

SEMINAR
HUMAN ORGAN
TRANSPLANTATION ACT &
AMMENDMENTS

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Transplant – Legal Framework in India

- **1983:** The Kidney Transplantation Act – Maharashtra
- **1991:** The Singhvi Committee – Brain Death
- **1994:** Transplantation of Human Organs **Act**
- **1995:** Transplantation of Human Organs Rules
- **2008:** Transplantation of Human Organs (Amendment) Rules
- **2011:** Transplantation of Human Organs (Amendment) **Act**
- **2014:** Transplantation of Human Organs & Tissues Rules
- **2015:** National Organ & Tissue Transplant Registry launched

THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994 [THOA]

- Aim –
 - regulation of removal, storage, and transplantation of human organs for therapeutic purposes
 - prevention of commercial dealings in human organs
- Major Problem
 - Brainstem death not recognized by the Indian law
 - Rampant Trade of human organs, esp. Kidney
- Based on the report of the Singhvi Committee 1991
 - Conceptualized the legal framework of brain-death
 - Methodized legal utilization of organs for transplantation

- Authorization in written by ≥ 18 yr with two witnesses of whom one must be near relative.
- Board of four Medical-experts to certify Brain-death
 - RMP in-charge of the concerned hospital
 - A member of a panel approved by the Appropriate Authority
 - A Neurologist / Neurosurgeon
 - The Attending Physician
- Live donor Transplant
 - Near relative – Spouse or 1st degree relatives
 - Approval from Authorization Committee for all except near relative
- Cadaveric donor – consent of near relative

Major Changes in 2011 Amendment THOTA

- **Tissues** included along with the Organs.
- **Near relative** definition expanded to include grandchildren, & grandparents.
- **Retrieval Centre** registration for retrieval of organs from deceased donors.
- **Tissue Banks** also to be registered.
- **Swap Donation** included.
- **Mandatory inquiry** from the attendants of potential donors.

- **Mandatory “Transplant Coordinator”** in all the hospitals registered under this act.
- **Higher Penalties** for trading in organs.
- **Brain death certification board** expansion – to include Physicians, Surgeons, Anesthetists or Intensivists.
- National human organs & tissues removal & storage Network and National Registry for Transplant are to be established.

- **Advisory committee** to aid and advise Appropriate Authority.
- Enucleation of corneas permitted by a **trained technician**.
- Greater caution in case of **minors** and **foreign nationals**
- prohibition of organ donation from **mentally challenged**.

Table 1: Differences in THOA 1994 and Transplantation of Human Organs and Tissues Act 2014

	THOA 1994	THOTA 2014
Advisory committee	No	Yes
Appropriate authority	Mentioned	Defined: Who and what
Authorization committee	State	Included hospitals of >25 transplants/year
Video	No	Video recording
Definition of brain death	Yes	Yes
Brain death declaration team	Neurology/neurosurgeon	Added physician, anesthetist, intensivist
Hospitals	Transplanting centers	Added nontransplant retrieval centers
Which hospital	-	Any hospital with RMP and ICU facility
Registration of hospital	Organ retrieval	Yes for organ retrieval but not needed for tissue retrieval
Scope of donor	"Near-relative" means spouse, son, daughter, father, mother, brother, or sister	Near relative included grandparents, grandchildren
Swap donations	No	Yes
Pledge	No	Yes form 7
Counseling for donation	Mentioned	Mandatory
Medicolegal cases	Not defined	Simplified
Number of forms	13	21
Role of doctor	Needed for organ retrieval	Yes for organ retrieval not for tissue
Transplant coordinators	Mentioned	mandatory
Organ retrieval charges	Not mentioned	Recipient/Govt/NGO
Scope	Organs	Organs and tissues
Penalties	Less	More
Registries	No	Yes

Regulatory Bodies

- **Advisory committee** – To assist appropriate authority
 - administrative expert (Secretary to the State Govt.) – Chairperson
 - Two PG medical experts with ≥ 5 y experience in transplant
- **State-level Authorization Committee** –
 - CMO of major Govt. Hospt. – Chairperson
 - Two senior RMP's not part of any transplant team
 - Secretary of health or nominee & Director health services or nominee
 - Two senior persons of high integrity, credibility, & social standing
- **Hospital Authorization committee** –
 - Hospitals which do > 25 transplants per year.

