Determination of Death by Brain Criteria for Infants and Children Policy

Policy Owner: Chief Medical Officer

POLICY STATEMENT
This document establishes a uniform approach to rendering a diagnosis of death based on failure of brain function for infants and children. This has been referred to as brain death, but must be understood to be no different than a diagnosis of death made by other criteria.

Death by brain criteria is defined under Georgia state law as the total and irreversible cessation of spontaneous brain functions, in which further attempts of resuscitation or continued supportive maintenance would not be successful in restoring such function. Stated more simply, brain death is the irreversible loss of all function of the brain, including the brainstem. A patient determined to be brain dead is legally and clinically dead.

AFFECTED STAKEHOLDERS
Indicate all entities and persons within the Enterprise that are affected by this policy:

☐ Administrative Services
☐ Hired Staff
☒ House Staff/Residents & Clinical Fellows
☒ Leased staff
☒ Medical Staff (includes Pediatric neurologists, neurosurgeons, and critical care physicians who provide care to infants/children < 18 years)
☒ Patient Care Services (Nursing, PCT's, Unit Clerks)
☐ Professional Services (Laboratory, Radiology, Respiratory, Pharmacy; etc.)
☐ Vendors/Contractors
☒ Other: Allied health professionals who provide care to critically ill infants and children should be familiar with this policy.

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DEFINITIONS
The three essential findings in brain death are coma, absence of brainstem reflexes, and apnea. An evaluation for brain death should be considered in patients who have suffered a massive, irreversible brain injury from an identifiable cause. Brain death from primary neurological disease is usually a result of severe head injury or cerebrovascular events. Global ischemic brain insults or fulminant hepatic failure, among other diagnoses, may also result in irreversible loss of brain function.

The diagnosis of brain death is primarily clinical. No other tests are required if two full clinical evaluations which includes an examination of brain stem reflexes and an apnea test, are conclusively performed. Ancillary testing is required ONLY in situations in which the clinical determination is unavoidably inadequate, e.g., in cases of severe facial trauma, drug intoxication, severe metabolic disturbances, or when the apnea test cannot be performed safely. In the absence of complete clinical findings consistent with brain death (with or without the aid of ancillary tests demonstrating brain death), brain death cannot be diagnosed. These guidelines do not replace the physician's judgment in individual cases since brain death is a clinical diagnosis.

PROCESS & PROCEDURES

General Information:
A neurologist, neurosurgeon, or critical care specialist must perform two full neurological examinations including an apnea with each examination. If a resident or fellow performs the exam, it must be under the direct supervision of the attending physician.

This policy and procedure was developed utilizing the guidelines outlined by the Society of Critical Care Medicine; the Section on Critical Care and Section on Neurology of the American Academy of Pediatrics; and the Child Neurology 2011 task force.

A member of the Respiratory Therapy Department must be present during the apnea testing procedure.

As soon as it is anticipated that a patient will meet criteria for being a potential organ donor, a referral must be made to the organ procurement organization (LifeLink of Georgia), ideally within 1 hour and prior to the withdrawal of any life sustaining therapies (State Operations Manual Appendix A-survey Protocol, Regulations and Interpretive Guidelines for Hospitals-Tag A0886 §482.45(a)(1)).

Whenever possible, the referral should be made early enough to allow the organ procurement organization to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor.
In cases in which the process of determining death by brain criteria may be in conflict with religious, cultural or personal beliefs of the patient or the patient's family, consultation of the Medical Ethics Committee may be helpful.

Waiting Period before Initial Clinical Examination:

Waiting for 24 hours after cardiopulmonary resuscitation or severe acute brain injury is recommended if there are any concerns about the neurologic examination or if dictated by clinical judgment.

Number of Clinical Examinations and Apnea tests:

Two separate examinations and two separate apnea tests irrespective of ancillary study results should be performed by 2 separate examiners. (If ancillary testing is being done in lieu of initial examination elements that cannot be safely performed, the components of the second examination that can be done must be completed.)

Critical Care Physicians should have primary responsibility for the clinical examinations, but Pediatric Neurologist or Neurosurgeon may perform second clinical examination.

Observation Interval between 2 Clinical Examinations:

- Term newborn (37 weeks gestation) to 30 days of age: 24 hrs
- 31 days to 18 yrs: 12 hrs

Patient Status Prior to Initiation of Testing for Death by Brain Criteria:

1. The proximate cause must be known, and must be known to be irreversible. There must be clinical or neuroimaging evidence of an acute central nervous system catastrophe that is compatible with the clinical diagnosis of death by brain criteria.

2. The patient must demonstrate an absence of severe acid-base, electrolyte, or endocrine abnormalities that may confound clinical assessment. What constitutes a "severe" abnormality is left to the judgment of the evaluating physician.

