

Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOS/SOTTOs

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General Background

- There is huge shortage of Organs available for carrying out Transplants as compared to the number of patients who require Organ transplants. There is huge Gap between demand and supply of organs.
- There is a need to promote deceased organ donation, rather than relying on living donors, because of risk of commercial trading and inherent risk to the health of living donor.
- Cadaveric organ donor transplant can be done from “brain stem dead” persons before the heart stops beating.
- About 1.5 lakhs deaths happen annually due to road traffic accidents in India – a large number of these cases could be harvested for organs.
- Organ donation rate (Number of persons who donate organs after death in one million population) in India is less than one as compared to maximum of around 48 in the Spain. **However**, it is encouraging to note that Organ donation rate has increased **to about four times as compared to 2012, when it was 0.16.**

Legal Framework

- The Transplantation of Human Organs Act (THOA), 1994 was enacted in the year 1994 and has been adopted in all States except erstwhile State of J&K and Andhra Pradesh which have their own legislation in this regard. Main purpose of the Act is to regulate the removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs.
- The Act was amended in 2011 and the Transplantation of Human Organs (Amendment) Act 2011, has come into force on 10-1-2014 in the States of **Goa, Himachal Pradesh, West Bengal, and Union Territories.** Other States who have adopted the amendment Act till date are **Rajasthan, Sikkim, Jharkhand, Kerala, Orissa, Punjab, Maharashtra, Assam, Haryana, Manipur, Gujarat, Bihar and Uttar**

Pradesh. The amended Act is now named **Transplantation of Human Organs and Tissues Act (THOTA), 1994.**

- Brain Stem death is recognized as a legal death in India under the Transplantation of Human Organs and Tissues Act, since 1994 like many other countries, which has revolutionized the concept of organ donation after death. After natural cardiac death only a few organs/tissues can be donated (like cornea, bone, skin and blood vessels) whereas after brain stem death almost 37 different organs and tissues can be donated including vital organs such as kidneys, heart, liver and lungs.
- In pursuance to the Amendment Act, the Transplantation of Human Organs and Tissues Rules have been notified on 27th March, 2014. The amended Act and revised Rules have many provisions for promotion of organ donations from cadavers.

Important amendments under the (Amendment) Act 2011 are as under:-

- (i) Tissues have been included along with the Organs.
- (ii) 'Near relative' definition has been expanded to include grandchildren, grandparents.
- (iii) Provision of 'Retrieval Centres' and their registration for retrieval of organs from deceased donors. Tissue Banks shall also be registered.
- (iv) Provision of Swap Donation included.
- (v) There is provision of mandatory inquiry from the attendants of potential donors admitted in ICU and informing them about the option to donate – if they consent to donate, inform retrieval centre.
- (vi) Provision of Mandatory 'Transplant Coordinator' in all hospitals registered under the Act
- (vii) To protect vulnerable and poor there is provision of higher penalties has been made for trading in organs.
- (viii) Constitution of Brain death certification board has been simplified- wherever Neurophysician or Neurosurgeon is not available, then an anaesthetist or intensivist can be a member of board in his place, subject to the condition that he is not a member of the transplant team.
- (ix) National Human Organs and Tissues Removal and Storage Network and National Registry for Transplant are to be established.
- (x) There is provision of Advisory committee to aid and advise Appropriate Authority.
- (xi) Enucleation of corneas has been permitted by a trained technician.
- (xii) Act has made provision of greater caution in case of minors and foreign nationals and prohibition of organ donation from mentally challenged persons

Source of Organs for Transplant:

Source may be, Living or Deceased Donor:

Living Donor Transplant:

- Near Relative donor (mother, father, son, daughter, brother, sister, spouse)

- Other than near relative donor: Such a donor can donate only for the reasons of affection and attachment or for any other special reason and that too with the approval of the authorisation committee.
- By SWAPPING of near relative donors between pairs of unmatched donor and recipient

Deceased donor Transplant:

