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DRAFT

NATIONAL ACADEMY OF MEDICAL SCIENCES (INDIA)

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

REPORT OF TASK FORCE

ON

"Organ" Donation and Transplantation

2022

NAMS – DGHS – Govt. of India - Task Force Series No. 02

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Contents

Acknowledgement

The contributions made by various domain experts in the field of “Organ” Donation and Transplantation, NOTTO, Ministry of Health & Family Welfare GOI, and the support provided by National Academy of Medical Sciences (India) and MOHAN Foundation are acknowledged.

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Preface

Organ transplantation is known to save lives. There is a huge unmet need for organs and there is widening gap between the requirement of Organs and transplant in patients with End Stage Organ Failure. While live donor Organ donation is well established in India, but despite an enabling law, deceased Organ donation has not picked up across the country except for States in South and West because of the proactive action taken by individual State authorities along with non-government bodies. While there is a wide publicity on Organ donations, the awareness is far from optimum. In fact, reluctance of clinicians to identify and certify Brain Stem Death (BSD) and counselling the families for organ donation has been a major factor that has hampered the growth of deceased Organ donation in our country. Hence there is **an urgent need to take an audit of all deaths including brain stem deaths that occur in the Hospitals**. It is imperative to highlight that with advancement in medical skills and technology, patients in need of Organ transplant should be given another chance in life to live and contribute to the society. We must recognize that **Organs donated by families are a National Asset.**

List of Abbreviations

THOTA: Transplantation of Human Organs and Tissues Act, 1994

NOTP: National Organ Transplant Program

NOTTO: National Organ & Tissue Transplant Organization

ROTTO: Regional Organ & Tissue Transplant Organization

SOTTO: State Organ & Tissue Transplant Organization

DDOT: Deceased Donor Organ Donation & Transplantation

WHO-GODT: WHO Global Observatory on Donation and Transplantation

TC: Transplant Coordinator

NTORC: Non-Transplant Organ Retrieval Centers

BSD: Brain Stem Death

MLC: Medico Legal Case

AA: Appropriate Authority

IKDRC-ITS: Smt. G.R. Doshi and Smt. K.M. Mehta Institute of Kidney Diseases and Research Center and Dr. H.L. Trivedi Institute of Transplantation Sciences (IKDRC-ITS), Ahmedabad

PMJAY: Pradhan Mantri Jan Arogya Yojana

CSR: Corporate Social Responsibility

INI: Institute of National Importance

UNOS: The United Network for Organ Sharing

ZTCC: Zonal Transplant Coordination Centre

DCD: donation after circulatory death

ILBS: Institute of Liver and Biliary Sciences, New Delhi

PGIMER: Postgraduate Institute of Medical Education & Research, Chandigarh

GOI: Government of India

Operational Definition of Terms used in the Report

Brain Stem Death: Transplantation of Human Organs and Tissues Act (THOTA) defines Brain Stem Death (BSD) as "the stage at which all functions of the brain stem have permanently and irreversibly ceased" and is so certified under Section 3 (6) of the Act. The Brain Stem Death can be certified only by a board of Medical experts nominated from the panel of names approved by the Appropriate Authority (AA).

Circulatory Death or Cardiac Death: Irreversible cessation of circulatory and respiratory functions.

Deceased Donation: Organ donation by an individual who has been certified as deceased according to either brain stem or Cardiac Death.

Living Donation: Organ donation by a living donor generally limited to renal and hepatic donation

Organ Transplantation: This involves a surgical procedure to implant Organs or composite tissue from the donor into a recipient. Not all donations result in actual transplantation.

Organ Procurement Process: This involves:

A. Identification of potential BSD patient in ICU, family counseling about criticality of clinical situation by treating clinicians and Intensivist, followed by confirmation of BSD by expert clinical team as per the THOTA, discussion with family about Organ donation by clinicians and transplant coordinator and seeking consent for Organ donation from family of a deceased individual.
B. Communication with local Organ Distribution Organization in the state for Organ Allocation to recipients as per the Organ specific allocation guidelines.

Organ Retrieval, Preservation and Transportation: This involves surgical procedure of retrieving various Organs, their cold preservation and transportation to transplant centers.

Executive Summary

To promote Deceased Organ Donation Government of India enacted **Transplantation of Human Organs and Tissues Act, 1994 (THOTA**) for regulating **Organ Retrieval, Storage and Transplantation** for therapeutic purposes and prevent commercial dealing in human Organs and tissues. Since 2011, Government of India also implemented **National Organ Transplant Program (NOTP)** through States/Union Territories (UTs), to provide an Organizational and financial framework for promoting Deceased Organ and Tissue Donation and Transplantation in the country.

However, there is a huge shortage of availability of Organs as compared to the number of patients who require Organ transplantation, resulting in a wide gap between demand and supply.

National Academy of Medical Sciences (NAMS) India formed a **Task Force** to identify the current status of Organ Donation and Transplantation, the exact deficiencies in the system and to recommend ways to improve Organ Donation and Transplantation in India.

The **Task Force** formed a consensus amongst the members based on their expertise, experience, and extensive review of up-to-date published literature from India and abroad and made following key observations & recommendations:

- **The Committee felt that Organs donated are a National Asset and Organ Transplantation should be a National Priority.**
- The Ministry of Health and Family Welfare assessed that there is an estimated need of 175000 kidney and 50000 liver heart, lung and 2500 pancreas transplants in India per year. Organ donation Rate in India has remained stable to less than 1 per million population (PMP) from 2013 till date. To achieve the self-sufficiency in organ donation the estimated rate would be around 124 PMP.
- The committee noted that the Southern and Western States in India have been doing better in the field of Deceased Organ Donation and Task Force suggested a

need to duplicate their best practices to increase momentum in other parts of the country.

- They also noticed lack of information and training of **Brain Stem Death Identification, Certification and Maintenance of Organ Donor** coupled with shortage of manpower, suboptimal utilization, and lack of infrastructure in Government as well as Private hospitals. Hence, dedicated Department of Intensive Care Medicine, Non-Transplant Organ Retrieval Centers (NTORC) and Organ Transplantation should be created in all Medical colleges and major Government Hospitals.
- The committee felt that all Deaths in the hospital's ICU should be identified and communicated to the concerned SOTTOs or Health authority. **The declaration of 'Brain Stem Death' should be made mandatory for all Government &Private hospitals, as provided in the THOTA Rules.**
- Hospitals with more than 200 beds should be involved in Organ Donation.
- Widespread recognition of NTORC should be implemented using Hub and Spoke model and simplifying requirements in Form 13 of THOTA Rules of 2014.
- Dedicated infrastructure and Organ transplant department/Unit manned by trained dedicated faculty must be created in at least one Public Sector Hospital in each state for Organ Transplantation on lines of IKDRC-ITS), ILBS, New Delhi and PGIMER, Chandigarh, which can function as Organ Retrieval centres in the first phase. **Multi Organ Retrieval** teams should be formed in all major hospitals. Infact, all INIs should be made Organ Transplantation Centres and respective Departments supporting them should be made, e.g. Department/Division of Hepatology, Division of Pancreatology.
- To maximise the utilisation of deceased Organs particularly **Extended Criteria of Organs** should be adopted and provision should be made to do **Machine Perfusion of Organs.** For that a clause should be added in THOTA Rules 2014 or a circular be issued by GoI.
- **Ancillary test**s for BSD certification should be permitted when Apnoea test cannot be performed.
- A **Standard Operating Procedure (SOP**) to be prepared for Organ donation after DCD.

