SOTTO GUJARAT-STUDY OF ENABLING FACTORS IN DECEASED ORGAN DONATION

Dissertation Submitted to the Panjab University, Chandigarh for the award of degree of **Executive Masters in Public Administration and Public Policy,** in partial fulfilment of the requirement for the Advanced Professional Programme in Public Administration (2023-24)

Submitted by

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INDIAN INSTITUTE OF PUBLIC ADMINISTRATION

NEW DELHI

SELF DECLARATION CERTIFICATE

I, the undersigned hereby declare that the dissertation titled **'SOTTO GUJARAT-Study of Enabling Factors in Deceased Organ Donation '** ,submitted by me for the award of the Degree of Executive Masters in Public Administartion is original and this work or part thereof has not been submitted for the award of any degree or diploma either in this or any other University. All the sources I have accessed or quoted have been indicated or acknowledged by means of references.

Date : March

Place : New Delhi

(Manoj Somasekharan)

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CERTIFICATE

I have the pleasure to certify that Brig Dr Manoj Somasekharan **,** has pursued his research work and prepared the present dissertation titled '**SOTTO GUJARAT-STUDY OF ENABLING FACTORS IN DECEASED ORGAN DONATION'** , under my guidance and supervision. The same is the result of research done by him/her and to the best of my knowledge; no part of the same has been part of any monograph, dissertation or book earlier. This is being submitted to the Panjab University, Chandigarh, for the purpose of **Executive Masters in Public Administration and Public Policy** in partial fulfillment of the requirement for the Advanced Professional Programme in Public Administration (APPPA) of Indian Institute of Public Administration (IIPA), New Delhi.

I recommend that the dissertation of Brig Dr Manoj Somasekharan is worthy of consideration for the award of Executive Masters degree of the Panjab University, Chandigarh.

Date March

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This research was educative, as much as it, installed a sense of hope and confidence in me, about the direction of Health policy in India, especially in the area of Organ Donation and Transplantation. Iam sure it will provide impetus for further research in this field. JAI HIND

Date: March 2024

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CONTENTS

CHAPTER 01
INTRODUCTION

1.1 BACKGROUND

Organ transplantation is the ultimate treatment for the patients with end organ failure. However, there is a demand and supply mismatch in organ transplantation across the countries. In India too ,the gap is fairly wide .Thousands of patients die every year waiting for an organ for transplant.The two accepted ways of getting an organ are from (i) an Alive person like a relative or ii) a Deceased person. A single Deceased person like a patient of road accident or a brain catastrophe like a stroke can help upto 8 other patients. However the deceased organ transplant numbers are dismal in India being <0.8/ million whereas death due to road accidents alone is >160000/year.[1]

The commonly transplanted organs are Kidneys, Liver, Heart, Pancreas, Gut etc. Corneal and other tissues like skin too are transplanted. The demand for the organs are to tune of 175000 kidney recipients in waiting lists and 40000 liver recipients in waiting till 2022 ,many of whom will die waiting. However the total kidney transplant in 2022 for the country was 10164 living and 1541 deceased donor kidneys and for liver transplant, 3174 living donor and 737 from deceased donors.[2] Even in this there is a state wise disparity with some state like Tamilnadu,Gujarat,Telengana etc doing better than rest of the country.

Common reasons or barriers for transplant of deceased organs are both at Individual, Institutional & Governmental levels. The individual reasons are lack of awareness, suspicion of mal intent of the hospital, religious beliefs, suspicion of mutilation of the body of the dear one etc. At an institutional level, the barriers are the lack of identifying potential brain stem death, the apathy to counsel ,lack of a transplant coordinator or team, lack of protocols. At a policy level the reasons can be, lack of public awareness about organ donation, poor media management, proper policy and policy support like incentives or cash support for post transplant etc.India surely needs to push up deceased organ donation substantially from current levels to cater for the existing needy patients.It also needs to encourage many more transplant centres and states to actively pursue organ donation.

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[1] Ministry of Road Transport and Highways, Government of India.
https://morth.nic.in/sites/default/files/Road_Accident.pdf Accessed 11 February 2024

[2] Navin S, Suryamoorthi S. Current state of acceptance of brain stem death and organ donation in India. Amrita J Med. 2022;18:65–67. doi:10.4103/ AMJM.AMJM

The corrective measures in India have been started for quite some time. Government of India has passed the Transplantation of Human Organ Act in 1994[3] which came into force in 1995. Further, a national organ registry was set up in 2005. The act underwent an amendment in 2011 to set up National Organ and Tissue Transplant Organisation (NOTTO)[4] and National Organ and Tissue Transplantation rules in 2014. It was tasked with main focus on promotion of deceased organ donation, prevention of commercial trade of organs and creating a National registry[5]. Accordingly, states have to set up their own State organ and tissue transplant organisations (SOTTOs). Organ Transplantation in India is still picking up and we follow the opt in system for the same. Many states have constituted the SOTTOs, however a large part of East India and the North East still are yet to do so. Government is proposing to create a medical college in every district of the country and all of these will have the basic infrastructure for Transplantation work.

FIGURE 1
2016 AUGUST ARTICLE IN TOI NEWSPAPER ON ORGAN DONATION

Gujarat SOTTO leads the country in the Deceased Organ Donation in the country by percentage of Deceased organs transplanted .It won the PM Excellence award in Public administration in 2022. Why it is succeeding in Deceased organ donation, where many other

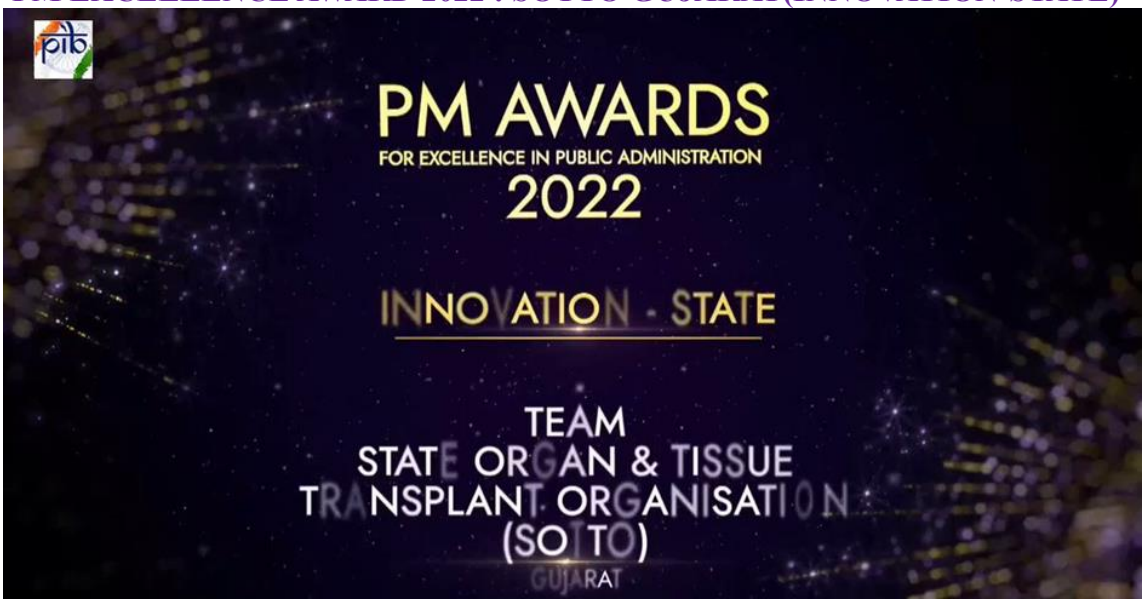
[3] The Transplantation of Human Organs and Tissues Act. 1994. https://www.indiacode.nic.in/handle/123456789/1962?sam_ handle=123456789/1362 Accessed 11 January 2024

[4] Ministry of Law and Justice (Legislative Department). The Transplantation of Human Organs (Amendment) Act, 2011: An Act to amend the Transplantation of Human Organs Act, 1994.

[5] National Organ & Tissue Transplant Organisation (NOTTO). National Organ Transplant Programme guidelines. https://notto.gov.in/WriteReadData/Portal/News/772_1_final_BOOK.pdf. Accessed February 10, 2024.

states have not, is an area of interest, and it was decided to take a closer look at the Deceased Organ Donation program in Gujarat.

FIGURE 2
PM EXCELLENCE AWARD 2022 : SOTTO GUJARAT(INNOVATION-STATE)



1.2 PURPOSE OF THE RESEARCH

GUJARAT SOTTO has worked remarkably well and has contributed to 35% of all donated organs in 2022 being from deceased donors. It likely has a well oiled system which has got streamlined Government machinery, Policy, Institutions and Transplant coordinators. The data of transplant of Gujarat of Deceased Organs in 2017 and 2022 show that in 2017, 106 kidneys & 63 livers were transplanted from deceased persons. This has shown an exponential rise to 252 Kidneys and 124 livers transplanted from deceased in 2022.

The Gujarat SOTTO was, therefore, given the PM Excellence award in 2022[6] for the same reason. This study covers Gujarat transplant programme, as its success over a short period provides hope of enabling factors which if identified and replicated may provide other states with an impetus in their transplant programs.

[6] https://government.economictimes.indiatimes.com/news/governance/gujarat-wins-pms-awards-for-excellence-in-public-administration-in-2-categories/99666314?utm_source=copy&utm_medium=pshare

1.3 RESEARCH STRATERGY AND RESEARCH DESIGN

Using Qualitative research methodology the proposed study covers Gujarat SOTTO at the Institutional level and Governmental level. The study particularly covers transplant of kidney and liver which are most crucial parts of human body.

Few transplant centres will be identified and their work loads of deceased organ retrieval for Kidney & Liver in a time series data will be compared.

In addition the transplant coordinators will be interviewed through a structured questionnaire .

At Governmental level ,select interview also will be held to cover the top policy makers of Gujarat and SOTTO dealing with organ transplant to understand the states initiatives and NOTTO at national level.

1.4 JUSTIFICATION

A rapid increase in deceased organ transplant in Gujarat has been due to intervention at institutional or governmental level as changes in Individual factors of beliefs ,religion etc will take time.The study focusses on these two aspects to understand better the enabling factors .

The study will be based on two time periods(2016-2018) vs (2020-2022) to serve as a comparison and an internal control mechanism for other confounding factors identified.

1.5 RESEARCH QUESTIONS

1. How the Deceased organ retrieval and transplantation in Gujarat has undergone a change from 2016 to 2022 ?

2. What are the factors responsible for improvement in Deceased organ transplantation in Gujarat ?

3. What are the enabling factors at Policy and Institutional level in SOTTO Gujarat which can be applied nationally to promote Deceased Organ Donation?

1.6 METHODS AND DATA SOURCES-

QUALITATIVE RESEARCH

1. Collection of Primary Data- A visit to Ahmedabad was done for a week to collect organ retrieval and transplant data on Kidney and Liver transplants and interact with the relevant policy makers at State Government and Regional SOTTO. Interactions with Doctors working in Organ donation,ICUs and Transplantation also was done.

2. Got data on a Pre structured Questionnaire for transplant coordinators of these high volume transplant hospital under SOTTO Gujarat. **(APPENDIX A)**

3. Obtained Relevant Data from Secondary sources like Guidelines, Media, NGOs about state interventions for improving transplant rates.

4. An interaction was done with NOTTO Director and national level inputs taken. The Data on Gujarat prior to establishment of SOTTO in 2019 and Live transplantation data both for Gujarat and India was collected from NOTTO.

1.7 STRENGTHS OF THE STUDY

1.Detailed interaction with Transplant coordinators who have for years coordinated transplants,all over Gujarat.

2.Interaction and Inputs from the Doctors at the largest Government Hospitals in Ahmedabad and Surat.

3.Interaction and Inputs provided by Covener SOTTO Gujarat,himself a transplant surgeon for > 25 years & Director NOTTO which has given a broader perspective at Policy level.

4.Complete and verified Organ Transplant data of Gujarat and India for the period 2016-2022.

5.The researcher himself being a Neurologist ,has background knowledge on Brain death and Organ donation and this has helped in conducting this research.

1.8 LIMITATIONS OF THE STUDY

1. There are numerous organs transplanted : however the study limited itself to the two most commonly transplanted organs-kidney and liver from Deceased Donors.

2. The study focused on enablers at Policy and Institutional level: The community and the Donor families were not approached in this study and are spread all over Gujarat.

3. Comparison to another state SOTTO would have made this study canvas too broad and heterogenous: hence it was restricted to Gujarat SOTTO and comparison with all India figures.

4.The COVID pandemic in 2020-2021 reduced all surgeries in India including Organ transplantation.

CHAPTER 2
REVIEW OF LITERATURE

2.1 ORGAN FAILURE AND TRANSPLANTATION

India with its 140 crore population has an ever improving health system and longeivity of its population .However the life style diseases are on an increase like Hypertension, diabetes, obesity, cardiovascular diseases etc.Also the complications of these diseases like organ dysfunction and organ failure like kidney, liver failure. We will briefly take a look on these common organ dysfunctions and transplantation scenarios.

2.1.1 KIDNEYS

As the population lives longer, the functioning of various tissues and organs decline over age. However certain diseases like Diabetes,Hypertension affect millions and if not well controlled affect the organ function and cause it to decline exponentially. These life style diseases are not diagnosed in the majority, and by the time the organ involvement occurs the deterioration is quite advanced. A study by Verma P in 2015[7] showed the prevalence of Chronic kidney disease as 13-15.04% with stages 1, 2 and 3 as 6.62 %,5.40% 3.02% and found it is equally prevalent in urban as well as rural population in the country.

A study from India looked at the basic charecteristics in Chronic kidney disease in India in 2022[8]. They studied 4056 patients of CKD and found 2/3 rd patients were in rural areas. 87% were found to be hypertensive, 37% were diabetic, 22 % had cardiovascular disease and 23% had used alternative drugs. Diabetes and Chronic interstitial nephritis were found as the most common causes for the Chronic Kidney disease.

It has been found that the kidney functions in Chronic kidney disease reduces over years and to sustain the life and to ensure the waste product clearance from the body, the renal replacement therapies in varying forms of Dialysis are started. Most patients undergo varying modes of Dialysis like peritoneal or haemodialysis in multiple days of a week and in addition, medicines and dietary restrictions. Life can be sustained if adequate dialysis is given ,however it is a tedious

[7] Varma PP. Prevalence of chronic kidney disease in India - Where are we heading? Indian J Nephrol. 2015 May-Jun;25(3):133-5. PMID: 26060360; PMCID: PMC4446915.

[8] Kumar, V., Yadav, A. K., Sethi, J., Ghosh, A., Sahay, M., Prasad, N., Varughese, S., Parameswaran, S., Gopalakrishnan, N., Kaur, P., Modi, G. K., Kamboj, K., Kundu, M., Sood, V., Inamdar, N., Jaryal, A., Vikrant, S., Nayak, S., Singh, S., Gang, S., … Jha, V. (2021). The Indian Chronic Kidney Disease (ICKD) study: baseline characteristics. *Clinical kidney journal*, *15*(1), 60–69. https://doi.org/10.1093/ckj/sfab149

and repetitive process, costs money and involves lot of logistics. So for a patient in ESRD -the ideal treatment will be a renal transplantation.

Kidneys can be transplanted after compatibility of various types including ABORh blood group and HLA antigens. These are done prior to transplantation, from a potential donor and seen prior to the procedure. Definitive clinical guidelines exist on which all cases ,this can go ahead. There are two types of Kidney donation- Live or Deceased Donor. Live Donor transplantation is from a near relative and usually someone in the family. This is a major surgery for the Living relative and they are left with one kidney only thereafter. Deceased donor transplant is from a Brain dead patient through NOTTO/SOTTO as per the turn and has been demonstrated to have equally good outcomes in the long run in terms of graft survival and complications in a study by Fakhr in 2021.[9]

These patients undergo Kidney transplantation after proper counselling, authorisation of it by the committee and thereafter remain on immunosuppression and follow up. As the kidneys function normally, the drug requirement comes down and the quality of life becomes near normal. The weekly thrice dialysis requirement vanishes and so does the tiredness,anaemia,bone disease,loss of appetite etc. Numerous studies have shown that kidney transplantation has improved the quality of life of innumerable patients and their relatives and is the treatment of choice. The number of patients needing Kidney transplantation in a year in India are to the tune of 1.75000 wheras we are barely able to manage 12000 transplants in a year. This points to an integrated effort needed in capacity building and also accelerating the Deceased donor organ donation. A single brain dead donor can provide a much better life to 2 different End stage kidney patients.

2.1.2 LIVER

Liver failure too occurs due to many causes and many are young patients who are faced with a life threatening condition. Liver is vital for digestion,protein production,immune system and also blood clotting factors. Usually liver failure can happen after Viral infections,Toxin intake,some drug intake and certain diseases where there is metallic deposition in the liver. Alcohol and chronic hepatitis due to viral and autoimmune causes too add to the enormilty of the problem by causing liver inflammation, Cirrhosis and liver failure. A study in 2015 by Dipankar etc al has shown that India has 18.3% of overall burden of the liver related deaths in the world.[10]

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[9] Fakhr Yasseri AM, Namdari F, Gooran S, et al. Living versus deceased kidney transplantation: Comparison of complications. Urologia Journal. 2021;88(3):185-189. doi:10.1177/0391560321993540

[10] Mondal, D., Das, K., & Chowdhury, A. (2022). Epidemiology of Liver Diseases in India. *Clinical liver disease*, *19*(3), 114–117. https://doi.org/10.1002/cld.1177

What sets liver apart from the kidney is the ability to regrow even if a section has been removed from it. However any surgery on the liver is technically challenging and risky for both the donor and the recipients. Liver transplants-both from a deceased donor & another one from a living donor were done in India first time in 1998. Approximately 1800 or so transplantations occur in the whole of India put together. There are approximately 100 active liver transplant centres in the country.[11]Live Liver transplantation is predominant in the country which is exactly opposite to the case of the developed world.

Deceased liver transplantation is increasing in the country and as the overall deceased donations pick up the liver transplant rates from deceased donors too will go up. Even with the number of centres we have, the distribution is skewed and are all in major urban centres. The shortage of Deceased livers are causing wastage of the technical team and also death of many patients of end stage liver disease. The financial costs of a liver transplantation are near 30 lakhs and again the patients need immunosuppression for the long term. A study from Medanta,Gurugram in 2021 has shown 1, 5 and 10 year survival of 84.3,75.5 and 72.2% respectively which is comparable to the rest of the world.

2.1.3 ORGANS THAT CAN BE HARVESTED FROM A DECEASED DONOR

A deceased donor can provide life to 8 other end stage patients- 2 kidneys, 1 liver, 1 heart, 2 lungs ,pancreas and small intestine. The bulk of demand for terminal illness in the world is of Kidneys and thereafter the liver. The rest of the organs too are harvested and transplanted as per SOTTO/NOTTO guidelines. This study was focussed only on the Kidney and liver transplants from deceased donors only and hence no further analysis about other organ transplantation will be done in this study.

2.2 NEED TO REGULATE

In the 80s Indians with end-stage heart, lung, and liver disease were doomed to die and only a few wealthy patients with kidney failure could obtain a living donor transplant. The Indian government passed the Transplantation of Human Organs (THO) Act 1994. The THO Act legalized brain death and made the sale of organs a punishable offense. However, the passage of the THO Act was not accompanied by government-funded initiatives to advance development of deceased donor programs. Unsurprisingly, transplantation in India still is predominantly based on living donation. The THO Act was amended in 2011 and it led to National Organ and Tissue transplantation Organisation(NOTTO) being launched in 2014. NOTTO aims to work with

[11] Choudhary, N. S., Bhangui, P., & Soin, A. S. (2022). Liver Transplant Outcomes in India. *Clinical liver disease*, *19*(1), 32–35. https://doi.org/10.1002/cld.1166.

existing regional- and state-level organizations to co-ordinate interstate transplants. In addition, NOTTO's mandate includes establishment and implementation of protocols and guidelines, monitoring of transplant activity, maintenance of a national organ and transplant registry, promotion of organ donation, and training of organ donation staff. Regional Organ and Tissue transplantation Organisation(ROTTO) and State Organ and Tissue Transplant Organisations (SOTTOs) were established in many states which work under the NOTTO.

2.3 THE TRANSPLANTATION OF HUMAN ORGANS ACT 1994 (THOA)[3]

An act to provide for the regulation of removal,storage and transplantation of human organs and tissues for theraeupetic purposes and for the prevention of commercial dealings in Human organs and tissues and for matters connected therewith or incidental thereto.

The act speaks on

- Why the act was brought in
- Definitions of various terms including Braindeath, Transplantation, Donor, Recipient etc
- Which all situations removal of organs are permitted & what conditions they are not to be done
- Registration & Regulation of Hospitals for transplantation and retrieval
- Appropriate authority to sanction various procedures
- Irregularities and their punishment

As the scenario and scope of Organ donation and transplant increased, Government amended this Act in 2014-**THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES RULES 2014(APPENDIX B)**

Salient additions were

- Changes in definition of near relatives to add grand parents,grand kids
- Committee for Brain death declaration
- Duties of RMP to facilitate
- Clarity on medicolegal cases and transplantation
- Authorisation committees at various levels,duties and constitution
- Donation to foriegners
- Registration of Organ and tissue banks
- Role of Transplant coordinators in Hospitals
- National Organ transplant registry.

