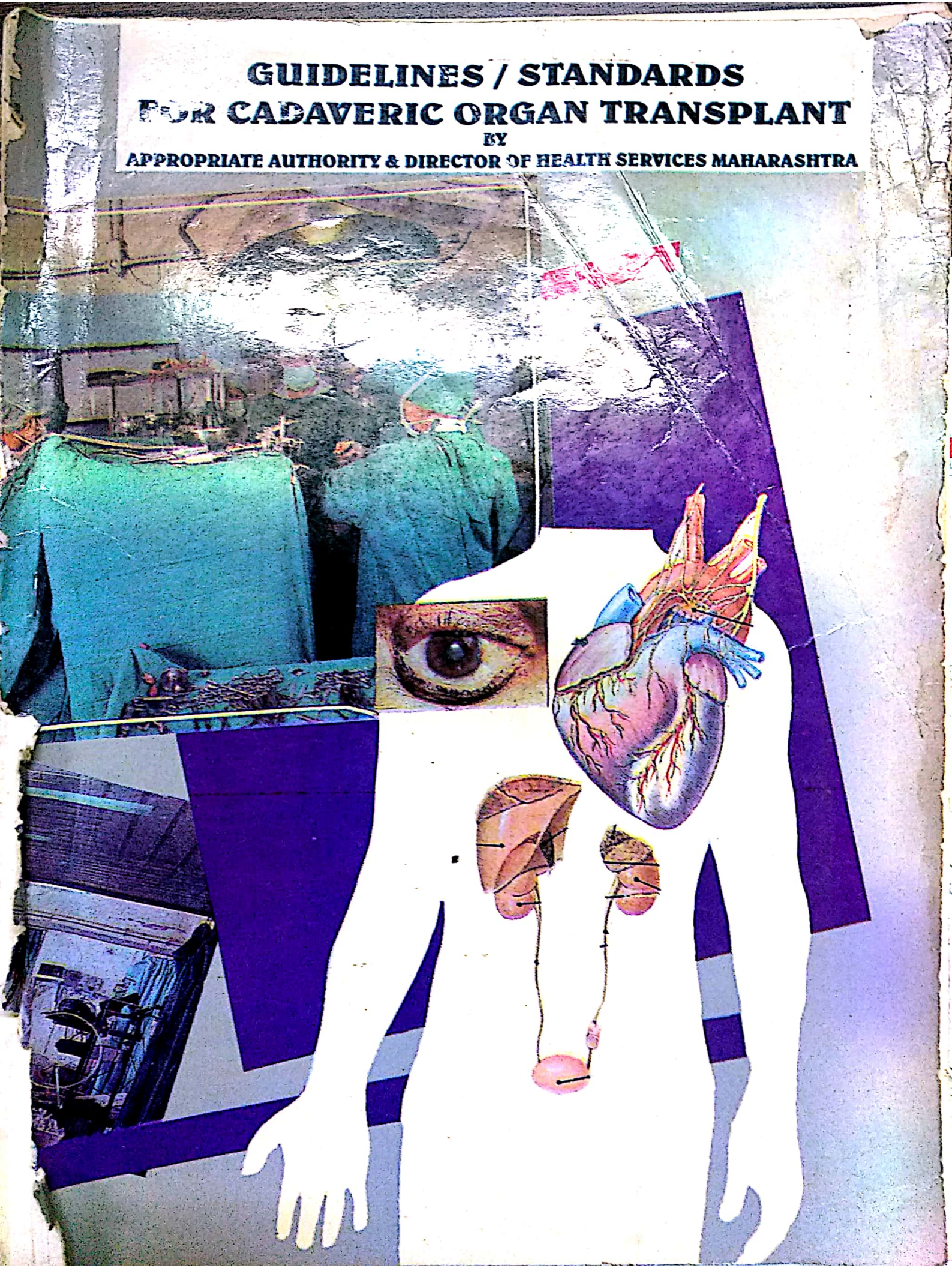
GUIDELINES / STANDARDS
FOR CADAVERIC ORGAN TRANSPLANT

BY

APPROPRIATE AUTHORITY & DIRECTOR OF HEALTH SERVICES MAHARASHTRA



PREFACE

The government of Maharashtra adopted on 23rd February 1995 the "Transplantation of Human Organs Act" published by Govt. of India in July 1994.

After implementation of the said Act. transplantation of human organs from live donors particlarly kidney is in progress. However a dream of transplantation of organs from brain dead donor came in reality when the kidney transplant from cadaver was carried out successfully at L. T. M. G. Hospital, Sion, Mumbai and then subsequently at other hospitals.

It is my great pleasure to circulate the guidelines / standards from cadaver organ transplant Programme in the State of Maharashtra.

It was just impossible for me to formulate these guidelines without the help of experts from medical faculty who were involved in preparing the criteria for transplantaion of various organs.

I am greatful to Dr. Subash Salunke, the Hon. Director of Health Services and to all the experts who spared thier valuable time inspite of thier busy schedule and offered their valuable suggestions specially Dr. (Smt) V. N. Acharya, Chairperson CTP Committee. National Kidney Foundation (India), Mumbai and Dr. G. B. Daver, Prof. of Surgery, Grant Medical College, Mumbai.

I am thankful to the experts who lent their energy and time in the preparation of these guidelines / standards and also to my colleagues in the Directorate specially Dr. S. B. Chavan, Jt. Director, Dr. V. B. Pande, Dy. Director and Dr. S. M. Sakpal, Asst. Director.

I hope these will be of use to all the professionals and hospitals engaged in organ transplantation.

Place : Mumbai
Date : May , 1999

Dr. B. M. DAMA
Appropriate Authority for
Organ Transpalntation &
Director of Health Service
Maharashtra State, Mumbai

INDEX

GUIDELINES/STANDARDS FOR CADAVER TRANSPLANT PROGRAMME

UNDER TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

INTRODUCTION :

Transplantation of Human Organs Act, 1994 was implemented in the State of Maharashtra on 23rd February1995.

After implementation of the Act, Government of Maharashtra appointed Director of Health Services as "Appropriate Authority" vide notificatin dated 23rd March 1995.

At the same time Authorisation Committee was appointed comprising of the following members vide Govt. Resolution dated 29th March 1997.

1.	Director of Medical Education & Research, Mumbai	Chairman
2.	Director of Health Services, Mumbai	Member
3.	Dean, Grant Medical College, Mumbai	Member

As the main objective of this Act is to have legal and qualitaive organ transplantation of human organs, the general norms/guidelines are necessary for the medical professions and hospitals involved in organ transplantaion.