- Creation of Independent State Appropriate Authority to exclusively look after issues related with Organ Transplantation.
- Advisory **committee** should be formed to promote **Service, Education and Research** in organ transplantation.
- Organ Donation Pledges have significantly increased in the country but awareness and ease of doing should be publicised. Infact, all driving licences should include provision for pledging of Organs.
- **NOTTO should be made administratively and financially robust.**
- There should be **more manpower and budget in NOTTO office** for service, education and research in Organ donation and Transplantation.
- Appointment of Director of NOTTO/ROTTO/SOTTO by central agency and lateral Entry to be permitted for these appointments with no age bar.
- Regular Review of performance of ROTTO/SOTTO by an independent Audit committee of NOTTO.
- Linking of all the Hospitals with SOTTO to ROTTO to NOTTO through ONE Digital Platform with daily updation of the information.
- Revision of General and Organ specific Listing and Allocation policies.
- Rules for Organ donation from Deceased Donor and Living donors to be separated.
- Rules for Tissue donations to be separate from Deceased Organ donations.
- **Research on Organ Preservation and Organ Resuscitation** using modern technology should be permitted using discarded/unutilised deceased donor Organs and for that make amendment in the Law /Rules.
- There is need of more guidelines and consensus statement from NOTTO with inputs from transplant professionals and societies such as Indian society of Organ Transplantation (ISOT) on common clinical practice issues.
- Reporting of long-term **Transplant Recipient and Donor** outcome to NOTTO should be mandated.
- **Legal hurdles** like **hierarchy of consent**, **Post-mortem permissions** throughout the day and **SOPs for Donation in Medico-legal cases** should be clearly defined.
- **PMJAY- Ayushman Bharat Scheme has included Kidney and Bone Marrow transplantation. There is a need to widen its ambit to include Heart, Lungs, Liver, Pancreas and other Organs and the amount should be increased.**

1. Introduction

Organ transplantation gives new lease of life to patient of End Stage Organ Failure. While in India, over the years living donors had been the primary source of kidneys for transplantation, last decade and a half has seen live donor being main source of livers also. However, there is need to reverse this trend.

Almost 160,000 fatal road traffic accidental (RTA) deaths happen in India and almost 60% have associated head injury (almost 90 per million possible brain deaths from RTA). Similarly, CVA is another common cause of BSD in India (prevalence rate of CVA ranging from 44.54 to 150 per 100,000 population) and 30 days case fatality rate ranging from 18% to 46.3% (1) and these are also part of Deceased donor pool in our country. A large number of Organs from these patients could be harvested for transplantation.

The number of persons donating Organs after death in India, is less than one per million population which is almost similar to some Asian countries like Japan, but far less than most Western countries. [In 2020, United States and Spain had the highest rates of deceased Organ donors select OECD countries with almost 38 people per million population, whereas Greece (4.6), Russia (3.9) and Turkey (3) had least donation rate].

Surprisingly, according to an **Ipsos survey** in 2018 about people's willingness to donate Organs after death Colombia and India with 75 and 74 percent respectively had highest percent of willing people to donate Organs after death, ahead of Spain (72%), UK (67%) and Germany (53%). This may be due to the campaigns undertaken by nongovernment organisations in the country. Mass media, religious and political leaders may be involved to maximize awareness about Organ donation. Thirty two percent of the study participants believe that there is a danger that donated Organs could be misused, abused or misappropriated (2).

Organ transplantation represents the final choice for life as without a transplant the patient will die. Thus, Organ transplantation is a field of medicine with extremely huge stakes. In this huge stake area, transplant community should be constantly looking at mechanisms to

boost the Organ supply. This also includes utilising maximising the utilisation of brain deaths, diminishing the missed opportunities for donation, and also considering expanded Criteria of Donor Organ.

Barriers to Donation: While the need for Organ donors is high in the Indian population, the actual numbers of donors remain low to help the numbers of recipients on the wait list. Reluctance to donate Organs is not only within Indian borders, but also extends to Indian population in UK & Canada (3).

Societal Issues: In certain regions of the country there is less reluctance when it comes to donation in comparison to other regions. A study in north India found that found that majority of individuals who were suffering from renal failure and on dialysis were unlikely to be an Organ donor since their family had not been initiated for any conversation on Organ donation. Such conversations play an important role in decision making during consent. Many have been unaware of how to register, which means campaigns for Organ donation registration should be improved. Fear and mistrust also were important possibly due to news items appearing of illegal Organ donation and transplant practices. Body disfigurement was least reason for Organ donation. Though no religion is against Organ donation, many donors use this as a reason for not giving consent. It was also found that nuclear families agreed more rapidly for Organ donation (4). In a survey from South India involving 300 participants to a questionnaire on Organ donation, less than half of the study participants were knowledgeable on the definition of brain death and existence of organ donation law. Although they were in favour of organ donationn but there were still some doubts related to family support (5).

Hospital Issues: A recently published study showed a lack of knowledge on clinical criteria for brain death & legal issues pre intervention which improved post intervention, after they participated in an interactive educational module. This intervention significantly improved the tendency of doctors & nurses to promote Organ donation, for pledging their own Organs and for counseling of patients/attendants on this cause (6).

There is no magic bullet to increase the Organ donation rates. Addressing donor shortages require a multipronged strategy considering barriers to Organ donation as they manifest across a society.

Spain's achievements of a high Organ Donation rate are attributed to its systems in place and wide Government support. It has a vast transplant coordination network of doctors and nurses specially trained on reporting and approaching family members for Organ donation. They also stress on education/health care infrastructure & human resource forming a multipronged approach that is tailored to develop transplant in that country (7).

As part of a national network, **National Organ & Tissue Transplant Organization (NOTTO)** and five regional Organizations namely **Regional Organ & Tissue Transplant Organization (ROTTO)** at Mumbai, Kolkata, Chandigarh, Chennai, and Guwahati to cover Western, Eastern, Northern, Southern and North-Eastern regions of country, respectively were established. It was envisaged to set up one **State Organ & Tissue Transplant Organization (SOTTO)** in each state with 14 SOTTOS already sanctioned so far. These Organizations integrate efforts of the States, institutions, healthcare professionals, non-government Organization and members of community.

