

**National Organ & Tissue Transplant Organization
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services**

(Report)

**National Symposium on Legal and Ethical Aspects of
Organ Donation and Transplantation**

On

19th January, 2024

At

**India Habitat Centre, Lodhi Road, Lodhi Estate, New
Delhi-110003**

Organized by

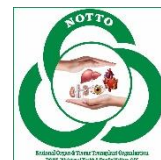
**National Organ & Tissue Transplant Organization
(NOTTO)
Government of India**

TABLE OF CONTENTS

S.No.	Content	Page No.
1	Table of Contents	2
2	Agenda	3
	Summary Of Presentations & Panel Discussions	
3	Introduction	6
4	Structure of the Symposium	6
5	Panel Discussion 1- Key Legal Procedures	7
6	Panel Discussion 2- Brain Stem Death: Challenges and Possible Solutions	10
7	Inauguration Session	13
8	Panel Discussion 3- “One Nation One Swap Program”	15
9	Panel Discussion 4- Issues with Organ Donation and Transplantation of Foreigners in India	17
10	Panel Discussion 5- Facilitating Organ Donation and Transplantation in General and in Medico Legal Cases	18
11	Panel Discussion 6- Possible Legal and Ethical Solutions in Organ Transplantation in India	19
	Key outcomes and action points	
12	Key outcomes and action points	22
	List of Participants	
13	Annexure 1: List of Participants	24
	Picture Gallery	
14	Annexure 2: Picture Gallery	30

AGENDA

Symposium on Legal and Ethical Aspects of Organ Donation and Transplantation



Theme: Uniform legal and ethical guidelines for organ donation and transplantation across the nation in alignment with the vision of “One Nation, One Policy”

S. No	TIME	ACTIVITY	NAME OF SPEAKER/MODERATOR /PANELIST
	09:00AM -09:30AM	REGISTRATION	
1		Key note address(es)	
1.1	09:30AM – 09:50AM	Organ Donation & Transplantation in India: Legal framework and responsibilities of various authorities	Dr. Anil Kumar (Director NOTTO)
1.2	09:50AM – 10:10AM	Ethical Dilemmas & Challenges in Organ Donation & Transplantation in India	Dr. Sanjay Nagral (Co-chair, DICG)
2	10:10 AM - 11:10AM	Panel Discussion on “Key Legal Procedures”	Dr. Anil Kumar (Director, NOTTO) (Moderator) Dr L Dorairajan, In-charge, Authorization Committee, JIPMER
2.1	10:10 AM - 10:20 AM	Procedure of registration of Transplant/Retrieval centres and tissue banks with NOTTO	Sh. Sandeep Rawat, NOTTO
2.2	10:20 AM- 10:30 AM	NTORC <ul style="list-style-type: none"> • Simplifying Registration Process • Problems and Possible Solutions • Empowerment 	Dr. Sunil Shroff, Managing Trustee, Mohan Foundation & Honorary Consultant, Madras Medical Mission Hospital
2.3	10:30 AM- 10:40 AM	Approval of Living Donors by Competent Authority / Authorization Committee: Procedures & Checklist	Dr. Anil Agarwal, Director, GB Pant Hospital New Delhi
2.4	10:40 AM- 10:50 AM	Consent for transplant surgery: Legal rights of donors and recipients	Sh. Mahendra Kumar Bajpai, Advocate Supreme Court of India and Hon. Director, Institute of medicine and Law
2.5	10:50 AM – 11:00AM	Legal aspects of Data privacy	Prof. (Dr.) Sanjay K. Aggarwal, Senior Nephrologist, Ex HOD AIIMS, New Delhi
2.6	11:00 AM – 11:10 AM	Recent high court judgement on Functioning of Authorization and Appellate committee	Dr Shobhika Shree, MO NOTTO
	11:10 AM- 11:30 AM	TEA BREAK	
3	11:30 AM -12:30 PM	Panel Discussion on Brain Stem Death: Challenges and Possible Solutions	Dr.Deepak Gupta(Moderator)
3.1	11: 30AM- 11:40 AM	Brain Stem Death Audit in ICUs to maximize deceased organ donation	Dr. Rahul Pandit
3.2	11:40AM-11:50AM	Difficulties in Declaring Brain- Death – Battling the Perceptions	Dr. Easwer HV

