



Australian and New Zealand Intensive Care Society (ANZICS)

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**THE ANZICS STATEMENT
ON DEATH AND ORGAN DONATION**

Edition 3.1

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FOREWORD

The first edition of the ANZICS Statement was published in 1993. The focus was on providing recommendations for the determination of brain death, setting a standard of practice that was widely endorsed. The process described for the clinical determination of brain death has withstood the test of time.

The second edition in 1998 built on the first, expanding recommendations for the determination of absence of intracranial blood flow and the conduct of organ and tissue donation in the intensive care unit.

This third edition builds on the first two, but provides greater detail on the determination of brain death and the responsibilities of intensive care staff. An additional chapter (Chapter 5) has been added on donation after cardiac death (DCD), in recognition of the increasing DCD activity in Australia and New Zealand. We recognise that so-called 'cardiac death' includes death of the person as a whole, with death of the brain being an inevitable consequence of permanent cessation of the circulation.

The process of revision for the third edition of the Statement has been exhaustive, with a comprehensive review of relevant literature, including comparable documents from other countries, and a complete rewriting of the content to enhance clarity and expand the detail around the more complex issues. An exposure draft was made available for comment to ANZICS members, medical and nursing colleges, state-based organ donation agencies, other societies and associations. These comments were collated and reviewed by the Committee, with further changes being made to the draft Statement where appropriate.

We have chosen not to provide conventional levels of evidence for the recommendations in the Statement. Practice is now based on many years of observation and experience in the care of thousands of patients. However, this area of medical practice, as with many others, does not lend itself to the large randomised clinical trials that provide evidence to support many of our current treatments. Nevertheless, we are satisfied that none of the reports of alleged recovery after determination of brain death would have met the strict preconditions and criteria described in this Statement. We assure the Australian and New Zealand communities that they can have absolute confidence in the determination of death when it is carried out according to the standards we describe.

Some other changes need to be highlighted and explained. The first of these is a change to the minimum period of observation and mechanical ventilation during which the preconditions for clinical determination of brain death are fulfilled and the patient is unresponsive (Glasgow Coma Score 3), has no pupil reaction to light, no cough reflex and no spontaneous breathing efforts, before clinical testing to determine brain death. Previously, a minimum of four hours was recommended, with a minimum of two hours before clinical testing was repeated. However, there has been no reported instance of clinical testing determining brain death on a first occasion and not on the second. There is therefore no rational basis for the minimum period of two hours before testing is repeated.

Secondly, we make a very clear recommendation that whenever death is determined using the brain death criteria, it is certified by two medical practitioners as defined by local legislation. This is consistent with the original intent of the Australian Law Reform Commission that the determination of brain death should have general application, whether or not organ and tissue donation and subsequent transplantation were to follow. Consistent with this, we also recommend that the time of death is recorded as the time when the second clinical examination to determine brain death has been completed. That is, when the process for determination of brain death is finalised, recognising that death will have occurred some indeterminate time before this but is only determined at this point.

The Statement was written during a time of considerable change within the organ and tissue donation sector. An imbalance between donated organs and tissues, and the needs of potential recipients, has caused increasing public, political and media scrutiny. This can have positive effects in terms of public awareness of organ and tissue donation. Other considerations include:

- ❖ initiatives such as the Australian Organ Donor Register and the National Organ Donation Collaborative;

- ❖ enactment of the Human Tissue Act 2008 in New Zealand and phasing out of the 1987 New Zealand Department of Health Code of Practice (to be replaced by this Statement); and
- ❖ clinical changes such as the introduction of DCD and increasing recognition of the role of emergency medicine physicians in referring patients with severe brain injury for intensive care.

The implications of all of these changes are recognised within the Statement.

The recommendations from the National Clinical Taskforce on Organ and Tissue Donation and Transplantation¹ suggested a key role for ANZICS in providing guidance to clinicians and others working in the organ and tissue donation sector. This has encouraged our use of professional writers to assist us with the formatting, style and language of the final document.

It is our expectation that the third edition of the ANZICS Statement will provide a framework for 'best practice' in respect to the determination of death, aspects of end-of-life care in the intensive care unit, and providing the best possible care when patients or their families support organ and tissue donation after death. During the life of this Statement it will be reviewed and updated to remain consistent with legislative or other changes. The most current version can be accessed at www.anzics.com.au.

The revisions leading to the third edition of the ANZICS Statement required a huge amount of time and work from all the members of the ANZICS Committee on Organ and Tissue Donation and this is very gratefully acknowledged. I also acknowledge the constructive comments received on the exposure draft of the Statement and the financial support provided by Australians Donate and the Australian Department of Health and Ageing.

This is a working document and will be made available to all Australian and New Zealand hospitals, intensive care units and emergency departments. Please use it in your practice and teaching. As always, we appreciate your constructive feedback.

Prof. Geoffrey J. Dobb

Chair, ANZICS Committee on Organ and Tissue Donation

INTRODUCTION

This is the third edition of the Australian and New Zealand Intensive Care Society (ANZICS) *Statement on Death and Organ Donation*. The Statement is intended to provide a relevant and accessible resource for intensive care specialists (intensivists) and other health care workers involved in the determination of death and in the care of potential organ donors. It encourages consistency of approach in addressing clinical issues, caring for families, and engaging with other expert opinion in Australia and New Zealand.

The Statement has been developed by the ANZICS Committee on Organ and Tissue Donation, which comprises intensivists with expertise in end-of-life care, death and organ donation. It draws on the best available scientific evidence, the extensive experience of the Committee, and consultation with other organisations concerned with organ and tissue donation in Australia and New Zealand.

ANZICS endorses the Statement and the high standard of medical practice it documents.

The full Statement will be reviewed in 2013. The electronic version of the Statement, available on the ANZICS website, will be updated to reflect significant changes in evidence and practice as they occur.

PURPOSE AND SCOPE

The main purposes of the Statement are:

- ❖ to provide a standard for intensivists and other health care workers in relation to the determination of death and the conduct of organ and tissue donation, including donation after cardiac death (DCD); and
- ❖ to provide assurance to the Australian and New Zealand communities that determination of death and the conduct of organ and tissue donation are undertaken with diligence, integrity, respect and compassion, and in accordance with available medical evidence and societal expectations.

The Statement includes some discussion of the ethical issues surrounding death and organ and tissue donation. It does not address end-of-life care or the ethics of withdrawal of treatment. The ethics of withdrawal of treatment are discussed separately in the ANZICS *Statement on Withholding and Withdrawing Treatment*.² The National Health and Medical Research Council (NHMRC) publication entitled *Organ and Tissue Donation, After Death, for Transplantation: Guidelines for Ethical Practice for Health Professionals* provides further discussion of the ethics of organ and tissue donation.³

TERMINOLOGY

The language used during discussion of death and organ and tissue donation is important and needs to be precise. Recommended language is explained in Sections 3.9.1 and 3.9.2 (pages 30 and 31) and terms used in the Statement are defined in the Glossary (page 53).

STRUCTURE

The Statement includes discussion of:

- ❖ the development of the concept of brain death and the legal context for organ and tissue donation (Chapter 1);
- ❖ the process of determining brain death (Chapter 2);
- ❖ responsibilities of intensive care staff in organ and tissue donation (Chapter 3);
- ❖ requirements for organ and tissue donation (e.g. legal context, medical suitability and medical management of the potential organ donor) (Chapter 4);
- ❖ donation after cardiac death (Chapter 5); and
- ❖ tissue donation (Chapter 6).

1 BACKGROUND

1.1 DEATH IN PERSPECTIVE

Death has always had immense cultural, religious and mystical significance to the human race. From ancient times until the Renaissance there was no understanding of the biology of death. At a spiritual level, death was when life or the soul departed from the body.

Understanding death at a biological level was only possible after William Harvey⁴ in the 17th century described the circulation of blood and the function of the heart as a pump. Harvey stated that ‘...the heart is the principle of life...from which heat and life are dispersed to all parts...’. Under this concept, death was when the heart and circulation stopped.

By the end of the 19th century it was known that, during an increase in intracranial pressure, respirations suddenly stopped whereas the heart continued to beat for some time. It was also recognised that the heart could continue to beat if artificial respiration was performed.^{5,6,7}

During the 1952 Copenhagen poliomyelitis epidemic,^{8,9} it was found that with positive-pressure ventilatory support outside the operating room, inadequate breathing did not automatically lead to coma and cardiac arrest. The success of mechanical ventilation, and the subsequent development of intensive care units (ICUs), rapidly led to positive-pressure ventilation being used in other diseases and conditions, including severe brain injury.

The absence of blood flow in the cerebral arteries of patients with respiratory arrest from neurological catastrophes was recorded in 1953¹⁰ and in 1956.¹¹ An isoelectric electro-encephalogram in this syndrome was reportedly noted in 1954.¹²

In 1959, Wertheimer and others in Lyon described the syndrome of coma, areflexia and apnoea in some detail and called it death of the central nervous system.¹³ They described signs that indicated the definitive absence of all central nervous system activity in order to define criteria for abandoning ongoing intensive therapy. They referred to an isoelectric electro-encephalogram and absent evoked cerebral responses, reporting that the heart rate did not change after giving atropine while it increased after dextroamphetamine.

Later in the same year, Mollaret and Goulon in Paris¹⁴ described 23 patients with the same syndrome (deep coma with no spontaneous respiration, no reflexes, polyuria and low blood pressure if noradrenaline was not given continuously, in the absence of all electro-encephalographic activity) and called it *le coma dépassé* (literally, beyond coma). They pointed out that if mechanical ventilation or the infusion of noradrenaline was stopped, cardiac arrest would follow.

UNITED STATES

In 1968, an *ad hoc* committee of Harvard Medical School produced a report on the ‘hopelessly unconscious patient’. The committee members agreed that mechanical ventilatory support could be withdrawn from patients diagnosed with ‘irreversible coma’ or ‘brain death’ (terms that they used interchangeably) and that, with consent, organs could be removed from such patients for transplantation. They stressed that their primary concern was to provide an acceptable mechanism to permit withdrawal of mechanical ventilatory support from such patients, and that the sanction this gave to removal of organs for transplantation was secondary.¹⁵

Lack of precision in the definition of brain death caused considerable confusion in subsequent years. To deal with this a United States President’s Commission was appointed, which declared in 1981 that individual death depended on either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the entire brain.^{16,17} The consequent Uniform Determination of Death Act¹⁸ referred to ‘whole brain death’ as a requirement for the determination of brain death. Subsequently, this declaration has been enacted into law in most states.¹⁹

UNITED KINGDOM

In 1976, a Conference of the Royal Colleges and Faculties of the United Kingdom published a statement called *Diagnosis of Brain Death*, which set out preconditions and diagnostic criteria

for establishing when death had occurred in patients whose vital functions were being maintained mechanically.²⁰

In 1979, this statement was supplemented with an opinion in a second statement, called *Diagnosis of Death*, that brain death represents the stage at which a patient becomes truly dead, whether or not the function of some organs, such as a heartbeat, is still maintained by artificial means.²¹

In 1995, the United Kingdom uniquely defined brain death as brain-stem death, being irreversible loss of the capacity for consciousness together with the irreversible loss of the capacity to breathe.²² This definition is used in some Commonwealth countries but not in Australia or New Zealand.²³

AUSTRALIA AND NEW ZEALAND

In 1972, a New Zealand High Court judge, the Hon. Mr Justice D.S. Beattie, submitted that doctors should endeavour to agree among themselves on the criteria by which death can be determined, and should ensure that their criteria accord with the concept that the ordinary man has of death.²⁴ In New Zealand, death and organ donation are covered by the Human Tissue Act 2008, which uses the words ‘satisfied... that the individual concerned is dead’ without statutory definition.

In 1977, the Australian Law Reform Commission addressed the absence of definition of death in Australian law, recommending that a statutory definition of death should be introduced. They recommended that death be defined as: a) irreversible cessation of all function of the brain of the person; or b) irreversible cessation of circulation of blood in the body of the person. They did not provide detailed criteria, on the grounds that ‘the creation and prescription of techniques of diagnosis should be the responsibility of the medical profession’. They specified that, although it appeared in the context of transplantation, the definition should have general application. Current Australian state and territory laws vary but all are based on the recommendations of the Australian Law Reform Commission.²⁵

1.2 DEATH, ORGAN AND TISSUE DONATION, AND THE LAW

Dying is a process rather than an event. The determination and certification of death indicate that an irrevocable point in the dying process has been reached, not that the process has ended. Determination of death by any means does not guarantee that all bodily functions and cellular activity, including that of brain cells, have ceased. Several tissues can be retrieved for transplantation long after death has been determined by cessation of circulation. Similarly, after death has been determined by loss of whole brain function, the circulation can be maintained for hours or days to enable organs to be retrieved. Maintaining the circulation can continue even longer: for example, in the case of a pregnant woman, so that the foetus can reach viable independent existence.

Donation of organs and tissues after death takes place within a legal context. All states and territories of Australia, and New Zealand, provide a legislative basis for the removal of organs and tissues after death for the purpose of transplantation (see Section 4.1 on page 37). In most of these jurisdictions, but not Western Australia or New Zealand, death is defined in law.

The Australian and New Zealand Human Tissue Acts prohibit trading in human organs or tissue. ANZICS believes that:

- ❖ no person, organisation or company should profit financially from organ or tissue donation; and
- ❖ neither the estate of an organ or tissue donor nor his or her family should incur any cost from the processes that occur to facilitate organ and tissue donation.

DIRECTED DONATION

Current Australian and New Zealand practice is based on donation of organs and tissues being an unconditional altruistic, non-commercial act. Donated organs and tissues are allocated to the most suitable recipients on the waiting list.

ANZICS opposes negatively directed donation (i.e. donors or their families expressly excluding specific persons or groups as recipients) as counter to the altruistic spirit of donation. Similarly, ANZICS opposes ‘apparently positively’ directed donation — including only specific members of groups (e.g. members of a specific religion) as recipients.

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Positively directed donation (i.e. donors or their families wishing an organ to go to a particular recipient) is emerging as an issue that may confront intensivists. However, positively directed donation might be reasonable under certain uncommon specific circumstances. Some argue that directed deceased donation to a relative or friend in need of a transplant is ethically no different from directed donation from a living donor. The NHMRC ethical guidelines³ suggest that 'this would only be so under the following conditions:

- ❖ there is evidence that the person wished to donate organs and tissues to the general pool after death;
- ❖ there is evidence (e.g. through a living will or advance directive) that the person expressed a preference for certain organs or tissues to be donated to a specific relative or friend in need of a transplant;
- ❖ the transplant candidate is medically suitable and consents to receiving organs or tissues from that donor; and
- ❖ the family is not imposing conditions on the deceased person's behalf.'

There has not yet been adequate consideration by the community, ethicists and health professionals for ANZICS to make a generic recommendation on positively directed donation. ANZICS recommends that any intensivist involved in a situation of potential positively directed donation should refer to the NHMRC document and discuss the specific circumstances with the donor coordination agency and other colleagues.

2 DETERMINATION OF BRAIN DEATH

2.1 BRAIN DEATH

This Statement takes into account:

- ❖ the criteria for determination of brain death, outlined in the joint statement of the Medical Royal Colleges and their Faculties of the United Kingdom;²⁰
- ❖ the criteria for determination of brain death in the *Report of the Medical Consultants on the Diagnosis of Death to the President's Commission* (the President's Commission);¹⁷ and
- ❖ many other more recent documents on brain death and determination of intracranial blood flow.