The **National Organ Transplant Program** was first conceived in 2011-2012 and its detailed guidelines entitled "Highlights of National Organ and Tissue Transplant Programme & Operational Guidelines for its implementation" were first published in 2015. After the inception of the program, total numbers of Organ transplants in the country have increased from 4990 in the year 2013 to 12746 in the year 2019 and Organ donation Rate (no. of deceased donors per million populations) increased from 0.16 in the year 2012 to 0.65 in the year 2018.

2. Terms of Reference (TORs) for the Task Force

The Executive Council of the National Academy of Medical Sciences had assigned the following terms of reference for the Task Force on Organ Donation and Transplantation in April 2022.

a. To identify the current status of Organ Donation & Transplantation in India.
b. Identify the exact deficiencies.
c. To suggest & recommend ways of improvement in the area of Organ transplantation.

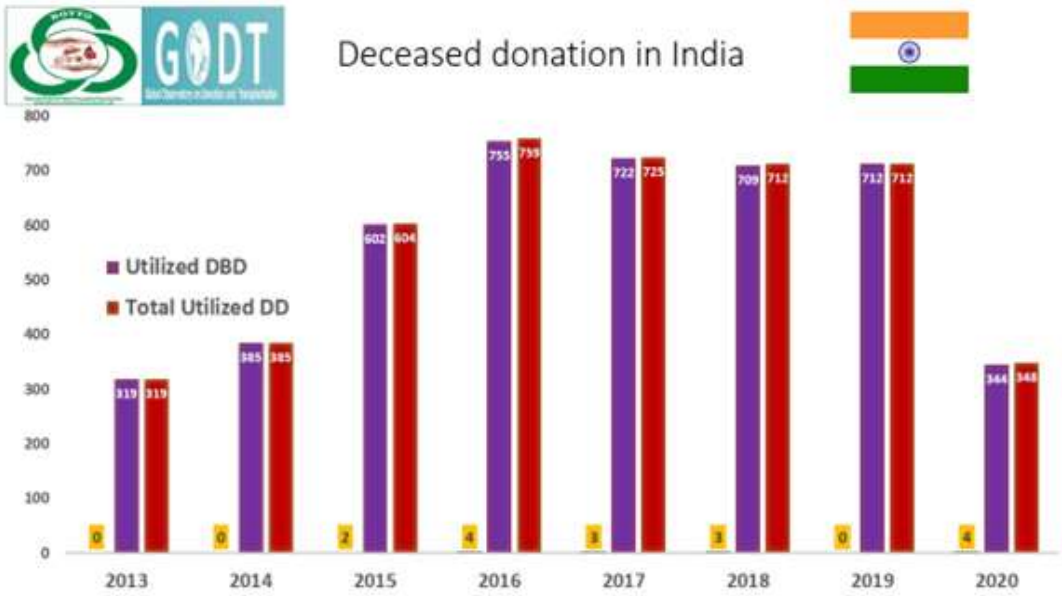
3. Methodology

The Task Force conducted meetings using virtual platform and Focused Group Discussions were held. In addition, the Chairperson co-opted expert members as and when required to facilitate the discussions. The relevant technical documents, published papers, reports, like NOTP Guidelines and various State Guidelines were used as background materials.

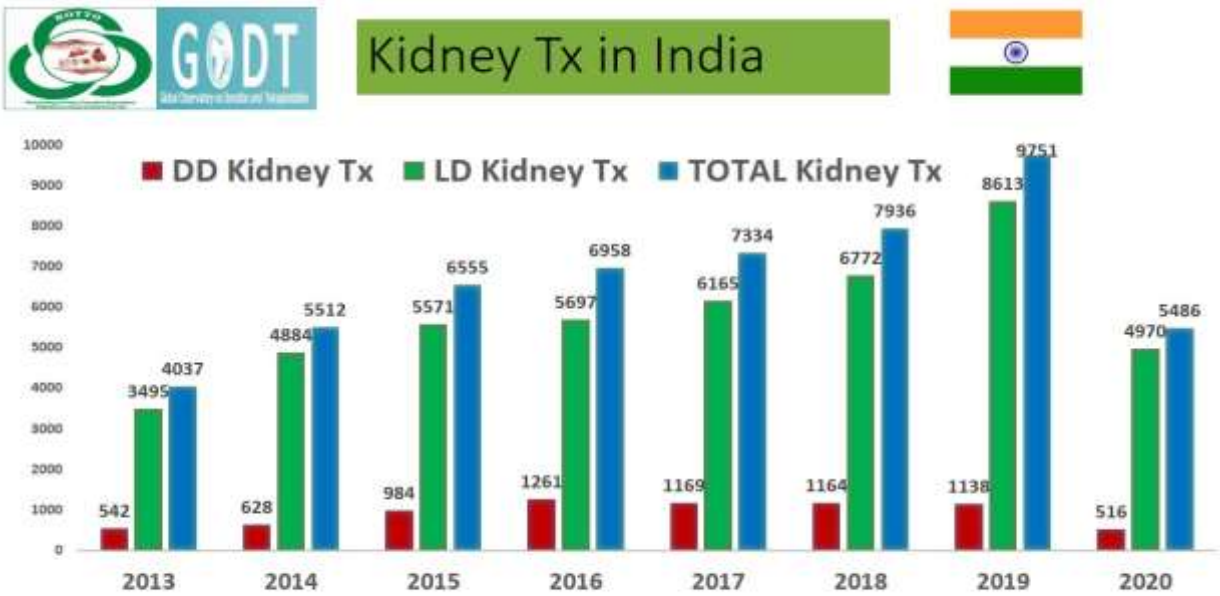
The key recommendations were arrived at by consensus of the members based on their expertise and experience.

4. Background: How Many Transplants are Conducted in India per million?

The current status of Organ Donation & Transplantation in India is shown below:



Transplantation. 2021 Aug 1;105(8):1625-1630. doi: 10.1097/TP.0000000000003677. PMID: 34291760.