3.3	11:50 AM – 12:00 PM	<ul style="list-style-type: none"> • Can BSD certification be made mandatory? • Withdrawal of ventilatory support after BSD: Current Status and way forward 	Dr. Nobel Gracious
3.4	12:00PM- 12:30 PM	<ul style="list-style-type: none"> • Controversies in BSD- Current Legal Status of BSD, need for uniform declaration of death. • Minimum no. of donation/transplantation required for renewal of license of retrieval centres and/or transplant centres 	Dr. SK Mathur Dr. Dhawani Mehta (Vidhi Law Firm) Dr Arpita Roy Chaudhary
4	12:30 PM- 01:00 PM	Inauguration session	
4.1	12:30 PM- 12:35 PM	Lamp Lighting and Saraswati Vandana	
4.2	12:35 PM- 12:40 PM	Welcome address	Dr Anil Kumar, Director, NOTTO
4.3	12:40 PM- 12:50 PM	Address by Special Guest	
4.4	12:50 PM – 12:55 PM	Address by DGHS	Prof. (Dr.) Atul Goel
4.5	12:55 PM- 01:00 PM	Address by Secretary (H&FW)	Shri. Apurva Chandra
	01:00 PM- 02:00 PM	LUNCH	
5	02:00 PM – 02:40PM	One Nation One SWAP Program	Dr Sourabh Sharma (Moderator)
5.1	02:00 PM- 02:10 PM	One Nation One SWAP Program to expand donor pool: Legal/Ethical Challenges & Solutions	Prof. Vivek Kute (IKDRC) (Speaker/Panelist)
5.2	02:10 PM- 02:20 PM	Alliance for Paired Kidney Donation: Suggestions for India	Sh. Atul Agnihotri, Chief Growth Officer APKD, USA (Speaker/Panelist)
5.3	02:20 PM- 02:40 PM	Panel Discussion	Dr. Vineet Mishra Dr Anup Kumar Dr Himanshu Verma Dr Vipin Kaushal Dr. Manish Balwani, Secretary ISOT
6	02:40 PM – 03:30 PM	Panel Discussion: Issues with Organ Donation and Transplantation of Foreigners in India	Dr Awadhesh Kumar Yadav, Joint Director NOTTO (Moderator)
6.1	02:40 PM – 03.30 PM	Deceased donation from Foreigners in India: Challenges and Possible Solutions	Dr Harsha Jauhari, SGRH Dr. Sunil Shroff Dr Sanjay Nagral Dr SK Mathur Dr. S. Senthilnathan (IH Division) Ms.Pallavi kumar Law Expert- Dr. Sanjay Jain Representative BOI/Ministry of External Affairs
6.2		Ethical Challenges in Foreigners coming for Transplants in India: Reforming the Regulatory Procedures (s) for dealing with foreigner cases of transplant and NOC from Embassy	
6.3		Can we facilitate transplant of foreigners waiting for more than a certain number of years and in super urgent critical cases.	
6.4		Stakeholders for real time data sharing with NOTTO for Foreigners Organ Transplant	
6.5		Post- Transplant follow up of Foreigners	
7	03:30PM- 04:10PM	Facilitating organ donation and transplantation in General and in Medico Legal Cases	Dr S S Lalwani (Moderator)

7.1	03.30 PM- 03.40 PM	Legal reforms for augmenting organ donation and transplantation	Ms Dhvani Mehta, Vidhi Centre for Legal Policy, New Delhi
7.2	03.40 PM- 03.50 PM	Tamil Nadu experience in Facilitating deceased organ donation	Dr. Amalorpavanathan
7.3	03.50 PM- 04:00 PM	Proposal for reforms for augmenting Organ Donation in Medico Legal Cases	Dr. Thejaswi HT, HoD Forensic Medicine, Dr RML Hospital
7.4	04:00 PM – 04:10 PM	Panel Discussion: Medico Legal Cases	Dr. Sarvesh Tandon, HoD Forensic Medicine, SJH Hospital Representative, Dept of Legal Affairs
	04:10 PM- 04:30 PM	TEA	
8	04:30 PM- 05:15 PM	Panel Discussion: Possible Legal and ethical solutions in Organ Transplantation in India	Dr Avnish Seth (Moderator)
8.1	04:30 PM- 04:40 PM	Ethical responsibility of organ donation, allocation and retrieval teams in multi organ donations: Need for audit, training and awareness of responsibility of their roles.	Dr Vrishali Patil
8.2	04:40 PM- 04:50 PM	Legal challenges and solutions in DCD (Donation after Cardiac Death) in India	Dr. RK Mani
8.3	04:50 PM- 05:15 PM	Is India ready for an opt out system for Organ Donation Incentivization of BSD Certification & Retrieval team Protection of Living Donors: Mandatory health insurance for living donors	Dr. R Raghvendran Dr Pranjal Modi Dr Sumana Arora Dr Arti Vij IRDAI representative
9	05.15PM to 5.45 PM	Summarization of Days Proceeding and Action Points/ Resolutions	Dr. Anil Kumar Dr Reena Paul, Consultant NOTTO Mrs Girija Sikarwar, Coordinator NOTTO
10	05:45 PM- 05:50 PM	VIDEO Messages (NOTTO/ Pledging)	
11	05:50 PM- 05:59 PM	Vote of Thanks	Dr. Shiny Suman Pradhan (NOTTO)
12	05:59 PM- 06:00 PM	National Anthem	