The President's Commission defines relevant brain functions as 'those that are clinically ascertainable', a position consistent with the philosophical basis on which the concept of brain death and its general acceptance are established.

Brain death occurs in the setting of a severe brain injury associated with marked elevation of intracranial pressure. Inadequate perfusion pressure results in a cycle of cerebral ischaemia and oedema and further increases in intracranial pressure. When intracranial pressure reaches or exceeds systemic blood pressure, intracranial blood flow ceases and the whole brain, including the brain-stem, dies.

Determination of brain death requires that there is unresponsive coma, the absence of brain-stem reflexes and the absence of respiratory centre function, in the clinical setting in which these findings are irreversible. In particular, there must be definite clinical or neuro-imaging evidence of acute brain pathology (e.g. traumatic brain injury, intracranial haemorrhage, hypoxic encephalopathy) consistent with the irreversible loss of neurological function.

Brain death cannot be determined without evidence of sufficient intracranial pathology. Cases have been reported in which the brain-stem has been the primary site of injury and death of the brain-stem has occurred without death of the cerebral hemispheres (e.g. in patients with severe Guillain-Barré syndrome or isolated brain-stem injury).²⁶ Thus brain death cannot be determined when the condition causing coma and loss of all brain-stem function has affected only the brain-stem, and there is still blood flow to the supratentorial part of the brain. Whole brain death is required for the legal determination of death in Australia and New Zealand. This contrasts with the United Kingdom where brain-stem death (even in the presence of cerebral blood flow) is the standard.

Brain death is determined by:

- ❖ clinical testing if preconditions are met;
- or**
- ❖ imaging that demonstrates the absence of intracranial blood flow.

The overall function of the whole brain is assessed. However, no clinical or imaging tests can establish that every brain cell has died.

There is no documented case of a person who fulfils the preconditions and criteria for brain death ever subsequently developing any return of brain function.

2.2 DETERMINATION OF BRAIN DEATH BY CLINICAL EXAMINATION

2.2.1 PRECONDITIONS

As well as the evidence of sufficient intracranial pathology, as outlined in Section 2.1, all the following preconditions must be met if brain death is to be determined by clinical examination:

- ❖ normothermia (temperature > 35°C);
- ❖ normotension (as a guide, systolic blood pressure > 90 mmHg, mean arterial pressure (MAP) > 60 mmHg in an adult);

- ❖ exclusion of effects of sedative drugs (self-administered or otherwise) — the time taken for plasma concentrations of sedative drugs to fall below levels with clinically significant effects depends on the dose and pharmacokinetics of drugs used, and on hepatic and renal function. If there is any doubt about the persisting effects of opioids or benzodiazepines, an appropriate drug antagonist should be administered;
- ❖ absence of severe electrolyte, metabolic or endocrine disturbances — these include: marked derangements in plasma concentrations of glucose, sodium, phosphate or magnesium; liver and renal dysfunction; and severe endocrine dysfunction;
- ❖ intact neuromuscular function — if neuromuscular-blocking drugs have been administered, a peripheral nerve stimulator or other recognised method (e.g. electromyography) should always be used to confirm that neuromuscular conduction is normal;
- ❖ ability to adequately examine the brain-stem reflexes — it must be possible to examine at least one ear and one eye; and
- ❖ ability to perform apnoea testing — this may be precluded by severe hypoxic respiratory failure or a high cervical spinal cord injury.

2.2.2 CLINICAL TESTING OF BRAIN-STEM FUNCTION

Observation

There is a minimum of four hours observation and mechanical ventilation during which the patient has unresponsive coma (Glasgow Coma Score of 3), with pupils non-reactive to light, an absent cough/tracheal reflex and no spontaneous breathing efforts. These observations are recorded by attending nursing or medical staff.

Return of brain function may be delayed for more than four hours after resuscitation from cardiorespiratory arrest.²⁷ It is therefore recommended that, in cases of acute hypoxic-ischaemic brain injury, clinical testing for brain death be delayed for 24 hours subsequent to the cardiorespiratory arrest. Brain death may be determined prior to this by demonstration of absent cerebral blood flow (see 2.3).

Formal examination

Clinical testing is carried out by two medical practitioners with specific experience and qualifications (see Section 4.1.7, page 40). It is recommended that two sets of tests be performed separately, in order that the doctors and the tests are seen to be truly independent. That is, each doctor is responsible for performing one set of tests. The tests may be done consecutively but not simultaneously. There is no requirement for one doctor to be present during the test performed by the other doctor but such presence is acceptable.

All of the clinical tests, including apnoea testing, must be performed on each occasion. No fixed interval between the two clinical tests is required, except where age-related criteria apply (see Section 2.4, page 21).

The following need to be established to determine brain death by clinical testing:

- ❖ absence of responsiveness; **and**
- ❖ absence of brain-stem reflexes; **and**
- ❖ apnoea.

The following table sets out the process for testing, with response and cautionary remarks for each test.

Clinical testing for:	Test and response	Cautionary remarks
COMA	<p>Test: Apply noxious stimuli in the cranial nerve distribution and all four limbs and trunk, observing for motor responses (e.g. pressure over the supra-orbital nerve, sternal rub, and deep nail bed pressure).</p> <p>Response: <i>There should be no responsiveness. This equates to a Glasgow Coma Score of 3.</i></p> <p>Any motor response within the cranial nerve distribution, or any response in the limbs in response to cranial nerve stimulation, <i>precludes determination of brain death.</i></p>	<p>Spinal reflexes may be present in patients with brain death (see Section 2.2.3, page 19).</p> <p>Spinal reflexes are not to be confused with a pathological flexion or extension response. If motor responses in a somatic distribution are observed after non-cranial nerve stimulation and not after stimulus in the cranial nerve territory, these may represent spinal reflexes.</p>
BRAIN-STEM REFLEXES	<p>General remarks</p> <p><i>Testing of the brain-stem reflexes comprises examination of the cranial nerves: pupils, ocular movements, facial sensation and movement, pharyngeal and tracheal response. These are tested sequentially and bilaterally when possible. Not all cranial nerves have a testable reflex associated with them.</i></p> <p><i>All brain-stem reflexes must be absent to determine brain death.</i></p>	
Pupillary light reflex — cranial nerves II & III	<p>Test: Shine a bright light into the eye and look for a pupillary constrictor response.</p> <p>Response: No pupillary constriction response: <i>proceed with testing other brain-stem reflexes.</i></p> <p>Pupillary light reflex is observed: <i>stop clinical testing, as this precludes determination of brain death.</i></p>	<p>The pupils must be ≥ 4 mm in diameter.</p> <p>Anti-cholinergic drugs such as atropine can cause pupillary dilatation.</p> <p>Cataract or iris surgery is not a contraindication to clinical testing.</p>
Corneal reflex — cranial nerves V & VII	<p>Test: Touch the corneas with soft cotton wool or gauze and examine the eyes for blinking or a withdrawal response.</p> <p>Response: No blinking or withdrawal response: <i>proceed with testing other brain-stem reflexes.</i></p> <p>Blink reflex is observed: <i>stop clinical testing, as this precludes determination of brain death.</i></p>	<p>Touching the sclera is not sufficient.</p> <p>Examine the cornea gently as it is easily damaged.</p>
Reflex response to pain in the trigeminal distribution — cranial nerves V & VII	<p>Test: Apply pain over the trigeminal distribution, e.g. pressure over the supra-orbital nerve.</p> <p>Response: No facial or limb movement: <i>proceed with testing other brain-stem reflexes.</i></p> <p>Facial or limb movement is observed: <i>stop clinical testing, as this precludes determination of brain death.</i></p>	
Vestibulo-ocular reflex — cranial nerves III, IV, VI & VIII	<p>Test: Inspect the external auditory canal with an otoscope to confirm that the eardrum is visible. If the eardrum is not visible, the canal must be cleared before testing can occur. Elevate the head to 30° to place the horizontal semicircular canal in a horizontal position. Instil 50 mL of ice-cold water into the ear canal using a syringe. Hold eyelids open and observe for eye movement for a minimum of 60 seconds.</p> <p>Response: No eye movement in response to the cold water; the eyes remain in the midline within the socket: <i>proceed with testing other brain-stem reflexes.</i></p> <p>Presence of any movement, including tonic deviation or nystagmus: <i>stop clinical testing, as this precludes determination of brain death.</i></p>	<p>Presence of a ruptured eardrum does not invalidate the test.</p> <p>Fractures to base of skull or petrous temporal bone may obliterate the response on the side of the fracture.</p> <p>Testing for the oculo-cephalic reflex (head turning) examines the same reflex pathways but is a sub-maximal stimulus and is not recommended. It may also aggravate a pre-existing cervical spinal injury.</p>

Clinical testing for:	Test and response	Cautionary remarks
Gag reflex — cranial nerves IX & X	<p>Test: Stimulate the posterior pharyngeal wall, on both sides, with a tongue depressor or cotton swab.</p> <p>Response: No gag response: <i>proceed with testing other brain-stem reflexes.</i></p> <p>Gag response: <i>do not proceed with clinical testing, as this precludes determination of brain death.</i></p>	If the patient is orally intubated, the gag reflex may be difficult to discern.
Cough/tracheal reflex — cranial nerve X	<p>Test: Stimulate the tracheo-bronchial wall with a soft suction catheter.</p> <p>Response: No cough response is seen: <i>proceed with testing other brain-stem reflexes.</i></p> <p>Cough response is observed: <i>do not proceed with clinical testing, as this precludes determination of brain death.</i></p>	The efferent limbs for this reflex are the phrenic nerve and the innervation of the thoracic and abdominal musculature. Therefore it cannot be assessed in patients with high cervical cord injury.
APNOEA	<p><u>ONLY</u> if all the above reflexes are <u>absent</u>, proceed with testing for apnoea.</p> <p>The apnoea test should be conducted last so that a high P_aCO_2 does not confound the testing of the other cranial nerves.</p> <p>General remarks</p> <p>Apnoeic oxygenation is used to demonstrate lack of ventilatory drive. This involves the supply of 100 per cent oxygen to the trachea, without providing ventilatory assistance. Through mass-movement, oxygen reaches the alveoli, allowing for transfer to the blood. In the absence of ventilation, P_aCO_2 rises and stimulates the brain-stem respiratory centres, causing spontaneous breathing.</p> <p>Usually P_aCO_2 rises by ~ 3 mmHg (0.4 kPa) for every minute of apnoea.^{28,29} As the P_aCO_2 rises, the ventilatory centre is maximally stimulated by a P_aCO_2 of ~ 60 mmHg.</p> <p>Attempt at breathing is defined as any respiratory muscle activity that results in abdominal or chest excursions or activity of accessory respiratory muscles.</p>	
APNOEA	<p>Test: Throughout the procedure, monitor the patient's SpO_2.</p> <p>Pre-oxygenate the patient with 100 per cent oxygen for at least 5 minutes³⁰ to eliminate nitrogen in the respiratory tract and prevent hypoxaemia during the test.</p> <p>An option to minimise the time required for the P_aCO_2 to rise to the desired level, is to mechanically ventilate to mild hypercarbia (P_aCO_2 ~ 45 mmHg [6 kPa]) before disconnecting the patient from the ventilator.</p> <p>Disconnect the patient from the mechanical ventilator. While mechanical ventilation is temporarily stopped, supply oxygen at ~ 2 L/min through a catheter inserted through the endotracheal tube and placed above the carina. Alternatively, a T-piece or a continuous positive air pressure (CPAP) circuit can be used to supply oxygen to the tracheal tube.</p> <p>Observe continuously for any spontaneous breathing.</p> <p>Take an arterial blood gas to document the rise in P_aCO_2.</p> <p>At end of test, reconnect the patient to the mechanical ventilator.</p> <p>Response: No breathing effort is seen with testing: <i>this concludes the clinical testing of brain function.</i></p> <p>Spontaneous breathing is observed during the test: <i>stop testing as this precludes brain death.</i></p>	<p>At the end of the period without mechanical ventilation, apnoea must persist in the presence of an adequate stimulus to spontaneous ventilation, i.e. an arterial P_aCO_2 > 60 mmHg (8 kPa) and an arterial pH < 7.30. In patients with pre-existing hypercapnia, it is recommended to wait for a P_aCO_2 rise of > 20 mmHg (2.7 kPa) above the chronic level, with a pH < 7.30.</p> <p>If starting from normocapnoea, the P_aCO_2 is likely to be > 60 mmHg (8 kPa) after 10 minutes. If this is not the case, wait a further 5 minutes and repeat the arterial blood gas.</p> <p>The period of observation to achieve an adequate threshold of stimulus of the respiratory centre is variable. Failure of the P_aCO_2 to rise is most likely due to an inappropriately high oxygen flow rate via a tracheal catheter.</p> <p>Patients may become hypoxic or develop haemodynamic instability during this process. Adequate pre-oxygenation usually avoids this problem. <i>If hypoxia does occur, give 1–2 mandatory breaths and/or add CPAP and continue apnoea testing. If the patient develops malignant dysrhythmia, then testing may need to be abandoned.</i></p> <p>When a CPAP circuit on a ventilator is used, back up apnoea ventilation needs to be turned off. If the patient remains connected to a mechanical ventilator, the small changes in airway pressure caused by cardiac contraction may trigger gas flow from the ventilator. This must be distinguished from attempts at spontaneous breathing.</p> <p>Care should be taken to avoid high oxygen flows and wedging of the catheter — high intrapulmonary pressure may cause barotrauma.³¹</p>

2.2.3 OBSERVATIONS THAT ARE COMPATIBLE WITH BRAIN DEATH

The following do not preclude determination of brain death:

- ❖ spinal reflexes — these can be either spontaneous or elicited by stimulation, including a painful stimulus applied to limbs or sternum, tactile stimulation applied to palmar or plantar areas, neck flexion, limb elevation or hypoxia (such as during ventilation disconnection). Spinal reflexes are not to be confused with a pathological flexion or extension response. Spinal movements may include:^{32,33,34,35}
 - extension-pronation movements of the upper limbs or non-specific flexion of the lower limbs;
 - undulating toe reflex (plantar flexion of great toe, followed by brief plantar flexion sequentially of second to fifth toes);
 - Lazarus sign (bilateral arm flexion, shoulder adduction, hand raising to above the chest, and may include flexion of trunk, hips and knees);^{36,37}
 - deep tendon reflexes;
 - plantar responses, either flexor or extensor;
 - respiratory-like movements (shoulder elevation and adduction, back arching or intercostal expansion) without significant tidal volume; and
 - head turning;
- ❖ sweating, blushing, tachycardia;
- ❖ normal blood pressure without the need for pharmacological support; and
- ❖ absence of diabetes insipidus (DI) (preserved osmolar control mechanism).

2.2.4 OBSERVATIONS THAT ARE INCOMPATIBLE WITH BRAIN DEATH

The following are incompatible with the presence of brain death:

- ❖ decerebrate or decorticate posturing;
- ❖ true extensor or flexor motor responses to painful stimuli; and
- ❖ seizures.

2.3 DEMONSTRATING THE ABSENCE OF INTRACRANIAL BLOOD FLOW

If brain death cannot be determined clinically (see preconditions in Section 2.2, page 15), it should be determined by demonstrating the absence of intracranial blood flow. In the pathogenesis of brain death, injury (of any cause) to brain tissue and subsequent oedema cause the intracranial pressure to rise to equal, or exceed, the systemic arterial pressure, thus occluding intracranial blood flow. This occlusion is external and the arteries are not immediately thrombosed.^{10,11,38} When intracranial pressure is not consistently greater than blood pressure, or subsequently falls below it, delayed filling of major vessels can occur. This may occur in infants, in patients with massive skull fractures, or if craniotomy with extensive bone removal has occurred.³⁹ It may then take some time before blood flow stops completely and permanently. Arteriography may still show some delayed large vessel filling.