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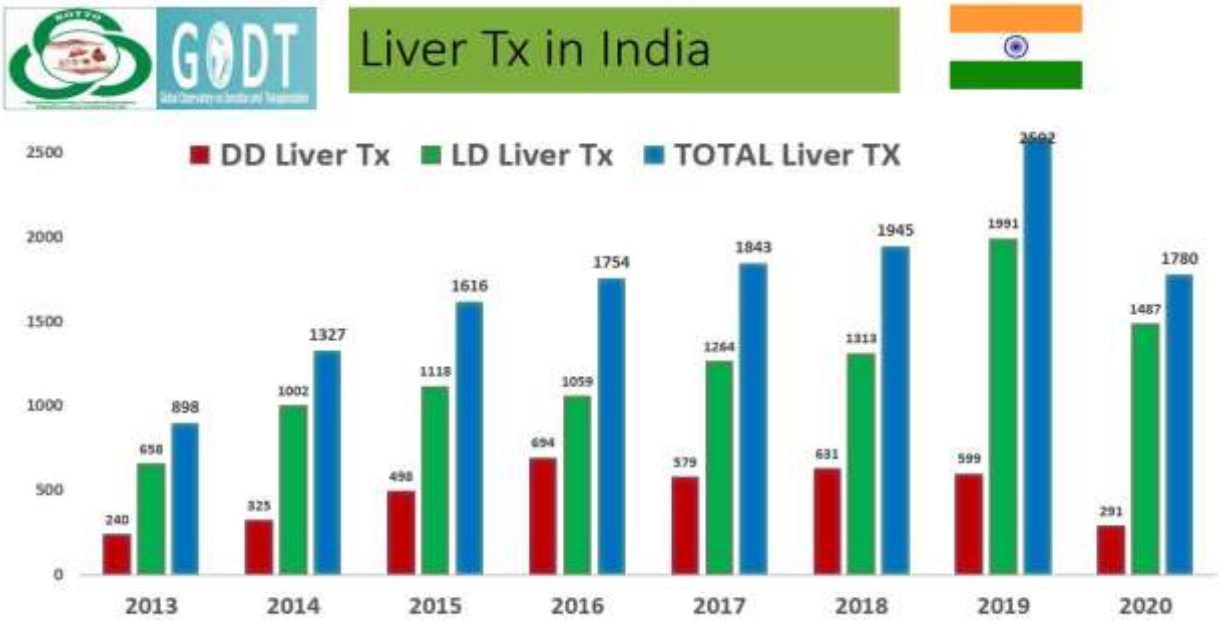
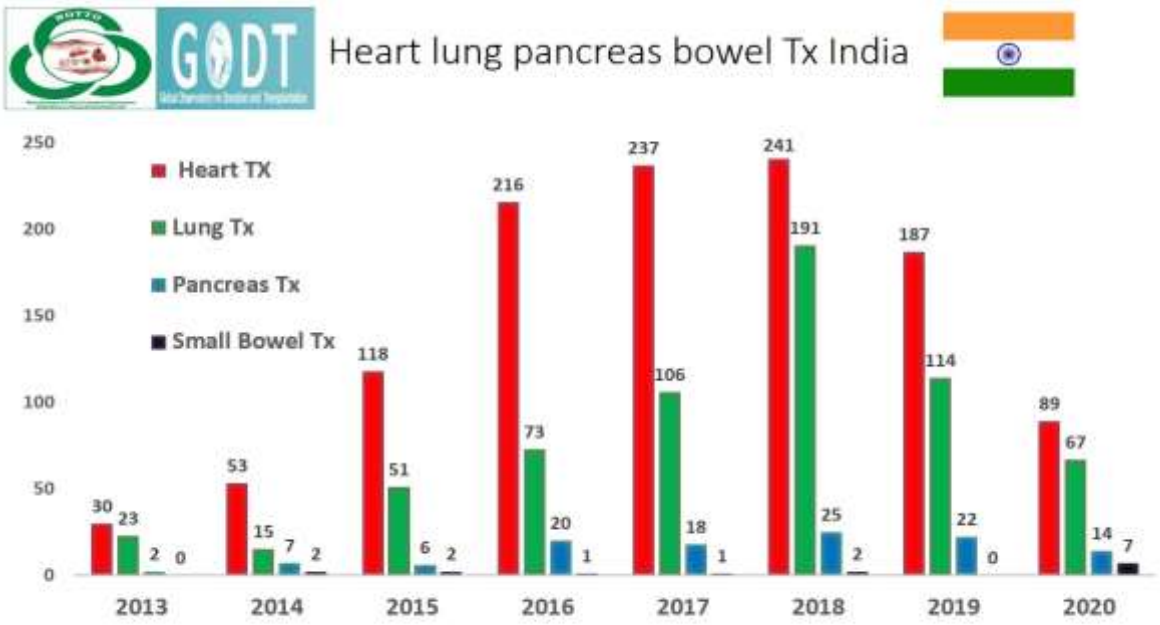
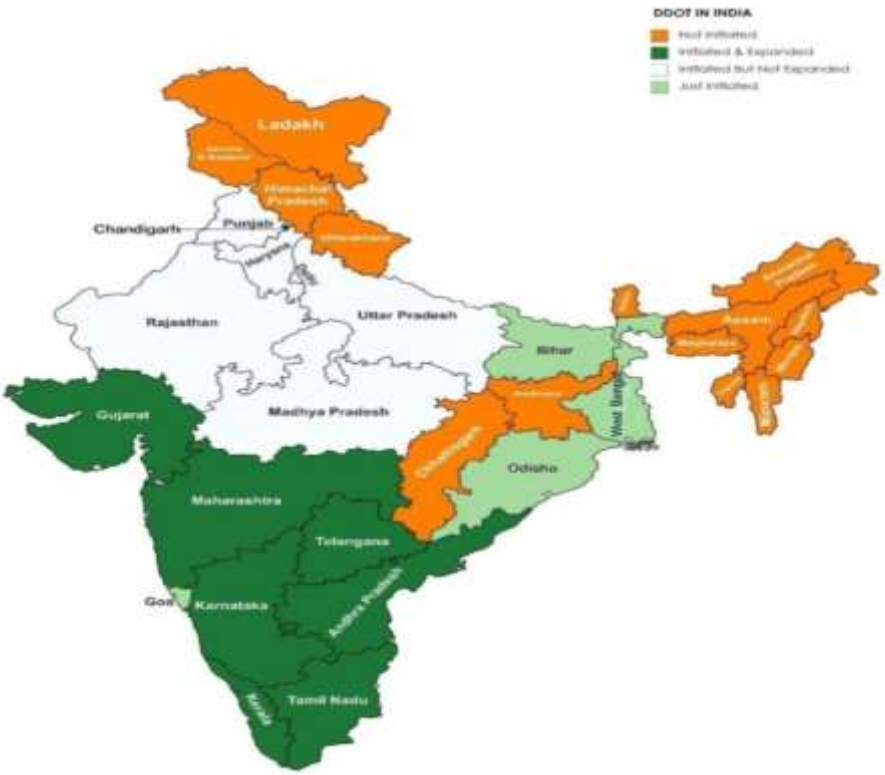


Transplantation. 2021 Aug 1;105(8):1625-1630. doi: 10.1097/TP.0000000000003677. PMID: 34291760.



