



MaineHealth System-Wide Policy

This policy was approved jointly by MaineHealth member organizations and applies to all MaineHealth system members and subsidiaries including each of the entities below: MaineHealth Corporate, MaineHealth Medical Group, Maine Medical Center-Portland, Maine Medical Center-Biddeford, Maine Medical Center-Sanford, Lincoln Hospital, Franklin Hospital, Mid Coast Hospital, Stephens Hospital, Pen Bay Hospital, Waldo Hospital, Memorial Hospital, Behavioral Health at Spring Harbor (MaineHealth Behavioral Health), MaineHealth Care at Home, MaineHealth CHANS Home Health & Hospice, and NorDx.

Policy Title: Determination of Brain Death/Death by Neurologic Criteria – Adult (>18 years)

Search Word: Brain Death, Neurological Death, Death, Organ Transplant, Transplant

Policy Summary: It is the policy of MaineHealth (MH), in accordance with Maine law, that an individual is dead when there is a permanent, irreversible, cessation of all brain function, including the brain stem. In 1981, the President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research introduced the Uniform Determination of Death Act, which embraced the cardiac criteria for determination of death, and extended the definition of death to include irreversible cessation of all brain function, including the brain stem. The criterion set forth by the President's Commission has been implemented in total or with modification in all 50 states. The following guidelines provide neurological criteria for the diagnosis of death in adult patients, often referred to as brain death/death by neurologic criteria, but which is understood to be no different than the diagnosis of death made by other criteria.

Background:

I. Definitions & Scope:

Death: An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions or (2) permanent and irreversible cessation of all functions of the entire brain, including the brain stem, is dead.

Scope: This policy applies to determining brain death/death by neurologic criteria (BD/DNC) in an adult patient, age equal to or greater than 18 years, in MaineHealth facilities. Please see the separate policy *Determination of Brain Death/Death by Neurologic Criteria – Pediatric (<18 years)* if the patient is less than 18 years of age.

II. Policy Statements:

1. Pronouncement of Death by Neurologic Criteria: When death is determined by neurologic criteria, death must be pronounced by an attending physician. Documentation that death has occurred must be entered into the patient's record by the patient's physician. It must include a record of the examinations performed, the times they were performed, and

the time it was determined that the brain has ceased functioning and that, therefore, the patient is dead. For other information on pronouncing death, see Patient Death and Post-Mortem Policy.

2. Consultation Requirement: If the patient is under the care of a physician other than an Intensivist, Neurologist or Neurosurgeon, then one of these specialists must concur with the diagnosis of BD/DNC and document this in the medical record
3. Credentialing: Any medical provider performing BD/DNC examination and declaration must be sufficiently trained and hold expertise in the criteria, pre-requisites, and neurological examination for BD/DNC. ME Health requires that providers who will perform BD/DNC be credentialed by attesting to review of the current BD/DNC policy every two years and encourages participation in additional training exercises for maintenance of competency.
4. Any ME Health facility that does not have the expertise or resources necessary to perform this testing should request patient transfer to a ME Health facility that is capable of making this determination.

III. Procedures:

1. Guidelines for determining death by neurologic criteria in adults: A form to document the aspects of the clinical examination for BD/DNC is available as a progress note template in the electronic medical record (EMR). Documentation of the exam must include, at a minimum, (1) the etiology and irreversibility of the condition; (2) the absence of brain stem reflexes and purposeful motor response to pain; (3) results of the apnea test; and (4) justification for and results of any ancillary tests if these are performed.

2. Pre-requisites: Prior to moving onto the clinical evaluation, all of the following pre-requisite criteria must be met.

A. Indications for BD/DNC Evaluation

- a. BD/DNC evaluation requires that a patient has evidence of a catastrophic, permanent, and irreversible brain injury with a known cause or mechanism that has led to BD/DNC.
- b. If a patient clinically appears to meet criteria for BD/DNC evaluation but no mechanism of brain injury has been identified, evaluation cannot be performed.