Types of Donors

Living Donors

1. Near-related donors – Evidence of relation to be attached.
2. Swap donation –
 - Donor & Recipient pair of each family should be near related.
 - Donation should be simultaneous to there is no donor renegeing.
3. Other than near-related donors –
 - Possibility of monetary transaction.
 - Permission granted by authorization committee after evaluation –
 - Link between donor & recipient with documentary evidence.
 - No e/o Financial transaction / Middleman / drug-addict donor.

- Foreign donors – all cases dealt by authorization committee
 - Indian donor & Foreign recipient and vice –versa – only near relative
 - Foreign donor & recipient – confirmation from embassy

Deceased Donors

- consent of near-relative or person in lawful possession of the body required.
- mandatory to enquire of pledged organs or option to donate.
- **MLC** – acceptable but ensure that, determination of the cause of death is not jeopardized

Priority of Recipient

1. No suitable near-relative living donor
2. Suitable near-relative donor refused in writing
3. Suitable donor did not officially refuse.
4. Allocation in following order
 - 1) State List
 - 2) Regional List
 - 3) National List
 - 4) Person of Indian origin
 - 5) Foreigner

Hospital Registration

- 24hr availability of –
 - Medical, Surgical & Nursing staff
 - ICU units with equipments & staff
 - Operation theater, Blood-bank, & Laboratory services
 - HLA lab
 - Experts of specialties
- Expertise in each organ transplant clearly defined
- maintenance of minimum standards of hospital as per the Clinical Establishment Act 2010.
- Valid for 5 years

Table 2: Transplantation of Human Organs and Tissues Act forms

Form	Given by
1 For organ or tissue donation from identified living near-related donor	Donor - him or her
2 For organ or tissue donation by living spousal donor	Spouse - him or her
3 For organ or tissue donation by other than near-relative living donor	Donor - him/her
4 For certification of medical fitness of living donor	Registered medical practitioner
5 For certification of genetic relationship of living donor with recipient	Head of pathology laboratory
6 For spousal living donor	Competent authority and authorization committee in case of foreigners
7 For organ or tissue pledging	Individual of age 18 years or above
8 For declaration cum consent	Near relative or lawful possessor of brain-stem dead person (including minors)
9 For unclaimed body in a hospital or prison	Person in lawful possession of the unclaimed body
10 For certification of brain stem death	Board of medical experts certifying brain stem death
11 Application for approval of transplantation from living donor	Proposed recipient and the proposed living donor
12 Application for registration of hospital for organ or tissue transplant other than cornea	Head of the institution
13 Application for registration of tissue banks other than eye banks	Head of the institution
14 Application for registration of tissue banks other than eye banks	Head of the institution
15 Application for registration of eye bank, corneal transplantation center, eye retrieval center under THOTA	
16 Certificate of registration for organ/tissue transplantation/retrieval and/or tissue banking	
17 Certificate of renewal of registration	Appropriated authority on the letterhead
18 Certificate by the authorization committee of hospital	Issued on the letterhead
19 Certificate by competent authority for Indian near relative other than spouse	Issued on the letterhead
20 Verification certificate in respect of domicile status of recipient or donor	Tehsildar/authorized officer (required only for donor - other than near relative or recipient if they do not belong to state where transplant hospital is located)
21 Certificate of relationship between donor and recipient in case of foreigners	Embassy concerned

NOTP: National Organ Transplant Programme

- Implemented by DGHS, MOHFW, GOI to enforce THOTA-2011
- Aim – improve access to transplantation by promoting deceased organ donation
- Objectives –
 - Organize a system of Organ and Tissue procurement & distribution.
 - Promote deceased Organ and Tissue donation.
 - Train required manpower.
 - Protect vulnerable poor from organ-trafficking.
 - Monitor transplant services and bring policy changes as needed.

