

#### GOVERNMENT OF KERALA Abstract

Health & Family Welfare Department – Transplantation of Human Organs – Cadaver Organ Transplantation Programme – Procedure to be adopted by the Government and Private Hospitals approved for Organ Transplantation – Guidelines Issued

## HEALTH AND FAMILY WELFARE (S) DEPARTMENT

# G.O (MS)No.37/2012/H&FWD Dated, Thiruvananthapuram, 04.02.2012

Read: - G.O.(MS)No.36/2012/H&FWD dated 04.02.2012

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Being aware that a large number of patients who are suffering on account of various organ ailments ranging from heart, liver, kidney etc. have to wait long periods due to paucity in organs donated by living donors, Government as per the Government Order read above have issued orders for implementing Cadavar Organ Transplantation in the State. Government is also aware that the success of Organ Transplant especially Cadaver Organ Transplantation depends on efficacious donor management and meticulous co-ordination with Organ Retrieving Centres and Organ Transplant Centres. Government have considered the suggestions and opinions from stakeholders and Non Governmental Organisations working for the cause of organ donation and opinions brought forward by the medical professional related to this field and the combined opinions of the Director of Medical Education and Director of Health Services and they felt the need for an established procedure and guidelines for the effective co-ordination and implementation of the programme. Accordingly the following orders are issued:

2) When the family of the brain dead patient is willing to donate his/her organ(s) to benefit others, the following procedures shall be strictly adhered to:-

(i) The procedures in declaring brain death shall be adhered to as laid out in the Government Order read above.

(ii) Form 6 as laid out in the Transplantation of Human Organs Rules, 1995 shall duly be signed by the person(s) responsible for the brain dead patient and in the case of children below the age of eighteen years, the appropriate form namely Form 9 of the Transplantation of Human Organs Rules, 1995 requires to be signed by the persons concerned before organ retrieval.

(iii) Organ(s) retrieval shall not be carried out on a brain dead patient merely due to an earlier declaration by the said patient in Form 5 of the Transplantation of Human Organs Rules, 1995. While such a declaration shall presuppose the previous intensions of the brain dead patient to donate his/her organ(s), consent in form 6 of the Transplantation of Human Organs Rules, 1995, is necessary to continue with the process of organ retrieval.

(iv) Each hospital should have its own waiting list for each organ, which will include the date of registration. The criteria as well as the prioritized waitlist, continually updated, should be made available online to the Convenor, Cadaver Transplant programme, Kerala. Some hospitals may prefer date of registration. Exceptions to the already notified criteria must be substantiated with reasons to the Convenor, Cadaver Transplant programme, Kerala when a request is made otherwise. The decision of the Convenor, Cadaver Transplant Programme, Kerala when a request is made otherwise.

(v) Any individual needing organ transplant through cadaver organ donation can be registered through only one hospital at a given time. She or he is free to change the registration to any other transplant hospital, but the original date of registration will continue to apply for purposes of prioritization or organ allocation.

3) Following the above criteria for allocation, the organ(s) of the brain dead patient shall be shared in the following order, based on the respective prioritization list.

(i) If there is a patient who is to be a multi organ recipient and a matching organ donor is available, then the multi organ recipient takes precedence over all others on the regular waiting list. The Convenor, Cadaver Transplant program, Kerala will take the appropriate decision regarding allocation criteria when such a situation arises.

(ii) Considering the peculiar nature of certain liver ailments, a provision is made, which is as follows:

4) Potential liver recipients in hospitals are to be listed in one of the two categories namely 'Urgent' or 'Standard'.

(a) Urgent: Those on the urgent list are those who have:

- (i) Hepatic Artery Thrombosis following a liver transplant.
- (ii) Primary Non function of a graft
- (iii) Fulminant hepatic failure.

These conditions do not require a waiting time on the list.

(b) Standard: This list refers to all patients who need a liver transplant but do not fulfill criteria for urgent listing. Patients on the standard list have to be registered for more than 24 hours to be listed in this category.

The Liver is to be allotted to participating hospitals in turn.

Note: Patients on the urgent list supersede the standard list and the hospital misses

#### its regular turn on the rota.

(iii) Similarly, potential heart recipients in hospitals are to be listed in one of the two categories namely 'Urgent' or 'Standard'.

(a) Urgent:

(i) Patients with Left Ventricular Assist Device (LVAD).

(ii) Followed by patients with Intraaortic Balloon Pump(IABP)

(b) Standard: Sick, but stable patients waiting at home for a heart transplant.

A Heart is to be allotted to participating hospitals in turn.

(iv) Likewise for lungs, prioritization would be made according to the urgency of transplant and allotted to participating hospitals in turn.

(v) For kidneys no out of turn allocation would be permitted and the sharing criteria in the following para shall be followed.

5) Sharing of Organs for waitlisted recipients, retrieved from cadaver donors in Government Institutions will be as follows:

(i) First priority to the list of the Government Hospital where the deceased donor is located, for liver, heart and one kidney. The other kidney would be allocated to the general pool in the priority sequence as listed below.

(ii) Second priority to the combined Government Hospitals list

(iii) Third priority to the combined Private Hospitals list

(iv) Fourth priority to Government Hospitals outside the State, (in order to maximize organ utilization)-provided earlier information and such a request has been registered with the Advisory committee / Convenor, Cadaver Transplant Program, Kerala.

(v) Fifth priority to Private Hospitals outside the State (in order to maximize organ utilization) provided earlier information and such a request has been registered with the Advisory committee / Convenor, Cadaver Transplant Program, Kerala.

