Cadaveric Organ and Tissue Donation and Transplantation

Protocol for Organ and Tissue Donation after Cardiac Death (DCD)

1. Purpose

This Protocol describes the mandatory steps that support ethical and clinically consistent, effective and safe organ and tissue donation.

2. Scope

This Protocol applies to all Hospital and Health Services.

This Protocol applies to all Hospital and Health Service employees and all Queensland Health employees working in or for Hospital and Health Services. This Protocol also applies to all organisations and individuals acting as an agent for Hospital and Health Services (including Visiting Medical Officers and other partners, contractors, consultants and volunteers).
3. Process for Organ and Tissue Donation After Cardiac Death (DCD)

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Disclaimer
This document has been developed to provide a framework for the practice of Donation after Cardiac Death. This document should not be considered exhaustive or be used in exclusion of other relevant references, policies, procedures, clinical guidelines and protocols. It does not replace the need for professional and clinical judgement and expert advice according to specific clinical requirements and the circumstances of individual cases.

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Glossary Of Abbreviations

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<th>Term</th>
<th>Definition</th>
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<tr>
<td>ATCA</td>
<td>Australasian Transplant Coordinators Association</td>
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<td>CJD</td>
<td>Creutzfeldt-Jacob Disease</td>
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<td>CVL</td>
<td>Central Venous Line</td>
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<td>DCD</td>
<td>Donation after Cardiac Death</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>ICU</td>
<td>Intensive Care Unit</td>
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<tr>
<td>IDC</td>
<td>In Dwelling Catheter</td>
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<tr>
<td>IV</td>
<td>Intravenous</td>
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<tr>
<td>IVC</td>
<td>Intravenous Cannula</td>
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<td>TSANZ</td>
<td>Transplantation Society of Australia and New Zealand</td>
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Introduction
The objective of the Queensland Donation after Cardiac Death (DCD) program is to extend the opportunity for Queenslanders, who are supportive of organ donation, to donate organs after their death in circumstances other than brain death.

This Queensland Procedure for Donation after Cardiac Death is a refinement of the guidelines originally published in 2008[1]. The revisions are based on recommendations from the Queensland DCD pilot project report 2010[2] and the Australian Organ and Tissue Donation and Transplantation Authority’s (AOTA) National Protocol for Donation after Cardiac Death[3] released in October 2010.

The Queensland DCD Procedure has been developed to assist healthcare professionals in Queensland to offer DCD within their hospitals. The procedure provides standard frameworks by which local procedural DCD policies can be developed that are consistent with Queensland legislation and DonateLife Queensland practice.

Support for implementation of a DCD hospital program in Queensland is provided by DonateLife Queensland, through tailored education of staff members and assistance in development of local procedure and policy.

Principles of Organ Donation and Medical Decisions at the End of Life
a) The decision to withdraw cardio-respiratory support (WCRS) is independent of any consideration of donation, and must be consistent with local practice guidelines and policies.

b) The decision to WCRS must be in accordance with jurisdictional guidelines (Queensland Guardian and Administration Act 2000) [4] ; and must be consistent with good medical practice[5-8].

c) Discussions with family, other attending specialists or healthcare staff regarding WCRS must be documented.

Section One – DCD Donor Selection Criteria

1. DCD DONOR SUITABILITY
Potential DCD donors are recognised by the following criteria.

a) Age: > 5 years and < 65 years of age

i. Age per se is not a contraindication and these are guides rather than strict rules, as marginal donors are always considered.

b) Patients in whom continuation of life sustaining therapies is considered inappropriate and not in the patients best interest. This can be due to catastrophic, irreversible cardiorespiratory or neurological injury: not fulfilling brain death criteria[9].
c) Cessation of circulation is expected to occur within 90 minutes after WCRS

2. GENERAL CONTRAINDICATIONS TO ORGAN DONATION\(^{[10]}\)

There are few absolute contraindications other than non-curable malignancy, HIV, CJD and untreated sepsis. All potential donors should be referred to DonateLife Queensland which will liaise with the transplant teams to determine medical suitability for donation.

