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POLICY

This policy will detail the medical practice parameters at Beaumont Hospitals for the determination of death by neurological criteria.

DEFINITION

The Michigan “Determination of Death Act” of 1992 defines death as follows:

An individual, who has sustained either of the following, is dead:

- Irreversible cessation of circulatory and respiratory functions.
- Irreversible cessation of all function of the entire brain, including brain stem.

A determination of death shall be made in accordance with accepted medical standards.

GENERAL

1. Death by neurological criteria (Brain death) is diagnosed by clinical criteria, at times supported by ancillary studies as outlined below. Ancillary studies are not required to establish brain death and are **not** a substitute for neurologic examination.
2. Two (2) full clinical neurologic examinations, each including an apnea test, by two different physicians, as outlined below, must be performed and documented on the age-appropriate “Determination of Death by Neurological Criteria” form. The first examination determines that the patient has met the accepted neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition.
3. No member of the transplant team and no physician caring for an intended recipient may participate in either exam or certify the patient’s death.
4. The decision to certify brain death must be independent of decisions regarding the appropriateness and feasibility of organ or tissue donation.
5. Irreversibility of loss of brain and brain stem functions is recognized when the cause of the patient’s unresponsive state is established by clinical evaluation and appropriate investigations, and is sufficient to account for the loss of function of the entire brain. The possibility of recovery is excluded by observation as outlined below and an unchanged second clinical examination.
6. The first brain death examination should be done at least 4 hours after the initial brain insult to allow for stabilization time. In children, assessment of neurologic function may be unreliable immediately following resuscitation after cardiopulmonary arrest or other acute brain injuries. It is reasonable to defer the neurological examination to determine brain death for ≥ 24 hours in children if dictated by the clinical judgment of the treating physician in such circumstances.

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<p>7. The recommended observation periods between the first and second examinations are age-specific as outlined below.</p> <p>8. Ancillary studies are not required to establish brain death except in one of the following situations:</p> <ul style="list-style-type: none">a. A portion of the clinical examination, including apnea testing, cannot be fully performed due to the underlying medical condition of the patient.b. If a neurodepressant drug alters the clinical examination, in which case a brain perfusion test must be done.c. The etiology of coma is not certain or there is uncertainty about the results of the neurologic examination.d. To reduce the observation period between the two (2) clinical examinations. In this instance, the second clinical examination is to be performed after the results of the supporting ancillary study are documented in the medical record by the radiologist or by the neurologist, neurosurgeon, or intensivist performing the clinical examination. <p>If the ancillary study supports the diagnosis, a second clinical examination and apnea test should be performed and components that can be completed must remain consistent with brain death. If the ancillary study is equivocal, a waiting period of 24 hours should be observed before further clinical re-evaluation or repeat ancillary study is performed. Supportive patient care should continue during this time period.</p> <p>9. Ancillary studies are classified in two categories:</p> <ul style="list-style-type: none">a. Brain perfusion tests that include: Conventional four-vessel cerebral contrast angiography, cerebral perfusion scintigraphy, magnetic resonance angiography (MRA), CT angiography (CTA) with CT perfusion, or transcranial Doppler ultrasound. A brain perfusion scan must be done if a neurodepressant drug alters the clinical examination. Conventional four-vessel cerebral contrast angiography is the gold standard for determining absence of cerebral blood flow (CBF). This test can be difficult to perform in infants and children. Radionuclide CBF determinations to document the absence of CBF remain the most widely used brain perfusion scan to support the clinical diagnosis of brain death in infants and children. Radionuclide CBF testing must be performed in accordance with guidelines established by the Society of Nuclear Medicine and the American College of radiology. MRA, CTA, perfusion MRI and transcranial Doppler have not been studied sufficiently nor validated in infants and children and cannot be recommended as ancillary studies to assist with the determination of brain death in children at this time.b. Electroencephalography (EEG) is acceptable if there is no concern about neurodepressant drugs. The EEG should show no electrocerebral activity during a 30-minute period using techniques for brain death examination in accordance with standards established by the American Electroencephalographic Society. The presence of EEG artifacts should not exclude the diagnosis of brain death as long as there is no discernible electrocerebral activity.			

