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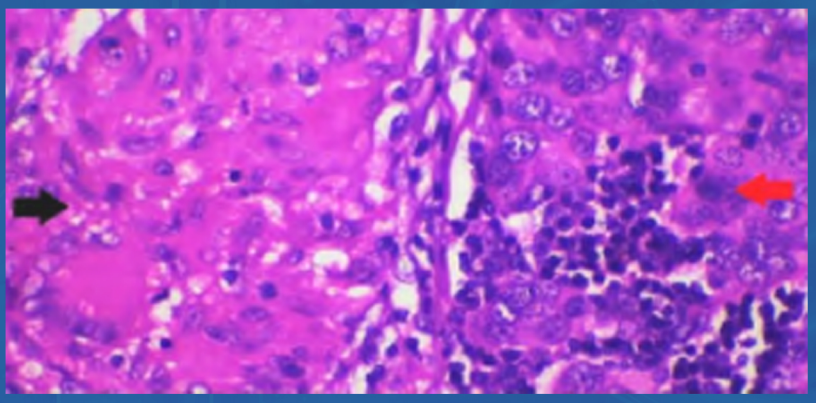
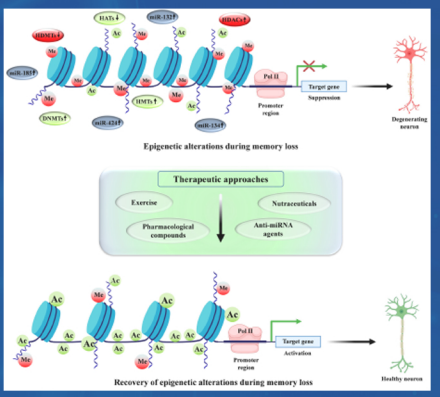


Epithelioid granuloma (black arrow) with invasive breast carcinoma (red arrow) (Haematoxylin & Eosin ×400).



Epigenetics in memory decline during aging

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Annals of the National Academy of Medical Sciences (India)

Task Force Report

NAMS task force report on Organ donation and transplantation

National Academy of Medical Sciences (India), New Delhi, India.*

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*A list of Task force members of the Venous thromboembolism can be found in the report.

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PREFACE

Organ transplantation is known to save lives. There is a huge unmet need for organs and there is a widening gap between the requirement of Organs and transplants in patients with end stage organ failure. While live donor Organ donation is well established in India, despite an enabling law, deceased Organ donation has not been picked up across the country except for states in the south and west because of the proactive action taken by individual state authorities along with non-government bodies. While there is wide publicity on Organ donations, the awareness is far from optimum. In fact, the reluctance of clinicians to identify and certify brain stem death (BSD) and counseling 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 advancements in medical skills and technology, patients in need of Organ transplants 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.

EXECUTIVE SUMMARY

To promote deceased organ donation, the Government of India enacted the Transplantation of Human Organs and Tissues Act, 1994 (THOTA) to regulate Organ retrieval, storage, and transplantation for therapeutic purposes and prevent commercial dealing in human Organs and tissues. Since 2011, the Government of India also implemented the 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 enormous 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.

The National Academy of Medical Sciences (NAMS) of 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 among the members based on their expertise, experience, and extensive review of up-to-date published literature from India and abroad and made the following key observations and 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 for 175,000 kidney, 50,000 liver, heart, lung, and 2500 pancreas transplants in India per year. The Organ donation rate in India has remained stable at less than 1 per million population (PMP) from 2013 till date. To achieve 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 the Task Force suggested a need to duplicate their best practices to increase momentum in other parts of the country.
- They also noticed a lack of information and training on brain stem death identification, certification and maintenance of Organ donor coupled with a 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 State Organ & Tissue Transplant Organization SOTTOs or health authorities. The declaration of "Brain Stem Death" should be made mandatory for all government and 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 the Hub and Spoke model and simplifying requirements in Form 13 of the 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 the lines of Institute of Kidney Diseases and Research Center – Institute of Transplantation Sciences (IKDRC-ITS), Institute of Liver and Biliary Sciences (ILBS), New Delhi and Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh, which can function as Organ retrieval centers in the first phase. Multi-Organ Retrieval teams should be formed in all major hospitals. In fact, all Institute of National Importance (INI) should be made Organ transplantation centers and respective departments supporting them should be made, e.g., Department/Division of Hepatology, Division of Pancreatology.
- To maximize the utilization 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 tests for BSD certification should be permitted when the Apnoea test cannot be performed.
- A Standard Operating Procedure (SOP) is to be prepared for Organ donation after donation after circulatory death (DCD).
- Creation of an Independent State Appropriate Authority to exclusively look after issues related to Organ transplantation.
- Aν 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 publicized. In fact, all driving licenses should include a provision for pledging of Organs.
- National Organ & Tissue Transplant Organization (NOTTO) should be made administratively and financially robust.
- There should be more manpower and budget in the NOTTO office for service, education, and research in Organ donation and transplantation.
- Appointment of Director of NOTTO/Regional Organ & Tissue Transplant Organization (ROTTO)/State Organ & Tissue Transplant Organization (SOTTO) by a central agency and lateral entry to be permitted for these appointments with no age bar.
- Regular review of the performance of ROTTO/SOTTO by an independent audit committee of NOTTO.
- Linking of all hospitals with SOTTO/ROTTO/NOTTO through One Digital Platform with daily updates of the information.
- Revision of general and Organ-specific listing and allocation policies.
- Rules for Organ donation from deceased donors 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/unutilized deceased donor Organs and for that amend the law/rules.
- There is a need for more guidelines and consensus statements from NOTTO with inputs from transplant professionals and societies such as the Indian Society of Organ Transplantation (ISOT) on common clinical practice issues.
- Reporting of long-term Transplant Recipient and Donor outcomes to NOTTO should be mandated.
- Legal hurdles like the hierarchy of consent, post-mortem permissions throughout the day, and SOPs for donation in medico-legal cases should be clearly defined.
- Pradhan Mantri Jan Arogya Yojana (PMJAY) – Ayushman Bharat Scheme has included kidney and bone marrow transplantation. There is a need to widen its ambit to include the heart, lungs, liver, pancreas, and other Organs, and the amount should be increased.