Section Two – Medical Suitability

1. CONFIRMATION OF POTENTIAL DONOR SUITABILITY

   a) The managing specialist should consider DCD as a routine aspect of end of life care and it should be offered when:

      i. The decision has been made to WCRS.
      ii. There is no absolute contraindication to donation \(^{[10, 11]}\).
      iii. The patient is expected to proceed to circulatory arrest and death within 90 minutes following WCRS\(^{[3]}\).

   b) The use of tests or procedures to predict the likelihood of the patient progressing to cardiac death within 90 minutes of WCRS is at the discretion of the treating Intensive Care Specialist \(^{[12-14]}\), following consultation with family.

   c) The specialist offering donation must be independent of the transplant team and should not be the clinical advocate of a potential transplant recipient.

2. REFERRAL OF DONORS

Patients identified as potential DCD donors should be referred for evaluation of suitability for donation by the Donor Coordinator on-call. Donor Coordinators are responsible for coordination of the organ and tissue donation, retrieval and offer process from deceased donors in Queensland and other States and Territories.

Section Three – Family Discussion

1. RAISING ORGAN AND TISSUE DONATION

   a) Unless initiated by a family member, discussion regarding the opportunity for organ and tissue donation should be clearly separated from discussions regarding WCRS. At times, this may involve a separate meeting or different individuals conducting the two discussions (eg: another Intensive Care Specialist, Donor Coordinator or other appropriately skilled staff member).
b) Some families may independently raise the possibility of organ and tissue donation, prior to the decision to WCRS. If this occurs, the wish should be recognised and validated and documented in the medical record. The family is advised that further discussions will only take place if end of life care discussions are undertaken.

c) Healthcare providers have an ethical obligation to respect the wishes of patients if these can be known. Practitioners have an obligation to ascertain if possible, and facilitate their patient’s wishes about donation. This is done by asking the family and consulting the Australian Organ Donor Register for evidence of objection, or prior consent to organ donation.

2. PRINCIPLES OF FAMILY DISCUSSION

a) With the agreement of the family, the Donor Coordinator will interview the family and explain in detail, the process and requirements involved with DCD to ensure the family are fully informed prior to authorisation for donation to proceed[5].

b) Clear documentation of any discussions with the family regarding DCD is necessary.

c) Prior to consent to proceed with DCD, family discussion must include: [3, 14]

- Details of the process of WCRS and location.
- The medical and nursing management of end of life care, including treatments such as sedatives and/or analgesia that may be initiated.
- The method of confirming circulatory arrest and declaration of death (refer to Section 6).
- Organ retrieval needs to commence as soon as possible after the declaration of death to ensure organs function optimally after transplantation. The time between confirmation of circulatory arrest and declaration of death gives opportunity for family to prepare to leave the body of their relative.
- Donation will not proceed if a family are unable to leave the body of their relative after declaration of death.
- If the patient has not progressed to cardiac death after 90 minutes, the donation process will not proceed.
- The timing of WCRS will be confirmed when the Donor Coordinator has coordinated staff from the operating theatre and transplant teams.

Section Four – Consents and Coordination Process

AUTHORISATION AND CONSENT TO PROCEED TO DONATION

The formal consenting processes (as defined by the Queensland Transplant and Anatomy Act 1979) [15, 16] are performed by the attending Donor Coordinator. The Donor Coordinator will:

a) Obtain consent and complete the “Authority for Removal of Tissue after Death” form with the senior available next-of-kin, including consent for blood specimens for disease screening and tissue typing.
b) Obtain signed authorisation by the Designated Officer.

c) Obtain Coroner’s authorisation (if the death is reportable)[17] and consult with the Forensic Pathologist on-call.

**COMPREHENSIVE EVALUATION OF DONOR**

a) Blood is taken from the patient in the ante-mortem period for processing of serology and tissue typing.

b) The Donor Coordinator attending will complete the TSANZ/ATCA Confidential Donor Referral Form to compile clinical and risk assessment of the patient [10, 11].

c) The Donor Coordinator will refer clinical and risk assessment information to the Queensland abdominal and thoracic transplant teams for determination of medical suitability for donation and potential recipients for solid organ transplantation.