SUMMARY OF PRESENTATIONS & PANEL
DISCUSSIONS

Introduction:

The national-level symposium on 'Legal and Ethical Aspects of Organ Donation and Transplantation' was held on Friday, January 19, 2024, at India Habitat Centre, New Delhi, hosted by the National Organ & Tissue Transplant Organization. The theme of the event was **Uniform legal and ethical guidelines for organ donation and transplantation across the nation in alignment with the vision of "One Nation, One Policy."**



Structure of the Symposium:

This symposium witnessed the enthusiastic participation of over 170 people, including various legal experts from the Supreme Court and the High Court, medical experts in the field of organ donation & transplantation, and representatives from ROTTOs and SOTTOs. The event was divided into eight sessions, covering the following broad topics:

- 1) Key note address by Dr. Anil Kumar and Dr. Sanjay Nagral
- 2) Panel Discussion on Key Legal Procedures
- 3) Panel Discussion on Brain Stem Death: Challenges and possible solutions
- 4) Inauguration session
- 5) Panel Discussion on One Nation one SWAP Program
- 6) Panel discussion on Issues with Organ Donation and transplantation of foreigners in India
- 7) Panel Discussion on Facilitating Organ Donation and Transplantation in General and in Medico Legal Cases
- 8) Panel Discussion on Possible Legal and Ethical Solutions in Organ Transplantation in India

Dr. Anil Kumar (Director NOTTO) welcomed the participants and delivered the key note address on estimated need and gap of organ donation and transplantation in India: Legal framework and responsibilities of various authorities where he highlighted the current status of organ donation and transplantation in India, organ transport policy, Aadhar authenticated digital pledge campaign.



He also underlined the idea of establishing at least one multiorgan transplant centre in each state along with one organ retrieval centre in every medical college and to identify the skill centres for training purpose and emphasized on One Nation, One Allocation Policy, One Portal for National Registry and Digitalized Allocation.

Dr. Sanjay Nagral (Co-chair, DICG) was then invited to deliver key note address on ethical dilemmas and challenges in organ donation and transplantation in India. He talked about the various aspects of ethics in organ donation and transplantation wherein he highlighted the non-uniformity in the transplantation process globally and pointed out the recent global guidelines specifically highlighting the Declaration of Istanbul. These guidelines oppose commercialism in transplantation, trading and trafficking which is the focus of the Declaration of Istanbul. They also oppose the violation of human rights. The idea behind all this is to promote public trust in the process of donation.



One of the challenges that he shared was that of the cost involved in transplantation. Another challenge would be that the Brain Stem Death should not be looked only from the point of view of organ donation. So, the idea that we should have a national policy is essentially inevitable but we need to integrate local views and we also need to encourage the privacy and yet we need to remove inequity with structural biases. Also, we need to be careful about elite capture and precaution. We need to bring in professional procedure and policy and procedural uniformity at the same time.

Panel Discussion 1- Key Legal Procedures



The session was moderated by Dr. Anil Kumar, and the panel members were Dr. Sunil Shroff (Managing Trustee, Mohan Foundation), Dr. Sanjay K. Aggarwal (Sr. Nephrologist, AIIMS), Dr. Anil Agarwal (Director, GB Pant & In Charge of Delhi Organ Transplant Cell), Sh. Mahendra Kumar Bajpai (Advocate, Supreme Court of India), Dr. Shobhika Shree (MO, NOTTO), and Sandeep Rawat (IT, NOTTO).

Sandeep Rawat presented the procedure for registration of transplant/retrieval centres and tissue banks on the NOTTO website.



Dr. Sunil Shroff presented a presentation on Non-Transplant Organ Retrieval Centres (NTORC), where he gave the definition of NTORC and explained the role of NTORC by showing the statistics of hospitals and the deaths that occur in our country, the criteria for becoming a NTORC, and the conditions and standards required for the registration process.

Problems/ Challenges:

- Getting a NTORC license is cumbersome; the form itself has 49 fields.
- Inadequate knowledge leads to poor documentation of brain death certification.
- How to handle postmortem cases
- Lack of resources for maintaining brain death donors
- Lack of knowledge in brain death declarations, not only in public but also among doctors
- Problem of funding for NTORCs
- Shortage of manpower, non-availability of brain death-certifying experts



Possible Solutions:

- Simplify Form 13
- Providing SOPs, developing checklists, and creating state-specific flowcharts in MLC cases
- Sensitize police and forensic
- Should make 700 medical colleges as retrieval centres, and in the second phase, they can become transplant centres.
- There is a need to promote awareness through professional bodies like the IMA, and training opportunities need to be provided.
- can provide funding to these medical colleges to implement the infrastructure.
- Highlight the donations in the media and the helpline for NTORCs. NTORCs will certainly help in improving organ donation in the country.

