



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department - Cadaver transplantation - Brain Death Certification - Standard Operating Procedure for Brain Death Certification in Government and Private Hospitals in the State - Approved - Orders issued.

HEALTH AND FAMILY WELFARE (B) DEPARTMENT

G.O(Ms.)No.53/2018/H&FWD.

Dated, Thiruvananthapuram, 03/04/2018.

- Read:-
1. G.O (Ms) No.36/2012/H&FWD dated 04.02.2012.
 2. G.O (Ms) No.16/2017/H&FWD dated 01.02.2017.
 3. Judgement dated 28.07.2017 of the Hon'ble High Court of Kerala in WP(C) No.5552 of 2017 filed by Dr. Ganapathy
 4. Letter No.K3/9508/DME dated 22.03.2018 of the Director of Medical Education.

ORDER

The Hon'ble High Court, while disposing WP(C) No.5552/2017 filed by Dr. S. Ganapathy, have directed the Government as per the Judgment read as 3rd paper above, to issue directives for taking special or extra ordinary care in the certification of brain death and to ensure that hospital stick to highest level of medical ethics and follow the laws strictly.

2. On the basis of the Judgment of the Hon'ble High Court, the Director of Medical Education as per the letter read as 4th paper above, has submitted Standard Operating Procedure for brain death certification prepared after multiple brain storming sessions involving the experts in the filed on brain death certification.

3. Government have examined the matter in detail and are pleased to issue the following Standard Operating Procedure to be followed in brain death certification by the Government and Private hospitals in the State.

STEP 1— PREREQUISITE FOR BRAIN STEM DEATH TESTING

The most important steps before subjecting a patient for brain stem death testing is to rule out any reversible causes of coma.

1. Establish irreversible and proximate cause of coma

Clinical and/or neuro-imaging evidence of an acute central nervous system (CNS) catastrophe that is compatible with the clinical diagnosis of brain stem death. Severe head injury, aneurysmal subarachnoid hemorrhage, hypoxic ischemic brain injury etc.

2. Exclusion of reversible cause of coma.

a. Intoxication (Alcohol)

b. Relaxants (Neuromuscular blocking agents)

- Drug induced residual neuromuscular junction blockade must be excluded if neuromuscular blocking agents have been used.

c. Depressant Drugs

- The length of time between discontinuation of depressant drugs and undertaking brain-stem testing depends on several factors including total dose, duration of treatment, the underlying renal and hepatic function and the availability of measurement of drug concentrations. Hence it is essential that the recent history of the drugs have been ingested or administered should be carefully reviewed by the brain stem death certifying team.

d. Primary Hypothermia

- Temperatures between 32-34°C are occasionally associated with an impaired level of consciousness but brain-stem reflexes tend to be lost if the temperature falls below 28°C. These deficits are potentially reversible. Hence it is recommended the core temperature should be > 35°C at the time of brain stem death testing.
- Core temperature:
 - Age \geq 18 years - core temperature \geq 35° C (95 °F)
 - Age \geq 1 year < 18 years - core temperature (35° C)

e. Hypovolemic shock

Systolic blood pressure:

Age \geq 18 years, systolic blood pressure \geq 90 mm Hg

- f. **Endocrine & metabolic disorders:** (It is recognized that, metabolic and endocrine disturbances (e.g. hypernatremia, diabetes insipidus) are likely accompaniments of death as a result of cessation of brain-stem function. It is important to emphasize that these may be the effect rather than the cause of cessation of brain-stem function and do not preclude the diagnosis of death by neurological testing of brain-stem reflexes. Furthermore it may be detrimental to correct such abnormalities too rapidly and, equally, to delay testing of brain-stem reflexes unnecessarily, simply because of strict adherence to the requirement to attain a predetermined blood electrolyte concentration)

STEP 2— ASSESSMENT OF BRAIN STEM REFLEXES

2.1 Two sets of tests are required to be done, the minimum time interval between the first and second testing will be 6 hours in adults. In the case of children of age 6-12 years, 1-5 years and infants time interval shall increase depending on the opinion of brain stem death certifying experts

(Ref: Form 10 see rules 5(4) © and 5(4) (d), The transplantation of human organ and tissues rules 2014).

2.2 It is mandatory for the two series of test (at an interval of 6 hours) to be witnessed by all four members of brain stem death certification panel and the procedure should be videographed as per Government Order read as 2nd paper above.

2.3 Tests for absence of brain stem functions

To be done twice at 6 hours interval

(NB: the whole process to be video recorded and archived)

- Coma
- Cessation of spontaneous breathing (patient maintained on ventilator)
- Pupillary size
- Pupillary light reflexes (The pupils are fixed and do not respond to sharp changes in the intensity of incident light)
- Dolls head eye movements
- Corneal reflex (There is no. corneal reflex - care should be taken to avoid damage to the cornea- Both sides)
- Motor responses to any cranial nerve distribution, any response to stimulation face, limb or trunk (No motor response can be elicited within the cranial nerve or somatic distribution in response to supraorbital pressure)
- Cough and Gag reflex (There is no cough reflex response to bronchial stimulation by a suction catheter placed down the trachea to the carina, or gag response to stimulation of the posterior pharynx with a spatula)
- Eye movements on caloric testing (No eye movements are seen during or following the slow injection of at least 50 ml of ice cold water over one minute into each external auditory meatus in turn. Clear access to the tympanic membrane must be established by direct inspection and the head should be at 30° to the horizontal plane, unless this positioning is contraindicated by the presence of an unstable spinal injury).

