

DETERMINATION OF NEUROLOGICAL DEATH POLICY[®]

DOCUMENT SUMMARY/KEY POINTS

- Neurological death was formally known as brain death.
- Determination of neurological death requires understanding of the pathophysiology that leads to cessation of whole brain function.
- Before neurological death testing can occur all preconditions and periods of observation must be met. During this time the patient must be intubated and ventilated with an absence of responsiveness, brain-stem reflexes and breathing that is irreversible.
- Neurological determination of death clinical testing must be performed by 2 medical practitioners who must each independently determine death. The age-appropriate waiting and observation periods must be met prior to the clinical testing.
- ALL components of the clinical test must be performed by each medical practitioner to determine the diagnosis of neurological death. If the patient cannot complete all aspects of the test, then consider imaging that demonstrates the absence of intracranial blood flow to the brain.
- The clinical test is comprised of three main components:
 - Absence of responsiveness
 - Absence of Brain Stem Reflexes
 - Absence of breathing
- The time of death should be recorded as the time of completion of the second clinical test or review by second medical practitioner following intracranial blood flow imaging. Documentation of neurological death should be made on the Neurological Determination of Death form to demonstrate all the criteria have been met.
- Refer to the Determination of Neurological Death Flowchart.
- Refer to <u>Glossary</u> for definitions of terms.

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.

Approved by:	proved by: SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st May 2024	Review Period: 3 years
Team Leader:	Organ & Tissue Donor Co-Ordinator	Area/Dept: Intensive Care Unit

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This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.



CHANGE SUMMARY

- Document due for mandatory review.
- Updated pre conditions
- Updated links, NSW Health Policy Directives and references
- 23/08/24: Minor review. Updated NSW Policy Directives, links and references

READ ACKNOWLEDGEMENT

- ALL medical practitioners that perform clinical testing for the diagnosis of neurological death should read and acknowledge this document.
- Training/Assessment Required for registrars/fellows in PICU.
- Nursing staff caring for neurologically deceased children should read this document.

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1 Policy Statement

Neurological determination of death, formally known as brain death, should be determined whenever it has occurred irrespective of organ donation. In cases where organs or tissues are to be retrieved for the purpose of transplantation, cessation of neurological function need to be certified according to Australian and New Zealand Intensive Care Society (ANZICS) recommendations.

The following information is based on the document: <u>"The ANZICS Statement on Death and</u> Organ Donation – Edition 4.1: 2021

The SCHN critical care teams recognise and identify the unique spiritual, religious, and cultural needs of each family. They assist in the engagement of culturally appropriate support, including the Aboriginal Health Worker Team for families that identify as Aboriginal or Torres Strait Islander in accordance with the <u>Aboriginal Health Impact Statement Policy</u> <u>Directive (PD2017_034)</u>.

2 Legal definition of death

Death legally occurs when there is irreversible cessation of circulation of blood in the body of a person, or irreversible cessation of all function of the brain of the person. <u>Human Tissue</u> <u>Act 1983 (NSW).</u>

The term "neurological death", formally known as brain death, should be used when death is certified using the brain function criteria.

Determination of neurological death requires:

- Understanding of the pathology that led to the cessation of **whole** brain function. Clinical or neuroimaging evidence of intracranial pathology with the permanent loss of neurological function.
- Cessation of **whole** brain function, determined by clinical testing if preconditions are met and clinical testing can be completed or imaging that demonstrates the absence of intracranial blood flow.

3 Clinical Determination of Neurological Death

Once neurological death has been determined- the child has died.

Testing is carried out to diagnose neurological death and to determine death in the presence of a beating heart. Determination of neurological death confirms for staff and families that death has occurred, Neurological death testing should be performed irrespective of the consideration of donation.

Formal clinical neurological death testing is a legal requirement for the purpose of organ donation for transplantation via the neurological death pathway.





3.1 Preconditions prior to formal brain stem function testing

The following conditions must ALL be met before the observation period and throughout clinical neurological death testing. If any cannot be met, brain perfusion studies should be used to determine neurological death.

