ORGAN DONATION: CIRCULATORY DEATH PATHWAY

PRACTICE GUIDELINE ©

DOCUMENT SUMMARY/KEY POINTS

- Organ donation may only occur after the neonate, infant or child donor has been pronounced dead according to legally recognised criteria (brain death or circulatory death). In this document we will only be discussing the procedure for Organ donation following circulatory death.
- Exceptional end-of-life care must be the focus for ICU staff and this is not altered by the decision of a family to consent to organ donation. The respect and dignity of the deceased and the families well being will always be our paramount concern.
- A family has the right to withdrawal their consent to the donation process at any time.
- This document provides an operational outline of how organ donation can be facilitated at SCHN.
- As part of the funding agreement between SCHN and NSW OTDS the KPI are:
  - 100% of potential donors are identified and notified to NSW OTDS
  - 100% of potential donors have a request made
  - 75% (or more) of requests made receive valid consent for donation
  - 70% of potential donors become actual organ donors
- Enquiries concerning this Practice Guideline please contact:
  - Medical Specialist (DSM) or Nursing Specialist (DSN): schn-otds@health.nsw.gov.au

Approved by:	SCHN Policy, Procedure and Guideline Committee	
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Team Leader:	Donation Specialist Medical (SCHN)	**Area/Dept:** Intensive Care Unit

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CHANGE SUMMARY

- This SCHN document and the "Organ Donation: Brain Death Pathway" replaces the SCH Organ Donation policy [SCH.C.3.D.2] and the CHW Organ and Tissue Donation guideline [1/C/11:8059-01:00]. The SCH and CHW documents have been rescinded.

READ ACKNOWLEDGEMENT

- Clinical staff (medical and nursing) working in intensive care areas must read and acknowledge they understand the contents of this document.
- Other relevant clinical staff, as identified, should read this document.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

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1 Organ Donation

1.1 Introduction

In accordance with NSW Ministry of Health and ANZICS policy, the ICUs of the Sydney Children's Hospital Network (SCHN) support the donation of organs after death with informed parental consent.

ICU staff are aware and sensitive to the extreme stress and grief felt by parents and other relatives following the death of a child. Accordingly this guideline, and the accompanying procedures, identifies ways to offer organ donation in all potential cases, in a way that supports the parents and family and respects their values and decisions.

Organ donation may ONLY occur after a neonate, infant or child has died, i.e. been lawfully declared dead.

Circumstances where organ donation may be feasible in the ICU setting are when death has been declared on the basis of neurological criteria (i.e. the patient has declared brain dead) or the patient experiences permanent circulatory arrest ("acirculation") following (planned) withdrawal of cardiorespiratory support (inotropes and mechanical ventilation).

Donation after circulatory death (DCD), formally known as Non Beating Heart Donation (NBHD) and donation after cardiac death (DCD), enables children who do not meet the criteria for brain death to donate organs. Internationally kidneys, lungs, liver and pancreas are transplanted due to the development of DCD protocols.

1.2 Suitable Donors

Neonates, infants and children (weighing greater than 3 kg) who have a planned removal of cardiorespiratory support (mechanical ventilation and inotropes) are potentially suitable to be multiorgan donor. Each potential donor should be referred to the NSW Organ and Tissue Donation Service and will be assessed individually for medical suitability.

Donation after Circulatory Death (DCD) may be appropriate following:

1. Catastrophic, irreversible cardiorespiratory or neurological injury, not fulfilling brain death criteria, where withdrawal of life sustaining treatment is considered appropriate (independent of prospect for organ donation) and following which rapid progression to death is anticipated.
2. Expectation that death is likely to occur within 90 minutes following the removal of the ventilator and other supportive measures. An influential factor is whether the child may breath effectively when extubated. Observing a trial of spontaneous ventilation, for example via bag mask if clinically safe, prior to discussions with the family may assist in assessing if donation is a realistic option.

2 DCD Donor categories in NSW

The Maastricht categories for DCD have been developed and accepted internationally to categorise potential donors on a clinical basis.

