

## Organ Donation and Transplantation: Legal Aspects, Procedures, Protocols and Recommendation

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### Abstract

Organ Transplantation is seen as the best solution to end stage Organ Failure. Several changes have been instituted through The Transplantation of Human Organs and Tissues Rules 2014 (THOTR 2014) to provide a fresh impetus to organ donation in the country. Twenty years after the landmark Transplantation of Human Organs Act of 1994 (THOA 1994) was published, still India by far stands last on the donor statistics when compared with developed countries. Several changes like Presumed Consent<sup>4</sup>, Required Request<sup>5</sup> etc still needed to promote and streamline the process of declaration of brain death and organ retrieval. Doctors and Health-Care professionals can play a huge role here in spreading awareness regarding the benefits of Organ Donation, its procedure and Path breaking timely changes in legislation, coupled with increasing awareness on socially relevant and altruistic issues will boost organ donation rates in India.

**Keywords:** Organ Donation, Organ Transplantation, End- Stage Organ Failure.

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### Introduction

Organ Donation is the process of surgically removing an Organ/Tissue from a person – living or recently dead and placing it in another person. While the person who gives his/her organ/tissue for donation is called the donor, the person to whom it is transplanted is called the Recipient. The entire process is collectively called as Organ Transplantation.<sup>1</sup> It is the most preferred treatment modality for end stage organ disease/failure serving as a ray of hope for survival. However the need for transplant is high with consequent shortage of Organ Donors globally, despite great advances in both Surgical Technologies and the discovery of potent medications for rejections treatment.<sup>2,3</sup> Different approaches are taken to meet this demand like live donation and cadaveric donation.<sup>4,5,6</sup> The

concept of Organ Donation is a sensitive issue having various ethical, legal and social aspects attached to it. The pre-requisites for the success of the Organ Transplantation program includes public awareness and a positive attitude towards the same along with consent by relatives for Organ Donation in the event of Brain Death.<sup>7</sup> Lack of Knowledge and understanding about Organ Donation, Religious Attitude and Superstitious Beliefs have generated fear and mistrust in the minds of common man.<sup>3,8</sup>

### Types of Organ Donation:<sup>1,2,9</sup>

- Living Person donating to a relative or anyone – In such a case 1 portion of Kidneys /Liver/Lung/Pancreas can be donated. In case of Donor Incompatibility , SWAP Transplant by means of registering at SWAP registry and Subsequent matching with a similar incompatible pair /recipient pair .
- Following Brain Death, there is complete and irreversible loss of Brain-Stem function. Almost all Organs can be retrieved for Organ Transplantation.

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However, prior consent of Family Members is essential. It is also called Cadaver/Deceased Donor donation & one Cadaver donation can save up to 8 lives.

Donation after Natural Death –In such a case Organs like Eyes, Skin and Fascia, Heart Valves, Bones and Tendons, Cartilage, Veins and Arteries, Middle Ear Bones can be donated. Kidneys, Heart, Liver, Lungs and Intestines can't be donated in this case.

### **Organ Donor Statistics:**

According to Indian Statistics, there are about 1, 50,000 people in India who are waiting for a Kidney Transplant whereas Only about 3,000 Kidney Transplants take place each year. In addition, the dialysis population is growing at a rate of 10-20% annually. India by far stands last on the donor statistics as countries like Spain have 35 organ donors per million people, USA has 26, Britain has 27, Canada 14, Australia 11 while India has a mere 0.16 per million population.<sup>10,11,12,</sup>

### **The Legislative Aspects of Organ, Tissue Donation and the procedures:<sup>1,2,5,9</sup>**

There is a need to allow the transplantation as an instrument for saving lives and secondly to ensure that trafficking in human organ does not take place by exploiting poverty, illiteracy and ignorance of a large section of Indian society. The Transplantation of Human Organs and Tissues Act, 1994 (THOTA) was enacted to provide for the regulation of removal, storage and transplantation of Human Organs for therapeutic purposes and for prevention of Commercial Dealings in Human Organs and for Matters Connected there with or incidental thereto.<sup>1,9</sup>

The primary objectives of The Transplantation of Human Organs and Tissues Act, 1994 (THOTA) were<sup>9</sup>

- 1.To curb the commercial purchase of organs from live donors.
- 2.To protect the donors who are usually from the low socio-economic status from being exploited by the middlemen

- 3.To restrain the removal of organs from patients without their knowledge.