B. Timing of BD/DNC Evaluation

- a. Clinicians must wait a sufficient amount of time after brain injury occurs before initiating BD/DNC evaluation to ensure that there is no potential for recovery of brain function.
 1. In hypoxic ischemic brain injury (HIBI), clinicians should wait a minimum of 24 hours after acute injury before initiating BD/DNC evaluation.
 2. In patients whose core body temperature has been <35.5C, clinicians should wait a minimum of 24 hours after the patient has been rewarmed to 36C before evaluating for BD/DNC.

3. In pathologies other than HIBI and hypothermia, observation period is at the clinical discretion of the clinician based on the pathophysiology of the brain injury.

C. Confounding variables: The presence of sedative drugs, hypothermia, shock or other potentially reversible conditions that may depress brain function must be excluded for BD/DNC to be determined by clinical criteria. Specifically:

- a. Body temperature must be 36 degrees Celsius or higher.
- b. Clinical examination to determine BD/DNC cannot be done in the presence of sedating or paralyzing medications. Estimation of drug levels by relying of elimination half-life may be confounded by renal or hepatic dysfunction or periods of significant hypothermia. Laboratory testing for drug levels may be unavailable or require several days to result (e.g., for barbiturates). Clinical judgment must be used to be certain that no relevant medications remain in the system to affect the brain death examination. (See appendix A supplementary tables for common drug half-lives.)
- c. Severe hypotension (shock) should be absent. Systolic blood pressure should be 100mmHg or greater and MAP >75mmHg. This may include the use of crystalloids and/or vasoactive medications.
- d. Absence of severe electrolyte, acid base or endocrine disturbance that may confound clinical judgment (See appendix A supplementary tables for details regarding metabolic derangements that may confound BD/DNC evaluation)
- e. Absence of neuromuscular blockade must be ensured. This can be confirmed with the use of train-of-fours or deep tendon reflexes.

3. Clinical Evaluation: Once the prerequisites listed above are satisfied, BD/DNC clinical valuation may be performed. A neurologist, neurosurgeon, or intensivist familiar with the neurological examination for BD/DNC should perform the clinical evaluation. One clinical examination is required for determination of BD/DNC in adults >18 years of age.

- A. Cerebral unresponsiveness: The patient must be comatose with no behavioral response (withdrawal or posturing) to noxious stimuli and no purposeful spontaneous movement, which would indicate function above the level of the foramen magnum. Spinal level reflexes, including the presence of deep tendon reflexes or other spinally-mediated reflexes, do not preclude diagnosis of BD/DNC. (See appendix A supplementary tables for details and descriptions of spinal reflexes).
- B. Brain stem unresponsiveness: Declaration of BD/DNC requires the absence of all brain stem reflexes bilaterally.
 - a. Pupils are 4mm in diameter or larger and nonreactive to bright, diffuse light bilaterally.
 - b. Oculocephalic and/or oculovestibular reflexes are absent on standard testing bilaterally. There should be no spontaneous eye movements, and the eyes should remain in neutral position (straight ahead, not deviated) on testing the oculocephalic or oculovestibular reflexes. The oculocephalic response is tested by rapid rotation of the head to either side. In eliciting the oculovestibular reflex, 20 to 30 ml of ice water is instilled into each clear

