Penn Presbyterian Medical Center Clinical Practices of the University of Pennsylvania ADMINISTRATIVE POLICY MANUAL	Number: 11.123 Pages:: **1** of **7** Effective: 1.8.2020
SUBJECT: **POLICY REGARDING DETERMINATION OF DEATH BY NEUROLOGIC CRITERIA IN PATIENTS 18 YEARS OF AGE OR OLDER**	

Key Words:
Brain Death
Coma

See Also:
11.124 "Criteria for Post Morten Care"

11.136 Organ and Tissue Donation

11.121 Withholding and Withdrawal Life Sustaining Therapy

01.183 Treatment and Admission of Adolescent Patients

11.123A Determination of Death in Neonates or Patients Less than 18 years of Age by Neurological Criteria

POLICY

In accordance with the Pennsylvania Uniform Determination of Death Act, an individual is dead after sustaining either: (1) irreversible cessation of circulatory and respiratory functions; or (2) irreversible cessation of all functions of the entire brain, including the brain stem. The determination of death must be made by two clinical examinations including an apnea test, in accordance with acceptable medical standards.

PURPOSE

An individual with irreversible cessation of all brain function, including the brain stem, is dead. The purpose of this policy is to define the medical criteria that are to be used in the determination of death of a patient due to irreversible cessation of functioning of the entire brain (death by neurologic criteria). It is not intended to replace the judgment of a physician regarding futility of care in an acute situation.

SCOPE

This policy applies to Penn Presbyterian Medical Center (PPMC) and all patients who are at least 18-years-old, admitted to a bed or service at Penn Presbyterian Medical Center (PPMC). For patients less than 18-years-old, see separate policy, "11.123A"

IMPLEMENTATION

This policy applies to attending physicians with privileges to determine brain death, and for the apnea testing portion of brain death determination, to select house staff who are acting as a proxy for or under the authority of attending physicians with privileges to determine brain death and to auxiliary staff who are authorized to perform apnea testing within their scope of practice.

Chair of the Medical Executive Committee (MEC), chair and chief of clinical departments, Attending Physicians and house staff physicians are to implement this policy.

SUPERSEDES: 1.20.15; 6.2013; 9.2001; 3.2005; 7.2004; 3.1994; 3.1991; 11.1.1988;	ISSUED BY: /s/ Gregory Tino, MD

PROCEDURE

Determination of Irreversible Cessation of all Functions of the Entire Brain Including the Brain Stem

DIAGNOSTIC CRITERIA AND EXAMINATION PROCEDURES

The clinical diagnostic criteria in sections A, B, and C below must be met to declare death by neurologic criteria. Where indicated, the clinical diagnosis must be confirmed by a "confirmatory study."

A. Prerequisites:
Prior to initiating the clinical examinations and the apnea test, the following prerequisites must be met:
1. The cause of coma must be known and there must be clinical and/or neuroimaging evidence of an acute central nervous system catastrophe that is compatible with the clinical diagnosis of brain death. The injury must, in the clinical judgement of the examiner, be sufficient to cause irreversible loss of whole brain function.
2. Exclusion of the following medical conditions that might, according to the judgment of the examiner, confound the clinical assessment:
    a. Severe electrolyte, acid-base, endocrine, or nutritional disturbances.
    b. Intoxication. Toxicological screening should be performed when drug intoxication, medication intoxication, or poisoning is suspected. Specific levels of central nervous system (CNS) depressants that might complicate the examination are left to clinical judgment. Narcan administration should be considered prior to formal examination of patients that have a history of opiate use, to whom opiates have been administered, or in whom toxicological screening is positive for opiates.
    c. Pharmacological paralysis. Absence of neuromuscular blockade must be established either by history or with the use of a twitch monitor.
    d. Significant hypothermia. Core body temperature must be $\geq$ 36° C (96.8° F)
    e. Significant hypotension. Systolic blood pressure must be $\geq$ 100 mmHg or, for patients on ECMO, MAP must be $\geq$ 65 mmHg. These targets may be achieved with or without pressors.
    f. Medical conditions that might mimic brain death. These include a locked-in state, severe neuromuscular disease (e.g. Guillain-Barre syndrome, botulism), and akinetic mutism. These conditions may be excluded by clinical history, physical examination, or further testing.