The guidelines have been formulated by the Appropriate Authority which is Director of Health Services, Mumbai, as per the recommendations of the Panel of Experts established by the Authority.

After the implementation of the Act, the Appropriate Authority had several meetings and discussions with the varios experts and based on their recommendations, the draft norms / guidelines have been formulated.

1) GENERAL INSTRUCTIONS :

The general guidelines / norms which all hospitals and organ transplant centres should follow have been put forward. They are :

1) All brain death cases should be reported to Appropriate Authoriy as per circular issued in November, 1996. However all potential organ donors should be specifically informed to ZCC and Appropriate Authority. Till such time ZCC is formed Appropriate Authority alone will receive such reports.

2) Each hospital should establish local comittees which are responsible for matters pertaining to brain death cases and organ transplantation in the respective hospitals as follows :

a) Brain Stem death Committee : It should be formulated as per the Act and approved by Appropriate Authority. This committee will be responsible for follow up

of all matters related to brain death cases and their reporting. The committee also will submits / proposals for developing the brain death programme in its region to the Appropriate Authority. They will also report brain death cases to Zonal Co-ordinating Centre (ZCC) / Appropriate Authority and to update follow up information of these cases continuously.

Brain Stem death Committee should inform brain stem death cases to transplant committee.

b) Social Service Committee : It should consist of hospital administrator, Medical Social Worker & members from Trauma Care Unit. This committee should be established by the Dean / Medical Superintendent / Hospital Director. Its responsibilities being to approach the family and relatives of brain-death case for the purpose of obtaining their consent for organ donation and to help the relatives of the donor / recepients in all possible ways.

c) Transplant Committee : The physician, surgeons and anaesthetist associated with each type of organ transplant.

d) Local transplant co-ordinating committee : The registered hospitals should make a group of medical intensivist with a Medical Social Worker / Senior Nurse / a representative of medical administrator to act as local transplant co-ordinating committee. Local transplant co-ordinating committee will activate brain stem death committee. Brain Stem Death committee should inform the local transplant co-ordination committee about confirmation of brain stem death so as to enable them to arrange all necessary blood samples to the laboratory to ensure fitness of brain stem dead donors organs and act as liason between ZCC and Appropiate Authority. They should also inform transplant committee about availability of organ.

3) Documentation of brain death is done in accordance with the steps laid down in the Brain-death Documentatation Form as per the Act & according to special procedures that have been laid down. If the Brain-dead patient is a female, it shold be ensured that she is not pregnant and if so, organ donatian is not considered at all except when there is foetal death. Also no member involved in the transplantation of organs should participate in the diagnosis of brain stem death.

4) Consent for organ donation should be obtained from the next of the kin of brain death cases whether they are inside or outside the state and in accordance with the special consent form mentioned in the Act.

If brain stem dead case is unclaimed, the consent of administrative head of the institution should be obtained before harvesting is performed.

5) The hospitals in the city should co-ordinate with the Zonal Co-ordinating Centre before performing any organ harvesting to enable benificial distibution of organs in accordance with the norms in this directory.

6) Organ harvesting should be performed in the same hospital where brain stem death is diagnosed and no case should be transferred to another hospital except when there is an absolute necessity. The hospital in which brain stem death is diagnosed is responsible for issuing death certificate.

7) When brain stem death is confirmed and consent is obtained from the next of kin as per act for organ donation, distribution & transplantation of the organs should be carried out as laid down in the norms concerning each organ.

8) Local Organ Transplant Co-ordination Committee in individual hospital should be entrusted with following responsiblities.

- Acts as liason between the ZCC / Appropriate Authority and Centre for Organ Transplantation and the Organ transplant Institute .
- Reporting the names of all patients awaiting transplantation to the Zonal Co-ordinatig Centre in order to include them in the city waiting list. They will also prepare a local waiting list for each organ transplant centre, according to priority norms for each organ.
- Co-ordination with the ZCC / Appropriate Authority of Organ Transplantation when there is a brain-death case in any of the hospitals affiliated to ZCC and extending assistance as needed.
- Informing the ZCC / Appropriate Authority for Organ Transplantation when a suitable patient fit for transplantation is not available in the local waiting list.
- To send updated all information related to patients with end stage organ failure (kidney, heart, liver, lung etc.) who are fit for transplantation in accordance with special forms issued for that.

9) Each hospital and organ transplant centre should send a list of names of end stage organ failures patients to the ZCC / Appropriate Authority for Organ Transplantation which in turn establishes city waiting lists for each organ transplant in accordance with priority norms. The waiting list is sent back to organ transplant centres to act accordingly.

10) Each transplant centres should provide reports and statistics of organ transplant recipients both from living and cadeveric donors every month to the Appropriate Authority for Organ Transplantation through its transplant committee in accordance with the special forms of transplant follow-up and other forms circulated by the Appropriate Authority.

11) All kidney transplant centres have to carry out their responsiblities towards the patients registered with them by doing their regular follow-up. This will essentially depend on patient registered with individual hospitals who are under dialysis else where while awaiting cadveric kidney for transplantation.

12) Evaluation of organ trasplant centre will be done every five years by specialised technical experts authorised by Appropriate Authority in each respective field and in accordance with the criteria laid down by the Appropriate Authority, besides sudden surprise evaluations within five years.

II) BRAIN STEM DEATH CRITERIA :

In the event that the traditional cardio-respiratory death cannot be determined to have occured, as universally accepted hitherto, because of the use of artificial medical measures such as respirators, pace-makers or other similar machines, a medical examination for the possible existance of brain stem death should be undertaken in deeply comatose patients.

For determination of brain-stem death, the following criteria and tests should be applied to clearly identify the irreversible cessation of brain-stem (mid brain,pons & medulla oblongata) function has occured.

Conditions under the diagnosis of brain-stem death shall not be considered :

(1) The absence of coma in patient.

(2) The children below the age of three years.

(3) In deeply comatose patients where there is a suspicion that coma may be due to :

- (a) Depressant drugs.
- (b) The presence of primary hypothermia.
- (c) The presence of metabolic or endocrine disorders which may be responsible for or can contribute to the patients comatose state.
- (d) Severe shock
- (e) Respiratory insufficiency or arrest requiring use of a respirator possibly because of the use of relaxtant drugs or neuromuscular blocking agent and other drugs.

(4) a) When a diagnosis of a disorder likely to result in brain stem death is not fully established.

b) In the absence of objective clinical evidence of irremediable structural brain damage.