Dr. Anil Aggarwal talked about the approval of living donors by the Competent Authority/Authorization Committee. He explained the composition of the competent authority and the procedures and checklist for the same.

Recommendations:

- DNA profiling can be suggested in cases where poor documentation or documents are suspected to be fabricated.
- SOPs should be made for SWAP donations.
- Minor living donors in cases of exceptional medical grounds should only be allowed after in-depth justification with prior approval from appropriate authorities and state government concerns.



Advocate Sh. Mahendra Kumar Bajpai talked about consent for transplant surgery and the legal rights of donors and recipients. He emphasized that if a person has already consented in Form 7 to organ donation during his or her life, then the additional consent from relatives after his/her death is morally and ethically not correct.



Dr. Sanjay K. Aggarwal elucidated the legal aspects of data privacy and highlighted the importance of protecting data privacy laws for donors and recipients in the process of organ donation. He also explained the Digital Personal Data Protection Bill passed by the Government of India.

Recommendations:

- There is a need for a robust law for the protection of the data privacy of donors and recipients in the process of organ donation as the medical history and records are shared.
- There is a need for transparency and ethical practices in the handling of personal data related to organ transplants.
- Deceased donor details, such as name and identifiable information, should not be published in the media.



Dr. Shobhika Shree presented the recent two Delhi High Court judgements for approval of near-relative living donations, wherein one of the presentations, she explained the prescribed timelines of the entire process of submission and approval for the authorization committee to function as given in by the Hon'ble Court in its order and in the second, support required by the donor for good accommodation and a clean environment post-surgery to be provided by the recipient. She also mentioned the ministry order for the same.



During the discussion, Director NOTTO highlighted the second judgement, where any kind of support could be interpreted as anything, and that needs to be challenged. The Law Ministry was approached for the same, and they agreed.

Further, Advocate Dhvani Mehta was asked: Can the first judgement be the guidelines for the whole country or can it be for Delhi as passed by the Delhi High Court? For this, she responded that, as a matter of good policy, uniform guidelines can be made.

Adv. Sh. Mahendra Kumar Bajpai made the point that some judgements are case-specific, so we should see whether that judgement is setting precedent. The health ministry has the power to make guidelines. Dr. Sunil Shroff suggested that NOTTO should make clear guidelines on post-surgery donor management. Dr. Sanjay Nagral made the point that a donor has a right to be looked after; now, who should look after and upper limits are matters of discussion as donors often take leave and lose income.

Recommendations:

Draft guidelines and timelines for functioning of Authorization Committee may be prepared by NOTTO and shared with stakeholders for public comments before finalization.

Panel Discussion 2- Brain Stem Death: Challenges and Possible Solutions



The discussion was moderated by Dr. Anil Kumar and the panelists were Dr. Easwer HV, Dr. Nobel Gracious, Dr. SK Mathur, Ms. Dhvani Mehta and Dr. Arpita Roy Chaudhary.

Some of the issues shared by Dr. Easwer through his experiences are as below:

- Although critical care and number of ventilators have improved in our country post-covid, still Brain Stem Death (BSD) declaration is low due to lack of sensitization among the doctors.
- Harassment of the BSD certifiers by police due to lack of proper law and guidelines especially in Kerala.
- Post-mortem/ autopsy takes another 24-48 hrs after BSD declaration which is a difficult time for the relatives of the donor and need to be facilitated.
- Lack of Standard Operating Procedures (SOP's) other than the THOTA as THOTA still has grey areas on situations such as certifying brain stem death where suggested neurological tests are not possible. In such cases, which ancillary tests should be conducted has not been clarified.
- BSD certification for children or new born/ neonates is still unresolved.



Possible solutions as mentioned by him are:

- There is a need to alter our medical curriculum that includes BSD also as a form of death, mid-career educational programs should be there and nurses and ASHA workers should be included to spread the message.
- NOTTO should come forward with directives stating BSD declaration to be a statutory process and guide the legal process of BSD certification.
- Doctors should be compensated for the time and effort they put in for declaration of brain stem death and transplantation.
- Auditing of Brain Stem Death certification, should be made mandatory to avoid any kind of unnecessary litigation and in order to improve the quality of services.
- Although Tamil Nadu has already started autopsy to happen parallelly with organ retrieval, NOTTO should come forward with sufficient directions and legal corrections required for this happen in all the states.
- Centers of Excellence should be set up by Government to increase the involvement of Public hospitals in transplant as they are the only ray of hope for poor people.
- Sustained media campaign in order to bridge the awareness gap.
- In order to increase the organ donation rate, NOTTO should come forward to involve religious gurus and leaders for awareness and sensitization purpose to increase the involvement of their communities.

