

Penn Presbyterian Medical Center Administrative Policy Manual	Number: 11.123A Page 1 of 11
SUBJECT: DETERMINATION OF DEATH IN NEONATES OR PATIENTS LESS THAN 18 YEARS OF AGE BY NEUROLOGIC CRITERIA	Effective: 1.8.2020

KEY WORDS:

Brain Death
Coma

SEE ALSO

11.136 “Organ and Tissue Donation and Pennsylvania’s Anatomical Gift Act”

#11.121
“Withholding and Withdrawing Life Sustaining Therapy”

#11.131 “Advance Directives: Living Wills, Health Care Powers of Attorney, and Other Advance Health Care Directives”

Department of Respiratory Care
“Testing for a Respiratory Response in the Determination of Brain Death”

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 a clinical examination and 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 those parts of the Clinical Practices of the University of Pennsylvania (CPUP) which practice at or in conjunction with PPMC operating under the PPMC license. This policy also applies to: (i) those practices and sites that are off campus facilities or departments of PPMC and operating under its license, including e.g., the Surgery Center at Penn Medicine University City; (ii) private practices or entities that lease space in property owned or leased by PPMC only if and to the extent that they provide contracted clinical services to PPMC; and (iii) all ambulatory care facilities (ACF) that are off campus departments of PPMC operating in New Jersey

This policy applies to all neonates born and patients under 18 years of age at PPMC. For adults, see separate policy “Policy Regarding Determination of Death by Neurologic Criteria in Patients 18 Years of Age or Older.”

IMPLEMENTATION

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This policy applies to attending physicians with privileges to determine brain death and to select house staff who are acting as a proxy for or under the authority of attending physicians with privileges to determine brain death.

DEFINITIONS

- A. The attending physician: This phrase designates the attending physician(s) responsible for the overall care of the patient in the hospital during the time period when the procedures detailed in this policy would be conducted.
- B. An attending physician evaluator: This phrase specifies that the physicians who perform and interpret any aspect of the evaluation of the patient detailed in this policy must be attending physicians with experience and expertise in determining whether patients have experienced the irreversible cessation of all brain function.

PROCEDURE

- A. In the Commonwealth of Pennsylvania, death exists when a person exhibits irreversible cessation of all functions of the entire brain, including the brain stem, as outlined below. Restated in different terms, by Pennsylvania law, a person who is shown to have irreversible cessation of all brain function is legally dead. At the same time, the law does not impose a legal obligation to conduct an evaluation of whether or not a person has experienced irreversible cessation of all brain function, nor does the law dictate what is to be done after a person has been determined to have irreversible cessation of all brain function.
- B. The decision to undertake an evaluation of whether or not a patient has irreversible cessation of all brain function is a clinical decision made by the attending physician. In making this decision, the attending physician is encouraged to first determine whether the diagnosis of an irreversible cessation of all brain function meets important goals for the patient, family and health care team. It is not necessary to make a diagnosis of an irreversible cessation of neurologic function in order to withhold or withdraw life-extending therapies in cases where the team and family agree that it is in the patient’s best interests to discontinue such therapies (See PPMC Policy, 11.121, “Withholding and Withdrawing Life Sustaining Therapy.”).
- C. In rare cases, patients’ legally authorized representatives may have pre-existing cultural or religious objections to the concept of the declaration of death by neurologic criteria. In

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such cases, the attending physician is strongly encouraged to consider consultation with the intensive care unit leadership and/or the hospital ethics consultation service prior to attempting to diagnose the irreversible cessation of all brain function.

D. The protocol to determine irreversible cessation of all brain function varies depending on the patient's age:

Age	Criteria
Less than or equal to 30 days of age:	<p>1. Neonate must be supported for a minimum of two days (48 hours) of age prior to the initiation of the formal evaluation of brain function. Both a physical examination showing no brain function and an isoelectric EEG must occur at the beginning of the evaluation and then must be repeated again 48 hours later.</p> <p>2. The observation period can be shortened if an ancillary test (typically a cerebral blood flow study) is performed and is consistent with death by neurologic criteria. In these situations, the second examination is still required and may be performed at any time after results of the ancillary test are received.</p>
Greater than 30 days of age:	<p>1. In some cases (particularly hypoxic-ischemic brain injury due to cardiac arrest), it may be prudent to wait 24 hours or more after the time of the brain injury before attempting to begin the diagnostic process for DNC by physical examination as the acute event could lead to difficulty interpreting the exam.</p> <p>2. The evaluation should then occur over a 12-hour period of observation, with physical examinations at the beginning and end of the period.</p> <p>3. The observation period can be shortened if an ancillary test (typically a cerebral blood flow study) is performed and is consistent with death by neurologic criteria. In these situations, the second examination is still required and may be performed at any time after results of the ancillary test are received.</p>