- 4.To recognize the concept of brain death in order to encourage cadaveric donation.

The Transplantation of Human Organs and Tissues Rules 2014 (THOTR 2014) are likely to provide a fresh impetus to organ donation in the country. Twenty years after the landmark Transplantation of Human Organs Act of 1994 (THOA 1994) was published, several changes have been instituted to promote and streamline the process of declaration of brain death and organ retrieval. The Act is broadly divided into Seven Chapters consisting of 25 Sections.<sup>9</sup>

Following are the after effects of 1994 Act THOTR 2014:<sup>2</sup>

- (i) Concept of Brain Stem death accepted
- (ii) Only Living related Donors are allowed to donate organs without legal problems
- (iii) For unrelated donors- Permission from Authority i.e. "Authorization Committee" required prior to surgery
- (iv) Requires- regulation and "Registration of hospitals" undertaking transplantation
- (v) Punishment for any commercial dealings in organs.

### **Chapter I constitutes the following:<sup>9</sup>**

**Under Section 1:** it is applicable all over India including J & K state.

**Under Section 2:** Definitions of various terms has been given such as:

- Brain Stem Death - means the stage at which all the functions of the Brain-Stem have permanently or irreversibly ceased and is so certified by a Board of Medical Experts.
- Donor means any person, who is 18 years and older, who voluntarily authorizes the removal of any of his human organs or tissues or both for therapeutic purposes under sub-section 1 or sub-section 2 of section 3. As per the act, a donor can be a live near relative, 'live unrelated' or 'deceased/ cadaver'.
- 'Near Relative' of the donor means spouse, son, daughter, father, mother,

brother or sister. Amendment: Grandparents and Grandchildren added as well to the concept of near relative

#### **Amendments:**

- 1) Two Definitions added to broaden the scope of Donation:
  - **Tissues** means a group of cells, except blood, performing a particular function in the human body.
  - **Human Organ Retrieval Centre** is a hospital which has adequate facilities and staff for treating critically ill patients who can be potential donors of organs in the event of death/ brain death and which are registered under sub- section (1) of Section 14 for retrieval of Human Organs.
- 2) Appointment of:
  - **Transplant Co-coordinator**: Transplant co- coordinator is a person appointed by the hospital for co-ordinating all matters/issues relating to removal and transplantation of human Organs or tissues and for assisting the authority for removal of the same.
  - **Authorization Committee** (AC): - The ACs, constituted under clause a) or clause b) of sub- section (4) of section 9, of the respective States or Union Territories, & have a functions to —approve or —reject transplants between the recipient and unrelated donors, organ or tissue donation for non-Indian nationals.
  - **Appropriate Authority** (AA): The Appropriate Authority, constituted by the state government under section 13, has powers to Inspect and grant / renew / suspend / cancel the registration of the hospital for transplant surgery.

#### **Chapter II constitutes the following:**<sup>9</sup>

**Under Section 3:** Who can authorize the removal of Human organs or tissues?

- If the donor had in writing given his consent to donate organs post death in presence of two witnesses, at least one of whom is a near relative before his death, then for the removal of any organ post death, the person legally in possession of the body shall allow doing so.

Amendment: Where no authority as is referred to in sub- section (2), was made by any person before death without any objection, the person legally in possession of the body shall allow doing so unless he believes the near kin of the deceased will have an objection for organ removal.

- Where brain stem death occur in a person less than 18 years of age, one of the parents of the deceased may give authorization for removal of organs from the deceased person. Amendment: Only for eye donation, a technician may also enucleate the cornea provided he has the necessary qualifications and experience.
- Where any human organ is to be removed in the event of brain- death, the manner of such a death has to be certified by a board of medical specialists constituting of registered medical practitioners treating the person, the one in charge of the hospital, also one having an independent practice and a neurologist/neurosurgeon. Amendment: If neurologist/neurosurgeon is not available, the registered medical practitioner may nominate an independent registered medical practitioner being a surgeon or a physician and an anesthetist/intensivist subject to the condition that they are not members of the transplantation team for the concerned recipient.

**Under Section 4:** The removal of organs is not authorized if inquest is required or if the body is entrusted solely for interment cremation or other disposal.