Dr. Nobel Gracious next talked about BSD certification and withdrawal of ventilatory support after BSD. He explained the current process of BSD certification and stated that declaration of death by BSD certification criteria has been given a legal recognition in THOA 1994, still the current law has confusion regarding how the BSD will be certified in two different hospital settings if BSD takes place in a non- transplant hospital or NTORC. As already the declaration of BSD has been made mandatory by the Government of Kerala, still hospitals are not reporting it, hence any executive orders or Government orders are not sufficient to declare BSD if doctors are not ready or willing to declare BSD. Also, when certified, Form 10 already states that the patient is dead, so no other certification is required, hence there is no ambiguity regarding removal of ventilatory support after Brain Stem Death.



Dr. SK Mathur raised a question that “if death has been defined under any act/ law of India, is it applicable uniformly or not”. Opinions were that the definition is mentioned under a particular act, it will be applicable to that particular act/ law only. Therefore, in order to have a common definition of death, Ministry of Health should approach the Supreme Court and if required get the definition of death passed from the parliament accordingly. THOTA needs to be modified to allow organs to be used for the purpose of research also which will allow marginal organs to be utilized. Strict rules are required under the law for the protection of doctors declaring BSD.



Dr. Arpita Roy Chaudhary mentioned that since the inception of THOTA, we have not progressed much and the growth is uneven which indicates non-comfort in declaring BSD. Hence, BSD must be de-linked from organ donation.

- She further suggested that medical curriculum must include every single part of organ donation and the related law.
- Modifications in the allocation criteria are required.
- All the medical colleges can be declared as NTORC's.
- Quarterly training should be implemented for medical staff related to organ donation and transplantation.
- Problem, discussion with the NTORC's for possible solutions and hand holding till the center matures is needed.
- Renewal of license for transplant centers must include questions such as the



presence of transplant coordinator, number of BSD's declared, number of families counselled, number of organs donated, etc.

- Equal medical care and attention must be provided to elderly with transplants unbiased as results have shown that elderly patients also respond well and have better survival.

Conclusively, Ms. Dhvani Mehta came forward with 3 key legal interpretations as mentioned below:

- Brain Stem Death is an objective clinical fact and is a procedure that can be carried out by doctors irrespective of the fact that there is a consent for organ donation or not. As there is already sufficient text available clinically, this should be accompanied by strong medical guidelines.
- BSD can be recognized as a legal form of death without any doubt.
- Treatment or life support can be withdrawn from a brain-dead person without having to follow the "Three Tier Process"



The panel discussion ended with a brief note on the "Three Tier Process" that includes broadly the formation of two different medical boards for declaration of death and informing the district magistrate for the withdrawal of life support. Also, panel members emphasized on the need for rapport building and counselling of BSD patient relatives.

Inauguration Session



The session began with the felicitation of distinguished guests namely Sh. Elangbam Robert Singh (JS, MoHFW), Prof. (Dr.) Atul Goel (DGHS, MoHFW), Dr. Anil Kumar (Director, NOTTO), Sh. Adish Agarwal (Advocate President, Supreme Court Bar Association) and Dr. Pranjal Modi (Director, IKDRC) and further proceeded towards the lamp lighting session.

Dr. Anil Kumar (Director NOTTO) welcomed the esteemed guests and thanked Dr. Atul Goel for his guidance and expansion of the transplant program nationally as well as internationally. He further thanked Sh. Elangbam Robert Singh for his constant support towards the transplant program of India. He emphasized on the aim of the conference that is to bring in uniformity in a legal and transparent manner and to find solutions to various issues related to organ and tissue transplantation.

Moving further, Sh. Elangbam Robert Singh addressed the gathering and delivered his speech on organ donation and transplantation. He stated that it is our responsibility to ensure that our healthcare system operates in a compassionate manner and it is imperative that our approach is of highest ethical standards. He also talked about the huge requirement of transplants as compared to the donation citing the figures of organs availability versus requirements which is continuously growing.



Therefore, the need for regular assessment and refinement of legal instruments such as THOTA to address emergency challenges like organ donation, ensuring transparency and allocation mechanism is required. He emphasized on the solutions for speedy disposal of grievances received regarding delay in acceptance of applications for organ donation by various authorization committees and institutions. He added that India's third rank worldwide in organ donation and transplantation is a testament of tireless efforts of our states and medical professionals, along with that also raised a concern on the non-reporting of data specially living transplant data by the states. And, he wished the symposium to be a platform to discuss and work upon such issues to achieve the call of "One Nation One Policy on Organ Donation and Transplantation".