Various formats and forms for the above mentioned procedures were also part of this Act for transparency and uniformity . A program of this nature is a serious one and if left to unscrupulous people can result in large scale exploitation of the poor of the country. Hence the government has aptly brought these acts and further modified it.

2.4 CONCEPT OF CARDIAC DEATH, BRAIN STEM DEATH

The concept of death is important and is considered as an irreversible state. There are two ways death is considered in medical science. The commonest is cardiac death or circulatory death where the heart stops functioning, the blood stops circulating to the various vital organs and if not restarted in few minutes results in irreversible state of end of life. Many time Cardiopulmonary resuscitation is initiated either by medical staff or automated machines and after an hour of no success the person is declared dead. Many cases especially in young,in reversible conditions the person is salvaged.

The other concept is of Brain stem Death- defined as the irreversible end of all brain stem functions. Brain stem is the lower part of the brain which has the vital centres for the coordination of the brain, the sleepwake cycle, the autonomic system, the breathing, swallowing, cardiac function regulation etc. The function of the brain stem is usually assessed by checking the brain stem reflexes, coordinated eye movements, gag reflex on touching the back of the throat, Spontaneous breathing, Caloric test in the ear etc. The Apnea test if patient is on a ventilator, in which the persons blood gases are calculated, ventilator disconnected and the person observed closely whether any breathing effort by brain is there or not, Arterial blood gases checked again-if no effort by the person is there and CO2 increases by 20mm it suggests the apnea test is postitive and the Brain stem is not functioning.[12]

Usually the Brain stem function cessation happens in conditions affecting the brain directly-like a massive blow to the head and blood or fluid accumulation inside leading to large pressures on the brainstem which if not relieved in time leads to irreversible brain stem death. This is usually seen in cases of Road traffic accidents and trauma to the head from sports injuries etc or an intracranial catastrophe like a stroke. Many a time the patient is young and the head has sustained the trauma whereas the rest of the body is intact. Most of these patients reach the hospital and are put on a ventilator which supports them. In this state they can remain for weeks but as the brain stem is irreveribily damaged there is no chance of survival .This concept and identification of Brain stem death is important for the process of Organ transplantation. A deceased person can donate upto 8 organs and can save lives of so many with end organ

[12] Dhanwate A. D. (2014). Brainstem death: A comprehensive review in Indian perspective. Indian journal of critical care medicine : peer-reviewed, official publication of Indian Society of Critical Care Medicine, 18(9), 596–605. https://doi.org/10.4103/0972-5229.140151

failure.However as this involves removing the organs after consent of relatives it requires accurate and thorough documentation and clinical assessment. The patient should not be on any sedatives or hypothermic state which might vitiate assessment. The tests of brain stem function are done and if none are present on ventilator, then it is disconnected and a formal Apnea test is done. Two Apnea tests if positive 6 hours apart are sufficient to declare brain stem death for the purpose of Organ retrieval.[13] However even if a patient is brain dead on ventilator the heart is still functional and the ventilator or monitor will show cardiac activity. This creates a difficulty for the next of kin to accept the patient is dead. So in such a case a detailed interaction with them right from the beginning and to explain about brain death and the futility of just maintaining on a ventilator with zero chances of survival needs to be explained to them. Usually this requires multiple interactions and in a mature way. This requires time and empathy and usually is done by the treating doctor and also the transplant coordinator of the hospital.

2.5 RETRIEVAL PROCESS:

The retrieval of organs are done after brain stem death is certified by a Organ Donation Authorisation Committee which is different from the team which treats the patient. All these hospitals have a Transplant Coordinator who actively works bringing in solace to the deceased family as well as tactfully urging them for organ donation. Once the brain stem death is testified after testing for signs of brainstem activity twice 6 hours apart ,and family consents for donation, the coordinator liases with the state registry SOTTO and potential recipients are identified as per the policy of the state in vogue. Usually proximity and combatibility is identified by the system and the transplant teams are activated for harvesting of the organ from the dead donor. Then it transferred as rapidly as possible & transplantation done in the recipients. Sometimes a green corridor too needs to be created for smooth transfer of the organs with help of the police .

2.6 BRAIN STEM DEATH CERTIFICATION COMMITTEE

This is a mandatory committee different from the treating team of doctors in the ICU of the hospital.This committee needs to be registered with the SOTTO and should constitute of

- Hospital Administrator
- Another nominated doctor
- A neurologist/physician/surgeon/ Neurosurgeon nominated
- Medical officer treating patient

[13] Goila, A. K., & Pawar, M. (2009). The diagnosis of brain death. *Indian journal of critical care medicine : peer-reviewed, official publication of Indian Society of Critical Care Medicine*, *13*(1), 7–11. https://doi.org/10.4103/0972-5229.53108

Once this committee does the assessment twice 6 hours apart and are convinced of Brain stem death they certify it. Thereafter the body can be used for organ retrieval provided the patients family has given explicit consent for the same.

2.7 TRANSPLANT COORDINATORS

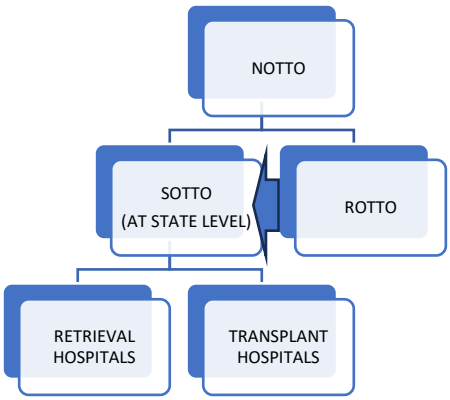
As per the THOA 2014, they will be an employee of the registered retrieval or transplant hospital and will be either a Doctor in any stream or system of medicine, a nurse or a sociology, public health, psychiatry or social science degree holder. They will be given induction, periodic retraining and will consel, encourage the family members or the near relatives of the deceased person to donate the human organ or tissue and he/she will coordinate the whole process.

The role of a transplant coordinator is pivotal to the whole process of Deceased organ donation and transplantation. They are not part of the treating team and are assosciated with the family giving them the time, counsel and empathy during the difficult time as well as arriving in the decision making.Their prerequisite for the job will be immense patience and compassion. Such programs will succeed more if the transplant coordinator herself /himself is convinced and motivated for the process of Organ transplantation.

2.8 AUTHORISATION COMMITTEES

For the purpose of transplantation authorisation Authorisation committees are laid out in THOA 2014 at District, State or SOTTO level and at national or NOTTO level. They authorise the transplants,move of organs intra state and interstate and peculiar cases like donation to foriegners etc.

FIGURE 3
TRANSPLANTATION ORGANISATION IN INDIA (CREATED BY SELF)



2.9 ORGAN TRANSPLANT CONTROL ARCHITECTURE IN INDIA

a) NOTTO works at national level for registration , maintaining waiting lists
b) It works under Health and Family Welfare Ministry
c) It maintains National data base on Transplantation and centres for the same.
d) 5 ROTTOs work at regional level under NOTTO for administration of SOTTOs .
e) Health being state subject,states need to create SOTTOs which primarily handles intrastate organ retrieval and transplantation
f) Any hospital with adequate facility and expertise can register as a retrieval centre with SOTTO
g) Currently the SOTTOs are active most in the southern and western India
h) Few states like the northeastern states,eastern states are still to constitute the SOTTOs.

2.10 ALLOCATION OF DECEASED ORGAN KIDNEY BY A SOTTO-AN EXAMPLE

Organ transplant has two sources: living donor and deceased donor. In case of living donor source, donor is already decided for a specific recipient. For deceased donor source, recipient needs to be selected out of a large recipients' pool. The allocation of organ is a complex process, influenced by a number of factors including medical urgency and donor & recipient matching. Following facts need to be kept in mind for organ allocation for kidney transplantation.

2.10.1 CERTAIN FACTS FOR END STAGE RENAL DISEASE (ESRD)

1. There is disparity between number of recipients requiring kidney transplant and the deceased organs available for kidney transplantation.

2. Some patients need kidney transplant on priority basis because of their medical condition, as delay in transplant may lead to mortality.

3. For End Stage Renal Disease (ESRD), maintenance dialysis is an acceptable and reasonably good alternate therapy so for majority of ESRD patients, renal transplant is not an emergency procedure.

2.10.2 RECIPIENT REGISTRATION, LISTING AND SCORING SYSTEM IN THE WAITING LIST

(Before deceased donor availability)

1. Patient is to be registered by the concerned hospital through online registration form on website www.notto.gov.in

2. A kidney advisory committee will approve registration and urgency criteria, if any.

The kidney advisory committee will confirm need for renal transplant of every newly registered patient. Once approved, ONLY then patient will be put on active list in the system and ALLOCATION SCORING for that patient will be done based on the guidelines formed.

1. Patient should be less than or equal to 65 years of age at the time of registration.
2. Patient should be a case of End Stage Renal Disease on Maintenance dialysis for more than three months on regular basis.
3. Patient should not have an absolute contraindication for renal transplant, as given under:
    a. Advanced untreatable cardiovascular disease
    b. Irreversible cerebrovascular accident
    c. Inoperable malignancy
    d. Untreatable major psychiatric illness (to be certified by a psychiatrist)
4. Patient should be registered ONLY in ONE hospital registered under the Transplantation of Human Organs and Tissues Act (THOTA) with State authority.
5. However, he/she can change the hospital at any stage and his allocation scoring and seniority in central waiting list will not change. However, his/her seniority in the waiting list of locally available kidney, with the new Hospital will be applicable one month after date of change.
6. Patient can be registered for deceased donor even though patient is waiting for living donor transplant.
7. Status of patient must be updated regularly by the hospital in one of the following status:
8. Active
9. Unfit
10. Suspended
11. Lost to follow-up
12. Transplant done
13. Death

2.10.3 SCORING SYSTEM FOR MAKING PRIORITY IN KIDNEY TRANSPLANTATION

SOTTO follows a system of scoring for allotting priority in organ waiting lists.The below example is that of kidney allotment on priority. Patients with the same score, priority will be decided based on the seniority in the waiting list

TABLE 1
KIDNEY ALLOCATION CRITERIA (NOTTO GUIDELINES)

Sl. No.	Criteria for scoring	Points allotted
1	Time on dialysis	(+1) for each month on dialysis
2	Previous immunological graft failure within 3 months of transplantation	(+3) for each graft failure
3	Age of recipient	(+3) for less than 6 years (+2) for 6 to less than 12 years (+1) for 12 to less than 18 years
4	Patient on temporary Vascular access	
(a)	With Failed all AV Fistula sites	(+ 2)
(b)	With Failed AV Graft after all failed AVF sites	(+ 4)
5	PRA (Panel Reactive Antibody)	(+ 0.5) for every 10% above 20%
6	Previous Living donor now requiring Kidney Transplant	(+5)
7	Near relative (as per definition of THOTA) of Previous deceased donor now requiring kidney transplant	(+5)

2.10.4 ALLOCATION PRINCIPLES

1. Allocation will be done first based on city waiting list. If no recipient eligible in city waiting list then allocation will be done to state and then to other States in the ROTTO and then to other ROTTO nationally.
2. In order to minimize cold ischemia time, most donated organs should be allocated within the city or at the most state, where retrieval has been done.
3. Kidney from Pediatric donor (less than 18 years) first will go to pediatric patient. If no pediatric patient eligible, then to adult patient.
4. Blood group O kidney will be allocated to recipient with group O, then to next available on waiting list of other compatible blood groups i.e. first group A, then group B and lastly group AB in that sequence.
5. In case of blood group A or B, the organ will be allocated to same blood group failing which to blood group AB. AB will be allocated to AB only.

2.10.5 ALLOCATION ALGORITHM-Once there is a call for possible deceased donor

STEP-1: Check Blood Group of available deceased donor to follow principle of allocation based on blood group as above.

STEP-2: If there is recipient in "urgent list" as per accepted criteria and approved by the appropriate committee, then one of the two available kidneys will go to the urgent case.

STEP-3: Recipient requiring multi-organ transplant will get priority.If there are more than two recipients in the multi-organ recipient list, then allocation will be done to patient having more points in the scoring system.

STEP-4: If NO urgent case and NO multi-organ recipient, then allocation will be done to patient registered for 'Kidney alone' transplantation based on the status of hospital doing retrieval of kidneys means whether it is transplant hospital or retrieval only hospital If Transplant Hospital-One kidney be used locally and other will be allocated. It is expected that the scoring system will also be followed by the hospital for local allocation of kidney. If Retrieval Hospital-Both will be allocated

STEP-5: See Kidneys retrieval hospital, whether it is government hospital or private hospital

- Kidney retrieved from a government hospital will be allocated as follows
    - First patients listed in Government ONLY hospitals list, then

- Patients listed out of combined government and private hospital list, then
- Patient listed out of private ONLY hospital list

- Kidney retrieved from a private hospital will be allocated as follows:
  - First patients listed in private hospitals list, then
  - Patients listed out of combined government and private hospital list, then
  - Patient listed out of government hospital list

2.10.6 INTER-STATE ISSUES

1. It is expected that all SOTTOs will broadly follow the same guidelines /protocols for organ allocation.
2. The appropriate authority of state government in consultation with SOTTOs will approve the inter-state transport of organs for transplantation.

Summing it up, India has a system of opting in, for deceased organ transplantation and it has a structure in place guided by the NOTTO and various ROTTOs, SOTTOs. Also the Transplantation of Human organ act has been passed and updated to bring in clarity. However much more streamlining needs to be done, to boost the organ transplantation in India as per needs of the populace. The present transplantation rates are increasing but cannot cover the pending demands at the current rates. With the advent of improving medical infrastructure in India with a medical college envisaged in every district, it will need also create robust public awareness about organ transplantation, so that the deceased organ donation rates accelerate in India.

CHAPTER 3

ORGAN TRANSPLANTATION- GLOBAL AND INDIAN SCENARIO

The first Kidney transplantation happened in 1954 and the first liver transplantation in 1967 in the world. The procedures and the surgical techniques had a growing and a learning curve and what has really boosted this is the evolution of better and more potent immunosuppression, transplantation immunology and pathology- so that early graft rejections can be recognised and treated. India too has done its first kidney transplant in CMC Vellore in 1971 and the first liver transplant in 1998 from a living donor. This timelag has been due to lack of the infrastructure needed ,the various facilities, expertise to conduct and manage a patient of transplant.

We will briefly discuss the world scenario and the systems of donation followed worldwide. We will see the organ donation per million population from a world perspective.In addition we will discuss the evolution of Deceased organ donation in India over the last 10 years and the uneven nature of the performance of various states-some doing reasonably well and some lagging far behind. We will look at the all india figures for transplantation of deceased liver and kidney,the various infrastructure availability currently and the barriers in transplantation from deceased persons.To conclude the chapter we will highlight the points from the interaction with Dr Anil Kumar, NOTTO Director.

3.1 WORLD SCENARIO

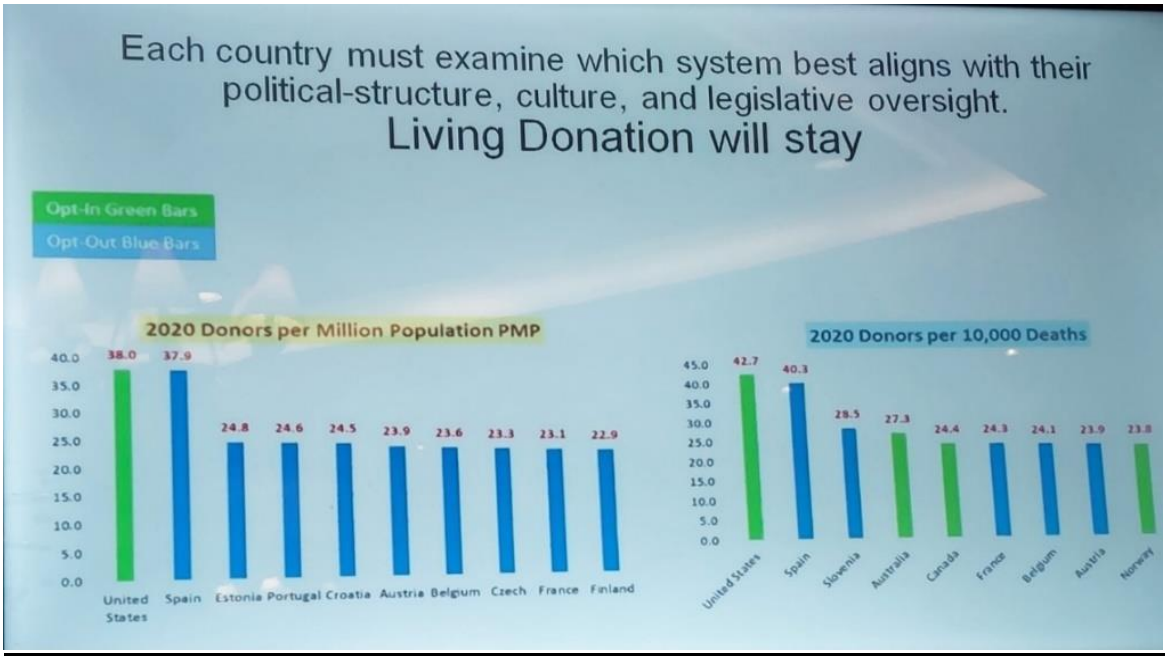
By the 80s multiple organs like Kidney,liver, lung,cardiac transplant programmes were well established in the western countries and as to date more than a million transplants happen in the US yearly with the majority being deceased donor transplants.[14] The costs of a transplant of Kidney are different in Government hospitals-5000$ to 10-20000 $ in a private sector hospital in the USA. The cost of a liver transplant is similarly 15000-20000 $ in a government hospital whereas in a private sector hospital it is roughly double this. These are the surgical costs and the costs after this, for consultations and immunosuppression are an additional cost. USA spends appx 15% of its GDP on healthcare and the insurance system is very robust. The case in many European countries is a state funded health system which bears all the costs.

[14] World Health Organization. Human organ and tissue transplantation. May 21, 2010. https://apps.who.int/gb/ebwha/ pdf_files/WHA63/A63_R22-en.pdf?ua=1

3.2 WORLD WIDE VARIATIONS

There are two systems in organ donation followed worldwide **-Opt in** where the person or family has to select to donate organs and the **Opt out** system where everyone is considered a Donor on death unless he has opted out of it explicitly documenting it earlier. Most of the European countries follow the opt out system which ensures the availability of sufficient organs.However the United states is an exception which follows the opt in system.The public awareness and the awareness of the medical fraternity is robust and they consider organs as a source of national asset which can be of use for another human person and the transplantation rates are > 20 per million in most of these countries.

