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Brain stem death certification protocol

Col Vikas Srivastava^{a,*}, Col Monish Nakra^a, Col Anand Shankar K.^a,
Col Pawan Dhull^b, Col R. Ramprasad^a, Maj Gen N.S. Lamba^c

^a Senior Adviser (Anaesthesia & Critical Care), Army Hospital, (R & R), New Delhi, India

^b Senior Adviser (Medicine and Neurology), Army Hospital, (R & R), New Delhi, India

^c Dy Commandant, Army Hospital (R & R) New Delhi, India

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ABSTRACT

Transplantation of Human Organs is guided by laid down specific Laws in India. The organs which are targeted to be transplanted are liver, kidney and cornea. The waiting list is enormous but the donor pool is meagre. This document has been made with a view that the donor pool can be enlarged by identifying patients who are 'Brain Dead' while still not having 'Cardiac Death'. The steps include the prerequisite conditions which must be satisfied by patients who have suspicion of being brain dead, detailed examination of the patient, confirmation of the Brain Death and Counselling of the relatives for organ donation.

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Introduction

1. Transplant of human organs are governed in India by Transplant of Human Organs Act 1994,¹ Transplant of Human Organs Rules 1995²⁻⁴ and Transplant of Human Organ and Tissue Rules 2014.⁵ Armed Forces of India has been given special permission by THOA 2014 31 (4) f to have an independent method for allocating organs between various Military Hospitals for transplant of Liver, Kidney and Cornea. Waiting list for organs is massive but the organs available are few, and many a times the patient passes away during the endless wait. The pool of organs could be much bigger if specialists, administrators and relatives are sensitized about the potential of organ donation and also that knowledge needs to be improved about standard method of evaluating of patients who are qualifying for organ donation. This document has been

made with a view that the actions by various specialists and hospital administrators be channelized in synchronized method to ensure that the clientele and organization benefits from increasing the donor pool.

2. The usual mode of death is when patient has a cardiac and consequently circulatory arrest. When this occurs all the organs of the deceased are rendered non-retrievable except cornea. To facilitate organ retrieval and consequent transplant into another human, another mode of dying viz., Brain Stem Death (BSD) has been invented where there is an irreversible cessation of all brain-stem functions.⁷ BSD precedes cardiac arrest and it gives time for harvesting human organs for transplant. The basic premise of BSD is that the patient will eventually have cardiac death. This time has been utilized for counselling of relatives to consent for organ donation, following all procedures and protocols for harvesting and transplanting organs. Transplant is the

* Corresponding author.

E-mail address: vikas.icu@gmail.com (V. Srivastava).

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only permanent solution of end stage organ failure giving patients new lease of life.

3. Who should diagnose: There is general lack of awareness as to who can diagnose a BSD. For the purpose of transplant a medical team as per THOA Rules 2014 is required which comprises of
 - Medical Administrator in charge of the hospital.
 - Intensivist/Anaesthesiologist
 - Neurologist/Physician/Neuro-Surgeon/Surgeon
 - Medical Officer treating the patient

Amendments in the THOA Rules (2014) have allowed selection of a surgeon/physician and an anaesthetist/intensivist, in the event of the nonavailability of neurosurgeon/neurologist. It is important that a team of doctors in each hospital should get registered and approved with NOTTO (National Organ & Tissue Transplant Organisation) for the purpose of testing and declaring BSD.

Step – 1: Pre-requisites for brain death certification (all must be checked)

4. The most common causes of BSD are severe head injury due to trauma, subarachnoid haemorrhage and stroke – both ischaemic and haemorrhagic. Brain death certification must be done on the basis of reliable clinical and ancillary tests if required as mentioned below. Testing for BSD is done twice by set of four doctors to eliminate any observer bias.⁶ First test should be done after consultation between the above mentioned doctors who have a strong suspicion that the patient is brain dead. Detailed Brain Stem Death Protocol is a useful clinical tool for all clinicians and based on THOA Rules 2014 and strives to remove all ambiguity.