INTRODUCTION

Organ transplantation gives a new lease of life to patients with end stage Organ failure. While in India, over the years living donors had been the primary source of kidneys for transplantation, the last decade and a half has seen live donors being the main source of livers also. However, there is a 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, Cerebro Vascular Accident (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%,[1,2] 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, the United States and Spain had the highest rates of deceased Organ donors in select Organisation for Economic Co-operation and Development (OECD) countries, with almost 38 people per million population, whereas Greece (4.6), Russia (3.9), and Turkey (3) had the least donation rate].[3]

Surprisingly, according to an Ipsos survey in 2018 about people's willingness to donate organs after death, Colombia and India, with 75% and 74%, respectively, had the highest percentage of willing people to donate organs after death, ahead of Spain (72%), UK (67%), and Germany (53%).[4] This may be due to the campaigns undertaken by non-government organizations 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.[5]

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, the transplant community should be constantly looking at mechanisms to boost the Organ supply. This also includes maximizing the utilization 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 number of donors remain low to help the number of recipients on the waiting list. Reluctance to donate Organs is not only within Indian borders but also extends to the Indian population in the UK and Canada.[6]

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 the majority of individuals who were suffering from renal failure and on dialysis were unlikely to be an Organ donor since their families had not initiated 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 are also the main roadblocks due to media news items appearing of illegal Organ donation and transplant practices. Body disfigurement was the 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.[7] In a survey from South India involving 300 participants to a questionnaire on Organ donation, less than half of the study participants were knowledgeable about the definition of brain death and the existence of organ donation law. Although they were in favor of organ donation, there were still some doubts related to family support.[8]

Hospital issues: A recently published study showed a lack of knowledge on clinical criteria for brain death and legal issues pre-intervention, which improved post-intervention, after they participated in an interactive educational module. This intervention significantly improved the tendency of doctors and nurses to promote Organ donation, pledging their Organs, and for counseling patients/attendants on this cause.[9] There is no magic bullet to increase the Organ donation rates. Addressing donor shortages requires 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 in reporting and approaching family members for Organ donation. They also stress education/health care infrastructure and human resources, forming a multipronged approach that is tailored to develop transplants in that country.[10]

As part of a national network, the National Organ & Tissue Transplant Organization (NOTTO) and five regional organizations, namely Regional Organ & Tissue Transplant Organization (ROTTO) at Mumbai, Kolkata, Chandigarh, Chennai, and Guwahati cover Western, Eastern, Northern,

Southern, and North-Eastern regions of the 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 the 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, the total number of Organ transplants in the country increased from 4990 in the year 2013 to 12,746 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.

TERMS OF REFERENCE (TORS) FOR THE TASK FORCE

The Executive Council of the National Academy of Medical Sciences (India) 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 and transplantation in India.
b. Identify the exact deficiencies.
c. To suggest and recommend ways of improvement in the area of Organ transplantation.

METHODOLOGY

The Task Force conducted meetings using a 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.

BACKGROUND: HOW MANY TRANSPLANTS ARE CONDUCTED IN INDIA PER MILLION?

The current status of Organ donation and transplantation in India is shown in Figure 1–7:

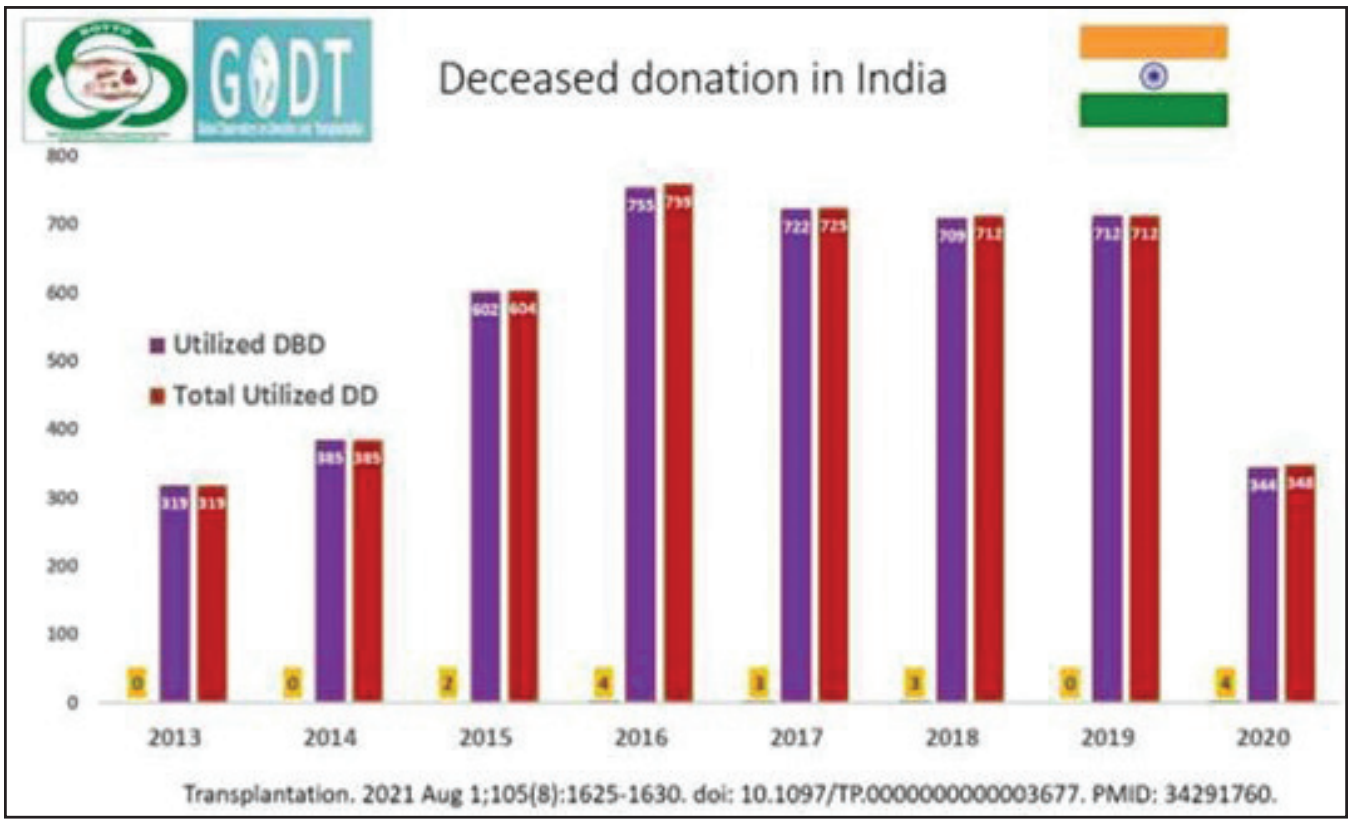

Figure 1: DD: Deceased donor; DBD: Donation after Brain Death.
Source: National Organ & Tissue Transplant Organization (NOTTO)

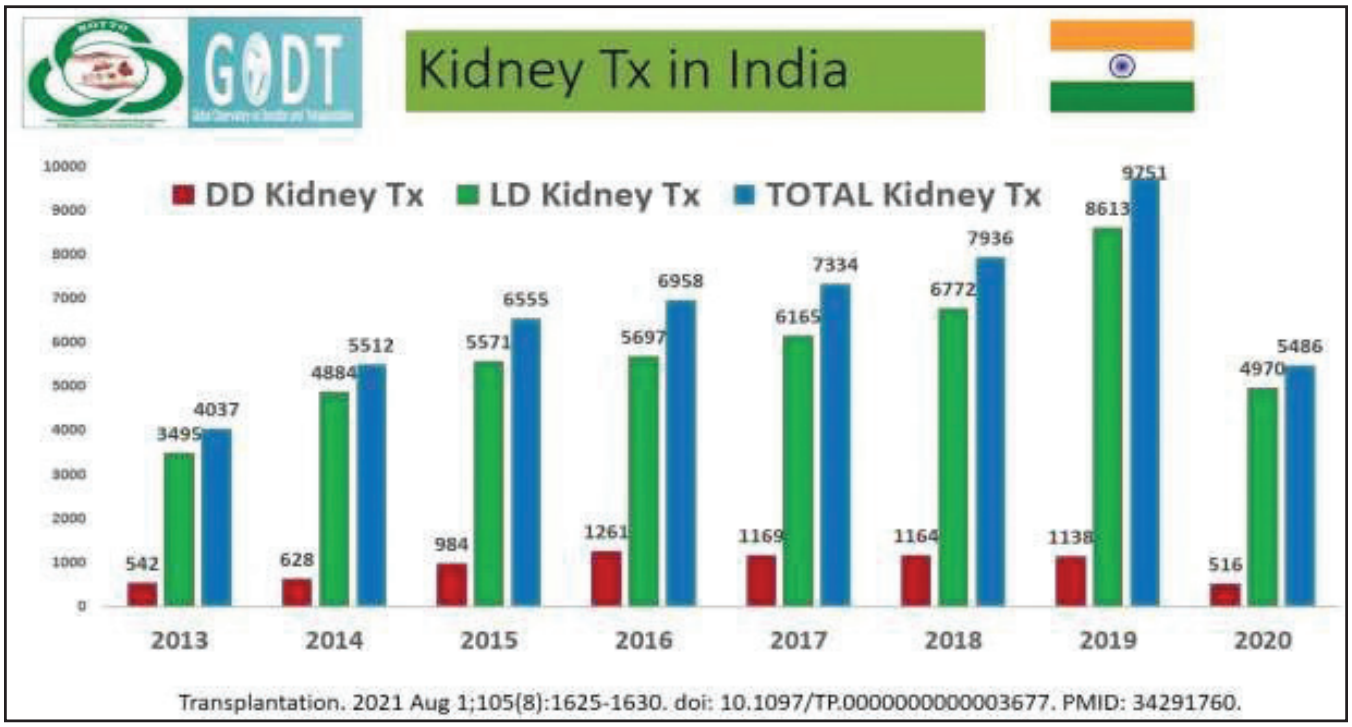

Figure 2
DD: Deceased Donor; LD: Live Donor; Kidney Tx: Kidney transplant.
Source: National Organ & Tissue Transplant Organization (NOTTO).