3. Toxicology screening must be negative for significant confounding substances. CNS-depressing medications (e.g., narcotics, sedatives, hypnotics, anticholinergics) should be discontinued. Adequate clearance (based on the age of the child, presence of organ dysfunction, total amount of medication administered, elimination half-life of the drug, and any active metabolites) should be allowed before the neurologic examination. In some instances, this may require waiting several half-lives and rechecking serum levels of the medication before conducting the brain death examination. Renal or hepatic dysfunction or preceding hypothermia may prolong clearance. If high suspicion for unknown or unmeasurable CNS-depressants, consider ancillary testing. The half-life of the above mentioned drugs could be prolonged in patients who have received
Therapeutic Hypothermia. Caution is advised, and in stable, recently rewarmed patients, several days of observation may be needed to allow for clearance of the medications.

4. The patient must demonstrate an absence of neuromuscular blockade through electrical stimulation (e.g. with train-of-four nerve stimulation) if neuromuscular blocking agents have been administered recently or for a prolonged period.

5. The patient must be normothermic (core temperature \( \geq 35^\circ\text{C} \) (95°F). Temperature may be supported artificially (e.g. with a warming blanket, etc.).

6. The patient must maintain a stable systolic blood pressure (greater than 2 Standard Deviations or 5th centile for age). Blood pressure may be supported pharmacologically.

In the presence of confounding variables, brain death may be determined with the aid of ancillary tests (see ancillary testing section below).

Components of the Clinical Examination:

The cardinal findings in brain death are coma, absence of brainstem reflexes, and apnea.

1. **Coma**: defined as the absence of any cerebrally-mediated response to noxious stimuli including pain in all extremities (nail-bed pressure) and in the head (e.g. supraorbital or temporo-mandibular joint pressure). "Spinal" reflexes are consistent with brain death, but decorticate and decerebrate posturing are not.

2. **Absence of brain stem reflexes:**
   - **Pupils**
     - No response to bright light. A magnifying glass may be useful if response is questionable.
     - Size: from mid-position (4 mm) to dilated (9 mm). Small or pinpoint pupils should alert the clinician to the possibility of narcotic intoxication (but may also be seen with pontine injury or ocular surgery/disease).
   - **Ocular movement**
     - No oculocephalic reflex (test only when the integrity of the cervical spine is ensured).
     - No oculovestibular reflex: Deviation of the eyes to irrigation in each ear with 10 – 50 ml of ice water. Observe for 1 minute after irrigation and wait at least 5 minutes before testing on the opposite side. Testing may be confounded by blood or cerumen in the auditory canal, a disrupted tympanic membrane or injury to the globes or orbits. Perform otoscopy prior to oculovestibular testing.
   - **Facial motor response to stimulation**
     - No corneal reflex to touch with a cotton swab.
• No facial grimacing to any noxious stimulation, including insertion of a Q-tip into the nares.
• Facial myokymias (from denervation of the facial nerve) are permissible.
• **Pharyngeal and tracheal reflexes**
  • No response to stimulation of the posterior pharynx with tongue blade.
  • No coughing or significant bradyarrhythmia with bronchial suctioning.

3. **Apnea:**
   In addition to previously described pre-examination conditions, the patient also must demonstrate the following conditions before initiation of the apnea test:
   • **Eucapnea** (PaCO2 35 – 45 mmHg)
     o For patients with chronic CO2 retention (e.g., COPD, severe obesity), the baseline PaCO2 (if known) represents the state of eucapnea. Ancillary testing should be considered in such cases, especially if the baseline PaCO2 is unknown.
   • **Euvoolemia**
     o If the patient requires significant pharmacologic support to maintain blood pressure or demonstrates unstable cardiac dysrhythmias, consider ancillary testing.

**The Apnea Test**
There should be 2 documented apnea tests at required interval.

1. **Preparation:**
   • Set the patient’s ventilator to deliver 100% oxygen and reduce the positive end-expiratory pressure (PEEP) to 5cm H2O for 10 or more minutes prior to initiating the test. Oxygen desaturation or PaO2 < 200mmHg with these ventilator settings may predict difficulty with apnea testing that would preclude safe completion of the examination.
   • After 10 or more minutes on the prescribed ventilator settings, obtain a baseline arterial blood gas.

2. **Procedure:**
   • Remove the patient from the ventilator.
   • Deliver oxygen via a T-Piece connected to 5 cm PEEP valve at 10 liters per minute.
   • Observe the patient for respiratory effort (abdominal or chest excursions).
   • Monitor Oxygen saturation and Blood Pressure.
   • Obtain an arterial blood gas 5 minutes and 10 minutes after the initiation of the apnea test.

3. **Interpretation of test:**
   • If spontaneous respiratory movements are not observed and the final arterial blood gas shows a PaCO2 greater than or equal to 60mm Hg (or in the case of known CO2 retention, a PaCO2 20mm Hg above the pre-test baseline), apnea has been demonstrated. This supports the diagnosis of death by brain
criteria.
- If the PaCO2 was inconclusive after 10 minutes and the patient remained stable for the duration of the testing, the test may be repeated with the time extended to 12-15 minutes.