- auditory canal with an intact tympanic membrane with the head elevated 30 degrees and the eyes are observed for 60 seconds.
 - c. Corneal reflexes are absent bilaterally. There is no blink response when the cornea is touched by gauze bilaterally.
 - d. Cough reflex is absent when suctioning is performed at the level of the carina.
 - e. Gag reflex is absent bilaterally when stimulated with a hard suction catheter at the posterior oropharynx.
- C. Apnea testing: An apnea test should be pursued once all clinical criteria above are satisfied. One apnea test is required for determination of BD/DNC in adults >18 years of age. The apnea test evaluates for spontaneous respiratory effort in response to a hypercarbic and acidotic challenge.
- a. A patient should be deemed safe and medically stable for apnea testing to be performed. This should include absence of hypoxia, hypotension, or hypovolemia prior to initiating the apnea test.
 - b. A provider proficient in cardiopulmonary resuscitation should be present and/or should perform the apnea test in case of clinical deterioration. Apnea testing should be aborted in the setting of hemodynamic instability (SBP <100 mmHg or MAP <75 mmHg), hypoxia (SpO₂ <85%), or cardiac arrhythmia. Apnea testing must also be aborted if the patient takes 1 or more spontaneous breaths, as this does not meet criteria for BD/DNC.
 - c. Patients without chronic hypercarbia should have a normal PaCO₂ (35-45mmHg) and normal pH (7.35-7.45) prior to apnea testing. In patients with chronic hypercarbia, if the chronic PaCO₂ level is known, the pre-apnea pCO₂ should be at their chronic baseline level. In patients suspected to have chronic hypercarbia but baseline PaCO₂ is not known, pre-apnea testing pCO₂ should be at the estimated chronic baseline. If apnea is confirmed in this setting, ancillary testing should be performed in addition.
 - d. Patient should be pre-oxygenated with 100% oxygen for at least 10 minutes prior to apnea testing to achieve PaO₂ of >200 mmHg.
 - e. Clinicians should obtain an ABG after pre-oxygenation and prior to disconnecting from the ventilator to obtain baseline PaO₂, PaCO₂, and pH levels.
 - f. Clinicians should disconnect patient from the ventilator and should deliver 100% oxygen at 4-6L/min via a catheter placed through the endotracheal tube/tracheostomy to the level of the carina
 - g. ABG should be measured after 8-10 minutes of apnea
 - h. Apnea test is consistent with BD/DNC if all of the below criteria are satisfied:
 - i. No respirations occur
 - ii. Arterial pH level is <7.30
 - iii. PaCO₂ level is >or= 60 AND 20mm Hg above the patient's pre-apnea testing baseline
- D. Apnea testing in ECMO patients: Follow the above steps and criteria with the following additional considerations or adjustments. (See Appendix B for perfusionist procedural instructions)

- a. Given that ECMO patients may have non-pulsatile blood flow, MAP goal >75 should be used during testing.
- b. Pre-oxygenate using 100% FiO₂ on the ventilator and through the membrane lung
- c. To achieve adequate potential rise in PaCO₂, adjust the sweep gas flow rate to 0.2-1L/min
- d. For patients on VA ECMO: Sample ABG measurements from both the patient's right upper extremity, distal arterial line and the ECMO circuit post-oxygenator. PaCO₂ and pH levels from both locations are required to meet BD/DNC criteria.
- e. For patients on VV ECMO: Sample ABG measurements from the patient's right upper extremity, distal arterial line.
- f. Apnea test is consistent with BD/DNC if all of the below criteria are satisfied:
 - i. No respirations occur
 - ii. Arterial pH level is <7.30
 - iii. PaCO₂ level is >or= 60 AND 20mm Hg above the patient's pre-apnea testing baseline

4. Ancillary Testing: Ancillary testing may only be used to assist with BD/DNC determination if full examination(s) or apnea test(s) cannot be completed or if the clinical exam cannot be interpreted adequately. In those scenarios, the clinical examination should be performed to the greatest extent possible and ancillary testing can be pursued in addition. Ancillary testing should not be used in the setting of hypothermia or sedating drugs. Ancillary tests are not necessary for the diagnosis of brain death and do not replace a neurologic exam. They should be interpreted by the physician with an understanding of the potential for false-positives and an appreciation of the clinical context. Acceptable ancillary tests are listed below.