- *Category 1:* Dead on scene (out of hospital) - Unknown warm ischaemic time.
- *Category 2:* Unsuccessful resuscitation- Known warm ischaemic time.
- *Category 3:* Waiting cardiac death after planned treatment withdrawal - Known and limited warm ischaemic time.
- *Category 4:* Cardiac arrest after confirmation of brain death but before planned organ procurement - Known and potentially limited warm ischaemic time.
- *Category 5:* Cardiac arrest in a hospital patient.

Of these, only **category 3** and **category 4** are currently permitted to become organ donors in NSW.

Optimising end-of-life care for the patient and family should take precedent at all times not organ donation.

2.1 Pathway to Multi Organ Donation after Circulatory Death (DCD)

1. Irreversible cardiorespiratory or neurological injury / illness
2. Decision to withdraw cardiorespiratory support (WCRS)
3. End of life discussion and agreement with family to proceed with withdrawal of treatment
4. Medical Assessment
5. Donation Discussion
6. Family Consent
7. Tissue typing and serology
8. Organ and tissue offer and allocation
9. Withdrawal of Cardiorespiratory support as per unit protocol
10. **Death Certified**
11. Coronial consent if applicable
12. Donation retrieval surgery

In cases where DCD is being considered, a multidisciplinary meeting should be convened involving the intensivist, the primary medical / surgical team, nursing staff, social worker, pastoral care and other consulting services as relevant. The purpose of the meeting is to review any possible conflicts of interest and anticipate any other clinical or ethical concerns or issues that should be addressed in the consent process.

All attending medical specialists involved in the patient's care should be informed where DCD is being considered.

Clear documentation of any discussions with the family regarding withdrawal of life-sustaining treatment and DCD in the medical record is essential.

2.2 Family Discussions

After a discussion regarding prognosis and plan for end of life care, time should be allowed for the family to process and understand this information and ask questions.

The intensive care consultant will maintain continuity of care and in a separate meeting with the family discuss the possibility of organ and tissue donation. If the possibility of organ donation is raised by the family prior to the family agreeing with the withdrawal of active treatment, it is to the discretion of the intensivist to continue or defer the organ donation conversation.

2.3 Donor Referral and Coordination

The Donation Specialist Nurse (DSN) and Donation Specialist Medical (DSM) are notified when a family are considering Organ and Tissue Donation. They will be available to meet with the family to provide information regarding the DCD process. They are able to be contacted via the hospital switch board.

The role of the DSN includes:

- Consult with the ICU medical team to obtain accurate information regarding the child's current status.
- Obtain a medical and social history for risk assessment and determine suitability of organs and tissues for donation.
- Meet with the family and provide information about organ and tissue donation to support informed decision making.
- Complete formal documentation of consent.
- Refer information via the Electronic Data Referral to the Donation Specialist Coordinator (DSC) who will liaise with the surgical and theatre teams, Transplant coordinators, Forensic pathologist and Coroner.
- Organise donor bloods for serology, tissue typing and HLA testing.
- Ensure all documentation is complete prior to going to Operating Theatres (OT) (including determination of death, consents and that legal requirements are met).
- Liaise with ICU staff, Designated Officer, Donation Specialist Coordinator, theatres and the family.
- Ensure confidentiality of both donor and recipients.
- Provides ongoing care to the family including information on available support services and feedback on initial transplant outcomes.
- Support health professional and provide information to those involved.
- Maintain up to date documentation and data base records.

3 Consent

3.1 Consent issues specific to DCD

Consent to any pre-mortem intervention, which is not in the best interest of the child, by surrogate decision-makers, such as a child's parents, would not be permitted under the *Children And Young Persons (Care and Protection) Act 1998 and Guardianship Act 1987 (NSW)*. The Act requires that 'the safety, welfare and well-being of the child or young person must be the paramount consideration' and those providing consent may do so only for treatments that 'promote or maintain the health and well-being' of the person involved.

Consent regarding DCD must include:

- The decision to WCRS must be made independently to the consideration of donation with agreement of the family and medical teams
- Permission must be sought from the family for all aspects of the donation process
- Members of the transplant and retrieval teams must NOT participate in the decision or be present for withdrawal of treatment. They cannot participate in the certification of death.

