REPORT OF THE CADAVER TRANSPLANTATION ADVISORY COMMITTEE (CTAC)

(Constituted through G.O.Rt.No.1462, HM & FW (M.1)Dept, dt. 11.11.2009)

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1.0 Background

Government of India had passed the Transplantation of Human Organs Act 1994 with the objective of promoting and regulating the transplantation of human organs like kidney, liver and heart - both live as well as cadaver. The Government of Andhra Pradesh had adopted the aforesaid Act of Govt. of India in the form of AP Transplantation of Human Organs Act 1995. The Govt. of Andhra Pradesh had also framed the "A.P. Transplantation of Human Organs Rules 1995", which, inter-alia, specify the duties of the authorities and also the formats for various purposes under the Act.

1.1 Even though fourteen years have elapsed after passing of the Act & Rules by the government, the number of transplantations, especially "cadaver transplantations" occurring in the state has not increased significantly, primarily because of lack of a centralized coordination mechanism and the absence of a streamlined procedure for facilitating and regulating the cadaver transplantations on an end-to-end basis. With a view to give a fillip to the cadaver transplantations, the Government of AP, through their G.O.Rt.No.1462, HM & FW (M.1) Dept, dt. 11.11.2009, appointed a high level advisory committee called the Cadaver Transplantation Advisory Committee (CTAC) headed by the Principal Secretary, HM & FW Department and consisting of experts in the field of organ transplantation, with a direction to make its recommendations on the following aspects:

a) Prescribing eligibility criteria for registering institutions as organ transplanting centers or organ harvesting centers in terms of qualifications and experience of staff, infrastructure and other facilities.

b) Evolving mechanisms for coordination of all aspects relating to donation and transplantation of deceased organs.

c) Creation of a registry (preferably on-line) for donors and potential recipients.

d) Design of guidelines for allocation of organs, separately for kidney, liver and heart and for authorization of cadaver transplantations.

e) Recommendations on the creation of an organizational structure for the Cadaver Transplantation Coordination Authority and its functions and powers along with financial implications in establishing the same.

1.2 The CTAC at its first meeting held on 26th Nov, 2009 constituted 3 sub-committees for a detailed examination of the following three distinct areas:-

i) Requirement and feasibility of establishing the Non-Transplantation Organ Harvesting Centers and the procedures to govern the same.

ii) Creation of a centralized registry and procedures for allocation of organs.

iii) Administrative and financial requirements for implementation of the cadaver Program.

1.3 At its second meeting held on 11th Feb, 2010, the Committee considered in depth the recommendations of the three sub-committees and arrived at a set of comprehensive recommendations addressing the Terms of Reference of the CTAC specified in the aforesaid G.O. The Committee considered the draft report at its 3rd meeting held on 6th March, 2010. This report attempts to incorporate the result of the discussions of the CTAC and its sub-committees as well as the recommendations of CTAC in a comprehensive and structured manner.

1.4 A large number of patients are suffering on account of irreversible organ ailments involving heart, liver, pancreas and kidney and lot of them could lead healthy lives if they had the opportunity to have transplant surgery. Considering the ethical issues surrounding live and deceased donor organ donation, there is a need for streamlining procedures for Deceased Donor Organ Transplantation (DDOT), otherwise called "Cadaver Transplantation" in Government and Private Hospitals.

1.5 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 within months after diagnosis because organ replacement therapy is either not available or not affordable. The deceased organ donation rate in our country is 0.08 per million population and the overall potential of organ donation following brain death is extremely high. Transplantation of Human Organs Act 1995 is an enabling legislation as far as deceased donor transplantation

is concerned. There is at present no established procedure or guideline to deal with situations that arise when brain deaths occur in hospitals that are not registered under THOA 1995, 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 donation is 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. This will ensure that the sentiments of donors' relatives are fully respected. A high degree of accountability ought to be insisted upon by all the persons and organizations participating in the cadaver transplantation program. Moreover, there should be an effort to establish appropriate machinery for implementing and monitoring the scheme of organ donation and transplantation, besides significant amount of awareness building in the general population, if the spirit of THOA 1995 has to be realized, to save hundreds of lives.

2.0 Statutory Provisions

The recommendations of the Committee are based on the following statutory provisions that exist in the Human Organs Transplantation Act 1994, the AP Transplantation of Human Organs Act, 1995 and the rules framed thereunder, in so far as they relate to removal and transplantation or organs from deceased donors, otherwise called 'cadaver transplantations'.

i) The terms 'brain-stem death' (co-termed as brain death) and the 'deceased person' have been defined in Section 2 (d) and 2 (e) of the AP Act and are extracted below:

"....(d)'brain-stem death' means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3;

(e) 'deceased person' means a person in whom permanent disappearance of all evidence of life occurs; by reason of brain-stem death or in a cardio pulmonary sense, at any time after live birth has taken place;.......”

ii) Sub-Section (5) of Section (3) of the AP Act authorizes the removal of a human organ from the body of a deceased person, subject to the extinction of life in the body of the person or in the case of brain-stem death, duly certified by a Board of Medical Experts.

iii) The authority for declaring the brain death has been vested, under Sub-Section (6) of Section (3) of the AP Act, in a Board of Medical Experts with the 4 members specified therein.

iv) The registration of hospitals for various purposes under the AP Act is provided under Section 14 of the AP Act. It is significant to note here that this Section provides for registration of hospitals for various purposes under the Act,

viz., “removal, storage or transplantation of any human organ for therapeutic purposes”. It is clear from this section that a hospital can be registered under this Section for one or more purposes, that is to say, for removal and storage or for transplantation or for both. In other words, a hospital can be registered exclusively for removal and storage (harvesting), though it can not undertake transplantation, which can be effected in a different hospital, registered for transplantation.

v) The Act and Rules are silent on the establishment of a central registry of patients seeking donation of organs by compatible donors or the procedures for allocation of the organs of deceased person to the patients requiring the same following a specified priority. This report also seeks to fill this critical gap, so as to give a fillip to the number and nature of cadaver transplantations.