- A. Four-vessel cerebral angiography
 - a. Should demonstrate no cerebral arterial blood flow beyond the level of entry of the carotid or vertebral arteries into the skull
- B. Radionuclide cerebral blood flow study
 - a. Should demonstrate no radionuclide localization in the middle cerebral artery, anterior cerebral artery, or basilar artery territories of the cerebral hemispheres
- C. Transcranial Doppler ultrasonography
 - a. Should demonstrate presence of oscillating flow or systolic spikes in proximal large intracranial arteries (internal carotid, middle cerebral, anterior cerebral, posterior cerebral, and basilar arteries).

5. Ethical Considerations

- A. Consent for BD/DNC examination: Evaluating that a person has died is a traditional and fundamental responsibility of physicians. The determination that a person is dead has legal implications for a range of issues (e.g., termination of the physician-patient relationship, criminal indictments, matters relating to the estate of the patient). Thus, clinicians have an obligation to determine that death

has occurred in a timely and accurate manner. The decision when to initiate BD/DNC testing is a clinical decision made by an attending physician. Family member consent is not required.

- B. Disclosure of BD/DNC examination: Because the loss of a family member can be an emotionally traumatic experience, and in support of transparent communication with a patient's legally authorized representative (LAR), the LAR should be informed of the plan to perform a BD/DNC examination if this is feasible.
- C. Foregoing of hemodynamic support: Mechanical and pharmacological support of respiratory and cardiac function is typically discontinued after a determination of death unless organ donation is under consideration. However, some families may wish to spend time prior to foregoing support of respiratory and cardiac function. Other families may not be familiar with BD/DNC and require a period of time for explanation and processing information. Yet other families may be skeptical about the validity of the concept of brain death. In all of these cases, it is reasonable to delay the foregoing of support for a limited period in order to allow for discussion and resolution of any misunderstandings or disagreement or to allow additional time for visitation. This period should typically not exceed 72 hours. Family members may wish to consult an attorney or the courts during this period if resolution cannot be reached.
- D. BD/DNC evaluation in a patient that is pregnant: Pregnant persons may undergo BD/DNC evaluation and be declared deceased based on this testing. In some situations, it may be medically reasonable to continue organ support with the goal of delivering a viable infant. In this situation, the primary team, clinicians knowledgeable in maternal-fetal medicine, neonatology and other specialists as indicated should discuss the risks and benefits of continuing organ support with the patient's LAR and other family members. The prior wishes and values of the pregnant person and the best interest of the fetus are relevant consideration in this discussion. An ethics consult may be helpful.

Related References:

- 1. Local Institutional Policy: Patient Death and Post-Mortem Policy
- 2. Local Institutional Policy: Organ and Tissue Donation
- 3. **Maine Statutes: Title 22:** Subtitle 2: Part 6: [Chapter 706: UNIFORM DETERMINATION OF DEATH ACT](#). An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards. [1983, c. 33 (new).]
- 4. Wijdicks EFM, *et al.* Evidence-based Guideline Update: Determining Brain Death in Adults. Report of the Quality Standards, Subcommittee of the American Academy of Neurology, *Neurology* 2010;74:1911-1918

5. Guidelines for the Determination of Brain Death in Children. Report of the American Academy of Pediatrics Special Task Force, *Pediatrics* 1987;80(2): 298-299
6. Mathur, Mudit, *et.al.* Variability in Pediatric Brain Death Determination and Documentation in Southern California. *Pediatrics* 2008; 121: 988-993
7. For pediatric checklist see Nakagawa, Thomas, et al. Clinical Report - Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations. *Pediatrics* 2011;128:e720-e740. Appendix 1 page e735. <http://pediatrics.aappublications.org/content/128/3/e720>
8. Greer et al. Pediatric and Adult Brain Death/Death by Neurologic Criteria Consensus Guideline. Report of the AAN Guidelines Subcommittee, AAP, CNS, and SCCM. *Neurology* Oct 2023.
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