If a contrast study demonstrates any evidence of parenchymal blood flow, a subsequent study showing absent parenchymal blood flow is needed before brain death can be determined.

Visualisation of contrast on computerised tomography (CT) at the level of the Circle of Willis, in the absence of distal flow in the parenchyma, is a reflection of the high sensitivity of CT to small amounts of contrast that may mix within the Circle of Willis in the absence of parenchymal flow.

Ideally, before any investigation, there will have been at least four hours of observation of coma and of absence of those brain-stem responses that can be assessed. This will increase the likelihood that the test will confirm absent intracranial blood flow. Transcranial Doppler (TCD) may be used as a screening test to optimise the timing of the contrast study, the aim being to avoid performing the contrast study before cessation of intracranial blood flow and thus reduce the need to repeat the contrast study.

Determination of brain death is provided by two medical practitioners (not including the medical practitioner who performed the imaging investigation) who, having examined the patient and in the knowledge of the circumstances of the onset of coma, are further assisted in determining brain death by evidence of absent intracranial blood flow, as reported by a specialist in radiology or nuclear medicine. Imaging should not be performed unless systemic blood pressure is adequate (as a guide, systolic blood pressure > 90mmHg, mean arterial pressure (MAP) > 60mmHg in an adult).

If any of the tests show some persistent, minor intracranial blood flow, repeating the test sometime later may be worthwhile (see Section 3.7.3, page 29).

2.3.1 IMAGING TECHNIQUES FOR ASSESSING INTRACRANIAL BLOOD FLOW

Four vessel intra-arterial catheter angiography, with digital subtraction

- ❖ Intra-arterial catheter angiography is regarded as the gold standard test for absence of perfusion.
- ❖ To determine brain death, blood flow should not be demonstrated above the level of the carotid siphon in the anterior circulation, or above the foramen magnum in the posterior circulation.⁴⁰
- ❖ Four-vessel angiography is direct injection of contrast medium into both carotid arteries and both vertebral arteries.⁴¹

Radionuclide imaging

- ❖ To determine brain death, imaging should demonstrate absence of intracranial perfusion.
- ❖ Tc-99m HMPAO (technetium 99m radiolabelled hexamethyl propylene amine oxime) is a radionuclide that demonstrates perfusion and crosses the blood–brain barrier to be retained by brain parenchyma (by conversion from a lipophilic to a hydrophilic form).^{42,43}
- ❖ Blood pool or blood-flow agents, such as Tc-99m pertechnetate, Tc-99m DTPA or Tc-99m glucoheptonate, *are not acceptable* radionuclides to determine brain death, because they do not cross the blood–brain barrier and do not remain within the intracranial cavity long enough for static gamma camera imaging, leading to false positive and negative results.
- ❖ Although two-planar imaging is still used, single photon emission computerised tomography (SPECT) provides superior imaging in adults^{44,45,46} and in children.⁴⁷

Contrast CT or CT angiography

- ❖ Several small studies of patients with brain death^{48,49,50,51,52} have shown absent enhancement bilaterally of peripheral intracranial arteries and central veins on CT angiography at 60 seconds after bolus intravenous injection of contrast agent. Absent enhancement bilaterally of all of the following are likely to be the most reliable early CT indicators of brain death:
 - middle cerebral artery cortical branches — that is beyond the Sylvian branches;
 - P2 segment of the posterior cerebral arteries;
 - pericallosal arteries; and
 - internal cerebral veins.
- ❖ These findings must be in the presence of contrast enhancement of external carotid artery branches to confirm a technically adequate study.
- ❖ Contrast enhancement on CT of more proximal intracranial arteries (Circle of Willis, A₁, M₁, P₁) and other veins and dural sinuses is not indicative of parenchymal blood flow and, therefore, may occur in brain death.
- ❖ There are no large studies with matched controls (e.g. coma without brain death). In particular, there are very small numbers of normal controls and this limits assessment of specificity. Further large prospective studies are recommended. There have not, however, been any cases of absent intracranial parenchymal contrast enhancement in patients who were not declared brain dead by clinical criteria or four-vessel angiography (no false positive results).

Magnetic resonance imaging

- ❖ Magnetic resonance imaging (MRI),⁵³ flow sensitive gradient-echo MRI⁵⁴, post-gadolinium MRI⁵⁵ and magnetic resonance angiography⁵⁶ (MRA) have all been used to demonstrate absence of intracranial blood flow in brain death. Assessment of intracranial blood flow by MRI will usually be a less attractive option than CT, due to the logistical difficulties with performing MRI on monitored intensive care patients.
- ❖ Several small studies of MRA have shown parenchymal and blood-flow changes consistent with brain death. These have included:
 - tonsillar herniation;^{55,56, 57}
 - no arterial flow in the intracranial circulation above the supraclinoid internal carotid artery on ‘time-of-flight’-MRA;²²
 - absent flow in intracranial veins and sinuses on non-contrast magnetic resonance venography (MRV);²²
 - widespread, diffuse, bilateral high signal on diffusion-weighted imaging with corresponding severe drop in apparent diffusion coefficient;⁵⁸ and
 - no intracranial enhancement but intravascular enhancement in the internal carotid artery.⁵⁵
- ❖ Cautionary notes:
 - It is important to be aware of the reduced sensitivity of some MRI techniques to slow flow which may mimic occlusion and lead to a false positive determination of brain death.
 - Flow detection with MRI depends on a large number of variables including field strength, sequence type, sequence parameters such as slice thickness and echo time, and physiological variables such as direction of flow relative to image slice and flow velocity and pulsatility. MRI technique should aim to optimise detection of slow flow.
- ❖ There are no large magnetic resonance studies with matched controls (e.g. coma without brain death). In particular, there are very small numbers of normal controls and this limits assessment of specificity. Due to the potential risk of a false positive determination of brain death, MRI is not recommended. Further large prospective studies are recommended.

Transcranial Doppler

Apart from its use as a screening test, as noted above, TCD is *not* regarded as an acceptable imaging technique to demonstrate absence of brain perfusion, because of operator dependence and diagnostic inaccuracy.^{59,60}

ANZICS recommendation:

Four-vessel angiography and radionuclide imaging are the preferred imaging techniques for assessing intracranial blood flow. Subject to the radiological diagnostic guidelines given above, CT angiography may be acceptable, although experience in the technique is limited. MRI and TCD are not recommended.

2.4 DETERMINATION OF BRAIN DEATH IN INFANTS AND CHILDREN

2.4.1 BRAIN DEATH IN CHILDREN

The clinical determination of brain death in children is regarded as more problematic than in adults because of the difficulties of performing the examination, the presence of open cranial sutures and fontanelles and the relative immaturity of some brain-stem reflexes. However, these issues are really only important in the very young infant. Regardless of age, the clinical examination remains paramount in the determination of brain death in children.

2.4.2 EXISTING GUIDELINES

International guidelines on determination of brain death in children vary with respect to the age at which adult criteria are applicable, minimum observation periods, the required interval between two clinical examinations and the need for supplementary tests.^{61,62,63,64}

Several of these guidelines were formulated some time ago and do not reflect the increasing confidence with which a determination of brain death can be made in younger children.^{65,66}

In fact, there is a lack of good evidence that children of any age require criteria for determination of brain death that are different to those for adults.⁶⁷ All current guidelines, however, recommend an increasingly cautious approach with decreasing age.

The most recent and relevant international recommendations are those from a Canadian forum that met in 2003.⁶⁴ The recommendations below are intentionally similar to these, in the interests of commonality of approach.

2.4.3 SPECIAL CONSIDERATIONS IN NEWBORN INFANTS

For newborns, a prolonged period of observation before initial clinical testing is warranted in light of the frequent inability to define the timing, severity and duration of the initial insult leading to coma.⁶⁸ Based on data from brain-dead newborns referred for organ donation, it is suggested that 24–48 hours is a sufficient minimum observation period.⁶⁹ Similar concerns about the initial insult, along with the particular difficulties of performing clinical testing in the newborn period,^{65,69} give rise to the frequent recommendation that two sets of clinical tests be separated by a defined minimum period of 24–48 hours.^{64,65,70}

2.4.4 PREMATURE NEWBORNS

Below 36 weeks post-conceptual age, difficulties arise because many of the reflexes to be tested are developing or have recently developed.⁶⁸ For example, the pupillary response to light appears at 30 weeks, but is only consistently present at 32–35 weeks of gestation,⁷¹ and the central respiratory response to CO₂ is relatively poorly developed below 33 weeks of gestation.^{72,73} Furthermore, clinical examination is technically more difficult in these very small infants⁶⁵ and there is an isolated report of good neurological recovery after apparent fulfilment of brain death criteria.⁷⁴ The uncertainty surrounding determination of brain death in this population is such that no international guidelines currently address this problem.

2.4.5 CEREBRAL BLOOD-FLOW STUDIES

Intracranial blood-flow studies should be undertaken if the preconditions (see Section 2.2.1, page 15) cannot be met or clinical testing is precluded by gestational age. Demonstration of absent intracranial blood flow is sufficient to make a determination of brain death. However, preservation of some intracranial blood flow in brain-dead infants and children has been widely reported.^{75,76,77} A repeat study will usually show loss of intracranial blood flow within 48 hours.⁶⁵

ANZICS recommendations:

Children over 30 days old

The criteria for determination of brain death are the same as those in adults.

Term newborns (≥ 36 weeks post-conception)

A clinical determination of brain death can be made in the first 30 days of life, but should be approached with more caution. The minimum period of observation before the first clinical testing is 48 hours after birth. Two clinical examinations should be performed, separated by a minimum interval of 24 hours.

Premature newborns (< 36 weeks post-conception)

Clinical determination of brain death cannot be done with certainty.

2.5 DOCUMENTATION OF BRAIN DEATH

The process and clinical tests or investigations leading to determination of brain death must be documented in the medical record. Death is certified when the two medical practitioners defined by local legislation have both completed the process required for determination of brain death. This requirement was a recommendation of the Australian Law Reform Commission, which intended the determination of brain death to have general application, irrespective of whether or not organ or tissue donation is to follow.²⁵

The time of death should be recorded as the time when the second clinical examination to determine brain death is completed. The rationale for this recommendation is that the process of determining brain death is only complete at this time. The time of death should be recorded as the time the second clinician determines that brain death has occurred whether this is by clinical examination or imaging to confirm the absence of intracranial blood flow.

It is recommended that determination of death be documented using a form, to demonstrate explicitly that all criteria set out in these guidelines are met. An example of such a form is included as Appendix C, page 55.

3 RESPONSIBILITIES OF INTENSIVE CARE STAFF IN ORGAN AND TISSUE DONATION

3.1 BACKGROUND

Donation of organs for transplantation is sometimes possible after the death of a patient in the ICU, or less commonly in other hospital areas such as the emergency department. Usually the death is the result of a sudden, unexpected illness or injury and this is a time of great distress for the patient's family.

The staff caring for the patient must ensure that organ and tissue donation processes are carried out to an exemplary standard and in a way that respects the patient and is sensitive to the needs of the family and everyone else involved. This requires expertise in donation, good communication and a strong professional commitment to the quality of the process.

3.2 EXPERT KNOWLEDGE AND SKILLS

Intensivists should ensure that they:

- ❖ have been well educated about brain death and organ and tissue donation (including donation after cardiac death [DCD]);
- ❖ achieve and maintain competence in the performance of all necessary processes; and
- ❖ provide accurate information on these subjects.

The Australasian Donor Awareness Programme (ADAPT) Medical Module⁷⁸ is now a mandatory requirement for intensive care training in Australia and New Zealand (under the College of Intensive Care Medicine [CICM]) and is strongly recommended to all specialists who might be responsible for the care of potential donors and their families.

ADAPT covers:

- ❖ the determination of brain death;
- ❖ the physiological support of brain-dead patients;
- ❖ the process of donation, including DCD;
- ❖ grief and bereavement; and
- ❖ communication with grieving families about bad news, brain death and organ and tissue donation.

ANZICS recommendations:

Intensivists involved in the care of potential donors and their families require specific expertise that may be acquired through specialised education, reference documents and ongoing clinical experience.

Intensive care trainees should be involved in circumstances of potential organ donation whenever possible, supervised by intensivists and supported by intensivists and other involved staff.

3.3 RESPONSIBILITIES OF THE INTENSIVIST IN ORGAN AND TISSUE DONATION

Intensivists have responsibilities in *all* of the following components of the donation process:

- ❖ care of the dying patient;
- ❖ care of the family;
- ❖ recognising the possibility of organ and tissue donation;
- ❖ determination of death (through loss of brain function or cessation of circulation);
- ❖ respectful treatment of the deceased patient;
- ❖ discussing the option of donation with the family;

- ❖ liaison with the donor coordination service (which in turn liaises with organ and tissue removal and transplantation services);
- ❖ maintaining physiological stability and good organ function until organ removal; and
- ❖ providing aftercare for the family of the deceased patient, irrespective of whether or not donation takes place.

Optimal physiological support for the potential donor preserves the opportunity for organ donation. It allows for the determination of brain death, where this has occurred, and allows time for the family to make a decision about donation. At the same time, it ensures the best possible organ function for potential recipients.

ANZICS recommendation:

Intensivists must accept responsibility for leadership in organ and tissue donation because they, with other members of the intensive care team, care for dying patients and their families in the ICU, and donation occurs in this end-of-life context. Leadership and support for donation may also extend outside of the ICU.

3.4 CARE OF THE DYING PATIENT AND OF THE DECEASED PATIENT

The primary responsibility of intensive care staff is to assist the critically ill patient to recover and resume a good quality of life. The severely brain-injured patient will have been admitted to the ICU because it was seen to be in the best interests of the patient and the family. There is usually uncertainty about the outcome, a need for investigations, a period of intensive treatment and ongoing clinical observation. At some stage it will have become clear that the patient will not recover, leading to a decision to withhold or withdraw specific brain-oriented intensive treatments (e.g. medications, induced hypothermia, or further surgery). At such a stage, it is reasonable to continue providing extracranial physiological support, while awaiting determination of brain death or very severe irreversible brain damage. This is an appropriate use of intensive care resources and of the skills and time of the intensivist.

Care and respect for dying and deceased patients includes usual nursing care (e.g. turns, washes, skin care) and the regular attendance and involvement of the intensivist. Attendants must behave professionally at the bedside. Procedures (e.g. echocardiography, bronchoscopy) should only be performed for non-therapeutic (donation) purposes if the information they provide is essential to best practice in organ or tissue donation. The bedside must be screened during procedures.

ANZICS recommendation:

All staff must treat the dying patient (and the deceased patient) with care and with respect for the patient's humanity and dignity.

3.5 CARE OF THE FAMILY

3.5.1 ESTABLISHING A RELATIONSHIP

Mutual trust and respect are fundamentally important aspects of the relationship between the family (a definition of 'family' is provided in the Glossary, page 53) and the health care team, in every instance when a patient has been admitted to an ICU. Such a relationship is established during meetings between the family and the health care team. These meetings are often called 'family meetings', 'family conferences' or 'family group conferences'.

The importance of holding the first such meeting early after ICU admission and of having repeated meetings is increasingly recognised.^{79,80} The content of these meetings is usually wide-ranging and includes:

- ❖ sharing of information about the patient;
- ❖ treatment goals and realistic expectations of the treating team, the patient and the family;

- ❖ the treatment options available; and
- ❖ any previously expressed patient preferences or opinions, and family preferences and opinions.