The process involved in organ donation following circulatory death must be explained to the parents in detail by the DSN/DSM. Interpreters are available if English is not the family's first language. Consent must be given for each organ and/or tissue to be removed, as well as a post-mortem examination if appropriate.

The withdrawal of life sustaining treatments will be conducted in a compassionate and sensitive fashion that respects the wishes and dignity of the child and family. There is no change in the care of their child in ICU and no hastening of death by the DCD protocol.

Parents will be provided with the following information to be able to give fully-informed consent:

- That some or even all of the organs may not be suitable for transplantation;
- Duration of the donation process;
- That tissue donation alone (e.g. corneas, heart valves) can be an alternative to organ donation;
- They can change their mind at any stage;
- The steps in the process – e.g. **Rapidly transporting** to the operating theatre following death certification for 2-4 hours for the surgery, returning to a single room in the ICU where they can spend time with their child;
- The process if the potential donor does not die within the 90 minute timeframe for organ retrieval;
- Whether the death will need to be reported to the Coroner and, if it does, how does the coronial process affect the donation process;
- That organ donation doesn't have any benefits for their child;
- Whether non-transplantable organs will be returned to the body;

Parents need to be given time to consider if organ donation is the right option for them as a family and allows them time to be with their child. Bloods for serology and tissue typing at the SEAL laboratory/ARCBS may be collected following verbal consent due to the length of processing time. Pre mortem blood sampling is permissible in NSW for the purpose of Organ Donation. The DSN will organise the collection and transportation of these bloods.

If the child is **<18months of age** or has been breast fed in the last 6 months, **maternal bloods** will also need to be taken for screening.

When the family are ready, parents (or 'senior available next of kin' –see glossary) are requested to sign the Consent Form (SMRO20.030 Consent and Authority for Removal of Tissue After Death) with the DSN / DSM.

The Designated Officer for the SCHN campuses is contacted via switchboard that will have a list of the all certified DO for the network. The Designated Officer must sign and verify consent has been given by the Senior Next of Kin and authorise the organ donation and removal of tissue. The DO may want to be present for the consent and speak to the consenting family. The DSN will ensure the DO is informed as soon as possible.

3.2 Coroners Cases

Where the death of the patient is reportable to the Coroner, the investigating Police, forensic pathologist and State Coroner should be contacted pre-mortem by the organ donor coordinator to seek the Coroner's "in principle" consent, and to arrange the logistics of post-mortem notification and confirmation of donation approval.

The Coroners Forensic Pathologist is also contacted regarding limitations on organ and tissue retrieval.

The Coroner does not have jurisdriction over a child's body until death has been certified. The DSC will contact the Coroner to inform them of the time of death and authority for removal of organs. Consent from the Coroner must be after death and before the retrieval commences.

The medical officer that has certified the death will be required to complete Form A (SMR010.510 Report of Death of a Patient to the Coroner)

The local police will be contacted and identify the child with the Next of Kin following organ donation. The Police will organise the Government Contractor to collect the child from the hospital.

3.3 Child in the care of the State

When a child is in the care of the State immediately prior to their death (i.e. in FACS care/under the care of the Minister for Community Services), consent must be obtained from:

- the Coroner;
- the Principal Care Officer of the designated agency which has full case management responsibility of the child, must "…must use reasonable efforts to contact persons who have been significant in the child's or young person's life and who the PCO considers to be appropriate to assist in the decision making process. These may include: Birth parents; Foster parents; Extended family; If the child/young person is Aboriginal or Torres Strait Islander, appropriate persons from the child's or young person's Aboriginal

and/or Torres Strait Islander community; and persons considered relevant by the PCO". (Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements; PD2013_001)

- the Designated Officer; must ensure that the above has occurred prior to authorising the removal of organs

3.4 Screening

Interventions for the benefit of the future organ recipient and of no benefit of the child cannot be administered in order to optimise organ function. Blood samples are permitted as part of the authorisation process.

