Ontario Health
Trillium Gift of Life Network

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GUIDELINES FOR DEATH DETERMINATION BY NEUROLOGIC CRITERIA (DNC) FOR THE PURPOSES OF ORGAN DONATION IN ONTARIO: INFANTS 2 MONTHS TO LESS THAN 1 YEAR AND NEWBORNS 37 WEEKS CORRECTED GESTATIONAL AGE TO LESS THAN 2 MONTHS OF AGE

Overarching Principles

In accordance with the *Gift of Life Act*, Ontario Health (Trillium Gift of Life Network [TGLN]) has aligned clinical protocols with *A Brain-Based Definition of Death and Criteria for its Determination After Arrest of Circulation or Neurologic Function in Canada: A 2023 Clinical Practice Guideline*. For the purposes of post-mortem donation for transplantation, two physicians must confirm death with the legal time of death recorded as the time of completion of the last test required to fulfill death determination criteria by the first physician. For Death Determination by Neurologic Criteria (DNC) in infants aged 2 months to less than 1 year, a full clinical assessment separated in time must be performed by two physicians, with no fixed time interval between the assessments. For newborns, 37 weeks corrected gestational age to less than 2 months, a full clinical assessment separated in time must be performed by two physicians in DNC, with the first assessment being delayed until 48 hours after birth and a minimum of 24 hours between the two assessments. The time interval may be extended according to the physician's judgment.

Physicians Determining Death

Physicians performing DNC must hold full and current licensure for independent (non-educational) medical practice in Ontario. The physician must have skill and knowledge in the management of patients with infants and neonates with severe brain injury, as well as in DNC. Forthe purpose of donation for transplantation, clinicians determining death must not have an association or active involvement in transplant procedures, organ allocation, or care of the intended transplant recipient.

Clinical Requirements for Death Determination by Neurologic Criteria

There must be an established cause of devastating brain injury severe enough to cause death and supported by neuroimaging evidence. Potential confounders of an accurate clinical assessment must have been considered and excluded. Death has been determined when all components of the clinical assessments are fully performed, complete, and consistent with DNC. The clinical assessments for DNC must fulfill the following criteria: (1) absence of consciousness demonstrated by a lack of arousal and awareness in response to stimuli, (2) absence of brainstem function as demonstrated by cranial nerve testing, and (3) absence of the capacity to breathe demonstrated by formal apnea testing. For patients with isolated brainstem or infratentorial brain injury without supratentorial involvement, a clinical assessment is necessary however, alone, this no longer fulfills DNC. An ancillary test is required to determine death in this scenario or a period of observation and reimaging demonstrating whole-brain involvement. If any portion of the clinical assessment for DNC cannot be complete and/or confounding factors cannot be excluded, expert consultation with the Ontario Health (TGLN) Donation Support Physician (DSP) and ancillary testing must be considered.

Confounding Factors and Other Clinical Situations Requiring Special Consideration

Confounding factors may prevent the observation of neurologic responses and/or mimic death, therefore, where feasible, the DNC clinical assessment should be performed in the absence of confounding factors. Potential confounding factors include, but are not limited to, less than 48 hours from the return of spontaneous circulation following cardiac arrest, unresuscitated shock, hypothermia, drug intoxications, administration of cycloplegic or muscle relaxant drugs, neuromuscular disorders, decompressive craniectomy, spinal cord injury, isolated brainstem or infratentorial brain injury and severe metabolic disorders such as hypoglycaemia, severe hypophosphatemia, hypernatremia, and/or liver or renal dysfunction (see page 2). Confounding factors must be reviewed by the Most Responsible Physician (MRP) in the context of the primary etiology and the clinical assessment. In the context of donation, Ontario Health (TGLN) will collaboratively review confounding factors with the MRP prior to initiating DNC testing.