2.1 As a corollary to para 2.1 (v) above, it is necessary for the Government to carry out an appropriate amendment to the Rules issued in 1995 or to promulgate a new set of rules, to give a legal effect to the recommendations contained in this report, in relation to the cadaver transplantations.

3.0 Bottlenecks and Lacunae in the existing scenario

Before suggesting improvements to the present system, it is necessary to identify the bottlenecks and lacunae as well as the inefficiencies in the existing framework in managing the cadaver transplantations. These are discussed below:

A. Issues relating to declaration of brain death

i) Mortality is very high in complicated cases like poly-trauma. However, the team of doctors attending to such cases hesitate to declare the brain stem death, apprehending a possible adverse impact on their professional reputation.

ii) As for the relatives, it is a highly sentimental issue to permit the medical team to declare the brain death and extract the organs.

B. Issues involving infrastructure and finance

i) Maintenance of a person in the ICU after the declaration of brain death and before the organs are harvested, involves significantly high costs. While there is no formal mechanism within the hospitals to defray such costs, even for the relatives of the deceased person it becomes a psychological and financial burden.

ii) Maintenance of infrastructure within each hospital and networking of all the hospitals interested and specialized in the organ harvesting and transplantation involves additional cost without proportionate financial returns. The maintenance of staff round the clock is an additional financial burden on the respective hospitals and difficult to support in these days of budgetary constraints.

C. Issues of coordination

i) The absence of a centralized mechanism for managing

cadaver transplantations is the biggest lacuna in the current system. In the absence of such a coordinating body, the patients / potential recipients or their relatives do not have information on the availability of organs. Similarly, the donor and the relatives of the deceased persons who may have the best intention to donate the organs, may not have the access to vital information required to make the critical decision.

ii) Any delay in shifting of the cadaver or transportation of the organ may defeat the very purpose by rendering the organ unfit for transplantation. This can happen in the absence of a network of specialists, coordinators, technicians and field workers **being available on 24 x 7 basis** in the designated hospitals and sites, so as to handle each and every case of deceased donor on top priority and as an emergency.

iii) Lack of professional counselors who are adequately trained in the area of **grief counselling** adds to the problem. This is in view of the fact that the relatives of the deceased person are already in a great grief and are not in a frame of mind to take such a profound decision as giving consent for the harvesting and donation of the organs of their relative. The availability of counselors would considerably improve the situation as they would be able to communicate effectively with the relatives and enable them to make an appropriate decision on donating the organs.

iv) In a few cases, it might become necessary to undertake transportation of the harvested organs by air. This involves a critical coordination with the authorities of the airlines and the transportation logistics at both the ends.

D. Awareness

I) The level of awareness among the general public of the various issues as well as the societal benefits of cadaver transplantation is also one of the factors adversely affecting the uptake of cadaver transplantations. In the absence of authentic information about the number of lives that can be saved through one cadaver, the readiness to think of it would be non-existent or quite low. Unless the acceptability of cadaver transplantation as an act benefiting the society at large, is widely publicized and accepted by the community, mere enactment of a legislation or mere establishment of infrastructure and the machinery for transplantation would be of very little utility.

3.1 The Committee has deliberated on all the above issues and is of the view that we need to adopt a multi-pronged approach that can address all the above issues viz., medico-legal, financial, managerial and mass communication issues. Otherwise, the cadaver transplant Program would not take-off nor confer significant benefits on the society. The recommendations made in the report are, therefore, aimed at addressing the above issues adopting a multi-pronged approach.

4.0 The Proposed Scheme - JEEVANDAAN

Against the above background and the current scenario, the Committee has examined the national and international best practices in the area of cadaver transplantation and designed an overall scheme and structure that can not only address the issues and bottlenecks pointed out in Section (3), but is also suitable to the conditions

prevailing in Andhra Pradesh. The salient features of the proposed scheme are briefly described below.

i) The proposed scheme for cadaver organ transplantation can be called **"JEEVANDAAN",** connoting donation of life.

ii) The Cadaver Transplantation Advisory Committee (CTAC) shall be the APEX level body charged with the responsibilities of policy design, monitoring and implementation oversight of the scheme of Jeevandaan. The structure, functions and responsibilities of CTAC are described in Section 5.

iii) The legal authority for governing the various aspects like registration of hospitals and patients as well as allocation of organs and those relating to the organ transplantation shall be vested with the entity called the Appropriate Authority for Cadaver Transplantation (AACT). The structure, functions and responsibilities of AACT are described in Section 6

iv) At the heart of the Jeevandaan scheme is the AP Network for Organ Sharing (APNOS), which is virtual coordinating mechanism within the AACT, with the necessary infrastructure and governance structure for providing 24 x 7 services to the donors, recipients, hospitals, NGOs and the general public. The structure, functions and responsibilities of APNOS are described in Section 7.