Transplantation. 2021 Aug 1;105(8):1625-1630. doi: 10.1097/TP.0000000000003677. PMID: 34291760.

Organ Deceased Donor Organ Donation &Transplantation (DDOT)



States shown in green have well established Deceased Organ Donation programs (dark green states) to expand DDOT in emerging states (light green, orange states).

Total Transplants in India (2020)

Total Transplants in India (2021)

*2021 data is tentative (before submission to WHO-GODT 2021) as some of the states may make minor changes in their data.

Organ Donation Statistics

Organ Donation Statistics				
	2020		2021	
	Public	Private	Public	Private
Deceased	118	458	171	521
Living	492	4152	827	6029
Total	610	4610	998	6550

Data shared by NOTP

Note: Public facilities include Autonomous Hospitals and Private facilities include Trust Managed Hospitals.

*Data as per the survey conducted in January 2022 for 618 Hospitals that are the part of National Registry.

5. Observation

5.1. Current Situation in the Country

- About 160,000 deaths happen annually due to road traffic accidents in India –even if 10 percent (16000) of these are converted as Organ donors that will generate on an average 3 Organs per donor (as per ZTCC Mumbai data) resulting in 450, 00Organ transplantations (Livers, Kidneys, Hearts, Lungs, Pancreas and Small bowel).
- CVA is another common cause of BSD in India, and these could also add to Deceased donor pool in our country (ZTCC Mumbai donor data).
- Organ donation Rate (No. of deceased donors per million population) in the country increased from **0.27 in the year 2013** to **0.65 in 2018,** however it has dipped to **0.52 in 2019.** And are far less than compared to maximum of around 48 in Spain.
- There is estimated need of 175000 Kidney and 50000 each of Liver, Heart, Lung transplants in India.80% of Kidney and Liver transplant and 95% of Heart, Lung and Pancreas transplant services are in private hospitals where cost is prohibitive for common man with end stage Organ failure.
- Currently it is estimated that only 10% of kidney failure patients get some form of renal replacement therapy (dialysis or transplant) due to the problems of access to

tertiary care and financial constraints. However, the growth of healthcare, provision of dialysis facilities in all the 773 districts in the country by GoI, would mean a spurt in the patients requiring access to transplants.

- India is the **3rd country in the world** after USA and China, in terms of total number of transplants done in a year.
- Total number of transplants done in the country has **increased from 4990 in 2013 to 12666 in 2019** indicating marked improvement in infrastructure for undertaking transplants in the country and this was mostly due to the growth of private healthcare.
- **Organ transplantation in India to date relies predominantly (80.3%) on living donor procedures for kidney and liver transplantation**. Heart, lung, Pancreas, and Small bowel transplants are therefore less frequent.

5.2. Current Infrastructure, Facilities, Technologies, Policies, Programs, etc. in the Country in Context of the Problem/Health Issue

- A total of 618 Hospitals undertaking transplantation or retrieval in the country are now registered with NOTTO for the purpose of networking and National Registry. This indicates a significant progress in establishment of an Organized system in the country for Organ procurement from deceased donors and their distribution and transplantation to the needy citizens of the country. However, the **data entry by the hospitals in the National Registry remains incomplete.**
- Number of persons who have pledged for Organ and/or tissue donation with NOTTO is now more than 1.4 million, out of which more than 300,000 have been registered online. This indicates a significant improvement in awareness about Organ donation.
- Capacity for undertaking rare transplants e.g., Pancreas, Intestine, Hand, Limbs, Lung, Uterus have developed within the country, besides a significant enhancement in capacities for undertaking relatively common transplants of Kidney, Liver and Heart.
- Some transplant centres including PGIMER Chandigarh have also developed capacities for undertaking Donation after Cardiac Death.

5.3. Current Budget

The following is the grant in aid under National Organ Transplantation Program (NOTP) available for promotion of Organ Transplantation.

	Amount
ROTTO: Recurring Grant per annum	**Rs. 1.05 crore**
SOTTO: 1. Non-Recurring grant for setting up of SOTTOs 2. Recurring grant for manpower.	**Rs. 36 lakh** **Rs. 48 lakh**
RETRIEVAL CENTRE: for setting up	**Rs. 75 lakh**
TRANSPLANT CENTRE: For setting up	**Rs. 1.50 Cr.**
UPGRADATION of existing retrieval/transplant unit	**Rs. 75 lakh**
TRANSPLANT COORDINATORS:: Govt. institutions-2 TCs, PVT. Centres- 1 TC Identified Govt. Trauma Centres- 1 TC	**Rs. 35,000/PM per transplant coordinator**
Bio-material Centre (only for ROTTO)-	**Rs. 1.0 Cr.**
IMMUNO-SUPPRESSANT THERAPY to BPL transplant recipients in Govt. hospitals	**Rs. 10,000/month**
DIGNIFIED FUNERAL OF DECEASED DONOR	**Rs. 10,000/per deceased person**
MAINTENANCE OF BODIES OF DECEASED DONOR	**Rs. 1,00,000/- per donation**

Summary Table of Total Budget for Organ Donation and Transplantation

(Tentative year wise distribution for 2021-22 to 2025-26 as per proposed outlay in Lakhs of Rupees)

S.No	Component	(2021-22) Proposed Outlay	(2022-23) Proposed Outlay	(2023-24) Proposed Outlay	(2024-25) Proposed Outlay	(2025-26) Proposed Outlay	Total in Rs. (Lakh)
1	IEC Activities	129	129	114	114	114	600
2	National THOA and NOTP Cell	25	40	45	45	45	200
3	NOTTO including National Biomaterial centre	300	325	325	375	400	1725
4	ROTTO cum SOTTO (5)	109	114.25	119.76	125.55	131.63	600.19
5	SOTTO (20)	450	480	534	588	600	2652
6	Bio-material Centres -3 @ ROTTOs/SOTTOs/	100	-	100	-	100	300

	States @ 100 lakh per centre)						
7.	Govt. supported Online system of Networking	150	50	50	25	25	300
8	Training	50	75	75	100	100	400
9	Skill Centre(s)	50	50	50	50	-	200
10	Support for immune-suppressants	75	75	100	125	125	500
11.	Coordination with trauma centres	10	10	10	10	10	50
12	Coordination with Govt. Medical Colleges and good performing private centres	50	50	50	75	75	300
13.	New Retrieval / transplant facility and strengthening old transplant facility in Government medical colleges / institutions	200	300	200	200	200	1100
14.	Support for maintenance of Cadavers in retrieval centres @ Rs. 1,00,000 per cadaver For 5 Cadavers per year	5	5	5	5	5	25
15.	Support for Organ Transportation through ROTTO and NOTTO @ 1 Crore per year	10	10	10	10	10	50

