
REFORMS TO THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994

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ABSTRACT

The enactment on the transplantation of human organs covers the procedure from removal, storage and transplantation of organs and tissues. The rising health failures have created a hike in the demand for organs and tissues to save lives. The ambit of the law is very wide and covers various definitions, procedures, eligibility, and penalties, but why does it still suffer from infirmities itself? From its year of enactment in 1994 until now major objectives of the act stand largely unfulfilled. With the passage of time and the gravity of the situation has changed the objectives have again transformed themselves into challenges. The establishment of authorities doesn't suffice for the fulfilment of objectives and streamlining the efficiency of the process. The paper covers proposed reforms which should be holistically implemented to enhance organ availability and strengthen the process without further delays. The utmost need to spread information, education and proper propagation of the provisions of the act is pending. This shouldn't be the last option for a family to consider but plan post-death or if someone wishes to make a living donation to save another life without harming or causing detrimental effects to oneself.

1. INTRODUCTION

The discussion on the issue must begin with the basic definitions of the process. This act covers 3 main processes and regulates their efficiency, they are

- removal of the organs and tissues,
- Storage of the organs and tissues and
- Transplantation of organs and tissues.

The definition of word “transplantation” is defined under Section 2 sub-section (p), and includes the removal or grafting of any organ or tissue from one human body (living or dead)

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to another human body for therapeutic purposes.

This understanding is required to comprehend the objectives of the Act.

To begin with the statute, the objectives of the enactment must be understood in brief to carefully analyze their present status. The law came in the year of 1994 and had laid the following objectives: -

1. To encourage organ donation and spread awareness
2. Prohibit commercialization of organ trafficking or dealings in any manner
3. Establish a regulatory authority that will regulate removal, storage and transplantation of organs and tissues for therapeutic purposes only.
4. Establish a registry that will keep record of the details of the process.

There are nearly 4 lakh death every year in India due to organ or tissue failure and the need is similar, I.e. around 4-5 lakhs organs and tissues every year, as per National Organs and Tissue Transplantation Organization (NOTTO)². The numbers have increased from the year of enactment in 1994. This is where the point of its ineffectiveness is highlighted. The failure of the law to meet ends of its objectives.

Let's say one strikes up a conversation with a layman, about whether he would pledge to donate his/her organs/ one of the common responses would be that s/he lacks awareness of the whole procedure. There is a lack of information, education and proper propagation of the provisions of the act. This leads to what- creation of stereotypes, myths and hesitancy to donate. There are various religious barriers people start to quote to make organ donations, but there are none.

Secondly, we regularly read or hear about commercial dealings of organ trafficking, again what is it highlighting the lack of legal enforcement mechanisms.

2. THOA, 1994: IN BRIEF

The enactment covers the definitions and some important ones to be known are of brain stem death³, deceased person⁴, donor⁵ and recipient⁶.

² <https://notto.mohfw.gov.in/faqs.htm>

³ 2(d) "brain-stem death" means the stage at which all functions of the brain stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3;

⁴ 2(e) "deceased person" means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place;

⁵ 2(f) "donor" means any person, not less than eighteen years of age, who voluntarily authorizes the removal of any of his human organs for therapeutic purposes under subsection (1) or sub-section (2) of section 3;

As per the law⁷ the person who wishes or voluntarily wills to donate his/her organs or tissues can expressly state to donate his/ her organ in the presence of 2 witnesses who may be your near relative or of your close circle.

The wills should be expressly stated without fear or undue influence or in expectation of any monetary or any other form of benefit. This must be done with an altruistic intention to donate if it is in case of donating not to a family member.

The Form 7 of the Act has the particulars of information one must fill for the process. This must be submitted to NOTTO as per the latest developments either online or to its postal address.

In case of any contravention to the procedure or any commercial dealings witnessed, the penalties will be imposed covered under the statutes.⁸

To simply let's classify the act into 3 main processes preceding transplantation -

1. **Who can donate?**
2. **How to donate?**
3. **Where to donate?**

- **Who can donate?**

Under section 3 of the Act (1994), any person above the age of 18 years, who is willing or voluntarily wants to donate his organs or tissues to someone for therapeutic purposes is legible to donate.