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- E. Neonates with an estimated gestational age of less than 37 weeks cannot be adequately assessed on physical examination due to the normally occurring absence of certain brain-mediated reflexes in earlier stages of development. The assessment of irreversible cessation of all brain function can occur in these infants only when the estimated gestational age and the post-natal life span in total exceeds 37 weeks.
- F. A physician establishes death due to irreversible cessation of all brain function based on **all four** of the following requirements being satisfied:
1. **Identify a cause** of irreversible cessation of all brain function. These causes include but are not limited to:
 - a. Hypoxic-ischemic brain injury
 - b. Traumatic brain injury
 - c. Intracranial tumors
 - d. Intracranial pressure consistently elevated above arterial blood pressure
 2. **Assess potentially confounding factors**, which would compromise the quality of the physical examination assessment or the EEG test, and assure that none are present. These factors include but are not limited to:
 - a. Hypothermia of the patient (core body temperature < 35°C).
 - b. Sedation of the patient due to sedation medications or anticonvulsant medications that are above the usual therapeutic range (and specifically a serum level of pentobarbital \geq 5mcg/ml or a serum level of phenobarbital of > 50 mcg/ml).
 - c. Pharmacologic neuromuscular blockade within 24 hours.
 - d. Injuries to the patient's face or eyes that preclude elements of the physical examination as outlined below.
 - e. Significant hypotension in the patient as judged by the attending physician (reference values for blood pressure vary by patient age and clinical circumstances).
 - f. Significant electrolyte, acid-base, or endocrine disturbances as judged by the attending physician.

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3. **Perform physical examination** twice (see TABLE 1), at time periods specified above in section D, by two different attending physician evaluators, revealing all of the following:
- a. Coma (complete unconsciousness, no vocalization or volitional activity)
 - b. Pupils un-reactive to light in the absence of drugs influencing pupillary activity
 - c. No spontaneous or induced (oculocephalic, oculovestibular) eye movements
 - d. No bulbar (facial or oral pharyngeal) muscle movement
 - e. Absence of the following reflexes:
 - f. Corneal
 - g. Gag
 - h. Cough
 - i. Sucking (in neonates and infants)
 - j. Rooting (in neonates and infants)
 - k. Flaccidity, with no spontaneous movements, excluding reflex withdrawal or spinal myoclonus
 - l. Apnea, as determined by the following protocol:
 1. Confirm rectal or esophageal body temperature $\geq 35^{\circ}\text{C}$.
 2. Confirm no sedative medications or neuromuscular blocking agents are interfering with the examination.
 3. Pre-oxygenate patient with 100% oxygen to allow a sufficient apneic period for pCO₂ to rise.
 4. Confirm baseline arterial PCO₂.
 5. Discontinue mechanical ventilatory breaths by removing ventilator rate or disconnecting patient from the ventilator. Continue to provide a source of 100% oxygen at a rate to match the patient's estimated minute ventilation.
 6. Follow sequential measurements of arterial pCO₂, but stop the test and resume ventilation if patient becomes hypoxic or hemodynamically unstable.
 7. If the arterial pCO₂ rises to a value > 60 mmHg and more than 20 mmHg above the documented baseline pCO₂, and the patient makes no respiratory effort, then the apnea test is 'positive', consistent with cessation of all brain function.
 - m. If the apnea test was stopped due to the patient becoming hypoxic or hemodynamically unstable, then the full physical examination including the

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apnea test may be repeated after enough time has passed that the attending physician judges the patient may be better able to tolerate the test. Alternatively, a cerebral blood flow study may be used to confirm irreversible cessation of all brain function even if the apnea test cannot be completed.