FIGURE 4
DECEASED ORGAN DONATION/MILLION IN VARIOUS COUNTRIES



3.4 INDIA IN ORGAN TRANSPLANTATION

India by its sheer population, stands at 3rd in transplantation numbers, and follow opt in system: however the sheer numbers are overwhelmingly miniscule by the number of patients in End organ failure waiting for an organ. We still are pushing up our transplantation rates by multiple efforts and stand at a dismal 0.67/million population in 2022 whereas the rates in European countries are all over 20/million population.[15]

[15] Kute, V. B., Ramesh, V., & Rela, M. (2021). On the Way to Self-sufficiency: Improving Deceased Organ Donation in India. *Transplantation*, *105*(8), 1625–1630

FIGURE 5
INDIA COMPARED TO THE WORLD -2022 (DECEASED ORGAN DONATION)

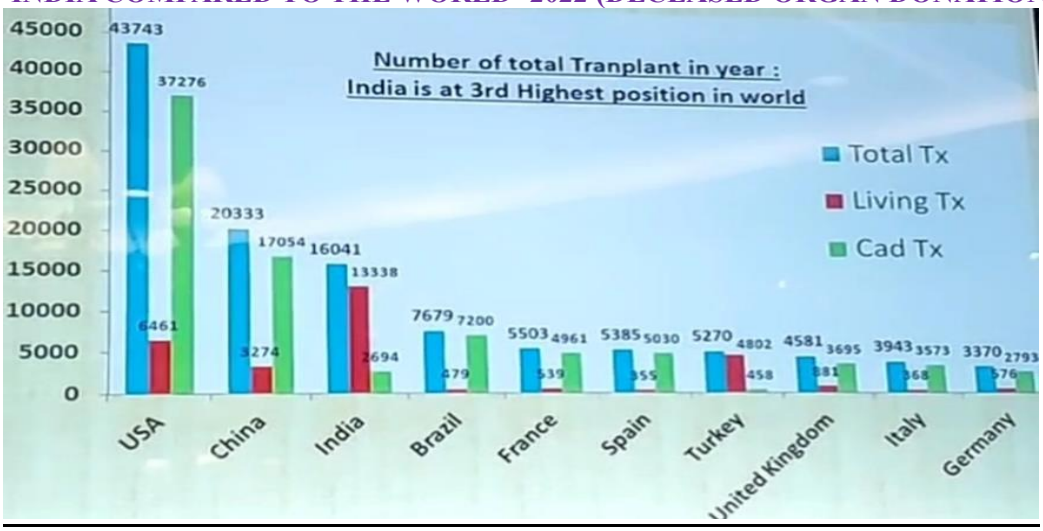
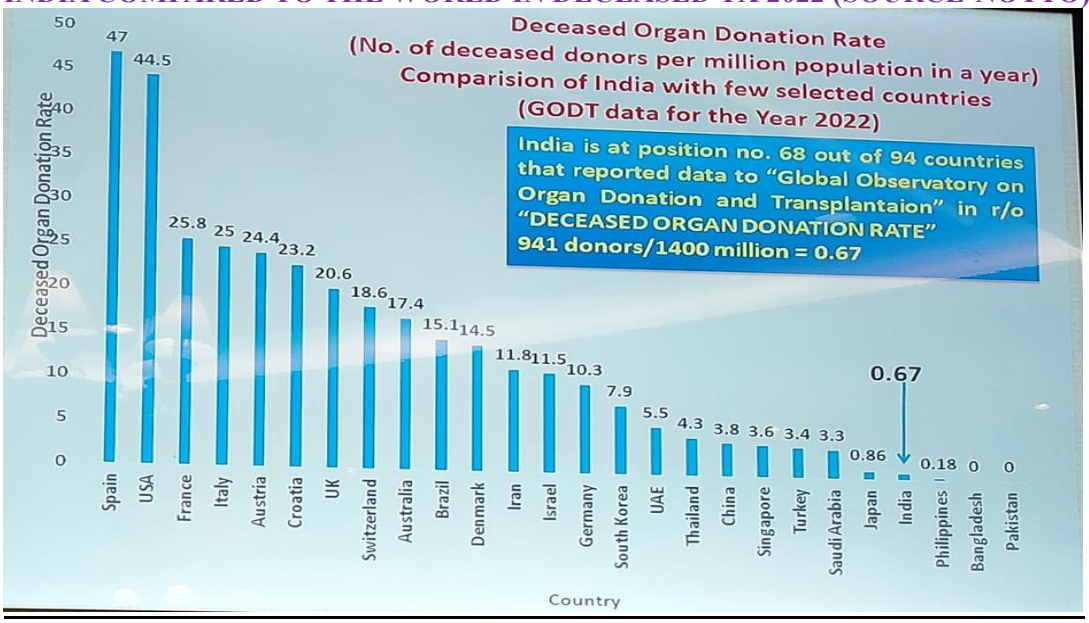


FIGURE 6
INDIA COMPARED TO THE WORLD IN DECEASED TX 2022 (SOURCE-NOTTO)



3.3 INDIAN SCENARIO OF TRANSPLANTATION

Indian transplantation of Deceased Donor Organs has picked up from what was in infancy and restricted to few states in south and west of the country, to include many more parts of the country: even though there are many states, which still have not formed their SOTTOs or transplant programs.

FIGURE 7
2011- INDIAN DECEASED DONOR RATE WAS 0.08/MILLION

FIGURE 8
2023 - INDIAN DECEASED DONOR RATE IS 0.69/MILLION

3.4 DECEASED ORGAN DONATION INDIA -CURRENT STATE

Today, India performs the highest number of living donor kidney and liver transplants in the world but only a small number of deceased donor transplants.[16,17]. An estimated 220,000 persons

[16] International Registry in Organ Donation and Transplantation. https://www.irodat.org Accessed 1 September 2023.
[17] Global Observatory on Donation and Transplantation, 2020. http:// www.transplant-observatory.org Accessed 1 September 2023.

die of chronic kidney disease in India annually. And 200,000 and 300,000 persons die of liver failure annually with about 25,000 of the deaths among patients who could have been transplant candidates. Only 20% of kidney and <5% of liver, heart, lung, and multiorgan transplants are performed in government hospitals. High costs of transplants at private hospitals are,in general, not affordable for most patients in the absence of governmental healthcare plans.

There were over 160,000 fatalities due to road traffic accidents in India in 2022 with the majority being young men who presumably would have been suitable organ donors. Delhi performed a total of 21,471 organ transplants between 1995 and 2019; however, 97% (20757) were living donor transplants. States of Tamil Nadu, Gujarat, Telengana have however shown a dramatic increase in deceased donation and organ transplantations.

FIGURE 9
TOI ARTICLE 2017 AUG ON ORGAN DONATION INDIAN SCENARIO

THE TIMES OF INDIA, NAGPUR
TUESDAY, AUGUST 1, 2017

TIMES NATION 5

Over 2.5 Lakh Die In The Country Due To Organ Failure Annually While Cadaver Donations Are Marginal In Comparison

Organ donation up 4-fold in India, but still a long way to go

Some States Are Yet To Make A Debut

TEAM TOI

The death of a teenager who consumed rat poison after being repeatedly sodomized shook Mumbai last week. The boy fought liver failure in a public hospital as his parents and doctors desperately prayed for an organ. But no matching donor could be found for a liver transplant and the 13-year-old succumbed 13 days later.

Of the 85,000 liver failure patients who join the country's waitlist annually, less than 3% get an organ. Also, of the two lakh fresh annual registrations for kidneys, 4,000 manage a transplant. Thousands waiting for heart or lungs face bigger odds as barely 1% get an organ before time runs out.

Despite cadaveric organ donations witnessing a near four-fold increase in the last five years, the demand-supply disparity in the country remains grave. Over 2.5 lakh deaths in India are attributed to organ failure annually while cadaver donations are still very few in comparison. India's organ donation rate in 2016 stood at an abysmal 0.8 persons per million population compared to Spain's 36 per million, Croatia's 32 per million or US's 26 per million.

Experts say the gap exists because only ten states and two UTs have an active donation and transplant programme. States such as UP, Chhattisgarh, Himachal Pradesh, Goa and the North East are yet to make a debut. Stakeholders blame lack of awareness, infra and political will as well as myths and misconceptions for the sluggish pace of cadaver donation.

"Even after decades, the programme is a non-starter because of systemic complexities. The problem lies within hospitals and is not so much about people's acceptance any more. Police formalities remain difficult and time-consuming, discouraging people from donating," says Dr Sunil Shroff of Chennai-based Mohan Foundation.

ONE DONOR CAN SAVE UP TO EIGHT LIVES

CADAVER ORGAN TRANSPLANT IN INDIA

Organ	2017	2016	2015	2014	2013
Kidney	805	2,345	1,017	720	548
Liver	316	733	523	354	257
Heart	190	217	110	54	25
Pancreas	12	21	06	05	NA
Lung	41	58	37	16	22
Intestine	NA	05	02	01	NA
TOTAL	1,364	3,079	1,695	1,150	852

ORGAN TRANSPLANTS IN INDIA IN 2016

Cadaver 3,079 — Organ is taken from a brain dead person

Live 9,936 — Donor is a living person

INDIA'S WAITLIST

Estimated Annual Requirement (Source: National Organ and Tissue Transplant Organisation (NOTTO))

Kidney	2 SL	
Liver	80,000	
Heart	50,000	
Cornea	1L	

STATE-WISE CADAVER DONATIONS IN 2016

Chandigarh 28, Indore 25, Jaipur 06, Gujarat 54, Maharashtra 110, Telangana 93, Andhra Pradesh 18, Karnataka 70, Kerala 73, Tamil Nadu 185, Puducherry 01

Over 1.5lakh deaths occur due to road accidents annually. If we can convince even 1% of these families to donate, we can wipe out India's waitlist in a few years

Dr Vimal Bhandari | DIRECTOR OF NATIONAL ORGAN AND TISSUE TRANSPLANT ORGANISATION

WHAT IS ORGAN TRANSPLANT

It is an advanced procedure of surgically removing an organ or tissue from the donor and placing it into the recipient. It is the last resort for recipients as his/her organs have failed

TYPES OF ORGAN DONATION

Live donation | Where a healthy kidney or a segment of a healthy liver or lung from a living person is given to the recipient, it involves risk for the donor as healthy individuals are exposed to surgery and hospitalisation

Cadaver donation | Organs are removed from a recent brain-dead donor. It is the preferred approach as it negates the risks of a live donation

"There have been cases where people have approached us wanting to donate organs but either the hospital or the city lacked the infrastructure to retrieve organs," he says, underlining how in a country with an acute shortage, organs get wasted.

Tamil Nadu, Maharashtra, Kerala, Karnataka, Telengana and Gujarat currently lead the way. Delhi and Chandigarh too managed 30 donations in 2016.

Dr Vimal Bhandari, director of the National Organ and Tissue Transplant Organisation, says the government is aware of the crisis. "We have signed an MoU with Spain which has the world's highest donation rate. About 100 countries are learning their model. Their experts will train five of our regional coordination centres," he says, adding that Spain took 30 years to build its programme. Unlike Spain, where majority of brain deaths occur due to haemorrhage, in India, road accidents are the main killer.

India's infrastructure too is growing. The national network facilitated 136 instances of organ sharing between cities and states. "Last year, we even saved the lives of two foreigners who underwent heart transplants here," Dr Bhandari says.

Tamil Nadu runs India's most successful programme by taking a slew of decisions to ease donations about a decade back: families donating organs don't have to move for NOCs or post-mortems. Also, the state offers free kidney, liver and heart transplants in government hospitals like developed nations.

Maharashtra, that crossed 100 cadaver donations last year despite one of Mumbai's top hospitals being involved in a kidney racket, has carried out 1,064 transplants in the last five years. Pune has suddenly emerged as a high-donation centre, surpassing Mumbai. "Till April 2017, 69 donations took place in Maharashtra," said Dr Gauri Rathod, Maharashtra's nodal officer for organ donation.

Hyderabad and other districts of Telangana have crossed over 1,000 organ donations since 2013. From less than 1 per million population, the donation rate has now reached 4.4. From just 41 being recorded in 2013 to 106 organ donations in 2016. In 2017, over 80 organ donations have already been reported. "But there is an urgent need for education among doctors. In many cases, doctors are uncomfortable in declaring brain death. This is true of government hospitals," says Dr G Swarnalatha, in-charge, Jeevandan.

Karnataka, too, is charting its own success story with donations taking a leap from 18 in 2013 to 70 in 2016. Dr Kishore Phatke, convener at Jeevosarthakathe—the state organ transplant authority—attributes this to linked Aadhaar cards with pledging organs. "Anyone who enrols for Aadhaar will be directed to the website of Jeevasarthakathe where they can pledge organs," he says.

However, many states face unique problems. Consider Kerala which has recorded only 11 donations after 73 in 2016. "A doctor filed a PIL in the high court alleging hospitals are falsely declaring brain deaths to procure organs. It led to negative propaganda in the social media. Even government authorities didn't stand by the transplant doctors," says Dr Jose Chacko Periappuram of Lisie Hospital in Kochi, Kerala, however, has to its credit some of the unique organ transplants that include larynx, pancreas, small intestine and hand transplants.

Eastern India is the worst, with most states not having conducted cadaver donations at all. Only seven cadaver donations, including five in 2016, took place in West Bengal since 2012. According to Aditi Kishore Sarkar, state's nodal officer for cadaver donation, "The drive to popularize organ donation through donor card distribution has failed. In 2017, there has not been a single cadaver organ transplant so far." The state plans to introduce new laws to improve brain death screening.

Even states like Karnataka show a unhealthy skew. As Dr H Sudarshan Ballal, senior nephrologist and chairman at Manipal Hospitals, Bengaluru, says, "Of more than 300 transplants conducted by private hospitals, only 20% are cadaver organ transplants." He says India needs more retrieval centres. "India's largest centre of neuroscience, NIMHANS, is still not recognized as a retrieval centre."

SEMINAR ON ORGAN DONATION

Spiritual & Scientific Views

DATE: SATURDAY (AUGUST 5, 2017)

TIME: FROM 4PM-6PM

Venue | Convention Centre, Sixth Floor, Kokilaben Dhirubhai Ambani Hospital, Four Bungalows, Andheri (W), Mumbai

Invite | Take part as spiritual masters, medical experts, and donor & recipient families will share their insights

Mumbaikar's heart saves Washim man

Satish Aakhand had just finished his first year in mechanical engineering at a Nagpur college when the gripping stomach aches and breathlessness started. A local doctor diagnosed right away that the problem lay with his heart.

"I rushed back home to Washim where a doctor said I could be treated with life-long medication. But medicines gave me relief for barely 15 days," said Satish, who belongs to a farming family.

This was in November 2016. It took two more months and visits to several doctors before he got a full diagnosis at Andheri's Kokilaben Ambani Hospital. He had a heart failure and needed a transplant. He registered for transplant on January 9 and got a donation after six months, on June 22. "I am grateful a Mumbai family donated their dear one's organs," he said over phone from Washim. TNN

CALL TO ACTION

Times Organ Donation Drive, an initiative by The Times of India, is being presented in partnership with Kokilaben Dhirubhai Ambani Hospital, Mumbai to create public awareness and inspire readers to pledge their organs

TIMES ORGAN DONATION DRIVE 13TH AUGUST

THE TIMES OF INDIA

To sign up as an organ donor, log on to www.organdonationday.in

Once registered, you will receive a donor card. You can also download the e-donor card from the website

To show your support, give a missed call on 8080055555

NGO partners: MOHAN FOUNDATION, Gift an organ

DONOR METER 1,22,236 Donors registered online as part of TOI's initiative

This former govt employee gave gift of life after death

On July 10, Samita Banavali spoke to her 70-year-old mother Smita Habbu for a few minutes when the latter said she was feeling dizzy. "She got up but fell down again," recalled bank officer Banavali. Smita had suffered a massive brain bleed and was taken to a nearby hospital.

"We shifted her to Kokilaben Hospital but tests showed she was brain dead," said Banavali. Her father, Shashikant, who had heard about organ donation, was keen to donate his wife's organs when the hospital coordinator brought up the topic. "We were familiar with the concept. My mother was a helpful person. I am sure she would have approved," said Banavali.

As Smita was a diabetic, her kidneys couldn't be donated. "We wanted to donate her heart, lungs and cornea as well but doctors said it wasn't possible. We only donated her liver," she said. Habbu, an ex-government employee, was one of the 32 donors this year. TNN

TABLE 2
STATE OF ORGAN TRANSLANTATION IN INDIA AND ORGAN DEFICIT IN 2022

ORGAN	ESTIMATED NEED/YEAR	TOTAL TRANSPLANT NO-2022
KIDNEY	1.75-2 LAKHS	11705
LIVER	40000-50000	3920
HEART	50000	243

FIGURE 10
TOI ARTICLE ON ORGAN DONATION COMMUNITY AUG 2021

A salute to organ donation community for their tireless work in gifting life

TIMES NEWS NETWORK

Patients waiting for organ transplants across the country have had a rough time during the Covid-19 pandemic with hesitancy marking a 70% drop in donations after March 2020.

Kokilaben Dhirubhai Ambani Hospital & medical research institute
Every Life Matters
TIMES ORGAN DONATION DRIVE
an initiative by THE TIMES OF INDIA

To sign up as an organ donor, visit **organdonationday.in** or give a missed call on **8882110088**

With vaccination picking up, the government, NGOs, doctors, and corporates must clear the additional apprehensions about organ transplant and revive the donation drive, experts have said.

Bhavna Chhabaria, CEO of Shatayu, an organ donation initiative in Ahmedabad, said it is time now to move forward on organ donation and transplant with appropriate caution.

"In the current situation, people also need to be educated about the complete safety in donation, precautions and the process of organ retrieval," she added.

Even in the bleakest of times, the past year brought hope and many people and organizations continued working for organ donation, linking lives for ever by turning a loss by death into life for others.

Among the hundreds of organizations working tirelessly to train medical staff, provide grants, and spread the word about organ donation are the SBI Foundation, the Tata Trust, Tech Mahindra and Sanofi.

This year, the Times Organ Donation Drive will roll out on Friday, August 13. It will recognise the commendable work by these people and the organisations.

This initiative by The Times of India, in association with Kokilaben Dhirubhai Ambani Hospital, creates awareness about organ donation and encourages people to become donors.

Launched in 2013, the movement has roped in more than 1.72 lakh people who have signed up on the campaign's website. Their effort can save 1.3 million lives.

Organ donation in the country has received a boost after the National Organ and Tissue Transplant Organisation was set up and extended to the regional and state levels.

Many states have now incorporated a chapter on organ donation in school textbooks. The central government also announced an opt-in mechanism on driving licences for people to sign up.

Senior urologist Sunil Shroff, managing trustee of the Chennai-based Mohan Foundation, said corporates, NGOs and hospitals should now strengthen the processes to boost organ donation numbers.

Manjula Kalyanasundaram, managing director of SBI Foundation, said individuals have the power to save up to eight lives when they pledge their organs.

"We have been working with Mohan Foundation since 2019. We will scale up the programme to gift hope to those in need," she added.

TABLE 3
STATE OF ORGAN TRANSPLANTATION INFRASTRUCTURE INDIA 2022

INFRASTRUCTURE FOR ORGAN TRANSPLANT	NUMBERS
ORGAN TRANSPLANT CENTRES	643
ORGAN RETRIEVAL CENTRES	125
TISSUE TRANSPLANT CENTRE WITH BANK	46
TISSUE TX CENTRE WITHOUT BANK	19
TISSUE BANK	5
TOTAL	838

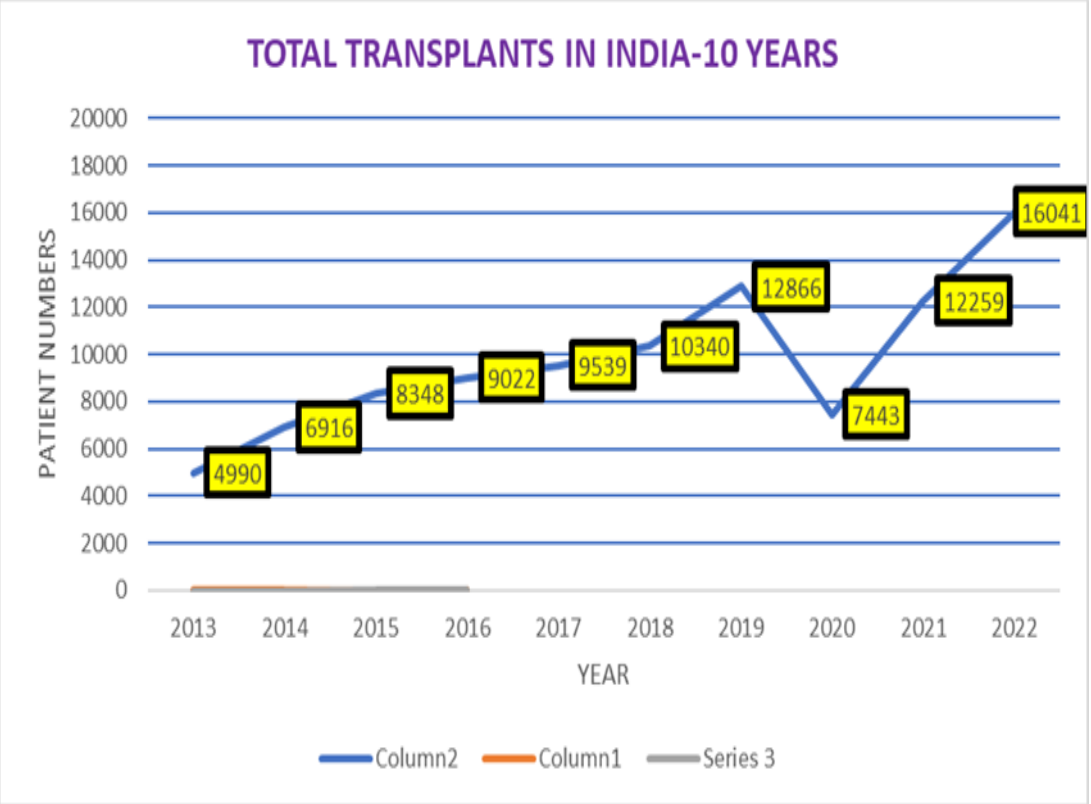
3.5 ALL INDIA DATA

Data of the live and deceased organs transplanted in India over the years are maintained by NOTTO.It shows an increase in Deceased kidney TX from 1261 in 2016 to 1541 in 2022 and an increase in deceased liver transplant from 694 to 737 in same period.The overall transplants of Kidney increased from 6958 to 11705 in same period and liver from 1754 to 3920 .There was a dip in all types of transplantation in the COVID affected 2020-2021 .In the 10 year period of 2013 to 2022 overall transplantation in India increased from 4990 to 16041 , a more than 3.5 time increase. A heartening thing to note is that the deceased donor program is steadily increasing over the years in India but the rate of increase is still dismal compared to the increase in population or end organ failure rates. .This will need to further increase to power the Tx program and to bring succour to the patients with end stage diseases

TABLE 4
ALL INDIA TRANSPLANTATION FIGURE KIDNEY ,LIVER 2016-2022

Year	Dec Kidney	Live Kidney	Total Kidney	Dec Liver	Live Liver	Total Liver
2016	1261	5697	6958	694	1059	1754
2017	1169	6165	7334	579	1264	1843
2018	1164	6772	7936	631	1313	1945
2019	1138	9613	10781	599	1991	2590
2020	516	4970	5486	291	1487	1780
2021	830	8275	9105	482	2363	2845
2022	1541	10164	11705	737	3174	3920

TABLE 5
TRANSPLANT TRENDS IN INDIA 2013-2022



3.6 DECEASED KIDNEY DONATION 2022

The Deceased Donor kidneys- 1541(14.5%) and Living Donor Kidneys- 10614((85.5%): showing the amount of catching up needed for the deceased transplant program in India.The best performing staes in deceased transplant are Tamil Nadu, Karnataka and Gujarat.