**PLANNING AND PREPARATION FOR DCD**

a) The timing of WCRS, for the purpose of DCD occurs at a planned time after discussion with the family, the Intensive Care Unit, Operating Theatre and transplant teams.

b) The location of WCRS must provide privacy and adequate access for the family, whilst having unimpeded access to the Operating Theatre. The location will be either in the Intensive Care Unit or an area adjacent to the Operating Theatre (such as the peri-operative recovery area). The location will depend on local hospital logistics.

c) Prior to WCRS interventions not intended to provide comfort or dignity should be discontinued. An arterial line, CVL/IVC and IDC are to be retained throughout the WCRS process.

d) Co-ordination of DCD donation is assisted by two meetings prior to the WCRS:

   o **ICU Planning Meeting** – This meeting takes place prior to WCRS and includes staff that will be involved in WCRS, care of the family and declaration of death. The meeting is to confirm the roles and responsibilities of the staff involved, confirm the location and time of WCRS and the steps involved in the process.

   o **Operating Theatre Meeting** – This meeting takes place 30 to 60 minutes prior to the planned WCRS time and involves the operating theatre staff, retrieval surgeons and Donor Coordinator. The purpose of the meeting is to review the legal paperwork, confirm the roles and responsibilities of the staff involved and the steps involved in the process and to complete preparations of the operating theatre.

   o WCRS can not occur until the operating theatre meeting occurs and preparation is completed.

**Section Five – Withdrawal of Cardiorespiratory Support**
a) WCRS for the purpose of donation is a planned and coordinated event with roles and responsibilities allocated to the intensive care staff members and donor coordinators involved.

b) The coordination of the process provides a dignified and respectful environment for the patient and their family and ensures warm ischaemic time of the donated organs is kept to a minimum.

c) A family's wish to be present during WCRS and until the person's death should be supported and facilitated.

d) Responsibility for all management after WCRS remains with the Intensive Care team. A member of the organ retrieval or transplant team may not manage either the WCRS or the care of the patient prior to declaration of death.

e) The ICU nursing and medical staff will remain with the patient following WCRS until death is declared and the patient is transferred to the operating theatre.

f) Appropriate palliative care and medications consistent with local practice guidelines should not be withheld because of a patient's potential donor status. (19) The intention of administration of drugs by the medical practitioner is the relief of symptoms in a dosage that is proportional to clinical need[18].

g) Following WCRS continuous arterial blood pressure monitoring and clinical observations including heart rate, blood pressure and respiratory rate are required to assist in the determination of circulatory arrest, declaration of death and warm ischaemic time. The Donor Coordinator is responsible for recording these clinical observations in the DCD Data Sheet.

h) A single clock provided by the Donor Coordinator will be used to time all events throughout the DCD process, to ensure that an accurate and consistent record of the sequence of events is maintained.

i) If the patient does not progress to cardiac death in 90 minutes, then DCD will not proceed. End of life care and management will continue to be provided by the Intensive Care team in the place and manner previously discussed with the family.

Section Six – Declaration of Death

1. DEFINITION OF DEATH

   a) Death, for the purpose of transplantation in Queensland is defined by the TAA Act 1979[15] as:

      i. irreversible cessation of all function of the brain of the person; or
      ii. irreversible cessation of circulation of blood in the body of the person.
b) For DCD the patient is recognised to have died when there is irreversible cessation of circulation of blood in the body of the person.

2. DETERMINATION OF CARDIAC DEATH FOR THE PURPOSE OF ORGAN DONATION

a) Death must be pronounced by an appropriately experienced doctor who must not be a member of the organ retrieval or transplant team.

b) The criteria for determination of death for the purpose of DCD donation[19], requires clinical demonstration of:
   - Immobility
   - Apnoea
   - Absent skin perfusion; and
   - Absence of circulation as evidenced by
     - Absent palpable central pulse; and
     - Pulse pressure of zero – as measured by intra arterial catheter

c) In Queensland it is recommended that two separate examinations are undertaken [1, 2]
   - 1st examination is a clinical confirmation of absence of circulation.
   - 2nd examination is performed after 5 minutes of continued absence of circulation, to confirm irreversible cessation of circulation: this is the Declaration of Death.