4. **Perform an ancillary test for patients less than or equal to 30 days of age or for patients greater than 30 days of age in the presence of confounding factors.** The attending physician can, based on the patient's clinical circumstances, select either one of the 2 ancillary tests (see above for the required timing of one of these tests during the required periods of observation):

TEST	FINDING	NOTES
Electro-encephalo-gram (EEG)	Electrocerebral silence on EEG in a patient with rectal temperature above 32.2°C (90°F) and anticonvulsant or sedative medication serum values not above the usual therapeutic range.	The pentobarbital serum level must be < 5 mcg/ml and the phenobarbital serum level must be < 50 mcg/ml. EEGs performed at the patient's bedside are accurate. The EEG must be performed according to specific protocol for determination of electro-cerebral silence. EEGs performed on patients connected to electrically powered mechanical devices such as ventilators may, however, have tracings that display a background artifact due to the mechanical device and not due to electrical activity from the brain.

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Cerebral blood flow study	A cerebral blood flow study demonstrating no flow through the cerebral arteries.	Absent flow on a cerebral blood flow study can confirm an irreversible cessation of neurologic function, but the presence of flow, however, is an equivocal result. Flow may be preserved, especially in cases of an open fontanelle or pre-existing brain abnormalities, and a patient may nonetheless have irreversible cessation of all brain function which would then need to be diagnosed by other means.
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5. As outlined above, in order for the findings of the physical examination to affirm irreversible cessation of all brain function, the entire requisite physical examination must be performed without the intrusion of confounding factors, such as hypothermia, high levels of sedative medications, severe eye/facial injury, or inability to complete apnea test. In instances where the entire physical examination cannot be performed, a cerebral blood flow study showing no blood flow may be used to declare death even in the presence of confounding factors, as long as there is no finding showing evidence of brain function on the portion of the physical examination that can be completed. Alternatively, a later physical examination may be performed with appropriate waiting periods as above if the confounding factors resolve with time.
6. In patients who have cervical spine injury, or other injuries that make oculocephalic response dangerous or impossible to test, the examination can be completed using only oculovestibular testing. If neither oculocephalic nor oculovestibular testing can be completed, a cerebral blood flow study is required to confirm irreversible cessation of all brain function.
7. In patients where any finding on the physical examination reveals evidence of brain function (e.g. breathing), ancillary testing is not warranted, as the patient does not meet criteria for irreversible cessation of all brain function.

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8. The time the physician of record or his/her designee concludes that all criteria for death by neurologic criteria have been met will be recorded as the official time of death, typically at the conclusion of the second physical exam, including completion of the apnea test. Once death is declared, the medical team and family will be informed.

In the event that the patient is pregnant, the physician of record will consult with the obstetrical and neonatal services and the Ethics Consultation Service, along with the family of the patient, to determine the best course of action. See policies “Withholding and Withdrawing of Life-Sustaining Therapy” #11.121, and “Advance Directives: Living Wills, Health Care Powers of Attorney, and Other Advance Health Care Directives #11.131.

9. Once death has been declared, the mechanical or pharmacologic support that is maintaining respiratory or cardiac function will typically be discontinued within a few hours, providing the legally authorized representative with a reasonable but limited amount of time with the deceased patient prior to the discontinuation of this support. In exceptional circumstances, at the discretion of the physician of record, this amount of time may be extended, but is not to exceed 48 hours.

10. Organ Donation

In accordance with the 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 when the brain death protocol is initiated.

References

Nakagawa TA, Ashwal S, Mathur M, et al. Guidelines for the determination of brain death in infants and children: an update of the 1987 Task Force recommendations. Appendix 2. *Crit Care Med.* 2011 Sep; 39(9): 2139-55.