Procedure for the cold caloric test:-

- i. The head end of the bed is elevated to 30 degrees.
- ii. 30 to 50 ml of ice-cold water is injected slowly (over 30 seconds) into the ear.
- iii. Once the water is injected, both the eyes are held open to observe the ocular movement.
- iv. In patients with an intact brain-stem, a slow movement of the patient's eyes to the side of the ice-water irrigation, followed by a rapid corrective movement of the eyes to the opposite side is noted.
- v. The second ear should be tested after a gap of 5 minutes.

STEP 3 - APNOEA TEST

The process for testing the respiratory system to hypercarbia (Apnea Test) should be the last brain stem reflex to be tested and should not be performed if any of the preceding tests confirm the presence of brain stem reflex.

Consent: Informed written consent to be obtained by treating doctor. Correction of hypotension, metabolic acidosis and pre-oxygenation is mandatory prior to apnoea testing.

3.1 Preparation for apnoea test

- I. Patient should have a temperature of more than 35 degree centigrade euvolemic and with Systolic pressure \geq 90mm of Hg.
- II. The first Apnoea test should be performed only after 4 hours of Coma associated with absence of brain stem reflexes. In the case of Anoxic brain damage, this period should be extended to 12 hours.
- III. The physician involved in certifying brain death shall be present during Ventilator removal to attest the presence of Apnoea if found.
- IV. Ventilator manipulation is performed to raise the PaCo₂ \geq 40 mmHg.
- V. The patient should be hyper oxygenated with 100% Oxygen for 15 minutes, while still on the Ventilator, prior to the Apnoea test.
- VI. Either a blood gas or trending of ETCO₂ should be used to determine the adequacy of the baseline prior to the test. SpO₂ should be monitored during Apnoea test.
- VII. Place the patient on 100% Oxygen through a tracheal catheter with the tip towards the end of the tube with a continuous 6L/min oxygen flow.
- VIII. The patient is taken off the Ventilator in the presence of a physician certifying brain death. The patient is kept off the Ventilator for a variable period of time (usually 3 to 8 minutes) to allow the PaCo₂ to rise \geq 55 mm Hg or \geq 15 mmHg over baseline. During this time, the patient is observed for respiratory movements.

Test interpretations:

a. Positive Test - implying Apnea despite adequate stimulation

- i. Patient remain Apnoeic, without respiratory movements.
- ii. PaCo₂ is \geq 55mm Hg or \geq 15mmHg from baseline.

b. Negative test - Implying Apnoea is not present

Respiratory efforts noted at any time during the test

c. Indeterminate test

PaCo₂ < 55mmHg or, there is less than 15mm Hg increase over baseline . Indeterminate tests can either be repeated or, another confirmatory test utilized.

- Apnoea test should be aborted if the patient develops hypotension, or significant cardiac arrhythmias.
- These norms will vary for patients less than 12 years and patients with major chest trauma.

d. When to Abandon the certification process:

Rather than ordering ancillary tests, physicians may decide not to proceed with the declaration of brain death if clinical findings are unreliable. After clinical confirmation of irreversible coma, absent brainstem reflexes and apnea test, no additional testing is required for determining brain death.

3.2 if the brain death certifying committee felt that residual neuromuscular blockade should be tested they may do so with the peripheral stimulation test as specified below:

- All four stimuli should produce a movement without fade 4/4.
- Apply train of four stimulus (20 mA, 0.2-millisecond julses, 500 milliseconds apart on Ulnar Nerve at the wrist and look for movements of adductor pollicis muscle (medial adduction movement of thumb across the palm).

DESCRIPTION

- a peripheral nerve is stimulated by an electrical signal
- Twitch = muscle response to stimulus
- Ulnar nerve is most commonly used; alternatives include posterior tibial, facial and peroneal nerve
- ECG dots (ensure good skin contact and current flow)
- Electrodes (black and red)
- Nerve stimulator console

METHOD OF USE

Ulnar nerve

- ECG dots placed
 - first dot on the palmar aspect of the wrist 1-2 cm proximal to the wrist
 - second dot in the same line 3 cm proximal to the wrist.
- Electrodes attached
 - black (negative) electrode is attached to dot closest to hand (place as close to nerve as possible).
 - red (positive) attached to the proximal dot (must be in line to minimize nerve- muscle artefact and ensure maximal stimulation).