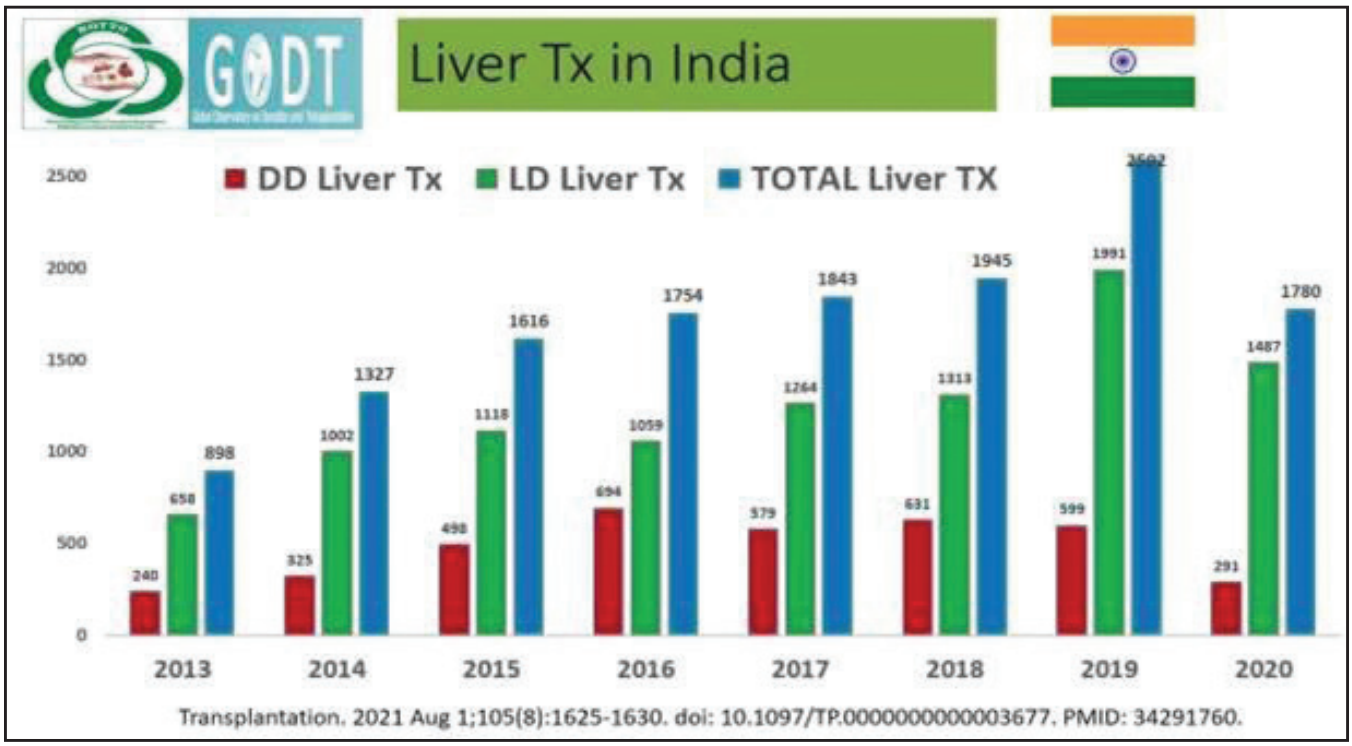

Figure 3
DD: Deceased Donor; LD: Live Donor; Liver Tx: Liver transplant.
Source: National Organ & Tissue Transplant Organization (NOTTO).

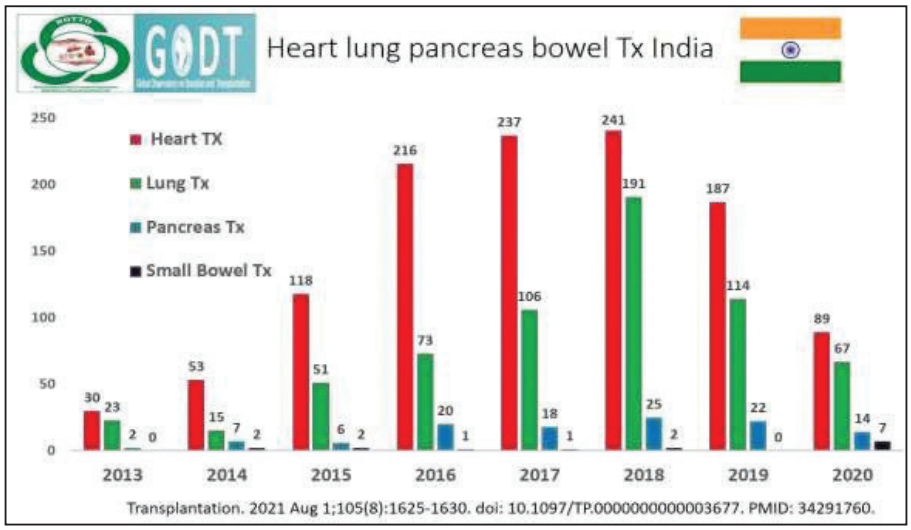

Figure 4: Transplantations done from 2013 to 2020 of Heart, Lungs, Pancreas & small bowel.
Tx: Transplant.
Source: National Organ & Tissue Transplant Organization (NOTTO).