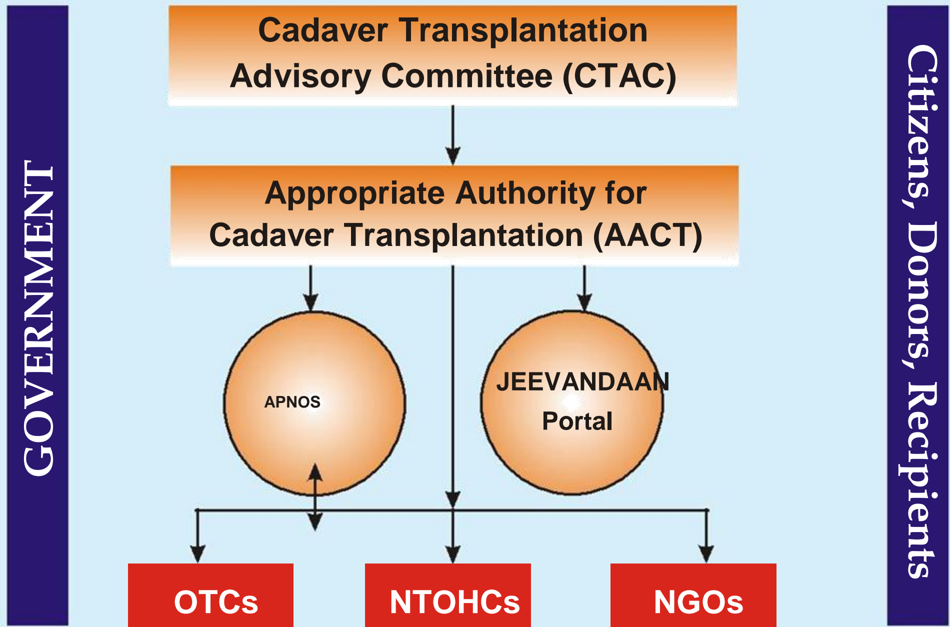
v) The Non-Transplanting Organ Harvesting Centers (NTOHC) are proposed to be established as a network

or chain of hospitals, to play a pivotal role in the initial but critical stages like declaration of brain death, extraction of the organs and their storage and
preservation. The infrastructure and manpower r e q u i r e m e n t s a s w e l l a s t h e f u n c t i o n s a n d responsibilities of NTOHC are described in Section 9.

vi) The Organ Transplant Centers (OTCs) perform the most critical aspect of the Jeevandaan scheme viz., undertaking of the actual transplantation for saving the lives of the recipients. The infrastructure and manpower requirement, functions and responsibilities of OTCs are described in Section 9.

vii) The success of the Jeevandaan Scheme depends critically on sharing the real-time information about the availability of organs and allocating them to the needy patients with matching requirements. This is proposed to be achieved through the establishment of a portal (www.JEEVANDAAN.org) which will provide information and also alerts all the appropriate persons on a real time basis so as to facilitate the management of cadaver organ harvesting and transplantation on an end-to-end basis. In essence, the proposed portal ensures efficiency, effectiveness and transparency in the entire operations forming part of the JEEVANDAAN scheme. The features of the proposed portal are described in Section 10.

4.1 The diagram represented below indicates the overall structure of the Jeevandaan scheme and the various components that it comprises.



The functions and responsibilities as well as the requirement of infrastructure and manpower regulation / management of the various components of the Jeevandaan scheme are detailed and specified in Sections 5 to 10.

5.0 Cadaver Transplantation Advisory Committee (CTAC)

The CTAC is the APEX level body authorized to take appropriate high-level decisions in relation to Jeevandaan program.

5.1 The CTAC shall comprise the following members:

No.	Member	Role
1.	Principal Secretary, HM & FW	Chairman
2.	Director of Medical Education	Member
3.	Superintendent, Osmania General Hospital	Member
4.	Professor of Surgical Gastroenterology, Osmania General Hospital	Member
5.	Superintendent, Gandhi Hospital	Member
6.	Professor of Nephrology, Gandhi Medical College	Member
7	A representative of an NGO working in the area of Organ Transplantation	Member
8	A Senior Police Officer of the rank of DIG or above to be nominated by the DGP	Member
9	Director, NIMS	Member-Convener

The Committee can co-opt a multi-organ transplantation experts to advise it in the discharge of its functions.

5.2 Functions and responsibilities of CTAC

The CTAC shall be responsible for the following:

i) Taking appropriate policy decisions on establishing and/ or managing various procedures, provisions and protocols relating to registration of NTOHC and OTCs, declaration of brain-stem death, harvesting of organs from the deceased persons, storage, preservation and transportation of organs for transplantation.

ii) Reviewing the performance of AACT, OTCs and NTOHCs at least once in every 6 months.

iii) Making appropriate recommendations to the Government for sanction of funds for running of the Jeevandaan scheme.

iv) Providing appropriate guidance and issuing directions to the AACT as may be needed in the overall interest of implementation of Jeevandaan scheme;

v) Causing enquiries into the complaints and grievances arising out of the implementation of the Program.