Ancillary Testing to Support Clinical Requirements for Determining Death by Neurologic Criteria in the Presence of Confounding Factors

Any ancillary test is considered supportive, not confirmatory, for DNC. The only accepted ancillary test in pediatric patients are the radionuclide brain perfusion study employing a lipophilic radiopharmaceutical, if available, with or without tomographic imaging. If a lipophilic radiopharmaceutical is not available, a lipophobic may be used. If performed, the test must be interpreted by test-specific qualified imaging physician specialists. Written confirmation of the ancillary test result must be documented by a physician for donation to proceed and the time of death is documented as the time that the ancillary test was completed. Ancillary testing is not recommended for newborns under 2 months corrected age.

TGLN# _____

DEATH DETERMINATION BY NEUROLOGIC CRITERIA CONFOUNDING FACTORS CHECKLIST

This tool has been developed to address potential confounding factors prior to the examination of death determination by neurologic criteria. No worksheet can adequately address all confounding factors. After reviewing concerns raised here with the Most Responsible Physician, please call the Donation Support Physician as needed.

Laboratory & Physiologic Values (results within last 6-12hours)		Patient Value	Recommended Limits for DNC
All Patients	Sodium (Na)		125 – 159 mmol/L
	Phosphate (PO_4^{3-})		Above 0.4 mmol/L
	Glucose		3 – 30 mmol/L
	pH		7.28 – 7.50
	PaCO2		Below 60
Renal Function	Blood Urea Nitrogen (BUN)		Below 40 (if available)
	Creatinine		Below 400
	Estimated Glomerular Filtration Rate (eGFR)		Above 30
Liver Function	Bilirubin (total)		Less than 100

What is the mechanism of devastating brain injury that has led to suspected death?	☐ Elevated ICP/Hydrocephalus ☐ Anoxic brain injury ☐ Infratentorial Brain Injury	**Is the mechanism indicated, supported by imaging?**	☐ Yes ☐ No

Any existing high-risk conditions identified below, require consultation with the Donation Support Physician

- ☐ Determination of death less than 6 hours from the loss of the last brain stem reflex
- ☐ Determination of death less than 48 hours from a cardiac arrest
- ☐ Cardiac arrest thought to have resulted from drug exposure or ingestion AND has never had brain stem reflexes
- ☐ Patient has a neuromuscular disorder (e.g. ALS, Myasthenia Gravis, etc.) or cervical spinal cord injury
- ☐ Brain injury isolated to brainstem or posterior fossa without herniation
- ☐ The patient has had a decompressive craniectomy
- ☐ Central venous sinus thrombosis with ongoing treatment
- ☐ N/A

Does the patient have a positive toxicology screen in the last 48 hrs or on admission AND BOTH of:	☐ A positive that is not marijuana (THC) or cocaine or methamphetamine AND ☐ A positive that is not explained by drugs given in the emergency department or critical care unit ☐ N/A

Has the patient had prolonged sedation or analgesia infusions in the last 48 hours (see definitions)?

Drug	Propofol	Midazolam	Fentanyl	Other
Cumulative Dose	Off < 6 hrs or Duration ≥ 48 hours Duration			
Duration		Any duration	≥ 24 hours	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Other comments				

Does the patient have severely abnormal organ function that may affect the DNC examination?	☐ No severe organ function impairment ☐ Yes – Severe liver dysfunction ☐ Yes – Severe renal dysfunction ☐ Yes – Respiratory function (e.g. COPD, chronic elevated Co2)
Does the patient have severe unresuscitated shock?	☐ Yes ☐ No
Does the patient have uncorrectable electrolyte abnormalities?	☐ Yes ☐ No
Is the patient's core temperature (esophageal, rectal, bladder, central venous or arterial catheter monitoring) below 36 degrees Celsius?	☐ Yes ☐ No

Confounding factors reviewed by_____ **(name of Specialist - Organ and Tissue Donation) with Dr.**_____ **(name of Most Responsible Physician).**