**Under Section 5:** A body lying in a hospital or prison for over 48 hours and not claimed by any of the relatives in this time period, in such a case the authorization for removal of the organs may be given by the person in charge of the hospital or prison.

**Under Section 6:** when a body is sent for post- mortem examination for medico- legal purposes by reason of the death being unnatural cause or pathological purposes , the person competent to give authority may authorize for the organs not needed for post-mortem to be removed. For e.g. Removal of

eyes which in no way affects the post-mortem.

**Under Section 7:** Registered medical practitioner should take necessary steps for the preservation of the human organs so removed.

**Under Section 8:** all previous lawful activity remains as such and shall in no way be rendered unlawful or a punishable offence under section 297 of the Indian Penal Code.

**Under Section 9:** there is a restriction on removal and transplantation of organs such that before death the recipient of the donor's organs is the near relative, after death it may be anyone in need. Before death it could be to anyone with affection or attachment when authorized by one or more authorisation committee of the state/central government.

**Amendments:**

- Where the donor or recipient of the near relative is a foreign national, prior approval of the authorization committee is required before removing or transplanting a human organ or tissue or both.
- No human organs or tissues shall be removed from the body of a minor, where in a minor is a person less than 18 years of age before his death for the purpose of transplantation.

By Donor / (Next of Kin)	Recipient
Before death	Near relative (spouse, son, daughter, father, mother, brother, sister, grandparents and grandchildren)
After death	To anyone in need
Before death	Other than Near relative with affection or attachment (if authorized by authorisation committee )
Minor / mentally challenged before death	Not Permitted

- No Organs/Tissues or both shall be removed from the body of a mentally

challenged person before his death for the purpose of Transplantation.

- If the donor is not biologically compatible for transplantation is permitted to swap with another pair of such persons, and the agreement between both sets has to in all cases be approved the Authorization Committee.

**Chapter III constitutes the following:<sup>9</sup>**

**Section 10:** states about the law for regulation of hospitals, where in no hospital which is not registered under this ACT, shall conduct or associate with organ removal, storage and transplantation. Also, no medical practitioner may aid the hospital in such a process. However the eyes or ears (ear drums/bones) maybe removed at any place for therapeutic purposes.

**Section 11:** states that no donor and person allowed to give authority for removal of the organ shall do so for any purpose besides therapeutic ones.

**Section 12:** states that removal of organ by a registered medical practitioner shall take place only when he has explained the effects, complications and hazards of the process to the donor and recipient respectively.

**Chapter IV constitutes the following:<sup>9</sup>**

**Section 13:** states Central and State governments shall appoint one or more officers as Appropriate authorities for the purposes of this ACT who shall grant or suspend registration, enforce standards for hospitals for organ removal and inspect them periodically, and also investigate complaints due to breach of the act.

**Amendments:**

- The Central/State Governments shall constitute an advisory committee for a period of two years to aid the appropriate authority to discharge its functions.
- Also, the Central Government may by notification establish a National Human Organs and Tissues Removal and storage network at one or more places along with a regional network branch to perform functions.



**Chapter V constitutes the following:<sup>9</sup>**

**Section 14** – No hospital shall engage in removal, storage and transplantation of Organs for therapeutic purpose unless it is duly registered under this ACT.

**Section 15** – The appropriate authority shall grant a certificate of registration only after holding an inspection to see that all requirements and standards as specified by the ACT are met properly. The appropriate authority may also conduct regular inspection of the hospitals to examine the quality of transplantation and follow up medical care of donors and recipients.

**Section 16** – The appropriate authority may revoke the registration of the Hospital by issuing a notice for reasons mentioned in it and/or due to breach of any provisions of the ACT.

**Section 17** – An appeal may be filed, within 30 days limit, by any person aggrieved by an order of the Authorization.

**Chapter VI constitutes:** laws pertaining to offences and penalties.

**Chapter VII constitutes:** a list of miscellaneous rules for protection of action taken in good faith for provisions of this act.

**Checklist Protocol for Live Related Donor transplant cases:<sup>2,9</sup>**

- 1) Application on the letter head of the hospital with name of donor & operating surgeon to the hospital based authorization committee for transplant approval.
- 2) Photo, Name and Addresses and age of donor and recipient signed by the treating registered medical practitioner of the case and countersigned by hospital medical director/admin.
- 3) Information in form no 1A/1B/1C, form no2, form no.3, and form no 10 with respective documents as per the format given in amendment of the transplant ACT.
- 4) Certification of operating surgeon's qualification by medical director/admin of the concerned hospital.
- 5) Recipients' diagnosis and recommendation for transplant by the

treating registered medical practitioner/nephrologists.