Meetings are attended by the family (as defined by family members), and by the intensivist, an intensive care nurse, and sometimes a chaplain, social worker, cultural health worker or other support person if the family wishes. Meetings should occur away from the bedside, in a separate private room large enough to accommodate everyone involved, and should be protected from interruption.

In these meetings, the intensivist and nurse (as members of the treating team) need to show, by their words and actions, their compassion^{81,82} for the patient and the family. They should:

- ❖ use everyday language (not technical or medical terminology);
- ❖ ensure that discussion is unhurried;
- ❖ listen attentively to what family members say;^{83,84}
- ❖ allow for silence;
- ❖ present accurate clinical information in a manner that the family can understand; and
- ❖ answer all questions truthfully and fully.

Sections 3.9.1 and 3.9.2 (pages 30 and 31) provide examples of suitable language to be used when discussing end-of-life care and organ and tissue donation with family members.

A strong and mutually respectful relationship between the health care team and the family enables complex and difficult issues (e.g. limiting or withdrawing treatment, the imminent death of the patient, and the option of organ and tissue donation) to be properly addressed when appropriate and for the health care team to work cooperatively and professionally with the family. By not being seen by the family as also a 'bearer of bad news', the intensive care nurse should remain able to support the family during and after the receipt of information from the intensivist. There are likely to be several family meetings over hours and days in a setting of possible organ and tissue donation.

ANZICS recommendation:

A family meeting is recommended soon after ICU admission, particularly if the likely clinical course of the patient is not one of straightforward recovery. Such a meeting should be held within 12–24 hours of ICU admission and may be the first of several meetings in the hours and days that follow.

3.5.2 PROGRESSIVE COMMUNICATION

What is discussed at family meetings will change over time with the patient's illness. Initially there may be considerable uncertainty about the prognosis, even though the illness may ultimately be fatal. Early communications are important and should be undertaken by medical staff with appropriate expertise.

Medical staff should give the family an explanation of the sequence of events, the patient's current condition, and the immediate plan of treatment, investigation and observation. If death seems likely, the family should be forewarned of this. If brain death seems likely, this process should be explained in simple, everyday language. It may help to describe the effects of severe intracranial hypertension (due to 'brain swelling within a closed box') in cutting off the flow of blood to the brain with the result that the brain dies. The use of visual aids in explaining this concept may be helpful to some family members.

There should be subsequent regular family meetings to provide updates on the patient's course and the intended treatment plan, and to answer any questions the family may have. To ensure consistency of style and content, the same intensivist should be responsible, whenever possible, for talking with the family about the illness, death and organ and tissue donation. If that is not possible, it is the responsibility of the first intensivist involved to fully inform the subsequent intensivist, and to introduce him or her to the family.

Often, family members need to absorb and understand a great deal of information in a short time. However, the family must have time to understand the nature and severity of the brain injury, and time to adapt to the impending outcome. The family is very likely to be unfamiliar with brain death, but when it occurs it is important that they understand the concept. Even if the concept of brain death is understood intellectually, emotional acceptance may be very difficult. The option of being present

during clinical examination for brain death may be given in some cases (see Section 3.7.2, page 289). Diagrams, CT scans and other imaging can sometimes help the family's understanding. However, it is important to realise that the acceptance of the interpretation of such information is based on the family's trust of the treating team.

Some families spontaneously raise the issue of organ and tissue donation before the determination of brain death and sometimes while there are still signs of brain-stem function. The timing of discussions of organ and tissue donation is discussed in Section 3.9.5 on page 33.

3.6 RECOGNISING THE POSSIBILITY OF ORGAN AND TISSUE DONATION

Virtually all patients who could become organ donors will be mechanically ventilated, usually because of a severe brain injury. Some will become brain dead. Others may be able to donate after death has been determined on the basis of absence of vital signs ('donation after cardiac death, DCD').

3.6.1 DONOR IDENTIFICATION

In most cases, potential donors are identified in the ICU. Clinical triggers to assist in the identification of potential donors have been introduced in some Australian hospital emergency departments. These are used to initiate consultation with intensive care medical staff before the withdrawal of treatment in patients with brain injury that is thought to be irrecoverable.

3.6.2 DONOR SUITABILITY

While there may be medical contraindications to donation of *some* organs or tissues, few people have absolute medical contraindications to *all* donation. Before discussing donation with the family, it is recommended that intensivists check that there are no medical contraindications or other reasons why donation should not proceed (e.g. interdiction of the coroner). Some families may experience distress, guilt or regret following a death if they had known their relative wanted to be a donor, and yet donation was not discussed with them. If there are medical or other reasons why donation is not possible, it is recommended that the intensivist sensitively inform the family of these reasons, at a suitable time during a family meeting, so that such potential distress can be relieved.

Medical suitability for organ and tissue donation is discussed in more detail in Section 4.2, page 41.

3.6.3 TISSUE DONATION

Most patients (including ICU patients) can donate tissues after their death. Commonly donated tissues include eyes (for corneas and sclera), heart valves, bone and skin. The possibility of tissue donation should be considered for every patient dying in the ICU. Tissue donation is discussed further in Chapter 6.

ANZICS recommendation:

All intensive care staff should be alert to the possibility of organ and tissue donation, and be familiar with the relevant legislation, the processes for determination of death, and local procedures for organ and tissue donation.

3.7 DETERMINATION OF DEATH

3.7.1 PROCEDURES FOR DETERMINATION OF DEATH

Procedures for the determination of brain death are given in Chapter 2, page 15 and procedures for the determination of death by cessation of circulation, in the context of DCD, in Section 5.8, page 50. The legal requirements for determination of brain death are discussed in Section 4.1.7, page 40 and those for the determination of death by cessation of circulation, in the context of DCD, in Section 4.1.6, page 39.

3.7.2 FAMILY PRESENCE DURING CLINICAL EXAMINATION

In some instances, the family may be given the option of being present during the clinical examination to determine brain death. If this is to be undertaken, the intensivist should talk to family members about the tests to be undertaken, preparing and forewarning them about the responses to testing, automatisms (spinal reflexes), and the next steps involved after clinical testing. There must be someone available (e.g. a nurse) to support the family. It may also be helpful if there is a 'designated person' who is able to explain the process as the clinical examination is carried out.

3.7.3 REPEAT TESTING

If clinical examination or imaging demonstrate that brain death has not yet occurred, consideration should be given to repeating these tests after a suitable interval and with the agreement and understanding of the family.

ANZICS recommendation:

In the context of organ donation, determination of death, either through loss of brain function or cessation of circulation, is a responsibility of the intensivist. Intensivists and trainees in intensive care medicine must achieve and maintain competence in the determination of brain death.

3.8 LIAISON WITH DONOR COORDINATORS

3.8.1 THE ROLE OF THE DONOR COORDINATOR

Donor coordinators play a central role in the process of organ and tissue donation. As well as coordination of the donation process, this includes staff support and education, community education and support of donor families. Specifically, this role includes:

- ❖ providing accurate and specific information about organ and tissue donation possibilities;
- ❖ often meeting with staff and the family and completing the details of consent;
- ❖ obtaining the necessary information about the donor's medical and social history;
- ❖ ensuring that all the necessary documentation is complete (including determination of death, relevant consents, donor information and any other legal and administrative requirements);
- ❖ liaising with the ICU staff, coroner, designated officer, transplant services and organ removal teams, operating room, transport and tissue banks; and
- ❖ providing support and information to the families of donors.

Donor coordinators in Australia have access to the Australian Organ Donor Register (AODR) and those in New Zealand have access to the drivers' licence database (see Section 3.10, page 34).

3.8.2 INFORMATION ON ORGAN AND TISSUE DONATION

Intensivists are encouraged to speak to the donor coordinator to seek advice about possible exclusion criteria or other logistical or treatment issues. For example, it should not be assumed that any particular clinical feature (e.g. age, infection or malignancy) would constitute an absolute contraindication to donation. Donor coordinators are available to give information and advice on organ and tissue donation at any time during the process, not only at the time that donation may occur. It is reasonable to seek such advice before brain death has occurred. In the situation of DCD, discussion with the donor coordinator will always take place before death.

ANZICS recommendation:

Intensivists should clarify matters of donor suitability through an early discussion with the donor coordinator, before donation is discussed with the family.

3.8.3 SUPPORTING FAMILIES

In some jurisdictions, the donor coordinator is available to meet the potential donor's family. Unless the family has expressed an objection to organ and tissue donation, the potential donor's family should always be offered the opportunity to meet the donor coordinator. Intensivists should facilitate this introduction at a suitable time (e.g. shortly after the issue of donation has been raised), while being sensitive to the family's grief, needs and requests for information. Donor coordinators are able to speak with the family by telephone if they are not able to attend in person.

ANZICS recommendation:

The intensivist should ensure that:

- the family of a potential donor is given the opportunity to meet with the donor coordinator (in person if possible, or by telephone), in order to meet the family's needs for information, care and support; and
- the donor coordinator or another suitable person (e.g. link nurse, medical donor adviser) is able to ask the family the necessary questions about the potential donor, relating to exclusion requirements for organ and tissue donation.

3.9 DISCUSSING THE OPTION OF ORGAN AND TISSUE DONATION WITH THE FAMILY

ANZICS recommends that intensivists and trainees develop their communication skills in a natural individual style, using sensitive language that is 'plain' and 'everyday' and avoids technical or insensitive terms. The ADAPT workshops provide an opportunity to develop this competency.

The importance of sensitive communication, using appropriate language, is increasingly recognised in intensive care practice. Some words and phrases recommended by ANZICS are discussed below, together with examples of the type of language that should be avoided when speaking with patients and families.

3.9.1 THE LANGUAGE OF END-OF-LIFE CARE

Language used in end-of-life care should be sensitive to the needs and perceptions of dying patients and their families. Some words and phrases have acquired a technical meaning in medicine but retain other common-use meanings that can be distressing to patients and families and therefore should not be used.

Limiting or withdrawing treatment (NOT 'withdrawal of care')

ANZICS recommends using the terms 'limiting treatment' or 'withdrawing treatment' rather than 'withdrawal of care' when describing withdrawal of certain therapies or treatments.

The words 'therapy', 'treatment' and 'care'⁸⁵ are sometimes used interchangeably and inappropriately. Care is never withdrawn but treatment is changed. Intensive care staff should make clear that care for the patient continues after treatments are withdrawn and should describe in plain speech exactly what this will involve.^{86,87}

The likelihood of poor outcome should be addressed without using the terms 'futility' or 'medical futility'. These concepts arose in the United States in the context of a decision-making framework dominated by legal judgements and the concept of a 'legally designated surrogate decision-maker' for incompetent patients.^{88,89} It was an attempt to bring objectivity to medical decision-making, based on statistical probability. The terms are problematic for several reasons: they are highly subjective; cannot be defined prospectively; and are open to the interpretation that the treating team views treatment of the patient (and perhaps therefore the patient) as 'worthless'. Some take the view that any treatment that prolongs life, even briefly or at any cost, has utility and cannot ever be described as 'futile'. Decision-making in Australia and New Zealand about limiting or withdrawing treatment² takes place in a consensual⁹⁰ rather than an adversarial manner. ANZICS recommends that these terms not be used in such discussions.

The term 'passive euthanasia' is sometimes used (in southern Europe in particular, but not in Australasian intensive care practice) to mean 'death after treatment withdrawal' or even the process of treatment withdrawal itself. The word 'euthanasia' has inevitable overtones resulting from its

historical context,⁹¹ has been used to mean different things in different contexts and should not be used in end-of-life care.⁹² ANZICS recommends the terms 'limiting' or 'withdrawing' treatment to describe this process.²

End-of-life care or comfort care (NOT 'terminal care')

ANZICS recommends the use of a term such as 'comfort care' to describe end-of-life care, as comfort is a familiar and unambiguous concept in everyday experience. The word 'terminal' carries an implication of expected or inevitable death. The objective of end-of-life care is *not* to ensure that it is in fact 'terminal' but that it is focused on symptom control and comfort rather than cure. The term 'palliative care' is a technical medical term and therefore requires additional explanation if it is used.

3.9.2 THE LANGUAGE OF ORGAN AND TISSUE DONATION

The language used in organ and tissue donation has historically been largely dominated by the language of transplantation. For example, the Medical Subject Heading (MeSH) term for organ and tissue donation is 'Tissue and Organ Procurement', which itself is defined as:

'The administrative procedures involved with acquiring tissues or organs for transplantation through various programs, systems, or organizations. These procedures include obtaining consent from tissue donors and arranging for transportation of donated tissues and organs, after tissue harvesting [sic], to hospitals for processing and transplantation.'⁹³

This harsh, impersonal terminology continues to be used in the medical literature.

Intensivists and ICU nurses, however, experience organ and tissue donation as part of end-of-life care in the ICU, rather than as 'acquiring tissues or organs for transplantation'. The process of organ and tissue donation involves a person who is dying or has recently died, the family of that person, the ICU staff, and other health care personnel.

Our use of language shapes the perceptions, thoughts and feelings of others. In the medical literature and in clinical conversation about organ and tissue donation, terms are often used that are imprecise, ambiguous or have other common-use connotations. Such phrases, when heard by patients and their families, may affect their perceptions and feelings and can negatively influence their relationship with the clinical team. The language used when discussing donation with families should therefore be considered carefully.

Refer to the patient by name

ANZICS recommends that the patient continue to be referred to by their name after death. The brain-dead person, with ventilatory support and persistent circulation, has a different appearance from the individual who is not breathing and has no pulse. Technical or legal terms commonly used to describe dead people are insensitive to the family, for whom the patient remains a person (albeit a dead person) after death.

Organ removal or retrieval (NOT 'harvest')

ANZICS recommends the terms 'organ removal', 'organ retrieval', 'organ procurement' or even 'organ donation' to describe the operative process of organ removal. The term 'harvest' arose within transplantation and is still commonly used by some transplant professionals and media to describe this process. However, the term has agricultural connotations that are inappropriate to apply to people and are insensitive from the perspective of families.⁹⁴ Although the word 'retrieval' has also recently been considered unacceptable in the United States,⁹⁵ ANZICS does not share this view.

Mechanical ventilation (NOT 'life support')

ANZICS recommends the terms 'mechanical ventilation' or 'mechanical ventilatory support'⁹⁴ rather than the term 'life support', which is often used loosely by the media. This term is particularly problematic and potentially very confusing to family members when used after brain death.

'Family-focused' language

ANZICS recommends the use of 'family-focused' terms to describe donation processes, such as 'discussing organ donation', 'offering the option of donation', 'family agreement to donate' and 'declining organ donation'. Other commonly used phrases are 'organ-focused' and are not recommended;⁹⁶ for example, 'seeking consent', 'obtaining consent', 'requesting organs', 'asking for organs', 'denying consent', 'refusing organs', 'consent rate' and 'conversion rate'.⁹⁷

3.9.3 WHO SHOULD BE INVOLVED

Organ and tissue donation occurs at a time of grief and distress for the family of the potential donor. All staff involved in care of the patient and those involved in the donation process must be sensitive to the family's emotional, psychological, spiritual, cultural and religious needs at this time.

Discussing the option of donation with the family is a professional responsibility of the intensivist. An intensive care trainee may be involved as an observer, or may lead the discussion under supervision of the intensivist as part of training. The nurse caring for the patient should be present to support the family and to ensure that consistent answers are given to questions that the family may address to the nurse later at the patient's bedside. The family may wish others (e.g. a senior nurse, social worker, chaplain, cultural leader or family doctor) also to be present.