Sh. Adish Agarwal also addressed the gathering and applauded the efforts of NOTTO for hosting such an event. He appraised the efforts of current Government in helping the speedy amendments required in the existing acts and legal system. He emphasized on the necessity and importance of digitization in any sector.



Dr. Pranjal Modi then appreciated the efforts of Director NOTTO towards organizing the symposium. He further addressed the gathering stating transplantation has to be a multidisciplinary approach that includes medical fraternity, law, ethics etc with service, education and research to be an integrated component of it. He emphasized on establishing a structure and function in such a way so as to establish one of the best transplant centers and universities. He also highlighted Gujarat University of



Transplantation Sciences and Institute of Kidney Disease and Research Center to be one of the first few in steps towards giving a model to the country which will work as benchmark to other parts of the country.

Prof. (Dr.) Atul Goel, Chief Guest shared wonderful words of encouragement with the gathering, emphasized bio-ethics, and elucidated the significance of prevention in order to reduce the number of organ failures. He shared the achievement of acceptance by court of flowchart of withdrawal of life support in the impending that situation with futility of care. He also requested that doctors be more patient-oriented and thoughtful about prescriptions and avoid prescribing unnecessary medications.



Panel Discussion 3- “One Nation One Swap Program”

The session was moderated by Dr. Sourabh Sharma and the panel members were Prof. Vivek Kute, Sh. Atul Agnihotri, Dr. Pranjal Modi, Dr. Anup Kumar, Dr. Himanshu Verma and Dr. Manish Balwani.



Recommendations:

- NOTTO, ROTTO and SOTTO should promote SWAP donation through IEC activities
- One nation one advisory is needed for SWAP transplantation along with state and central registry.
- No need to take legal permission from different states when donor and recipient are from different states. Hospital, district or state in which transplantation proposed to be done should give permission for the SWAP.
- Robust structural framework will be way forward for INDIA in view of swap donation and transplant.
- User friendly software for digitalized application and document verification (linked with Aadhar) can be helpful in streamlining and fastening the SWAP transplant.

- The transplant human organ reforms are needed. Single Window Clearance through NOTTO. (Action point Notto)
- Mandatory counselling about all replacement therapies so that patients can take informed decision before registering into deceased organ donors list.
- Process should be equity and utility based.
- Every document including marriage certificate to be available online.
- Creating trust b/w countries.
- There should be provision for inter organ transplant
- City wise list for living transplant donors.
- Software to be either at authorization committee level or at institute level
- Felicitation to the deceased donor family and incentives to support donor families in the form of any insurance or other benefits to boost their confidence.
- SOPs are required for paired kidney donation.
- APKD (Alliance for Paired Kidney Donation) software can be solution for India for best output in terms of kidney donation. It is an improvised version to cater all recent developments in medical science to give better output.

Way forward:

- Other than near relative donor to be given permission for SWAP donation. Need to amend the organ transplant act. (**Action point MOHFW**).
- Resist political influence
- Flow of organ to various sections of the society not to the riches only.
- There should be flexibility in organ donation system
- swap donation is the cost-effective way to expand the living kidney transplant donor pool.
- Same checklist criteria for all states.

Why one nation one transplant program

- donor pool increased in swap donation
- better quality of organ matches
- cost effective

Panel Discussion 4- Issues with Organ Donation and Transplantation of Foreigners in India



The session was moderated by Dr. Awadhesh Kumar Yadav and the panelist were Dr. Harsha Jauhari, Dr. Sunil Shroff, Dr. Sanjay Nagral, Dr. S.K Mathur, Dr. S Senthilnathan and Ms. Pallavi Kumar.

Recommendations:

- Mandatory NOTTO ID registration for all foreigners who are coming to India for transplantation.
- Portal for registration and transplant of foreign nationals to be explored in line with IH division under the aegis of NOTTO.
- Detail of arrival, transplantation, follow up and departure. All information under one portal.
- Arrangement of interpreter for foreign nationals
- Representative from the concerned embassy to be present at the time of consent.
- SOP's and guidelines are required for transplant in foreign nationals in India.
- Notto must be empowered to have all the information regarding the foreign donors and recipients.
- Strict audit to be in place in regards to the transplantation process of foreigners.



Panel Discussion 5- Facilitating Organ Donation and Transplantation in General and in Medico Legal Cases



The session was moderated by Dr. S.S. Lalwani and the panel members were Dr. Thejawsai HT, Dr. Yogendra Singh Bansal, Mr. Sanjay Kumar Nagpal and Dr. Sarvesh Tandon.