The word “voluntarily” is the keyword of this legislation. The discussion below would cover how the use of voluntariness of either the donor or even the near relatives of the donor in case of the deceased, if withdraws the consent to donate cannot be compelled to donate even at the later stage or at the time of transplantation to donate. The legislative intent is to safeguard the consent of the donor and at any stage he/she/his or her near relatives can influence the decision, whatever deems fit to them. This would further not lead to any kind of forceful or illegal transplantation which has been covered in the later discussion.

- **How to donate?**

⁶ recipient” means a person into whom any human organ is, or is proposed to be, transplanted;

⁷ Section 3: Authority for removal of human organs

⁸ Sections 18,19,20,21 and 22

It is further sub-classified into

- **“Procedure of Organ Donation & Transplant in Case of Near Relatives”⁹**
 - **“Procedure of Organ Donation & Transplant in Case of Other Than Near Relatives”¹⁰**
 - **“Procedure of Organ Donation & Transplant in Case of Foreigners”**
 - **“Procedure For Donation of Organ or Tissue in Medico-Legal Cases”¹¹**
- **“Procedure of Organ Donation & Transplant in Case of Near Relatives”¹²**

Under section 3, under this category of transplantation to near relatives, the act covers the large ambit of genetic relationships like grandmother, grandfather, mother, father, brother, sister, son, daughter, grandson and granddaughter, who must be above the age of 18 years

The genetic relationship between the donor and the recipient as a near relative must be established by documentary evidence

(i) Documentary evidence includes birth certificate, marriage certificate, Elector's Photo Identity Card or AADHAAR card, ration card or voter identity card or passport or driving license or PAN card or bank account. depicting the proposed donor and the proposed recipient along with another near relative, or similar other identity certificates like AADHAAR Card (issued by the Unique Identification Authority of India). In the case of married couples, the marriage certificate, marriage photograph, in cases where there are issues in the marriage, the birth certificate, family picture, any hospital records, and municipality data all would be considered to establish a spousal relationship.

- (1) In case the competent authority is not satisfied by the inconclusivity of the genetic relationship established by the donor and the donee through documentary evidences. The authority can order a medical test, namely, Deoxyribonucleic Acid (DNA) Profiling.

- **“Procedure of Organ Donation & Transplant in case of Other Than Near**

⁹ section 3

¹⁰

<https://notto.mohfw.gov.in/WriteReadData/Portal/Images/ProcedureofOrganDonationasperTHOA31102015.pdf>

¹¹ Section 6

¹² section 3

Relatives”¹³

The process of approval in case of no genetic relationship between the donor and the donee is regulated by the approval of Authorisation Committee (hospital/district level/ state level).

- “Procedure of Organ Donation & Transplant in case of Foreigners”

Similarly in the case as above (of other than near relatives), the approval would be done by the authorization committee of either the hospital or of any district or state level.

When the proposed donor or the recipient are foreigners;

The process of authorization includes the

- Embassy official(senior) to verify or certify the relationship between the donor and donee.
- And, in cases where the India Nationals are willing to donate to foreign nationals then the authorization process is strict and is carefully permitted in rarest of the rare cases.

- “Procedure For Donation of Organ or Tissue in Medico Legal Cases”¹⁴

(1) In cases of brain-stem dead either through accidents or any other undiscovered reasons. The medical practitioner after the examination of the body deems the body (organs and tissues) fit to be transplanted and not get affected by the cause of death.

The authority of the hospital would seek permission from the Station House Officer or Superintendent of Police or Deputy Inspector General of the area and from the donor and a copy of such a request would be sent to the designated postmortem doctor of area simultaneously.

What is imperative in the process is that the cause of death must not be jeopardized by this process of transplantation.

• Where to donate?

The process of donation would occur at any registered hospital defined under Section 2 (g), which includes nursing home, clinic, medical center, medical or technical institution for therapeutic purposes and other like institutions under the head hospital.

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<https://notto.mohfw.gov.in/WriteReadData/Portal/Images/ProcedureofOrganDonationasperTHOA31102015.pdf>

¹⁴ Section 6

3. CHALLENGES

One reading of the enactment will make the procedural lapses more prominent.

1. **Delayed establishment** : As one the objectives was to establish a regulatory authority to regulate the process from removal to transplantation, though until 2011 it was the hospitals tasked to act both as the regulatory body and as a registry. But what if the hospital is involved in any illicit trade who would investigate that?

