This form is consistent with and should be used in conjunction with, the AoMRC (2008)¹ A Code of Practice for the Diagnosis and Confirmation of Death and RCPCH (2015) The diagnosis of death by neurological criteria in infants less than two months old ² and has been endorsed for use by the following institutions: Paediatric Intensive Care Society, Royal College of Paediatrics and Child Health and National Organ Donation Committee: Paediatric Subgroup. Review date: 1/5/2023

HOSPITAL ADDRESSOGRAPH or Surname:
First Name:
Date of Birth:
NHS / CHI Number

Objective of Care

- To diagnose and confirm the death of a mechanically ventilated, severely brain injured infant from 37 weeks corrected gestational age in coma, using neurological criteria.
- Validity of neurological criteria to diagnose death in infants below 37 weeks corrected gestational age: the concept of brain-death is inappropriate for infants in this age group.

Academy of the Medical Royal Colleges Definition of Human Death (2008)1

"Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person and, thus, the definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe. The irreversible cessation of brain-stem function whether induced by intra-cranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state and therefore irreversible cessation of the integrative function of the brain-stem equates with the death of the individual and allows the medical practitioner to diagnose death."

Context

- National professional guidance advocates the confirmation of death by neurological criteria wherever this seems a likely diagnosis and regardless of the likelihood of organ donation. 3,4,5,6
- UK General Medical Council (GMC) guidance on end of life care (2010) states that national procedures for identifying potential organ donors should be followed and, in appropriate cases, the specialist nurse for organ donation (SN-OD) should be notified. NICE guidance and PICS Standards recommend that the specialist nurse for organ donation (SN-OD) should be notified at the point when the clinical team declare the intention to perform brain-stem death tests.^{4,5,6}
- Date and time of referral to SN-OD: Whilst most infants will already be in an Intensive Care Unit (ICU) when the diagnosis is suspected, some may be in other areas, e.g. the Emergency Department. On such occasions, it is legitimate, if considered necessary, to transfer a patient to the ICU for the diagnosis to be made.
- For many clinicians, the diagnosis and confirmation of death using neurological criteria, will be a relatively infrequent task and may be complicated by uncertainties regarding the nature of the primary diagnosis, irreversibility and the availability of suitably experienced personnel.
- Updated guidance on the diagnosis and confirmation of death by neurological criteria in infants less than two months old was published by Royal College of Paediatrics and Child Health (RCPCH) in 2015, at the request of the AoMRC. ² These recommendations form an update to the 1991 BPA report included as an appendix in the AoMRC 2008 guidance¹.

The person with parental responsibility for the infant and other close family members should be made aware that the purpose of testing is to confirm the baby's death. If given an opportunity to witness the neurological examination, they should be appropriately supported and prepared for the possibility of spinal reflexes and their lack of relevance in the diagnosis of death by neurological criteria. Whether the baby's close family witness the clinical examination or not, the baby's need for dignity and privacy should remain paramount.

Patient Name: DOB: NHS / CHI Number:

Preconditions

The following preconditions should be met prior to testing:

- The infant is comatose and mechanically ventilated for apnoea.1
- The diagnosis of structural brain damage has been established or the immediate cause of coma is known and in particular:
- > Drugs are not the cause of coma
- Neuromuscular blockade has been demonstrably reversed
- Core temperature is > 34°C
- ➤ There is no endocrine or metabolic disturbance that could be the primary cause of the state of unresponsiveness.¹

An additional precondition to be taken in this patient population:

• In post-asphyxiated infants, or those receiving intensive care after resuscitation, whether or not they have undergone hypothermia, there should be a period of at least 24 hours of observation during which the preconditions necessary for the assessment of Diagnosis by Neurological Criteria should be present before clinical testing. If there are concerns about residual drug-induced sedation, then this period may need to be extended.²

Examining Doctors					
Examining DC	octors				
Date and time:	Patient Location				
Doctor One, Name and Designation	Doctor Two, Name and Designation				
Name: Grade:	Name: Grade:				

Guidance

- 1. The diagnosis of death by neurological criteria should be made by at least two medical practitioners. Both medical practitioners should have been registered with the General Medical Council (or equivalent Professional Body) for more than five years and be competent in the assessment of a patient who may be deceased following the irreversible cessation of brain-stem function and competent in the conduct and interpretation of the brain-stem examination. Both doctors should be paediatricians, with one being a consultant.
- 2. Those carrying out the tests must not have, or be perceived to have, any clinical conflict of interest and neither doctor should be a member of the transplant team. Clinical Leads for Organ Donation can carry out testing and are likely to have significant expertise.
- 3. Clinicians unfamiliar with the test should seek advice from Neonatal or Paediatric Intensivists in Regional Units.
- 4. Testing should be undertaken by the nominated doctors acting together and must always be performed on two occasions. A complete set of tests should be performed on each occasion, i.e. a total of two sets of tests will be performed. Doctor One may perform the tests while Doctor Two observes; this would constitute the first set. Roles may be reversed for the second set. The tests, in particular the apnoea test, are therefore performed only twice in total.