Tamil Naidu experience

Web application, Dedicated transplant coordinator, Dedicated transplant coordinator, Continuous training, are the few crucial things which strengthen the deceased donation program in Tamil Nadu.

Way forward:

All regions need to have homogeneous transplant facility so all the organs can be utilized within the region
Organ donation-legal cases

- More IEC to strengthen awareness with police and other stakeholders.
- NOC not be obtained from police.
- Simultaneous autopsy or virtual autopsy can be explored in view of strengthening the program.

In case of Brain Stem Death, hospitals need to inform the nearest police station, postmortem doctor and the retrieval team as soon as possible after confirmation of 1st apnoea test of a potential brain stem dead donor in medico legal cases. Physical presence of postmortem doctor is not required during organ retrieval as it takes 6-8 hours for retrievals to be completed. Therefore, simultaneous forensic examination is not feasible.

A discussion regarding the difference between the definitions of death for postmortem and organ donation and transplantation was done in detail, it was concluded that postmortem should be done subsequently rather than simultaneously, only after organ retrieval is done. Hence it may not be required for the postmortem doctor to be present alongside the transplant surgeon, as it will consume a lot of time of forensic experts.

It was discussed that protocol for virtual autopsy (postmortem CT) could also be an option before organ retrieval, however, it was opined that it may be as ascertained from radiology physicians, whether the

radiations used during virtual autopsy can cause damage to organs. Further, some samples of the potential donor can be collected prior to organ retrieval like urine, blood and vitreous fluid, which can be sent for toxicological analysis later on in MLC cases.

Honorarium for postmortem doctors deputed for postmortem in private hospital was also suggested for the postmortem doctors. Exemption for postmortem can be allowed in Medico Legal cases of railway accidents/Road Traffic Accidents (RTA), as it is already being practiced in many states of India like Rajasthan. It was emphasized that SOPs should be created in order to designate a nodal officer (SHO) at each police station, district, and state level. Additionally, it was considered for private hospitals that, should forensic experts not be able to arrive, retrieval may still occur with police clearance. Retrieval notes, which would be included in the post-mortem report, would be written for each patient.

Panel Discussion 6- Possible Legal and Ethical Solutions in Organ Transplantation in India



The session was moderated by Dr. Avnish Seth (HOD Gastroenterology & Hepatology, Manipal Hospitals) and the panel members were Dr. Vrishali Patil (Program Director, HOD Multiorgan Transplant & Hepatobiliary Surgeon, DY Patil Hospital), Dr. RK Mani (Director of Clinical Services, Yashoda Hospital), Dr. R Raghvendra (Director, Madras Medical College), Dr. Pranjal Modi (Director, IKDRC), Dr. Sumana Arora (Senior Consultant, NITI Aayog) and Dr. Sonal Asthana.

Dr. Vrishali Patil started the discussion through a presentation on ethical responsibility of organ donation, allocation and retrieval teams in multi-organ donations. She shared some of her experiences and difficulties faced in organ donation in everyday life. She put forth the idea of bringing opt-in system and spreading awareness regarding the organ donation pledge linked with AADHAR to be a valid consent. Emphasis was made on further clarification on distribution of responsibilities between the clinicians and the management of the hospital in terms of authentication of the patient and relatives. She suggested for bringing in the health insurance scheme for family of deceased donor and for the patient itself in case of living donor by the Government. She emphasized on asking for multi organ rather than individual organ consent.

In order to provide better transplant outcomes more number of investigations are required sometimes, which according to her, require either more funds or distribution of these funds. Hence, revised SOP's and guidelines on donor management are needed. Additionally, she stressed on the mandatory yearly audit including organ injury audit, precise operative summary, six months course for the coordinators and an established legal pathway to be contacted in case of any emergency.

Dr. Sonal Asthana shared his valuable comments that organ donations have increased in the past few years, but problems like availability of logistics are still major concerns. Huge gap persists between the deceased organ donations in the north and the south which is high in the south as compared to the north. Moving towards the end he stated that all over India, the system is individual led rather than system supported, the knowledge about law is still inconsistent and a lot of public versus private bias that needs to be confronted.



Moving further, Dr. RK Mani stressed on the importance of delinking organ donation from the withdrawal of life support highlighting drawbacks of continuing life support such as perpetuation of unethical activities, financial and emotional drain to the family, distress to the caregivers etc. Huge pool is available in case of cardiac death, which is not utilized to its full, as declaring cardiac death is not controversial as in the case of brain stem death. It can increase the organ pool which is an extremely desirable outcome.