FIGURE 11
ALL INDIA KIDNEY TRANSPLANT IN 2022 (SOURCE- NOTTO)

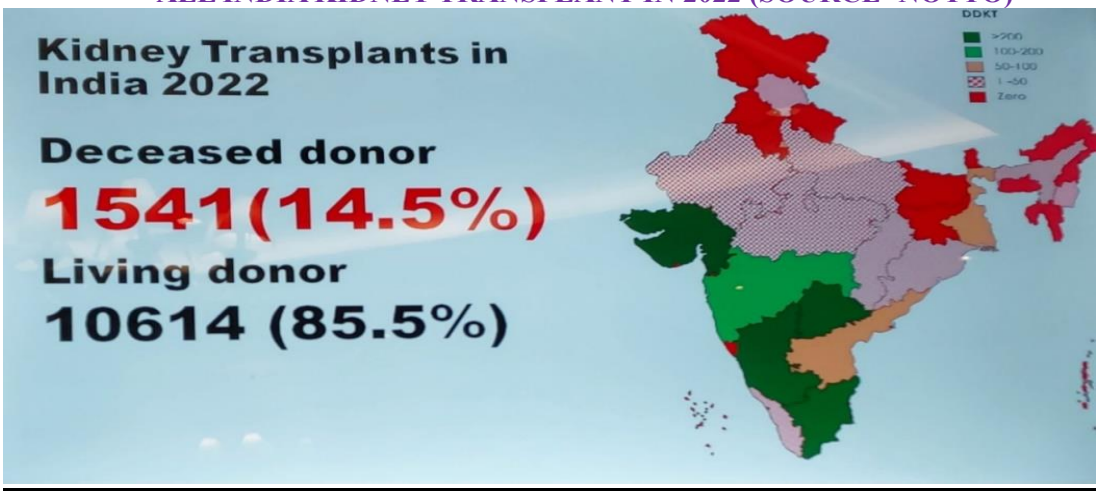
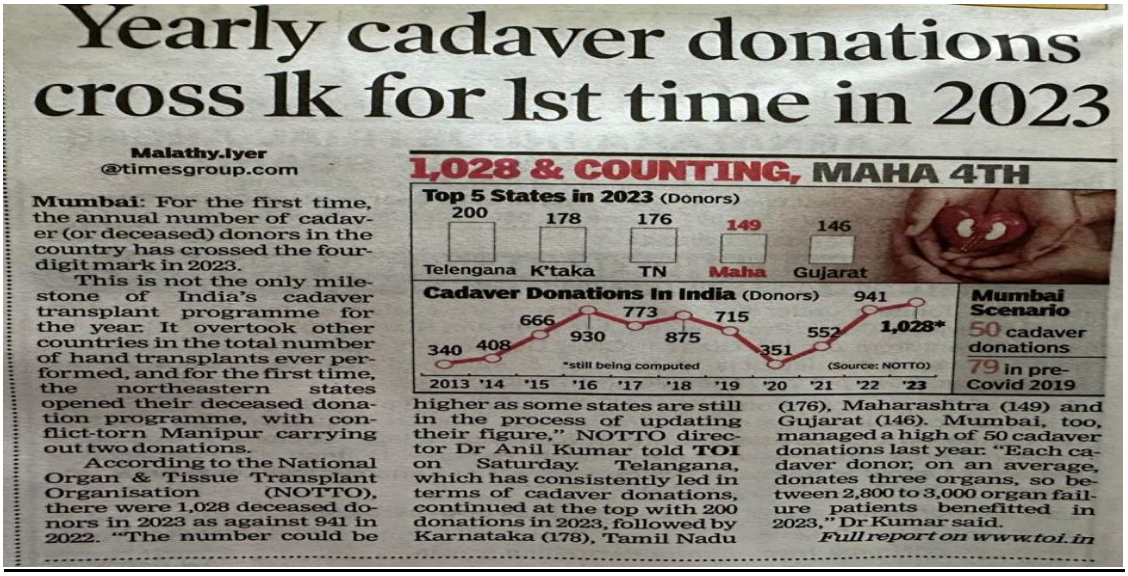


FIGURE 12
TOI ARTICE JAN 2024 ON > 1000 DECEASED DONATIONS ALL INDIA IN 2023



Yearly cadaver donations cross lk for lst time in 2023

Malathy.Iyer
@timesgroup.com

Mumbai: For the first time, the annual number of cadaver (or deceased) donors in the country has crossed the four-digit mark in 2023.

This is not the only milestone of India's cadaver transplant programme for the year. It overtook other countries in the total number of hand transplants ever performed, and for the first time, the northeastern states opened their deceased donation programme, with conflict-torn Manipur carrying out two donations.

According to the National Organ & Tissue Transplant Organisation (NOTTO), there were 1,028 deceased donors in 2023 as against 941 in 2022. "The number could be higher as some states are still in the process of updating their figure," NOTTO director Dr Anil Kumar told **TOI** on Saturday. Telangana, which has consistently led in terms of cadaver donations, continued at the top with 200 donations in 2023, followed by Karnataka (178), Tamil Nadu (176), Maharashtra (149) and Gujarat (146). Mumbai, too, managed a high of 50 cadaver donations last year. "Each cadaver donor, on an average, donates three organs, so between 2,800 to 3,000 organ failure patients benefitted in 2023," Dr Kumar said.

Full report on www.toi.in

1,028 & COUNTING, MAHA 4TH

Top 5 States in 2023 (Donors)

Cadaver Donations in India (Donors)

Mumbai Scenario
50 cadaver donations
79 in pre-Covid 2019

Highlighting relevance of organ donation in saving lives, Hon'ble PM Sh. Narendra Modi lauded India crossing over 1000 deceased organ donations in the year 2023 in the 109th edition of his Mann Ki Baat program-JAN 28 2024

3.7 DECEASED ORGAN DONATION:

3.7.1 FACTORS THAT INCREASE IT

The major motivators for organ donation identified are saving the life of others, moral obligation, an extension of life, relief of grief, and being a role model for others. In a study from Gujarat, organ donation is seen as an opportunity to extend life[18]. The relative's decision was motivated by a belief that donation would give life to others. The interplay of sociocultural factors, beliefs and superstitions, communication, organizational support, and media also play important roles. During the counselling of brain-dead patient's relatives, they are in a complex decision-making situation for accepting the idea of donation. Families must consent to donate their deceased relative's organs or tissues and transplant coordinators play a vital role in communicating, motivating and also grief redressal[19]. It has been found world wide[20] that dissemination of awareness about organ donation, before the event, translates to more willingness to donate the organ of a near relative. In India transparency in communication, media etc play a big role in building a positive sentiment.

3.7.2 BARRIERS

Barriers to an effective deceased organ transplantation programme are at Individual, Institutional and Public policy level. The individual barriers consist of knowledge ,beliefs including religious, lack of awareness etc of the relatives. There is difficulty in understanding the concept of brain stem death. Second are religious beliefs of an incomplete body. Other barriers are that the whole family might not agree and because of that donation is denied. Additional barriers are mindset of conspiracies, fed by news paper articles or media including OTT.[21] Lack of empathy and communication to the next of kin, in an effective manner, compounds this problem. The

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[18] Saxena, D., Trivedi, P., Bhavsar, P., Memon, F., Thaker, A., Chaudhary, C., Yasobant, S., Singhal, D., & Zodpey, S. (2023). Challenges and Motivators to Organ Donation: A Qualitative Exploratory Study in Gujarat, India. *International journal of general medicine*, *16*, 151–159

[19] Adithyan, G. S., & Mariappan, M. (2017). Factors that determine deceased organ transplantation in India. Indian Journal of Transplantation, 11(2), 26-30.1

[20] Miller, C., & Breakwell, R. (2018). What factors influence a family's decision to agree to organ donation? A critical literature review. *London journal of primary care*, *10*(4), 103–107.

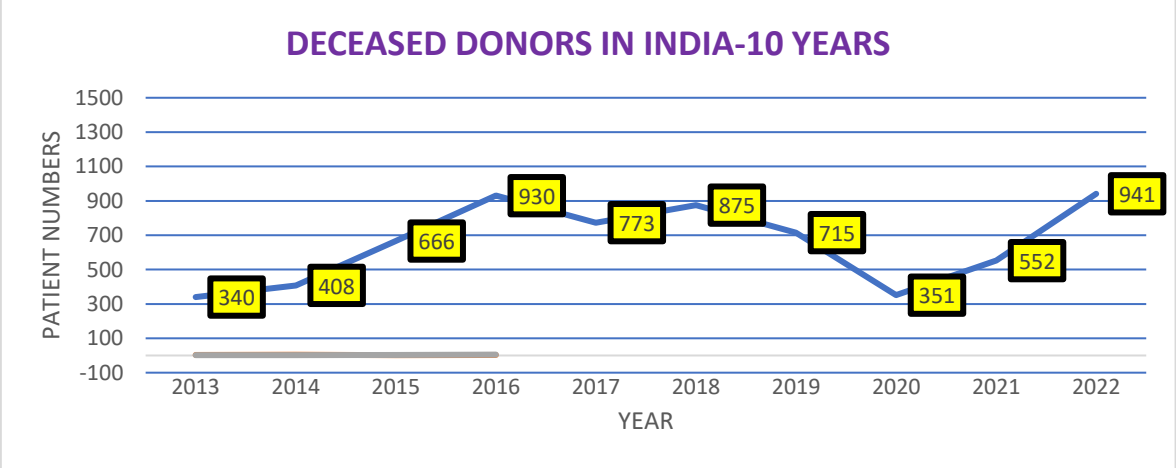
[21] Vijayalakshmi, P., Sunitha, T. S., Gandhi, S., Thimmaiah, R., & Math, S. B. (2016). Knowledge, attitude and behaviour of the general population towards organ donation: An Indian perspective. *The National medical journal of India*, *29*(5), 257–261

transplant coordinators are a vital cog in the Transplantation program and play a role in motivating the deceased family for organ donation.

The barriers at an institutional level are lack of protocols, brain stem death declaration being not considered or delayed, either due to lack of identifuying it, lack of sensitivity or it considered as an extra work by the already stressed ICU staff. There are also issues of organ transport and a protocol for rapid coordinated action is needed. Police too needs to be involved at times,so do the airports, if transport of organs are involved. At a policy level there are need for guidelines, supervision, facilitation like incentives or subsidising for the poor patients, effective public outreach through media, green corridor creation and also effective policy formulation.[22]

A survey done at AIIMS Newdelhi in 2016 showed that only 70% were aware that organs can be donated, and 44 % were aware of the concept of Brain death[23].Information among the aware were from the internet or media. Even among those aware of Organ donation, appx 80% were willing to donate organ, but only 1.4% had already pledged their organs. In addition to lack of awareness, religious beliefs, the other prominent reason to refuse was lack of faith in the healthcare system .Higher education was assosciated with better willingness.

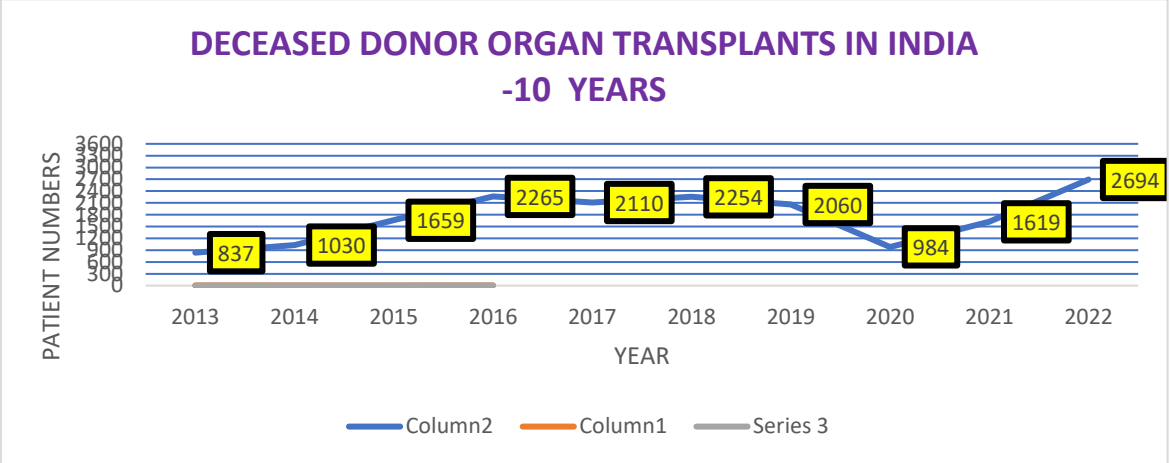
TABLE 6
TREND OF DECEASED DONORS IN INDIA IN LAST 10 YEARS



[22] Kute, V., Ramesh, V., Shroff, S., Guleria, S., & Prakash, J. (2020). Deceased-Donor Organ Transplantation in India: Current Status, Challenges, and Solutions. *Experimental and clinical transplantation : official journal of the Middle East Society for Organ Transplantation*, *18*(Suppl 2), 31–42.

[23] Panwar, R., Pal, S., Dash, N. R., Sahni, P., Vij, A., & Misra, M. C. (2016). Why are we Poor Organ Donors: A Survey Focusing on Attitudes of the Lay Public From Northern India. *Journal of clinical and experimental hepatology*, *6*(2), 81–86. https://doi.org/10.1016/j.jceh.2016.04.001

TABLE 7
TREND OF DECEASED ORGAN TRANSPLANT IN LAST 10 YEARS



3.8 POINTS OF NOTTO DIRECTOR FOR ALL INDIA IMPROVEMENT IN DECEASED ORGAN TRANSPLANTATION IN SEVEN IMPORTANT FOCUS AREAS

i. Brain stem Death (Subsec 6 of Section 3 of THOA 2014)

Inspite of the guidelines, the identification of potential Organ donors are not happening in the ICUs to a large extent . This needs sensitivisation of ICU staff, including doctors, and should be periodically audited by the hospital management. > 1.60 lakh RTA deaths happened last year, but donors were a small percentage- This points to the need to sensitivise and recharge, these Trauma care ICUs. Incentivisation of Brain stem death declaration can be considered as a policy.

An additional vexing issue, is the lack of Brain stem death, as a way to certify, in the death form of the hospitals.This has to be rectified, by adding this term too, to the death certificate as per amending the Birth and Death Act or bringing in a Separate law. Doing this will automatically enable ICU doctors to also declare a patient as dead, and withdraw ventilator or life support : thereby preserving resources for another salvageable patient.

ii. Organ Retrieval Centres

Organ Retrieval Centres with an ICU, Operation theatre, Transplant coordinator, Authorisation committee of death certification, should be established in every district, preferably in the medical colleges and every trauma centres. Airport Health officers too to be trained. Standard Organ Transport Boxes to be developed with DRDO.

iii. Government Multiorgan Transplant centres(1/state)

These will serve as a hub in every state, with the spokes being the Organ retrieval centres, who will retrieve organs, and send there. Aim is to augment the capacity, to increase Kidney transplant in India to 1.75 lakhs per year. AIIMS Bhubaneshwar is to be developed as a model Organ Transplant Program in the country.

iv. Transplant Training

Every Medical college should have a transplant unit, in which the nephrologist, Surgeons are intensely trained in transplant. They will train further PG residents too, thereby augmenting national capacity. Transplant coordinator training too, can be systematised. Regular CME programs too can be conducted for Doctors, Nurses and paramedicals.

v. Curriculum

Organ donation and transplantation awareness should be introduced in Schools, Colleges and also in MBBS curriculum. Transplant surgery has to be part of GenSurgery curriculum**.**

vi. Donor family

The donor families are felicitated in some states. There can be a uniform policy of some benefits like reservation or Income tax benefits etc.

vii. Central e Registry and allocation & SOTTOs

We should create central e-registry for Live, Cadaveric donors and a dialysis registry nationwide. As of now the SOTTOs allot organs predominantly inside the state, and if no donors found then offered at a national level . Central guidelines for all SOTTOs are needed. A central dash board at All India level will be ensure transparency in the process.

Finally it is noted that Organ transplantation in India has increased 3.5 times in last 10 years , however the picture is a complex mosaic as brought out in this chapter with some southern, western states far ahead and a few eastern states very far behind.The infrastructure for transplant, the expertise needed, the public awareness, the will of the medical fraternity and the policy makers, all need to improve exponentially for organ transplantation to reach meaningful levels in India. Another prohibitive factor is the costs involved during the procedure and also the immunosuppresive drugs needed in the long term which are way beyond the paying capacity of a majority of Indians**.**

CHAPTER 4

GUJARAT DECEASED ORGAN DONATION

The deceased organ availability is the key to make India selfsufficient in organ transplant. Unfortunately with such a large number of Brain dead victims,the people ending donating organs are a miniscule percentage . As Transplant centres too go up, both live and deceased transplantations will go up. However we need to focus on Deceased Donor programme in the long run, for the deficit to be bridged and in this the Gujarat model of SOTTO and its working is an example from where we can pick up valuable learnings. Deceased organ transplantation is the field, where Gujarat leads the way in India. Institute of Kidney Disease and Research centre (IKDRC) the government hospital[24]of Ahmedabad has been spear heading the Gujarat effort in the Deceased donations. After the baseline data, the interactions were held with SOTTO, the ICU doctors in Ahmedabad , Surat and Transplant coordinators in the large hospitals, spread all over Gujarat. The purpose was to know the reasons of relatively better performance of Gujarat in Deceased organ donation. Why is the deceased transplantation so dismal, in large parts of the India, [25]and what can be done for correcting it, may have answers in Gujarat.

4.1 Salient features of Gujarat Deceased Organ Transplantation are as follow

a) SOTTO Gujarat has been formed in 2019, however the first transplant has happened in Gujarat in 1998 in Surat.
b) Government and private hospitals are sharing the load appx 50% each which is showing the proactiveness of Government hospitals .
c) Throughout India in 2020-21, due to the COVID pandemic there was a dip in Organ transplantation from previous years .
d) If we compare 2016-2018 vs 2020-2022 inspite of the COVID, the deceased kidney transplantation increased by 140.59% and the deceased liver transplantation by 133.34% in Gujarat.

[24] Kute, V. B., Patel, H. V., Modi, P. R., Rizvi, S. J., Shah, P. R., Engineer, D. P., Banerjee, S., Butala, B. P., Gandhi, S., & Mishra, V. V. (2020). Two Decades of Deceased Donor Kidney Transplantation at Ahmedabad, India. *Experimental and clinical transplantation : official journal of the Middle East Society for Organ Transplantation*, *18*(5), 549–556.

[25]Sachdeva S. (2017). Organ donation in India: Scarcity in abundance. *Indian journal of public health*, *61*(4), 299–301.

e) The Deceased Kidney transplants in Gujarat for 2020-2022 was 22.04% whereas in All India, it was 10.20 %.

f) The Deceased Liver transplants in Gujarat for 2020-2022 was 65.59% wheras All India it was 17.67%.

g) The deceased transplantation of kidney in Gujarat in 2022 alone was 252 which translates to 28.99% of all Kidney transplants and that of Liver 124 which translates to 66.67% of all liver transplants which happened in the state and it is way ahead of national averages.

h) Comparing 2020-22 to 2016-18 deceased kidney transplant increased from 303 to 426 registering a 140.59% increase inspite of COVID .

i) In same periods deceased liver transplants increased from 161 to 223 registering a 133.34% increase.

j) Comparing years of 2016 and 2022, the change is more perceptible with deceased kidney tx increasing from 103 to 252 in 6 years and liver from 59 to 186 ,a > 300% increase.