16	Grant to cover expenses for dignified funeral of deceased Donor (support of Rs. 10,000 to each donor family)	40	50	60	70	80	300
17	Outcome monitoring	2	2	2	2	2	10
18	International cooperation	30	30	30	30	30	150
19	Evaluation	0	0	0	0	30	30
	Grand Total	1785	1795.25	1879.76	1949.55	2082.63	9492.19

Total Proposal for Five Years = 9492.19 Lakh = 94.92 Crore

Data given by NOTTO

6. Key Issues/ Gaps Identified in the Current Situation in the Country in the Context of the Problem/Health Issue

6.1 Deficiencies in the Program

- Lack of Brain Stem Death Identification, Certification and Maintenance of Organs for donation
- Shortage of manpower in Government as well as Private hospitals
- Lack of Infrastructure/Suboptimal utilization of infrastructure in Government sector
- Provision of Non-Transplant Organ Retrieval Centers (NTORC)in the law has also not been optimally utilized
- Guidelines related to donation after Circulatory death are lacking
- Non-utilisation of the grant under various heads of the National Programme.
- There is a regional imbalance. The Organ Donation should happen in all the regions and should not remain concentrated in any geographical region. This creates problems with equity and allocation of Organs.
- **Manpower working in SOTTO/ROTTO is having additional charge of SOTTO/ROTTO so adequate time cannot be devoted to Organ donation related activities**. It would be better to have such post on fulltime basis to devote more time for Organ donation rather than just giving additional charge of SOTTO/ROTTO posts.

6.2. Recommendations Made to Bridge the Critical Gaps/ Deficiencies in this Aspect

a. Brain Death

- There should be a uniform declaration of death with mode of death being **Brain Stem Death (BSD)/Cardiopulmonary Death (Circulatory Death).**
- The declaration of 'Brain Stem Death' should be made mandatory for all hospitals, both private and government. The THOTA Rules provide for the same, however, the rule is not being followed in letter and spirit.
- The hospital staff in Medical Colleges, District Hospitals and other retrieval centres which have an ICU and Ventilator facilities should be trained in the concept of Brain Stem Death. There should be regular training programs on BSD for staff from Medical Colleges, District Hospitals & major Corporate Hospitals.
- All BSD Certifying specialists should be registered with local authorities.
- Procedure for donation of Organ in MLC should be streamlined and SOPs made Nationally/State wise.
- **Monthly Audit of BSD must be done on a regular basis by the concerned SOTTOs**. The data pertaining to declaration of BSD should be online as well Re-certification process should have mandatory review of Number of brain death identified and audit reports of such activities from ICU**.**
- **Training of ICU staff in family conversation for end-of-life care should be regularly conducted**. Number of trained staff in ICU for end-of-life conversation should be introduced in a phased manner. SOP for Donation procedure within the hospital should be a mandatory requirement for certification

b. Regulatory Bodies

- There are around 618 registered transplant centres and only 140 Non-Transplant Retrieval Centres. The retrieval centres must proportionally increase by incentivising them.
- **Registration of Non-Transplant Organ Retrieval Centres (NTORC):**
  The process for registration of Non-Transplant Organ Retrieval Centres (NTORCs) should be simplified. Hub and spoke model can be followed with big hospital as hub and NTORCs as spokes. **Registered Transplant hospitals can be tied up with Trauma Centres. Infact, all the Trauma Centres in country should be registered.**

- All the Medical Colleges and Hospitals can be identified as Non-Transplant Organ Retrieval Centres.
- **Written SOPs with clear guidelines regarding manpower and equipment requirement should be shared with these NTORC's**.
- **Apex National Body – Empowered and robust NOTTO with more financial powers should be there to work in the field of Organ Donation and Transplantation.**
- **Appropriate Authority should be a designated Senior Official only handling Organ donation & transplant on a fulltime basis.**
- Independent Oversight committee with representation of AA & Apex National Body
- Monthly activities of NOTTO, SOTTO, ROTTO should be notified on website including future workshops.
- **The performance of SOTTOs should be assessed on a regular basis with a possibility of transfer if found unsatisfactory.**

c. Hospitals & ICU

Death Audits

- Monthly audit of death including BSD must be done on a regular basis by the concerned SOTTOs with the objective to find out the missed opportunities and possible solution. The data pertaining to declaration of BSD should be reported online on a central NOTTO interface.
- Training of ICU staff in family conversation for end-of-life care should be regularly conducted and made mandatory.
- SOP for Donation procedure within the hospital should be a mandatory requirement for certification.
- Re-certification process for transplant license should have mandatory review of
  - Number of brain death identified and audit reports of such activities from ICU.
  - SOPs for Organ Donation pathways.
  - Family conversation for end-of-life care workshops conducted.
  - Number of trained staff in ICU for end-of-life conversation should be introduced in a phased manner. Re-Certification should consider the performance in this aspect.

Grief Counsellors / Transplant Coordinators

- **At least 4 (four) existing staff in the hospitals can be identified, trained and designated as Transplant Coordinators.**
- The Transplant coordinators for deceased donor family counselling should be different from those handling transplant recipients.

Role of Police

- **The police must designate Nodal Officers to coordinate Organ Donation related activities.**
- The Investigating officers/ Station house officer of the police station under which the hospital falls should be directed to give assistance for Organ procurement as mandated in THOTA Act.
- The respective Governments must be directed to instruct Police Chiefs to hold regular awareness meets for all Investigating officers / Station house officer.
- The Police also needs to be sensitized about the importance of Organ Donation and Medico Legal Issues should be eased.

Education and Training

- Organ Transplant Units should be there in all Medical Colleges and All India Institute of Medical Sciences (AIIMS) like institutions. Such Units should have the faculty with expertise in the field of Organ Transplantation and at least should become Organ Retrieval centres in the first phase and have a brain death certification committee wherever possible. Multi Organ retrieval team be made in all major hospitals.
- States government should identify one Medical College in their state that can become a centre for excellence as a Multi Organ Transplantation hospital to help with training of manpower and growth of the program.
- Advanced Transplant Centres should be there in all INIs with individual Organ subdivisions. These centres should have a common ICU so that it could be managed with lesser logistics and manpower. Specialised departments for cardiac, lung and HPB surgery & Liver Transplant should be created in all INIs to enhance the seriousness towards Multi-Organ Transplant. Stress must be laid on the recruitment of people with passion in the field of Organ Transplantation to give a fillip to the programme.

