



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – Transplantation of Human Organs – Declaration of brain death mandatory in Government and Private Hospitals in the State – Procedure for declaration of brain death -- Orders issued

HEALTH AND FAMILY WELFARE (S) DEPARTMENT

G.O (MS)No.36/2012/H&FWD

Dated, Thiruvananthapuram 04.02.2012

Read:- 1) GO(Rt)No.572/2011/H&FWD dated 14.2.2011
2) Letter No.A1-11317/MCT/2011 dated 20.06.2011 from the Principal, Government Medical College, Thiruvananthapuram

ORDER

1. A large number of patients are suffering from on account of irreversible organ ailments involving heart, liver, pancreas and kidney. Many of them could lead healthy lives if they had the opportunity to have transplant surgery. Considering the ethical issues surrounding the live and deceased organ transplantation, Government felt the need to streamline the procedures for deceased donor organ transplantation (DDOT) in the State.

2. In order to study the feasibility of deceased donor organ procurement and transplantation in the State, a Committee of doctors was constituted as per the Government Order read above. A detailed report in this regard was submitted by the Committee to Government as per the letter read as 2nd paper above.

3. Government have considered the report in detail. Organ transplantation is a life saving procedure and a large number of patients with end stage organ failure are waiting to undergo organ transplantation. Majority of end stage organ failure patients in India die due to the non availability of organs and / or non affordability. The deceased organ donation rate in our country is 0.08 per million populations and the overall potential of organ donation following brain death is extremely high. The Transplantation of Human Organs Act, 1994 (THOA) is an enabling legislation as far as deceased donor transplantation is concerned. There is at present no established procedure or guideline in the State to deal with situations that arise when brain deaths occur in hospitals that are not registered under THOA, 1994, even when the families of brain dead persons wish to give consent to donate the organs of their deceased family member. Considering the fact that the deceased donor organ donations are done with altruistic motive and in a generous and charitable manner as a willing contribution to the society, it is necessary that this organ donation be governed by transparency on all fronts to ensure that the sentiments of the donor's relatives are adequately respected.

4. One of the major impediments in deceased donor transplantation in the State is the lack of clarity in brain death certification and its optional nature. There are also doubts in medical circles on the authority by which doctors may declare "Brain Death", whenever required. The Transplantation of Human Organs Act, 1994 (THOA, 1994) and the Transplantation of Human Organs Rules, 1995 (THO Rules) made there under are the only pieces of legislation available wherein brain death certification procedures have been elaborately laid down, it is hereby decided that the procedures outlined therein will also be adopted as brain death certification procedure in Kerala. This order will also elaborate on the above format to ensure its applicability to the entire State of Kerala. Government therefore hereby order and made it mandatory that whenever the medical condition (clinical and medical criteria have been met for) of a patient has reached a brain death stage, brain death certification is done as stipulated in this order. This will come into force with immediate effect in all Government District Hospitals & General Hospitals and all the 5 Government Medical Colleges and Private hospitals in the State registered as Transplant Centres with the Appropriate Authority for certifying Brain Death as per the THO Act, in the event of a family of brain dead person consenting to organ donation. All Organ Transplantation Centres will register with the Appropriate Authority for this purpose.

5. From 8 of the THO Act and Rules as found in the Annexure-I to this order are prescribed as the brain death certification format to be utilised for any given situation requiring certification that a person is dead on account of permanent and irreversible cessation of all functions of the brain stem. The tests prescribed therein and the findings required shall remain the same.

6. According to Form 8 of the said Act and Rules, when such certification is required, there shall be two medical examinations conducted by a team of doctors after a minimum interval of six hours and the findings made based on the tests prescribed therein. One aspect of the above form requires further classification and this is provided in Annexure II of this Order. Section 3(6) of the THO Act and Rules prescribes a Board of Medical Experts consisting four Doctors, who are authorised to certify brain death and this provision is clarified further.

(A) Doctor No.1 is the 'R.M.P'. in charge of the hospital in which brain-stem death has occurred.' Accordingly, the Registered Medical Practitioner in charge of the hospital in which brain-stem death has occurred shall refer to either the Head of the Institution or RMO.

(B) Doctor No.2 is an independent R.M.P. nominated from the panel of names approved by the Appropriate Authority.' Accordingly, a panel of names shall be sent by the Medical Superintendent/Medical Director of the hospital through the District Medical Officer to the Appropriate Authority namely the CCCT (Core Committee for Cadaver Transplantation) and on approval shall then be utilised as the panel from which a R.M.P. shall be nominated for each brain death certification. Each hospital may decide on the panel of names for this duty.

(C) Doctor No.3 is 'Neurologists/Nuero-Surgeon nominated from the panel of names approved by the Appropriate Authority'. Again, a panel of names shall be sent by the Medical Superintendent/Medical Director of the Hospital through the District Medical Officer to the Appropriate Authority and on approval shall then be utilised as the panel from which one specialist as in the category therein shall be nominated for each brain death certification. Each hospital may determine its own procedure for this duty.