Organ Deceased Donor Organ Donation & Transplantation (DDOT)

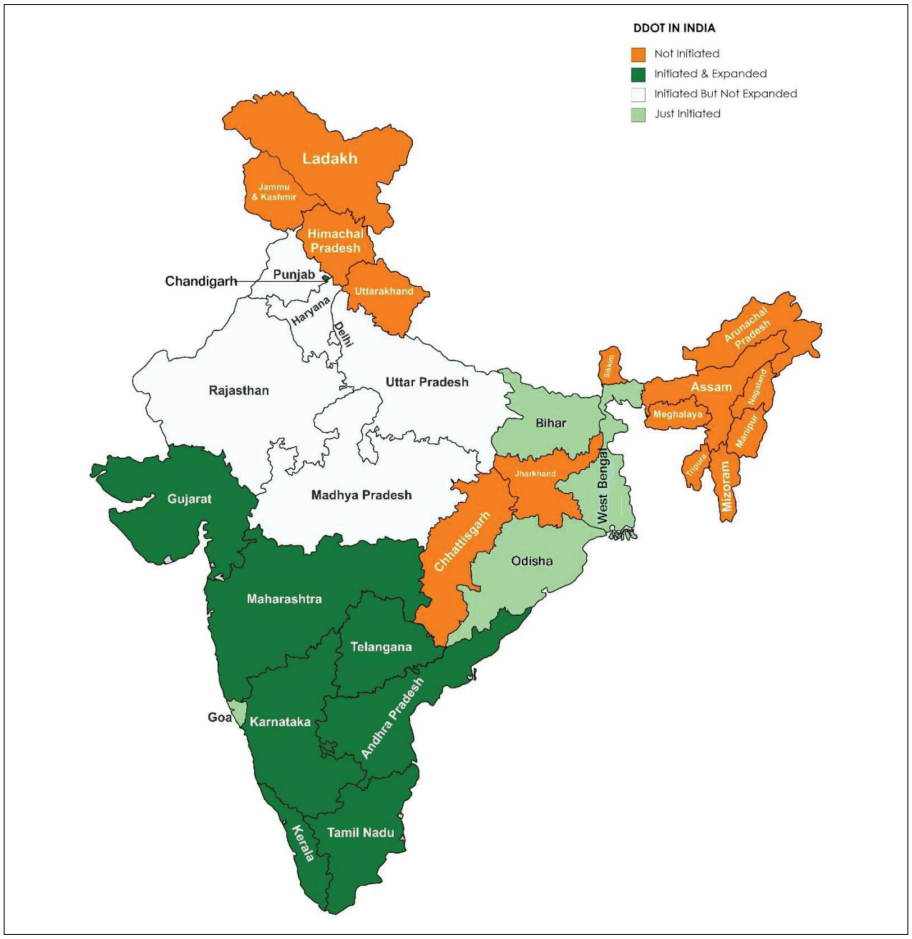

Figure 5
States shown in green have well-established Deceased Organ Donation programs (dark green states) to expand DDOT in emerging states (light green, orange states).
Source: National Organ & Tissue Transplant Organization (NOTTO).

Total Transplants in India (2020)

Figure 6: Distribution of total transplantation in Different Regions of India 2020
Source: National Organ & Tissue Transplant Organization (NOTTO).

Total Transplants in India (2021)

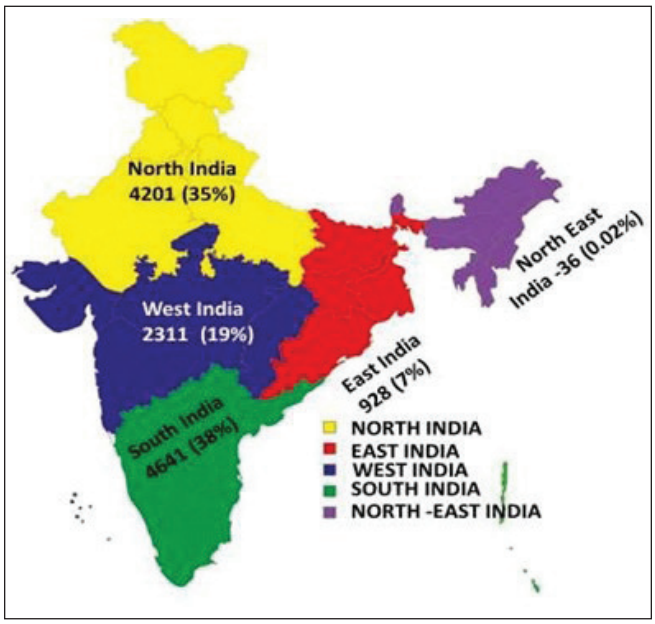

Figure 7: Distribution of total transplantation in Different Regions of India
Source: National Organ & Tissue Transplant Organization (NOTTO).