PRECAUTIONS :

(1) Details of administration of drugs should be clearly evaluated and sufficient time should be allowed for the drug effects to disappear. This is essential in patients where the coma is due primarily to the toxic effect of drugs followed by anoxic brain-stem damage. It should be remembered that hypnotics tranquillisers, narcotics and other similar drugs have occasionally a prolonged action especially when the affected individuals are also hypothermic. The benzodiazepines, such as diazepam, nitrazepam and others have a cumulative and persistent action. These drugs are often used for patients on artificial respirators or ventilators as anticonvulsants.

(2) Serios abnormalities of serum electrolytes, acid base balance of blood glucose (sugar) should not exist. All metabolic and endrocrine functions possibly causing or complicating a comatose state should be carefully evaluated.

(3) Immobility, unresponsiveness and lack of spontaneous respiration may be due to the use of neuromuscular blocking drugs and the persistance of their effects should be excluded by elicitation of spinal reflexes (flextion or stretch) or by the demonstration of adequate neuromuscular conduction with a conventional nerve stimulator. Equally persistent effects of hypnotics and narcotics should be excluded as a cause of respiratory failure.

(4) It may be obvious within hours of primary intracranial event such as a severe head injury, spontaneous intracranial haemorrage or following neurosurgery that the condition is irremediable. However when a patient has suffered primarily from a cardiac arrest, hypoxia or severe circulatory insufficiency with an adequate period of cerebral anoxia, or is suspected to having cerebral air or fat embolism, it may then take much longer to establish the diagnosis and to be confident of the prognosis . In some patients , the primary pathology may be a matter of doubt and a confident diagnosis may only be reached by continued clinical observation and investigation.

DIAGNOSTIC TESTS FOR THE CONFIRMATION OF BRAIN-STEM DEATH :

(a) The patient must be comatose and usually for at least six hours or if cardiac arrest was the cause of the coma, for at least 24 hours after the circulation had been restored.
(b) No abnormal decorticate or decerebrate postures should be present.
(c) No epileptic movements should be observed.
(d) No spontaneous respiratory movements should be present.
(e) All brain-stem reflexes must be absent.

The following responses must be confirmed :

(1) The pupils should be fixed in diameter and must not respond to rapid changes in intensity of bright light-source on the pupils.
(2) There must be no corneal reflex.
(3) The oculo-cephalic reflex or doll's head eye movements must be absent.
(4) The vestibulo-ocular reflexes (caloric responses) must be absent.
(5) No motor responses within the cranial nerve distribution should be elicited after adequate stimulation of any body area.
(6) The gag reflex and reflex response to bronchial stimulation by a suction caheter passed down the trachea must be absent.
(7) No respiratory movements must occur when the patient is disconnected from the mechanical respirator(ventilator) for a long enough period to ensure that the arterial carbon dioxide tension rises above the threshold for stimulation of respiration.

OBSERVATIONS :

(1) Oculo-Cephalic reflex or doll's head eye movements should be elicited by rotation of the patients head from one side to the other maintaining each position for a few seconds while observing movements in both eyes if any, while the palpebral fissures are held open.

(2) Vestibulo-ocular reflexes - To elicit these reflexes in both eyes the tympanic membrane must be clearly seen and 20ml of ice-cold water should be injected slowly into each external auditory meatus and directed at the tymanic membrane. This test may very occasionally be contra-indicated in the presence of local trauma.

(3) Apnoea test determination of "Brain Stem Death".

This test is done on patient on Ventilator.

- Initially pure oxygen is supplied through the ventilator for 10 minutes.
- This is followed by 5 % CO_2 in oxygen for 5 minutes whenever clinically indicated in appropriate situations only.
- Thereafter the patient is "disconnected" from the ventilator for ten minutes or more.

However during this time oxygen is continued to be delivered by a catheter into the trachea at the rate of 6 litres/minute.

- Blood collected from blood gases after 10 minutes when $PaCo_2$ should reach 50 mm Hg or above with Po_2 of more than 100 mm Hg.
- If inspite of this, spontaneous respiration does not occur, the test is considered positive.

The test must be repeated once again and confirmed from 6 to 24 hours after the first test for positivity.

A) The patient is then declared "Brain-Stem Death".

B) The decision to withdraw artificial support should be made after all the criteria presented above have been fulfilled and endorsed by 4 medical practitioners as per the provision of law : who are not directly or indirectly connected with any "Transplant Team".

OTHER GUIDELINES :

(A) Repeatition of testing : It is customary to repeat the test to ensure that there has been no observer error. The interval between tests must depend upon the primary pathology and the clinical course of the disease. The interval between tests depend upon the progress of the patients and might be as long as 24 hours. This is matter for medical judgement and repitition time must be related to the signs of improvement, stability or deterioration which present themselves.

(B) Integrity of Spinal Reflexes : It is well established that spinal cord functions can persist after insults which irretrievably destroyed brain-stem function. Reflexes of spinal origin may persist or return after an initial absence in brain dead patients.

(C) Body Temperature : The body temperature in these patients may be low because of depression of central temperature regulation by drugs or by brain-stem damage and it is recommended that it should be not less than 35 C before the diagnostic tests are carried out. A low reading thermometer should be used if necessary.

(D) Specialist Opinoin on the Status of Doctors Concerned : Experienced clinicians in intensive-care-units , acute medical wards and accident and emergency departments should not normally require specialist advice. After the Brain stem death has been clinically diagnosed by above clinicians they would need referral to members of brain stem death committee to confirm Brain stem death as per provisions of law.

It is imperative neverthless, that those registered medical practitioner certifying the occurence of brain stem death should not be connected directly or indirectly with any "transplant team" if there is any intention of donating any part of organ of body of the deceased individual for transplantation purposes. Likewise certifying registered medical practitioners should not be interested in obtaining any part or organ of the deceased's body for medical or scientific research.

III) PROTOCOL FOR MAINTENANCE OF CADEVER ORGAN DONOR :

The aim of brain death maintenance is to obtain viable organs fit for transplantation.
To achieve this goal following measures are suggested :

1. Keep systolic blood pressure more than 100 mm Hg in adults by giving appropriate fluids to keep CVP around 12 cms of H_2O and the use of vasopressors as needed. Dopamine singly or in combination with other vasopressors may be used.

2. Keep urine output between 80 to 100 ml per hour and maintain balance between fluid intake and urine output.

3. Keep blood gases in normal level (pa02 100 mm Hg. pa c02 35mm Hg).

4. Keep acid base status normal and maintain blood electrolytes in the normal range.

5. Diabetes insipidus is a common complication in these patients in which case vasopressin with all necessary precautions may be used if required to keep urine output between 1.5 to 3.0 ml/kg/hr.