Issues and Challenges

- High Demand versus Supply gap.
- Poor Infrastructure esp. in Govt. Sector Hospitals.
- Lack of Awareness of concept of Brain Stem Death.
- Poor rate of Brain Stem Death Certification by Hospitals.
- Poor Awareness and attitude towards organ donation.
- Lack of Organized systems for organ procurement.
- Maintenance of Standards in Transplantation, Retrieval and Tissue Banking
- Prevention and Control of Organ trading
- High Cost (especially for uninsured and poor patients)
- Regulation of Non- Govt. Sector

NOTP achievements

- National Organ and Tissue Transplant Organization (NOTTO)
 - Establishment of an apex national level organization – NOTTO.
 - Functional website (www.notto.nic.in) & helpline number 1800114770.
 - Policy for Organ allocation in case of kidney – finalized and approved.
 - SOPs for Brain-dead Donor maintenance & Organ retrieval developed.
- Online system of registry and networking
 - Online and offline organ donation pledging operationalized.
 - Online registration & networking of Transplant hospitals
 - National collection of transplant data

- Regional Networking centres
 - Regional Organ and Tissue Transplant Organizations (ROTO) – 5
 - State Organ and Tissue Transplant Organizations (SOTTO)
- Awareness
 - Hon'ble PM highlighted the importance of organ donation in the Mann Ki Baat Programme Nov. 2015.
 - Indian Organ Donation Day – annually since 2010 (Nov 30 – 2019)
 - National Organ & Tissue Transplant Registry (NOTTR) – 27 Nov 2015
 - IEC activities.