Evidence for Irreversible Brain Damage of known Actiology

Primary Diagnosis:

Patient Name:	DOB:	NHS / CHI Number:

Evidence for Irreversible Brain Damage of known Aetiology:

Guidance

- 1. The infant must have a Glasgow Coma Scale score of 3 and be mechanically ventilated with apnoea.
- 2. There should be no doubt that the infant's condition is due to irreversible brain damage of known aetiology.
- 3. It remains the duty of the two doctors carrying out the testing to be satisfied with the aetiology, the exclusion of all potentially reversible causes, the clinical tests of brain-stem function and of any ancillary investigations, in order that each doctor may independently confirm death following irreversible cessation of brain-stem function.
- 4. Occasionally it may take a period of continued clinical observation and investigation to be confident of the irreversible nature of the brain injury. The timing of the first test and the timing between the two tests should be adequate for the reassurance of all those directly concerned.
- 5. In post-asphyxiated infants, or those receiving intensive care after resuscitation, whether or not they have undergone hypothermia, there should be a period of at least 24 hours of observation during which the preconditions necessary for the assessment for DNC are present. See below for 'Red Flag' patient groups.
- 6. Stabilisation of the patient prior to testing, especially support of the cardiovascular system, is a prerequisite to testing. Mean Arterial Pressure should be consistently > 37mmHg ^{7,8} and appropriate fluid resuscitation administered. This almost invariably requires the use of inotropes / vasopressors via central or umbilical venous access.
- 7. Diabetes insipidus can develop rapidly and should be suspected in patients with a high urine output (typically >4ml/kg /hr) and rising serum sodium concentration. Matched urinary and plasma electrolytes and osmolality may assist in the diagnosis. Treatment with desmopressin, 400 nanograms IV bolus, is usually sufficient for treatment but repeated doses or vasopressin infusion may be required. Serum sodium should ideally be maintained within normal limits.

Diagnostic caution is advised in the following 'Red Flag' patient groups. (Based on the literature and unpublished case reports.) For advice in difficult circumstances contact the local or regional Clinical Lead for Organ Donation, or regional paediatric / neonatal intensive care unit.

1. Testing < 6 hours of the loss	4.	Patients with any neuro-	6. Prolonged fentanyl		
of the last brain-stem reflex		muscular disorders	infusions		
2. Testing <24 hours from the loss of last brain stem reflex where aetiology primarily anoxic damage	5.	Steroids given in space occupying lesions such as abscesses	7. Aetiology primarily located to the brain-stem or posterior fossa		
3. Hypothermia 24-hour observation period following re-warming to normothermia					

Patient Name: DOB: NHS / CHI Number:

Preparation

Evidence for Irreversible Brain Damage of known Aetiology

Case records, past medical history including possibly contacting the GP, relevant imaging.

Exclusion of Reversible Causes of Coma and Apnoea

Standard ICU cardio-respiratory monitoring (to ensure haemodynamic stability), medication chart and history, blood and urine drug assay results (where relevant), drug antagonists (e.g. flumazenil, naloxone), peripheral nerve stimulator, recent serum glucose and biochemistry, thermometer, patient warming device.

Tests for Absence of Brain-Stem Function

Brain-stem reflexes

Bright light source; small gauze sterile swabs, otoscope with disposable ear pieces, 20 - 50ml luer lock syringe and disposable quill, ice-cold water; a spatula, Yankauer sucker or laryngoscope, endotracheal suction catheters.

Apnoea test

Haemodynamic monitoring (continuous ECG, invasive arterial pressure), arterial blood gas analysis including blood gas syringes x 4, pulse oximetry and end-tidal CO₂ monitoring, means of delivering oxygen to the trachea by bulk flow (e.g. Neopuff, Ayres T piece which allows CPAP or endotracheal suction catheter and oxygen tubing).

Exclusion of Reversible Causes of Coma and Apnoea

Guidance

Attempts should be made to maintain relatively normal cardiovascular and respiratory physiological parameters in the preceding hours prior to testing. *This may not be possible and does not necessarily preclude testing.*

The key question the two doctors must exclude is the possibility that cardiovascular and respiratory instability is the cause of the observed coma and apnoea.