- 6) Histo-compatibility Reports, Blood Reports, HIV AND HBS-AG and ANTI-HCV test reports.
- 7) Police verification of recipients and donors address and criminal record clearance.
- 8) Copy of ration card, pass port, election and identity card, marriage certificate, family photo, birth certificate, education certifications – school leaving certificate and domicile.
- 9) Affidavit of recipient on Rs 20 stamp paper- notarized and registered with list of all family members and relatives, their profession and age and medical, blood reports.
- 10) Affidavit on Rs.50 stamp paper of donor countersigned by notary citing reasons for donation facts and support proof.
- 11) Affidavit of Rs. 20 notarized and registered of donor's relative/kin giving approval for the donation procedure.
- 12) Income particulars and profession of donors and recipients for the last 3 financial years.
- 13) In case the donor and recipient do not possess domicile of the same state then approval and no objection certificate by authorization committee
- 14) In case of foreign nationals no objection certificate and an additional certificate stating that donation is free, voluntary & without any transaction. It should also indicate relation between recipient and donor.
- 15) Hospital transplant Registration Certificate
- 16) Hospital Local Authorization Approval Certificate issued by state appropriate authority.
- 17) Donor's Psychiatric Evaluation Report & Fitness for Surgery Evaluation Report.

**Deceased Donor transplant cases Protocol:<sup>2,9</sup>**

Following Steps should be taken for deceased donor management

- 1) Identification of donor

- 2) The Intensive care Surgeon /Physician must identify brain stem death patients as early as possible.
- 3) Confirmation of the donor and declaration and certification of brain stem death by 4 consultants at twice at a minimum interval of 6 hours.
- 4) Patients can be declared brain dead after the proper pre-conditions are met with proper attention given to necessary exclusions.
- 5) The certification procedure to be done by a brain stem death committee recognized by the state appropriate authority.
- 6) Consent for organ retrieval has to be obtained from next to kin who is in lawful possession of the body.
- 7) Screening & maintenance of the Donor.
- 8) Counselling & Consent of Relatives for Organ Retrieval is taken on form 6 & 7.
- 9) Other formalities to be completed in the hospital like informing the Nurse in charge of the OT, Local/Zonal Transplant coordinator.
- 4) Where it is possible, RMP doing post-mortem to be present at the time of organ or tissue retrieval.
- 5) In case a private retrieval hospital is not doing post mortem, they shall arrange transportation of body along with medical records, after organ or tissue retrieval, to the designated post-mortem centre and the post mortem centre shall undertake the post-mortem of such cases on priority, even beyond office timing, so that the body is handed over to the relatives with least inconvenience.

#### **Body Disposal after Organ Donation:**

- 1) Following tissue procurement, the donor's body is to be reconstructed to closely approximate its original anatomical configuration and to make usual funeral proceedings possible.
  - 2) In case the cause of death a natural one, body is handed over to relatives and cause of death will be issued by treating doctor.
  - 3) In case of death was unnatural and MLC requiring PM, ADR (after death report) is sent to the concerned police station who will send their personal to the hospital for "panchanama" and will issue a No Objection Certificate to carry out the post mortem. After the post mortem, body is handed over to relatives for cremation /burial.
- Procedure For Donation Of Organs Or Tissue In Medicolegal Cases:<sup>9</sup>**
- 1) In medicolegal cases where post mortem is required, after the consent is obtained to donate organs, the registered medical practitioner of the hospital shall make a request to the senior officer of police station of the area directly to facilitate timely retrieval of organs or tissue from the donor and a copy of such a request should also be send to the designated post mortem doctor of area simultaneously.
  - 2) It shall be ensured that, by retrieving organs, the determination of the cause of death is not jeopardized.
  - 3) The medical report in respect of the organs or tissues being retrieved shall be prepared at the time of retrieval by retrieving doctors and shall be taken on record in post-mortem notes by RMP doing post-mortem.