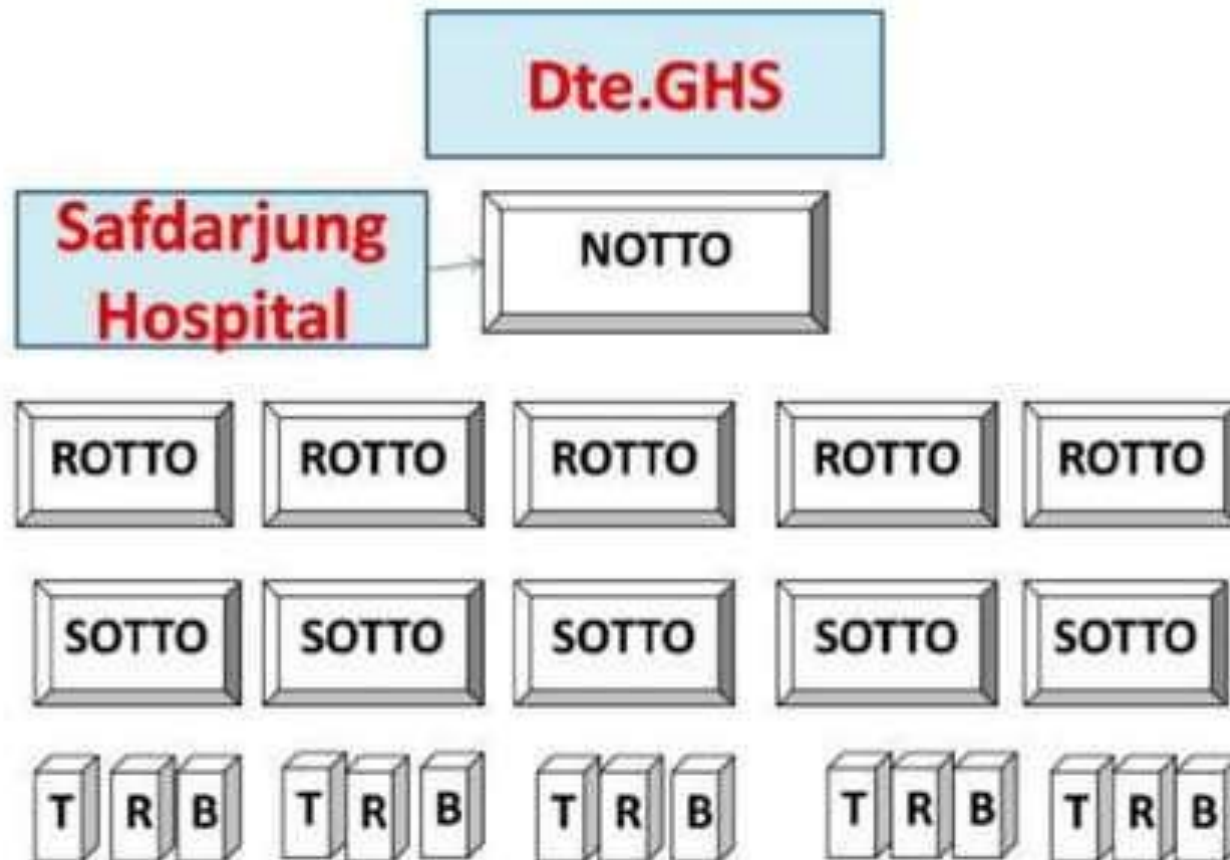
- Trainings

- Transplant Coordinator training programmes
- Post Doctoral certificate course in Dialysis Medicine through IGNOU

- Financial assistance

- 100 BPL transplant recipients/y – Rs.6000/m for immunosuppressants
- maintenance Rs.50000/ per deceased donor in a private hospital when organ is allocated to a Govt. institution.
- providing transplant coordinators at Govt. Medical Colleges, Trauma Centers and good performing Private Institutions.

National Human Organs and Tissues Removal and Storage Network



NOTTO: National Organ and Tissue Transplant Organization

ROTT0: Regional Organ and Tissue Transplant Organization

SOTTO: State Organ and Tissue Transplant Organization

T: Transplant Centre

R: Retrieval Centre

B: Biomaterial Centre (Tissue Bank)

National Organ and Tissue Transplant Organization (NOTTO)

- National level organization set up under the aegis of NOTP
- Located at Safdarjung Hospital New Delhi
- It has two divisions –
 - **National Human Organ and Tissue Removal and Storage Network** – apex centre for All India activities of coordination and networking for procurement & distribution of Organs & Tissues and Registry of Donations & Transplantations.
 - **National Biomaterial Centre (National Tissue Bank)** – National level Tissue Bank for procurement, storage and distribution of biomaterials.

National Human Organ & Tissue Removal & Storage Network

- Functions at National level –
 - Lay down policy guidelines and protocols.
 - Network with ROTTO & SOTTO organizations.
 - Compile & publish all Registry data from Regions & States.
 - Creating awareness, promotion of organ donation.
 - Co-ordination when organ is allocated outside the region.
 - Monitoring of transplantation activities in the Regions and States.
- Functions for Delhi-NCR
 - Maintaining Waiting-list & matching of recipients with donors.
 - Networking with transplant centres, retrieval centres & tissue banks.
 - Allocation, Transportation, Storage & Distribution within Delhi-NCR.