If family members wish to meet the donor coordinator and if this is possible, they should be introduced to the donor coordinator in order to be informed about the donation process and to receive answers to their questions. It may also be appropriate to ask the donor coordinator to speak to the family at an earlier stage, before there is certainty about donation, if the family has questions about donation.

Other health professionals with relevant education and experience (e.g. nursing staff) may also be able to assist.

Consideration should be given to the balance of staff and support personnel in relation to family. An imbalanced ratio of staff to family may cause family members to feel overwhelmed.

Intensivists who do not support organ and tissue donation

Intensivists who do not support organ and tissue donation, or do not feel sufficiently skilled to discuss it, should ensure that a suitably skilled alternative person discusses the possibility of donation with the family of a potential donor.

It is recommended that the intensivist seeks advice and assistance early, as needed, so that family concerns can be addressed in an informed manner and without delay.

Conflict of interest

Very rarely, the intensivist is also caring for an intensive care patient (e.g. with acute liver failure who is listed for urgent transplantation) who is a potential recipient of organs from the potential donor. If there is a conflict of interest, it is recommended that another intensivist, who does not have responsibility for the potential recipient, should discuss donation with the family of the potential donor.

3.9.4 WHAT THE DISCUSSION SHOULD COVER

When offering the option of organ and tissue donation, the intensivist should ensure, with the assistance of the donor coordinator if required, that family members understand:

- ❖ that the intensivist's role is to provide information and support to the family and facilitate family decision-making, not to coerce or persuade the family to a particular donation outcome;
- ❖ that donation is an option and not an obligation;
- ❖ that they can change their decision before organ retrieval;
- ❖ that donation can only take place after death;
- ❖ how death has been determined or will be determined (including DCD);
- ❖ in Australia, that the AODR (see Section 3.10, page 34) has been accessed and what information was recorded;

- ❖ the specific organs and tissues that may be donated, the nature of the organ and tissue removal processes in the operating room and the appearance of the deceased patient after organ and tissue removal — unless it is local practice to take corneas only, the removal of the whole eye must be made clear; similarly, removal of the heart (for heart valves), blood vessels, plus the spleen and lymph nodes for tissue typing, must be included when these are needed;
- ❖ that there will be the opportunity for unusable tissue (e.g. the heart after heart valve removal, or a removed organ that is unsuitable to transplant) to be returned to the deceased patient's body before the funeral;
- ❖ that there will be an opportunity for the family to spend time with the deceased patient after organ and tissue removal;
- ❖ any time limitations on reaching a decision on organ and tissue donation;
- ❖ the time frames involved in the overall process — families should be advised that there would be some delay (usually 6–12 hours after brain death) before organ and tissue donation occurs;
- ❖ the availability of support for family members — this may be from hospital staff, chaplains, social workers and donor coordinators, in accord with the needs and wishes of the family;
- ❖ that there are no charges for health services related to donation;
- ❖ details of the clinical actions and procedures required (e.g. tests to determine organ function, tests to exclude transmissible disease, physiological support and monitoring);
- ❖ the possibility that some or all organs or tissues may not be able to be donated or transplanted for medical, technical or logistical reasons — any questions about the suitability of the donor should be answered openly, honestly and with sensitivity;
- ❖ the distinction between organ and tissue donation for therapeutic purposes (transplantation) and research purposes — it should be made clear that agreement to donate organs and tissues for therapeutic purposes does not constitute agreement to donate for research purposes, and that a separate consent would be needed for research if this is a possibility;
- ❖ the possible involvement of the coroner, including coronial post-mortem examination processes where relevant; and
- ❖ the general outcome of transplantation, if requested by the family.

In considering the option of organ and tissue donation, the family may wish to discuss specific details, including, for example, when and where the family will then be able to spend time with their deceased family member, what the person may look like at this stage, whether an open-casket funeral is possible, and when the person's body will be released to the family or funeral directors. All relevant information should be given. Information should not be withheld because of a belief that it may cause distress for the relatives of the deceased patient.

The family should be given privacy, support and adequate time to consider the option of donation, including the opportunity to leave the hospital to consult with others if they wish to do so. The intensivist should offer to withdraw from the discussion if the family wishes, but remain immediately available to the family for assistance.

Post-mortem examination

The Transplantation Society of Australia and New Zealand (TSANZ) recommends consent also be obtained for a post-mortem examination when this is not otherwise being performed (non-coronial cases), to exclude occult malignancy or other disease that might jeopardise the health of potential recipients.⁹⁸ The family should be informed that donation is not dependent on consent to post-mortem examination. It is recommended that the request for post-mortem examination be accompanied by an undertaking to write to the family with the post-mortem examination results, to send a full copy of the examination report to the family doctor and to meet with the family, if requested, to discuss the post-mortem examination results.

3.9.5 TIMING OF DISCUSSIONS OF ORGAN AND TISSUE DONATION

In the setting of a serious brain injury, it is not uncommon for a family member to spontaneously raise the issue of organ and tissue donation. This may constitute an 'offer to donate if appropriate', it may

relay the patient's previously expressed wishes, it may be a pre-emptive statement objecting to later donation, or it may simply be a request for information. In such situations, the intensivist should:

- ❖ sensitively acknowledge the communication;
- ❖ provide whatever information and clarification is needed;
- ❖ reassure the family that treatment will continue at this time in accordance with the patient's best interests; and
- ❖ ensure that the family understands that the intensivist will revisit the issue of organ and tissue donation with the family, without being further prompted, should it become appropriate in the future.

Families, intensivists and circumstances vary considerably and there is no single 'right time' to raise the issue of organ and tissue donation. While opportunities for misunderstanding are probably minimised if the possibility of donation is not raised until after brain death is determined, there may be other reasons why raising the issue at an earlier stage is reasonable and not to the detriment of the patient or the family. For example, having the discussion at this stage may be clearly in accord with the family's expressed needs or the outcome from that discussion may have a significant impact on patient treatment decisions (e.g. on whether to perform a major procedure for haemostasis or if treatment withdrawal is otherwise being considered in a patient in whom impending brain death is suspected). If such a discussion does take place and the family needs further information about organ and tissue donation, it is reasonable for the donor coordinator to be contacted.

Clearly, the possibility of organ and tissue donation is not definite until after brain death is determined, but raising the issue earlier, when death appears imminent or inevitable, may allow family members more time to consider and discuss the possibility of donation. They may value this, and see it as reasonable to discuss these matters as the patient is deteriorating. Early discussions must be undertaken with great care to avoid any potential for misunderstanding.

If the intensivist recommends that treatment be withdrawn and the family accepts and agrees with this, it may also be appropriate to discuss the possibility of maintaining physiological support for some hours, to provide time to discuss and consider organ donation (DCD or donation after brain death), or to allow the patient to deteriorate to brain death. It is important to emphasise that 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.

3.9.6 RECORD OF DISCUSSIONS

Discussions with families of potential donors should be recorded in the patient's medical records. The formal consent document, signed by a suitable family member, should include a list of all organs and tissues for which consent to remove, for transplantation or research, has been given.

3.10 DONOR REGISTRIES AND OTHER PRIOR EXPRESSIONS OF THE POTENTIAL DONOR

The AODR was established in 2000 and its legal status was amended in 2005 to require signed written consent in order to comply with human tissue act requirements in each jurisdiction (see Section 4.1.2, page 38). A record of 'objection' is sufficient to preclude organ and tissue donation. The Australian Health Ministers' Advisory Council (AHMAC) Organ Donation Working Party recommended that the AODR 'be routinely consulted whenever a medically suitable donor is identified prior to discussing organ and tissue donation with the family', and this was adopted by the Australian Health Ministers' Conference in January 2005. As a consequence, Australian governments' policy is that the AODR should be consulted to ascertain the potential donor's registration status and any recorded wishes and that the potential donor's family should be informed of these. Access to the AODR is restricted to 'Authorised Medical Personnel', predominantly donor coordinators and authorised doctors.

The intention of the AHMAC recommendation, which was adopted by the health ministers and the jurisdictional health departments and endorsed by the Australian Health Ethics Committee (AHEC) of the NHMRC, was to ensure that the family was informed of the deceased patient's wishes as recorded in the register. Furthermore, there was recognition that registration would carry an expectation that the AODR would be accessed and any registration conveyed to the family.³

In New Zealand there is no national organ donor register although the Human Tissue Act 2008⁹⁹ allows for the possible future establishment of a register by regulation. The same Act phases out the current system under which each applicant for a vehicle driver's licence is required to choose between 'donor' and 'non donor' as a prerequisite to obtaining a licence. ANZICS recommends that, should an organ donor register be established in New Zealand in the future, the information in it should be treated in the same way as ANZICS recommends it be treated in Australia.

ANZICS recommendation:

ANZICS supports the statement by the AHMAC Organ Donation Working Party that 'a sincerely held objection by the family should be respected even if it is in conflict with the known intention of the potential donor'.

3.11 CONFIDENTIALITY

The Australian Human Tissue Acts and the *Privacy Act 1988* (Cwth) stipulate that it is an offence to disclose information concerning the deceased, the use of retrieved organs and tissues, and information about recipients. The Acts do not prevent families and others from disclosing or actively seeking information in order to identify donors or recipients. Donor coordination agencies discourage this due to concerns about unforeseen psycho-emotional ramifications.

The New Zealand Health Information Privacy Code 1994¹⁰⁰ stipulates that 'the Health Agency must not disclose the information unless the disclosure is one of the purposes in connection with which the information was obtained'.

ANZICS recommendation:

The intensivist and all other hospital staff should ensure that the anonymity of the donor, of the donor's family and of the recipient is safeguarded during and after the donation process.

3.12 ONGOING SUPPORT OF THE FAMILY

Ongoing support of the family may be provided by medical staff, nurses, a social worker, chaplain, cultural leader, family doctor, psychiatrist, counsellor and (when organ and tissue donation has occurred) a donor coordinator. The family should be offered an opportunity to meet with the treating team at a later time if they wish. Some ICUs have established aftercare programs to address the variety of family needs. These are generally very much appreciated by family members and may assist with grief as well as with practical issues resulting from the bereavement.

The families of donors may also have specific needs related to the process of donation. The intensivist should ensure that family members are supported until they leave the hospital. This may include spending time with the deceased patient after organ and tissue removal. In some hospitals, the most suitable place for this is in the ICU, ideally in a single room. The family may wish to have the support of the hospital chaplain or another religious or cultural leader at this time. The donor coordinator may be able to assist with these arrangements.

If the family is required, for coronial purposes, to officially identify the deceased patient after death, the intensivist should ensure that this is completed while the deceased patient is still in the ICU, before organ and tissue removal. This avoids the family being asked to do this at a later time in the mortuary.

Donor coordinators also provide follow-up and support for members of the donor's family. This support varies between jurisdictions.

ANZICS recommendation:

Intensivists should ensure that emotional and social support is made available to families of all patients dying in the ICU.

3.13 CARE AND SUPPORT OF HOSPITAL STAFF

Many staff members are disturbed by death in all its forms, including brain death. This is a common human response, and a response to the grief of others. The processes and delays associated with donation can also be a source of distress for staff as well as families.

Needs vary from person to person and depend on the particular circumstances. Ongoing peer support is important, and intensivists have an obligation to ensure that this is provided. Support might also, for example, take the form of an informal debriefing or talking session for those interested in attending or, when necessary, professional counselling. Donor coordinators may also be able to provide case reviews for hospital staff. ADAPT workshops provide further education about the donation process and the support requirements of families of donors.

ANZICS recommendation:

All staff involved with organ and tissue donation should have access to care and support.

4 ORGAN AND TISSUE DONATION

4.1 THE LEGAL CONTEXT

All states and territories of Australia, and New Zealand, provide a legislative basis for the removal of tissues (including organs) after death, for the purpose of transplantation. In alphabetical order of legal jurisdiction, the relevant Acts are as follows (most of the Acts have been amended over the years and several jurisdictions also have statutory regulations under the relevant Act):

- ❖ Australian Capital Territory (ACT): *Transplantation and Anatomy Act 1978*¹⁰¹ and *Transplantation and Anatomy Regulation 2001*;¹⁰²
- ❖ New South Wales (NSW): *Human Tissue Act 1983*;¹⁰³
- ❖ New Zealand (NZ): *Human Tissue Act 2008*;⁹⁹
- ❖ Northern Territory (NT): *Human Tissue Transplant Act 1979*;¹⁰⁴
- ❖ Queensland (QLD): *Transplantation and Anatomy Act 1979*¹⁰⁵ and *Transplantation and Anatomy Regulation 2004*;¹⁰⁶
- ❖ South Australia (SA): *Transplant and Anatomy Act 1983*¹⁰⁷ and *Death (Definition) Act 1983*;¹⁰⁸
- ❖ Tasmania (TAS): *Human Tissue Act 1985*;¹⁰⁹
- ❖ Victoria (VIC): *Human Tissue Act 1982*¹¹⁰ and *Human Tissue Regulations 2006*;¹¹¹ and
- ❖ Western Australia (WA): *Human Tissue and Transplant Act 1982*¹¹² and *Human Tissue and Transplant Regulations 2006*.¹¹³

Legislation in the various jurisdictions uses the word ‘tissue’ in a legal sense (see Glossary, page 53), which includes what health care professionals customarily refer to as organs. **Accordingly, in reading this section, wherever the word ‘tissue’ appears, it should be read as ‘tissues, including organs’.**

Legislation in the various jurisdictions specifies who may authorise removal of tissue and when they may authorise it. In different ways, they all provide a sound legal basis for the removal of tissues after death. However, there is considerable variation in how far legislation goes in defining death and specifying criteria and requirements for the determination of death. None provide specific details on how death should be diagnosed, on the grounds that ‘the creation and prescription of techniques of diagnosis should be the responsibility of the medical profession’.²⁵ As a consequence, there is scope for variation in interpretation and clinical practice across the different jurisdictions, and between individuals within the same jurisdiction.

ANZICS believes that determination of death and all aspects of tissue donation should be carried out in accordance with:

- high ethical standards;
- good medical practice;
- this Statement;
- the law of the particular jurisdiction in which death occurs; and
- local policy directives, if applicable.

The same standard should be used across all jurisdictions within Australia and New Zealand because:

- ❖ there is variability and lack of precision in the legislation; and
- ❖ tissue transplantation programs must meet the highest standards to maintain public confidence.

In the legislation of the various jurisdictions, the following matters relating to the removal of tissue after death in hospital are particularly relevant to this ANZICS Statement.

4.1.1 THE RESPONSIBILITY FOR AUTHORISING REMOVAL OF TISSUE

The legislation in all jurisdictions recognises a specific role within the hospital of an officer responsible for authorising or helping with the removal of tissue for the purpose of transplantation, and other therapeutic, medical or scientific purposes.

- ❖ In ACT, NSW, QLD, SA, TAS, VIC and WA legislation, the role is referred to as ‘the designated officer’.
- ❖ NZ legislation refers to the role as ‘the person lawfully in possession of the body’.
- ❖ NT legislation refers to it as ‘the person in charge of the hospital’.
- ❖ ACT, SA, TAS, and WA legislation specifies that the designated officer must be a medical practitioner. In TAS legislation it is stipulated that the designated officer is not involved in clinical care of the potential donor.

Most (but not all) legislation states that authorisation for removal of tissue must be in writing.

ANZICS recommendations:

All hospitals involved in tissue donation should designate an officer (or officers), separate from those determining brain death and removing tissues, to ensure that documentation of death has been done correctly; that all relevant consents from the deceased patient, the family and the coroner have been obtained; and to authorise removal of tissue according to legislative requirements.