(D) Doctor No.4 is the R.M.P. treating the aforesaid person. (No clearances are required from the Appropriate Authority in this category).

Note: i) Doctor No.2 and 3 should be from outside the Hospital where the Brain stem death patient is taking treatment and to get their services, the hospital concerned, shall make a request to the DMO concerned.

ii) The 1st and 2nd Medical examination as defined in Form-8 of the THO Rules shall be conducted by category 2 and 3 Doctors from the panel approved by the Appropriate Authority.

7. This procedure shall be applicable to all hospitals including private hospitals which wish to certify Brain Death as and when required. Accordingly, the categories that require for the panel to be approved shall be done so on submission to the Appropriate Authority (Core Committee for Cadaver Transplantation).

8. The Director of Medical Education and the Director of Health Services are directed to periodically organise awareness workshops on the provisions of this order.

(By Order of the Governor)
RAJEEV SADANANDAN
Principal Secretary to Government

To

The Director Medical Education, Thiruvananthapuram
The Director of Health Services, Thiruvananthapuram
The Principal, Medical College, Thiruvananthapuram, Kottayam,
Alappuzha, Thrissur & Kozhikode
All the District Medical Officers (Health) (through DHS)
Stock file/Office Copy

Forwarded by Order

Section Officer

FORM 8

[Refer rule 4(3) (a) and (b) of the THO Rules 1995]

We, the following members of the Board of Medical Experts after careful personal examination, hereby certify that Shri/ Smt. / Km
aged about S / o, W /o, D / o, Shri.....
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.

Date.....

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 approved by the
Appropriate Authority

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2. Neurologist / Neuro-Surgeon nominated
from the panel of names approved by
the Appropriate Authority

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

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BRAIN-STEM DEATH CERTIFICATE

Patient Details:

1. Name of the Patient: Shri/ Smt. / Km.
S/o. / W/o / D/o : Shri
Sex..... Age.....

2. Home Address:
.....
.....
.....

3. Hospital Number:

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 transplant?
.....
.....

6. Is this a Police Case? Yes..... No.....

Pre-Conditions:

1. Diagnosis: Did the patient suffer from any illness or accident that led to irreversible brain damage? Specify details:
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Date and time of accident/onset of illness:

Date and onset of non-responsible coma:

2. Findings of Board of Medical Experts:

(i) The following reversible cause of coma have been excluded:-

Intoxication (Alcohol)

Depressant Drugs

Relaxants (Neuromuscular blocking agents)

First Medical Examination Second Medical Examination

1st

2nd

1st

2nd

Primary hypothermia

Hypovolaemic shock

Metabolic of endocrine disorders

Test for absence of brain-stem functions

(ii) Coma

(iii) Cessation of spontaneous breathing

(iv) Pupillary size

(v) Pupillary light reflexes

(vi) Doll's head eye movements

(vii) Corneal reflexes (Both sizes)

(viii) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk

(ix) Gag reflex

(x) Cough (Tracheal)

(xi) Eye movements on coloric testing bilaterally

(xii) Apnoea tests as specified

(xiii) 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,

Shri / Smt / Km..... is declared brain-stem dead.

1. Medical Administrator In charge of the hospital.

2. Authorised Specialist.

3. Neurologist / Neuro-Surgeon.

4. Medical Officer treating the patient.

N.B I. The Minimum time interval between the first testing and second Testing will be six hours.

II. No. 2 and No. 3 will be co-opted by the Administrator in charge of the hospital from the panel of experts approved by the Appropriate Authority.

ANNEXURE – II

Guidelines for Apnoea Test:

Patient should have a temperature of more than 35⁰ centigrade euvolemic and with Systolic pressure \geq 90mm of Hg.

- i. 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.
- ii. The physician involved in certifying brain death shall be present during Ventilator removal to attest the presence of Apnoea if found
- iii. Ventilator manipulation is performed to raise the PaCo₂ \geq 40 mmHg
- iv. The patient should be hyper oxygenated with 100% Oxygen for 15 minutes, while still on the Ventilator, prior to the Apnoea test
- v. 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.
- vi. Place the patient on 100% Oxygen through a tracheal catheter with the tip towards the end of the tube with a continuous 6L/min O₂ flow.
- vii. 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 15mmHg over baseline. During this time, the patient is observed for respiratory movements.
- viii. Test interpretations:
 - a. Positive Test – implying Apnea despite adequate stimulation
 - i. Patient remain Apneic, without respiratory movements
 - ii. PaCo₂ is \geq 55mm Hg or \geq 15mmHg from baseline
 - b. Negative test – Implying Apnea is not present
 - i. Respiratory efforts noted at any time during the test
 - c. Indeterminate test
 - i. PaCo₂ < 55mmHg or there is less than 15mm Hg increase over baseline
 - d. Indeterminate tests can either be repeated or another confirmatory test utilised.
- ix. Apnoea test should be aborted if the patient develops hypotension, or significant cardiac arrhythmias.
- x. These norms will vary for patients less than 12 years and patients with major chest trauma.