TABLE 8

GUJARAT ORGAN TRANSPLANTATION 2016-2022(SOURCE- SOTTO, NOTTO)

Year	Dec Kidney	Live Kidney	Total Kidney	Dec Liver	Live Liver	Total Liver
2016	103	241	344	54	5	59
2017	106	239	345	63	1	64
2018	94	256	350	49	9	58
2019	104	622	726	52	25	77
2020	61	318	379	31	27	58
2021	113	572	685	66	28	94
2022	252	617	869	124	62	186

TABLE 9
KIDNEY TX TRENDS-GUJARAT 2016-2023(SOURCE-SOTTO,NOTTO)

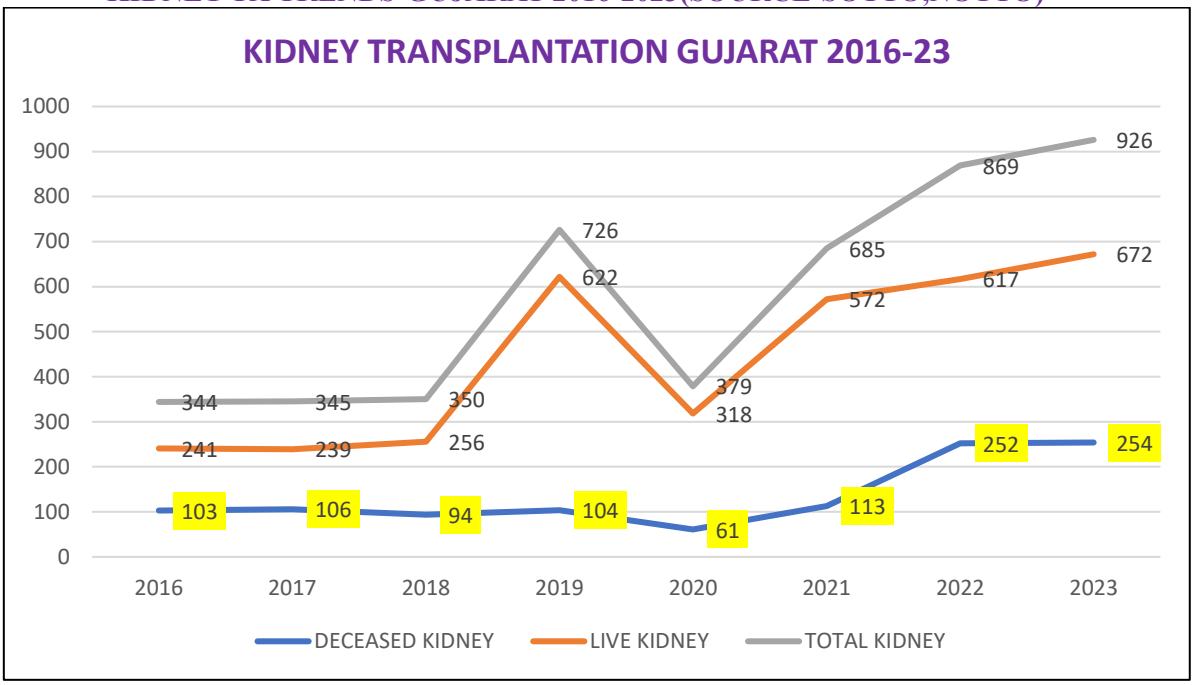


TABLE 10
LIVER TX TRENDS GUJARAT 2016-2023(SOURCE-SOTTO,NOTTO)

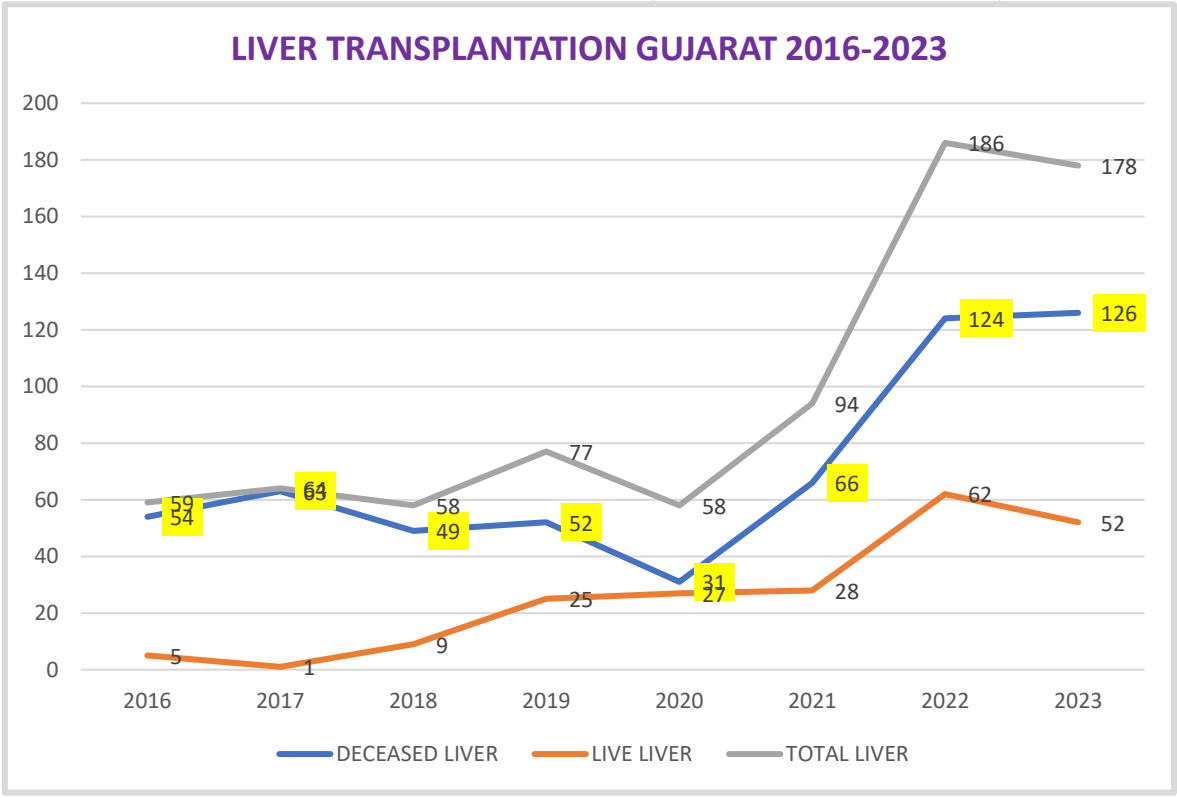


TABLE 11
DECEASED KIDNEY TRANSPLANT 2016-18 VS 2020-22 GUJARAT

Year	Dec Kidney	Live Kidney	Total Kidney	Dec Liver	Live Liver	Total Liver
2016-2018	303	736	1039	166	15	181
2020-2022	426	1507	1933	223	117	340
comparison	303 vs 426			166 vs 223		
Increase	140.59%			133.34 %		

TABLE 12
COMPARISON OF DECEASED TX IN GUJARAT VS ALL INDIA (2016-18 & 2020-22)

Year	Dec Kidney-GUJRAT % OF TOTALKIDNEY TX	Dec Kidney All india %	Dec Liver Gujarat% of Total liver Tx	Dec Liver All India %
2016-2018	29.16 %	16.16%	88.26%	34.35%
2020-2022	22.04%	10.20%	65.59%	17.67%

TABLE 13
DECEASED DONATION IN 4 GOVERNMENT HOSPITALS GUJARAT SINCE 2019

HOSPITAL	2019	2020	2021	2022	2023
CIVIL HOSPITAL,AHMEDABAD	0	0	22	67	41
CIVIL HOSPITAL,SURAT	0	0	0	11	36
SSG HOSPITAL,BARODA	0	0	0	3	2
SIR T HOSPITAL,BHAVNAGAR	11	2	0	0	1

After looking at the impressive figures we proceeded to look at the feedbacks from the key players on the ground. The Transplant coordinators are spread out in all the hospitals doing retrieval and also organ transplantation and work under the supervision of NOTTO. They were spoken to and the study and its aim was explained and thereafter a questionnaire of 6 questions in an open ended qualitative format was administered to them. They were encourage to give direct verbal feedback too, in addition to the questions.

They participated willingly and inspite of their busy schedules interacted personally .All of them gave impression of being passionate about organ transplantation and were proud of their work as well as the Gujarat programme. The summary of the questions and their responses from the varied transplantors in various hospitals are given below and is tabulated as 2 tables.

4.2 FEEDBACK FROM TRANSPLANT COORDINATORS

After the interaction with the Transplant coordinators in various hospitals in various cities the following points have come out

1. Prominent challenges they faced while coordinating transplants

Most of them faced no issues in coordinating transplants, as the machinery of the hospital has got used to it over time. However certain concerns they had was the question of Brain Death certification to be done promptly, so that the rest of the process can start. The relatives are counselled with all family members usually, grief counselling too is done and Audio/video assisted counselling is done. They try to convey the concept of Brain death and its irretrievability, which needs to be understood to give willingness to donate organs.

A question they usually face is on the time, it will take to release the body, after organ donation and the rapidity in this, will assist in more people willing to come forward. If a patient agrees to Donate there are no hospital charges therafter till the body is released to the NOK.

2. Type of support availed from the hospital while coordinating transplants

The transplant coordinators are getting acceptance, as part of the hospitals and most departments are cooperating.They are on Ad hoc employment, and are sent for training programmes and in turn, they conduct classes for hospital staff and paramedics, and also CMEs etc, to improve awareness and responsiveness.

In addition, the hospitals are giving them logistic and administrative support in their functioning and have formed whatsapp group etc, to hasten the responses, should an organ donor be available. Also educational material on Donation, are available to them and also displayed in ICU areas.

3. Family Acceptance to donate organs

There is a positive sentiment in patients relatives to donate organs and more people are coming forward for Organ donation from their brain dead relatives even in times of grief.

4.Reasons that have led to more people willing to donate organs

One of the most important reason felt by most, is the improvement in counselling. They are doing it more structured, using Audio/video etc and spending time, answering all queries. Many a time in addition, a trained doctor too is available to answer all the queries.

Second reason, they feel is the awareness drive, they are doing and SOTTO is doing, like Marathons,CMEs,Media clips,social media messages etc. Also practise of felicitation of a family

which is donating the organ of a relative, and also its prominence in newspapers and media, encourages more to come forward, and also contributes to awareness.

Third reason is the assosciation of Social,Religious ,Political leaders with organ donation and their messaging. This reaches more people and creates a positive sentiment on Organ donation.

5.Five factors leading to more deceased organ transplantation

The first improvement they feel is training and practise of identifying potential donors and brain death by the ICU team. This alerts the Transplant coordinator and the wheels are set in motion. There is also concept in some hospitals of 2 beds kept in a side of the ICU, where such patients are kept for closer monitoring and organ support, before the procedures are completed as viability depends on maintain the blood pressures etc.

The second improvement they feel, is the public awareness about organ donation even while patient is in ICU, which is increasing thanks to the multitude of factors. The third is the smooth functioning and coordination both within the hospital and also with the SOTTO Gujarat. Fourthly the use of Audiovisual aids is assisting in the process. Lastly they feel the trained Neurointensivist teams are contributing in a big way in identifying the potential cases.

6. Suggestions to increase deceased organ transplantation

More awareness drives, including short capsules on organ donation in media,social media etc, will improve awareness. They also feel some incentivisation of Organ donation will help. An additional suggestion has been a Zone wise allocation policy for Donor organs and transparency about recipients. They also feel prominent citizens,media personalities should be roped in as the face of Organ donation. School children too should be made aware of this.

TABLE 14
TRANSPLANT COORDINATORS FEEDBACK QUESTIONS 1-3

TX COORD NAME PLACE	Q1-CHALLENGES IN COORD TX	Q2-HOSPITAL SUPPORT U GET	Q3-ARE RELATIVES MORE WILLING NOW
1.DR NILESH **CIVIL HOSP SURAT**	Difficulty identifying brain death	2 room icu set for potential donors Whatsapp group drs and coordinator	Yes
2.NIKHIL VYAS **KD HOSP AHMD**	None	Good coordination	Yes
3.DR ALPA PATEL **KIRAN HOSP SURAT**	Doubts on organ allocation Doubts on cost	Logistic support Financial support	Yes
4.KALPESH **SSG HOSPITAL Baroda**	Counsel all Relatives religious doubts body return time	Overall logistic support	Yes
5.PRIYA SHAH **IKRDC AHMD**	None at present	Hospital departments are now fine tuned	Yes

TABLE 15
TRANSPLANT COORDINATORS FEEDBACK QUESTION 4-6

TX COORD NAME PLACE	Q4-IF YES THEN WHY	Q5 - IMPROVEMENTS IN YOUR CENTRE	Q6-WHAT MORE ARE NEEDED
1.DR NILESH **CIVIL HOSP SURAT**	Doctors trained to counsel	Counsel for 1hr all relatives nok AV Aids used	Infra Edn activities
2.NIKHIL VYAS **KD HOSP** **AHMD**	IEC Activities Community awareness Media +ve role	IEC Activities Grief counsel Public awareness activities	Family needs support Central Org Retr Team Leaders political,religious need to involve more
3.DR ALPA PATEL **KIRAN HOSP** **SURAT**	SOTTO giving 50000rs harvesting charge	Counseling better Infrastructure Well trained intensivist & Neuroteam	Zone wise allocation policy
4.Kalpesh **Baroda**	Counseling Awareness Seminar	Counseling Family awareness	Social media,radio Felicitation
5.PRIYA SHAH **IKRDC** **AHMD**	Public awareness Grief counseling	Brain death pickup Grief counseling	More centres

4.4 SPECIAL INPUTS FROM DR PRANJAL MODI- SOTTO GUJARAT CONVENOR AND DIRECTOR, IKDRC

It was observed that the concept of philantrophy in Gujarat exists for a long time. Number of hospitals doing transplants have been going up steadily. Presently appx 50% of the organ transplant work happens in government & 50 % in private hospitals. Intercity transport of Organ after harvesting is actively promoted and Govt hospitals reaching out is novel idea of Gujarat where a team goes out to procure organs from the periphery. Felicitation of Donors and also the transplant teams by the government has been happening since 2005 causing an improvement in motivation .Media has been always highlighting organ donation positively and causing a positive public sentiment.

Specific suggestions which emerged after discussions are

I. Medical college per district are being set up and Organ retrieval needs to be happening in them, and more private hospitals in the state .

II. Financial remuneration of Transplant coordinators should further improve and permanent job will improve their commitment further and should be considered.

III. Organ Procurement Organisation as adapted in western countries of mobile teams to retrieve organs is a brilliant concept and we too can have retrieval teams to fly in, retrieve organs and transport to the transplanting centres.

IV. Brain Death Certification- should be made mandatory, if identified. If donation not being done also, there should be rules to remove life support thereafter. This will preserve precious resources like ICU Beds, Ventilators too in a developing country.

V. THOA 2014- Need for a revision and clear demarcation of chapters, on live and deceased transplantation is needed. Also can include guidelines on donation after Cardiac death.

VI. In borderline cases, Organ perfusion systems have a role in identifying organ vitality-so these should be made available- also the costs of maintaining the organ must be borne by the government.

VII. Education- On organ donation awareness in Highschool, colleges- NCERT can take a lead by adding to sylabbus . In Medical colleges-it should be added to MBBS, MS gen surgery curriculum. Also more focused training in aspects of Transplant radiology, pathology needs to be done.

VIII. Government hospitals are still trusted by the public and these hospitals should take the lead in Organ Donation and transplantation

Deceased organ transplant in Gujarat is robust and also further picking up. Government Hospitals are taking the lead in Transplantation and this is propelling the program. Rapid increases of 30-40% in 5-6 years has to be related to Institutional and Policy level changes translating to better willingness to donate on ground. The civil hospitals in Ahmedabad, Surat are large public hospitals taking pole position . This ensures public trust in the program and accessibility for the masses.Also they have become centres of best practices for the medical and paramedical staff of the whole state. The machinery at Hospital level seem very well oiled and responsive for the process of Organ donation and transplantation.

FIGURE 12
2021-TOI- MULTIPLE DONATIONS ON SAME DAY IN GUJARAT CIVIL HOSPITAL

Record 3 organ donations in 24 hours at Civil Hospital

TIMES NEWS NETWORK

Ahmedabad: In a major feat in the field of organ donation, Civil Hospital recorded three cadaver donations and nine transplants in a matter of 24 hours. The State Organ and Tissue Transplant Organization (SOTTO) officials got congratulatory message from state health minister Rishikesh Patel as they worked continuously for 20 hours.

"It could well be a first for any government-run hospital in India according to our information," said Dr Rakesh Joshi, medical superintendent of Civil Hospital. "Six kidneys and three livers are retrieved and transplanted at IKDRC. The number also indicates that now there is awareness among people about the noble cause."

The patients included Bhavin Parmar, 19, a resident of Mehmdabad; Jyotsna Parekh, 65, a resident of Gandhinagar; and Bhavna Thakor, 40, a resident of Viramgam. In the past 14 months, Civil Hospital has got 119 organs from 39 brain-dead patients.

FIGURE 13
PUBLIC AWARENESS POSTER SOTTO GUJARAT(AN EXAMPLE)

FIGURE 14
2 SUCCESSFUL DECEASED DONATIONS IN PRINT MEDIA -SOTTO GUJARAT

His father lives on in 8 people

Tejas Patel's Wedding This Year Was Attended By Organ Recipients

Parth.Shastri
@timesgroup.com

When Jagdish Patel, 49, an employee with a private firm in Surat, met with an accident on Surat-Hazira Road while going to his native place in December 2015, it changed course of life for not one or two, but eight persons spread across four states.

Relatives of Patel, who was declared brain dead by a Surat-based hospital, decided to donate his organs as his heart, liver, pancreas, kidneys and eyes were provided to patients from Gujarat, Rajasthan, Madhya Pradesh and Maharashtra. Rajan Desai, an officer with IOC, got Patel's heart at a Mumbai hospital in the first inter-state heart transplant in western India.

When Tejas, Patel's son, got married three months ago, the event was attended by all the recipients of Patel's organs. "We felt that he was with us to bless the union," said Tejas.

While thousands die in India due to want of organs, the case of Jagdish Patel and his family exemplify how the organ donation is not the end for a person but a new beginning for families.

"My father was generous to a fault all his life – helping his family and all from his native place in whichever way possible. After we got to know that he would not be survived, we were contacted by Donate Life's Nilesh Mandlewala who advised us to donate his organs. We could not have thought of a better way to celebrate his life," said Tejas, working with a private firm in Surat.

BOND FOR LIFE: (Top) Rajan Desai (left) with the late Jagdish Patel's family, at Tejas' wedding in Surat in March 2018. Patel's heart was transplanted into Desai in 2015; (Left) Patel's heart was transported to Mumbai in 92 minutes flat in 2015

To sign up as an organ donor, log on to www.organdonationday.in | Or give a missed call on 8826262626

Kokilaben Dhirubhai Ambani hospital & medical research institute presents

Every Life Matters

TIMES ORGAN DONATION DRIVE

an initiative by THE TIMES OF INDIA

The family made it a point to reach out to all the recipients of organs and invite them for 'Tejas' wedding in March. It was an emotional moment for the family to realize that eight persons got a new lease of life. "Desai asked us to consider his home in Mumbai as ours whenever we visit the city," said Tejas.

Mandlewala said that every organ donation connects two families or more through a unique bond of life. "We thus promote the cadaver organ donation so that a brain-dead person can give life to someone. It's important to create awareness about the procedure and to counsel the family with all the facts," he said.

For Vijay Rayani, 28, running a pesticide business in Gondal, the news of his kidney failure came as a shock as till the diagnosis, he seemingly led a normal life. "The decision was taken on the spot when my father Chandubhai decided to donate one of his kidneys. But I am aware that not all are as fortunate as me who get the willing donor. I would thus appeal all to pledge the organs in case of brain death or help out the close relative in need," he said.

Dr Sanjay Pandey, Kidney Transplant Surgeon, Kokilaben Dhirubhai Ambani Hospital (KDAH) at Mumbai, echoed Rayani's sentiments. "Out of the 100 patients on dialysis, only two to 10 would get the kidney they need. The situation arises as not all can get the donation from their close ones allowed to donate. While there is awareness about organ donation, there is a long way to go," he said.

Pandey said that kidney is a wonder organ as a person can donate it during his/her lifetime unlike some other organs. "Each organ donation is a gift of life. I vividly remember a case where a jawan from Indian Army was declared brain dead after an accident. His family decided to donate his organs and thus he, who was ready to give his life for the country, instead gave new lease of life to four persons," said Dr Pandey.

GUJARAT
THE TIMES OF INDIA, AHMEDABAD
FRIDAY, OCTOBER 30, 2020

Brain-dead diamond artisan brightens up lives of eight

28-Year-Old's Eight Organs Transplanted

TIMES NEWS NETWORK

Surat: He had been giving rough diamonds the lustre and shine for nearly a decade. And, in his death too, 28-year-old **Piyush Mangukiya** brought a glow in the lives of as many as eight critically ill patients.