6) Sharing of Organs for waitlisted recipients retrieved from cadaver donors in Private Hospitals, which are transplant centres.

(i) First priority to the list within the Private Hospital where the deceased donor is located, for liver, heart and one kidney. The other kidney would be allocated to the general pool in the priority sequence as listed below.

(ii) Second priority to the combined list of Government and Private Hospitals.

(iii) Third priority to Government / private hospitals outside the State,

(in order to maximize organ utilization) provided earlier information and such a request has been registered with the Advisory committee/Convenor, Cadaver Transplant Program, Kerala.

(iv) Finally, if the organ(s) remains unutilized by the above criteria, it may be offered to a foreign national registered in Government or private hospital within and then outside the state, provided earlier information and such a request has been registered with the Advisory committee /Convenor, Cadaver Transplant Program, Kerala.

7) Whenever a deceased donor becomes available in a hospital, the concerned hospital shall contact the Transplant Co-ordinator, Government Medical College, Thiruvananthapuram, who will then make allocations based on the above. Non Governmental Organisations promoting organ transplantation may assist the Transplant Co-ordinator, Government Medical College, Thiruvananthapuram to facilitate this arrangement and ensure that most number of cadaver organs donated are utilized to benefit organ failure patients.

8) Considering that a number of practical issues are involved such as

(i) establishing formats and procedures for recipient listing, organ allocation and transfer

(ii) co-ordination between hospitals where donor / recipient are located

(iii) working towards a coordinating body that would be institutionalized and fine-tuning identification criteria to determine the beneficiaries-

(iv) Proposing policy initiatives from time to time.

(v) Need for watching the working of the cadaver organ transplantation program, the Government have decided to form an Advisory committee at the State Level called CTAC that would address the above issues and ensure stability in functioning of the cadaver organ transplant program 9) The Advisory committee shall consist of: (i) Principal Secretary, Health & Family Welfare Department -- Chairman (ii) Law Secretary or his nominee -- Member One Senior Police Officer of DIG rank nominated by (iii) ↓ ├ – Member the Director General of Police, Kerala (iv) Director of Medical Education – Member (v) Director of Health Services – Member (vi) Principal, Government Medical College, Thiruvananthapuram (vii) Professor & Head of Department, Forensic Medicine, - Convenor Government Medical College Thiruvananthapuram

(viii) An NGO to be nominated by the Government -- Member

(ix) One transplant team member from three different private hospitals that currently have largest cadaver donation experience – Member

10) Besides the CTAC another Committee at the State Level named 'Core Committee for Cadaver Transplantation (CCCT)' will be formed for co-ordination with Non Transplant Organ Retrieval Centres and Organ Transplant Centres engaged in Cadaver Transplant Programme. The composition of the Core Committee for Cadaver Transplantation will be as follows:

- (i) The Director of Medical Education Chairman
- (ii) The Director of Health Services Co-Chairman

Thiruvananthapuram

íiií) Principal, Government Medical College, ך

e, } –Member

(iv) Prof & HoD, Forensic Medicine & Transplant Co-ordinator Kerala – Convenor

(v) Core Committee for Cadaver Transplantation can co-opt another member, who is a multi organ transplant expert to assist and advice subject, however to the condition that such a person shall not have any affiliation to any Pvt. Hospital registered as a Organ Transplantation Committee.

11) The Core Committee for Cadaver Transplantation shall in turn nominate four sub-committees to assist in its functioning for

- (i) Liver
- (ii) Heart
- (iii) Kidney

(iv) other organs- to determine the severity of illness for listing a patient for transplant.

12) The Core Committee for Cadaver Transplantation shall discharge the following functions and responsibilities:

(i) The Core Committee for Cadaver Transplantation is the legal entity authoroised with statutory powers under the Transplantation of Human Organs Rules, 1995. It shall act as the Appropriate Authority under the Transplantation of Human Organs Act, 1994.

(ii) Registration of hospitals as Non Transplant Organ Retrieval Centres or Organ Transplant Centres

(iii) Supervision and regulation of the functioning of Non Transplant Organ Retrieval Centres and Organ Transplant Centres, including exercising the powers to suspend the registration in the event of any deviation or misconduct

(iv) Allocation of the organs available from cadavers to the registered patients (recipients) strictly following the priority laid down ibid.

(v) Empanelment of specialists, especially in the specialities of Neurosurgery, Neurology and Physicians/Surgeons whose services can be availed by Non Transplant Organ Retrieval Centres or Organ Transplant Centres to be part of the Medical Board for the purpose of declaring brain death.

(vi) Conduct of programmes to raise awareness in general public (Se 3.0,D), such as mass media communication, conduct of annual events, establishing a system of online and postal pledging of organs by willing individuals in a central registry through a Web based portal, and issuing donor cards.

(vii) Any other functions and responsibilities for the effective implementation of Cadaver Transplant Programme.

13) The CCCT will meet as and when required or at least once in every month and will furnish necessary recommendations to the Cadaver Transplant Advisory Committee upon receipt and evaluation of feed back from the Organ Transplant Centres and Non Transplant Organ Retrieval Centers (NTORC), on the modifications if any, as they deem necessary in the implementation of the programme. The Cadaver Transplant Advisory Committee (CTAC) will meet periodically at least once in every 3 months and will review the performance of Core Committee for Cadaver Transplantation, Organ Transplant Centres and Non Transplant Organ Retrieval Centre and will make appropriate recommendations to Government for modifications in the implementation of the scheme.

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

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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

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