- Normothermia core temperature >35°C.
- **Normotension** age-appropriate systolic blood pressure and mean arterial blood pressure.
- Exclusion of effects by sedative drugs care must be taken when considering the continued effects of sedative drugs and in particular the decreased metabolic clearance rate of the drugs when therapeutic hypothermia (post-cardiac arrest) has been used or there is evidence of liver or kidney failure. If barbiturates have been used, levels should be shown to be below clinically significant levels (Thiopentone: <10mg/L). If barbiturate levels are elevated or unable to be measured, neurological death should be demonstrated by absence of cerebral blood flow. If there are concerns about the persistent effects of benzodiazepines or opiates the appropriate reversal agent should be administered.
- Absence of electrolyte, metabolic or endocrine disturbances. This includes plasma concentrations derangements of:

Glucose (<3mmol/L or >25mmol/L) Sodium (<125mmol/L or > 160mmol/L) Phosphate (<0.5mmol/L) Magnesium (<0.5mmol/L) Urea (>40mmol/L)

Derangements should be corrected prior to clinical examination.

- Absence of neuromuscular blocking drugs if neuromuscular blocking agents have been administered then recognised methods such as peripheral nerve stimulation should be used to confirm normal neuromuscular conduction.
- Ability to examine brain stem reflexes ability to examine at least one eye and one ear. Care must be taken to ensure that dilating eye drops have not been used.
- Cervical level spinal cord injury may preclude sensory and motor assessment.
- Ability to perform apnoea test may not be able to perform if the patient also has severe hypoxemic respiratory failure or high cervical spinal cord injury.

3.2 Clinical Testing of Brain Stem Function

This is divided into two sections: (1) Observation period and (2) Formal examination.

Observation period for clinical testing.

The child or infant must have met the preconditions, before the appropriate period of observation can commence. The preconditions must be met during the entire observation period. This observation period must occur before neurological death testing can be performed. During this time the patient must be intubated and ventilated with:



Policy No: 2013-9067v5 Policy: Determination of Neurological Death



- No response to Stimuli GCS 3.
- No spontaneous breathing efforts.
- Pupils non- reactive to light (fixed and dilated).
- Absent cough and gag reflexes.

Neurological death can be confirmed prior to completion of the observation periods with imaging that demonstrates absent cerebral blood flow.

Infants greater than 30days – Adults: Minimum 4 hours observation period prior to first clinical examination. No set interval between clinical tests.

Neurological death cannot be conducted by clinical examination in term or pre term neonates in the first 24hours after birth.

Term Neonates greater than 37weeks gestation 24hrs old – 30 days: Minimum 24 hours observation period prior to the first clinical examination followed by a further 24-hour interval before the second clinical examination is conducted.

Pre term neonates less than 37 weeks gestation: Clinical neurological death testing is not reliable and not recommended. Brain perfusion imaging to demonstrate an absence of intracranial blood flow is needed to determine neurological death.

Recommended waiting periods

- Acute Hypoxic -Ischaemic Encephalopathy or post cardiac arrest: Clinical examination delayed for 24hrs after return of spontaneous circulation. If the underlying cause is not evident from clinical history (e.g. cardiorespiratory arrest from drowning), neuroimaging should be performed to investigate intracranial pathology.
- Prolonged hypothermia (less than 35°C for greater than 6hrs) induced or as a consequence of prolonged cardiac arrest event: Clinical testing delayed for 24 hours after re-warming to 35 C. If temperature less than 35°C for *less than* 6hrs the 24hrs waiting period is not required.

Formal examination

Two medical practitioners perform the clinical examinations for determination of neurological death. The two tests must be performed separately, to independently determine death. They must each perform a complete set of tests including the apnoea test and blood gas.

NSW legislation mandates that each practitioner:

- Have practiced medicine for not less than 5 years in the preceding 8 years
- 1 practitioner MUST be an endorsed Designated Specialist for the hospital (see glossary)
- MUST NOT be the Designated Officer (DO)
- MUST NOT be involved in organ/ tissue retrieval
- MUST NOT be responsible for care of the intended recipient





All of the components of the clinical test must be performed to determine neurological death. The clinical test **must confirm all** of the following:

- Absence of responsiveness
- Absence of brain-stem reflexes
- Absence of breathing

The time of death should be recorded as the time of completion of the second clinical test or clinical examination by second medical practitioner following intracranial blood flow imaging demonstrating absent cerebral blood flow.