Date: (DD/MMM/YYYY):_____ **Time:** _____

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CONFIRMATION OF DEATH DETERMINATION BY NEUROLOGIC CRITERIA (DNC): PEDIATRICS 37 WEEKS CORRECTED GESTATIONAL AGE TO LESS THAN 1 YEAR

TGLN ID:					
Prerequisites					
Age:	☐ Infants 2 months to less than 1 year	☐ Newborns 37 weeks corrected gestational age to less than 2 months			
What is the mechanism of devastating brain injury that has led to the suspected death?		☐ Elevated ICP/Hydrocephalus ☐ Anoxic Brain Injury ☐ Isolated Infratentorial Brain Injury ☐ Other (please explain):			
Is the mechanism of devastating brain injury indicated above supported by imaging?				☐Yes	☐No
Potential confounders of an accurate clinical assessment have been considered and excluded. If confounders cannot be excluded, the clinical assessment must be completed to the fullest extent possible and ancillary investigation is recommended. If no, please explain:				☐Yes	☐No
Core Body Temperature (esophageal, bladder, central venous, or arterial catheter monitoring)				°C	
Clinical Assessment		**Exam 1**		**Exam 2**	
Absent motor responses (excluding spinal reflexes)		☐Yes	☐No	☐Yes	☐No
Absent cough (tracheal) reflex		☐Yes	☐No	☐Yes	☐No
Absent gag (pharyngeal) reflex		☐Yes	☐No	☐Yes	☐No
Absent (bilateral) corneal reflexes		☐Yes	☐No	☐Yes	☐No
Absent (bilateral) vestibulo-ocular reflexes		☐Yes	☐No	☐Yes	☐No
Absent (bilateral) pupillary response to light		☐Yes	☐No	☐Yes	☐No
Absent rooting and sucking (newborns only)	☐N/A	☐Yes	☐No	☐Yes	☐No
Apnea Testing Apnea testing should be the final element of the clinical assessment.					
Baseline		pH _____ $PaCO_2$ _____ mmHg		pH _____ $PaCO_2$ _____ mmHg	
At completion of apnea test		pH _____ $PaCO_2$ _____ mmHg		pH _____ $PaCO_2$ _____ mmHg	
$PaCO_2 \geq 20$ mmHg above the baseline level **and** pH ≤ 7.28		☐Yes	☐No	☐Yes	☐No
Absent breathing/respiratory efforts		☐Yes	☐No	☐Yes	☐No
Date/time blood sample was taken when $PaCO_2$ reached targets:		(DD-MM-YY): (00:00)		(DD-MM-YY): (00:00)	
Criteria: *pH less than or equal to 7.28, $PaCO_2$ greater than or equal to 60 mmHg and greater than or equal to 20 mmHg rise from baseline CO_2*					
Ancillary Testing If any portion of the clinical assessment cannot be completed and/or potential confounders of an accurate clinical assessment cannot be excluded, an ancillary test should be performed. Ancillary testing is not recommended for newborns under 2 months corrected age.					
Date/time ancillary test performed:		(DD-MM-YY):		(00:00):	
Ancillary Test Performed:					
☐ Radionuclide Perfusion	Read by (PRINT):				
Absent intracerebral blood flow/perfusion				☐Yes	☐No
Time of Death The legal time of death is recorded as the time of completion of the last test required to fulfill death determination criteria (typically, the time the blood sample was taken when the $PaCO_2$ reached the apnea test targets, or the time ancillary test was performed). When death is determined independently by two physicians, the legal time of death is the time of completion of the first physician's assessment.					
This patient fulfills the criteria for death determination by neurologic criteria				☐Yes	☐No
Date/time of death:		(DD-MM-YY):		(00:00):	
Physician 1 (PRINT):		Signature:			
Physician 2 (PRINT):		Signature:			

Physician 1 and Physician 2's death determinations must be performed at different points in time. For infants, there is no fixed exam interval between the two. For newborns, the first assessment must be delayed until 48 hours after birth with a minimum of 24 hrs between the two assessments.