Dr. R Raghvendran was then called to share his thoughts on “whether India is ready for opt out system”. He talked about the apprehensions of people on donating organs fearing their organs might be used for research purpose later. Also, experiences from other countries show that opt-out system increases initially to a certain stage and then becomes stagnant. The success of Spain is not only because of the opt-out system but also because of educating the public through mass media. So, every country needs to examine which system best aligns with their political system.



Also, he commented that the success of opt-out system relies on the clear communication from the state to the public responding to the public as and when required, improve human resource infrastructure, establishing registry and maintaining transparency. He suggested on implementing opt-out system in few states initially as a pilot project to see the outcomes and meanwhile maximally utilize the opt-in system.

Dr. Avnish Seth concluded the thought stating that opt-out system can initially be implemented for cornea donation and after proper research, accordingly results can be utilized for other organs as well. Dr. Pranjal Modi finalized the discussion by supporting on the provision of professional fee for the clinicians as it helps in the overall declaration of brain stem death.

Dr. Shiny presented a vote of thanks to the chief guest DGHS, other dignitaries, senior officers from Ministry & Dte. GHS, legal luminaries, panelists, speakers and participants for their active participation.



Key Outcomes and Recommendations

Key Outcomes and Recommendations

By the end of this symposium, the following key outcomes and action points are recommended by participants:

Development of Infrastructure:

- To increase organ donation, the government should register all 700 plus medical colleges as Non-Transplant Organ retrieval centres, and in the second phase, they can become transplant centres. The Government can provide funding to these medical colleges to build the infrastructure required.
- Centres of Excellence of Multi-Organ Transplant should be set up by the Government to increase the involvement of public hospitals in transplants, as they are the only ray of hope for poor people.

Reforms in law:

- Single Window Clearance through NOTTO (Action Point NOTTO) for implementing One-nation One Swap program.
- There is a need for a robust law for the protection of the data privacy of donors and recipients in the process of organ donation as the medical history and records are shared.
- Other than a near-relative donor may also be considered for giving permission for SWAP donation, for this we need to amend the Organ Transplant Act. (Action point: MOHFW).
- An opt-out system can initially be implemented for corneal donation, and after proper research, the results can be utilised for other organs.

Guidelines and SOPs should be made for the following:

- SOPs on SWAP donations.
- In MLC cases, state-specific flowcharts are required for providing SOPs and developing checklists.
- NOTTO should make clear guidelines and protocols for post-surgery donor and recipient management.
- Draft guidelines and timelines for the functioning of the Authorization Committee may be prepared by NOTTO and shared with stakeholders for public comments before finalization.
- SOPs should be created in order to designate a nodal officer (SHO) at each police station, district, and state level.

BSD Declaration:

- NOTTO should come forward with directives stating BSD declaration to be a statutory and mandatory requirement and guide the legal process of BSD certification.
- Doctors should be compensated for the time and effort they put in for the declaration of brain stem death and transplantation.
- Auditing of brain stem death certification should be made mandatory to avoid any kind of unnecessary litigation and to improve the quality of services.
- Brain stem death is an objective clinical fact and is a procedure that can be carried out by doctors irrespective of whether there is consent for organ donation or not. As there is already sufficient text available clinically, this should be accompanied by strong medical guidelines.
- BSD should be recognized as a legal form of death without any doubt and information should be widely disseminated.

Registry and digitalization:

- One nation-wide advisory is needed for SWAP transplantation, along with a state and central registry.
- APKD (Alliance for Paired Kidney Donation) software can be considered as a solution for India for the best output in terms of kidney donation, already software is being used in IKDRC. It is an improvised version to cater to all recent developments in medical science and give better output.
- User-friendly software for digitalized applications and document verification (linked with Aadhar) can be helpful in streamlining and fastening the SWAP.
- Portal for registration and transplant of foreign nationals are to be explored in line with the IH division under the aegis of NOTTO. Details of arrival, transplantation, follow-up, and departure; all information should be under one portal. A strict audit is to be in place in regards to the transplantation process for foreigners.
- City-wise list for living transplant donors can be part of the registry.

Awareness-related recommendations:

- In order to increase the organ donation rate, NOTTO should come forward to involve religious gurus and leaders for awareness and sensitization purposes to increase the involvement of their communities.

LIST OF PARTICIPANTS

LIST OF PARTICIPANTS

S.No.	Confirmed Participants	Institution
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2	Mr. Zuber Ahmed Khan	DS, MoHFW
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Picture Gallery

Picture Gallery



Pic 1: Participants



Pic 2: NOTTO Staff



Pic 3: Inauguration of National Symposium



Pic 4a



Pic 4b

Pic 4a: Address by Director General of Health Services

Pic 4b: Address by Director NOTTO



Pic 5: Participants attending the National Symposium