The answer should be no.

Suggested cardiovascular goals:

- Sinus rhythm >120 beats per minute ^{7,8}
- Mean arterial pressure >37 mmHg ^{7,8}

	1st 7	Гest	2 nd	Test
Mean arterial pressure at time of testing?				
Should be consistently > 37mmHg prior to testing.	mmHg		mmHg	
PaCO ₂ at time of testing?				
A goal of normocarbia (PaCO ₂ < 6.0 kPa), if possible, is		kPa		kPa
recommended in the preceding hours prior to testing.				
See below for <i>starting PaCO</i> ₂ in the apnoea test.				
PaO ₂ at time of testing?				
Hypoxia should be avoided ($PaO_2 > 10 \text{ kPa}$). For		kPa		kPa
infants with congenital cyanotic heart disease oxygen				
levels should be kept in their normal range				
Arterial pH/[H+] at time of testing? Acidaemia and alkalaemia should be avoided, if possible, aiming for a relatively normal pH 7.35-7.45 / [H+] 45-35 nmol/L	pH/[H+]=		pH/[H+]=	
Is the coma or apnoea due to ongoing cardio- respiratory instability? (To diagnose death using neurological criteria, ALL answers should be NO)	Dr One Yes/No	Dr Two Yes/No	Dr One Yes/No	Dr Two Yes/No

Guidance

- The infant should not have received any drugs that might be contributing to the unconsciousness, apnoea and loss of brain-stem reflexes (narcotics, hypnotics, sedatives or tranquillisers); nor should

Patient Name: DOB: NHS / CHI Number:

they have any residual effect from any neuromuscular blocking agents (atracurium, vecuronium or suxamethonium).

- It remains the duty of the two doctors carrying out the testing to be satisfied that sufficient time has elapsed to ensure that any remaining drug effect is non-contributory to the unconsciousness and loss of brain-stem reflexes. This will be based on an assessment of the medications the infant has received and from knowledge of the pharmacokinetics of these agents. Renal or hepatic failure and immaturity may prolong metabolism / excretion of these drugs. See above for 'Red Flag' patient groups.
- Serum Na⁺ levels below 115 or above 160mmol/l are associated with unresponsiveness. This should be borne in mind if the primary cause of unresponsiveness is uncertain. Testing for DNC should not be carried out if serum K^+ <2 mmol/L, or serum PO_4^{3-} and/or Mg^{2+} < 0.5 mmol/L or > 3.0 mmol/L as there may be associated severe neuromuscular weakness.
- Blood glucose should be between 3.0 20mmol/L before each brain-stem test. If there is any clinical reason to expect endocrine disturbances, then it is obligatory to ensure appropriate hormonal assays are undertaken.

appropriate normonal assays are undertaken.	1		1		
		Test		d Test	
Where there is any doubt, specific drug levels should	Drug levels		Drug levels		
be measured (Testing for DNC should not be carried	(if meas	(if measured):		(if measured):	
out if midazolam level is > 10mcg/L, or thiopentone					
level is > 5mg/L)					
Antagonists such as flumazenil, naloxone and	Drug ant	agonists	Drug anta	gonists	
neostigmine may be used but there is no specific	(if used):		(if used):		
pharmacological data for predicting the dose effect of					
these antagonists.					
Residual neuromuscular blockade can be tested for, if	Train of	Four	Train of Fo	our	
felt necessary, by peripheral nerve stimulation.	(if measu	ıred):	(if measur	ed):	
Is the coma or apnoea due to depressant drugs?	Dr One	Dr Two	Dr One	Dr Two	
	Yes/No	Yes/No	Yes/No	Yes/No	
(To diagnose death using neurological criteria,					
ALL answers should be NO)					
Body temperature at time of testing?					
If core temperature is ≤34°C testing cannot be carried		$^{\mathrm{o}}\mathrm{C}$		۰C	
out.					
Serum sodium (Na+) at time of testing?					
Serum sodium should not be < 115 or > 160 mmol/L.	mmol/L			mmol/L	
Rapid rises or falls in Na+ should be avoided					
Serum potassium (K+) at time of testing?		mmol/L		mmol/L	
Serum potassium should be >2mmol/L					
Serum phosphate (PO ₄ 3·) at time of testing?					
Serum phosphate should not be profoundly elevated		mmol/L		mmol/L	
(>3.0mmol/L) or lowered (<0.5mmol/L) from					
normal.					
Serum magnesium (Mg2+) at time of testing?					
Serum magnesium should not be profoundly elevated	vated mmol/L mm		mmol/L		
(>3.0mmol/L) or lowered (<0.5mmol/L) from					
normal.					
Blood glucose at time of testing?					
Blood glucose should be between 3.0 - 20.0 mmol/L	mmol/L mmol		mmol/L		
and should be tested prior to each test.					
If there is any clinical reason to expect endocrine	Hormone level Hormone level				
disturbances hormonal assays should be undertaken.	(if measured): (if measured)		ed):		
					