Policy Owner:

- Critical Care Committee, Chair

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TABLE 1

Physical Examination	
Required Action Steps	Supplemental Guidance
Assess Coma	
If spontaneous eye opening is not demonstrated, use verbal stimuli.	<ul style="list-style-type: none"> • If necessary, raise your voice to elicit a response.
If the patient did not open his/her eyes to verbal stimuli, apply a physical peripheral stimulus to all four extremities.	<ul style="list-style-type: none"> • To apply stimulus to extremities: <ul style="list-style-type: none"> • Use a pen and apply pressure to the distal end of the nail bed. • Apply pressure with increasing intensity for 10 seconds. • Applying pressure to the nail and varying the finger that is used should minimize the potential for harm. • Do this for all four extremities. • Apply pressure to the supraorbital and temporomandibular joints.
Note responses to noxious stimuli.	<ul style="list-style-type: none"> • Noxious stimuli should not produce a motor response other than spinally mediated reflexes. • The clinical differentiation of spinal responses from cerebrally mediated motor responses may be challenging. • Decorticate and decerebrate posturing responses are not compatible with death by neurologic criteria. • If motor movements are present and it is unclear whether they are cerebral or spinal reflex in origin, the death by neurologic criteria evaluation should be stopped and neurology consultation obtained.
Assess Absence of Brain Stem Reflexes	
Assess pupillary response (in the absence of drugs influencing pupillary activity) with a bright light. Record pupil size and whether there is a reaction to light.	<ul style="list-style-type: none"> • Usually the pupils are fixed in a midsize or dilated position (4-9mm). • Constricted pupils suggest the possibility of drug intoxication. • When uncertainty exists, a magnifying glass should be used.

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Assess absence of ocular movements by using oculocephalic testing (dolls eyes) and oculovestibular reflex testing (calorics).	<ul style="list-style-type: none"> • To perform oculocephalic testing: <ul style="list-style-type: none"> • Once the integrity of the cervical spine is ensured, the head is briskly rotated horizontally and vertically. • There should be no movement of the eyes relative to head movement. • To perform oculovestibular reflex testing: <ul style="list-style-type: none"> • Elevate the head to 30 degrees. • Irrigate each ear (1 at a time) with approximately 50 ml of ice water (caloric testing) after the patency of the external auditory canal is confirmed. • Movement of the eyes should be absent during 1 minute of observation. • Both sides are tested with an interval of several minutes in between. • If the cervical spine is not cleared or is unstable, or if other injuries make the oculocephalic response difficult to test, the examination can be completed using only oculovestibular testing. • If neither oculocephalic nor oculovestibular testing can be completed, a cerebral blood flow study is required as an ancillary test.
Assess absence of facial and oropharyngeal muscle movement to stimulation.	<ul style="list-style-type: none"> • Test the corneal reflex to touch with a cotton swab or a drop of saline in each eye. <ul style="list-style-type: none"> • No eyelid movement should be seen. • Care should be taken not to damage the cornea during testing. • Test for facial grimacing to noxious stimulation. <ul style="list-style-type: none"> • Options for noxious stimulus include insertion of a cotton swab into the nares, deep pressure on the condyles at the level of the temporomandibular joints and deep pressure at the supraorbital ridge. • Facial myokymias (from denervation of the facial nerve) are permissible.

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Assess absence of gag and cough reflex.	<ul style="list-style-type: none"> • The pharyngeal or gag reflex is tested after stimulation of the posterior pharynx bilaterally with a tongue blade or Yankauer suction device. • The tracheal reflex is most reliably tested by examining the cough response to tracheal suctioning. <ul style="list-style-type: none"> • A suction catheter should be inserted into the tracheal through the endotracheal or tracheostomy tube and advanced to the level of the carina. • This should be repeated 2 times to assess for cough.
Assess lack of spontaneous movements during examination above.	<ul style="list-style-type: none"> • The patient's extremities should be examined to evaluate tone by passive range of motion, assuming that there are no limitations to performing such an examination (e.g., previous trauma, etc.) and the patient observed for any spontaneous or induced movements. • There should be no movement with the exception of reflex withdrawal or spinal myoclonus. If there is uncertainty about whether movements represent spinal reflexes, the evaluation process should stop until expert consultation can be sought.
Record physical examination findings in the patient's medical record immediately following the examination.	<ul style="list-style-type: none"> • Choose the appropriate Death by Neurologic Criteria form. • Include the time and date the examination was performed. • Record the findings and indicate whether or not the examination demonstrates death by neurologic criteria. • Once two physical exams and ancillary testing are completed, an attending physician must document whether or not the patient has met criteria for death by neurologic criteria. • The time the attending physician of record concludes that all criteria for death by neurologic criteria have been met will be recorded as the official time of death, typically at the conclusion of the second physical exam, including completion of the apnea test.

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