6. Prevent infection.

7. Maintain core temperature within the normal limits using either cooling or warming blankets.

8. If patient develops bradycardia with less than 50 beats per minute Isoproterenol or any pharmacological or mechanical modalities could be used if needed.

9. Format for distribution of kidneys.
A form in triplicate has to be filled in with a copy to Appropriate Authority / ZCC in a format as per copy attached.

IV CRITERIA FOR FITNESS OF CADAVERIC ORGAN DONORS ; OTHER THAN CORNEA ; EAR DRUMS AND BONE GRAFTS.

a) *General Criteria :*

It is considered that the cadaveric organ donor is not suitable if the following are present :

1. Loss of his organs due to his initial insult or due to shock lasting for more than 30 minutes. ; unless it is corrected and biochemical parameters are shown to be within normal limits.
2. Malignancy confirmed or suspected (except primary brain tumour proved by brain biopsy and basal cell carcinoma of the skin)
3. Unexplained or unknown disease.
4. Active generalised viral or bacterial infection
5. HIV positive patients.
6. * Hepatitis B and C positive patients.
7. Neurological diseases e.g Reye's syndrome, slow virus diseases e.g Creutzfeldt-Jacob disease or subacute selerosing panencephalitis, rabies or Kawasaki disease.
8. Narcotic addiction

HBsAg positive donor may be used for hepatitis B immune patients or HBsAg positive patients on the conditions that they do not have active hepatitis.

b) *Special criteria for kidney transplantation :*

It is considered that the cadaveric organ donor is fit for donation except in the following conditions.

1. The donor has one of the problems mentioned under general criteria.
2. Creatinine is more than 2.5 mg/dl despite adequate fluid replacement.
3. The donor has chronic renal disease and/or uncontrolled chronic hypertension. Mild diabetic patients or patients with inactive SLE may be suitable for donation.
4. Presence of viral infection like hepatitis B or HIV.
5. If age of the donor is less than 2 yrs or more than 65 yrs he is not fit to donate. If donor age is unknown decision is taken depending on his physiologic age, his past medical history and Se Creatinine levels.

HBsAg positive donor may be used for hepatitis B immune patients or HBsAg positive patients on the condition that they do not have active hepatitis.

c) *Special Criteria for heart transplantation :*

It is considered that the cadaveric organ donor is fit for donation except in the following conditions :

1. The donor has one of the problems mentioned under the general criteria.
2. Male donors should be less than 40 yrs of age and female less thal 50 yrs.
3. The heart should be normal on physical examination, ECG and 2-dimentional echo assessment and cardiac enzymes should be within normal limits.
4. If the cadaveric donor is suffering from severe chest trauma injuring the heart.
5. If cold ischaemia time exceeds 5 hrs.
6. In the cases where an older donor heart is to be used, the donor heart should be assessed noninvasively as well as invasively including coronary angiography.

d) *Special Criteria for lung transplantation :*

It is considered that the cadaveric organ donor is fit for donation except in the following conditions:

1. The donor has one of the problems mentioned under the general criteria.
2. If the donor age exceeds 50 yrs for male & 55 yrs for female..
3. If the past medical history of the donor reveals evidence of chronic respiratory disease or he was a smoker or if he has had thoracic surgery knowing that a unilateral thoracic surgery does not affect the stability of the other lung, or if he has had bronchial disease or recurrent repiratory infections.
4. If the donor has had trauma that has caused injury to the lungs, exposure to toxic gases or fumes or aspirations of the gastric contents.
5. If the lungs were abnormal by clinical evaluation. X-ray chest & blood gases examination performed after putting the patient on FiO2 of 100 % with PEEP of 5 cms of water for 5 minutes.
6. If the donor has purulent tracheobronchial secretions and gram stain and possibly culture reveals pathologic organisms.
7. If there is size incompatibility between the donor and the recipient.

e) *Special Criteria for liver transplantation :*

It is considered that the cadaveric organ donor is fit for donation except in the following conditions :

1. The donor has one of the problems mentioned under the general criteria.
2. If his age exceeds 65 years.
3. If the liver function tests are abnormal (more than 4 times normal).
4. If there is chronic alcoholic liver disease.

V REGULATION FOR TRANSPLANTATION IN PRIVATE HOSPITALS

FIRST :
All the rules and norms issued by the Appropppriate Authority for Organ Transplantation will be applicable to Private Hospitals as for any other Public Hospitals and same penalties apply in case of non-compliance.
If the organ is being transplanted to a patient in private hospital the hospital will have to pay the ZCC an amount so worked out for each organ.

SECOND :
Organs should be transplanted to patients on the waiting list in the city only according to the norms laid down by the Appropriate Authority for Organ Transplantaion. If any of the hospitals does not have any patients fit for transplantation, it should co-ordinate with Zonal Co-ordinating Centre / Appropriate Authority for Organ Transplantation for transplantation of the organ to any other Maharashtra patient according to priority in the city waiting list. If this waiting list also has no Maharashtra patient fit for transplantation ; another suitable patient from other state could be transplanted according priority level related to each organ.

VI KIDNEY TRANSPLANTATION

Criteria for establishment of Kidney Transplant Centre :

The Appropriate Authority for Organ Transplantation through specialised committees has laid down certain standards for establishment of kidney transplant centres in the State :

1. *Working Staff :*

1.1 Consultant Kidney Transplant Surgeon :
One consultant kidney transplant surgeon with at least three year's training from a recognised kidney transplant centre must be available.

1.2 Consultant Nephrologist :
At least one nephrologist with a minimum three years experience from a recognised kidney transplant centre with facilities for dialysis available in the centre.

1.3 Nursing Staff:
They must be highly experienced to care for the patients during and after kidney transplantation.

1.4 Organ Transplant Co-ordinator

1.5 Dietician

1.6 Social Worker

2. *Technical facilities required :*

2.1 The hospital in which a kidney transplant centre will be established must have the following services available.

Cardiology, Gastroenterology (with endoscopy), Chest (with endoscopy), Radiology, Haematology, Pathology laboratory, Biochemistry laboratory, Nephrology and Haemodialysis unit (preferably containing portable dialysis machines) and ICU.

2,2 At least two operating rooms must be available.

2.3 There should be at least two rooms for management of post transplant patients.

3. *Support Services :*

3.1 Laboratory
All routine investigations necessary for the patients either before or after the transplantation must be available.

Facilities to do tissue typing, cytotoxic antibodies and blood levels of drugs including Cyclosoporine or similar drugs should be available in the institution or any other recognised laboratory in the city.