Eight organs including heart, kidneys, lungs, liver, eyes and pancreas, were transplanted in needy patients in Ahmedabad and Mumbai, on Thursday. In fact, this is said to be the first donation where all eight organs of a deceased have been transplanted. Mangukiya, who was working with Shree Ramkrishna Exports, suffered severe head injuries after his bike slipped on the road near Sayan check-post on October 24. He was rushed to SMC-run SMIMER Hospital and later shifted to a private hospital where doctors declared him brain dead on Wednesday.

Mangukiya is survived by his wife Nayna, daughter Dhanshree (9) and son Panth (6) who live in Nandini Society in Kamrej adjoining Surat.

Narayan Mangukiya, the donor's father, said, "We had read about cadaver donations in the newspapers, but did not know the process. After final rites, his body would have turned into ashes. It's better that my son's vital organs give new life to people. We will feel that he is living in all these eight people now."

After the family's consent, the State Organ and Tissue Transplant Organisation (SOTTO) convener Dr Pranjal Modi in Ahmedabad was informed and the procedure was initiated. Two eyes were donated to Surat Eye Bank.

"This was the first case where eight organs have been donated," said Nilesh Mandlewala, founder and president, Donate Life, Surat.

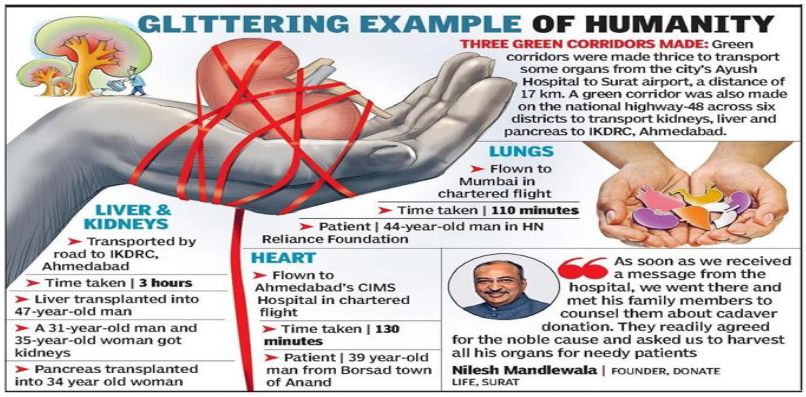


FIGURE 15
GUJARAT SOTTO IT WEBSITE UPGRADATION HIGHLIGHTED BY MEDIA

EXPERTS, STAKEHOLDERS MEET FOR 3RD TOI-KDAH ROUNDTABLE ON ORGAN DONATION IN GUJARAT

Gujarat to get website for cadaver organ donation in Feb

Pics: Yogesh Chawda

STALWARTS SAY

The state government has created necessary infrastructure for organ donation through transparent system. In coming days, we are focusing on large-scale awareness to motivate people for cadaver organ donation

Nitin Patel | DEPUTY CM, GUJARAT

We are creating a cadre of transplant coordinators and intensivists with help of medical colleges. We will ensure a sustainable and all-inclusive cadaver transplant programme

Dr Jayanti Ravi | PRINCIPAL SECRETARY (HEALTH)

Maharashtra was the leader in cadaver organ donation in 2019 with multi-pronged approach and involvement of ZTCC. Smaller centres and hospitals should also be involved in the process and awareness among doctors should be created right from MBBS level

Dr Santosh Shetty | EXECUTIVE DIRECTOR AND CEO, KDAH

Parth.Shastri
@timesgroup.com

A year after setting up the State Organ and Tissue Transplant Organization (SOTTO), Gujarat will now launch a dedicated website for coordination of cadaver organ donation. Dr Jayanti Ravi, principal secretary, health, informed the same on Friday to participants of the 3rd roundtable on organ donation organized by The Times of India and Kokilaben Dhirubhai Ambani Hospital in Ahmedabad. Ravi said the website will be launched in February, within a month.

"The development is in final stage. After deliberations, we decided it would be modelled on the NOTTO website and hosted by National Informatics Centre (NIC) for safety and privacy concerns," said Dr Ravi. States like Tamil Nadu and Kerala already have such websites in place.

The roundtable was also attended by Jai Prakash Shivahare, commissioner (health); Dr Somnath Chattopadhyay and Dr Santosh Shetty from KDAH, Mumbai; Dr Rajesh Chandwani from IIM Ahmedabad; Dr Dhiren Shah, heart transplant surgeon; Dr Chirag Desai, liver transplant surgeon; Dr Kavita Parihar, nephrologist; and Bhavna Chhabria from Shatayu.

While Dr Chattopadhyay deliberated on hand-holding of smaller centres and hospitals by major hospitals to create a cohesive ecosystem, citing example of Mumbai, Dr Desai advocated a system of transplant coordinators at both transplant and non-transplant hospitals that can work closely with relatives of brain-dead patients.

Dr Parihar put forth the issue of non-representation of private hospitals in SOTTO and said that the robust model should have organ-specific committees involving all stakeholders.

Dr Shah seconded her, adding that steps such as generation of common waiting list have not been implemented so far.

"The hospitals affiliated with medical colleges have been authorized for declaration of brain stem death in the state. Extensive training workshops have been organized for the doctors and staff which is yielding good results," said Shivahare.

Dr Chandwani said organ donation is a complex process and at initial stage should focus on organ retrieval. It needs training and transparency. Chhabria mentioned that non-transplant hospitals in Gujarat have no transplant coordinators or 'grief counselors' who could work with doctors and relatives and also stressed on early-stage education initiatives.

(With inputs from Kapil Dave)

STRIVING FOR A CAUSE: (from Left) Bhavna Chhabria, Dr Somnath Chattopadhyay, Jai Prakash Shivahare, Dr Santosh Shetty, Dr Jayanti Ravi, Dr Dhiren Shah, Dr Chirag Desai, Dr Rajesh Chandwani and Dr Kavita Parihar at TOI-KDAH roundtable for organ donation in Gujarat

Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute
Every Life Matters
TIMES ORGAN DONATION DRIVE
THE TIMES OF INDIA

To sign up as an organ donor give a missed call on 8826262626 or visit www.organdonationday.in

Learning empathy

OI-KDAH organized a two-day awareness campaign on organ donation at Subhash Bridge and Vastral RTOs for learning licence aspirants. Several Amdavadis took pledge to donate their organs.

FIGURE 16
ORGAN DONOR FELICITATION EVENT INVITATION- SOTTO GUJARAT 2022

Felicitation of Organ Donor families

by

State Organ & Tissue Transplant Organization, Gujarat

&

Gujarat University of Transplantation Sciences

Chief Guest

Shri Rushikesh Patel
Hon'ble Cabinet Minister
Health and Falimy Welfare Department
Government of Gujarat

Shri C.R. Patil
Hon'ble Member of Parliament
President of BJP,Gujarat

Guest of Honor

Smt. Sunitaben Trivedi

Shri Dilip Deshmukh

Date: 31st August, 2022
Time: 03 PM to 05 PM

Venue
Maa Sharda Laxmi Audotorium
IKDRC-ITS GUTS
Opposite Trauma Centre, Civil Hospital Campus,
Asarwa, Ahmedabad

Invitee

Prof. (Dr.) Pranjal Modi
Vice-Chancellor
Gujarat University of
Transplantation Sciences

Shri Manoj Aggarwal, IAS
Additional Chief Secretary,
Health & Family Welfare Department
Government of Gujarat

Public awareness is increased by the Hospitals, SOTTO, NGOs, Media and Sociopolitical figures,all working in tandem. The policy makers seem aware of the need to promote further transplantation and are active in felicitation of doctors, donor families, educational programs etc. Public awareness events like camps ,marathons etc are held frequently and media too also

has played a constructive role in promoting good will and a feeling of pride among the donors and awareness in the public in general.Further boost to the program has happened after SOTTO Gujarat was awarded the PM Excellence award in 2022 for remarkable progress in deceased organ transplantation in the country.

FIGURE 17
GUJARAT SOTTO AWARDED PM EXCELLENCE AWARD-INNOVATION STATE

CHAPTER 5
ENABLING FACTORS IN SOTTO GUJARAT

Gujarat leads the country in proportion of Deceased kidney and Liver transplantations. Infrastructurally Gujarat has appx, 50 retrieval centres mainly in the various cities, and 25 transplanting centres again in the cities, some of them playing a dual role. States with much higher number of Hospitals, are far behind in Deceased organ donation, and hence this study tried to identify the reasons for the same.

The identified enabling factors in SOTTO Gujarat are enumerated below and similar examples in literature worldwide are quoted below each of them

a) Government Hospitals,SOTTO -Proactiveness in Gujarat

They have a lot of public trust earned over the years. These hospitals follow the process of even sending teams to peripheries to assist in retrieval, and bring the organ to the main hospital for transplant. This kind of outreach is Unique and effective, The government hospitals of Surat and Ahmedabad, have contributed the lions share in Deceased donation. Reason is the perception and good will among the public, as they are government hospitals, mainly catering for the poor and doctors are trusted. They have been getting active support from the police for organ transport too by creating green corridors.

SOTTO Gujarat too, functions out of the Civil Hospital and IKDRC complex, which is government owned. They are proactive and reaches out to other hospitals, for training and CMEs. They have a motivated set of doctors and staff, who are well aware of the procedures and are now spread out all across the state. They have created educational videoes and material, which is shared with the transplanting hospitals. In case of Donation, all expenses thereafter, till the body is handed respectfully to the relatives, are borne by the SOTTO upto max 50000rs.

Sarvesh pal Singh, in a study of thoracic organ transplant in 2020, [26]suggests all hospitals (either government or private) do not have the same reputation. Private hospitals charge between three and four times of government hospitals. Because the patient pays more, expectations about patient management are also high. Therefore, long admissions after transplant surgery often raise suspicions, and more so, adverse outcomes after long admissions trigger litigations. Government institutions have less of these problems. The buildup of public trust in government hospitals over

[26] Singh, S. P., & Hote, M. P. (2020). Opportunities and challenges for thoracic organ transplantation in government institutions. *Indian journal of thoracic and cardiovascular surgery*, *36*(Suppl 2), 210–214. https://doi.org/10.1007/s12055-019-00808-z

years, provides opportunity to refute popular or religious beliefs, especially in relation to organ donation.

b.Counseling and interaction with NOK of potential Donors.

i. ***Counseling Innovations***

Innovations which they have done, is the structure and way the counselling is done, with the next of kin of the potential donor. The transplant coordinators and the doctors are well trained, and they spend time -sometimes an hour or two, interacting with the family in times of grief, answering their doubts, explaining the concept of Brain stem death using audiovisual aids and also does grief counselling. All members of the family are called, the family structure understood and the decision makers in the family are called surely, for the counselling. This ensures better conversion ; family more likely saying yes to an Organ donation.

ii. ***Felicitation of Donor Families and Media Publicity***

The donor families are felicitated and also honoured in a solemn pious ceremony, before body is handed over, after organ retrieval and these are published in local media, news papers. This creates a positive sentiment.

Wojda et al in 2017 [27]published their pennysylvania approach, of the best practices in conversion for organ donation, in the next of kin of the Deceased donor. Their Best Demonstrated Practices (BDPs), developed by The Partnership for Organ Donation, encourage four key elements: timely referral of a potential organ donor, OPO evaluation of donation potential, an appropriately timed and planned family approach, and a collaborative family request by the healthcare team (HCT) and OPO staff. Referrals are considered timely, when made at the first indication of a non-recoverable neurologic injury or illness, prior to formal brain death exams, and before the family makes any decisions to limit or decelerate life sustaining therapies. A "planned approach" to the family discussion about donation occurs when the OPO representative initiates that conversation in consultation with the HCT, rather than if the attending physician or another member of the HCT initiates it independently. When a "timely referral" and "planned approach" occur together, optimal donation outcomes are observed; OPO data have shown that when these two metrics are in place conversion rates are higher .This approach is quite similar to the one being followed in

[27] Timar, J., Bleil, M., Daly, T., Koomar, S., Hasz, R., & Nathan, H. (2021). Successful strategies to increase organ donation: the Gift of Life Donor Program Philadelphia model. Indian journal of thoracic and cardiovascular surgery, 37(Suppl 3), 380–394. https://doi.org/10.1007/s12055-021-01219-9

SOTTO Gujarat and it has advantages of early family interaction, trust, involving all the family and devoting time .

c. ***Motivated vigilant ICU teams***

The team of doctors in the critical care and emergency, are of vital importance in success of any Deceased donor programme. They have to identify potential donors, support the patient and also alert the transplant coordinators. Critical patients can come at any time of day or night, and hence the alertness level needs to be 24 hrs. In the hospitals which were seen, they have young motivated doctors, who have one person who does the lookout for a potential donor, in every shift and they have a whatsapp group to communicate faster.

Mostly consisting of specialist doctors in ICU, they are alert about possibility of brain death and those patients are cared for separately. If patient cannot be salvaged, the transplant coordinators are informed, and the process of counselling starts to explore donation. After 2nd apnea test ,all the expenses are borne by SOTTO upto 50000 rs.

Karunakaran in an editorial[28] remarked that the biggest barrier in India, is not in obtaining consent, but in seeking it. It means the hospitals need to actively seek and identify donors, and this aspect is very important for deceased organ donation, and on ground many shy away from it, due to time which needs to be invested, the legalities and no financial incentives for the hospital. Global experience shows that mandating certification of all brain deaths, as well as required request as a solution to this, although with many practical issues, whereas nudging is known to work with hospitals. Hence, state agencies should promote Brain death identification and declaration in hospitals.

d) Transplant Coordinators

Gujarat has a set of motivated selfless transplant coordinators, in all the hospitals involved in the process under Ms Priyadarshini shah, the state transplant coordinators chairperson, located in the Civil Hospital at Ahmedabad. These coordinators are active since time of identification of the potential donor, informing SOTTO once Brainstem death is confirmed , till retrieval is done and organs transplanted. Many of them are on ad hoc employment and still quite motivated.

They are made to undergo training courses in state and ROTTO at Mumbai. They inturn also conduct training for the hospital staff of the place they are working on. This ensures readiness and a smooth well oiled machinery in the hospital for the Donation programme.

[28] Karunakaran C E, Amalorpavanathan J. Hospital awareness rather than public awareness is key to promote organ donation. Natl Med J India 2018;31:193-195

Patel in their study in 2018[29] lamented that the lack of an adequate number of transplant centers with staff, as well as transplant coordinators, who are adequately educated and well versed with the procedures required to conduct an organ donation program, is acting as a significant roadblock to the deceased organ donation program. Hospitals should have a clear protocol for declaring brain death and intensive care staff including paramedics, should be well aware of the protocols.

A Spanish study in 2021[30] states that the donation process is both complex and delicate, and care is an essential component. The care provided by the nurse transplant coordinator, has the donor at the centre of the process, driven by respect for their decision. The family is seen as an extension of the donor. The coordinator should focus on continuous, honest communication, coordinating care with the intensive care unit, ensuring privacy and intimacy. Mohan foundation in Chennai in early 2010 was one of the first NGOs to provide Transplant coordinators as an altruistic manner to large hospitals and this has significantly increased Deceased Organ donation there.

e. Multipronged Awareness Drives

Awareness drive has been a multipronged approach which is bearing fruit. Media and social media is active, highlighting positive stories of transplants and organ donation. Donor family members are felicitated and honoured as heroes. Doctors too are honoured every year. All this creates a basic level of background knowledge in the community in general and it helps in the process of counselling.

Additional awareness has been created by NGOs, like Donate life where the NGO is committed and has functionaries in varying parts of the state. They mainly help in transport of relatives of a potential donor, keeping a donor honour wall, felicitating the families and providing support in cremation etc. The NGOs are run by people who have had transplants in their family members and then became motivated to support this. Another important factor in public awareness, has been involvement of the politicians, social figures and large religious leaders with transplantation. This negates the negative barrier in peoples mind of rebirth or mutilation in next birth etc. Gujarat has a concept of giving and assosciated with a drive

[29] Patel, AnsyH & Balwani, Manish & Patel, Himanshu & Pasari, Amit & Patel, Utkarsh & Tolani, Priyanka & Kute, Van. (2018). Deceased organ donation in India – Current challenges and scenario. Indian Journal of Transplantation. 12. 174. 10.4103/ijot.ijot_26_18.

[30] Fernández-Alonso V, Palacios-Ceña D, Silva-Martín C, García-Pozo A. Deceased donor care provided by the nurse transplant coordinator: A qualitative research study among Spanish nurses. Int J Nurs Pract. 2021; 27:e12905. https://doi.org/10.1111/ijn.12905

involving SOTTO, Hospitals, CMEs, Media, Marathons, NGOs, sociopoliticoreligious figures ,it has created a positive sentiment about organ donation in the state.

A study by Alghamdi in Saudi Arabia in 2023[31] had 3507 individuals, in which around 68.1% were aged between 18 and 30 years. 58.5% believed that organ donation should be promoted; and 66.1% had a positive attitude toward donating body organs. Younger age (31– 50 years), male gender, being unemployed or working in a government job, and being married were factors that decreased the likelihood of having a positive attitude towards organ donation. Awareness was suboptimal. They concluded it is necessary to address the gaps in knowledge, and social media as well as mass media may have an important role in bridging the gaps.

A study in UAE in 2020[32] showed there is a knowledge gap, among the citizens with only 52% being aware of the law permitting transplantation from a living donor and even less (36%) knowing about the lawful organ donation from a person who has experienced brain death. Although the majority of the participants had knowledge about a brain-dead state, and nurtured positive beliefs regarding organ donation and transplantation, more than 30% of the participants strongly objected to the idea of organ donation at death.

Study by Tamuli in 2014 [33]noted that, Organ donation programs are at a very primordial stage in India and are almost negligible in its North-Eastern region. It is high time for the policy makers and other stake holders of a global giant like India to understand the magnitude of the benefits from these programs. Making tangible policies that are reflected nationally, emphasizing attention to both the organ donors and recipients, is the need of the hour.

In a study by Chandrasekharan in 2022 [34],all India among medical professionals and students a total of 1303 respondents were enrolled . The majority of the participants were students (66.5%)

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[31] Alghamdi, A., Alsaleh, A. A., Alfozan, O. A., Qutob, R., Alaryni, A., Bukhari, A., Hakami, O. A., Alhusaini, B. A., Alzmamy, S. A., Alhudayris, F. S., Alshuaibi, L. K., Alenazi, A. M., Alhosaini, L. S., Aljarba, N. K., & AlShammari, S. H. (2023). Awareness, Attitude, and Beliefs Regarding Organ Donation Among the General Public in Saudi Arabia. *International journal of general medicine*, *16*, 4973–4989. https://doi.org/10.2147/IJGM.S434589

[32] Janahi, F. K., Al Rais, A., Al Rukhaimi, M., Khamis, A. H., & Hickey, D. (2018). Public Awareness of Knowledge, Belief, and Attitude Regarding Organ Donation and Organ Transplantation: A National Survey From the United Arab Emirates. *Transplantation proceedings*, *50*(10), 2932–2938. https://doi.org/10.1016/j.transproceed.2018.08.006

[33] Tamuli, R. P., Sarmah, S., & Saikia, B. (2019). Organ donation - "attitude and awareness among undergraduates and postgraduates of North-East India". *Journal of family medicine and primary care*, *8*(1), 130–136. https://doi.org/10.4103/jfmpc.jfmpc_206_18

[34] Chandrasekaran, S., Chandrasekaran, V. P., Nandi, D., Setty, R. S., Srinivasan, O., & Kaur, K. N. (2023). Assessment of Awareness Level Regarding Organ Donation among Healthcare Professionals and Students in India. *Indian journal of critical care medicine : peer-reviewed, official publication of Indian Society of Critical Care Medicine*, *27*(1), 57–63. https://doi.org/10.5005/jp-journals-10071-24387

residing in southern India (89.6%) pursuing medical profession (88.9%). The predominant age group was 18–24 years (73.9%). The awareness level regarding organ donation among healthcare professionals and students was 69%. Healthcare professionals and respondents aged 40 years and above had better awareness levels regarding organ donation, which was reported as statistically significant ($p < 0.001$). It indicates incomplete awareness even among the care givers, and strategies including, but not limited to prioritizing employment and education, to the first relatives of the deceased organ donor should be implemented by the government, to legally improve organ donation willingness.

f. Infrastructure Improvements

The state is also witnessing increasing number of retrieval centres,transplant centres and also doctors, nurses and trained coordinators .This all translates to increased transplantation on the ground.

A study of South east Asian countries[35] showed they are lacking in healthcare resources such as workforce and materials, even though proper legislation, government support, and brain death laws along with an overall acceptance of brain death diagnosis. Priorities should include improving coordination, donor identification, and healthcare worker education. Countries in SEA have a lot of potential to increase deceased organ donation, especially by investing in healthcare and education.

Shroff in his study[36] noted that the vast majority of potential deceased donors, are poor motor vehicle accident victims, who present for care in hospitals, without the necessary infrastructure or expertise to support deceased donation. In contrast, transplant infrastructure and expertise are concentrated in private hospitals, and are only accessible to those with the ability to pay. Given these realities, the potential of deceased donor transplantation can only be recognized,if Indians who are likely to donate organs are also provided access to transplantation by reducing cost or providing insurance like Ayushman bharat scheme etc.