#### **Role of Transplant Co-ordination center**

The functions of the Regional/Zonal Transplant Coordination Centre like National / Regional/State Organ and Tissue Transplant Organization (NOTTO/ ROTTO/ SOTTO) are as follows:

- 1) Preparation of City Waiting List for Organ and Tissue Donation.
- 2) Distribution of Organs from the available cadavers in the hospitals.
- 3) Coordinating among all the hospitals.

#### **Discussion and Recommendations:**

- The act has put a check on trading in Organs & tissues, and approved the brain death organ donation.

- A major factor causing hindrance in the entire process is: lack of knowledge and awareness regarding Organ Donation in Public, lack of infrastructure, loop holes in the act. Many people are unaware about the procedure and legal aspects. People need to be made aware of the benefits of Organ Donation and its critical need by NGO's & Doctors.
- Family Disapproval / No support are also factors inhibiting people to donate. Doctors and NGO'S also in this case should counsel the family members and clear their myths.
- Doctors should also take awareness sessions on explaining the concept of Brain – Death Criteria for Donation as many times relatives of the patient refuse to acknowledge brain death.
- Major efforts and reforms need to be taken to reform the Organ Donation System and Bridge the gap between the demand and availability of the same with updated list of Donors and people in need of one.
- Provision of Presumed Consent which will enables the chief medical examiner as the case may be, to remove organ like cornea's from a dead body. This provision of presumed consent is followed in The United States of America along with Spain and Austria.
- Provision of Required Request in the act: The "Required Request" Provision of the law enacted in many states has also contributed to the increase in the volume of donor material. Under this provision, it is mandatory for the individual hospital authorities to solicit eye/organ donation from the next of kin in all cases of death in their hospital. This approach can have a positive impact.
- All these factors when implemented, over a period of time will work towards bridging the gap between the necessity and availability of Organ and thereby prolonging life.

**Conclusion:** Path breaking timely changes in legislation, coupled with increasing

awareness on socially relevant and altruistic issues will boost organ donation rates in India & will help in bridging the gap between the necessity and availability of Organ and thereby prolonging life.

## References:

- 1) Kataria R, Srinivas S, The Transplantation of Human Organs and Tissues Act, 1994 along with The Transplantation of Human Organs and Tissues Rules, 2014 & WHO Guidelines, 1<sup>st</sup> ed. New Delhi: Orient Publishing Company, 2014, p 29-218.
- 2) Manual for Deceased Donor Transplant, Deceased donor transplant programme, Govt. of Maharashtra, By Zonal Transplant Co-ordination centre (ZTCC), Mumbai, 2007. P30-36.
- 3) Reddy AV, Guleria S, Khazanchi RK, Bhardwaj M, Aggarwal S, Mandal S. Attitude of patients, the public, doctors, and nurses toward organ donation. *Transplant Proc.* 2003; 35:18. [PubMed: 12591287]
- 4) Rithalia A, McDaid C, Suekarran S, Myers L, Sowden A. Impact of presumed consent for organ donation on donation rates: a systematic review. *BMJ.* 2009 Jan; 338:a3162.
- 5) Shroff S. , Organ Donation and Transplantation in India: Legal aspects and solutions to help with Shortage of Organs, *Journal of Nephrology and Renal Transplantation*, 2009, vol.2, pp.22-34.
- 6) WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, World Health Organization. Available from: [http://www.who.int/transplantation/Guiding\\_PrinciplesTransplantation\\_WH\\_A63.22en.pdf](http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WH_A63.22en.pdf). [accessed on 25/08/2015]
- 7) Shroff S, Navin S, Abraham G, Rajan PS, Suresh S, Rao S, et al. Cadaver organ donation and transplantation-an Indian perspective. *Transplant Proc.* 2003; 35:15–7. [PubMed: 12591286]

- 8) Spencer M., The barriers to organ and tissue donation in palliative care. *End Life J.* 2012; 2:1–11
- 9) Government of India. Transplantation of Human Organs Act, 1994. Available at: <http://www.mohfw.nic.in/> accessed on 14.11.2015.
- 10) International organ donation registry: ORGANS, TISSUES & CELLS, 2010;13:5-8.
- 11) Singh P, Kumar A, Pandey CM, Chandra H. Level of awareness about transplantation, brain death & cadaveric organ donation in hospital staff in India. *Prog Transplant* 2002;12:289-92.
- 12) Mercer L. Improving the rates of organ donation for transplantation. *Nursing Standard.* 2013 Feb-Mar 5;27(26):35-40.