The radiologist determines absent brain perfusion. They are not the second medical practitioner to determine neurological death.

Documentation of neurological death should be made on the NSW Health Neurological Determination of Death form.

Family

Family members may be offered the option to observe the clinical testing at the bedside. The consultant should explain the testing and responses as they are carried out. A member of the team should be present to support the family throughout the clinical tests.

The clinical test is comprised of the following components:

1. Responsiveness

- **i. Test:** Apply noxious stimulus to the cranial nerve distribution (pressure over the supra-orbital nerve), sternal rub and deep nail bed pressure.
- **ii. Response:** No flexor or extensor motor response. Glasgow Coma Scale 3. Spinal reflexes may be elicited with painful stimulus.
- iii. NOT able to determine neurological death if: True extensor or flexor motor response demonstrated on stimulation → STOP clinical testing.

2. Brain stem reflexes (ALL MUST be absent to determine neurological death)

- Pupillary reaction to light (CN II and III)
 - i. Test: Shine bright light into the eye and look for pupillary constriction, Pupils must be \geq 4mm in size.
 - ii. Response: No pupillary constriction.
 - iii. NOT able to determine neurological death if: Pupils constrict → STOP clinical testing.
- Corneal reflexes (CN V and VII))
 - **i. Test:** Touch the corneas (not sclera) with a soft cotton wool or gauze. Ensure to be gentle as corneas may damage easily. Irrigate with saline following the test.
 - ii. Response: No blink reflex.
 - iii. NOT able to determine neurological death if: blink reflex is observed → STOP clinical testing.





- Pain reflex (V and VII)
 - i. Test: Apply pain over trigeminal nerve distribution (e.g. supraorbital ridge).
 - ii. Response: No facial or limb response.
 - iii. NOT able to determine neurological death if: Movement of face or limbs → STOP clinical testing.
- o Vestibulo-ocular reflexes (CN II, IV, VI, VIII)
 - Test: Use an otoscope to visualize the ear drum (ruptured ear drum does not preclude the test but wax must be removed before the test may proceed). Elevate the head to 30° to ensure the horizontal semicircular canal is in a horizontal position. Instil 20- 50mL of ice-cold water into the ear canal using a syringe. Eye lids must be held open to observe eye movement for a minimum of 60 seconds. Base of skull or petrous temporal bone fractures may obliterate the response on the fracture side.
 - ii. Response: No eye movement. Eyes remain midline.
 - iii. NOT able to determine neurological death if: ANY eye movement → STOP clinical testing.
- Gag reflex (CN IX and X)
 - **i. Test:** Stimulate both sides of posterior pharyngeal wall with a cotton swab or tongue depressor.
 - ii. Response: No gag.
 - iii. NOT able to determine neurological death if: Gag present → STOP clinical testing.
- Cough reflex (CN X)
 - **i. Test:** Stimulate the tracheal wall with a soft suction catheter. Cannot be assessed in patients with high cervical cord injury,
 - ii. Response: No cough.
 - iii. NOT able to determine neurological death if: Cough present → STOP clinical testing.
- **3. BREATHING** *Proceed ONLY if all of the above reflexes are ABSENT*. The apnoea test is performed as the final clinical test to determine neurological death.
 - i. **Test:** Pre-oxygenate with 100% oxygen for minimum of 5 minutes to eliminate nitrogen and prevent hypoxemia. An arterial blood gas should be collected prior to the start of the test. Expose the chest and abdomen to allow for observation of spontaneous breathing. The patient should be disconnected from the mechanical ventilator, and oxygen /PEEP administered via a self-inflating bag with a PEEP valve or T- piece circuit.

Oxygen delivery via a tracheal catheter is not recommended as the flow of oxygen may delay the rise in $PaCO_2$.

ECMO: Pre oxygenate with 100% O_2 via ventilator and ECMO for a minimum of 5 minutes. Ensure the PaCO₂ is approx. 45mmHg. Connect to a self-inflating bag with





a PEEP valve or T- piece circuit to maintain PEEP. Reduce ECMO sweep gas flow to 10-25% of the blood flow rate.