Appropriate Authority for Cadaver Transplantation (AACT)

The AACT is the legal entity authorized with the statutory powers under the THOA 1995. It shall act as the Appropriate Authority under the THOA Act.

6.1 Composition of AACT

The composition of AACT shall be :

i.	Director, Medical Education	Chairman
ii.	Director, NIMS	Co-Chairman
iii.	Chief Transplantation Coordinator	Member-Convener

AACT can co-opt another member who is a multi-organ transplantation expert to assist it, subject, however, to the condition that such a person shall not have any affiliation to any hospital registered as a OTC.

6.2 Functions and Responsibilities of AACT

The AACT shall discharge the following functions and responsibilities

i) Registration of hospitals as NTOHCs or OTCs.

ii) Supervision and regulation of the functioning of NTOHCs and OTCs, including exercising the powers to suspend the registration in the event of any deviation or misconduct.

iii) Allocation of the organs available from cadavers to the registered patients (recipients) strictly following the priority laid down in this regard and as specified in Section 11.4.

iv) Establishment and management of AP Network for Organ Sharing (APNOS).

v) Establishment, management and maintenance of JEEVANDAAN Portal.

vi) Empanelment of specialists, especially in the specialities of neuro surgery, neurology and anesthesiology, whose services can be availed by NTOHC or OTC to be a part of the Medical Board for the purpose of declaring brain death.

vii) Conduct of programs to raise awareness in general public (sec 3.0, D), such as mass media communication, conduct of annual events, establishing a system of online and postal pledging of organs by willing

individualsinacentralregistrythrou g h JEEVANDAAN portal, and issuing donor cards.

viii) Any other functions and responsibilities for the effective implementation of JEEVANDAAN Program.

6.3 Staffing and infrastructure of AACT

6.3.1 Staffing

The AACT shall be supported by appropriate staff to enable the authority to discharge its functions effectively. JEEVANDAAN program shall be headed by a Chief Executive Officer, to be appointed by the AACT, and designated as Chief Transplantation Coordinator. The CTC shall be responsible to discharge the day-to-day functions of the AACT, including, most importantly, the allocation of organs on a case-to-case basis, strictly conforming to the priorities laid down for the purpose and specified in Section 11. The initial staffing of the AACT shall consist of, apart from the CTC, a senior medical professional conversant with the transplantation procedures and 3 administrative / financial officers.

6.3.2 Infrastructure

The AACT shall have the following infrastructure:-

i) Office space of 2000 sft

ii) 2 dedicated telephone lines

iii) Broadband internet for online service

iv) IT infrastructure for management of JEEVANDAAN Portal

v) A Training Center for training of transplantation coordinators, counselors, and specialists belonging to the NTOHCs and OTCs.

6.4 Sub-Committees of AACT

The AACT shall constitute 4 sub-committees consisting of experts from

the respective areas to assist it in its functioning for allocation of:

I) Liver / Pancreas ii) Heart / Lung

iii) Kidney iv) Other organs

The sub-committees shall be required to make appropriate recommendations to the Chief Transplantation Coordinator for allocation of various organs in special situations and cases referred to them by the Chief Transplantation Coordinator, including those specified in Section 11.4.1.6. Any queries in allocation of organs even in regular situation can be referred to subcommittee for opinion.

AP Network for Organ Sharing (APNOS)

The APNOS (AP Network for Organ Sharing) is recommended to be established as a virtual organization to be promoted by the AACT for achieving the overall convergence of the efforts of various agencies in the implementation of the JEEVANDAAN Program, to benefit thousands of patients suffering from organ failure. The APNOS may be registered as a Society with the members of the AACT as its Governing Body, in addition to 3 members, one each from among the OTCs, NTOHCs and NGOs. The following recommendations are made in relation to the establishment and functions of the APNOS.

I) APNOS shall be registered as a Society with a corpus fund of Rs. 10 lakhs.

ii) The members of AACT shall be ex-officio members of the Society.

iii) Every hospital registered as NTOHC or OTC shall become a member of APNOS in order to avail services under the JEEVANDAAN scheme.

iv) All the NGOs who intend to participate in the JEEVANDAAN scheme, for training, counseling or for providing financial assistance to the deserving recipients shall also become members of the APNOS.

v) The APNOS shall charge the following membership fee:

a) OTC .. Rs. 1,00,000/-

b) NTOHC.. Rs. 5000/-

c) Recipient Registration fee.. Rs. 5,000/-

Rs 10,000 and Rs 1000 shall be charged annually per OTC and NTOHC towards renewal of membership.

The APNOS shall undertake the following activities:

i) Formulation and undertaking of training Programs.

ii) Advocacy and promotion of Cadaver Transplantation.

iii) Coordinating with various authorities for arranging railway /bus passes, health insurance, jobs as per eligibility to the members of the donors' family .

8.0 Organ Transplant Center (OTC)

The OTC is a hospital with the stipulated infrastructure which has been legally authorized to undertake transplantation of human organs in terms of THOA 1995 and the rules framed thereunder. An OTC automatically acts and discharges the functions of NTOHC specified in Section 9.