- The DSN will require the following information about the potential donor:
  - Name, DOB, Weight, Girth and Height
  - Cause of death and current status
  - ABO blood group (including A/AB subtypes)
  - FBC, EUC, LFT, CMP, coags , troponin, transaminases and microbiology
  - ABG on 100% 0_2, PEEP 5cm for 30minutes prior to gas
  - Current Chest x-ray
  - Medications and fluids
- Changes in the child's condition or care should be reported to the DSN
- Advice regarding medical management of potential donors is available at all times through the Donation service.

The Donor Coordinator will confirm operating theatre times and be present in the OR with the child to coordinate the donation and ensure the wishes of the family are met.

3.5 Withdrawal of life-sustaining treatment (WLST)

Responsibility for all end-of-life care will remain with the patient's treating team. This needs to be coordinated with the availability of retrieval teams and OT time. WLST includes extubation, cessation of ventilation and supportive infusions. Analgesia and sedation should be provided for symptom relief as per unit policy. Intra-arterial blood pressure monitoring, heart rate and oxygen saturations must be measured to record the warm ischaemic time and determine cessation of circulation.

A patient on Extracorporeal Membrane Oxygenation (ECMO) who would be a potential donor should have both ECMO and cardio-respiratory support withdrawn.

Usual 'comfort care' measures to continue

Any pain or distressing symptoms following withdrawal of life-sustaining treatment may be managed with analgesia and sedation, as they would be in any other instances of treatment withdrawal. Analgesia and sedation should be provided by whatever route is necessary for relief, in proportion with clinical need, and with the primary goal of relieving pain or other distressing symptoms.

The family should be informed that the comfort of their child is paramount and that all steps will be taken to ensure that is achieved. They must be informed that any drugs given following treatment withdrawal are to keep the patient comfortable, and do not form any part of the donation process.

'Non-therapeutic' premorbid interventions

In NSW it is not legally permitted to use drugs, such as Heparin to prevent small vein thrombosis, or cannulation of the femoral vessels, to infuse preservation solutions (once death has occurred) in the period before withdrawal of life-sustaining treatment.

Keeping at the forefront the needs of the family and child during the end-of-life phase, efforts should made to ensure that warm ischaemic time is minimised during the DCD process. For this reason the new NSW Ministry of Health guidelines recommend that withdrawal of life-sustaining therapy should occur in the operating theatres. However it is current practice that withdrawal of life-sustaining therapy occurs in the Intensive Care Unit, and a shift to the OT will require a collaborative approach from all key stakeholders at both campuses; ICU, Anaesthetics, Surgical teams.

Prior to WLST the DSN is to ensure the child is ready for OT including:

- Process for certification of death – Designated officer/Coroner
- Record keeping, timing and methods of communication with the DSC
- Consent and appropriate forms complete
- ABO in hard copy
- Theatre checklist complete
- Identification bands x 2 / Police ID band (if required)
- Current and old notes/scans
- Family contact details and introduction to DSC
- Skin is prepared (including shaving if age appropriate)
- Bed is ready for immediate transfer to OT (Porters in unit on standby/route & access to OT)

The family should be made fully aware prior to withdrawal of life-sustaining treatment that, in the event of death not occurring within the 90 minute period, DCD cannot proceed, but that the patient will be given continued care. This care is aimed at symptom control, optimal comfort and dignity.

The family should be prepared for the need to leave the bedside once death has been declared. If they are unable to do so, the organ donation will not proceed. Consent can be withdrawn at any point.

During the WLST, all vital signs will be recorded by the DSN on the DCD observation chart with intervals of no longer than 5 mins. A single clock must be used to time all events consistently. Telephone calls and text messages between the DSN and DSC in OT are made at regular intervals to update changes including:

- WLST
- Systolic BP <50mmHg
- Cessation of circulation
- 2 minute observation period with NO pulsatility on the arterial line due to absence of circulation (phase of acirculation)
- Certification of Death
- Transfer to OT

3.6 Certification of Death

Consistent with the *NSW Human Tissue Act 1983* and *ANZIC Statement on Death and Organ Donation*, death is declared when the attending Intensivist, or other designated doctor, determines that there is **irreversible cessation of circulation of blood in the person's body**.