3.2 Radiology Conventional X-ray, ultrasound must be available in the hospital. Radioisotope scanning and computerised axial tomography must be available in the hospital or in the neighbourhood in the city.

3.3 Blood Bank facilities must be available in the institution itself.

4. *Drugs :*

The following drugs must be permanantly available in the Centre :

4.1 Immunosuppressive drugs
- Cyclosporine
- Azathioprine
- Prednisolone
- Other similar drugs

4.2 Drugs for treating rejection episodes such as Methyl Prednisolone etc.

4.3 Solution for perfusing the organs such as Eurocollins solution or Wiscounsin University solution or such other solution.

4.4 Drugs for treating Bacterial, Viral, Fungal or Parsitic infection.

5. *Criteria for continuation of kidney transplant centres.*

5.1 Application of the Criteria relavant for the establishment of new transplant centres as mentioned previously.

5.2 The number of renal transplants performed in the centre as far as possible should be more than 12 per year.

5.3 The must contribute in the training activities to the staff and help in the management of brain-dead cases in the ICU's attached to it in the collaboration with the ZCC / Appropriate Authority for Organ Transplantation and must deliver to it reports about these activities.

5.4 The transplant centre must submit regular reports about its activities to the ZCC / Appropriate Authority for Organ Transplantation.

5.5 A detailed scientific annual report about the results of transplantation performed in each centre must be forwarded to the ZCC / Appropriate Authority for Organ Transplantation. It should include the following points.

- The conditions of the transplanted patients.
- The state of the transplanted kidney.
- Rate of complication

5.6 All the transplant centres will be evaluated every five years by Appropriate Authority for Organ Transplantation or any times as a surprise check.

5.7 The Kidney Transplant Committee will meet annually at the ZCC to review all the reports from different transplant centres in the State including mortality rate, incidence of organ rejection, complications of transplantation as well as the reprort submitted by the smaller committee. If it appears that one of these centres is not applying these norms and / or the success rate of transplant surgeries performed is not satisfoctory, the committee will visit the centre in order to explore the reasons and handicaps preventing this centre from carrying out its functions properly. The centre will be given three months to improve its performance following which the kidney transplant committee will re-evaluate the centre with the right to submit the proposal of closure of this centre to Appropriate Authority, if no improvement occurs.

5.8 These criteria apply to all kidney transplant centres currently existing in the State as well as to the centres that will be opened in the future.

5.9 A smaller committee will be established from the main committee, which has the right to visit any kidney transplant centre at any time and whenever it is judged necessary to examine the pace of work in the respective centre.

6. *Criteria for Cadaveric kidney transplantation :*

Patients would be included in the state and city waiting lists for kidney transplantation provided the following criteria are met with :

6.1 Patient should have end-stage renal disease (ESRD).

6.2 The patient should not have any other organ disease of significance.
(e. g. active tuberculosis, active peptic ulcer, malignancy or active acute or chronic infection).

6.3 The recipient has been proved not to have any suitable living geneticaly or emotionally related donor, and should be so certified by the hospital administration.

6.4 The results of all investigations done on this patient must be within normal limits except those mentioned in point No. 6.10 a. & b.

6.5 The patient must be between 3 and 60 years old and body weight must be more than 10 kg if a child. In case of diabetic patients, they will be evaluated on individual basis.

6.6 the patient must be psychologically stable and compliant to therapy.

6.7 the patient must be HIV negative

6.8 The patient must be hepatitis B & C negative. If he/she is hepatitis B positive, liver biopsy must be normal

6.9 Patients who are positive for anti glomerular basement membrane anti bodies, anti-DNA antibodies or antineutrophil cytoplasmic autoantibodies must remain negative for at least 3 months before they are put on the waiting list

6.10 Under special circumstances concerning hepatitis serology, the following is to be noted

a) HBsAg positive patients and hepatitis B immune patients can be transplanted with kidneys from HBsAg positive cadaveric donors

b) Hepatitis C positive donor's kidney should go to hepatitis C positive recipient. However normal kidney can be transplanted to hepatitis C positive recipient with adequate match. However there is no bar to transplant normal kidney to hepatitis B and C positive recipient

7. *Contraindications for kidney transplantation :*

7.1 Patients having incurable malignant disease

7.2 Patients with primary oxalosis (except if the patient will undergo a combined kidney and liver transplant)

7.3 Patients with positive HIV.

7.4 Patients addicted to narcotics and other similar drugs

7.5 Non-compliant patients

7.6 Patients with organ diseases like-

a) Liver cirrhosis.
b) Periportal fibrosis with advanced oesophageal varices.
c) End-stage heart failure, Class IV not responding to treatment.
d) End-stage respiratory failure which restricts the patient's daily activities.
e) Progressive cerebral disease (of any aetiology)
f) Irreversible collagen vascular disease
g) Chronic active hepatitis.

8. *Priority criteria for kidney transplantation :*

The Appropriate Authority for Organ Transplantation has laid down priority criteria for kidney transplantation as follows :

First : Vascular Access Failure :

i) Failure of A-V shunt / Fistula / Graft-0.2 per vessel failed (to maximum of 1) score

ii) Failure of Synthetic graft after multiple vascular access failure 3.0 (score)

Those who has had synthetic grant failure without prior A-V fistula failure will continue to get 0.2 per vessel failure. It is mandatory that the patients of multiple access failure will be scrutinised/examined by the Appropriate Authority before the scoring is awarded.

Second : For patients who do not have vascular access problem, the priority level is based on the points as follows :

	PRIORITY CRITERIA	*PRIORITY SCORE*
1.	Cytotoxic antibodies	1 for each 10 % more than 50 %
2.	Age : 3 to 5 yrs	3
	6 to 10 yrs	2
	11 to 45 yrs	1
3.	Period on dialysis	0.1 per each month on dialysis.
4.	Previous failed LRDT's	2
5.	HLA match	1 per each antigen match
6.	Identical blood group	3
7.	Identical age group	2

Third : Adequancy of dialysis cannot be achieved inspite of proper dialysis schedule due to various medical technical problems -1.5 points (score).

Distribution of kidneys :

The harvested kidneys will be distributed as follows :

One kidney will be transplanted to a suitable patient from the hospital where the kidney has been harvested according to the local priority list of that Institution. If the institution harvesting the kidneys has a suitable well matched recipient they are allowed to use the second kidney also. If not, the second kidney will be transplanted to the patient from the local city based waiting list : according to the priority which is put by ZCC / Appropriate Authority for Organ Transplantation. If there is no suitable recipient in the city waiting list, the second kidney will go to the recipient from the State waiting list. If there is no suitable Maharashtra patient anywhere in the State, the kidney may be transplanted to a non-Maharashtra patient with priority: and afer obtaining consent from the ZCC / Appropriate Authority.