8.1 Registration of hospital as OTC

8.1.1 The AACT shall be the authority competent to register hospitals as OTCs

8.1.2 The hospitals desirous to register themselves as OTC

shall apply to the AACT in the prescribed format accompanied by a fee of Rs. 100,000.

8.1.3 On receipt of the application from a hospital, the AACT shall cause inspection of the hospital by a team of specialists to satisfy itself that the requirements for permitting establishment of OTC, specified in sections 8.3, 8.4 and 8.5 exist in the applicant hospital.

8.1.4 On satisfaction of the adequacy of the applicant-hospital with reference to the requirements, the AACT may register the hospital as OTC for a period of 5 years.

8.1.5 The AACT may renew the registration from time to time, each time for a period of 5 years, subject to the hospital paying a renewal fee of Rs. 50000/- and subject to the continued conformance to the requirements under Sections 8.3, 8.4 and 8.5 .

8.2 Functions and Responsibilities of OTC:

The following are the functions and responsibilities of OTC:

i) Shall have its own waiting list for each organ, basing on the date of registration.

ii) Shall provide the prioritized waitlist of patients in each category mentioned above to 'JEEVANDAAN' by posting the same in the JEEVANDAAN portal.

iii) Shall update the list with Jeevandaan portal, whenever a new patient is added.

iv) Ensure that the patients on the hospital waiting list for DDOT are promptly registered with 'Jeevandaan'.

v) Shall promptly report all incidents of brain death declaration.

vi) Shall update recipient details of DDOT as well as Living donor Organ Transplantation (LDOT), within 48 hours of completion of procedure, in the Jeevandaan portal.

vii) Shall take the responsibility of transporting the organ allocated to their center from another OTC or NTOHC. It is their responsibility to carry all equipment, preservation fluids (HTK, UW solutions etc., in sufficient quantity) and ice boxes to transport the organs to the allocated center.

8.3 The OTC shall have the bed strength of a minimum 100 beds with the following departments:

8.3.1 Common Requirement for all OTCs

i) Biochemistry/ Microbiology /Pathology/ Hematology

ii) Radiology with Ultrasound Doppler, Fluoroscopy, X ray

iii) Anesthesiology

iv) Operation theatre & Intensive care department

Specific Additional Requirement for OTCs specializing in transplantation of particular organs

A. For transplantation of Kidney

i) Nephrology

ii) Urology

iii) Dialysis

B. For transplantation of Heart

i) Cardiothoracic Surgery

ii) Cardiology

iii) Blood Bank

iv) Dialysis

v) Cardiac ICU with Echocardiography

vi) Cardiac Catheterization Laboratory

C. For transplantation of Liver

i) Surgical Gastroenterology/Hepatobiliary and Liver

Transplant, Surgery Department

ii) Anesthesiology

iii) Blood Bank with facilities for blood and blood products (FFP, Platelets, Cryoprecipitate)

iv) Dialysis

v) Endoscopy

8.3.2 Equipment requirement of OTC

The departments specified above shall be equipped with diagnostic and surgical facilities as per the norms prescribed by the AACT from time to time.

8.4 Professional Staffing requirement of OTC

The Organ Transplantation Center shall mandatorily have the following specialists, apart from the required supporting staff:

a) Kidney transplantation: M.Ch(Urology)/ M.S (Gen) Surgery/ Equivalent Degree with three years post degree training in a hospital registered for kidney transplantations and having attended to adequate number of renal transplantations as an active member of the team, either in India or abroad.

b) Transplantation of Liver & other abdominal organs: M.Ch/DNB (Surgical Gastro-enterology) or M.S./DNB (Gen) Surgery or Equivalent Degree with 3 years' post degree training in Hepatopancreatobiliary and Liver /Pancreas transplant unit in a hospital in India or abroad registered for organ transplantations and having attended to adequate number of Liver /Pancreas transplantations as an active member of the team.

c) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation: M.Ch. (Cardio-thoracic and vascular surgery) or equivalent qualification in India or abroad with atleast 3 years experience as an

active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart valve surgery

d) Support staff

i) Surgical staff

ii) Cardiology staff

iii) Nursing staff

iv) Transplant Coordinator

9.0 Non-Transplantation Organ Harvesting Center (NTOHC):

The primary purpose of establishing the NTOHC is to establish the facilities for retrieval of organs in a network of hospital with the appropriate of authority of exercising all the functions relating to organ harvesting, when there is willingness among the relatives to donate the organs of a deceased donor and thereby increase the number of organs available for transplantation. The NTOHC is a hospital which has been authorized by the competent authority to declare brain death in respect of a person admitted to their hospital following the prescribed procedure, to perform the procedures relating to the removal of the donated organs and to store and arrange to transport them for the purpose of transplantation for therapeutic purposes in an authorized Organ Transplantation Center (OTC).

9.1 Registration of hospitals as NTOHC

9.1.1 The AACT shall be the authority competent to register hospitals as NTOHCs

9.1.2 The hospitals desirous to register themselves as NTOHC shall apply to the AACT in the prescribed

format accompanied by a fee of Rs. 1000.

9.1.3 On receipt of the application from a hospital, the AACT shall cause inspection of the hospital by a team of specialists to satisfy itself that the requirements for permitting establishment of NTOHC, specified in sections 9.2 and 9.3 exist in the applicant hospital.

