glossary

Designated officer (or officer holding an equivalent role)

A senior person within the hospital, usually a medical practitioner, the medical superintendent or a person acting in his/her place, who has been designated to be responsible for scrutinising the process of organ donation and authorising the removal of organs and tissues from a deceased person.

Donation after Cardiac Death (DCD)

Also known as non-heart-beating donation or donation after cardiocirculatory death, this refers to organ donation after death has been determined to have occurred, on the basis of the irreversible loss of circulation of blood in the body of the person.

End-of-life care

Care provided to the dying individual and their family [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].

Maastricht Categories

An international meeting on donation after cardiac death held in Maastricht, Netherlands in 1995, identified four categories of potential donors [32, 33]. These categories were developed to categorise potential organ donors on a clinical basis and are widely accepted internationally [7, 13, 34]. A fifth category was added in 2003 [8].

Categories are described as either uncontrolled (Categories 1, 2, 4 and 5) or controlled (Category 3). Due to the ethical and logistical difficulties in protecting organs while seeking consent from the family, Categories 1, 2 and 5 are not considered acceptable for organ donation in Australia at present.

- ▶ Category 1: Dead on arrival – unknown warm ischaemic time [1, 5]
- ▶ Category 2: Unsuccessful resuscitation – known warm ischaemic time [1, 5]
- ▶ Category 3: Awaiting cardiac arrest after planned withdrawal of cardio-respiratory support – known and limited warm ischaemic time [1, 5]
- ▶ Category 4: Cardiac arrest after confirmation of brain death [33], but prior to organ retrieval. Warm ischaemic time known and potentially limited [1, 5]
- ▶ Category 5: Unexpected cardiac arrest in a critically ill patient – warm ischaemic time known and potentially limited [8, 35]



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

Category 4, although a rare occurrence, is a realistic consideration when a family has already consented to organ and tissue donation [1, 5].

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 determination of death. The length of time for observation is not less than two minutes and not more than 5 minutes.

Senior available next-of-kin

The senior available next-of-kin, of a deceased adult, as defined in the human tissue acts in each jurisdiction is the person who is available and highest in the hierarchy determined in that jurisdiction's act (see Appendix B).

Warm ischaemic time

Warm ischaemic time (WIT) describes the period from the loss of adequate organ perfusion due to low blood pressure during the dying process to the commencement of organ perfusion with cold preservation solution in the retrieval surgery. Prolonged WIT compromises the quality of organs for transplantation. It is usually measured from the time when systolic blood pressure \leq 50mmHg to the commencement of cold perfusion.

Withdrawal of cardio-respiratory support

Withdrawal of cardio-respiratory support is defined as the cessation of cardiac and ventilatory support. This specific term is used in the setting of DCD because the potential DCD donor can only be a patient where there is absolute dependence on cardio-respiratory support and who will, therefore, progress rapidly to circulatory arrest. By definition, it stipulates that DCD can only be considered in a patient who is at a minimum, currently intubated and ventilator dependent. Thus the following less specific terms are not appropriate: "withdrawal of care", "withdrawal of life-sustaining therapy", "withdrawal of life support" and "withdrawal of treatment". The withdrawal of ventilatory support includes the removal of the ventilation tubing i.e. the endotracheal tube or the tracheostomy tube. The withdrawal of cardiac support most commonly refers to the cessation of inotropes and vasopressors but could also include the cessation of intra-aortic balloon counter pulsation and/or extra corporeal membrane oxygenation.