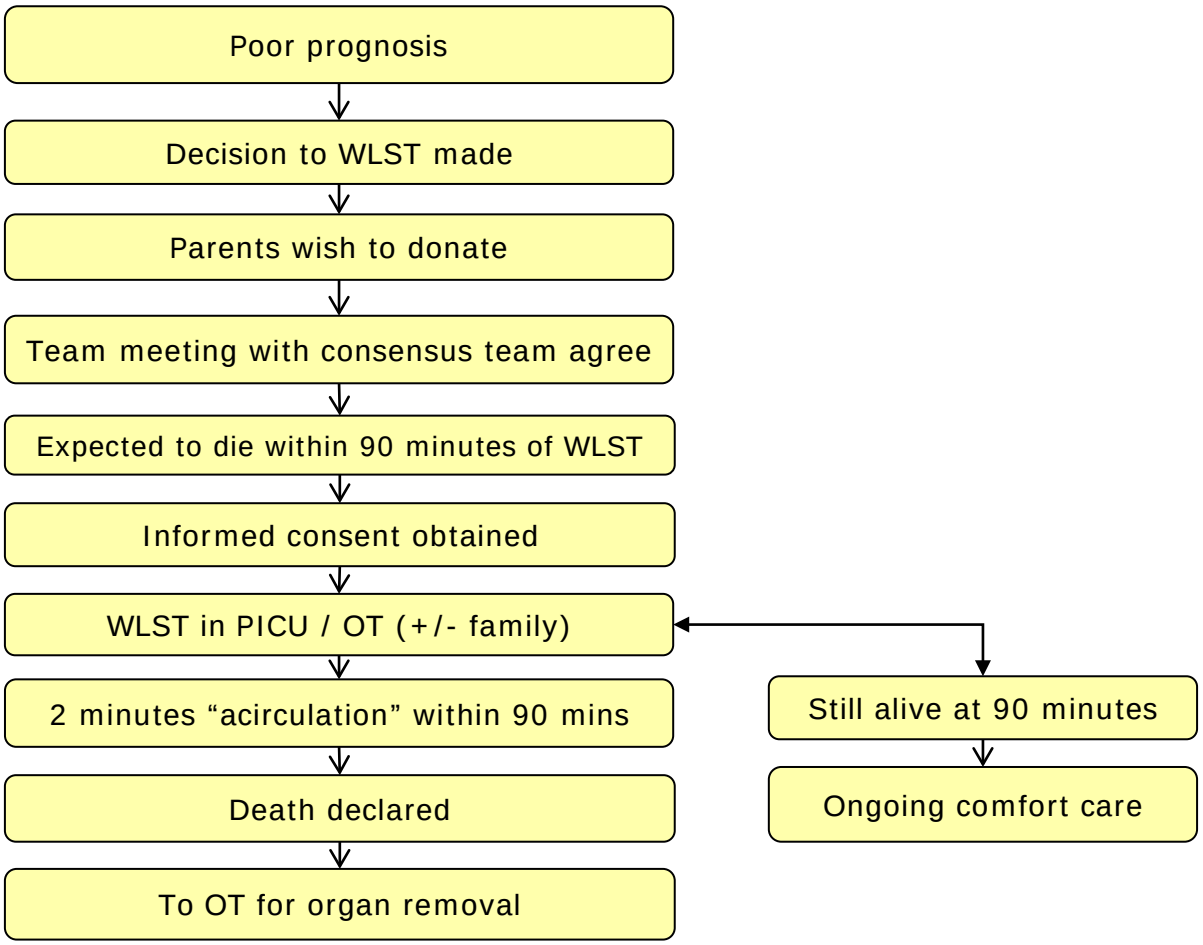
Death should be confirmed by clinical examination revealing:

- immobility,
- apnoea
- absent skin perfusion, and
- absence of circulation (absence of pulsatility on arterial line) for a minimum of **2 minutes**

Death is not to be certified by a member of the organ retrieval or transplant team.