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10. The two Beaumont Hospital forms “Determination of Death by Neurological Criteria – Adults” (form #4695) and “Determination of Death by Neurological Criteria – Pediatrics” (form #9) must be consistent with this policy and should include documentation of the cause of coma and results of any ancillary studies if performed.

11. The documented CPR status will be followed during the neurological examinations for determination of brain death as discussed with the family or next of kin.

12. Brain death is not the only circumstance in which termination of artificial life support is medically appropriate (See: Guidelines for Withdrawing or Withholding Life Sustaining Treatment, policy #307).

AGE-SPECIFIC REQUIREMENTS

Adult patients (18 years of age or older)

Only a neurologist, neurosurgeon or intensivist may perform the brain death examination.

a. Recommended observation periods between the two examinations are:

- 6 hours for direct structural cerebral damage (intra-cerebral hemorrhage, stroke, trauma, etc.)
- 12 hours for non-direct, non-structural cerebral damage (hypoxic-ischemic encephalopathy).

b. Ancillary studies are optional and not required to establish brain death unless:

- A portion of either of the two (2) required clinical examinations, including apnea testing, cannot be fully performed due to the underlying medical condition of the patient.
- The clinical examinations are altered by a neurodepressant drug, in which case a brain perfusion test is required.
- The etiology of the coma is not certain or there is uncertainty about the results of the neurologic examination.
- To reduce the observation period between the two (2) examinations. In this instance the second clinical examination is to be performed **after** the results of the supporting ancillary study are documented in the medical record by the radiologist or by the neurologist, neurosurgeon, or intensivist performing the clinical examination.

If applicable, documentation of the need for, as well as the results of, the ancillary study performed must be included on the “Determination of Death by Neurological Criteria – Adults” (form #4695)

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Pediatric patients (less than 18 years of age)

Only a neurologist, neurosurgeon, intensivist, or neonatologist may perform the brain death examination.

- Determination of brain death in term newborns (37 weeks gestational age), infants and children is a clinical diagnosis based on the absence of neurologic function with a known irreversible cause of coma. Two (2) examinations, including apnea testing with each examination, separated by an observation period are required.
- Recommended age-specific observation periods between the two examinations:
 - Term newborns (37 weeks gestational age) to 30 days of age: 24 hours
 - Infants and children >30 days to 18 years of age: 12 hours
 - Adults (18 and older): 6 hours for direct, structural cerebral damage (intra-cerebral hemorrhage, stroke, trauma, etc.) and 12 hours for non-direct, non-structural cerebral damage (hypoxic-ischemic encephalopathy).
 - The first examination determines the patient has met the accepted neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition.
 - Assessment of neurologic function following cardiopulmonary resuscitation or other severe acute brain injuries in children should be deferred for 24 hours or longer if there are concerns or inconsistencies in the examination.

a. Ancillary studies are optional and not required to establish brain death unless:

- A portion of the clinical examination, including apnea testing, cannot be fully performed due to the underlying medical condition of the patient.
- The clinical examination is altered by a neurodepressant drug, in which case a brain perfusion test is required.
- The etiology of the coma is not certain or there is uncertainty about the results of the neurologic examination.
- To reduce the observation period between the two (2) examinations. In this instance, the second clinical examination is to be performed **after** the results of the supporting ancillary study are documented in the medical record by the radiologist or by the neurologist, neurosurgeon, intensivist, or neonatologist performing the clinical examination.

If applicable, documentation of the need for, as well as the results of, the ancillary study performed must be included on the "Determination of Death by Neurological Criteria – Pediatrics" (form #9)

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CLINICAL CRITERIA FOR DETERMINATION OF BRAIN DEATH IN ADULT AND CHILDREN

Clinical Criteria Relating to Determination of Brain Death

1. The proximate cause of the patient's unresponsive state should be established, should be sufficient to account for the loss of brain and brain stem functions, and should be irreversible.

1. Reversible conditions should be excluded, such as:

- Acute intoxication or poisoning.
- Severe electrolytes, acid-base, or metabolic disorders.
- Severe hypothermia, 32° C (90°F) or lower.
- Severe hypotension (< 5th percentile for age for children or systolic blood pressure < 90 mm Hg for adults).
- Cardiogenic shock
- Administration of neuromuscular blocking agents.
- Administration of high dose sedatives, hypnotics, anesthetics or barbiturates for control of elevated intracranial pressure or status epilepticus.
- Presence of reversible peripheral neuropathy (i.e. Guillain-Barre).