Recommended Procedure for DNC

- Physicians performing Death Determination by Neurologic Criteria (DNC) must hold full and current licensure for independent (non-educational) medical practice in Ontario.
- Two clinical assessments for DNC are to be performed by two physicians. The physician must have skill and knowledge in the management of patients with severe brain injury, as well as in DNC.
- The first and second physician's death determinations must be performed at different points in time, including apnea test. For infants aged 2 months to less than 1 year, there is no fixed exam time interval between the two. For newborns aged 37 weeks corrected gestational age to 2 months, the first exam must be delayed until 48 hours after birth and the time interval between exams must be a minimum of 24 hours.
- The cause of devastating brain injury should be supported by neuroimaging evidence consistent with the established cause. A 48-hour delay after return of spontaneous circulation post-cardiac arrest in patients with hypoxic-ischemic injury who do not have imagining evidence consistent with devastating brain injury before conducting the clinical assessment for DNC.
- Documentation should be on designated DNC forms, signed and placed in the child's chart
- Minimal core body temperature at 36°C. (esophageal, bladder, rectal, central venous or arterial catheter monitoring)
- Rule out the presence of any clinically significant drug intoxications.
- Assess level of consciousness (Glasgow coma scale = 3)
- Observe the lack of response to painful central stimulation (E.g.: supraorbital pressure)
  - Movements should be examined closely to be distinguished from intact spinal reflexes
- Insert a suction catheter into the endotracheal tube and stimulate the trachea
  - Any effort to cough excludes DNC.
- Insert a Yankauer or tongue depressor to stimulate the back of the pharynx
  - Any gag excludes DNC.
- Check pupils for direct and consensual reaction
  - Any reaction or dilation at < 3 mm, excludes DNC.
  - For newborns (2 months to less than 37 weeks corrected gestational age) assess Sucking and Rooting Reflex. Place and lightly press the pad of the small finger against the roof of the mouth to determine if a response (movement of the tongue, mouth or pharynx) is elicited
- Caloric/oculovestibular
  - Position head at 30° horizontally, irrigate the auditory canals with at least 50 ml of ice water, and observe both eyes; any eye movement excludes neurological determination of death.
  - Five minutes should be observed before the other auditory canal is irrigated
  - The caloric test may be performed even if there is a basal skull fracture or damage to the auditory canals is present or suspected.
- **Apnea Test**
  - The physician must continuously observe the patient for respiratory effort.
  - Pre-oxygenate the patient with O2 at 100% for 10 minutes
  - Check ABG and disconnect the ventilator when PaCO2 / pH thresholds for initiation are met. A PaCO2 between 35 – 45 mmHg and the arterial pH ≥ 7.35 is recommended. If thresholds are not achievable, then discussion with Ontario Health (TGLN) Donation Support Physician is recommended
  - Attach the patient to positive pressure (such as a bag-valve device with a PEEP valve), connected to oxygen or an alternative established method for providing oxygenation.
  - For a period of 5 - 15 minutes, observe for the absence of any respiratory movement
  - Draw an ABG after 5, 10 and 15 minutes. **Thresholds for completion of apnea test include PaCO2 ≥ 60 mmHg and ≥ 20 mmHg above the pre-apnea test level and pH ≤ 7.28 as determined by arterial blood gases.**

Caution must be exercised in considering the validity of the apnea test in cases of chronic respiratory insufficiency or dependence on hypoxic respiratory drive.
If the above criteria are met, the test is documented as "absence of respiratory effort"

- If the patient becomes unstable it is recommended to draw an ABG before putting the patient back on the ventilator as they may have met the requirements outlined above
- Resume initial respiratory parameters to optimize lung strategies

If any of the minimal clinical criteria cannot be completed or confounding factors cannot be corrected, a repeat exam, ancillary testing or both may be recommended. Reminder: ancillary testing is not recommended under 2 months of age.
Discussion with the Specialist - Organ and Tissue Donation (S-OTD) or the Ontario Health (TGLN) Donation Support Physician on-call is recommended