[35] Cowie, S., Choy, S. H., Shah, D. M., Gomez, M. P., Yoong, B. K., & Koong, J. K. (2023). Healthcare System Impact on Deceased Organ Donation and Transplantation: A Comparison Between the Top 10 Organ Donor Countries With 4 Countries in Southeast Asia. *Transplant international : official journal of the European Society for Organ Transplantation*, *36*, 11233. https://doi.org/10.3389/ti.2023.11233

[36] Shroff, Sun & Gill, John. (2021). Bold policy changes are needed to meet the need for organ transplantation in India. American Journal of Transplantation. 21. 10.1111/ajt.16537.

CHAPTER 6
RECOMMENDATIONS AND CONCLUSION

Organ transplantation is a program which needs intervention, from the national level to the public at large, to propel India to Organ sufficiency state. Indian picture, is a mosaic at present, with few areas doing well and few not at all. Even though this study was restricted to Enabling factors in Gujarat SOTTO- A PM Excellence award winner in 2022: the study and my interactions with various stakeholders during the study have thrown up a few suggestions, which iam putting down for consideration at a national level. This is to flag important issues for focus and follow up.

6.1 RECOMMENDATIONS

1. *IMPROVEMENTS NEEDED IN POLICY*

ISSUE-Private hospitals are hesitant to be aggressive, in declaring brain death certification as it is an extra effort with no remuneration. Financial support may be considered for retrieval, or a retrieval central team may be constituted area wise, under the SOTTO. Brain death certification and removal from ventilator is permitted and reinforced by the Supreme court ruling in 2023: however many are hesitant to do this, as the Death certificate does not mention Brain death .

SOLUTION-An amendment to this, in Rule of Birth and Death will be in order. Also the Birth and Death certificate may be modified, to add the word Brain death, either by legislation or an amendment. Also making it legally mandatory to declare brain death, should it occur, will ensure more declarations and identification of brain death. Incentives for Donor families, like reservation for 1 member for a limited period, may be considered in certain jobs or exams. Transplantation and post transplant immunosuppression, should be covered under Ayushman Bharat and PM JAY programmes. All of these will need intervention at National level , the Parliament.

HOW IT WILL HELP- It will result in more Organ donation, Reduce hesitation in private hospitals to declare brain death and also save precious resources and ICU beds for critical patients and support poor patients.

2. *IMPROVEMENTS NEEDED IN NOTTO*

a) **A central waiting list and a national donor registry, with centralised organ allotment, also can be considered at a later stage after consulting all the stake**

holders. Also further modification of THOA, with clear demarcation of guidelines for Deceased organ donation, and a separate guideline for Live organ transplant is needed. Also Central Multitransplant centre in every state may be set up. improvement in SCHOOL, MBBS, MS gen surgery programmes, mentor-mentee programs too can be envisaged at the national level by NOTTO .

b) **Air transport Officers -may be detailed at airports for facilitating organ transplant. Airport transport officers, Police personell and Transplant coordinator training should be an ongoing frequent programme.**
c) **Also at least a 3 monthly meeting with all stake holders including ROTTO, SOTTOS and Transplanting hospital representatives with any grievances, should be held to thrash out issues.**
d) **Financial support to various medical colleges, may be provided by NOTTO to set up and maintain Transplant units, training and their incidental expenses. Also financial remuneration to support the Deceased organ donors family for cremation may be considered as an incentive.**
e) **E registries : They need to keep centralised registries of disease wise patients, waiting for Organ, Also of those, who have been transplanted. And these need to be reflected in an active dashboard. An app may be envisaged, for the process of smoothening and facilitating transplant and related activities, also giving information to the stake holders and the patients relatives.**

3. *IMPROVEMENTS NEEDED IN SOTTOs*

a) **Have to take the lead in local public awareness initiatives , training of the ICU teams and the first responders in every state.**
b) **Must make transplant coordinator job financially attractive, as they are the pivot, on which Deceased organ donations success will depend.**
c) **They must conduct local CMEs ,media interactions and form protocols, for compliance at a local level.**

4. *IMPROVEMENTS NEEDED IN TRANSPLANT AND RETRIEVAL HOSPITALS*

a) **They should be enabled, by having the processes more smoothened by digitisation and e registries.**
b) **Periodic interactions with SOTTO, ROTTO must be formalised to iron out issues.**
c) **Prizes for best performing centres may be considered.**
d) **Financial support after relatives agree for donation, upto 50000 to the retrieval hospital is given by SOTTO Gujarat. This is an enabling factor and can be adapted nationwide to cover the expenses once a family agrees for this noble task .**

e) **Hospitals too might need financial support, for maintaining organs with doubtful perfusion, in a perfusion machine to check viability: should they decide to not accept the organ, due to poor quality.**

5.*IMPROVEMENTS NEEDED IN TRANSPLANT COORDINATORS*

a) **Gujarat's system of calling all relatives, especially the decision makers in the family, have been giving it, high willingness for Donation. Another enabling factor is the use of Audio, video to explain the concept of brain death in detail, to the nonmedical persons. They also have been working at all times, because of vigilant persons specially trained, for identifying a potential donor in the ICU.**
b) **Interstate training programs of Transplant coordinators will help them inculcate best practices from one another.**
c) **Financial incentivisation to the coordinators from SOTTO may be considered.**

6. *SUGGESTION ABOUT MEDIA MANAGEMENT*

a) **Media including social and print media, can augment or destroy an Organ transplant programme. So media management by SOTTOs is of vital importance with positive messages, highlighting success stories and quickly dispelling any doubts.**

7. *SUGGESTION ABOUT INCREASING PUBLIC AWARENESS*

a) **School curriculums should involve organ transplantation awareness in detail, preferably a video module showing what all can be done and why it is noble.**
b) **Also social, religious, political figures should be co-opted to spread the message of this noble act and can be different for each state.**

6.2 CONCLUSION

Every major organ failure, has a demand-supply gap at present. For example, against a pending list of 2 lakh patients around 12000 kidney transplants happened in 2022, and more are getting added to the list every day. The Indian Transplant programme is improving but at not the pace it should. Also the Deceased Organ programme needs to really pickup. This will need guidance at a central level with policy, guidelines, supervision; however the SOTTOs and the transplanting centres, coordinators and the public awareness will be the critical factors, as we move towards an Organ sufficient country over the next 5-10 years.

The Gujarat Deceased Organ Transplantation programme stands out as a beacon with multiple strong enabling factors, which we can replicate at a national level. The Indian system of opting in for transplant is apt for the country, but we need more and more people coming forward ;more brain death declarations; more counselling on possible organ donations : more centres doing it and media highlighting it : more recognition and incentive for people to do it. It is achievable in a decades time ,and as the country progresses in all other fronts, these Organ failure victims too, need to be looked after and given every possible opportunity, to live and contribute in our Society. The states which are laggards in transplantation too, need to be coaxed and supported to promote transplantation.

Strict supervision, guidelines and implementation are needed to avoid any discrepancies or rich being favoured in lieu of the poor. The THOA act was implemented to regularise Organ transplantation and there is a need to further strengthen it. Brain death too should be legalised as a way of death and precious resources of Critical care, be economised. Organ Transplantation and Immunosupression therafter, should be covered under PM-JAY, Ayushman Bharat schemes completely. **As the country moves towards Sabke Saath, Sabke Vikas and Sabke Prayas in the Amrit Kaal, it would be a fitting tribute to our nation's founder fathers, if we achieve- Health for All -where even the poorest Indian is assured of quality healthcare, and Organ Sufficiency will be an important part of this vision.**

JAI HIND

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APPENDIX A

QUESTIONNAIRE FOR TRANSPLANT COORDINATOR

Name

Hospital

Date

Working as Coordinator from

1.What are the challenges you face while coordinating transplants?

2.What type of support you are getting from the hospital while coordinating transplants?

3.Are you getting more acceptance from your patients relatives now for accepting to donate organs?

4.What improvements do you consider to have led to more people willing to donate organs?

5.List five improvements which is leading to more deceased organ transplantation at your centre?

6.What more do you think can be done to increase transplantation?

APPENDIX B

TRANSPLANTATION OF HUMAN ORGANS AND TISSUES RULES 2014

MINISTRY OF HEALTH AND FAMILY WELFARE

NOTIFICATION New Delhi, the 27th March, 2014.

G.S.R. 218 (E).— In exercise of the powers conferred by section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994) and in supersession of the Transplantation of Human Organs Rules, 1995, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules, namely:-

1. **Short title and commencement** — (1) **These rules may be called the Transplantation of Human Organs and Tissues Rules, 2014.**

(2) They shall come into force on the date of their publication in the Official Gazette.

2. **Definitions:** - In these rules unless the context otherwise requires,—

(a) "Act" means the Transplantation of Human Organs Act, 1994;

(b) "cadaver(s)", "organ(s)" and "tissue(s)" means human cadaver(s), human organ(s) and human tissue(s), respectively;

(c) "competent authority" means the Head of the institution or hospital carrying out transplantation or committee constituted by the head of the institution or hospital for the purpose;

(d) "Form" means a Form annexed to these rules;

(e) National Accreditation Board for Testing and Calibration Laboratories (NABL) means the autonomous body established under the aegis of Department of Science and Technology, Government of India with the objective to provide Government, Regulators and Industry with a scheme of laboratory accreditation through third-party assessment for formally recognising

the technical competence of laboratories and the accreditation services are provided for testing and calibration of medical laboratories in accordance with International Organisation for Standardisation (ISO) Standards;

(f) "the technician who can enucleate cornea" means the technician with any of the following qualifications and experience who can harvest corneas (enucleate eyeballs or excise corneas), namely:- (i) Ophthalmologists possessing a Doctor of Medicine (M.D) or Master of Surgery (M.S) in Ophthalmology or Diploma in Ophthalmology (D.O.); and

(ii) registered Doctors from all recognised systems of medicine, Nurses, Paramedical Ophthalmic Assistant, Ophthalmic Assistant, Optometrists, Refractionists, Paramedical Worker or Medical Technician with recognised qualification from all recognised systems of medicine, provided the person is duly trained to enucleate a donated cornea or eye from registered, authorised and functional eye Bank or Government medical college and, the training certificate should mention that he has acquired the required skills to independently conduct enucleation of the eye or removal of cornea from a cadaver;

(g) words and expressions used and not defined in these rules, but defined in the Act, shall have the same meanings, respectively, assigned to them in the Act.

3. **Authority for removal of human organs or tissues**.—Subject to the provisions of Section 3 of the Act, a living person may authorise the removal of any organ or tissue of his or her body during his or her lifetime as per prevalent medical practices, for therapeutic purposes in the manner and on such conditions as specified in Form 1, 2 and 3.

4. **Panel of experts for brain-stem death certification**.—For the purpose of certifying the brain-stem death, the Appropriate Authority shall maintain a panel of experts, in accordance with the provisions of the Act, to ensure efficient functioning of the Board of Medical Experts and it remains fully operational.

5. **Duties of the registered medical practitioner**.— (1) The registered medical practitioner of the hospital having Intensive Care Unit facility, in consultation with transplant coordinator, if available, shall ascertain, after certification of brain stem death of the person in Intensive Care Unit, from his or her adult near relative or, if near relative is not available, then, any other person related by blood or marriage, and in case of unclaimed body, from the person in lawful possession of the body the following, namely:-

(a) whether the person had, in the presence of two or more witnesses (at least one of who is a near relative of such person), unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license, etc. wherein the provision for donation may be incorporated after notification of these rules, the removal of his or her organ(s) or tissue(s)

including eye, after his or her death, for therapeutic purposes and there is no reason to believe that the person had subsequently revoked the aforesaid authorisation;

(b) where the said authorisation was not made by the person to donate his or her organ(s) or tissue(s) after his or her death, then the registered medical practitioner in consultation with the transplant coordinator, if available, shall make the near relative or person in lawful possession of the body, aware of the option to authorise or decline the donation of such human organs or tissues or both (which can be used for therapeutic purposes) including eye or cornea of the deceased person and a declaration or authorisation to this effect shall be ascertained from the near relative or person in lawful possession of the body as per Form 8 to record the status of consent, and in case of an unclaimed body, authorisation shall be made in Form 9 by the authorised official as per sub-section (1) of section 5 of the Act;

(c) after the near relative or person in lawful possession of the body authorises removal and gives consent for donation of human organ(s) or tissue(s) of the deceased person, the registered medical practitioner through the transplant coordinator shall inform the authorised registered Human Organ Retrieval Centre through authorised coordinating organisation by available documentable mode of communication, for removal, storage or transportation of organ(s) or tissue(s).

(2) The above mentioned duties shall also apply to the registered medical practitioner working in an Intensive Care Unit in a hospital not registered under this Act, from the date of notification of these rules. (3) The registered medical practitioner shall, before removing any human organ or tissue from a living donor, shall satisfy himself –

(a) that the donor has been explained of all possible side effects, hazards and complications and that the donor has given his or her authorisation in appropriate Form 1 for near relative donor or Form 2 for spousal donor or Form 3 for donor other than near relative;

(b) that the physical and mental evaluation of the donor has been done, he or she is in proper state of health and it has been certified that he or she is not mentally challenged and that he or she is fit to donate the organ or tissue:

Provided that in case of doubt regarding mentally challenged status of the donor the registered medical practitioner may get the donor examined by a psychiatrist and the registered medical practitioner shall sign the certificate as prescribed in Form 4 for this purpose;

(c) that the donor is a near relative of the recipient, as certified in Form 5, and that he or she has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority as defined at rule 2(c) and specified in Form 19 and that the necessary documents as prescribed and medical tests, as required, to determine the

factum of near relationship, have been examined to the satisfaction of the registered medical practitioner and the competent authority;

(d) that in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 2 and has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority under the provisions of sub-rule (2) of rule 7;

(e) that in case of a donor who is other than a near relative and has signed Form 3 and submitted an application in Form 11 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained;

(f) that if a donor or recipient is a foreign national, the approval of the Authorisation Committee for the said donation has been obtained;

(g) living organ or tissue donation by minors shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior approval of the Appropriate Authority and the State Government concerned.

(4) A registered medical practitioner, before removing any organ or tissue from the body of a person after his or her death (deceased donor), in consultation with transplant coordinator, shall satisfy himself the following, namely:- (a) that caution has been taken to make inquiry, from near relative or person in lawful possession of the body of a

person admitted in Intensive Care Unit, only after certification of Brain Stem death of the person that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person),unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license etc. (wherein the provision for donation may be incorporated after notification of these rules), the removal of his or her organ(s) or tissue(s) after his or her death, for therapeutic purposes and it has been ascertained that the donor has not subsequently revoked the aforesaid authorisation, and the consent of near relative or person in lawful possession of the body shall also be required notwithstanding the authorisation been made by deceased donor:

Provided that if the deceased person who had earlier given authorisation but had revoked it subsequently and if the person had given in writing that his organ should not be removed after his death, then, no organ or tissue will be removed even if consent is given by the near relative or person in lawful possession of the body;

(b) that the near relative of the deceased person or the person lawfully in possession of the body of the deceased donor has signed the declaration as specified in Form 8.

(c) that in the case of brain-stem death of the potential donor, a certificate as specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act:

Provided that where a neurologist or a neurosurgeon is not available, an anesthetist or intensivist who is not part of the transplant team nominated by the head of the hospital duly empanelled by Appropriate Authority may certify the brain stem death as a member of the said Board;

(d) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 8 has been signed by either of the parents of such person or any near relative authorised by the parent.

6. **Procedure for donation of organ or tissue in medicolegal cases.**— (1) After the authority for removal of organs or tissues, as also the consent to donate organs from a brain-stem dead donor are obtained, the registered medical practitioner of the hospital shall make a request to the Station House Officer or Superintendent of Police or Deputy Inspector General of the area either directly or through the police post located in the hospital to facilitate timely retrieval of organs or tissue from the donor and a copy of such a request should also be sent to the designated post mortem doctor of area simultaneously.

(2) It shall be ensured that, by retrieving organs, the determination of the cause of death is not jeopardised. (3) The medical report in respect of the organs or tissues being retrieved shall be prepared at the time of retrieval by retrieving doctor (s) and shall be taken on record in postmortem notes by the registered medical practitioner doing postmortem.

(4) Wherever it is possible, attempt should be made to request the designated postmortem registered medical practitioner, even beyond office timing, to be present at the time of organ or tissue retrieval.

(5) In case a private retrieval hospital is not doing post mortem, they shall arrange transportation of body along with medical records, after organ or tissue retrieval, to the designated postmortem centre and the post mortem centre shall undertake the postmortem of such cases on priority, even beyond office timing, so that the body is handed over to the relatives with least inconvenience.

7 Authorisation Committee.

—(1) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation Committee constituted under the provisions of clauses (a) and (b) of sub-section(4) of section 9 of the Act.

(2) When the proposed donor or recipient or both are not Indian nationals or citizens whether near relatives or otherwise, the Authorisation Committee shall consider all such requests and the transplantation shall not be permitted if the recipient is a foreign national and donor is an Indian national unless they are near relatives.

(3) When the proposed donor and the recipient are not near relatives, the Authorisation Committee shall,- (i) evaluate that there is no commercial transaction between the recipient and the donor and that no payment has been made to the donor or promised to be made to the donor or any other person; (ii) prepare an explanation of the link between them and the circumstances which led to the offer being made;

(iii) examine the reasons why the donor wishes to donate;

(iv) examine the documentary evidence of the link, e.g. proof that they have lived together, etc.; (v) examine old photographs showing the donor and the recipient together;

(vi) evaluate that there is no middleman or tout involved;

(vii) evaluate that financial status of the donor and the recipient by asking them to give appropriate evidence of their vocation and income for the previous three financial years and any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing; (viii) ensure that the donor is not a drug addict;

(ix) ensure that the near relative or if near relative is not available, any adult person related to donor by blood or marriage of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ or tissue, the authenticity of the link between the donor and the recipient, and the reasons for donation, and any strong views or disagreement or objection of such kin shall also

be recorded and taken note of.

(4) Cases of swap donation referred to under subsection (3A) of section 9 of the Act shall be approved by Authorisation Committee of hospital or district or State in which transplantation is proposed to be done and the donation of organs shall be permissible only from near relatives of the swap recipients.

(5) When the recipient is in a critical condition in need of life saving organ transplantation within a week, the donor or recipient may approach hospital in-charge to expedite evaluation by the Authorisation Committee.

8**. Removal and preservation of organs or tissues**.—The removal of the organ(s) or tissue(s) shall be permissible in any registered retrieval or transplant hospital or centre and preservation of such removed organ(s) or tissue(s) shall be ensured in registered retrieval or transplant centre or tissue bank according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

9**. Cost for maintenance of cadaver or retrieval or transportation or preservation of organs or tissues**.—The cost for maintenance of the cadaver (brain-stem dead declared person), retrieval of organs or tissues, their transportation and preservation, shall not be borne by the donor family and may be borne by the recipient or institution or Government or non-Government organisation or society as decided by the respective State Government or Union territory Administration.

10. **Application for living donor transplantation**.—

(1) The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the competent authority or Authorisation Committee as specified in Form 11 and the papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation.

(2) The competent authority or Authorisation Committee shall take a decision on such application in accordance with the rule 18.

(3) If some State wants to merge Form 11 with Form 1, Form 2 or Form 3, they may do so, provided the content of the recommended Forms are covered in the merged Form and the same is approved by the State Government concerned.

11**. Composition of Authorisation Committees**

.(1) There shall be one State level Authorisation Committee.

(2) Additional Authorisation Committees in the districts or Institutions or hospitals may be set up as per norms given below, which may be revised from time to time by the concerned State Government or Union territory Administration by notification.

(3) No member from transplant team of the institution should be a member of the respective Authorisation Committee.

(4) Authorisation Committee should be hospital based if the number of transplants is twenty five or more in a year at the respective transplantation centres, and if the number of organ transplants in an institution or hospital are less than twenty-five in a year, then the State or District level Authorisation Committee would grant approval(s).

12. **Composition of hospital based Authorisation Committees**.— The hospital based Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

(a) the Medical Director or Medical Superintendent or Head of the institution or hospital or a senior medical person officiating as Head - Chairperson;

(b) two senior medical practitioners from the same hospital who are not part of the transplant team – Member;

(c) two persons (preferably one woman) of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member;

(d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration - Member.

13. **Composition of State or District Level Authorisation Committees.—** The State or District Level Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

(a) a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main or major Government hospital of the District – Chairperson;

(b) two senior registered medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team– Member; (c) two persons (preferably one woman) of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member; (d) Secretary (Health) or nominee and

Director Health Services or nominee from State Government or Union territory Administration– Member :

Provided that effort shall be made by the State Government concerned to have most of the members' ex-officio so that the need to change the composition of Committee is less frequent.