If any of the above conditions exist, they should be treated and corrected prior to the initiation of brain death examinations.

2. A clinical diagnosis of brain death can be made in patients who received sedatives, hypnotics, anesthetics or barbiturates if:
 - Drug levels (e.g. barbiturates) are in the therapeutic range and below clinically-significant neurodepressant levels, or
 - At least four times the elimination half-life of the medication has elapsed, or the effect of the medication was reversed.
 - In the case of a patient receiving a neuromuscular blocking agent, the peripheral nerve stimulation test is normal.

Clinical Examination Criteria

1. A core body temperature of ≥ 35 degrees Celsius (95 degrees Fahrenheit) should be achieved and maintained during examination and testing to determine brain death.
2. Coma characterized by absence of spontaneous or induced cerebral motor response to painful stimulation that is applied within the *cranial nerve* distribution. Decerebrate and decorticate responses or seizures are absent.
3. Absence of pupillary light reflexes (fixed pupils) and the pupil size is mid-position (4mm) or dilated (up to 9mm).

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4. Absence of corneal reflexes.
5. Absence of spontaneous eye movements.
6. Absence of eye movements in response to vestibular stimulation by cold caloric testing (50 ml ice water each side; 5 minute interval between sides).
7. Absence of eye movements in response to oculocephalic reflex testing.
8. Absence of gag reflex in response to stimulation of posterior pharynx.
9. Absence of cough reflex in response to deep bronchial suctioning.
10. Absence of spontaneous respiration at a $pCO_2 \geq 60$ mmHg and an increase in pCO_2 of ≥ 20 mmHg above pre-apnea test level. Evident respiratory acidosis at the completion of the apnea test. For adults, the apnea test should be done using the apneic diffusion oxygenation technique to prevent hypoxia performed with a 10cmH₂O peep valve. The body temperature should be at 35°C or higher before the apnea test. The patient should be monitored during the exam with an arterial line. The certifying physician must continuously observe the patient for any respiratory effort throughout administration of the test.

CLINICAL OBSERVATIONS STILL COMPATIBLE WITH THE DIAGNOSIS OF BRAIN DEATH

These manifestations are occasionally seen and should not be misinterpreted as evidence for brain stem function.

1. Spontaneous 'spinal' movements of limbs (not to be confused with pathologic flexion or extension response)
2. Respiratory-like movements (shoulder elevation and abduction, back arching, intercostals expansion without significant tidal volumes)
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)
6. Deep tendon reflexes, triple flexion responses or Babinski's reflex, all of which may be spinally-mediated reflexes
7. Facial myokymias

CERTIFICATION OF DEATH BY NEUROLOGICAL CRITERIA

1. The two physicians who perform the neurological examinations for determination of brain death must:

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<div>a. Document their findings on the age-appropriate “Determination of Death by Neurological Criteria” form.</div> <div>b. They should document the cause of the coma, the reasons for and the results of any ancillary studies, if performed. They should document the date and time of each clinical examination and sign the form.</div> <div>c. Upon confirmation of brain death following two (2) documented clinical examinations for determination of death by neurological criteria, a No CPR/Do Not Call the CPR Team order will be written in the medical record. If the patient is a consented organ donor and family has consented to full CPR status for the purpose of keeping the organs viable, this will be documented in the medical record.</div> <div>2. If the patient’s condition is within the described criteria, the patient is pronounced dead by the physician who performed the second clinical examination. The date and time of death are the date and time of completion of the second clinical examination. The completed form must be entered in the patient’s medical record.</div> <div>3. The pronouncing physician must inform the family or the next of kin that the patient has died. Mechanical ventilation and other supportive measures should be withdrawn unless organ donation is requested (see policy 311 “Anatomic Gift Requests”) or there are other documented reasons for maintaining ventilatory support for a brief time, except in rare cases not to exceed 24 hours. If the patient’s family objects to the use of neurological criteria for death, an Ethics Consultation should be requested before withdrawal of life support.</div>			

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