10. Procedures to be followed by kidney transplant centres to fulfil their responsibilities towards dialysis units as mentioned and the ICU's attached to them.

Every renal transplant centre renders the necessary technical assistance to all dialysis units where patients registered with them are undergoing dialysis. This includes the following things.

1. It constitutes a referral centre for difficult cases, surgical or non-surgical, concerning renal transplantation.

- It performs tissue typing on all ESRD patients fit for transplantation.

- It decides the fitness of patients for transplantation and sends their names and results of investigations to the ZCC / Appropriate Authority for Organ Transplantation in the special form assigned for this.

2. Every renal transplant centre organises training programmes for ICU personnel responsible for the diagnisis and management of brain-death; so as to enable them to identify brain-death cases and report them as early as possible to the Zonal Co- ordinating Centre. This is done so that the Zonal Co-ordinating Centre can participate in the documentation and management of brain-death cases in accordance with the procedure laid down by its Brain Death Committee.

3. Each renal transplant centre receives and follow-up every information about all brain death cases in the ICU's attached to it through Zonal Co-ordinating Centre. The initial reporting should always be to the Zonal Co-ordinating Centre for Organ Transplantation ; following which co-ordination between Appropriate Authority for Organ Transplantation, the organ transplant centre and the reporting ICU proceeds till organ retieval.

4. Every renal transplant centre should participate in incresing the awareness about brain-death and organ transplantation amongst all nationals and expatriates resident in the region attached to it by conducting regular meetings.

VII HEART TRANSPLANTATION

Norms for establishment of a heart transplant centre.

The Appropriate Authority For Organ Transplantation through specialised experts has laid down certain standards for establishment of heart transplant centres in the State. They are :

1. *Working Staff :*

1.1 Qualified cardiac transplant surgeons : there should be a team of 3 cardiovascular surgeons with good experience in performing open heart surgeries and the centre should have performed adequate number of pump cases per year (more than 150). The members of the team consists of a leader of team having more than 3 years of experience post MCH or any other recognised qualification who is fully certified and experienced from one of recognised heart centres national / international.

1.2 ICU Specialists: An ICU specialist with adequate experience in follow up of patients after open heart surgery and preferably having edequate experience in follow-up of organ transplant recipients.

1.3 Consultants in cardiology : They should have an adequate experience in dealing with pre-and-post open heart patients as well in performing all relevant cardiac investigations and interventions other members should have minimum 3 years of post recognised qualification.

1.4 Nursing Staff : They must be highly experienced to care for patients during and after open heart surgery / organ Transplantation.

1.5 Institutional Organ Transplant co-ordinator.

1.6 Social Worker

1.7 Dietician

2 *Technical facilities required :*

The hospital in which the heart transplant centre will be established should include :

2.1 Departments of cardiology and related ICU, radiology, haematology, pathology laboratory, biomedical laboratory, nephrology with hemodialysis unit and immunology and microbiology.

2.2 At least two fully equipped surgical theatres with one of them well equipped with circulatory support systems. e. g. intra-aortic ballon pump, with the availability of technicians necessary to handle them.

A fully equipped ICU should be available for managemnt of patients after open heart surgery with facilities to isolate patients. There should be facilities for both, temperory or permanant pace makers.

2.3 The following specialists should be available in the hospital.

- fully qualified cardiologist experienced in the follow-up of organ transplant recipients.
- immunologist experienced in follow-up of organ transplantation.
- qualified physiotherapist for respiratory therapy.
- qualified microbiologist
- team for infection control
- Qualified pathologists
- qualified psychiatrist

3. *Support Services :*

3.1 Laboratory

- All routine investigations for the patients either before or after transplnatation must be available in the centre.
- Access facilities to do tissue typing, cytoxic antibodies and blood level of drugs including cyclosporine and similar drugs must be available besides other immunological tests.

3.2 Conventional X-ray, ultrasound in the hospital.

3.3 Fully equipped cardiac cath laboratory.

4. *Drugs :*

The following must be permanantly available in the centre.

4.1 Immunosuppressive Drugs :

- Cyclosporine
- Azathiaprine
- Prednisolone
- Other similar drugs

4.2 Drugs for treating rejection episodes like methylprednisolone etc.

4.3 Drugs for treating bacterial, fungal, viral parasitic infections.

Indications for heart transplantations :

The Appropriate Authority for organ Transplantation through specialised experts has laid down indications for heart transplantation in the State as follows :

First : All patients who have end stage cardiac disease unresponsive to supervised medical therapy and conditions not amendable to established corrective sugical procedures.

Second : Cardiac conditions inclusive of complex birth defects of heart which are not amendable to established corrective surgical procedures

Cantra-indications for heart transplantation :

- Age more than 65 years
- High pulmonary vascular resistance
- Incurable Malignances
- Renal failure above and below the expected pre-renal failure.
- Hepatic failure which exceeds that explained by cardiac failure or when accompnied by significant coagulopathy.
- Other irreversible organ disease such as emphysema, intractable systemetic illness or amyloidosis.
- Patients who are emotionally unstable or irresponsible and who have psychological abnormalities and cannot cope with the demands and burdens of strict compliace with medications and follow up requirements
- Infection with HIV.
- History of substance abuse.
- Type II Diabetes, mellitus with tuberculosis.
- Peptic ulcer disease.
- Unresolved pulmonary infection.
- Marked obesity.
- Cachexic patients.
- History of EBV, toxoplamosis, sickle cell disease, or thyroid dysfunctin.
- Uncontrolled hypertension.
- Presnce of active system infection.

- Patients with positive PPD or clinical evidence of previos tuberculosis are to be treated prophylactically with appropriate drugs for 12 months.

Priority Criteria for Heart Transplantation :

The Appropriate Authority for Organ Transplantion has laid down priority criteria for heart transplantation as follows :

Priority 1 : Patients on mechanical cardiac support or on ventilator or those who cannot be weaned off inotropic support.

Priority 2 : Patients who are on waiting list.