National Biomaterial Centre

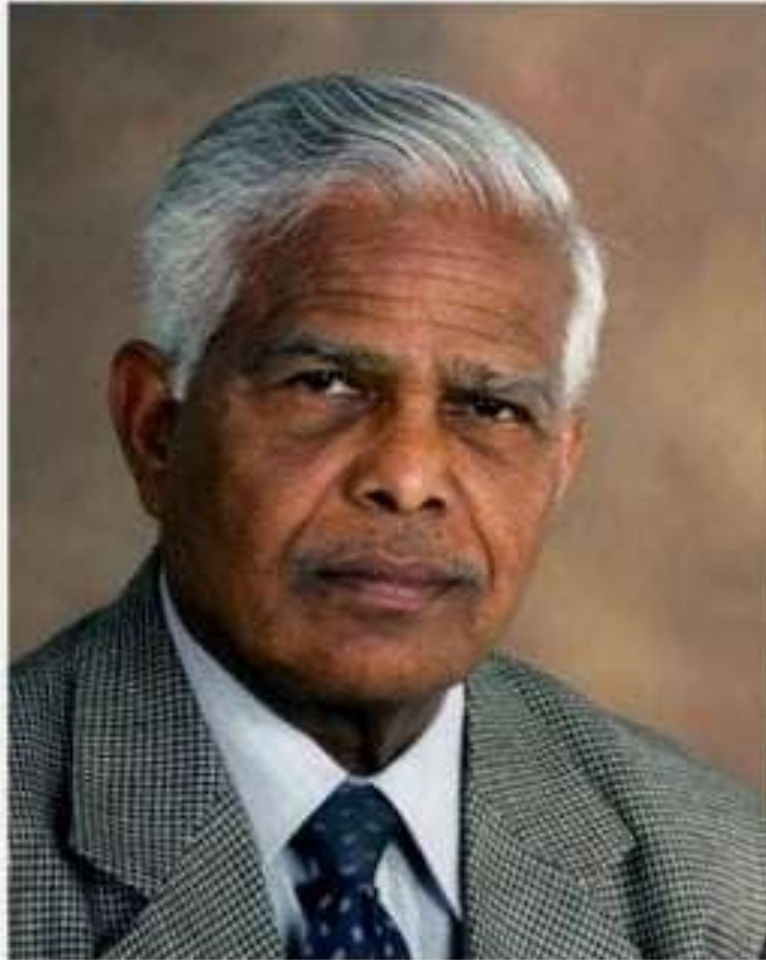
- National level Tissue Bank –
 - Bone, Bone products & Fascia
 - Skin graft
 - Cornea
 - Heart valves and vessels
- Functions –
 - Development of Guidelines, Protocols & SOPs.
 - Coordination for tissue procurement and distribution.
 - Tissue Screening, Sterilization, Preservation, & Quality control.
 - Records maintenance, Data Protection and Confidentiality.

Proposed States/UTs to Regional Organ and Tissue Transplant Organization(ROTO)

Regional Organ and Tissue Transplant Organization (ROTO)	States Under Regional Organ and Tissue Transplant Organization (ROTO)	State Organ and Tissue Transplant Organization (SOTTO)
ROTO WEST King Edward Memorial Hospital, Mumbai	Maharashtra Gujarat Goa UTs of Dadra and Nagar Haveli, -Daman, Diu Madhya Pradesh Chhattisgarh	KEM Hospital, Mumbai IKDRC, Gujarat GMC & Hospital, Bambolim -- -- MGMC Bhopal --
ROTO SOUTH Madras Medical College, Chennai	Tamil Nadu Kerala Andhra Pradesh Telangana Karnataka Puducherry Andaman and Nicobar Lakshadweep	Tamil Nadu Superspeciality Hospital Chennai Medical College Thiruvananthapuram -- -- -- -- -- --
ROTO EAST Post Graduate Medical Education and Research, Kolkata	West Bengal Jharkhand Sikkim Bihar Odisha	IPGMER, Kolkata, West Bengal -- -- IGIMS, Patna SCBM College and Hospital, Cuttack
ROTO NORTH Post Graduate Institute of Medical Education & Research, Chandigarh	Punjab Haryana Himachal Pradesh Jammu & Kashmir Chandigarh Rajasthan Uttarakhand Uttar Pradesh	GMC Patiala PGIMS Rohtak -- GMC Jammu PGIMER Chandigarh SMS Jaipur -- SGPIMS Lucknow
ROTO NORTH-EAST Guwahati Medical College	Assam Meghalaya Arunachal Pradesh Manipur Nagaland Mizoram Tripura	Gauhati Medical College, Guwahati -- -- -- -- -- --
NOTTO	Delhi NCR	Delhi NCR

THANK YOU

Rao, M Mohan



**Dr M. Mohan Rao – CMC Vellore 1955 Batch
1st successful renal transplant in India – Feb 02, 1971, at CMC Vellore**