- **Donor after Brain stem death:** Organ Donation is practically possible in the situation of Brain stem death e.g. a victim of road traffic accident etc. where the brain stem is dead and person cannot breathe on his own but can be maintained through ventilator, oxygen, fluids etc. to keep the heart and other organs working and functional.
- **Donor after cardiac death(DCD):** Practically in Indian scenario only tissues are donated after cardiac death. But few centres like PGI Chandigarh has started DCD

Issues and Challenges

- ❖ High Burden of Organ failure cases
- ❖ Poor availability of Donors (Demand Vs. Supply gap)
- ❖ Lack of Awareness of concept of Brain Stem Death
- ❖ Poor Brain Stem Death Certification by Hospitals
- ❖ Availability of Infrastructure esp in Government sector
- ❖ Awareness and attitude towards organ donation
- ❖ Organ Trading
- ❖ Reluctance of many States to adopt THOA amendment Act 2011
- ❖ Transportation of Donated Organs (especially inter State)
- ❖ Allocation of deceased donor organs especially heart to foreigners
- ❖ Gaps in Data Reporting especially online entry by hospitals/ States in National Registry
- ❖ Functional Organized networking systems
- ❖ High Cost (especially for uninsured and poor)
- ❖ Maintenance of Standards in Transplantation

Initiative taken

National Organ Transplant Programme

- Government of India is implementing National Organ Transplant Programme for carrying out the activities as per amendment Act, training of manpower and promotion of organ donation from deceased persons.
- Hon'ble Prime Minister has highlighted the importance of organ donation in the Mann Ki Baat Programme broadcast in October and November 2015. This has given impetus to the Organ Donation in the country.
- National Organ Transplant Programme aims to improve access to the life transforming transplantation for needy citizens of our country by promoting deceased organ donation.

Objectives of National Organ Transplant Programme:

- To bridge the gap between demand and supply of organs and/or tissues for transplantation.
- To improve access to the transplantation for needy citizens by promoting deceased organ/tissue donation.
- To organize an efficient mechanism for organ and tissue procurement/retrieval from deceased donors and its distribution for transplantation.
- To establish new organ and tissue retrieval and transplant facilities and strengthen existing facilities.
- To train required manpower.
- To monitor organ and tissue transplant services and bring about policy and program corrections/ changes whenever needed.

Situation before NOTP

- Till now who is handling transplant in States?: Health Department
- Registering / Appropriate Authority (Secretary/DHS)
- No dedicated staff
- No awareness/surveillance/no systems for organ donation /transplant/registry/training

Solution provided through NOTP:

- Dedicated Institutional mechanisms
- SOTTO is an institutional mechanism to support States
- ROTTO are identified institutions which are champions field in to take care of a group of states
- NOTTO at apex level

Components of National Organ Transplant Programme (2017-20)