It is in the new NSW Guidelines that the previous 5-minute stand down period is no longer advised and would increase the warm ischaemic time, injuring the donated organs.

Flow diagram outlining DCD process



4 Post-donation care

At the completion of surgery the family have the option to see their child. This can be negotiated and the child can either return to ICU or go to the mortuary viewing room, arranged by ICU staff and social workers.

If the death is a Coronial case, formal identification of the child with the police and family is required post donation surgery.

4.1 Follow-up of the family

1. Parents whose children die in ICU will be followed up by the Unit Social Worker by telephone communication at least once during the first week following the death and more often as required. They are also contacted by the DSN to outline the outcome of the donation and feedback.
2. Parents are offered an opportunity to re-visit the ICU approximately six weeks after the death to meet with the ICU consultant or Co-Consultant most involved with the family, together with the Social Worker. The DSN is also invited to this meeting.
3. Follow up by telephone with the offer of further meetings or counselling should be continued for at least twelve months.
4. Parents of children who are organ donors are also provided with support through NSW Organ & Tissue Donation Network NSW 'The Next Step Program'. This program includes regular contact and information regarding donation outcomes, counselling services, support groups and anonymous exchange of letters.
5. Parents of children who were considered for organ donation but family declined the donation process are also to be offered support through the NSW Donor Family Support Service. This program includes regular contacts, counselling services and support groups.

4.2 Patient privacy issues

The privacy of the recipients of the organs is important. The identity of recipients or donors must not be relayed to the relatives. It is an offence in Australia to disclose information regarding the donor or recipient under The Human Tissue Act 1983 Section 37(2) and 37(3). The DSN and DonateLife will provide families with appropriate information about the transplant outcomes.

4.3 Staff Support

The staff involved in then donation process will receive information about the outcomes of the donation from the DSN. Letters will be sent to all areas involved in the donation process. The DSN will arrange a case review at an appropriate date and time following each donation.

This will provide:

1. Feedback and debriefing for all staff involved
2. The identification of issues and develop action plans for future donation processes.

Staff should be offered counselling services and support as required through the Employee Assistance program.

5 Glossary

Acirculation

A state of no blood flow throughout the body; although there may be residual electrical activity, the heart muscle does not contract (c.f. 'asystole' where there is no electrical (ECG) activity or contraction of the heart muscle).

Brain death

Death defined by irreversible cessation of all function of the person's brain

Circulatory death

Death defined by irreversible cessation of circulation of blood in the person's body.

Cold ischaemic time

The period following cooling of the organs until perfusion to the transplanted organ/s is re-established in the recipient.

Designated Officer (DO)

A Designated Officer is:

- In relation to a hospital, a person appointed under s5(1) (a) of the Human Tissue Act 1983, to be a Designated Officer for the hospital, or
- In relation to a forensic institution, a person appointed under s5(1)(a) of the Human Tissue Act 1983, to be a Designated Officer for the forensic institution

Intensive Care Unit (ICU)

Includes Paediatric Intensive Care Units (PICU) and Neonatal Intensive Care Units (NICU)

Intensivist

Refers to Paediatric Intensive Care physicians and Neonatologists

Warm ischaemic time

The period of time following cessation of circulation (older child <50mmHg systolic BP; neonate/infant <30mmHg) and blood flow to the organs until the commencement of cold perfusion.

Senior Available Next of Kin

The hierarchy of Senior Available Next of Kin is defined in S4 of the Human Tissue Act 1983. In relation to a deceased child it is:

- Parent of the child;
- Sibling of child who is 18 years of age or over where a parent is not available; or
- Guardian of the child at the time of death where none of the above is available.

However, where the child is in the care of the state specific provisions for consent to organ and tissue donation apply (see Human Tissue Act 1983).

6 References and Further Reading

1. NSW Health, Policy Directive 2013_001, Deceased Organ and Tissue Donation -Consent and other Procedural requirements http://www.health.nsw.gov.au/policies/PD/2013_001.html
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11. Australian Transplant Coordinators Association (2008) National Guidelines for Organ and Tissue Donation 4th Edit.
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