4. **Reasons to abort the test:**
   - Spontaneous respirations or respiratory effort (absence of apnea does not meet criteria for brain death);
   - Pulse oximetry < 85% for more than 30 seconds (can re-attempt apnea test with a T-piece, Oxygen 100% at 12 liters per minute);
   - Systolic blood pressure of less than 5th centile for age (see Appendix E for table of acceptable ranges of systolic blood pressure for 5th centile by age group); and
   - If the apnea test is aborted due to dysrhythmias, oxygen desaturation, or hemodynamic instability, obtain an arterial blood gas and resume artificial ventilation at pre-test settings. Ancillary testing may be necessary to make the determination of death by brain criteria.
   - The patient should be placed back on mechanical ventilator support and medical management should continue until the second neurologic examination and apnea test confirming brain death is completed.

**Clinical Observations Compatible with the Diagnosis of Brain Death**

These manifestations are occasionally seen and may be misinterpreted as evidence of brain stem function:

1. Spontaneous spinal reflexes in the limbs (not to be confused with pathologic flexion or extension responses, which are NOT consistent with brain death);
2. Respiratory-like movements (shoulder elevation and adduction, back-arching, intercostal expansion without significant inspiratory tidal volumes) that may trigger the ventilator to deliver a breath;
3. Sweating, blushing, tachycardia;
4. Normal blood pressure in the absence of pharmacologic support;
5. Absence of diabetes insipidus (i.e., normal osmolar control mechanism remains intact);
6. Deep tendon reflexes, triple flexion responses or Babinski's reflex; and
7. Facial myokymias.

**Ancillary Tests Supporting the Diagnosis of Brain Death**

1. **Conventional angiography:** Contrast injected under pressure into the aortic arch should demonstrate no intracerebral filling at the point of entry of either carotid or vertebral artery to the skull. The external carotid circulation is patent, and delayed filling of the superior sagittal sinus may be seen.
2. **Nuclear flow study:** Scintigraphy using isotope should demonstrate no uptake or flow of isotope in the brain parenchyma. The extracranial circulation should
fill, allowing for uptake within the meninges and skull vessels. The nuclear medicine attending physician should interpret and report the test results.

3. **Electroencephalography**: Electrocerebral activity should be absent for the duration of a recording period of at least 30 minutes. The following parameters must be followed to ensure validity of the test:
   - Integrity of entire system tested by EEG technician (EKG artifact should be visible);
   - Minimum of 8 scalp electrodes used;
   - Distance between electrodes greater than or equal to 10 cm;
   - Interelectrode impedance between 100 and 10,000;
   - Sensitivity increased to at least 2 microvolts;
   - High and low frequency filters should not be set below 30 Hz or above 1 Hz, respectively;
   - Electroencephalography should demonstrate lack of reactivity to intense auditory, visual, or painful somatosensory stimulation; and
   - Absence of EEG activity must be confirmed and documented by a neurology attending.

4. **Transcranial doppler ultrasonography**: Reverberating flow or small systolic peaks in early systole without diastolic flow are consistent with brain death. The test must be performed bilaterally, as well as anteriorly and posteriorly. Complete absence of flow may not be reliable owing to inadequate transtemporal windows for insonation. Diagnosis established by intracranial examination must be confirmed by the extracranial bilateral recording of flow in the common carotid, internal carotid, and vertebral arteries.

5. Insufficient data exists to support the use of CT angiography, MRI, MR angiography, or somatosensory evoked potentials for brain death determination; thus these are not currently considered to be acceptable ancillary tests.

**Documentation in the Medical Record**

The declaration of death by brain criteria must be documented in the medical record as a death note in a manner similar to any other declaration of death and include the following information:

1. Etiology and irreversibility of coma;
2. Absence of motor response to pain;
3. Absence of brain stem reflexes;
4. Details of the apnea test, including pre and posttest arterial blood gas values;
5. Justification for ancillary testing, if performed, along with results and name of the attending physician responsible for interpretation;
6. Results of repeat neurological examinations;
7. The date and time of declaration of death
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- Time of death is defined as the time apnea is confirmed (the time the final arterial blood gas is recorded) or the time when the ancillary test is officially interpreted;
8. The name of the two attendings (critical care attending, attending neurologist, or attending neurosurgeon) that determined death by brain criteria;
9. Indication that the Medical Examiner was contacted (refer to the Report of Death Form); and
10. Indication that the OPO was contacted.

A procedural checklist form (Appendix A) is provided to assist with the documentation of brain death in the medical record. Its use is required and it must be filed in the patient's chart after completion of each brain death testing. For Infants and Children, one copy designated Initial Test is to be used for first examination performed. One copy designated 2nd Test is to be used for the second examination performed. It is appropriate to write a brief narrative note summarizing the indications for and results of brain death testing as recorded in this document.

REFERENCES, SUPPORTING DOCUMENTS, AND TOOLS


See Appendix A for Procedural checklist for documentation of brain death examination for infants and children.

See Appendix B for Medications administered to critically ill pediatric patients and recommendations for time interval to testing after discontinuation.


See Appendix D for Algorithm to diagnose brain death in infant and children.
See Appendix E for Table of acceptable ranges of Systolic BP > 2 Standard Deviations or 5th centile by age group.

RELATED POLICIES

Organ, Eye, Tissue Donation

APPROVED BY

Chief Executive Officer, AU Medical Center  Date: 07/28/2016