9.1.4 On satisfaction of the adequacy of the applicant-hospital with reference to the requirements, the AACT may register the hospital as NTOHC for a period of 5 years.

9.1.5 The AACT may renew the registration from time to time, each time for a period of 5 years, subject to the hospital paying a renewal fee of Rs. 1000/- and subject to the continued conformance to the requirements under Sections 9.2 and 9.3.

9.2 Infrastructure requirements for NTOHC

The following infrastructure shall be available in the hospital applying for registration as NTOHC:

i) A minimum bed strength of 100 beds;

ii) Operation theatre conforming to the specifications to be notified by the AACT.

iii) Intensive Care Unit conforming to the specifications to be notified by the AACT.

iv) Own ambulance

v) A room earmarked for grief counselor

vi) Blood bank or facilities to acquire blood products from recognized blood banks

9.3 Manpower requirement

The following manpower shall be available in the hospital applying for registration as NTOHC

i) Medical Superintendent

ii) Neuro surgeon (with 3 years of experience) on call

iii) Neurologist with 3 years of experience)on call

iv) General Surgeon

v) Supporting Staff:

a. 3 Staff Nurses (qualified in specialty nursing)

b. 3 Technicians (qualified to operate equipment specified)

c. Grief counselor/ Donor coordinator

9.4 Functions and Responsibilities of NTOHC

The following shall be the functions and responsibilities of hospital registered as NTOHC:

i) Arranging for declaration of brain-stem death following the due procedure prescribed under Section (2(d) and 2(e) of AP HOTA act 1995.

ii) Conducting an appropriate counselling to the relatives of the deceased persons to enable them to take an appropriate decision on organ donation.

iii) Notifying the admission of such critical patients to the AACT through the JEEVANDAAN website.

iv) Instantaneous notification through the website of the JEEVANDAAN Program about the availability of donated organs for transplantation.

v) Providing operating room, basic surgical equipment and nursing, medical and paramedical staff to assist the harvesting team

vi) Arranging for handing over of the donated organs to the team of specialists of the OTC or OTCs authorized by the AACT to receive the organs for transplantation

vii) Facilitating the conduct of postmortem simultaneously and the procedures relating to harvesting of the organs in medico legal cases.

10.0 Jee van daa n P ort al

As mentioned earlier, efficient and effective functioning of JEEVANDAAN Scheme shall depend substantially on the JEEVANDAAN Portal, which shall act as the back-bone for the scheme. The Portal shall be designed, got developed and maintained by the AACT. The following shall be the salient features and functional requirements of the proposed Portal.

i) Receiving applications of hospitals for registration as NTOHC and OTC.

ii) Applications for registration with the APNOS by OTCs, NTOHCs and NGOs.

iii) General information relating to various entities registered / participating in the activities relating to the Jeevandaan Scheme.

iv) Online central registry of patients requiring organ transplantation along with details of hospitals where they are currently receiving the treatment and basic details of cross-matching and compatibility of donors' organs.

v) Facility for the NTOHC / OTC for updating the availability of organs from cadaver.

vi) Online workflow for allocation of organs to the registered patients strictly observing the priority prescribed under rules.

vii) Security of information.

viii) Privacy of the personal data of patients and donors.

ix) Details of training programs.

x) Promotional information.

xi) Technical information about the cadaver transplantation.

xii) Information required by the RTI.

xiii) Grievance Redressal module.

xiv) MIS and Dashboard.

Procedures relating to JEEVANDAAN Scheme

As mentioned in Section (3), it is absolutely essential to build and maintain transparency in all the activities and operations relating to the Jeevandaan scheme, so as to generate the necessary confidence, credibility and trust among the donors as well as the recipients in particular and general public at large. This is possible only if the procedures and processes required to be fulfilled for organ donation and harvesting and transplantation are very precise, standards-based and simple to understand and implement. Accordingly, the following procedures are suggested for the various steps involved in a cadaver transplantation.

11.1 Declaration of brain death

11.1.1 The procedure prescribed under Section(3) & (4) of the APTHOA Rules 1995 shall be strictly followed.

11.1.2 The medical board comprising the following

members shall be constituted by the NTOHC or OTC as the case may be for the declaration of brain death, in each case:

i. Medical Superintendent of the Hospital

ii. An independent Registered Medical Practitioner, i.e Specialist with 5 years post PG experience (Physician/Surgeon/Intensivist) (specialist to be nominated by the Medical Superintendent of the Hospital from the panel of names approved by the AACT).

iii. A Neurologist or Neurosurgeon (to be nominated by the Medical Superintendent of the Hospital from the panel of names approved by the AACT).

iv. The consultant treating the patient.

11.1.3 Other procedural requirements

Post mortem and panchanama in case of Medicolegal cases to be done at the same place and the same time of harvesting. Availability of Police and Forensic experts round the clock is to be made mandatory for smooth running of brain death organ donation process.

11.2 Procedure for harvesting of the organs

The NTOHCs and OTCs shall adopt the procedure specified below for harvesting of organs from a deceased person.

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

2. Retrieval of organ(s) 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 intention of the brain dead patient to donate the organ(s), consent in Form 6 of the Transplantation of Human Organs Rules, 1995, is necessary to continue with the process of organ retrieval.