*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.

OBSERVATION

Current situation in the country

- About 160,000 deaths happen annually due to road traffic accidents in India – even if 10% (16,000) of these are converted as Organ donors, that will generate an average of 3 Organs per donor (as per Zonal Transplant Coordination Centre (ZTCC) Mumbai data), resulting in 45,000 Organ transplantations (livers, kidneys, hearts, lungs, pancreas, and small bowel).
- CVA is another common cause of BSD in India, and these could also add to the deceased donor pool in our country (ZTCC Mumbai donor data).
- The Organ donation rate (the number of deceased donors per million population) in the country increased from 0.27 in the year 2013 to 0.65 in 2018, however, it dipped to 0.52 in 2019. And are far less than compared to a maximum of around 48 in Spain.
- There is an estimated need for 175,000 kidney and 50,000 each liver, heart, and lung transplants in India. 80% of kidney and liver transplants and 95% of heart, lung, and pancreas transplant services are in private hospitals where the cost is prohibitive for the 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 and 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 third country in the world after the USA and China, in terms of the total number of transplants done in a year.
- The total number of transplants done in the country has increased from 4990 in 2013 to 12,666 in 2019, indicating a 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.

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 networking and National Registry. This indicates significant progress in the 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.
- The 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, and uterus has developed within the country, besides a significant enhancement in capacities for undertaking relatively common transplants of kidney, liver, and heart.
- Some transplant centers, including PGIMER Chandigarh, have also developed capacities for undertaking donation after cardiac death.

Current budget

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

ROTTO: Regional Organ & Tissue Transplant Organization; SOTTO: State Organ & Tissue Transplant Organization; TC: Transplant Coordinator.

Summary of total budget for Organ donation and transplantation

(Tentative year-wise distribution for 2021–2022 to 2025–2026 as per proposed outlay in lakhs of rupees)

S.No.	Component	(2021–2022) Proposed outlay	(2022–2023) Proposed outlay	(2023–2024) Proposed outlay	(2024–2025) Proposed outlay	(2025–2026) 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 Centee	300	325	325	375	400	1725
4	ROTTO and SOTTO (5)	109	114.25	119.76	125.55	131.63	600.19
5	SOTTO (20)	450	480	534	588	600	2652

(*Continued*)

S.No.	Component	(2021–2022) Proposed outlay	(2022–2023) Proposed outlay	(2023–2024) Proposed outlay	(2024–2025) Proposed outlay	(2025–2026) Proposed outlay	Total in Rs. (Lakh)
6	Bio-material Centers -3 at ROTTOs/SOTTOs	100	-	100	-	100	300
	States at 100 lakh per center						
7	Govt. supported online system of networking	150	50	50	25	25	300
8	Training	50	75	75	100	100	400
9	Skill center(s)	50	50	50	50	-	200
10	Support for immune-suppressants	75	75	100	125	125	500
11	Coordination with trauma centers	10	10	10	10	10	50
12	Coordination with goverment medical colleges and good performing private centers	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 centers at Rs. 100,000 per cadaver for 5 cadavers per year	5	5	5	5	5	25
15	Support for Organ transportation through ROTTO and NOTTO at 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 5 years = 9492.19 Lakh = 94.92 Crore; data given by NOTTO.
THOA: Transplantation of Human Organs and Tissues Act 1994; NOTP: National Organ Transplantation Program; ROTTO: Regional Organ & Tissue Transplant Organization; SOTTO: State Organ & Tissue Transplant Organization; NOTTO: National Organ & Tissue Transplant Organization

KEY ISSUES/GAPS IDENTIFIED IN THE CURRENT SITUATION IN THE COUNTRY IN THE CONTEXT OF THE PROBLEM/HEALTH ISSUE

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 the government sector.
- The 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-utilization of the grant under various heads of the National Program.
- 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 the 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 posts on full-time basis to devote more time to Organ donation rather than just giving additional charge of SOTTO/ROTTO posts.

Recommendations made to bridge the critical gaps/ deficiencies in this aspect

a. Brain death

- There should be a uniform declaration of death with a 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 centers that have ICU and ventilator facilities should be trained in the concept of BSD. There should be regular training programs on BSD for staff from medical colleges, district hospitals, and major corporate hospitals.
- All BSD certifying specialists should be registered with local authorities.
- The procedure for the donation of Organs in Medico Legal Case (MLC) should be streamlined and nation/state wise SOPs to be made.
- Monthly audit of BSD must be done regularly by the concerned SOTTOs. The data pertaining to the declaration of BSD should be online as well as re-certification process should have a mandatory review of the number of brain deaths identified and audit reports of such activities from the ICU.
- Training of ICU staff in family conversation for end-of-life care should be regularly conducted. The number of trained staff in the ICU for end-of-life conversations 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 centers and only 140 non-transplant retrieval centers. The retrieval centers must proportionally be increased by incentivizing them.
- Registration of Non-Transplant Organ Retrieval Centers (NTORC): The process for registration of NTORCs should be simplified. The hub and spoke model can be followed with big hospitals as hubs and NTORCs as spokes. Registered transplant hospitals can be tied up with trauma centers. In fact, all the trauma centers in the country should be registered.
- All the medical colleges and hospitals can be identified as NTORCs.
- Written SOPs with clear guidelines regarding manpower and equipment requirements should be shared with these NTORCs.
- Apex National Body: Empowered and robust NOTTO with more financial powers should be there to work in the field of Organ donation and transplantation.
- The Appropriate Authority should be a designated senior official only handling Organ donation and transplant on a full-time basis.
- Independent oversight committee with representation of Appropriate Authority (AA) & Apex National Body.
- Monthly activities of NOTTO, SOTTO, and ROTTO should be notified on the 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 and ICU*:*