	Dr One	Dr Two	Dr One	Dr Two	

Patient Name: DOB: NHS / CHI Number:

Is the coma or apnoea due to a metabolic orendocrine disorder? (To diagnose death using neurological criteria, ALL answers should be NO)	Dr One	Dr Two	Dr One	Dr Two
	Yes/No	Yes/No	Yes/No	Yes/No
!				

Guidance

It remains the duty of the two doctors carrying out the testing to be satisfied that the only explanation for the respiratory failure is due to the irreversible cessation of brain-stem function.

A train of four examination, using a peripheral nerve stimulator, may be required. See above for 'Red Flag' patient groups.

	1 st	Test	2no	d Test
Is the apnoea due to neuromuscular blocking agents, other drugs or a non brain-stem cause? (e.g. cervical injury, any neuromuscular weakness)?	Dr One	Dr Two	Dr One	Dr Two
	Yes/No	Yes/No	Yes/No	Yes/No

Tests for Absence of Brain-Stem Function

Guidance: A complete set of tests should be performed on each occasion, i.e. a total of two sets of tests will be performed. Doctor One may perform the tests while Doctor Two observes; this would constitute the first set. Roles may be reversed for the second set. The tests, in particular the apnoea test, are therefore performed only twice in total.

test, are therefore perior filed only twice	1st Test		2nd 7	Гest
To diagnose death using	Dr One	Dr Two	Dr One	Dr Two
neurological criteria,	Examining	Observing	Observing	Examining
ALL answers should be NO				
Do the pupils react to light?				
The pupils are fixed and do not	Yes / No	Yes / No	Yes / No	Yes / No
respond to sharp changes in the				
intensity of incident light - cranial				
nerves II, III.				
Is there any eyelid movement when				
each cornea is touched in turn?	Yes / No	Yes / No	Yes / No	Yes / No
Corneal reflex - cranial nerves V, VII.				
The use of sterile gauze is				
recommended.				
Is there any eye movement seen				
during or following the slow	Yes / No	Yes / No	Yes / No	Yes / No
injection of at least 20 - 50mls ice				
cold water over 1 minute into each				
ear with the head flexed at 30°? Each				
ear drum should be clearly visualised				
before the test. Vestibulo-ocular reflex				
- cranial nerves III, VI, VIII.				
Is the gag reflex present?	¥7 / ¥1	X7 / X7	X/ / N/	N7 / N7
Use a spatula or Yankauer sucker and	Yes / No	Yes / No	Yes / No	Yes / No
laryngoscope to stimulate the posterior				
pharynx - cranial nerves IX, X.				
Is the cough reflex response present when a suction catheter is passed	Yes / No	Yes / No	Yes / No	Yes / No
down the trachea to the carina?				
Cranial nerves IX, X				
Is there any motor response in a	Vec / Ne	Voc. / No.	Vog / No	Voc. / No
cranial nerve or somatic	Yes / No	Yes / No	Yes / No	Yes / No
distribution when supraorbital				
pressure is applied? Cranial nerves V,				
VII. Reflex limb and trunk movements				
(spinal reflexes) can be present				
			<u> </u>	<u>!</u>

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Patient Name: DOB: NHS / CHI Number:

Tests for Absence of Brain-Stem Function

Preparation for the Apnoea Test

- End tidal carbon dioxide can be used to guide the start of each apnoea test but should not replace the pre and post arterial paCO₂.
- Oxygenation and cardiovascular stability should be maintained through each apnoea test.
- Pre-oxygenate FiO₂ 1.0.
- The baseline PCO2 should be ≥ 5.3kPa (40mmHg) with a rise of > 2.7kPa (20mmHg) to > 8.0Kpa (60mmHg) with no respiratory response at that level. A stronger hypercarbic stimulus is needed to establish respiratory unresponsiveness in this patient population. The lack of spontaneous respiratory effort in response to this hypercarbic stimulus is the most important clinical observation during the apnoea test. It is recommended that the period of observation should be at least 5 minutes providing haemodynamic stability can be maintained.
- Cardiac pulsation may be sufficient to trigger supportive breaths if the patient remains connected to the mechanical ventilator and on a spontaneous breathing mode. Performing the apnoea test whilst remaining on mechanical ventilation is not recommended.