References

1. Australian and New Zealand Intensive Care Society. *The ANZICS Statement on Death and Organ Donation*. 3rd ed. Melbourne: ANZICS; 2008.
2. Rogers W. *Ethical Issues in Donations after Cardiac Death*. DCD Stakeholder Workshop. Sydney; 2009.
3. University of Pittsburgh Medical Center. *Policy and Procedure Manual*. Kennedy Institute Ethics J 1992; 3(2): A1–A15.
4. National Health and Medical Research Council. *Organ and Tissue Donation after Death, for Transplantation*. Canberra: Australian Government; 2007.
5. NSW Health. *Organ Donation after Cardiac Death: NSW Guidelines*. Sydney: NSW Health; 2007.
6. Shemie SD, Baker AJ, Knoll G, Wall W, Rocker G, Howes D, et al. *National recommendations for donation after cardiocirculatory death in Canada: Donation after cardiocirculatory death in Canada*. CMAJ. 2006 Oct 10; 175(8): 51.
7. Organ Donation New Zealand. *Protocol for Donation after Cardiac Death (DCD)*; 2007.
8. British Transplantation Society. *Guidelines Relating to Solid Organ Transplants from Non-Heart Beating Donors*. London, UK: British Transplantation Society; Nov 2004.
9. Alfred Health. *Guideline: Donation after Cardiac Death: Alfred Health*; 2009.
10. Silvester W. *Guidelines for Organ Donation after Cardiac Death (DCD)*. LifeGift-Vic/Tas; 2007.
11. Melbourne Health. *Donation after Cardiac Death Procedure*. Melbourne: Royal Melbourne Hospital; 2008.
12. AuSpen. *Clinical Practice Guidelines: Policy for Guideline Development and Endorsement*; 2008.
13. Bernat JL, D'Alessandro AM, Port FK, Bleck TP, Heard SO, Medina J, et al. Report of a National Conference on Donation after Cardiac Death. *Am J Transplant*. 2006 Feb; 6(2): 281–91.
14. DeVita MA, Brooks MM, Zawistowski C, Rudich S, Daly B, Chaitin E. Donors after cardiac death: validation of identification criteria (DVIC) study for predictors of rapid death. *Am J Transplant*. 2008 Feb; 8(2): 432–41.
15. Lewis J, Peltier J, Nelson H, Snyder W, Schneider K, Steinberger D, et al. Development of the University of Wisconsin donation After Cardiac Death Evaluation Tool. *Prog Transplant*. 2003 Dec; 13(4): 265–73.
16. Rudich S, Brooks M, Zawistowski C, Daly B, Chaitin E, DeVita M. Multi-centre study to validate UNOS criteria for predicting death within 60 minutes following withdrawal of life sustaining treatment. *Transplantation* 2006 July 15; 82 (1)(Suppl 3 WTC): 1059.
17. Coleman NL, Brieve JL, Crowfoot E. Prediction of death after withdrawal of life-sustaining treatments. *Crit Care Resusc*. 2008 Dec; 10(4): 278–84.
18. Thomson C. *The Matters on Which a DO Must Decide (and the Standard of that Decision)*. Melbourne; 2009.
19. Winters D, Smith M. *A Guide for Designated and Delegated Officers*. In: Government of Western Australia DoH, editor; 2008. p. 1–8.
20. Australian and New Zealand Intensive Care Society. *Statement on Withholding and Withdrawing Treatment*. Melbourne: ANZICS; 2003.
21. NSW Health. *Guidelines for End-of-life Care and Decision-Making*. In: NSW Department of Health, editor; 2005.
22. American College of Critical Care Medicine. *Recommendations for Nonheartbeating Organ Donation*. A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine, Crit Care Med 2001 Vol. 29, No. 9.
23. Non-Heart-Beating Organ Transplantation: Practice and Protocols, Committee on Non-Heart-Beating Transplantation II: The Scientific and Ethical Basis for Practice and Protocols, Division of Health Care Services, Institute of Medicine . 2000
24. Bernat JL, Capron AM, Bleck TP, Blosser S, Bratton SL, Childress JF, et al. The circulatory-respiratory determination of death in organ donation. *Crit Care Med*. 2010; 38(3):972–79.
25. Rogers W. *Two Tricky Issues in Donations after Cardiac Death*. National Organ Donation Collaborative - Learning Session 9. Sydney; 2009.
26. WK v Public Guardian (No 2). NSWADT 121; 2006.
27. FI v Public Guardian. NSWADT 263; 2008.
28. Richards B & Rogers WA. Organ donation after cardiac death: legal and ethical justifications for antemortem interventions. *Med J Aust* 2007; 187(3): 168–70.
29. Naffine N, Richards B, Rogers WA 'Scaring us all to death: the need for responsible legal scholarship on post mortem organ donation', J Law & Med 16: 696–707.
30. National Health and Medical Research Council Proposal from DoHA for the Development of a National Donation after Cardiac Death Protocol/ Statement. In: *Studies NloC*, editor.; 2008. p. 1–15.
31. Laurette A, M D, B M, LM J, S C, C A. A communication strategy and brochure for relatives of patients dying in ICU. *N Engl J Med*. 2007; 356: 469–78. Erratum in N Engl J Med 2007; 357-203.
32. Squifflet JP. Why did it take so long to start a non-heart-beating donor program in Belgium? *Acta Chir Belg*. 2006 Sep-Oct; 106(5): 485–88.
33. Koostra G. Categories of non-heart-beating donors. *Transplant Proc*. 1995; Oct; (27 (5)): 2893–94.
34. Potts JT. *Non-Heart Beating Organ Transplantation: Medical and Ethical Issues in Procurement*. Washington DC: Institute of Medicine (IOM); 1997.
35. Sanchez-Fructuosos AI, Prats, D., Torrente, J., Jesus Perez-Contin, M., Fernandez, C., Alvarez, J., Barrientos, A., Renal Transplantation from Non-Heart Beating Donors: A promising alternative to Enlarge the Donor Pool. *J Am Soc Nephrol*. 2000;11: 350–58.



www.donatelife.gov.au

Australian Organ and Tissue Authority
Level 5, 51 Allara St Civic ACT 2600
Phone: 02 6198 9800 Fax: 02 6198 9801
enquiries@donatelife.gov.au