All consents received and authorisations given throughout the process, including those provided verbally, should be documented in writing.

4.1.2 THE WISHES OF THE DECEASED PATIENT

In general, legislation states that the designated officer may authorise removal of tissue if the deceased patient had expressed a wish or given consent to donation of tissue, which had not been revoked, and had not expressed an objection to donation.

Some variations to this exist:

- ❖ NZ legislation states that informed consent must be given either in writing (with or without witnesses), or orally in the presence of two or more witnesses present at the same time;
- ❖ QLD legislation refers to the wish or consent as being in writing and signed; and
- ❖ VIC legislation refers to the wish or consent as being in writing at any time, or orally in the presence of two witnesses during the last illness.

ANZICS recommendations:

When the deceased patient is known to have expressed a wish or given consent to removal of tissue, all possible attempts should be made to contact the family to ascertain whether or not the wish or consent has been revoked, to discuss donation, and to ascertain their agreement or otherwise. Donation should not proceed if the family disagrees. Intensivists and designated officers should be guided by Section 3.10 on page 34 of this Statement.

4.1.3 THE WISHES OF THE FAMILY

In general, legislation states that the designated officer may authorise removal of tissue if, after reasonable enquiries, the deceased patient did not object and next-of-kin do not object. Australian state legislation refers to the ‘senior available next-of-kin’ and most state that, where there are two or more senior next-of-kin, the objection of any one of them has effect. In NZ law there is no recognised hierarchy of next-of-kin as such but ‘immediate family’ and ‘close available relative’ are defined.

QLD legislation states that next-of-kin consent must be in writing or, if given orally, reasonable attempts made to confirm in writing. NSW and TAS legislation state that it should be in writing.

VIC legislation states that, where two equally senior next-of-kin are available, the consent of one of them has effect.

ANZICS recommendations:

Irrespective of reference to senior next-of-kin in legislation, the intensivist should invite the family to determine who should be present for important discussions about death and organ and tissue donation. Intensivists should make themselves available, if required, to assist the family to achieve agreement on organ and tissue donation. Consensus does not necessarily require unanimity, but is agreement as defined by the family.

Consents and authorisations given by the family, including those provided verbally, should be documented in the medical record.

4.1.4 WHEN FAMILY CANNOT BE LOCATED AND THE WISHES OF THE DECEASED PATIENT ARE UNKNOWN

ACT, NT, SA and VIC legislation state that the designated officer may authorise removal of tissue if the next-of-kin cannot be located and the wishes of the deceased patient are unknown but there is no reason to believe that he or she would object. The legislation of other jurisdictions does not contain this provision.

ANZICS recommendation:

Where legislation permits, and it is known that no family exists, donation may proceed.

4.1.5 DEFINITION OF DEATH

ACT, NSW, NT, TAS and VIC legislation contain what is referred to as a 'definition of death' which states that, for the purposes of the law in the relevant jurisdiction, a person has died when there has occurred:

- ❖ irreversible cessation of all function of the person's brain;

or

- ❖ irreversible cessation of circulation of blood in the person's body.

In SA, the definition of death is contained in legislation separate from that covering tissue donation (in the *Death (Definition) Act 1983*).¹⁰⁸ QLD legislation states that its definition is only for the purposes of the Act. Although WA legislation has no definition of death, 'irreversible cessation of all function of the brain of the person' is specified as a criterion for removal of tissue where respiration and circulation of the blood of a person are being maintained by artificial means. NZ legislation has no definition of death.

ANZICS recommendation:

Given the intentional legislative silence²⁵ about how irreversible cessation of all function of the brain, or irreversible cessation of circulation of blood, should be determined, and the importance of achieving uniformity in clinical practice, brain death should be determined according to the procedures outlined in this Statement. ANZICS believes that adherence to criteria specified in this Statement will meet the legislative requirements of all jurisdictions.

4.1.6 DETERMINATION OF CARDIAC DEATH

VIC legislation states that when respiration or blood circulation is not being maintained by artificial means, before tissue is removed, a medical practitioner (not the designated officer) must certify that an examination has been carried out and the person has died (within the meaning of the definition of death in the Act). No other legislation contains this provision.

ANZICS recommendation:

The legal definitions of death in all jurisdictions are silent on the determination of circulatory 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 this Statement (see Section 5.8, page 50).

4.1.7 DETERMINATION OF BRAIN DEATH

In all jurisdictions of Australia, but not in New Zealand, it is required that the determination of brain death in the context of tissue donation be carried out by two medical practitioners, who must each have carried out a clinical examination.

The medical practitioners who are permitted to determine brain death are further specified, quite variably, in legislation as outlined in the table below.

ACT	<ul style="list-style-type: none"> • They must have been medical practitioners for not less than five years. • One must be a specialist neurologist or neurosurgeon or have 'other qualifications that are prescribed'.
NSW	<ul style="list-style-type: none"> • They must have practiced medicine for not less than five years in the preceding eight years. • At least one must be a designated specialist for the hospital. • They must not be the designated officer. • They must not be involved in tissue removal. • They must not be responsible for care of the intended recipient.
NT	<ul style="list-style-type: none"> • They must have been medical practitioners for not less than five years. • One must be a medical specialist (defined as an anaesthetist, a general surgeon, neurologist, neurosurgeon or physician).
NZ	<ul style="list-style-type: none"> • The number or qualifications of doctors are not specified.
QLD	<ul style="list-style-type: none"> • One must be a specialist neurologist or neurosurgeon or have such 'other qualifications as are prescribed for the purposes of this section'. The prescribed qualifications have been extended by regulation to anaesthetics, cardiology, emergency medicine, general surgery, intensive care, internal medicine, paediatrics, paediatric surgery and thoracic medicine. • They must not be the designated officer. • They must not be the person proposing to remove tissue. • They must not be attending the recipient.
SA	<ul style="list-style-type: none"> • They must have been medical practitioners for not less than five years.
TAS	<ul style="list-style-type: none"> • They must have been medical practitioners for not less than five years.
VIC	<ul style="list-style-type: none"> • They must have been medical practitioners for not less than five years. • They must not be the designated officer. • They must not be the remover of tissues.
WA	<ul style="list-style-type: none"> • They must have been medical practitioners for not less than five years. • One must be a specialist in general medicine, neurology, neurosurgery, or has such 'other qualifications as are accepted by the Executive Director'.

ANZICS believes that brain death is an exact diagnosis that is not necessarily linked to organ or tissue donation. Donation may or may not follow after brain death has been determined. The determination of brain death should be made (if it is going to be made at all) according to the same standard irrespective of donation. There should be only one standard for the determination of brain death.

ANZICS recommendations:

The determination of brain death should be carried out by two medical practitioners regardless of whether or not donation is to occur.

The two medical practitioners who determine brain death should have the requisite knowledge and skills, or should be supervised by a medical practitioner with those skills. This expertise should be a core part of intensive care training.

At least one of the medical practitioners should be employed as a specialist.

The person authorising removal of tissues and the person removing tissues must not be responsible for determining brain death.

The criteria set out above represent the ANZICS minimum requirement. Where particular jurisdictions or hospitals have further legislative requirements or local policy directives, for example relating to 'not less than five years' or 'neurologist or neurosurgeon or anaesthetist', they should be followed.

4.1.8 NEW ZEALAND LEGISLATION

The new NZ legislation is quite detailed in its consent provisions. It defines informed consent, informed objection and over-riding objection and states that they must take into account the cultural and spiritual needs, values, and beliefs of the immediate family of the individual. It further states that informed consent may be given by the individual before death; or after death by the individual's nominee, a member of the individual's immediate family, or a close available relative. It allows for over-riding objection by a close available relative. It states that a person who proposes to collect or use tissue from a dead human body must:

- ❖ ascertain what informed consent is required, whether it has been given and whether it has been over-riden by objection; and
- ❖ consult with the person lawfully in possession of the body (specified as the person in charge of the hospital).

4.2 MEDICAL SUITABILITY FOR ORGAN AND TISSUE DONATION

4.2.1 PATIENT CHARACTERISTICS AND DONOR POTENTIAL

The patient must be medically suitable for organ or tissue donation to proceed. As the criteria for suitability change over time and vary according to recipient circumstances, all potential donors should be referred to the donation agency (which will liaise with transplant teams to determine whether donation is contraindicated).

Absolute contraindications to solid organ donation are few and, in general, are changing in a permissive direction with time. They include:

- ❖ HIV or CJD infection;
- ❖ metastatic or non-curable malignant disease (curable malignancy such as localised small kidney tumours, localised prostate cancer may be considered after careful risk/benefit analysis); and
- ❖ a history of malignancy that poses a high risk for transmission no matter how long the apparent disease-free period (e.g. melanoma, choriocarcinoma).

Patients with past malignancy and a long cancer-free interval (including childhood leukaemia and lymphoma) represent a small risk of transmission and should be considered as potential donors.¹¹⁴

Those with treated bacterial infection (including meningococcal infection), infection with hepatitis B or C virus, or risk factors for HIV and viral hepatitis may also be suitable organ donors and should be referred to the donation agency for careful exploration of the risk to potential recipients.

Acute organ dysfunction, in particular acute renal failure in a potential donor with previously normal renal function, is not a contraindication to donation. Hypertension and diabetes mellitus do not preclude organ donation, nor does older age (persons in their late seventies or early eighties may be suitable kidney and/or liver donors). Criteria for tissue donation are different from organ donation and it is advisable to refer to the relevant donation agency or the donor coordinator.

4.2.2 INFORMATION REQUIRED BY THE ORGAN DONATION AGENCY

Data likely to be required by donation agencies include:

- ❖ age, sex, weight and height;
- ❖ previous medical history — including comorbidity, surgery, previous malignancy, medication, alcohol consumption, smoking, illicit drug use and allergies;
- ❖ detailed history of fatal illness — including infection, cardiac arrest, hypotension or hypoxia;
- ❖ current clinical status — including ventilatory and inotropic support and physiological parameters; and
- ❖ current investigations — including blood group, arterial blood gases, chest x-ray, electrocardiogram (ECG), urea, creatinine, electrolytes, glucose, bilirubin, transaminases, alkaline phosphatase and gamma glutamyl transpeptidase, prothrombin ratio, activated partial thromboplastin time, haemoglobin, white cell count, platelets and all microbiology.

The organ donation agency is responsible for taking blood for serologic testing and also for tissue typing. These tests should only be carried out after the family agrees to donation, with the family understanding that the results of such testing may (uncommonly) contraindicate donation. It may be appropriate for blood to be taken and transported, for example in rural settings, but not tested until the family consents to donation.

4.3 MEDICAL TREATMENT OF POTENTIAL DONORS

Brain death is associated with physiological instability, which may worsen over hours or days. Timely determination of brain death, referral to the donation agency and removal of organs will minimise the loss of donors due to cardiac arrest, maximise the number of organs suitable for transplantation and optimise subsequent transplant organ function.

In managing the potential donor, the aim is to maintain normal physiology (as with other critically ill patients) and this involves the usual spectrum of monitoring and interventions used in the ICU, including central vein and intra-arterial cannulation. It is essential to be aware of the specific physiological and metabolic changes that may accompany brain death, and to institute supportive treatment as needed.

4.3.1 PHYSIOLOGICAL AND METABOLIC CHANGES DURING BRAIN DEATH

Cardiovascular: The period during brain herniation with brain-stem compression may be accompanied by an intense sympathetic surge with marked hypertension, tachycardia and/or arrhythmias — the ‘autonomic storm’. This is usually of short duration but can result in cardiac ischaemia, ECG changes, cardiac dysfunction and myocyte necrosis.^{115,116}

Following the autonomic storm, there is usually loss of sympathetic outflow, resulting in vasodilation and hypotension. This may be exacerbated by pre-existing hypovolaemia, cardiac dysfunction and polyuria from DI.

Diabetes insipidus: DI occurs in approximately 80–90 per cent of brain-dead potential donors and is due to the loss of posterior pituitary function resulting in deficiency of anti-diuretic hormone (ADH, vasopressin).¹¹⁷ This results in polyuria, hypernatraemia and hypovolaemia. Hypernatraemia in the donor has been associated with worse outcomes for renal and liver transplant recipients.^{118,119} Polyuria can be marked if untreated (e.g. > 1 L/h) and attempts to replace the free water loss through the administration of large volumes of fluid may result in further derangements, such as hyperglycaemia and hypothermia.

Hypothermia: This is common after brain death, due to reduced whole-body heat production (loss of brain metabolism and resting muscle tone), inability to conserve heat by vasoconstriction or generate it by shivering, loss of heat by exposure or via the urine and by the administration of (cold) fluids, and loss of hypothalamic thermoregulation. Adverse effects include cardiac dysfunction, arrhythmias, coagulopathy and a leftward shift of the oxyhaemoglobin dissociation curve, with reduced oxygen delivery to tissues. Temperatures of < 35°C preclude or delay the clinical determination of brain death.

Anterior pituitary dysfunction and hormonal resuscitation: There is conflicting evidence on the occurrence and clinical significance of hypothalamic-pituitary-adrenal/thyroid dysfunction in brain death. It is suggested that a deficiency in thyroid hormone may decrease mitochondrial function and impair cardiac function, and that this, along with cortisol deficiency, contributes to haemodynamic instability.¹²⁰ However, most human studies suggest that anterior pituitary function is partially preserved, with normal levels of cortisol and thyroid hormone, or low thyroid hormone in the setting of normal or elevated levels of thyroid stimulating hormone (TSH) consistent with the sick euthyroid syndrome.¹²¹ Studies that suggest a benefit of hormone administration in humans are limited, in that most are retrospective, uncontrolled and non-blinded, or report on a ‘package’ of therapy rather than just hormonal resuscitation or its individual components.^{120,122,123,124,125} Two small randomised controlled studies of thyroid hormone failed to show a benefit on haemodynamics in brain-dead patients.^{126,127} A retrospective review of lung donors found an association between steroid administration and increased donor lung oxygenation and utilisation, perhaps via reducing pro-inflammatory cytokines and lung inflammation.¹²⁸

Anaemia, coagulopathy and immunological changes: Anaemia is commonly due to bleeding and may be exacerbated by coagulopathy and dilution from fluid administration. Coagulopathy may occur secondary to substances released from necrotic brain inducing fibrinolysis (especially in traumatic brain injury), or dilution from bleeding and fluid administration, and it may be worsened by hypothermia. Significant changes in cytokine profiles, including elevation of pro-inflammatory cytokines such as interleukin-6 (IL-6), are observed in humans after brain death.¹²⁹

4.3.2 MEDICAL TREATMENT

Autonomic storm: This is transient. If antihypertensive agents are used, they should be short-acting (e.g. esmolol, sodium nitroprusside). Longer-acting agents will exacerbate subsequent hypotension. It is unknown whether ablating the hypertension and tachycardia protects the heart or other organs from catecholamine-mediated injury.

Arrhythmias: These are more likely to be problematic the longer the time interval between brain death and organ removal, and may be minimised by maintaining normal serum electrolyte concentrations, blood pressure, volume state and temperature. Standard therapy may be administered for atrial and ventricular arrhythmias (e.g. amiodarone, cardioversion). In the event of cardiac arrest, cardiopulmonary resuscitation may result in recovery of cardiac function and successful transplantation.¹¹⁸ Bradycardia is usually resistant to atropine whereas adrenaline, isoprenaline or pacing may be effective.¹³⁰

Hypovolaemia: The volume state should be optimised by the administration of intravenous (IV) fluids. Competing requirements for optimising organ function may produce conflicting strategies for fluid replacement. Higher rates of lung recovery are associated with a minimally positive fluid balance.¹³¹ Identifying early which organs are suitable for transplantation makes it possible to develop focused medical management strategies (e.g. more aggressive fluid therapy when lung donation is contraindicated).