Distribution of Heart :

The harvested heart is distributed as follows :

a. Each heart transplant centre should establish a local waiting list which should be sent to the ZCC / Appropriate Authority for Organ Transplantation so that a city waiting list can be made according to the priority criteria. The heart transplant centres could change the patients priority level between the previously mentioned categories according to the patients condition after informing the ZCC /Appropriate Authority for Organ Transplantation about this.

b. All transplant centres should inform the ZCC / Appropriate Authority for Organ Transplantation about patients who need urgent heart transplantation so that they can be put in the urgent waiting list by ZCC / Appropriate Authority for Organ Transplantation

c. Patients in the urgent waiting list have the absolute priority wherever they are as patients on priority do not follow the rota system.

d. If there is no suitable person in the urgent waiting list, the heart will be transplanted in the heart transplant centre according to the rota. If the centre does not have a suitable patient, the heart will be given to the centre which has a suitable patient in which case the selection of the patient will be according to the blood group and the date from which the patient is registered in the local waiting list.

e. A suitable patient is the one who fulfils medical fitness and priority criteria.

VIII LUNG TRANSPLANTATION

Criteria for establishment of lung transplant centre :

Appropriate Authority for Organ Transplantation has laid down certain criteria for establishment of lung transplant centres in Maharashtra. They are :

1. *Working Staff :*

1.1 Consultant Lung Transplant Surgeons :
There should be a team of Chest and Vascular surgeons with good experience in performing lung surgeries acquired from a recognised national / international centre and they should have assisted / performed a sufficient numbers of these transplantations.

1.2 ICU Specialist :
An ICU specialist with an experience in follow-up of patients after lung surgery preferably having experience in follow-up of lung transplantation recipients.

1.3 Consultant in Chest Medicine :
There should be a team of consultants in Chest medicine who are capable of performing all respiratory investigations by conventional or advanced methods including necessary biopsies and who have experiece in evaluation of patients before lung transplantation and their follow-up after transplantation.

1.4 Nursing Staff :
They must be highly experienced in taking care of patients during and after lung transplantation.

1.5 Transplant Co-ordinator

1.6 Social Worker

1.7 Dietitian

2 *Technical facilities required :*

The hospital in which lung transplantation is established should have the following services.

2.1 Gastroenterology, Radiology, Pathology, Biochemical laboratory. Nephrology with Hemodialysis unit. Immunology, cardiology and cardiac surgery.

2.2 One fully equipped lung transplant theatre.
ICU with isolation possiblities.

2.3 The following specialists should be available in the hospital.
Nephrologist experienced in the follow-up of organ transplantation.
Immunologist
Cardiologist
Physiotherapists
Team for Infection Control
Pathologist with experience in interpreting lung biopsies
Psychiatrist to evaluate patients before and after transplantation

3 *Support Services :*

3.1 Laboratary
All routine investigations for the patients either before or after transplantation must be available.
Tissue typing and cytotoxic antibodies and measurements of drug levels including Cyclosporine or other similar drugs should be available besides other immunological tests.

3.2 Radiology
X-ray facilities for lung investigations conventional and advanced (e. g. C. T. Scan, Radioisotope, scanning etc.)

4. *Drugs.*

The following Drugs must be permanantly available in the centre :

4.1 Immunosuppressive Drugs :
- Cyclosporine
- Azathiaprine
- Prednisolone
- Other similar drugs

4.2 Drugs for treating rejection episodes like methylprednisolone etc.

4.3 Solution for perfusing the organs like Eurocolins solution or Wisconsin University solution.

4.4 Drugs for treating bacterial, viral, fugal or parasitic infections.

Indications for Lung Transplantations

The Appropriate Authority for Organ Transplatation has laid down the indications for lung transplant which is End Stage respiratory failure resulting from :

1. Severe Obstructive lung disease of any cause.
2. Restrictive lung disease
3. Primary pulmonary hypertension or secondary pulmonary hypertension with Eisenmengers Syndrome.
4. Suppurtive lung disease.

Contraindications for Lung Transplantation :

1. *Absolute Contraindications**

Active extrapulmonary infections or active pulmonary infection when single lung transplantation is contemplated

Associated systemic disease such as renal failure or liver failure

Significant coronary artery disease or dysfunction of left or right ventricles (with ejection fraction less than 25 %) unless the patient is considered for combined heart-lung transplantation

Significant psychological problems which could preclude compliance to follow-up and treatment

History and evidence of incurable malignant disease.

Patients who have a life expectancy of 18-24 months with their respiratory disease and not yet oxygen dependant and whose dynamic pulmonary function is still within acceptable limits

*Age is not a contraindication provided acceptable cardiac hepatic and renal function are present.

2. *Relative Contraindications*

Patients on prolonged mechanical ventilatory support. Though many centres do not consider this as a contraindication any more if the patient is well motivated and has acceptable cardiac, hepatic and renal functions

If the patient is receiving high dose systemic steroids (more than 15 mgs. of prednisolone per day). There is a new trend to accept such patients for lung transplantations even if they are not weanable from preoperative steroids as newer techniques of bronchoplastic procedures have led to acceptable bronchial anstomatic healing thereby avoiding risk of bronchial dehiscence.

If the patient has had thoracotomy with pleurectomy or pleurodesis though there is as new trend to accept such patients for lung transplantation such as single lung transplant or bilateral sequential lung transplant using anterior sternothoractomy

Should wait for at least one year after discontinuation of smoking.

Distribution of Lungs :

Lung will be distributed as follows* :

1. Each lung transplant centre should establish a local waiting list and send it to ZCC or Appropriate Authority for Organ Transplantation which will add the same to the city waiting list.

2. Lung transplant centres should report the names of patients needing urgent transplantation so that they will be included in the special urgent waiting list.

3. The patients on the urgent waiting list have absolute priority for lung transplant wherever they are.

4. If there is no patient on the urgent waiting list, lung is distributed to the centre according to rota on condition that this centre has suitable patient. If not, it is transported to the centre which has a suitable patient.

* Suitable patient is the patient who fulfils the medical fitness criteria and priority criteria and has a compatible chest size match.

IX LIVER TRANSPLANTATION

Criteria for establishment of liver transplant centre.

The Appropriate Authority for Organ transplantation has laid down certain criteria for establishment of liver transplant centres in the State. They are :

1. *Working Staff*

1.1 Consultants in liver transplantation :
SURGEONS :
At least one consultant transplant surgeon experienced in hepatobiliary surgery with adequate experience from liver transplant centre.

Gastroenterologist / Hepatologist / senior physician with adequate experience in gastro-enterology and hepatobiliary surgery.

1.2 ICU incharge

1.3 Microbiologist

1.4 Nursing Staff : They should be well trained with experience in taking care of patients during and after transplantation.

1.5 In a city, services of experts could be shared between transplanting units in the same city without institutionsl bias.

2. *Technical Equipment* : As per the Act.