Death audits

- Monthly audits of death, including BSD must be done on a regular basis by the concerned SOTTOs to find out the missed opportunities and possible solutions. The data pertaining to the 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 a transplant license should have a mandatory review of
  - Number of brain deaths identified and audit reports of such activities from ICU.
  - SOPs for Organ donation pathways.
  - Family conversation for end-of-life care workshops conducted.
  - The number of trained staff in ICUs for end-of-life conversations should be introduced in a phased manner. Re-certification should consider the performance in this aspect.

Grief counselors/Transplant coordinators

- At least four existing staff in the hospitals can be identified, trained, and designated as transplant coordinators.
- The transplant coordinators for deceased donor family counseling 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 assist in Organ procurement as mandated in the THOTA Act.
- The respective governments must be directed to instruct police chiefs to hold regular awareness meetings for all investigating officers/station house officers.
- The police also need 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) institutions. Such units should have faculty with expertise in the field of Organ transplantation and at least should become Organ retrieval centers in the first phase and have a brain death certification committee wherever possible. Multi-organ retrieval teams should be available in all major hospitals.
- State governments should identify one medical college in their state that can become a center for excellence as a multi-organ transplantation hospital to help with the training of manpower and growth of the program.
- Advanced transplant centers should be there in all INIs with individual Organ subdivisions. These centers should have a common ICU so that it could be managed with less logistics and manpower. Specialized departments for cardiac, lung, and Hepato Pancreato Biliary (HPB) surgery, and liver transplants should be created in all INIs to enhance the seriousness of multi-organ transplants. Stress must be laid on the recruitment of people with passion in the field of Organ transplantation to give a fillip to the program.
- Training related to Organ transplant and prospective donors after the declaration of BSD should be given to all concerned physicians/surgeons.
- All postgraduates should be trained in BSD like they are being trained in BLS and ALTS regularly. It would increase awareness and strengthen the concept of BSD, and make the foundation strong.
- More consultants should be systematically trained in the field of Organ transplantation.
- Transplant Societies and non-government organizations could help in the training of ICU professionals and surgeons in multi-Organ transplants. The competence of the transplant surgeons and the team should be objectively assessed.
- A letter from the Secretary of Health, Director General of Health Services (DGHS), or National Medical Commission (NMC) may go to different states and medical colleges to start donor action programs.
- Trauma centers should be better equipped to handle brain deaths (ventilators, Arterial Blood Gas (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 centers.
- A pool of certified transplant surgeons must be created for capacity building in the field of Organ donation and transplantation.
- The curriculum/training on BSD should be imparted to all residents, faculty, and nurse staff. Organ donation chapters should be included in the curriculum. Besides, public awareness should be increased.

Infrastructure

- All medical colleges, district hospitals, and trauma centers should be actively involved in transplant-related fields.
- INIs should have transplant departments for multi-organ transplants and have permission for fellowships training in transplant.
- A dedicated Department of Intensive Care Medicine should be created in all medical colleges and major government hospitals.
- Dedicated infrastructure must be created in the 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 ICUs and HDUs should be made as per standard protocol. This will strengthen the infrastructure for Organ transplantation from the beginning and new AIIMS will have accountability for Organ transplantation.
- To maximize the utilization of deceased Organs, particularly extended criteria Organs, a provision should be made to do machine perfusion of Organs and for that, a clause should be added in THOTA Rules 2014 or a circular should 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 centers in the first phase and have a brain death certification committee. Such units should have 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 and transplantation. Advanced transplant centers should be there in all INIs with individual Organ subdivisions. These centers should have a common ICU so that it could be managed with less logistics and manpower. Departments of HPB Surgery & Liver Transplant and Department of Hepatology should be created in all INIs to enhance the seriousness towards liver transplant. The 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.

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 non-government Organization support to overcome religious, socio-cultural barriers • Social media, TV, and digital reforms are quicker, easier, and more cost-effective to disseminate DDOT in large populations in India • Implementing options to Organ pledges 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 counseling	• Mandatory dedicated grief counselors 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 nurses, counselors, and coordinators • Early and proactive donor identification and management • The 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 systems should be developed at the national level and state level organizations should have admin access to state data • Government priority and support to develop self-sufficiency in transplant • The commitment of authorities, institutions, and individuals for the pledge, waiting list, and transplant outcome registry • Non-transplant Organ retrieval centers 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 the regional and national level
Nonfinancial incentives	• Honoring family members on Organ Donation Day and World Kidney Day • Memory tree plantation in honoring Organ donors • Social support (cremation rituals), government health cards to dependent family members of Organ donors 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 center has been made operational with the provision of a toll-free helpline by the National Organ and Tissue Transplant Organization (NOTTO) • NOTTO apex technical committees developed broad guiding principles 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 and orange states in Figure 1) • Initiate and expand DDOT for heart, lung, and pancreas • Living and deceased donors advocate 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 counseling, brain death declaration, Organ donation, utilization rate, and transplant outcome • Accountability of hospitals getting licenses 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 a need for "One Nation and One deceased donor allocation policy" and "One Nation and One Digital platform" for SOTTO/ROTTO/NOTTO website and data reporting
DDOT: Deceased Donor Organ Donation & Transplantation; NOTTO: National Organ & Tissue Transplant Organization; ROTTO: Regional Organ & Tissue Transplant Organization; SOTTO: State Organ & Tissue Transplant Organization.	