- Training related to Organ Transplant & Prospective donor after declaration of BSD should be given to all concerned Physicians/Surgeons.
- All Post-Graduates should be trained in BSD like they are being trained in BLS & ALTS regularly. It would increase awareness & strengthen the concept of BSD & make foundation strong.
- More Consultants should be systematically trained in the field of Organ Transplantation.
- Transplant Societies and non-government Organisation could help in the training of ICU professionals and Surgeons in multi-Organ transplant. The competence of the Transplant Surgeons and the team should be objectively assessed.
- A letter from Secretary Health, Director General of Health Services (DGHS) or National Medical Commission (NMC) may go to different States and Medical Colleges to start Donor Action Programme
- Trauma centres should be better equipped to handle brain deaths (Ventilators, ABG machines and other equipment). This would help in both saving lives and early identification of brain deaths.
- Fellowships as well as Short term attachments should be available/started at transplant centres.
- A pool of certified transplant surgeons must be created for the capacity building in the field of Organ Donation and Transplantation.
- The curriculum/training of Brain stem death should be imparted to all residents, faculty & nurse staff. Organ donation chapters should be included in the curriculum. Besides public awareness should be increased.

Infrastructure

- All Medical Colleges, District Hospitals, Trauma Centers should be actively involved in transplant related fields.
- INIs should have transplant departments for Multi Organ transplant and have permission of fellowships training in transplant.
- Dedicated department of Intensive Care Medicine should be created in all Medical Colleges and major Government Hospitals.
- Dedicated infrastructure must be created in Public Sector for Organ Transplantation on lines of IKRDC-ITS Ahmedabad, ILBS New Delhi and PGIMER, Chandigarh. Few ICU

Beds can be dedicated for Organ Donation in Government Hospitals. In all INIs dedicated ICU & HDU should be made as per standard protocol. This will strengthen the infrastructure for Organ transplantation from beginning and new AIIMS will have accountability for Organ transplantation.

- To maximise the utilisation of deceased Organs particularly extended criteria Organs, provision should be made to do Machine perfusion of Organs and for that a clause should be added in THOTA Rules 2014or a circular be issued by GoI.
- Organ Transplant Units should be formed in all Medical Colleges and AIIMS like institutions. At least they should become Organ Retrieval centres in the first phase and have a brain death certification committee. Such Units should have the faculty with expertise in the field of Organ Transplantation and plan to have Multi Organ retrieval team in all major hospitals.
- Separate departments for Multi Organ Transplantation need to be created in one Medical College of each state to promote Organ Donation & Transplantation. Advanced Transplant Centres should be there in all INIs with individual Organ subdivisions. These centres should have a common ICU, so that it could be managed with lesser logistics and manpower. Departments of HPB surgery & Liver Transplant &Department of Hepatology should be created in all INIs to enhance the seriousness towards Liver Transplant. Same should be adopted for other Organs as well. Stress must be laid on the recruitment of people with passion in the field of Organ Transplantation.

Table: Challenges and Solutions for Deceased Donor Organ Transplantation (DDOT) in India

Challenges	Solutions for Deceased Donor Organ Transplantation (DDOT) in India
Awareness	Prime Minister highlighted DDOT in “Mann Ki Baat” radio program
	“Mobile caller tune, festival celebration, walkathon” on Organ donation theme
	Religious/faith leaders and nongovernment Organization support to overcome religious, sociocultural barriers
	Social media, TV, and digital reforms are quicker, easier, and cost-effective to disseminate DDOT in large population in India

Challenges	Solutions for Deceased Donor Organ Transplantation (DDOT) in India
	Implementing options to Organ pledge while applying for a driving license in all states
	Include Organ donation in the education system syllabus, developing Information, Education, and Communication materials as per regional need
	Facility for offline and online pledging for donation of Organ
Grief Counselling	Mandatory dedicated grief counsellors in emergency rooms and ICU doctors, treating, and primary care doctors should initiate GC/DDOT
Brain Stem Death (BSD) Declaration	BSD declaration needs to be separated from DDOT
	Uniform guidelines for BSD declaration by government authority
	Mandatory BSD declaration and reporting to state authority
	Donor pledge form (form 7) requires a legal status
ICU Team	All transplant hospitals must have a team headed by an intensivist and supported by a team of ICU nurse, counsellor, coordinator
	Early and proactive donor identification and management
	Highest standard for donor care with no out-of-pocket expenditure
	Increase donor conversion rate with regular e-learning modules
Registry, Allocation, Transplant Team	Uniform data collection and data management system should be developed at the national level and state level Organization should have the admin access for state data
	Government priority and support to develop self-sufficiency in transplant
	Commitment of authorities, institutions, and individuals for pledge, waiting list, and transplant outcome registry
	Non-transplant Organ retrieval centres license on priority
	Government guidelines for donation after circulatory death donors
	"One Nation One Policy" for digital Organ allocation: must be localized to the state and when the state declines, it goes to region and national level
Nonfinancial Incentives	Honouring family members on Organ donation day and world kidney day
	Memory tree plantation in honouring Organ donors

Challenges	Solutions for Deceased Donor Organ Transplantation (DDOT) in India
	Social support (cremation rituals), government health card to dependent family members of Organ donor and educational support to children of a sole bread earning deceased donor
Collaboration, Advisory Committees	Government authority, transplant collaboration with related national societies including The Transplantation Society
	State- and national-level advisory committees of experts should be engaged in policy making and revisions
	A 24/7 call centre has been made operational with provision of a toll-free helpline by National Organ and Tissue Transplant Organization (NOTTO)
	NOTTO apex technical committees developed broad guiding principle for allocation
Expand DDOT in Public Sector Hospitals	Leadership and dedicated transplant team
	Use key features of successful DDOT model (dark green states in Figure 1) to expand DDOT in emerging states (light green, orange states in Figure 1)
	Initiate and expand DDOT for heart, lung, and pancreas
	Living and deceased donor advocates to decrease waiting time on DDOT
Training, Capacity Building	Organ transplant fellowships
	Local multi-Organ retrieval team to avoid delay in multi-Organ retrieval by multiple teams
Audit	Audit of counselling, brain death declaration, Organ donation, utilization rate, and transplant outcome
	Accountability of hospitals getting license for Organ donation and transplantation and outcome registry
	Regulatory oversight of the entire transplant program is the responsibility of the state authority
	Root cause analysis of social distrust and lack of awareness
Future	Machine perfusion to reduce discard rates
	There is need of "**One Nation and One deceased donor allocation policy**" and "**One Nation and One Digital platform for SOTTO/ROTTO/NOTTO website and data reporting**