11.3 Procedure for allocation of organs

Equitable allocation of organs harvested from deceased persons is critical to the effective functioning of the JEEVANDAAN scheme. There are two dimensions to the process of allocation of organs – the administrative process and the technical process. These are specified below:

11.3.1 Administrative process of allocation of organs:

(i) All the prospective recipients of organs shall register themselves with the APNOS, in the prescribed format, through the JEEVANDAAN portal, on payment of the registration fee of Rs 5,000. The application for registration of the recipients shall be counter-signed online by the OTC, where such patient receives or intends to receive treatment and to undergo the required transplantation.

(ii) The NTOHCs shall notify the details of all the organs harvested from the deceased persons admitted to their hospitals.

(iii)The JEEVANDAAN portal shall have an appropriately designed application for matching the organs available from cadavers with the requirements of one or more recipients on the waiting list, strictly following the priority laid down in this section. It should also simultaneously send an alert to the Chief Transplantation Coordinator of AACT, legally assigned the responsibility of allocation of the organ.

(iv) The allocation is done by the chief transplant coordinator strictly according to the criteria laid down in 11.3.2

(v) Immediately after the allocation has been approved by the Chief Transplantation Coordinator of AACT, the Portal shall send appropriate communications and alerts to the recipient(s), the OTC(s) with which the recipient(s) is(are) registered for treatment/ transplantation, the NTOHC where the organ is available and all others concerned with the cadaver transplantation(s).

(vi) The NTOHC and the OTC(s) shall update the progress of the cadaver transplantations within 24 hours at the JEEVANDAAN portal.

11.3.2 Technical process (priorities) for allocation of organs:

The following priority shall be strictly followed for allocation of organs harvested from cadavers:-

1. First priority shall be given to the OTC where the deceased donor is located, for liver, heart and one kidney, except in special situations defined in this

section. The other kidney and any other transplantable unutilized organs shall be allocated using criteria of allocation of General pool organs.

2. Second priority shall be given to the senior-most patient registered for the organ available, in the combined list of patients, in all the OTCs who are taking part in deceased organ donation transplant program (General Pool Criteria).

3. Third priority shall be given to the hospitals (OTCs) outside the State, provided earlier information and such a request has been registered with the APNOS.

4. Finally, if the organ(s) remains unutilized after exhausting all the above criteria, it may be offered to a foreign national registered in a Government or Private hospital within and then outside state

5. General pool:

   Organs retrieved in following situations are defined as general Pool

   a. Organs retrieved at non transplanting centers (NTOHCs).

   b. Organs retrieved at transplant centers on deceased donors shifted from non-transplant centers (NTOHCs) either before or after brain death declaration.

   c. Retrieved organs unutilized at transplant center or the second kidney of deceased person declared brain-dead at an OTC.

The general pool organs shall be allocated according to the following criteria:

1. Heart/Lung will be allocated to the patients listed, as per date of their registration with Jeevandaan.
2. Liver will be allocated to the patients listed, as per date of their registration with Jeevandaan.
3. Kidney will be allocated to the patients listed, as per date of their registration with Jeevandaan. There is no out of turn allocation for Kidney recipients.

6. Special situations for allotment:

a. Multi-organ recipient

If there is a patient who is to be a multi organ recipient (Heart/Lung, Heart /Kidney, Liver /Kidney, Kidney/Pancreas) and a matching (blood group and size) organ donor is available, then the multi organ recipient takes precedence over all others on the regular waiting list.

b. Urgent listings

Lifesaving organs, namely heart and liver may be listed as Urgent in certain situations. These conditions do not require a waiting time on the list and a respective committee will clear the urgent organ request.

Liver

A. Hepatic Artery Thrombosis following a liver transplant.
B. Primary Non function of a graft
C. Fulminant hepatic failure (Kings College criteria)

Heart

A. Patients with Left Ventricular Assist Device (LVAD).
B. Followed by patients with Intra Aortic Balloon Pump (IABP) The allocations under the category of 'Urgent Listings' shall have to be cleared by special committees constituted by AACT for the purpose.

Heart committee: A cardiologist and a cardiothoracic surgeon with transplant experience from Govt. /Private institutions will form the committee and oversee the urgent heart allocation.

Liver committee: Hepatoligist /Gastroenterologist/ Surgical Gastroenterologist with Liver transplant experience / Liver transplant surgeon from Govt. and private hospitals will oversee the urgent Liver allocations.

Note: Patients on the urgent list supersede the standard list and the hospital misses its regular turn on the roster.

c. Child deceased organ donors

In case of children below the age of eighteen years, the appropriate form mentioned in the THOA 1995 requires to be signed by the persons concerned before organ retrieval. The organs thus retrieved from the child deceased donor organs have to be offered to the children waiting for a deceased donor organ who are registered at Jeevandaan.

12.0 Promotion of JEEVANDAAN Scheme

The critical success factors for a scheme like JEEVANDAAN is the increase of awareness and popular support. Public at large should be addressed for a behavioural change so that there is more empathy to the idea of JEEVANDAAN scheme. Such an empathy would enable the relatives of the deceased donors to take a decision in favour of donation at the appropriate time. This would involve mass media campaign at the appropriate time during the early period of launch of JEEVANDAAN scheme. The DIPR may be requested to design and

implement appropriate media campaign for this purpose. Besides this, workshops and seminars may be held in all the medical colleges and major hospitals both the public and private sector.