2.1 The hospital in which the liver transplant centre will be established should have the following services :

- Cardiology
- Endoscopy
- Radiology
- Haematology & Blood Bank
- Pathology
- Biochemistry Laboratory
- Nephrology with hemodialysis Unit
- ICU facility
- Immunology
- Chest diseases
- Psychiatry
- Phsiotherapy
- Microbiology Laboratory

2.2 The hospital should contain two well equipped major operating rooms to perform major Hepatobiliary Surgeries containning all the necessary equipment for organ transplantation.

3 *Support Services :*

3.1 Good laboratory services including good banking.

- Routine laboratory services including pre and post transplant workup.
- HLA typing, cytotoxic antibodies, drug levels of cycloporine and similar drugs.

3.2 Imaging facilities and Endoscopy

4. *Drugs :*

The following must be permanantly available in the centre.

4.1 Immunosuppressive Drugs :

- Cyclosporine
- Azathiaprine
- Prednisolone
- Methylprednisolone
- Other similar drugs

4.2 Perfusion fluid for organ presrevation.

Indications for liver transplantation :

The Approppriate Authority for Organ Transplantation has established criteria under which a liver transplant could be performed.

First : fulminant hepatic failure resulting from

1. Viral hepatitis
   A, B, C, D, EBV, CMV etc.
2. Drug induced liver disease
   Halothane
   Disulfiram
   Acetaminophen
   Others
3. Meatabolic liver disease
4. Wilson's disease
5. Reye's Syndrome
6. Massive hepatic trauma
7. Others

Second : advanced chronic liver diseases such as

1. Primary biliary cirrhosis
2. Primary selerosing cholangitis
3. Biliary atresia
4. Idiopathic autoimmune hepatitis
5. Cirrhosis of any aetiology
6. Chronic toxic hepatitis
7. Vascular disease
   e. g. Budd-Chiari syndrome
   Veno-occlusive diseases
8. Others like Carolic disease, polycystic disease & Amyloidosis.

Third : Inherited metabolic diseases such as

1. Alfa1 antitrypsin deficency
2. Wilson's disease
3. Homozygous type II hyperlipoproteinemia
4. Crigler-Najjar syndrome
5. Glycogen storage diseases
6. Protein C deficiency
7. Oxalosis
8. Others

Fourth :

1. Primary hepatocellular carcinoma
2. Other liver tumors
3. Isolated hepatic metastatic disease
   e. g. Carcinoid

Contraindications for liver transplantation :

1. Detectable Extra hepatic malignancy
2. AIDS detected at the time of surgery
3. Non rehabilitative narcotic addicts
4. Active hepatitis B infection

- *Priority Criteria for liver transplantation :*

The Appropriate Authority for Organ Transplantation has laid down priority criteria for liver transplantation as follows :

- An ICU patient who is intubated and on mechanical ventilation (status 4)
  The patient has absolute priority and the status should be evaluated every week till he becomes status 2
- ICU patient not on ventilation (status 3).
- Hospitalised in stable condition (status 2).
- At home, stable condition (status1).
- If the patient has relative contra-indication (status 0) his condition should be re-evaluated after the relative contra-indication resolves.

Distribution of Liver :

The liver will be transplanted to suitable patient from the hospital where the liver has been harvested according to local priority list of that institution. If there is no suitable recipient in local priority list of that institution, it will go to the recipient in the city waiting list. If there is no suitable Maharashtra patient anywhere in the State it may be transplanted to a non Maharashtrian patient with priority and after obtaining consent from the State Appropriate

The liver would be distributed as follows :

1. Each liver transplant centre establishes a local waiting list and sends it to the ZCC or Appropriate Authority for Organ Transplantation which in turn establishes a city waiting list according to the priority criteria mentioned above.

2. Liver transplant centres should report the names of patients requiring urgent liver transplantation to the ZCC / Appropriate Authority for Organ Transplantation so that they are put in a special urgent waiting list.

3. Liver is distributed according to priority, a period on the waiting list and blood group. The centre to which the liver is to be transplanted has to report to the Zonal Co-ordinating Centre / Appropriate Authority for Organ Transplantation within one hour of receiving the information, whether or not it is able to perform the transplantation. All centres will be informed about availability of liver, however liver will be given to the centre in an order of priority list of the patient. If the centre first on priority list is unable to accept the liver, it willbe given to the centre second in the priority list and so on.

Criteria for living related liver donation :

1. The donor should be fit physically and stable psychologically.
2. The donor,s age should not be less than18 yrs. and more than 60 yrs.
3 The donor and recipient should be ABO compatible.
4. Liver function should be normal and the donor must negative for HBsAg and HCVAb.
5. The donor should not be addicted to narcotics or alcohol and should not be taking drugs that are toxic to the liver.

EXPERTS associated in preparing guidelines of various organ transplantation:

1) Dr. S. B. Chavan	Jt. Director of Health Services (Leprosy) Pune
2) Dr. G. B. Daver	Prof. of Surgery, Grant Medical College & Sir J. J. Hospital, Mumbai.
3) Dr.(Smt.)V. N. Acharya	Chairperson GTP Programme committee, National Kidney Foundation, (India) Mumbai.
4) Dr. (Smt.)Vatsala Trivedi	Prof. of Urology, Lokmanya Tilak Medical College & Hospital, Mumbai.
5) Dr. B. M. Wagh	Asst. Director of Health Services, Mumbai.
6) Dr. A. Kirpalani	Prof. of Nephrology, Bombay Hospital & Institute of Medical Sciences, Mumbai.
7) Dr. G. Shirhatti	Dean, Lokmanya Tilak Medical College & Hospital, Mumbai.
8) Dr. Bhalerao R. A.	Chief Surgeon, P.D. Hinduja Hospital, Mumbai.
9) Dr. S. K. Mathur	Prof. of Surgery, Topiwala National Medical College & Nair Hospital, Mumbai.
10) Dr. G. B. Parulkar	Cardiovascular & Thoratcic Surgeon & Ex-Dean, GS Medical College, KEM Hospital, Mumbai.
11) Dr. K. R. Shetty	Director, Cumbala Hill Hospital, Mumbai.
12) Dr. D. Saxena	Cardiothoracic Surgeon, Bombay Hospital Institute of Medical Sciences, Mumbai.
13) Dr. R. Mangotra	Prof. of Cardiothoracic Surgery, G. S. Medical College & KEM Hospital, Mumbai.
14) Dr. Ramakanta Panda	Hon. Consultant Cardiovascular Surgery Jaslok Hospital, Mumbai.
15) Dr. Suresh Joshi	Hon. Consultant Cardiovascular Surgery Jaslok Hospital, Mumbai.

16) Dr. DR Trivedi