There is a requirement for the hospital to maintain the record of the removal. Storage and transplantation of organs and tissues but isn't there a need to establish a state level and national level registry with date of donor, donee, hospital, medical practitioner involved and the other required details.

It was in 2011 from 1994 that NOTTO¹⁵ was established acting both as a regulatory body and registry for the same.

2. **Lack of sources of information**: Thus, if the hospitals were the known sources there wasn't any single window or source from where the whole information of the process could be retrieved. And thus, this remained inaccessible and unavailable, lack of awareness leading into lack of organ availability ‘

3. **Inconvenience to the donors**: The donors were bearing the inconvenience going door to door to different hospitals to check if they are open to the process of donation, that means the hospital is registered. Then the task to state its voluntary proposal to donate. Undergo long complex authorization procedure, if approved then a medical examination and then operated for donation.

4. **Stepping back by donors** when the whole inconvenience is to be borne by the donors. Thus, if withdrawn then it leads to fatal consequences to the donee.

5. **Less registration of hospitals**

6. Less registration of **independent medical practitioners**

7. Unclear status of the **cost of donation**

8. less **tissue banks**

9. **Lack of stringent legal enforcement mechanism** – like in the case of any medical practitioner ¹⁶involved in commercial dealings will be imprisoned and his medical license

¹⁵ *Ibid* 1

¹⁶ Section 18(b) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

will be suspended for 3 years and then can resume his service on completing his sentence. When the law prohibits commercialization then why is the doctor who is charged with such a grave offence not terminated from his services permanently. This reduces the gravity of offences with respect to any commercial dealing or organ and tissues.

4. REFORMS

Thus, what are these challenges highlighting, the **reforms** which need to be taken including the current developments in the field.

1. **More registrations of hospitals**
2. **More registration of independent medical practitioners**
3. **Establishing more banks for tissues and organs**
4. **Subsidizing the cost of donation**
5. **More research and training of the medical staff**
6. **Strengthen the legal enforcement mechanism, so that prima facie it should appear that it prohibits commercialization and not just regulates it.**¹⁷

Empower NOTP: National Organ Transplant Program

This is the umbrella organization which regulated the whole process of gathering information, keeping the records, propagating the word of transplantation, releasing new schemes, etc.

NOTTO took 15 years since the enactment of the statute to be in existence. Till then as mentioned above, it was the hospitals overburdened with the task to do all. It created maximum confusion amongst the donors and a lack of information was there which restricted the accessibility to the public.

In the later year the **NOTTO** has been decentralized into **SOTTO** (State Organ and Tissue Transplant Organizations) and **ROTO** (REGIONAL Organ and Tissue Transplant Organizations) in each State/UT,

In the year 2020. The National Organ Transplant Program was enrolled which includes: -

This has been enhanced by the 2011 amendment, Act No. 16 of 2011

¹⁷ State of Punjab v. Mohinder Singh (2019) and Mohan Lal v. State of Haryana (2011)

The provision under the program includes:

- Setting up of National/ Regional/State Bio-material centres
- Financial support
- Training transplant experts
- Post-transplant immune-suppressant drugs to Below Poverty Line (BPL) patients

Establishment of ROTTO AND SOTTO, like NOTTO the task of the same has been decentralized to promote its efficiency by streamlining the process. This would increase accountability and reduce burdening on one organization.

5. CONCLUSION

The rise in health disorders and organ failures needs more alternatives but one of them is to transplant them. The active participation by the citizens will not just reduce the gap between the needs of the people and organ donation but end the stigma around the whole process. The biases affect our functioning to an extent that it kills rationality largely.

Some unfortunate casualties in road accidents cause brain stem death. This is a favorable condition to donate nearly 37 organs and tissues but within 6-7 hours of removal of it. But the above-mentioned challenges never happen efficiently and get transplanted effectively.

The need for the government to be proactive in this field is an urgent need not just to facilitate saving lives but also to help streamline the whole process and setbacks will be brought back on track with the active implementation of the reforms holistically to strengthen the process without any further delays.

This paper is a very small initiative or step to draw attention to the issue, though there are many reforms which can be added. However, at this stage, if the above-mentioned are in due time and in the correct spirit executed, it can do wonders and yes, one day it can be the new normal.