1. National THOTA and NOTP Cell

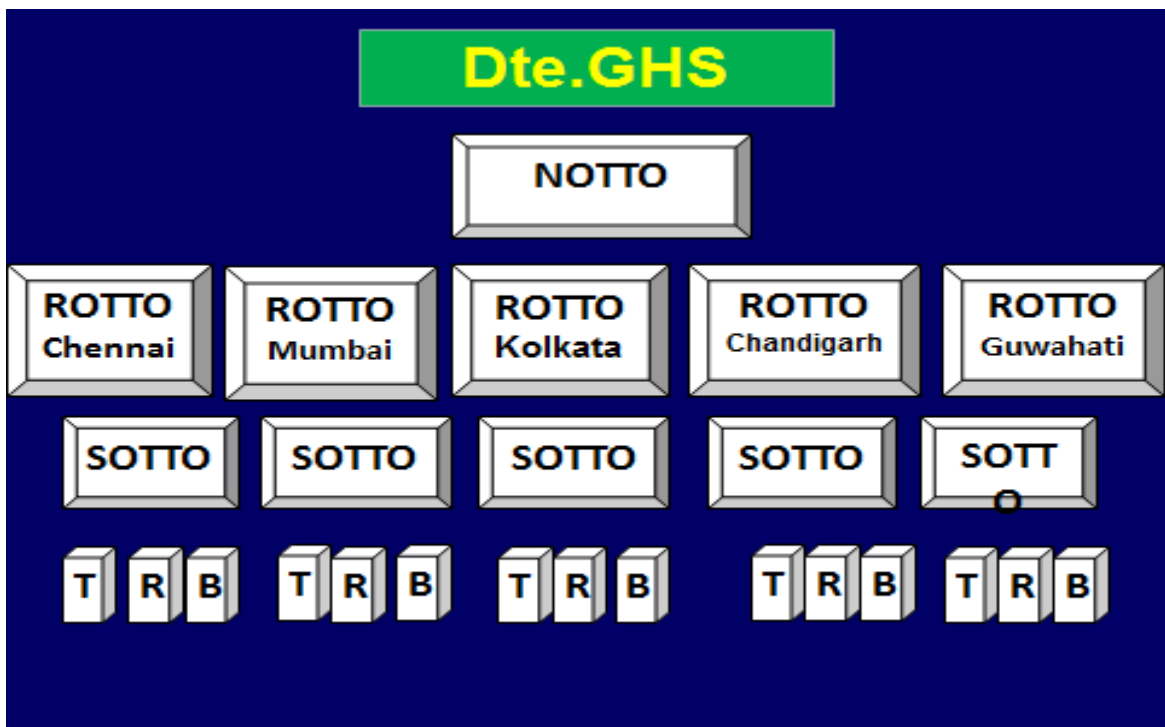
Located in MG section, DteGHS Headquarter, Nirman Bhawan, New Delhi.

The functions are

1. Registration and renewal of organ & tissue transplant centers, eye bank in all Union territories except Delhi as part of work of DGHS being the appropriate authority for all Union territories except Delhi. Organizing inspections for the same.
2. Monitoring of the transplant centers and Tissue Banks through regular data collection and inspections.
3. Cases of appeal against the decisions of authorization committee or appropriate authorities under THOTA 1994 of Union territory of Delhi and other UTs
4. RTI and Court matters etc. related to THOTA and NOTP
5. All technical, administrative and financial matters of NOTP including NOTTO/ROTTOS/SOTTOS
6. Implementation and Monitoring of various components of National Organ Transplant Programme through respective State Governments and NOTTO/ROTTOS/SOTTOS, as applicable
7. Facilitating Organizing Indian Organ Donation Day annually
8. Consultancy on all transplant law and program related matters.

2. Networking: through creating institutional mechanisms

Through National Human Organs and Tissues Removal and Storage Network



NOTTO: National Organ and Tissue Transplant Organization

ROTTTO: Regional Organ and Tissue Transplant Organization

SOTTO: State Organ and Tissue Transplant Organization

T: Transplant Centre

R: Retrieval Centre

B: Biomaterial Centre (Tissue Bank)

I. National Organ & Tissue Transplant Organization (NOTTO):

An apex level organization, National Organ and Tissue Transplant Organization (NOTTO) having components of National networking, National Registry, National level Biomaterial centre and facility of cadaver organ and tissue retrieval Operation theatre has been established in the Safdarjung Hospital Campus, New Delhi under Directorate General of Health Services.

Broad Functions of NOTTO are

- Drafting Policy guidelines and protocols
- Web based Networking
- Maintaining National Registry
- Advocacy and awareness
- Co-ordination when organ is allocated outside region and to PIO/Foreigner and in Delhi
- Research
- Dissemination of information
- Coordinate and Organize trainings
- Consultancy support on all aspects of donation and transplantation
- National Biomaterial centre
- SOTTO for Delhi

Detail of Achievements of NOTTO and Activities being undertaken is as under.

1) Website

A dedicated website (www.notto.gov.in) has been launched for providing information on organ and tissue donation, organ and tissue pledging, networking of hospitals and establishing National registry of organ and tissue transplantation and Donation. The work is being done through NIC.

2) Helpline/Call centre

A 24x7 days call centre has been made operational with provision of a toll free helpline (No. 1800114770) since 1-7-2015.

3) Registration of Hospitals with NOTTO Website

Online facility for registration of hospitals for networking and data collection for National registry has been made functional.