- stimulator is attached
- voltage is slowly increased starting at 20mA, voltage should not exceed 60 mA
- red pulse light indicates voltage conduction.
- observe twitching of adductor pollicis (medial adduction of the thumb across the palm) -

DOCUMENTATION OF BRAIN STEM DEATH

1. Ensure that all data is entered in Form 10 (Ref: THO Rule, 2014).
2. Ensure that all four doctors are signed and dated the form 10 (see Appendix).
3. Time of brain stem death is documented in medical records including EMR, if any.
4. After the completion of second apnea test (when the arterial PCO₂ reach the target value of positive Apnoea test) patient is declared brain stem death.
5. Inform the next of kin of the results

4. The Judgment read as 3rd paper above is complied with accordingly.

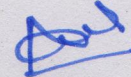
(By Order of the Governor),

RAJEEV SADANANDAN
Additional Chief Secretary

To

The Advocate General, Ernakulam (with C/L)
The Director of Medical Education, Thiruvananthapuram.
The Director of Health Services, Thiruvananthapuram
The Principal All Government Medical Colleges (Through DME)
The Nodal Officer, Kerala Network for Organ Sharing, Super Speciality
Block, Government Medical College, Thiruvananthapuram.
The Superintendent, All Government Medical Colleges (Through DME).
All District Medical Officers (Through DHS)
Information & Public Relations Department (Web & New Media)
Stock File/Office Copy.

Forwarded/By order



Section Officer

Form- 10

For certification of brain stem death

(To be filled by the board of medical experts certifying brain-stem death)

[See rules 5(4)(c) and 5(4)(d)]

We, the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt./Km
..... aged about
Son of/Wife of/Daughter of/Husband of.....Resident
of
is dead on account of permanent and irreversible cessation of all functions of the brain-stem. The tests carried out by us and the findings therein are recorded in the brain-stem death Certificate annexed hereto.

Dated: _____

Signature: _____

1.R.M.P.- In charge of the Hospital
In which brain-stem death has occurred

2. R.M.P. nominated from the panel
of names sent by the hospitals and
approved by the Appropriate
Authority.

3. Neurologist/Neuro-Surgeon

4 R.M.P. treating the aforesaid
deceased person

(Where Neurologist/Neurosurgeon is not available, any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator In-charge from the panel of names sent by the hospital and approved by the Appropriate Authority shall be included)

BRAIN-STEM DEATH CERTIFICATE

(A) PATIENT DETAILS:

1. Name of the patient:

Mr./Ms _____

S.O./D.O./W.O.

Mr./Ms _____

Sex _____ Age _____

2. Home Address:

3. Hospital Patient Registration Number (CR No.):

4. Name and Address of next of kin or person responsible for the patient (if none exists, this must be specified)

5. Has the patient or next of kin agreed to any donation of organ and/or tissue?

6. Is this a Medico-legal Case?
Yes.....No.....

(B) PRE-CONDITIONS:

1. Diagnosis: Did the patient suffer from any illness or accident that led to irreversible brain damage?

Specify details.....
.....
.....

Date and time of accident/onset of illness.....

Date and onset of non-reversible coma.....

2. Findings of Board of Medical Experts:

		First Medical Examination		Second Medical Examination	
		1 st	2 nd	1 st	2 nd
1.	The following reversible causes of coma have been excluded:				
	Intoxication (Alcohol)				
	Relaxants (Neuromuscular blocking agents)				
	Depressant Drugs				
	Primary Hypothermia				
	Hypovolaemic shock				
	Metabolic or endocrine disorders				
	Tests for absence of brain-stem functions				
2	Coma				
3	Cessation of spontaneous breathing				
4	Pupillary size				
5	Pupillary light reflexes				
6	Doll's head eye movements				
7	Corneal reflexes (Both sizes)				
8	Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk.				
9	Gag reflex				
10	Cough (Tracheal)				
11	Eye movements on caloric testing bilaterally				
12	Apnoea tests as specified.				
13	Were any respiratory movements seen?				

Date and time of first testing:

.....

Date and time of second testing:

.....

This is to certify that the patient has been carefully examined twice after an interval of about six hours and on the basis of findings recorded above,

Mr./Ms.....is declared brain-stem dead.

Date: _____

Signatures of members of Brain Stem Death (BSD) Certifying Board as under:

1. R.M.P.- In charge of the Hospital
In which brain-stem death has occurred

2. R.M.P. nominated from the panel
of names sent by the hospitals and
approved by the Appropriate
Authority.

3. Neurologist/Neuro-Surgeon

4 R.M.P. treating the aforesaid
deceased person

Note:

I. Where Neurologist/Neurosurgeon is not available, then any Surgeon or Physician and Anaesthetist or Intensivist, nominated by the Medical Administrator in Charge of the hospital shall be the member of the board of medical experts for brain-stem death certification.

II. The minimum time interval between the first and second testing will be six hours in adults. In case of children 6 to 12 years of age, 1 to 5 years of age and infants, the time interval shall increase depending on the opinion of the above BSD experts.

III. No.2 and No.3 will be co-opted by the Administrator Incharge of the hospital from the Panel of experts (Nominated by the hospital and approved by the Appropriate Authority).