Hypotension and/or low cardiac output: An adequate perfusion pressure should be targeted (e.g. MAP > 70 mmHg) by optimising volume state and use of inotropic agents. In Australia and New Zealand, more than 90 per cent of brain-dead donors receive inotropic support and, although there is a paucity of research to guide the choice of agent in terms of optimising organ perfusion and recipient outcome, noradrenaline is used in 85 per cent of donors who require such support.¹³² Although there are no controlled studies, this high prevalence of noradrenaline use is in the setting of a low incidence of failed physiological support and low rates of primary non-function in liver grafts and delayed function in kidney transplants.

Hormonal resuscitation: There is no Level I or Level II evidence to endorse the use of hormonal resuscitation. A number of authors have recommended its use if there is persistent haemodynamic instability and/or if echocardiography demonstrates an ejection fraction of less than 45 per cent and heart donation is being considered.^{121,133,134}

While hormonal resuscitation is not recommended other than as a treatment option, hormonal resuscitation regimens that have been used include the following:^{121,133,134,135,136,137}

	Adult	Paediatric
Vasopressin	0.5–4.0 U/h*	0.02–0.06 U/kg/h
Tri-iodothyronine (T3)	4 mcg IV bolus, then 3 µg/h	0.05–0.2 µg/kg/h
Methylprednisolone	15 mg/kg IV single bolus	15 mg/kg IV single bolus

*Most protocols recommend a dose of 0.5–4 U/h^{121,133,134}, although it has been suggested that vasopressin doses greater than 2.4 U/h may cause regional ischaemia.¹³⁸

Diabetes insipidus: DDAVP (desmopressin, 1-desamino-8-D-arginine vasopressin) or vasopressin (arginine vasopressin [AVP]) should be administered early in DI. An acceptable urine output is 30–200 mL/h (0.5–3 mL/kg/h for children). DDAVP is given as an IV bolus 2–4 µg (paediatric dose: 0.25–2 µg^{136,139}) every two to six hours, or as required. Vasopressin is given as an IV infusion at a dose of 0.5–2.0 U/h (paediatric dose: 0.002–0.04 U/kg/h^{135,140,141}). Some paediatric protocols for treatment of DI add vasopressin to IV hypotonic fluid which is titrated to urine output.^{140,141}

Early administration of antidiuretic agents in suspected DI (polyuria and rising serum sodium), rather than awaiting confirmation from serum and urinary osmolalities, may avoid physiological instability due to hypovolaemia and hypothermia from large volume IV replacement fluids.

Large urinary volume loss should be replaced intravenously with low-sodium content fluids (e.g. 5 per cent glucose or, if there is resistant hyperglycaemia, sterile water administered via a central venous catheter).

Metabolic derangement: Once DI is controlled and the fluid deficit has been corrected, IV fluid is required to maintain euvolaemia and electrolytes within normal range. Serum electrolytes (sodium and potassium) should be monitored every two to four hours to guide fluid replacement and electrolyte supplementation. Insulin may be given by infusion to maintain blood glucose within the normal range.

Hypothermia: This is easier to prevent than reverse and may be avoided with the use of warming blankets and ensuring inhaled gases are warmed and humidified. Intravenous fluid should be warmed if large volumes are required.

Respiratory: Routine suctioning, positioning and turning, ventilatory techniques that reduce atelectasis (e.g. positive end-expiratory pressure [PEEP], recruitment manoeuvres) and avoidance of interstitial fluid overload help to maintain adequate oxygenation and oxygen delivery to organs. Such an approach is vital for optimising lung utilisation and for successful lung transplantation outcomes. One retrospective study found an association between steroid use (methylprednisolone 15 mg/kg), and donor lung oxygenation and the likelihood of lung recovery and transplantation.¹²⁸

Anaemia and coagulopathy: Although an infrequent requirement, blood, coagulation factors and platelets may be transfused to correct severe anaemia and/or coagulopathy. Organ removal should be expedited if there is a worsening coagulopathy.

Nutrition: Continuing enteral feeding in the potential donor up until the time of organ removal may have beneficial effects on organ function in transplant recipients by restoring energy reserves, reducing cytokine generation, and protecting against ischaemia and reperfusion injury.^{142, 143}

4.3.3 DONOR MANAGEMENT DURING ORGAN REMOVAL

During the organ removal operation, the brain-dead donor's physiology is managed in the operating theatre by an anaesthetist. The anaesthetist should ensure that there is adequate monitoring and intravenous access. Blood products should be available, if required, and normal ventilatory and circulatory parameters maintained. It is usual to administer a neuromuscular blocking drug and volatile agent.¹⁴⁴ These agents serve to prevent spinal reflex movements and ablate sympathetic responses such as tachycardia and hypertension that may occur during organ removal surgery. Opioid agents are also sometimes used for this purpose although they may not be useful in suppressing catecholamine-mediated sympathetic activity.¹⁴⁵ This is not anaesthesia, as anaesthesia is not required in individuals with brain death who all lack consciousness and the ability to experience pain. These agents are used to prevent reflex movements and sympathetic responses to noxious stimuli that can be disconcerting for theatre staff. In addition, excessive sympathetic responses could result in myocardial injury and exacerbate bleeding, with subsequent haemodynamic instability and detrimental effects on graft function. Whether agents that more directly block the effects of sympathetic activity (e.g. beta-blockers and vasodilators) have advantages over a combination of volatile agent and high-dose opioid remains untested.

5 DONATION AFTER CARDIAC DEATH

5.1 INTRODUCTION

Determination of death after cessation of circulation is a very common event in medicine, and the signs of absence of life are well-known. Donation after cardiac death (DCD), formerly known as non-heart beating donation (NHBD), is organ donation occurring after cessation of circulation. Criteria for the determination of death in DCD are covered in Section 5.8 on page 50.

Before the legal recognition of brain death as death, organs for transplantation (mostly kidneys^{146,147}) were only removed after circulatory arrest, although the vast majority of these donors were brain dead.

After the recognition of brain death as death, organs for transplantation were removed while the circulation continued. This enabled donation of thoracic organs and reduced warm ischaemic damage to organs, with resultant improvement in graft function in recipients.

Over the last decade, DCD protocols^{148,149,150,151,152} have been developed in a number of jurisdictions and have increased the number of organs for transplantation;¹⁵³ specifically of kidneys,^{154,155} livers¹⁵⁶ and lungs.¹⁵⁷ In part, the emergence has been driven by relatives who wish to donate organs of severely brain injured, but not brain-dead, patients. Most of the Australian DCD experience in the last decade has been in NSW.¹³² This experience follows international trends where DCD is occurring with greater frequency and effectiveness in the United States, Canada, the United Kingdom, Holland and Japan.¹⁵³

DCD is possible in ICU patients if treatment is to be withdrawn and their families subsequently agree to donation. The decision to withdraw treatment must be made because ongoing treatment is not in the patient's best interests. DCD is acceptable ethically, legally and clinically when guidelines are followed, ensuring that there is no conflict of interest (perceived or actual) between treatment withdrawal and donation, for those involved in the decision to withdraw treatment. The *ANZICS Statement on Withholding and Withdrawing Treatment* (March 2003)² describes the principles to be followed in withdrawing treatment. The priority must always be the patient's best interests and the quality of end-of-life care, not organ and tissue donation.

The implementation of a DCD protocol in a hospital needs support and endorsement from all staff involved within the organisation. It should not be undertaken until the relevant staff members have been educated.

5.2 DCD GRAFT SURVIVAL

Patient outcomes after transplantation of kidneys from DCD donors are similar to those following donation after brain death (including primary non-function, graft loss in the first 30 days after transplantation, long-term allograft survival and long-term patient survival). The only difference is a higher incidence of delayed graft function in DCD kidneys.^{153,158,159} The results for pancreatic^{160,161,162} and lung^{153,163,164} transplantation after DCD are comparable with those after brain death.

Both liver graft survival and patient survival are lower, at one year and three years, in recipients of DCD livers compared to livers donated after brain death.¹⁵³ DCD livers have a higher incidence of biliary strictures, hepatic artery stenosis, hepatic abscess and biloma formation.¹⁵³

5.3 WARM ISCHAEMIA TIME

Warm ischaemia time (WIT) has been defined as the time from treatment withdrawal to the start of cold perfusion of the donated organs. The significance of WIT is the impact on graft function: it should not exceed 30 minutes for liver transplantation (this leads to a higher risk of biliary stricture),¹⁵⁹ 60 minutes for kidney or pancreas transplantation,¹⁴⁹ or 90 minutes for lung transplantation.¹⁶⁴ The most important phase of the WIT begins when the systolic blood pressure is < 60 mmHg. This phase

includes the waiting period from the absence of circulation to the declaration of death and the time before initiating the flow of cold perfusate through the cannula.

5.4 DCD DONOR CRITERIA

The following donor criteria apply for DCD:

- ❖ ventilated patient from whom treatment is to be withdrawn (e.g. with severe irreversible brain injury, severe cardiac or respiratory failure, or ventilator-dependent quadriplegia);
- ❖ when death is likely to occur within a time following treatment withdrawal that permits organ retrieval for transplantation; and
- ❖ medical suitability as determined by TSANZ criteria.⁹⁸

In Australia and New Zealand, only Maastricht category 3 and 4 patients are regarded as suitable for DCD. The Maastricht criteria were defined in 1995 to categorise potential DCD donors.¹⁶⁵

- ❖ Category 1: Dead on arrival at hospital — unknown WIT: ‘Uncontrolled’.
- ❖ Category 2: Failed resuscitation (in emergency department or ICU) — known WIT: ‘Uncontrolled’.
- ❖ Category 3: Withdrawal of treatment in ICU — known and limited WIT: ‘Controlled’.
- ❖ Category 4: Cardiac arrest following formal determination of brain death but before planned organ procurement — known and potentially limited WIT: ‘Uncontrolled’. Strictly speaking, this is not DCD as determination of death is by brain death criteria but, by convention, it is still included within DCD.

Categories 1 and 2 are considered ‘uncontrolled’ and are unlikely to be contemplated for DCD, due to the ethical and logistical difficulties of ‘protecting’ the organs while obtaining consent from grieving family members, and due to the prolonged or unknown WIT. Category 4 is a realistic consideration in cases where the family has already consented to donation. Category 3 is the most likely setting for DCD. Those in this category are most likely to be patients with severe brain injury, who are not going to deteriorate to brain death, but in whom treatment is to be withdrawn.

5.5 PREDICTION OF CIRCULATORY ARREST WITHIN 60–90 MINUTES OF TREATMENT WITHDRAWAL

It may be difficult to predict the likelihood that circulatory arrest will occur within 60–90 minutes of treatment withdrawal. If the patient remains severely hypotensive for a long time before asystole, the prolonged WIT will adversely affect graft function. Several predictive tools have been described.^{153,166,167,168} None of the tools has been adequately validated.

It is likely that the most influential factor is whether the patient will breathe when extubated and, if so, how effectively. Observing the patient during a trial of spontaneous ventilation may assist prediction. If required, this should be conducted by the intensivist in the ICU before discussions with the family, so that these discussions take place only if donation is a realistic option. This test should be conducted in a way that does not change the patient’s condition (e.g. if the patient becomes hypoxaemic to an unsafe level, then ventilation should be reinstated).

5.6 CONSENT FOR DCD

The laws that govern donation after brain death throughout Australia and New Zealand also govern DCD (see Section 4.1, page 37). There are some aspects of ‘agreement to proceed’ that are specific to DCD.

5.6.1 PRINCIPLES FOR DCD

Principles relevant to DCD include the following.¹⁶⁹

- ❖ The decision to withdraw life-supportive treatments must be made independently of consideration of donation and with the full agreement of the patient’s family and all the responsible medical staff involved in the patient’s care.

- ❖ Permission must be sought from the patient's family, or rarely from the competent patient, for all aspects of the donation process. (see section 5.6.2, page 47).
- ❖ Each step in the decision-making process should be clearly documented in the patient's case records.
- ❖ A discriminating assessment of the patient's probability of dying in the appropriate time frame should be undertaken, possibly in collaboration with the local organ donation agency.
- ❖ Appropriate processes must exist to seek permission from the coroner and the designated officer of the hospital in Australia or person legally in possession of the body in New Zealand.
- ❖ Members of transplantation and retrieval teams *must not*:
 - participate in the decision to withdraw treatment;
 - be present at the withdrawal of treatment; or
 - participate in the determination of death.
- ❖ No financial burden to the family or the estate of the deceased will ensue as a result of consenting to organ and tissue donation.

5.6.2 DISCUSSION OF DCD WITH THE FAMILY

Although the family may already have raised the subject, the intensivist should only introduce the possibility of DCD after a decision that treatment will be withdrawn has been made by the treating team and the family. The possibility of DCD may be discussed by the treating intensivist or by a second, independent intensivist. This is to be determined by the intensivists involved or by local hospital policy. The factors to consider include the comfort of the treating intensivist in raising the subject of DCD and any concern about a perception of conflict of interest. The intensivist may invite the donor coordinator to assist with the discussion.

The discussion with the family should include the following points:

- ❖ Details of the process of treatment withdrawal, including the available locations, and ability for the family to be present until shortly after the time of death.
- ❖ That 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 their loved one after death has been declared (staff must be available to support grieving families at this time).
- ❖ That anxiolytics and analgesics will be given, as necessary, until the moment of death.
- ❖ That predicting the time from treatment withdrawal to death is difficult. If this interval is greater than the maximum that allows organ retrieval for transplantation, organ donation will not be possible. Tissue donation may still occur if suitable and the family consents.
- ❖ The organs that may be suitable for transplantation and the effect on this of the time from treatment withdrawal to death.
- ❖ That if organ donation is not possible, care for the patient will be continued in the ICU or another suitable location.
- ❖ That consenting to donation will usually result in a significant delay in the time that treatment may be withdrawn, due to the complex logistics associated with arranging donation and transplantation. The family must be prepared for and consent to this.
- ❖ That blood is taken for serology and tissue typing before treatment is withdrawn.
- ❖ That the family's permission will be sought for the administration of drugs (e.g. IV heparin) and procedures (e.g. bronchoscopy) to facilitate organ donation (provided these may be legally administered).
- ❖ That pre-operative assessment or organ removal surgery may reveal medical reasons why donation may not proceed.
- ❖ That the circumstances of the death may need to be reported to the coroner and a coronial post-mortem examination may occur. This is independent of the donation process.
- ❖ That families may change their minds and withdraw consent at any time.

5.6.3 CORONER

Consent for retrieval of organs for transplantation is required from the coroner, if the death is reportable. In some jurisdictions the coroner may wish to withhold consent until circulatory arrest, although conditional approval will have been given before withdrawal of treatment.

5.6.4 AUTHORITY FOR REMOVAL OF ORGANS

In view of the responsibilities of the designated officer outlined in Section 4.1.1 on page 38, the designated officer needs to be fully aware of all relevant details before treatment is withdrawn, in order to authorise removal of tissue immediately after death has been declared.