- (a) **Clinical evaluation.**⁸⁻¹⁰ Clinical examination should establish a cause of coma and also establish irrefutably the irreversibility of it. The clinician has to keep in mind that in case of any ambiguity, benefit of doubt goes to the patient and testing is aborted till all the grey areas are sorted out. Before the clinical examination, it should be determined whether the patient was on any CNS depressants. If so, has the drug been completely eliminated from the body or not and for unknown history, a urine drug screen can be done. If the hepatic and renal functions are normal, a period of 5 times the drug's half life is sufficient to validate complete removal of the drug from the body. It should be kept in mind that prior hypothermia (commonly used for neuroprotection) delays drug metabolism. If there is a doubt regarding blood alcohol levels then a reasonable threshold would be the legal limit of blood alcohol for driving which is 0.08%. The patient monitoring and drug administration chart must be closely scrutinized and administration of neuromuscular blocking agents has to be ruled out in the previous 6 h at least. Sodium level should be between 125–159 mEq, severe acidosis or alkalosis is absent (it is not mentioned in the literature but suggested that pH should be between 7.200 and 7.500) and patient should not have severe thyroid or other endocrine dysfunction.

These patients are on the ventilator in a control mode. Trigger is reduced to a 1 cm H₂O and the patient is allowed to breath for few minutes and it should be definite that the patient is not triggering the ventilator. A very helpful manoeuvre is to observe if the patient is breathing or gagging during a suction procedure.

- (b) **Achieve normal core temperature.** Core body temperature should be more than 36 °C. If it is lower, then a warming blanket is used to ensure that the core body temperature is more than 36 °C during the testing.
- (c) **Achieve normal systolic blood pressure.** Hypotension should be treated with vasoactive drugs and systolic BP must be above 100 mmHg for reliable neurological testing. Hypotension could also be due to hypovolemia secondary to Diabetes Insipidus requiring fluid resuscitation.

Step 2: Examination of the patient

5. All the steps must be performed and documented with time.
 - (a) **Coma.** The patients have to be completely unresponsive. There should be no eye opening or eye movement to noxious stimuli. Spinally mediated response to noxious stimuli may be present and have to be differentiated from cerebral activity.
 - (b) **Absence of brainstem reflexes.**¹⁰
 - **Pupillary reflex** is absent in both eyes. It is done by shining bright light in the pupils and observing no contraction. Pupils should be in a dilated or semi-dilated position (size 4–9 mm). It maybe noted that this test is not reliable in an eye after cataract surgery.
 - **Doll's Eye movements.** This tests oculcephalic reflex. After ensuring stability of cervical spine, the head is briskly rotated horizontally and vertically. There should be no movement of eyes relative to the head movement. This is documented as Positive Doll's Eye sign.
 - **Cold caloric test.** Head is elevated by 30 °C and external auditory canal is irrigated with cold water, one ear at a time. Volume of 20–50 ml of water is sufficient and the temperature has to be less than 30 °C for the test to be validated. Movement of the eyes is observed for about 1 min after the test. Both sides are tested after a gap of few minutes.
 - **Corneal reflex.** The cornea is touched with a tissue paper or cotton swab or even with a squirt of water. During the test, no eyelid movement should be seen.
 - **Absence of facial muscle movement to a noxious stimulus.** This is done by applying deep pressure on the condyles at the temporomandibular joint, supraorbital ridge or on the nail bed on fingers with no grimacing or facial muscle movement.
 - **Absence of the pharyngeal and tracheal reflexes.** The pharyngeal reflex is tested by oral suctioning, endotracheal suctioning or by a direct pressure over the trachea in the neck. Gag reflex and cough should be definitely absent.
 - (c) **Apnea test.**¹⁰ This test is the core of BSD testing and is defined as absence of respiratory drive in presence of CO₂ challenge. It is a risky manoeuvre and due care has to be taken to ensure safety of the patient

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