4) National Registry:

NOTTR was launched on 6th Indian Organ Donation Day celebration on 27th November 2015. It has three components:

Pledge Registry: Online and offline provision to register your wish for organ donation is already in place

Waiting List Registry: Patients waiting for transplant can register themselves through hospitals in the National Waiting list registry

Transplant Registry: Provision of entering the data of transplant cases and follow up is already in place. Hospital can enter the data.

5) Pledging for Donation

Facility for Offline and Online pledging for donation of organ and/or tissue after death has been made functional.

6) Allocation Policy:

Polices for allocation of Vital organs Kidney, Liver, Heart & Lung and Cornea have been approved by DGHS. Approved Organ Policies are available on NOTTO website.

7) Standard Operative Procedures (SOPs)

SOPs for retrieval of various organs and management of Donors have been drafted and uploaded on NOTTO website

8) Operational Guidelines of National Organ and Tissue Transplant Programme for its implementation was also released on 27th March 2015 during NATIONAL ADVOCACY CONFERENCE.

9) Registration of Tissue Bank or Bio Material Centre: Tissue banks for Cornea, Skin, & Heart Valve have been registered and functional.

- 10) **Apex Technical committees** are functional and developed Broad Guiding Principle for the Allocation of organs for have been constituted for development of organ specific guidelines.
- 11) **Coordination & Collaboration with Other Organization:** Yes bank, Red Cross Society, ORGAN India to promote deceased organ donation and various other small NGOs.
- 12) **Coordination for Allocation of Organs:** when organs are to be allocated nationally and for foreigner cases and for Delhi NCR
- 13) **Capacity Building:**
Various Training programs are organized either directly by NOTTO or under its aegis.
- 14) **IEC AND AWARENESS ACTIVITIES** are organized including annual Indian organ donation day.
- 15) **National Transplant Specific Guidance during Covid 19 situation** has been framed.

II. ROTTO: Regional Organ and Tissue Transplant Organization

Name of ROTTO	States covered
Seth GS medical college and KEM Hospital, Mumbai (Maharashtra)	Maharashtra, Gujarat, Goa, UTs of DNH, Daman, Diu, M.P., Chhattisgarh
Govt. Multispecialty Hospital, Omnadurar, Chennai (Tamil Nadu)	TN, Kerala, Telangana, Seem Andhra, Karnataka, Pondicherry, A & N Islands, Lakshadweep
Institute of PG Medical Education and Research, Kolkata (West Bengal)	West Bengal, Jharkhand, Sikkim, Bihar and Orissa
PGIMER Chandigarh(UT of Chandigarh)	Punjab, Haryana, HP, J &K , Chandigarh , Rajasthan, Uttar Pradesh and Uttarakhand
Guwahati Medical College (Assam)	Assam, Meghalaya, Arunachal Pradesh, Manipur, Nagaland, Mizoram, Tripura.

Broad Functions of ROTTO are

- **Networking** including allocation, where SOTTOs not functional
- **Co-ordination when organ is allocated outside State**
- Collection of data and statistics from SOTTOs including **registry of the region**
- **Monitoring and surveillance**
- **Training** and workshops
- Developing IEC materials **as per regional need**
- **Intersectoral meetings, IEC and advocacy** for deceased organ donation in the region

- **Technical guidance and Support**
- Establishing and operationalizing **regional biomaterial centre**

It is envisaged to have a biomaterial centre at each ROTTO centre and till now funds have been given to Tamil Nadu for one State Biomaterial Centre.

Grant in Aid provided to each ROTTO

Financial Assistance of Rs. 81 lakh per year as Recurring grant and Rs. 68 lakh as Non-Recurring grant (Non- recurring was released already in 2014-2017 tom ROTTOs)

III. SOTTO: State Organ and Tissue Transplant Organization

It is envisaged to establish one SOTTO each State. So far following 12 SOTTOs have been sanctioned:

- 1) Government Medical College, Thiruvananthapuram, Kerala
- 2) Sawai Man Singh Medical College (SMS), Jaipur, Rajasthan
- 3) Mahatma Gandhi Medical College (MGMC), Indore, Madhya Pradesh
- 4) Goa Medical College (GMC), Bambolim, Goa
- 5) Government Medical College (GMC), Jammu, J & K
- 6) Pandit Bhagwat Dayal Sharma PGIMS, Rohtak, Haryana
- 7) Sriram Chand Bhanj Medical College (SCB), Cuttack, Odisha
- 8) Institute of Kidney Diseases and Research Centre (IKDRC), Ahmedabad, Gujarat
- 9) Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, UP
- 10) Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar
- 11) Government Medical College, Patiala, Punjab
- 12) RIMS : Rajendra Institute of Medical Sciences, Ranchi

5 ROTTOs are also SOTTOs for the States where they are located

NOTTO is SOTTO for Delhi

Broad Functions of SOTTO are

- 1) Coordinate for Implementation all schemes under NOTP in consultation with State Government
- 2) Maintain State wise Waiting list of patients
- 3) Networking and State level registry
- 4) Co-ordination from organ and tissue procurement, matching, allocation, transportation, storage and transplantation
- 5) Coordinate for BSD certification and retrieval teams
- 6) Dissemination of information to hospitals, organizations & individuals
- 7) IEC Activities
- 8) Training and CMEs with in the State

Grant in Aid provided to each SOTTO

Financial Assistance of Rs. 33 lakh per year as Recurring grant and Rs. 38 lakh as Non-Recurring grant.

3. Online system of networking and Registry

- Software developed and under further updation
- Website www.notto.gov.in
- Aim is to have a Computerised Impartial, and transparent organ allocation system
- networking & sharing as per allocation policy

4. Biomaterial Centres: National Biomaterial centre is now registered. One has been sanctioned for Tamilnadu. Other regional centres are also planned to have biomaterial centre

There is provision of Non recurring financial grant @ 100 lakh per regional / state biomaterial centre (For: Refurbishment of space, furniture, equipment) for upto 10 centres.

5. Developing New / Strengthening Existing Retrieval and/or Transplant Centres: Financial support in the form of one time grant

- @ Rs. 50 lakh per new retrieval centre
- @Rs. 100 lakh per new transplant centre
- @Rs. 50 lakh for up gradation of existing retrieval/transplant unit

6. Training and Capacity Building

There is provision of training of various cadres and stakeholders related to Transplant including Transplant Coordinators.

7. Financial Support for immune- suppressants, maintenance of deceased donor:

There is provision for financial assistance to BPL transplant recipients, who have gone under transplantation in Govt. Hospitals at the rate of Rs.10000/- per month for immunosuppressant therapy.

8. Financial support for maintenance of deceased donor to retrieval (Non-Transplant Organ Retrieval Centres) /Transplant Centres @ Rs 1 lakh per donation for maintenance of Cadavers and promoting Deceased Organ Donation with the condition that at least one organ is donated to a Government hospital for up to 50 donations per year.

9. Financial Support for hiring of Transplant Coordinators for the purpose of Coordination with Govt. Medical Colleges, Good Performing Private institutions and trauma Centers

There is provision of **Financial Support for hiring of Transplant Coordinators** as per norms given below:

- ❖ **Government Medical Colleges** (2 Transplant Coordinators per medical college),
- ❖ **Trauma Centers** (1 Transplant Coordinator)
- ❖ **Good performing private medical Institutions** (1 Transplant Coordinator)

10. Information, Education and Communication (IEC) activities:

The programme has main component of Information, Education and Communication (IEC) activities to promote organ donation from deceased donors. The focus is to dispel myths and misconceptions related to Organ Donation. Organ is a National Resource and not even one should be wasted if at all possible.

Various Activities include

- Indian Organ Donation Day
- Poster competitions
- Broadcasting Audio messages
- Video Spot: Telecast of video Spot.
- Information Kiosk during Trade Fair
- Walkathon/Organthon
- Newspaper Advertisement
- Various Awareness Talks during BSF function, CISF, Schools, Delhi Medical Association, IMA, Corporates offices, various Ministries
- Sending SMS to Mobiles
- Etc.

For further information please visit website www.notto.gov.in