NOTTO and financial aspect

- The Government of India has earmarked funds for setting up a transplant center but this needs to be widely publicized and centers pushed to accept these funds with financial accountability. The fund utilization in this field is sub-optimal.
- The grant allocated for various components should be visible at the level of NOTTO, ROTTO, and SOTTO. There should be a separate finance officer at the 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 grants allocated for various components under NOTTO.
- A full-time designated official in top positions (at NOTTO, ROTTO, and SOTTO) with a keen interest in Organ transplantation and 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 and transplantation affordable. Drugs like immuno-suppressants, preservative solutions for Organ transportation, and other consumables required for Organ transplantation should be made tax-free.
- The 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 Transplantation of Human Organs and Tissues Act 1994 (THOA) should be requested to do so. Letters from Director Genertal of Health Services (DGHS) enumerating all funds should be sent to all state Directorate of Health Services (DHS) for setting up SOTTO in their states and registering all licensed transplant centers and retrieval centers. Enhancement and improvement of the National Registry into computerized data collection and 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 and NOTTO.
- Regional Directors of the Government of India Health and Family Welfare should be involved in facilitating the operationalization and implementation of various schemes of NOTP.
- Greater involvement of the neuro critical care team of hospitals to enhance donor identification and Organ donation. They may be the preferred nodal officers of the hospital for all Organ donations and transplant-related matters.
- Conferences of these specialties should have a session on Organ donation and transplantation.
- Annual conferences should be organized by NOTTO/ROTTO/SOTTO and widely published.

National THOTA and NOTP Cell

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

Organ transportation

- Organ transportation by air can be taken up as a Corporate Social Responsibility (CSR) by corporates, the Indian Airforce can be involved in addition to the Ministry of Civil Aviation. Organ transportation by drones can also be considered.
- Facilities for Organ transportation by road/air ambulances should be available at subsidized 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 The United Network for Organ Sharing (UNOS) model has been in practice in Maharashtra for over 20 years should be looked into and implemented.

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 those

for registration of a transplant center. 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 the family is willing to donation of Organs and or tissues, then "In such non-registered hospital the death will be certified by two certified specialists 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 a registered NTORC or transplant hospital". In such cases, donor-specific/time-specific permission by Appropriate Authority may be granted when the 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, where actions to be taken.

Use ancillary tests to document the absence of cerebral blood flow as per international practices: BSD certifying specialist to decide the tests to be performed e.g., 4-vessel cerebral angio/CT cerebral Angio/MR angio/Trans Cranial Doppler/Isotope scan, depending on availability of facilities.

Any other

- In all cardiac deaths, the option of tissue donation should be offered.
- Role of digitization: the digitization of the Organ Donation Registry to avoid man-made errors.
- 24-hour call center at NOTTO.
- Tree plantation drives in the name of donors and other ways to honor their families.
- Awareness in schools and colleges on Organ donation.
- National Health Insurance for Organ Transplantation.
- Orientation and sensitization of various stakeholders like judges, legal experts, police, and traffic personnel, etc. on Organ donation and transplant centers.

WAY FORWARD

It is a well-known fact that Non Governmental Organisation (NGO) in the past have played a pivotal role in the promotion of eye and blood donation. An inclusive working group is required 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 NGOs.

Increasing awareness:

- More full-time manpower and budget should be allocated to NOTTO and NOTP.
- Creation of modified UNOS model of Organ Procurement and Transplantation Network (OPTN) and Organ Procurement Organisations (OPOS) as being practiced 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 center and ICU) and prominent places (such as shopping malls, railway stations, government offices, and banks). The "Ang Daan Jeevan Daan" posters having toll-free numbers should be installed at important places in all hospitals.
- If any Organ donation and transplantation is being performed, such an event may be displayed on LED or as a 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 the driving license 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 and transplant (identify medical colleges without infrastructure).
- Register all trauma centers as Organ retrieval centers.
- Have transplant coordinators in each hospital.
- Make intensivists and critical care doctors as Nodal officers.
- Creation of independent AA in each state.
- Reporting of long-term transplant recipient and donor outcomes to NOTTO should be mandated.
- Organ transplantation from deceased donors after cardiac death is underutilized in India and should be promoted.

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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 BSD 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 either due to brain stem or cardiac death.

Living donation: Organ donation by a living donor is 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 the criticality of the clinical situation by treating clinicians and intensivist, followed by confirmation of BSD by the 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 the family of a deceased individual.
B. Communication with local Organ Distribution Organizations in the state for organ allocation to recipients as per the organ-specific allocation guidelines.

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

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

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