Section Seven – Management after Declaration of Death

a) Immediately following the declaration of death, the attending doctor will complete the Life Extinct form, prior to transfer to the operating theatre.

b) The ICU nurse will immediately disconnect the arterial blood pressure monitoring and any IV infusions. Vascular lines and IDC must remain insitu.

c) Support is provided to the family throughout this process by the Intensive Care team and the Donor Coordinator.

d) Operating Theatre staff and the Donor Coordinator will then transfer the patient into the prepared operating theatre for the retrieval surgery.

e) The family will have been informed and prepared for the sequence of events. If they are unable to leave their relative, then donation can not proceed. In this event the Donor Coordinator and appropriate hospital staff will manage and support the family through this process.

Section Eight – Family Support and Staff Briefing
1. FAMILY SUPPORT

a) All donor families are offered the opportunity of viewing the deceased body after the retrieval surgery consistent with current DonateLife Queensland practices. Support is provided to families throughout this process by the Donor Coordinator or an appropriately trained health professional.

b) Counselling support to the family will be offered in the lead up to, and after the DCD process, consistent with current DonateLife Queensland practices.

2. STAFF BRIEFING

a) Feedback will be provided to health care staff regarding outcome of the donation and transplantation process consistent with current DonateLife Queensland practices.

List of Appendices

Appendix A: DCD Sequence of Events

Appendix B: References
Appendix A: DCD Sequence of Events

Organ Donation after Cardiac Death (DCD) Sequence of Events

DECISION HAS BEEN MADE TO WITHDRAW CARDIO RESPIRATORY SUPPORT (WCRS)

Patient identified as a potential DCD donor
- No absolute contraindications to donation
- Expected to proceed to cardiac death within 90 minutes following WCRS

Referral of potential DCD donor to Donor Coordinator for suitability assessment

Family discussion
- Opportunity for donation raised by Intensivist OR family

CONSENT TO PROCEED WITH DCD

Donor Coordinator will complete:
- Formal consenting processes
- Comprehensive evaluation of donor
- Planning and preparation for DCD

ICU Team Planning Meeting
- Location and planned time of WCRS confirmed
- Roles and responsibilities allocated

OT Team Planning Meeting
- Review legal documentation
- Roles and responsibilities allocated
- Preparation of operating theatre

Withdrawal of Cardio Respiratory Support
End of life care provided by ICU Team

Clinical observations recorded by
donor coordinator
- Arterial blood pressure
- Heart rate
- Respiratory rate

TIME OF APNOEA AND ZERO PULSE PRESSURE

1st clinical examination performed
Clinical confirmation of absence of circulation

5 minute period of observation
Continued absence of circulation

2nd clinical examination performed

TIME OF DECLARATION OF DEATH

NO CONSENT TO PROCEED WITH DCD

WCRS and end of life care and management as per local ICU protocol

If death does not occur in 90 mins post WCRS then donation process will be abandoned
Continuation of end of life care and management provided by the ICU Team
Appendix B: References


4. **Supporting and related documents**

- *Organ and Tissue Donation after Death, for Transplantation – Guidelines for Ethical Practice for Health Professionals*, National Health and Medical Research Council, 15 March 2007
- *National Protocol for Donation after Cardiac Death*, Organ and Tissue Donation and Transplantation Authority, Australian Government, 2010

**Authorising Health Service Directive**

- Cadaveric Organ and Tissue Donation and Transplantation HSD

5. **Definition of Terms**

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6. **Approval and Implementation**

**Protocol Custodian**

Chief Health Officer, Chief Health Officer Branch, Health Services and Clinical Innovation Division
Approving Officer:
Dr Michael Cleary, Deputy Director-General, Health Services and Clinical Innovation Division

Approval date: DD/MM/YYYY

Effective from: DD/MM/YYYY