

### HOSPITAL AND RESEARCH INSTITUTE MADURAI - 625009

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# National/ State level policies on Organ Transplantation as adopted by the Institution

#### Index

SI. No.	Particulars	Page No.
1.	Summary on	2
2.	National/State level policies on organ	3
	transplantation as adopted by the Institution	
3.	Highlights of National Organ and tissue	4 - 7
	transplantation programme & Operational	a a
	guidelines for its implementation	,

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#### Situation of organ shortage in India;

The shortage of organs is virtually a universal problem but Asia lags behind much of the rest of the world. India lags far behind other countries even in Asia. It is not that there aren't enough organs to transplant. Nearly every person who dies naturally, or in an accident, is a potential donor. Even then, innumerable patients cannot find a donor.

There is a wide gap between patients who need transplants and the organs that are available in India. An estimated around 1.8 lakh persons suffer from renal failure every year, however the number of renal transplants done is around 6000 only. An estimated 2 lac patients die of liver failure or liver cancer annually in India, about 10-15% of which can be saved with a timely liver transplant. Hence about 25-30 thousand liver transplants are needed annually in India but only about one thousand five hundred are being performed. Similarly, about 50000 persons suffer from Heart failures annually but only about 10 to 15 heart transplants are performed every year in India. In case of Cornea, about 25000 transplants are done every year against a requirement of 1 lakh.

## National / State level policies on organ transplantation as adopted by institution

Organ donation laws at the state and federal levels exist for two primary purposes. The first purpose of organ donation laws is to help ensure a safe and fair organ donation collection and distribution practice. The second type of organ donation laws have been enacted to widen the pool of potential donors in an effort to increase the number of organs available for transplant.

- Transplantation of Human Organs and Tissues Rules, 2014
- THOA amendment 2011
- Transplantation Of Human Organs (Amendment)Rules,2008
- THO Rules, 1995 (Original Rules)
- THOA 1994

THOTA 1994 with 2011 amendment and 2014 rules

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#### **Highlights of Transplantation program**

Transplantation of Human Organs Act (THOA) 1994 was enacted to provide a system of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs. THOA is now adopted by all States except Andhra and J&K, who have their own similar laws. Under THOA, source of the organ may be:

- Near Relative donor (mother, father, son, daughter, brother, sister, spouse)
- Other than near relative donor: Such a donor can donate only out of affection and attachment or for any other special reason and that too with the approval of the authorisation committee.
- Deceased donor, especially after 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. Other type of deceased donor could be donor after cardiac death.

Brain Stem death is recognised as a legal death in India under the Transplantation of Human Organs Act, like many other countries, which has revolutionised 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.

Despite a facilitatory law, organ donation from deceased persons continues to be very poor. In India there is a need to promote deceased organ donation as donation from living persons cannot take care of the organ requirement of the country. Also there is risk to the living donor and proper follow up of donor is also required. There is also an element of commercial transaction associated with living organ donation, which is violation of Law. In such a situation of organ shortage, rich can exploit the poor by indulging in organ trading.

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Government of India initiated the process of amending and reforming the THOA 1994 and consequently, the **Transplantation of Human Organs** (Amendment) Act 2011 was enacted. Some of the 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 simplifiedwherever 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

In pursuance to the amendment Act, Transplantation of Human Organs and Tissues Rules 2014 have been notified on 27-3-2014

Directorate General of Health Services, Government of India is implementing National Organ Transplant Programme for carrying out the activities as per amendment Act, training of manpower and promotion organ donation from deceased persons.

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National Organ Transplant Programme with a budget of Rs. 149.5 Crore for 12th Five-year Plan aims to improve access to the life transforming transplantation for needy citizens of our country by promoting deceased organ donation.

#### Issues and Challenges

- High Burden (Demand Versus Supply gap)
- Poor Infrastructure especially in Govt. sector hospitals
- Lack of Awareness of concept of Brain Stem Death among stakeholders
- Poor rate of Brain Stem Death Certification by Hospitals
- Poor Awareness and attitude towards organ donation--- Poor Deceased Organ donation rate
   Lack of Organised systems for organ procurement from deceased donor
- 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

#### **Objectives of National Organ Transplant Programme:**

- To organise a system of organ and Tissue procurement & distribution for transplantation.
- To promote deceased organ and Tissue donation.
- To train required manpower.
- To protect vulnerable poor from organ trafficking.
- To monitor organ and tissue transplant services and bring about policy and programme corrections/ changes whenever needed.

#### **NOTTO: National Organ and Tissue Transplant Organisation**

National Network division of NOTTO would function as apex centre for all India activities of coordination and networking for procurement and distribution of organs and tissues and registry of Organs and Tissues Donation and Transplantation in country. The following activities would be undertaken to facilitate Organ Transplantation in safest way in shortest possible time and to collect data and develop and publish National registry.

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#### At National Level: >

- 1. Lay down policy guidelines and protocols for various functions.
- 2. Network with similar regional and state level organizations.
- 3. All registry data from States and regions would be compiled and published.
- 4. Creating awareness, promotion of deceased organ donation and transplantation activities.
- 5. Co-ordination from procurement of organs and tissues to transplantation when organ is allocated outside region.
- 6. Dissemination of information to all concerned organizations, hospitals and individuals.
- 7. Monitoring of transplantation activities in the regions and States and maintaining data-bank in this regard.
- 8. To assist the states in data management, organ transplant surveillance & Organ transplant and Organ Donor registry.
- 9. Consultancy support on the legal and non-legal aspects of donation and transplantation
- 10. Coordinate and Organise trainings for various cadre of workers

#### For Delhi and NCR

- 1. Maintaining the waiting list of terminally ill patients requiring transplants
- 2. Networking with transplant centres, retrieval centres and tissue Banks
- 3. Co-ordination for all activities required for procurement of organs and tissues including medico legal aspects.
- 4. NOTTO will assign the Retrieval Team for Organ retrieval and make Transport Arrangement for transporting the organs to the allocated locations.
- 5. NOTTO will maintain the waitlist of patients. needing transplantation in terms of the following: -
- Hospital wise
- Organ wise
- Blood group wise
- Age of the patient
- Urgency (on ventilator, can wait etc.)
- Seniority in the waitlist (First in First Out)

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- 6. Matching of recipients with donors.
- 7. Allocation, transportation, storage and Distribution of organs and tissues within Delhi and National Capital Territory region.
- 8. Post-transplant patients & living donor follow-up for assessment of graft rejection, survival rates etc.
- 9. Awareness, Advocacy and training workshops and other activities for promotion of organ donation

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