- i. An arterial blood gas should be collected at the end of the test. The arterial pCO₂ should be greater than 60 mmHg and arterial pH should be less than 7.30 to provide adequate stimulus to spontaneous ventilation. In the case of chronic hypercarbia, the pCO₂ should have risen by 20 mmHg from baseline and a pH less than 7.30. Return the patient to mechanical ventilation and previous ECMO settings.
- **ii. Response:** No spontaneous breaths. Attempts at breathing includes any respiratory or accessory respiratory muscle activity that causes chest or abdominal excursion.
- iii. NOT able to determine neurological death if: Spontaneous breathing → STOP clinical testing.

3.3 Observations compatible/incompatible with the diagnosis of neurological death

Observations <u>Compatible</u> with the diagnosis of neurological death:

- **Spinal reflexes-** May be spontaneous or be initiated by stimulus outside the cranial nerve distribution. If there is doubt regarding the origin of these movements, cerebral blood flow imaging is recommended.
 - Lazarus sign.
 - Deep tendon reflexes.
 - Plantar responses; undulating toe reflex (plantar flexor or extensor response).
 - Extension pronation movements of the upper limbs.
 - Head turning.
- Sweating, blushing, tachycardia.
- Normal blood pressure absence of the need for inotropes.
- Absence of diabetes insipidus (DI).

Observations <u>incompatible</u> with the diagnosis of neurological death:

- Decerebrate or decorticate posturing.
- True extensor or flexor motor response to painful stimulus.
- Seizures.
- Limb movements caused by stimulation of the cranial sensory nerves.





4 Imaging to Assess Intracranial Blood Flow

In cases where clinical criteria for neurological death testing cannot be met, imaging can be used to demonstrate an absence of brain perfusion. It **must be preceded** by completing and documenting the components of the clinical tests that are possible.

For example:

- Cardiovascular instability or severe hypoxic respiratory failure precluding the apnoea test.
- Cranial nerves cannot be adequately tested.
- Concern that medications, metabolic state or organ failure may affect clinical neurological death testing.

In such cases, two medical practitioners, having examined the patient and in the knowledge of the circumstances of the onset of coma, are able to make the diagnosis of neurological death by radiological evidence of absent intracranial blood flow. The imaging should ONLY be performed once adequate blood pressure is achieved (with or without the use of inotropes). The absence of brain perfusion is demonstrated by the radiologist or nuclear physician; however, it is the responsibility of the two medical practitioners who have examined the child to determine neurological death. The time of death should be recorded as the time the second clinician confirms absence of intracranial blood flow.

Imaging techniques accepted to demonstrate neurological death.

- Intra-arterial catheter angiography with digital subtraction is considered to be the gold standard to demonstrate the absence of blood flow to the brain parenchyma. Three or Four vessel angiography is acceptable. The contrast must be absent above the level of the carotid siphon in the anterior circulation and the foramen magnum in the posterior circulation.
- Radionuclide imaging can be used to confirm absent blood perfusion. It is important to remember that the radio-nucleotide used needs to cross the blood-brain barrier. Tc-99m HMPAO is commonly used. Tc-99 DTPA, Tc-99m glucoheptonate and Tc-99m pertechnetate are not acceptable radionuclides to demonstrate absence of perfusion as they do not cross the blood brain barrier. Single Photon emission computerised tomography (SPECT) provides superior imaging.
- **Computed Tomography Angiography** (CTA) is acceptable to demonstrate absent brain perfusion if the previous forms of imaging are unavailable. If CTA is performed it is recommended to use the four-point scale and the ANZICS radiological diagnostics guidelines.

Imaging techniques not recommended.

• **MRI** and MRA have been used to demonstrate the absence of brain perfusion however reduced sensitivity of MRI to slow flow may mimic absence of flow. The ANZICS guideline does not recommend the use of MRI to determine absence of blood flow to the brain due to variables in flow detection and the potential of false positives. Further large studies are required.





• **Transcranial Doppler (TCD)** is an imaging technique that can be used as a screening tool to optimise timing of a contrast study. It is not an acceptable technique to determine absence of blood flow to the brain.

ANZICS recommendation: Three or Four-vessel angiography and radionuclide imaging are preferred imaging to assess intracranial blood flow. CTA may be used if ANZICS guidelines are followed. MRI and TCD are NOT recommended.