Guidance:

It is important to maintain oxygenation above 85% and cardiovascular stability. Recommended methods:

- CPAP circuit (e.g. Neopuff or Ayres T piece), especially if oxygenation is a problem, or
- Disconnect the infant from the ventilator and administer oxygen via a catheter in the trachea at a rate of 2 6 L/minute. Ensure oxygen catheter does not occlude ETT.
- Considerable atelectasis develops in the apnoeic period. At the conclusion of the apnoea test, manual recruitment manoeuvres should be carried out before resuming mechanical ventilation.

	1s	^t Test	2nd Test		
Arterial Blood Gas PRE apnoea test:	1st Test		2 nd Test		
Confirm $PaCO_2$ baseline is ≥ 5.3 kPa.	Starting PaC	O ₂ :	Starting PaCO ₂ :		
In patients with chronic lung disease, or		kPa		kPa	
those receiving intravenous bicarbonate,					
it is recommended that a higher PaCO2	Should b	oe ≥ 5.3 kPa	Should	l be≥5.3 kPa	
which results in a normal pH in that					
patient should be aimed for.					
Start time:		hr : min		hr : min	
Time when apnoea test was commenced.		(24-hour clock)		(24-hour clock)	
	Perform lui	ng recruitment	Perform lung recruitment		
Arterial Blood Gas POST apnoea test:	1st Test		2 nd Test		
Ensure the PaCO ₂ shows a clear rise of	Stopping Pa	CO_2 :	Stopping PaCO ₂ :		
> 2.7 kPa (> 20 mmHg) above the	kPa			kPa	
baseline to > 8.0 kPa (60 mmHg).	Should have increased			e increased	
	by > 2.7 kPa		by > 2.7 kP		
Stop time:		hr : min		hr : min	
Time when apnoea test was ceased.		(24-hour clock)		(24-hour clock)	
	Perform lung recruitment		Perform l	ung recruitment	
Was there spontaneous respiration	Dr One	Dr Two	Dr One	Dr Two	
during the apnoea test?					
_	Yes	Yes	Yes	Yes	
(To diagnose death using neuro-logical	/	/	/	/	
criteria, ALL answers should be NO)	No	No	No	No	

Patient Name: DOB: NHS / CHI Number:

Ancillary Investigations Used to Confirm the Diagnosis

Guidance

Ancillary tests are not required to make a diagnosis of the death by neurological criteria in infants from 37 weeks corrected gestation (post menstrual) to two months post term.

In cases where a clinical diagnosis of death by neurological criteria is not possible (for example because of extensive facio-maxillary injuries or high cervical cord injury), ancillary tests are not sufficiently robust to help confidently diagnose death by neurological criteria in infants. ²

Completion of Diagnosis							
	Те	st 1	To	est 2			
Are you satisfied that death has been confirmed following the irreversible cessation of brain-stem function?	Dr One Yes/No	Dr Two Yes/No	Dr One Yes/No	Dr Two Yes/No			
Legal time of death is when the 1st Test indicates death due to the absence of			Date: Time:				
brain-stem reflexes.	Dr One signature		Dr One signature				
Death is confirmed following the 2^{nd} Test.	Dr Two signature		Dr Two signat	ure			

References

- 1. Academy of Medical Royal Colleges (2008) "A Code of Practice for the Diagnosis and Confirmation of Death" http://www.aomrc.org.uk
- 2. Royal College of Paediatrics and Child Health (2015) "The diagnosis of death by neurological criteria in infants less than two months old" www.rcpch.ac.uk
- 3. Report from the Organ Donation Taskforce (2008) "Organs for Transplant" http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 082122
- 4. GMC (2010) "Treatment and care towards the end of life." www.gmc-uk.org/guidance/ethical guidance/end of life care.asp
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- 7. Advanced Paediatric Life Support A Practical Approach to Emergencies (2016)
- 8. Dionne et al (2012) Hypertension in infancy; diagnosis, management and outcome. Paediatric Nephrology 27:17-32 doi 10.1007/s00467-010-1755-z
- 9. A series of helpful education videos are available: https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/donation-after-brainstem-death/diagnosing-death-using-neurological-criteria/

Form authorship and feedback

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Patient Name:	DOB:	NHS / CHI Number:
ratient Name:	DOR:	NHS / CHI Number:



Attach Arterial Blood Gases

Additional notes