5.7 THE PROCESS OF WITHDRAWING TREATMENT AND PROCEEDING TO DCD

5.7.1 ORDER OF PROCEEDINGS

The order of proceedings should be as follows:

- ❖ The intensivist caring for the patient must document the reasons for treatment withdrawal. Other attending specialists should be notified and consensus achieved about a decision to withdraw treatment, consistent with the *ANZICS Statement on Withholding and Withdrawing Treatment*.²
- ❖ The intensivist, in collaboration with the donor coordinator or delegate from the donation agency, will determine whether the patient is a realistic potential DCD donor.
- ❖ The intensivist caring for the patient, or another intensivist not involved in the case, discusses DCD donation with the family and documents the outcome of the discussions. If the family supports DCD, the donor coordinator is called to coordinate the logistics of the donation process. The coordinator liaises with transplant units, the designated officer and the family to ensure that the '*Authority for Organ & Tissue Removal*' form is completed. In some jurisdictions, the coordinator approaches the coroner directly and in other jurisdictions this is a role of the intensivist. The coordinator ensures that preceding tasks are completed; some tasks will be undertaken by the coordinator and others by medical staff. It is recommended that hospitals create a specific 'checklist' for staff to follow.
- ❖ Blood samples are taken before withdrawal of treatment for serology and tissue typing. Treatment withdrawal cannot take place until the donor coordinator has ensured that necessary results are available and, following discussion with the transplant unit, the donor coordinator has determined which organs might be retrieved.
- ❖ The time and place of treatment withdrawal is negotiated by the intensivist and donor coordinator with the donor family, the retrieval surgeons, the operating room and ICU staff. The intensivist should ensure that the needs and wishes of the family members during the process of treatment withdrawal take precedence over the process of possible organ donation.
- ❖ Treatment withdrawal may occur in three different locations.
 - In the ICU, which maximises the opportunity for all family members who wish to be with the patient at this time, including at the time of death, to be present. The patient is not moved to the operating theatre until after death. If death does not occur within the predetermined time frame where organ donation is feasible, unnecessary patient movement is avoided. However, if death occurs within such a time frame, it requires a rapid transfer of the deceased patient to the operating theatre. In some instances, the additional WIT may make some organs (e.g. particularly the liver) unsuitable for transplantation.
 - In an appropriate room near the operating theatre, which involves moving the living patient but perhaps enables similar family access to the patient at the time of withdrawal as would occur in the ICU, while at the same time reducing the time between death and organ removal. However, it still requires rapid transfer of the deceased patient to the operating theatre, if death occurred within in the predetermined time frame, or perhaps transfer back to the ICU if this did not occur. It may reduce the possible exposure of operating room staff to the process of treatment withdrawal and this may be less confronting for them.

- In the operating theatre, which requires moving the patient before death and may limit family access at the time of death, as well as leading to the possible return of the patient to the ICU should death not occur in a predetermined time frame. Although this minimises WIT, it creates the maximum exposure of operating room staff to the grieving family. This may be the only logistically possible option in some institutions.
- ❖ It is recommended that a brief meeting of all staff who may be involved be held in a suitable private location, perhaps an hour before treatment is withdrawn. This meeting should be attended by ICU staff, retrieval team staff, operating room staff and donor coordination staff and should cover the specifics of this situation, so that all personnel are aware of the plan and their individual responsibilities and are prepared for it.
- ❖ Any evidence of patient distress will be treated with such analgesia and sedation as would be given in any other circumstances of treatment withdrawal and end-of-life care. Medication must not be administered with the intention of hastening death.
- ❖ Following determination of death, and consent from the designated officer (in Australia) or other appropriate person (in New Zealand) and if necessary, the coroner, organ retrieval can proceed. Some intensivists may prefer that withdrawal of treatment and the determination of death be managed by two intensivists acting independently.
- ❖ If circulatory arrest does not occur within the predetermined time frame, organs will not be retrieved. The intensivist will then inform the family and care will be continued in an appropriate location. Tissue donation can still occur following death.

5.7.2 RETRIEVAL-RELATED PROCEDURES BEFORE DEATH

The ethical guidelines published by the NHMRC³ support interventions to maintain organ viability occurring before death under the following circumstances, providing there is no legal impediment:

- ❖ there is evidence that the individual wanted to be an organ donor;
- ❖ the individual or their family has been provided with sufficient information and time to make an informed decision;
- ❖ consent for the specific intervention has been obtained from the individual or their family;
- ❖ such interventions do not contribute to the individual's death or compromise their care; and
- ❖ appropriate measures are taken to prevent any pain or discomfort.

Interventions considered in the NHMRC document include the administration of heparin to prevent small-vessel thrombosis, moving a patient to the operating room before withdrawal of treatments and cannulation of femoral vessels to infuse preservation solutions once death has occurred. Bronchoscopy is also commonly performed. Heparin (~20,000 units) improves organ preservation by preventing small-vessel thrombosis.^{170,171,172} There is no evidence that administering 20,000 units of heparin at the time of withdrawal of ventilatory and cardiovascular support, or when the patient has become hypoxic but still has a detectable circulation, has any impact on the patient or foreshortens the patient's life.¹⁵³ Some centres in Australia and New Zealand administer heparin before withdrawal of treatment and have inserted femoral cannulae before death. Many overseas centres are prepared to undertake all of these procedures before death. National guidelines in the United States and also in Canada are consistent with those in Australia and New Zealand in that these interventions only occur if the family consents.¹⁷³ ANZICS supports such interventions only on the basis that available scientific evidence confirms their utility in improving organ viability. The evolution in surgical and organ preservation techniques may in time remove the need for some of these interventions.

In the opinion of the NSW Health Department, it is illegal under NSW law for substitute decision-makers to consent to the administration of any medications or procedures before death that do not 'promote the health and well being of the person'. In short, such interventions are not permissible in NSW because the necessary conditions for consent by donors themselves are not currently present, and because laws relating to substitute consent do not have the scope to enable non-therapeutic procedures in competent patients.¹⁵¹

The wording of relevant acts elsewhere in Australia considers the best interests of the individual and published ethical and legal opinion contends that antemortem procedures are supported by such consideration.¹⁷⁴ This issue is one where opinion is strongly held and often polarised; to date these legal positions remain untested.

5.8 DETERMINATION OF DEATH FOR DCD

Determination of death after cessation of circulation is a very common event in medicine, and the signs of absence of life are well known. However, DCD requires that organ removal take place as soon as possible after death, to minimise the effects of warm ischaemia on the organs that may be transplanted. This has created a need for criteria to determine, as soon as is reasonable, that death has occurred, so that organ removal can commence without delay.

ANZICS recommendations:

ANZICS recommends that death be determined to have occurred when all of the following features are present:

- immobility;
- apnoea;
- absent skin perfusion; and
- absence of circulation as evidenced by absent arterial pulsatility for a minimum of two minutes,^{153,175,176} as measured by feeling the pulse or, preferably, by monitoring the intra-arterial pressure.

When all of these criteria have been met, the patient is determined to be dead and therefore organ removal may proceed.

ANZICS recommends that the ECG is not monitored, as electrical activity may persist for many minutes following the cessation of circulation, which is the basis for the declaration of death.

Once death has been declared, measures that may restore circulation must not be undertaken. Reintubation without ventilation to prevent aspiration and ensuing pulmonary damage is permissible.

5.9 DOCUMENTATION OF DEATH

The intensivist responsible for determining death should document the time and date of death, along with the intensivist's name and signature. A proforma (see Appendix D, page 56), analogous to the proforma used in brain death, will facilitate this. It is important that only one clock be used to time events relating to DCD, to ensure that operating theatre documentation does not inadvertently record organ removal as having begun before the time of death.¹⁷⁷

6 TISSUE DONATION

Although tissue donation tends to have a lower profile than solid organ donation in intensive care, it is important that the potential for tissue donation is considered after every death in the ICU, emergency department or elsewhere.

There are more potential and actual tissue donors than organ donors. Coronial referral does not exclude tissue donation. Tissue donation is less time critical than organ donation, however early notification to enable consent to be obtained facilitates the collection of blood specimens for nucleic acid testing for early detection of transmissible viral infections. In cases where pre-mortem blood samples are available, these should be identified to the donor coordinator. The range of tissues that can be donated includes corneas, whole eye, skin, heart valves and other cardiovascular tissues, musculoskeletal tissue including bone and tendons, but varies with the surgical skills available and local facilities. The procedures are performed with the usual care given during a surgical operation and the family can be reassured that all steps are taken to avoid disfigurement. For example, a plastic disc is left in place after eye donation and limbs are reconstructed following bone retrieval.

The exclusion criteria for tissue donation are more stringent than for organ donation because of regulatory requirements and the perceived relative balance of benefit and risk of tissue transplantation. In some jurisdictions, a full post-mortem examination that includes the brain (to exclude spongiform encephalopathies) is required if certain tissues are to be donated. Requirements vary between jurisdictions and between different tissues, in part because of the limited time that can elapse between donation and use for some tissues. The family must be informed and specific consent obtained for non-coronial post-mortem examination.

Tissue donor coordinators contact the families of recently deceased people to discuss tissue donation. In jurisdictions with multiple organ and tissue donation agencies, the intensivist can work with the agencies to minimise the number of separate contacts made with the families of recently deceased patients. The process can be facilitated by intensive care staff contacting a donor coordinator at the time of death if the patient expressed a wish to be an organ and tissue donor, or if this information is volunteered by the patient's family. Families can feel this to be particularly important in giving expression to the patient's wish to donate when the circumstances of death do not allow organ donation.

In some jurisdictions, namely WA, QLD and SA, automatic notification of death occurs electronically to the donor coordinators or tissue banks. Therefore it is imperative that, if a discussion about donation occurs in the ICU, emergency department or other place of death, it is documented in the medical record. Donor coordinators or tissue bank staff check the medical records and will contact the family for consent to tissue donation unless there is documentation to suggest otherwise.

Information on the contraindications to tissue donation is available from the local donor coordinator. At present each tissue bank sets its own exclusion criteria. Tissue-specific standards are being developed by the Australian Therapeutic Goods Administration in collaboration with the Australasian Tissue Banking Forum and the Eye Banks Association of Australia and New Zealand.

APPENDICES

A GLOSSARY OF TERMS

Designated officer, Person lawfully in possession of the body, Person in charge of the hospital:

A person responsible for authorising removal of organs and tissues for transplantation.

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

Donation after brain death: Organ donation occurring after brain death has been determined and before cessation of circulation.

End-of-life care: Care provided to the dying individual and their surviving loved ones.^{178,179}

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).¹⁸⁰

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.^{83, 179,181}

Intensivist: In this document, ‘intensivist’ means an intensive care specialist, or other specialist with rostered responsibility for patients in the ICU.

Tissues: Refers to donated tissues for transplantation (e.g. corneas, skin, heart valves) — in the context of legislation, ‘tissue’ also refers to organs (e.g. liver, kidneys).

B ACRONYMS AND ABBREVIATIONS

ADAPT	Australasian Donor Awareness Programme, see www.adapt.asn.au/default.asp
ADH	anti-diuretic hormone
AHEC	Australian Health Ethics Committee (a principal committee of the NHMRC)
AHMAC	Australian Health Ministers' Advisory Council
ANZICS	Australian and New Zealand Intensive Care Society see www.anzics.com.au
AODR	Australian Organ Donor Register see www.medicareaustralia.gov.au/public/services/aodr/index.jsp
AVP	arginine vasopressin
CICM	College of Intensive Care Medicine see www.cicm.org.au
CO ₂	carbon dioxide
CPAP	continuous positive air pressure
CT	computerised tomography
DCD	donation after cardiac death
DDAVP	desmopressin, 1-desamino-8-D-arginine vasopressin
DI	diabetes insipidus
ECG	electrocardiogram
ICU	intensive care unit
IL-6	interleukin 6
IV	intravenous
KPa	kiloPascal
MAP	mean arterial pressure
mmHG	millimetres of mercury
MRA	magnetic resonance angiography
MRI	magnetic resonance imaging
MRV	magnetic resonance venography
NHBD	non-heart beating donation
NHMRC	National Health and Medical Research Council see www.nhmrc.gov.au
PaCO ₂	pressure of carbon dioxide
PEEP	positive end-expiratory pressure
SPECT	single photon emission computed tomography
SpO ₂	percentage blood oxygen saturation
TCD	transcranial Doppler
TSANZ	Transplantation Society of Australia and New Zealand see www.tsanz.com.au
TSH	thyroid stimulating hormone
WIT	warm ischaemia time



AUSTRALIAN AND NEW ZEALAND INTENSIVE CARE SOCIETY

Hospital: _____

Affix patient label here

Known cause of irreversible loss of brain function

There is acute brain pathology consistent with the irreversible loss of brain function.

Doctor A: *Specify condition* _____

Doctor B: *Specify condition* _____

Period of continuous observation of apparent loss of neurological function

For determination of brain death by clinical examination there has been at least a 4 hour period of observation (24 hours for hypoxic-ischaemic encephalopathy) and mechanical ventilation during which the patient has unresponsive coma, with pupils non-reactive to light, absent cough/tracheal reflex and no spontaneous breathing efforts.

This period began at (Date and time) _____

Determination of brain death by clinical examination

Preconditions

1. Hypothermia is not present – temperature is $>35^{\circ}\text{C}$ Specify temperature: _____
2. Blood pressure is adequate (e.g. MAP >60 in an adult)
3. Sedative drug effects are excluded
4. There is no severe electrolyte, metabolic or endocrine disturbance
5. Neuromuscular function is intact
6. It is possible to examine the brain-stem reflexes (including at least one ear and one eye)
7. It is possible to perform apnoea testing

Doctor A

Please \checkmark

_____ $^{\circ}\text{C}$

Doctor B

Please \checkmark

_____ $^{\circ}\text{C}$

PCO₂ _____

pH _____

PCO₂ _____

pH _____

Clinical testing

1. There is no motor response in the cranial nerve distribution to noxious stimulation of the face, trunk and four limbs **and** there is no response in the trunk or limbs to noxious stimulation within the cranial nerve distribution
2. There are no pupillary responses to light
3. There are no corneal reflexes
4. There is no gag (pharyngeal) reflex
5. There is no cough (tracheal) reflex
6. There are no vestibulo-ocular reflexes on ice-cold caloric testing
7. Breathing is absent (despite arterial PCO₂ $> 60\text{mmHg}$ (8 kPa) and arterial pH < 7.30)
8. Specify PCO₂ in **mmHg** or **kPa** (*circle one*) and pH at end of apnoea

Determination of brain death when clinical examination cannot be done:

1. There is no intracranial blood flow
2. (*Delete one as appropriate*) This has been demonstrated by *either* **intra-arterial angiography** or **other suitably reliable method** (*Specify*) _____

Doctor A

Please \checkmark

Doctor B

Please \checkmark

We have determined, according to the above procedures, that this patient is brain dead:

Doctor A (Name): _____ Doctor B (Name): _____

Status: _____ Status: _____

Signature: _____ Signature: _____

Date and time of assessment: _____ Date and time of assessment: _____

Date and time of death (End of the assessment by second doctor) : _____



AUSTRALIAN AND NEW ZEALAND INTENSIVE CARE SOCIETY

Affix patient label here

Hospital: _____

Determination of death by absence of vital signs in the context of Donation after Cardiac Death (DCD)

A. Intensive therapies (including endotracheal tube, ventilatory support, inotropic support) were withdrawn at _____ hrs (24-hour clock) on ____ / ____ / _____

B. I have determined by the absence of vital signs that death has occurred.

All of the following features were present:

(Please ✓):

- Immobility
- Apnoea
- Absent skin perfusion
- Absence of pulsatility on the arterial line of at least 2 minutes duration

C. Death occurred at _____ hrs (24-hour clock) on ____ / ____ / _____

Doctor (Printed name): _____

Status: _____

Signature: _____

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