12.1 Transplantation Coordinators

All the NTOHCs and OTCs shall have a full time Coordinator, who can be a doctor or nurse not directly involved in the retrieval / transplantation activities. The Transplantation Coordinator identified for each institution shall get trained in communication skills and also handling the situation arising out of the proposed donation and transplantation.

12.2 Maintenance of Cadaver

A time period of a few hours / few days may elapse from the time of initiation of the process for declaration of brain death till the time the organs are harvested and the body handed over to the relatives. The cadaver has to be maintained by the NTOHC till such period. It may not be appropriate to charge from the relatives of the deceased in such cases. The Committee, therefore, recommends that the hospital (NTOHC only) be compensated at Rs. 10,000/- per each day,

counted from the date of declaration of brain death to the date of handing over the body to the relatives of the deceased donor. This will act as an incentive for the NTOHC to readily take up the cases who can prospectively become donors for cadaver transplantation and thus, increase the availability of organs in the State.

12.3 Counselling

As mentioned earlier, counselling plays a very critical role in enabling the relatives of the deceased persons to take a decision in favour of donation of the organ (s). Professionally trained counselors

will have to be appointed at all the NTOHCs and OTCs, so as to be on-call. The expenditure relating to the appointment and maintenance of the counselors in respect of NTOHCs will have to be borne either by the hospital or by an NGO attached to the NTOHC. In this regard, it is desirable that each NTOHC shall necessarily be attached to one or more NGOs which can not only promote the concept of JEEVANDAAN but also render critical service relating to counselling.

12.4 Nodal Centers for training & awareness

a. Given the fact that the cadaver transplantation and JEEVANDAAN scheme are being introduced newly in the State, it is necessary to undertake a systematic training for the Coordinators of NTOHCs and OTCs. The Committee recommends that Osmania Medical College (OMC) shall be the nodal place for training of Coordinators. A team of three members shall be identified from OMC and other public / private hospitals for training the co-ordinators. OMC can run a two-day course once in two months with the help of the three faculty members.

b. There is also immense need for a continuous promotion of the donation Program, as already emphasized earlier. The Gandhi Medical College / Hospital can be made as the Nodal Organization for undertaking promotional activities by engaging a professional agency for the purpose. They may also conduct liaison with the various regulatory authorities like RTA, Passport Office, Chief Rationing Officer etc., to inculcate the

habit or 'organ pledging' at the time of applying for or receiving driving license, passport, ration card etc. While such a pledge may not have any legal sanctity , it will still serve the purpose of sending the message to a large cross section of people that donation of organs is life saving in nature and beneficial to the society.

13.0 Financial implication

Implementation of JEEVANDAAN scheme has the following estimated financial implication:

i) Establishment of AACT (NIMS): (CTC @ Rs 2 lakhs p.m; one Sr. medical professional @ Rs.1,00,000 p.m.+3 Jr. personnel @Rs.25,000 p.m)	Rs. 45.00 lakhs
ii) Miscellaneous (NIMS)	Rs. 25.00 lakhs
iii) Promotion(Gandhi Hospital)	Rs. 25.00 lakhs
iv)Training(Osmania General Hospital)	Rs. 5.00 lakhs
Total:	**Rs. 100.00 lakhs**

The estimated expenditure for the first year is likely to be of the order of Rs.1 cr . The JEEVANDAAN scheme may subsequently become financially self-sufficient through the registration fee as well as contributions from the NGOs and other philanthropic organizations which may be mobilized in due course of time. It is proposed that the seed money of Rs. 1 cr will be mobilized within the overall budget allocated to DME and TVVP as well as from the budget of trauma-care Centers.

14.0 Homografts

There is an acute need for Homografts used for replacement of damaged cardiac valves. These are much superior to artificial valves

as they are biocompatible, need less medication and are much cheaper. The source of these Homografts is Cadaver heart. Harvested hearts can be preserved in Saline or may also be cryo-preserved.

14.1 AACT shall be the authority competent to register hospitals as Homograft Banks, provided there are adequate facilities in the hospital, after inspection by the experts.

14.2 Homografts may be made available to other hospitals also, at request

15.0 Conclusion

a)It is absolutely essential to promote cadaver transplantation Program in the State of Andhra Pradesh

b)JEEVANDAAN scheme has been designed as a comprehensive measure for promoting cadaver transplantations in an effective, efficient and transparent manner.

c) OTCs and NTOHCs shall play a key role in implementing the JEEVANDAAN scheme.

d) Organs harvested shall be allocated strictly in accordance with the protocol / priority laid down.

e) A significant emphasis has to be laid on promotion and training for the successful implementation of JEEVANDAAN scheme.

f) The initial seed money of Rs. 1 cr needed for the implementation of the Program for one year would be tapped from the existing financial resources of the HM & FW Department.

g)The Program will be housed in NIMS.

Principal Secretary, HM & FW
Chairman

Director of Medical Education
Member

Superintendent, OGH
Member

Principal, OMC
Member

Principal, GMC
Member

Superintendent, Gandhi Hospital
Member

DIG of Police
Member

Representative,
MOHAN Foundation
Member

Director-NIMS
Member-Convenor