3. For patients who have had a cardiac arrest, an observation period of at least 24 hours after return of spontaneous circulation if targeted temperature management was not employed, or 24 hours after rewarming if targeted temperature management was employed, must elapse prior to initiating brain death determination.

B. Clinical Examinations

1. Two examinations must be performed at Penn Presbyterian Hospital that each establish the cardinal features of brain death: coma; absence of brainstem reflexes; and apnea.
    a. Coma is defined as absence of observable motor responses, other than reflexes mediated by the spinal cord, after noxious stimuli. This is tested by the sequential application of pressure to both supraorbital ridges and nailbed pressure to each limb.
    b. Absence of each of the following brainstem reflexes:
        i. Pupillary light reflex
            1. The pupils should be $\geq$ 4 mm in diameter and demonstrate no response (constriction) to bright light. Examination of the pupils should be by direct observation and may (optional) be aided with the use of an automated pupilometer.
        ii. Facial motor responses to stimulation
            1. Absence of corneal reflexes (the cornea of each eye should be touched with a cotton wisp or gauze)
            2. No facial grimacing to pain applied in a trigeminal distribution (e.g. supra-orbital ridge pressure).
        iii. Oculocephalic and oculovestibular reflexes
            1. No oculocephalic reflex. This test should be deferred when cervical spine instability is suspected or has been established. If deferred for this reason, oculovestibular testing may be done in lieu of oculocephalic testing.
            2. No oculovestibular reflex. No deviation of the eyes after irrigation of each ear with 50 ml of ice water. For testing, head of bed position should be at 30°. A 1-minute period of observation should follow each irrigation. A period of at least 5 minutes should separate testing of each side. This test should be performed after otoscopic examination confirms that the tympanic membranes are intact and are not obstructed by cerumen.
        iv. Cough and gag reflexes
            1. No gag upon stimulation of the posterior pharynx (to be tested by gentle

tugging on the endotracheal tube or by stimulation with a rigid implement such as a tongue depressor or firm plastic suction tip).

2. No gag or cough response to stimulation of the carina with an endotracheal suction catheter.

v. Spontaneous breathing

1. During the clinical examination, there should be no evidence of spontaneous (patient-initiated) breaths while the patient is on the ventilator.

2. The two examinations may be performed by the same physician, or by different physicians.
3. The two clinical examinations must be separated in time by at least 6 hours.
4. Physicians eligible to perform the clinical examinations are as follows:
   a. The first examination must be performed by an attending physician with privileges to determine death by neurological criteria, a Neurocritical Care fellow, or a PGY-2 or higher resident in Neurology or Neurosurgery acting under the supervision of an attending who is privileged to determine brain death.
   b. The second examination must be performed by an attending physician with privileges to determine death by neurological criteria, a second-year (or higher) Neurocritical Care fellow, or a PGY-7 (or higher) Neurosurgery resident acting under the supervision of an attending who is privileged to determine brain death.

C. Apnea Test

A formal apnea test must be performed unless there is a contraindication (e.g. apnea testing is expected to cause hemodynamic or respiratory instability). Depending on the clinical situation, the apnea test may be performed in any of the following ways:

1. Off-ventilator apnea test (see Criteria Form for procedure).
2. On-ventilator apnea test (see Criteria Form or see Department of Respiratory Care "Testing for a Respiratory Response in the Determination of Brain Death" for procedure).
3. For patients on ECMO (extracorporeal membrane oxygenation), the apnea test should be performed as follows:
   a. Pre-oxygenate patient for 15 minutes by placing the ventilator FiO2 at 100%, the ECMO FiO2 at 100%, and by maintaining continuous positive airway pressure (CPAP) at the pre-apnea testing pressure.
   b. Obtain baseline arterial blood gas (ABG).
   c. Continue FiO2 of 100%, CPAP at pre-apnea testing level, and reduce ECMO gas sweep to 0.5L/minute.
   d. Observe patient for 10 – 15 minutes and at the end of the observation period obtain a repeat ABG.

e. The apnea test should be aborted if the patient experiences hemodynamic instability (i.e., mean arterial blood pressure falls to < 65 mmHg) or hypoxia. For patients on V-A (venoarterial) ECMO, cardiac arrhythmias do not necessitate aborting the apnea test so long mean arterial blood pressure remains ≥ 65mmHg and arterial oxygen saturation remains ≥ 90%. For patients on V-V (venovenous) ECMO, the apnea test should be aborted if new unstable arrhythmias develop during the test.