NOTTO & Financial Aspect

- **The Government of India has earmarked funds for setting a Transplant Centre but this needs to be widely publicised and centres pushed to accept these funds with financial accountability. The fund utilisation in this field is sub-optimal.**
- **The grant allocated for various components should be visible at level of NOTTO, ROTTO & SOTTO. There should be a separate Finance officer at National or Regional Level for the grant and processing of the payments.**
- **NOTTO could be made more robust by recruiting new officers with varied backgrounds like finance etc. and SOPs should be made for the use of grant allocated for various components under NOTTO.**
- **A Full-time designated official at top position (at NOTTO, ROTTO & SOTTO) with keen interest in Organ Transplantation & Donation should be appointed. Lateral entry for suitable candidates with experience in the field should be allowed with no age bar.**
- Audit should be conducted at the level of NOTTO to evaluate the work done by ROTTO and SOTTO and they should be made accountable.
- **There is an urgent need to make Organ Donation & Transplantation affordable. The Drugs like Immuno-Suppressants, Preservative solution for Organ transportation & other Consumables required for Organ Transplantation should be made tax free.**
- Inclusion of Organ Transplantation under Ayushman Bharat PMJAY by GOI is a good step and financial support from Corporates through Corporate Social Responsibility and Crowd Funding should be encouraged for poor patients. The post-transplantation expenditure should also be taken into account.
- States that have not adopted THOA should be requested to do so. Letters from DGHS enumerating all funds should be sent to all state DHS for setting up SOTTO in their states and registering all licensed transplant centers & retrieval centers. Enhancement & up gradation of National Registry into computerized data collection & automatic computerized allocation to have a transparent allocation.
- Incentives to hospitals- who provide complete data to health authorities such as SOTTO/NOTTO.
- Regular meetings by AA for reviewing the progress from time to time of SOTTO/ROTTO & NOTTO.

- Regional Directors of Government of India Health and Family Welfare should be involved in facilitating operationalization & implementing of various schemes of NOTP.
- Greater involvement of Neuro critical care team of hospitals to enhance Donor Identification & Organ Donation. They may be the preferred nodal officers of the hospital for all Organ donations & Transplant related matters.
- Conferences of these specialties should have a session on Organ donation & transplantation.
- Annual conferences should be Organized by NOTTO/ROTTO/SOTTO & widely published.

National THOTA & NOTP Cell

- It has a role of representing & renewal of all Organ & tissue transplant centers & monitoring transplants & retrieval in respective states & UTs.
- Give consultancy on transplant law & program related matters.
- Facilitating National Organ Donation/ World Organ Donation Day.
- Looking after technical, administrative & financial matters of NOTP, implementation & monitoring of its various components.

Organ Transportation

- Organ Transportation by Air can be taken up as a Corporate Social Responsibility (CSR) by Corporates, Indian Airforce can be involved in addition to Ministry of Civil Aviation. Organ Transportation by Drones can also be considered.
- Facilities for Organ transportation road/air ambulances should be available at subsidised rates.

Tissue Donation

- Tissue donation has to be promoted. The tissue donation needs to be looked at by an independent Apex Technical Committee constituted for this purpose.

Best Practices

- Best Practices from State Government Orders (G.O.) to Facilitate Deceased Organ Donation may be compiled and evaluated and later adopted based on merit.
- A modified UNOS model as being in practice in Maharashtra over 20yrs should be looked into and implemented.

6.3. Recommendations Made to Bridge the Critical Gaps/ Deficiencies in this Aspect in THOTA Rules of 2014

Current problem in Form 13: The requirements for infrastructure and manpower are almost similar to that for registration of a Transplant Centre. There is no need to change Form 13 for recognition of NTORC. There is a need to simplify the process and a MoU can be signed.

- All BSD Certifying specialists should be registered with local authorities.
- If there is a Deceased donor in a non-registered hospital and family is willing for donation of Organs and or tissues, then "In such non-registered hospital the death will be certified by two certified specialist from the registered Transplant hospital or NTORC and retrieval of Organs and tissues can be done at the same hospital by teams from Registered transplant hospital or shifted to an registered NTORC or Transplant hospital". In such cases, donor specific/time specific permission by Appropriate Authority may be granted when family comes forward to donate the Organs.
- Alternatives / Ancillary Tests to Apnea Test.

  BSD certification in a person where either:

  a. Apnoea test cannot be done due to hemodynamic instability or
  b. Cranial nerve reflexes cannot be tested due to eye/facial injuries

  Actions to be taken:

  Use Ancillary tests to document absence of cerebral blood flow as per international practices: BSD certifying specialist to decide the tests to be performed.eg 4 vessel cerebral angio /CT Cerebral Angio/ MR angio/ Trans Cranial Doppler/ Isotope Scan depending on availability of facilities.

6.4. Any Other

- In all cardiac deaths, option of tissue donation should be offered.
- Role of Digitisation: The Digitisation of the Organ Donation Registry to avoid man made errors.
- 24 hr call centre at NOTTO.
- Tree plantation drives in name of donors and other ways to honour their families.
- Awareness in schools and colleges on Organ Donation.
- National Health Insurance for Organ Transplantation.
- Orientation & sensitization of various stakeholders like Judges, Legal experts, Police & traffic personnel etc. on Organ donation & transplant center.

7. Way Forward

7.1 It is a well-known fact that NGOs in the past have played a pivotal role for promotion of eye and blood donation. An Inclusive working group requires to be created from all regions to include all the stakeholders from both public and private bodies including medical societies such as Indian society of Organ Transplantation (ISOT) and NGO's.

Increasing Awareness:

- More fulltime manpower and budget should be allocated to NOTTO and NOTP.
- Creation of Modified UNOS model of OPTN and OPOS as being practised in Maharashtra (ZTCCs) having financial self-sufficiency to be looked into.
- There is a need to increase awareness about Organ Transplantation among medical professionals.
- Awareness posters about Organ donation should be installed at all hospitals (trauma centre and ICU) & prominent places (such as shopping mall, railway station, Government offices and banks). The 'Ang Daan Jeevan Daan' posters having toll free numbers should be installed at important places of all hospitals.
- If any Organ donation & transplantation is being performed such an event may be displayed on LED or as blinking light on dashboards at NOTTO, ROTTO, SOTTO offices and other prominent places to sensitize the public at large.
- There should be a provision in Driving Licence about willingness to donate Organs in all states.
- Smart cards should be issued to Organ donors.

Key Actions

- Adoption of THOTA by states who have not accepted as yet.
- Establish SOTTO in each state to develop an effective and Organized system of Organ procurement.
- Govt institutions- augment infrastructure for Organ Donation & Transplant (identify Med colleges without infrastructure).
- Register all Trauma centers as Organ Retrieval Centers .
- Have Transplant Coordinators in each hospital.
- Make Intensivists, Critical care doctors as Nodal officers.
- Creation of Independent AA in each state.
- Reporting of long-term transplant recipient and donor outcome to NOTTO should be mandated.
- Organ transplantation from deceased donors after cardiac death is underutilised in India and should be promoted.

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