5 Documentation

Accurate documentation is paramount and all preconditions and components of the test need to be documented on the NSW Certification of Neurological Death form and noted in the medical records. This is a requirement recommended by the Australian Law Reform Commission.

Neurological determination of death is irrespective of organ and tissue donation. The time of death is recorded as the time the second medical practitioner determines death has occurred, from clinical examination or radiological imaging.

Neonates, infants and children that have been declared deceased by neurological criteria should be referred to the NSW Organ and Tissue Donation Service for assessment and consideration for potential organ and tissue donation.

NSW Health Policy Directive PD2024_022 Organ and Tissue Donation, Use and Retention.

The Donation Specialist Nurse (DSN) is contactable via switchboard throughout the SCHN.

6 Education

Education is provided by:

 SCHN DSN (CNC2) – regular education sessions throughout SCHN (Critical care/ OT/wards/BC/NETS). Replicated on both sites face to face organised via education teams in units/wards.

Post donation case reviews provided for units involved and OT staff post donation.

Standing item on PICU M&M/ CICU Consultant meeting to provide feedback and discussion. GNN consultant updates as required.

• **NSWOTDS and SCHN DSN**: The Organ and Tissue Donation Awareness Course (IDAT) is held at CHW and SCH 2nd yearly for staff (Nationally funded.) Staff can also attend course at other LHD's and information circulated in critical care areas throughout SCHN regarding this.

Peri operative Nursing Donation 1 day course (Nationally funded) also held at CHW. SCH are covered by the POW OT scheduled course.





7 Glossary

Term	Definition
Designated Specialist	Appointed by the Governing Authority, of appropriately qualified and experienced medical specialists for the purpose of certifying neurological death. Section 1 (5. 1)(b)Human Tissue Act 1983 (NSW).
Designated Officer (DO)	The role of the Designated Officer is to authorise:
	 the removal of tissue from a body for transplant or other therapeutic, medical, or scientific purposes. the performance of non-coronial post mortem examination. the release of a body for anatomical examination. The Designated Officer has discretionary authority not simply administrative authority. SCHN has multiple DOs appointed to ensure
	they are available when required particularity after hours. A DO has no role in death determination.
Donation Specialist Nurse (DSN)	A Clinical Nurse Consultant who is responsible for the coordination and facilitation of organ and tissue donation.
Extra Corporeal Membrane Oxygenation (ECMO)	A technique providing both cardiac and respiratory support to patients whose heart and lungs are poorly functioning.
Family	Recognising the collaborative nature of end-of-life decision-making, the term 'family' is used to refer to a person or persons who have a close, ongoing, personal relationship with the patient, whom the patient may have expressed a desire to be involved in treatment decisions, and who have indicated a preparedness to be involved in such decisions. This may or may not include biological family. However, it may include relatives, partner (including same sex and de facto), friend, or 'person responsible' according to any express wish of the patient.
Intensive Care Unit (ICU)	Includes Paediatric Intensive Care Unit (PICU), Children's Intensive Care Unit (CICU) and Neonatal Intensive Care Units (NICU).
Intensivist	Refers to Paediatric or Neonatal Intensive Care physicians.
Life-sustaining treatment	Life-sustaining treatment is any medical intervention, technology, procedure, or medication that is administered to forestall the moment of death, whether or not the treatment is intended to ameliorate life- threatening diseases or biological processes.
	These treatments may include, but are not limited to, artificial airways, mechanical ventilation, ECMO, artificial hydration and nutrition, cardiopulmonary resuscitation, or drugs to support circulatory function.
Neurological death	Death defined by irreversible cessation of all function of the person's brain. Formally known as Brain death.
Organ and Tissue Donation Service (NSW OTDS)	State service that is responsible to develop, coordinate and maintain clinical and operational protocols for state-wide organ and tissue donation in NSW.





8 References

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- TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors 1.12 Dec 2023: <u>https://tsanz.com.au/storage/documents/TSANZ_Clinical_Guidelines_Version-</u> <u>112_March2024Paedheart.pdf</u> (accessed 15/4/24) and <u>https://tsanz.com.au/clinical-guidelines</u>

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