f. At the end of the apnea test, place the ventilator and ECMO circuit back to clinically appropriate settings.

g. If, after at least 10 minutes of observation, the final $PaCO_2$ is ≥ 60 mmHg (option: 20 mmHg rise over baseline $PaCO_2$) AND there have been no spontaneous respirations AND no evidence of patient-initiated breaths on the ventilator, then the apnea test is consistent with brain death.

h. If prior loss of CO_2 responsiveness is suspected, as in patients with chronic CO_2 retention, then a final value of pH ≤ 7.26 (in a patient with a pre-test pH of ≥ 7.4) can be used as an adequate testing endpoint.

i. If the final $PaCO_2$ is < 60 mmHg, or if there is < 20 mmHg rise in $PaCO_2$ from baseline (or if final pH > 7.26 in patients with chronic CO_2 retention), then the test is indeterminate. If the test must be aborted due to physiological instability, then the test should be considered indeterminate.

CONFIRMATORY TESTS

A. Confirmatory testing is required under the following circumstances:

1. Conditions exist that preclude complete clinical evaluation, including the following:
    a. Severe facial trauma or pre-existing deformity that precludes complete clinical evaluation of brainstem reflexes.
    b. Pre-existing pupillary abnormalities (e.g. due to surgery) that preclude assessment of the pupillary light reflex.
    c. One or both tympanic membranes are ruptured, precluding testing of the oculovestibular reflex.
    d. Apnea testing is contraindicated, or otherwise cannot be performed, or is indeterminate.
2. The examiner deems that metabolic abnormalities or levels of sedative drugs might be sufficient to cofound clinical assessment.

B. Acceptable confirmatory tests are a nuclear isotope blood flow scan (preferred), brain-death protocol electroencephalography (EEG), or a four-vessel catheter cerebral angiogram.

SUPERSEDES: 1.20.15; 6.2013; 9.2001; 3.2005; 7.2004; 3.1994; 3.1991; 11.1.1988;	ISSUED BY: /s/ Gregory Tino, MD

DOCUMENTATION

A. The attached form "Certification of Death by Neurologic Criteria for Patients 18 Years of Age or Older" (Criteria Form) must be completed prior to certification of death. All applicable items must be marked "Yes" in order for brain death to be declared. The completed Criteria Form is to remain part of the patient's Medical Record.

The cause and irreversibility of coma should be determined and documented as a first step in the process.

B. It is also standard to document the following:
1. Absence of confounding conditions.
2. Absence of responsiveness to pain during each of the 2 clinical examinations
3. Absence of brainstem reflexes during each of the 2 clinical examinations
4. Absence of respiration with PCO_2 > 60 mmHg (or 20 mmHg rise in PCO2 from baseline)
5. Result of confirmatory test (if performed)

C. When the patient meets all the criteria on the Criteria Form, the attending physician or the covering attending must be notified. The form should be signed by the physician who completes the second clinical exam. Members of the transplant team may not be involved in any aspect of brain death determination. The time when the Criteria Form is signed is the legal time of death.

OTHER CONSIDERATIONS:

A. Determination of death by neurologic criteria is, by law, a medical responsibility and, therefore, consent of the family is not needed nor should it be requested. However, the responsible physicians should inform the family regarding the patient's grave prognosis at least by the start of the certifying process, and continue to keep the family informed throughout the process. Early and clear communication, as well as sensitivity for the family, is important during this time to prepare the family for cessation of continued medical therapy, e.g., removal of the mechanical ventilator from the deceased, which should occur after certification of death by neurologic criteria. Removal of medical therapy following determination of death does not require the permission of the family.

B. Medical Examiner cases undergo the identical processes for certification and cessation of medical therapy. (See policy 11.124, "Post Mortem Care")

C. Organ Donation

In accordance with PPMC policy, 11.136, "Organ Donation and Tissue Donation" and Pennsylvania's Anatomical Gift Act, the Organ Procurement Agency (Gift of Life) should be notified before the brain death protocol is initiated.

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Policy Owner:

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