14**. Verification of residential status, etc**.—When the living donor is unrelated and if donor or recipient belongs to a State or Union territory, other than the State or Union territory where the transplantation is proposed to be undertaken, verification of residential status by Tehsildar or any other authorised officer for the purpose with a copy marked to the Appropriate Authority of the State or Union territory of domicile of donor or recipient for their information shall be required, as per Form 20 and in case of any doubt of organ trafficking, the Appropriate Authority of the State or Union territory of domicile or the Tehsildar or any other authorised officer shall inform police department for investigation and action as per the provisions of the Act.

15. **Quorum of Authorisation Committee**.— The quorum of the Authorisation Committee should be minimum four and the quorum shall not be complete without the participation of the Chairman, the presence of Secretary (Health) or nominee and Director of Health Services or nominee.

16**. Format of approval of Authorisation Committee**.— The format of the Authorisation Committee approval should be uniform in all the institutions in a State and the format may be notified by the respective State Government as per Form 18.

17. **Scrutiny of applications by Authorisation Committee**.—

(1) Secretariat of the Authorisation Committee shall circulate copies of all applications received from the proposed donors and recipients to all members of the Committee along with all annexures, which may have been filed along with the applications.

(2) At the time of the meeting, the Authorisation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful, explanation should be sought from the applicant and if it is considered necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the concerned officer(s) of the State Government or Union territory Administration.

18**. Procedure in case of near relatives**.—

(1) Where the proposed transplant of organs is between near relatives related genetically, namely, grandmother, grandfather, mother, father, brother, sister, son, daughter, grandson and

granddaughter, above the age of eighteen years, the competent authority as defined at rule 2(c) or Authorisation Committee (in case donor or recipient is a foreigner) shall evaluate;

(i) documentary evidence of relationship e.g. relevant birth certificates, marriage certificate, other relationship certificate from Tehsildar or Sub-divisional magistrate or Metropolitan Magistrate or Sarpanch of the Panchayat, or similar other identity certificates like Electors Photo Identity Card or AADHAAR card; and

(ii) documentary evidence of identity and residence of the proposed donor, ration card or voters identity card or passport or driving license or PAN card or bank account and family photograph depicting the proposed donor and the proposed recipient along with another near relative, or similar other identity certificates like AADHAAR Card (issued by Unique Identification Authority of India).

(2) If in the opinion of the competent authority, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical test, namely, Deoxyribonucleic Acid (DNA) Profiling.

(3) The test referred to in sub-rule (2) shall be got done from a laboratory accredited with National Accreditation Board for Testing and Calibration Laboratories and certificate shall be given in Form 5.

(4) If the documentary evidences and test referred to in sub-rules (1) and (2), respectively do not establish a genetic relationship between the donor and the recipient, the same procedure be adopted on preferably both or at least one parent, and if parents are not available, the same procedure be adopted on such relatives of donor and recipient as are available and are willing to be tested, failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.

(5) Where the proposed transplant is between a married couple the competent authority or Authorisation Committee (in case donor or recipient is a foreigner) must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. are kept for records along with the information on the number and age of children and a family photograph depicting the entire family, birth certificate of children containing the particulars of parents and issue a certificate in Form 6 (for spousal donor).

(6) Any document with regard to the proof of residence or domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Competent Authority or Authorisation Committee as the

case may be, may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.

(7) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a competent authority of the transplant hospital.

(8) The competent authority may seek the assistance of the Authorisation Committee in its decision making, if required.

19. **Procedure in case of transplant other than near relatives.**—

Where the proposed transplant is between other than near relatives and all cases where the donor or recipient is foreign national (irrespective of them being near relative or otherwise), the approval will be granted by the Authorisation Committee of the hospital or if hospital based Authorisation Committee is not constituted, then by the District or State level Authorisation Committee.

20. **Procedure in case of foreigners**.—

When the proposed donor or the recipient are foreigners;

(a) a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient as per Form 21 and in case a country does not have an Embassy in India, the certificate of relationship, in the same format, shall be issued by the Government of that country;

(b) the Authorisation Committee shall examine the cases of all Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution and such cases should be considered rarely on case to case basis:

Provided that the Indian living donors wanting to donate to a foreigner other than near relative shall not be considered.

21. **Eligibility of applicant to donate.—** In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Authorisation Committee which shall be videographed and minutes of the interview shall be recorded.

22. **Precautions in case of woman donor**.—

In case where the donor is a woman, greater precautions ought to be taken and her identity and independent consent should be confirmed by a person other than the recipient.

23. **Decision of Authorisation Committee**.— (1) The Authorisation Committee (which is applicable only for living organ or tissue donor)should state in writing its reason for rejecting

or approving the application of the proposed living donor in the prescribed Form 18 and all such approvals should be subject to the following conditions, namely:-

(i) the approved proposed donor would be subjected to all such medical tests as required at the relevant stages to determine his or her biological capacity and compatibility to donate the organ in question; (ii) the physical and mental evaluation of the donor has been done to know whether he or she is in proper state of health and it has been certified by the registered medical practitioner in Form 4 that he or she is not mentally challenged and is fit to donate the organ or tissue:

Provided that in case of doubt for mentally challenged status of the donor the registered medical practitioner or Authorisation Committee may get the donor examined by psychiatrist;

(iii) all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation;

(iv) all interviews to be video recorded.

(2) The Authorisation Committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires transplantation on urgent basis.

(3) Every authorised transplantation centre must have its own website and the Authorisation Committee is required to take final decision within twenty four hours of holding the meeting for grant of permission or rejection for transplant.

(4) The decision of the Authorisation Committee should be displayed on the notice board of the hospital or Institution immediately and should reflect on the website of the hospital or Institution within twenty four hours of taking the decision, while keeping the identity of the recipient and donor hidden.

24. **Registration of hospital or tissue bank.**— (1) An application for registration shall be made to the Appropriate Authority as specified in Form 12 or Form 13 or Form 14 or Form 15, as applicable and the application shall be accompanied by fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be:-

(i) for Organ or Tissue or Cornea Transplant Centre: Rupees ten thousand;

(ii) for Tissue or Eye Bank: Rupees ten thousand;

(iii) for Non-Transplant Retrieval Centre: Nil.

(2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 16 and it shall be valid for a period of five years from the date of its issue and shall be renewable.

(3) Before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to appoint a transplant coordinator.

25. **Renewal of registration of hospital or tissue bank**.— (1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority at least three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be,-

(i) for Organ or Tissue or Cornea Transplant Centre: Rupees five thousand;

(ii) for Tissue or Eye Bank: Rupees five thousand;

(iii) for Non-Transplant Retrieval Centre: Nil.

(2) A renewal certificate of registration shall be as specified in Form 17 and shall be valid for a period of five years. (3) If, after an inquiry including inspection of the hospital or tissue bank and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of rule 24 has not complied with the requirements of the Act and these rules and the conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

26. **Conditions and standards for grant of certificate of registration for organ or tissue transplantation centres**.— (1) No hospital shall be granted a certificate of registration for organ transplantation unless it fulfills the following conditions and standards, namely:-

A. General manpower requirement specialised services and facilities:

(a) Twenty-four hours availability of medical and surgical, (senior and junior) staff;

(b) twenty-four hours availability of nursing staff (general and specialty trained);

(c) twenty-four hours availability of Intensive Care Units with adequate equipment staff and support system, including specialists in anesthesiology and intensive care;

(d) twenty-four hours availability of blood bank (in house or access) , laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, Pathology, Hematology and Radiology departments with trained staff;

(e) twenty-four hours availability of Operation Theater facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipment;

(f) twenty-four hours availability of communication system, with power backup, including but not limited to multiple line telephones, public telephone systems, fax, computers and paper photo-imaging machine;

(g) experts (other than the experts required for the relevant transplantation) of relevant and associated specialties including but not limited to and depending upon the requirements, the experts in internal medicine, diabetology, gastroenterology, nephrology, neurology, pediatrics, gynecology, immunology and cardiology, etc., shall be available in the transplantation centre;

(h) one medical expert for respective organ or tissue transplant shall be available in the transplantation hospital; and

(i) Human Leukocyte Antigen (HLA) matching facilities (in house or outsourced) shall be available. B. Equipments:

Equipments as per current and expected scientific requirements specific to organ (s) or tissue (s) being transplanted and the transplant centre should ensure the availability of the accessories, spare-parts and back-up, maintenance and service support system in relation to all relevant equipments.

C. Experts and their qualifications:

(a) Kidney Transplantation:

M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised transplant center in India or abroad and having attended to adequate number of renal transplantation as an active member of team;

(b) Transplantation of liver and other abdominal organs:

M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. experience in the speciality and having one year training in the respective organ transplantation as an active member of team in an established transplant center;

(c) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation:

M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least three years' experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-valve surgery;

(d) the hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010 (23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;

(e) the hospital registered shall have to maintain documentation and records including reporting of adverse events. (2) No hospital shall be granted a certificate of registration for tissue transplantation under the Act unless it fulfills the following conditions and standards, namely:-

(a) Cornea Transplantation:

M.D. or M.S. or Diploma (DO) in ophthalmology or equivalent qualification with three months post M.D. or M.S or DO training in Corneal transplant operations in a recognised hospital or institution; (b) Other tissues such as heart valves, skin, bone, etc.:

Post graduate degree (MD or MS) or equivalent qualification in the respective specialty with three months post M.D. or M.S training in a recognised hospital carrying out respective tissue transplant operations and for heart valve transplantation, and the qualification and experience of expert shall be MCh degree in Cardiothoracic and Vascular Surgery (CTVS) or equivalent qualification with three months post MCh training in a recognised hospital carrying out heart valve transplantation;

(c) the Hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010(23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;

(d) the Hospital registered shall have to maintain documentation and records including reporting of adverse events.

27. **Conditions and standards for grant of certificate of registration for organ retrieval centres**.—

(1) The retrieval center shall be registered only for the purpose of retrieval of organ from deceased donors and the organ retrieval centre shall be a hospital having Intensive Care Unit (ICU) facilities along with manpower, infrastructure and equipment as required to diagnose and maintain the brain-stem dead person and to retrieve and transport organs and tissues including the facility for their temporary storage.

(2) All hospitals registered as transplant centres shall automatically qualify as retrieval centres. (3) The retrieval centre should have linkages with nearby Government hospital designated for post-mortem, for retrieval in medico-legal cases.

(4) Registration of hospital for surgical tissue harvesting from deceased person and for surgical tissue residues, that are routinely discarded, shall not be required.

28. **Conditions and standards for grant of certificate of registration for tissue banks**.— A. Facility and premises:

(1) Facilities must conform to the standards and guidelines laid down for the purpose and the States and Union territories may have separate registration fee and procedure to keep track of their tissue bank activities. (2) The respective State or Union territory Appropriate Authority may constitute an expert committee for advising on the matter related to tissue specific standards and related issues.

(3) The tissue bank must have written guidelines and standard operating procedures for maintenance of its premises and facilities which include-

(a) controlled access;

(b) cleaning and maintenance systems;

(c) waste disposal;

(d) health and safety of staff;

(e) risk assessment protocol; and

(f) follow up protocol.

(4) Equipments as per scientific requirements specific to tissue (s) being procured, processed, stored and distributed and the tissue bank should ensure the availability of the accessories, spare-parts and back-up, maintenance and service support for all equipments.

(5) Air particle count and microbial colony count compliance shall be ensured for safety where necessary.

(6) Storage area shall be designated to avoid contact with chemicals or atmospheric contamination and any known source of infection.

(7) Storage facility shall be separate and distinguish tissues, held in quarantine, released and rejected.

B. Donor screening:

(8) Complete screening of donor must be conducted including medical or social history and serological evaluation for medical conditions or disease processes that would contraindicate the

donation of tissues and the report of corneas or eyes not found suitable for transplantation and their alternate use shall be certified by a committee of two Ophthalmologists.

C. Laboratory tests:

(9) Facility for relevant Laboratory tests for blood and tissue samples shall be available and testing of blood and tissue samples shall begin at Donor Screening and continue during retrieval and throughout processing. D. Procurement and other procedures:

(10) Procurement of tissue must be carried out by registered health care professionals or technicians having necessary experience or special training.

(11) Consent for the procurement shall be obtained.

(12) Procurement records shall be maintained.

(13) Standard operating procedure for following shall be followed, namely :-

(a) procurement or Retrieval and transplantation;

(b) processing and sterilisation;

(c) packaging, labeling and storage;

(d) distribution or allocation;

(e) transportation; and

(f) reporting of serious adverse reactions.

E. Documentation and Records:

(14) A log of tissue received and distributed shall be maintained to enable traceability from the donor to the tissue and the tissue to the donor and the records shall also indicate the dates and the identities of the staff performing specific steps in the removal or processing or distribution of the tissues.

F. Data Protection and Confidentiality:

(15) A unique donor identification number shall be used for each donor, and access to donor records shall be restricted. G. Quality Management:

(16) The Quality Management System shall define quality control procedures that include the following, namely:- (a) environmental monitoring;

(b) equipment maintenance and monitoring;

(c) in –process controls monitoring;

(d) internal audits including reagent and supply monitoring;

(e) compliance with reference standards, local regulations, quality manuals or documented standard operating procedures; and

(f) monitoring work environment.

H. Recipient Information:

(17) All tissue recipients shall be followed up and prompt and appropriate corrective and preventive actions taken in case of adverse events.

29. **Qualification, role, etc., of transplant coordinator**.— (1) The transplant coordinator shall be an employee of the registered hospital having qualification such as:

(a) graduate of any recognised system of medicine; or

(b) Nurse; or

(c) Bachelor's degree in any subject and preferably Master's degree in Social work or Psychiatry or Sociology or Social Science or Public Health

(2) The concerned organisation or institute shall ensure initial induction training followed by retraining at periodic interval and the transplant coordinator shall counsel and encourage the family members or near relatives of the

deceased person to donate the human organ or tissue including eye or cornea and coordinate the process of donation and transplantation.

(3) The transplant coordinator or counselor in a hospital registered for eye banking shall also have qualification specified in sub-rule (1).

30. **Advisory committee of the Central or State Government to aid and advise appropriate authority.**— (1) The Central Government and the State Government, as the case may be, shall constitute by notification an Advisory Committee under Chairpersonship of administrative expert not below the rank of Secretary to the State Government for a period of two years to aid and advise the Appropriate Authority and the two medical experts referred to in clause(b) of sub-section(2) of section 13A of the Act shall possess a postgraduate medical degree and at least five years' experience in the field of organ or tissue transplantation.

(2) The terms and conditions for appointment to the Advisory Committee are as under:

(a) the Chairperson and members of the Committee shall be appointed for a period of two years; (b) the Chairperson and members of the Committee shall be entitled to the air fare and

other allowances to attend the meeting of the Committee equivalent to the officer of the level of the Joint Secretary to the Government of India;

(c) the Central Government or State Government or Union territory Administration shall have full powers to replace or remove the Chairperson and the members in cases of charges of corruption or any other charges after giving a reasonable opportunity of being heard;

(d) the Chairperson and members can also resign from the Committee for personal reasons; (e) there shall not be a corruption or criminal case pending against Chairperson and members at the time of appointment;

(f) the Chairperson or any of the members shall cease to function if charges have been framed against him or her in a corruption or criminal case after having been given a reasonable opportunity of being heard. 31. Manner of establishing National or Regional or State Human Organs and Tissues Removal and Storage Networks and their functions.— (1) There shall be an apex national networking organisation at the centre, as the Central Government may by notification specify.

(2) There shall also be regional and State level networking organisations where large number of transplantation of organ(s) or tissue (s) are performed as the Central Government may by notification specify. (3) The State units would be linked to hospitals, organ or tissue matching laboratories and tissue banks within their area and also to regional and national networking organisations.

(4) The broad principles of organ allocation and sharing shall be as under,—

(a) The website of the transplantation center shall be linked to State or Regional cum State or National networks through an online system for organ procurement, sharing and transplantation.

(b) patient or recipient may get registered through any transplant centre, but only one centre of a State or region (if there is no centre in the State) and his or her details shall be made available online to the networking organisations, who shall allocate the registration number, which shall remain same even if patient changes hospital;

(c) the allocation of the organ to be shared, is to be decided by the State networking organization and by the National networking organization in case of Delhi;

(d) all recipients are to be listed for requests of organs from deceased donors, however priority is to be given in following order, namely:-

(i) those who do not have any suitable living donor among near relatives;

(ii) those who have a suitable living donor available among near relatives but the donor has refused in writing to donate; and

(iii) those who have a suitable living donor available and who has also not refused to donate in writing;

(e) sequence of allocation of organs shall be in following order: State list----Regional List----- National List---- Person of Indian Origin ----Foreigner;

(f) the online system of networking and framework and formats of national registry as mentioned under rule 32 shall be developed by the apex networking organisation which shall be followed by the States Governments or Union territory Administrations and the allocation criteria may be State specific which shall be finalised and determined by the State Government, in consultation with the State level networking organisation, wherever such organisation exists:

Provided that the organ sharing and networking policy of States or locations of hospitals shall not be binding on the Armed Forces Medical Services (AFMS) and the armed forces shall be free to have their own policy of organ or tissue allocation and sharing, and the Director General Armed Forces Medical Services shall have its own networking between the Armed Forces Medical Services hospitals, who shall be permitted to accept organs when available from hospitals with in their State jurisdiction.

(5) The networking organisations shall coordinate retrieval, storage, transportation, matching, allocation and transplantation of organs and tissues and shall develop norms and standard operating procedures for such activities and for tissues to the extent possible.

(6) The networking organisations shall coordinate with respective State Government for establishing new transplant and retrieval centres and tissue banks and strengthening of existing ones.

(7) There shall be designated organ and tissue retrieval teams in State or District or institution as per requirement, to be constituted by the State or Regional networking organisation.

(8) For tissue retrieval, the retrieval teams shall be formed by the State Government or Union territory Administration where ever required.

(9) Networking shall be e-enabled and accessible through dedicated website.

(10) Reference or allocation criteria would be developed and updated regularly by networking organisations in consultation with the Central or State Government, as the case may be.

(11) The networking organisation(s) shall undertake Information Education and Communication (IEC) Activities for promotion of deceased organ and tissue donation.

(12) The networking organisation(s) shall maintain and update organ or tissue Donation and Transplant Registry at respective level.

32**. Information to be included in National Registry regarding donors and recipients of human organ and tissue**.— The national registry shall be based on the following, namely:-

Organ Transplant Registry:

(1) The Organ Transplant Registry shall include demographic data about the patient, donor, hospitals, recipient and donor follow up details, transplant waiting list, etc., and the data shall be collected from all retrieval and transplant centers. (2) Data collection frequency, etc., will be as per the norms decided by the Advisory Committee which may preferably be through a web-based interface or paper submission and the information shall be maintained both specific organ wise and also in a consolidated format.

(3) The hospital or Institution shall update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with reasonable detail of each transplantation and the same data should be accessible for compilation, analysis and further use by authorised persons of respective State Governments and Central Government.

(4) Yearly reports shall be published and also shared with the contributing units and other stakeholders and key events (new patients, deaths and transplants) shall be notified as soon as they occur in the hospital and this information shall be sent to the respective networking organisation, at least monthly.

Organ Donation Registry:

(5) The Organ Donation Registry shall include demographic information on donor (both living and deceased), hospital, height and weight, occupation, primary cause of death in case of deceased donor, associated medical illnesses, relevant laboratory tests, donor maintenance details, driving license or any other document of pledging donation, donation requested by whom, transplant coordinator, organs or tissue retrieved, outcome of donated organ or tissue, details of recipient, etc.

Tissue Registry:

(6) The Tissue Registry shall include demographic information on the tissue donor, site of tissue retrieval or donation, primary cause of death in case of deceased donor, donor maintenance details in case of brain stem dead donor, associated medical illnesses, relevant laboratory tests, driving license or any other document pledging donation, donation requested by whom, identity of counsellors, tissue(s) or organ(s) retrieved, demographic data about the tissue recipient,

hospital conducting transplantation, transplant waiting list and priority list for critical patients, if these exist, indication(s) for transplant, outcome of transplanted tissue, etc.

(7) Yearly reports in respect of National Registry shall be published and also shared with the contributing units and other stakeholders

Pledge for organ or tissue donation after death:

(8) Those persons, who, during their lifetime have pledged to donate their organ(s) or tissue(s) after their death, shall in Form 7 deposit it in paper or electronic mode to the respective networking organisation(s) or institution where the pledge is made, who shall forward the same with the respective networking organisation and the pledger has the option to withdraw the pledge through intimation.

(9) The Registry will be accessible on-line through dedicated website and shall be in conformation to globally maintained registry (ies), besides having national, regional and State level specificities.

(10) National or regional registry shall be compiled based on similar registries at State level. (11) The identity of the people in the database shall not be put in public domain and measures shall be taken to ensure security of all collected information.

(12) The information to be included shall be updated as per prevalent global practices .

33. **Appeal.—** (1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9 or by an order of the Appropriate Authority under sub-section (2) of section 15 or sub-section (2) of section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government in case of the Union territories and respective State Government in case of States. (2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.