

## NAVIGATING THE NEXUS OF LAW AND ETHICS: ORGAN TRANSPLANTATION IN INDIA

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### ABSTRACT

*Organ transplantation is a lifesaving procedure that refers to the readiness of a person to donate his/her organs. Educating people about the "value of life after death" can help to validate transplantation as a legitimate medical procedure. To expedite organ donation and transplantation in India, the Transplantation of Human Organs and Tissues Act, 1994 was established. It outlines the procedures, rules, and steps that must be taken to regulate organ transplantation. It also regulates the **transplantation of human organs for therapeutic purposes** and for the prevention of commercial dealings in human organs. Nevertheless, there are significant challenges that need to be addressed to regulate organ donation. Some of the leading challenges include shortage of organs, organ trafficking, and commercialization. Additionally, organ donation raises several ethical and legal considerations, such as the rights of the donor and recipient, the principle of voluntariness, and the allocation of organs. To combat these issues, it becomes imperative to increase investment in medical infrastructure and expertise to carry out organ transplantation. Furthermore, there is a need for legal frameworks that acknowledge the right to informed consent for organ donation.*

**Keywords:** Organ Transplantation, Organ Trafficking, Transplant Tourism, Ethical Considerations, Brain Death, Transplantation of Organs Act.

### INTRODUCTION

The cycle of life and death is a very beautiful, undeniable concept that is beyond the control of human powers. However, saving lives and giving the gift of breath is within our powers and wholly human. On one hand, there are those who need an organ to survive, and on the other hand, those who have transcended into a different world and whose organs could potentially give life to those still alive around us. How can an individual exercise this power? Organ

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transplantation serves as a beacon of hope for innumerable individuals battling life-threatening illnesses.

Organ transplants made an appearance only in the 1970s in India, in contrast to other parts of the world. Today, almost 5 decades have passed since its inception, but we still have a significant journey ahead. In India, the organizational landscape of transplantation reflects not only medical advancement but also the intricate interplay between legal frameworks and ethical principles. Every aspect of the organ transplantation process in India is governed by detailed regulations aimed at promoting fairness and transparency.

For the past fifty years, transplant evolution has been marked by different stages. At first, there was a rush to improve surgical skills and the management of immunity suppression so that many surgery procedures were conducted. However, in the next decade, donation of unrelated kidneys increased significantly and it was a trend for organs to be sold.

As these practices spread, ethical concerns arose with debates on whether it was moral to put organs on sale. As this continued, criticism from international medical communities escalated locally through protests for legislation. The Transplantation of Human Organs and Tissues Act<sup>1</sup> (hereinafter called THOTA) which served as a regulation for organ transplantation in India made it illegal for one to do unrelated transplants. The THOTA also established protocols for deceased donations, including criteria for brain death determination.

Despite all the efforts made by the Government and medical authorities, a significant number of challenges persist. Deceased donation programs face major setbacks while living donor programs are mired in several scandals involving wrangles over promised compensation. Besides kidneys, organ transplants like liver, heart, and pancreas have also emerged from deceased donors, although this has its own challenges.

The beginning of cadaver transplants in the mid-1960s was faced with technical and immunological complications as well as societal resistance that was described to be a kind of neo-cannibalism thereby hindering progress at large.

The THOTA's intentions for change have failed to materialize. Commercial practices persist while knowledge about brain death remains substandard. Many non-related transplants occur legally without any ethical scrutiny. The government's efforts in enforcing the regulations

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<sup>1</sup> The Transplantation of Human Organs and Tissues Act 1994

through legislative amendments have received criticism from the general public and media indicating that there are loopholes in interpretation and implementation by both authorities and hospitals.

### **PRESSING NEED FOR ORGAN TRANSPLANTATION**

India witnessed 17,000–18,000 solid organ transplants performed every year, the most in the world after the US and China but remains behind several high-income countries in transplantation rates per million population (0.65).<sup>2</sup> There has been progress in this area, such as an improvement in the harvesting of organs from deceased donors, with the average number of organ transplants per donor increasing from 2.43 in 2016 to 3.05 in 2022.<sup>3</sup> However, these surgeries are majorly performed by privately owned hospitals, which makes them inaccessible to most patients. Inclusion and equity for many patients remain a major challenge, even with the advancements in organ transplantation in India over the past five to six decades, especially in the field of nephrology. The government is attempting to encourage kidney transplantation from deceased donors, which is widespread in developed nations. However, the region's use of deceased donors' organs is not at its best for a variety of reasons, including experiences with the healthcare system, cultural and religious views, and more.

The most transplanted organ in India is the kidney, but the current number of transplantations (11,243), is insufficient to meet the demand of an estimated 200,000 renal failures a year.<sup>4</sup> The prevalence of chronic illnesses like diabetes and hypertension is extremely high in India. Due to the high prevalence of chronic kidney disease in the nation, many patients are dependent on dialysis for the duration of their lives as they wait for financial assistance or a donor to undergo a transplant operation in a private hospital. Due to a shortage of readily available or reasonably priced medical care, many people stop receiving their prescribed medication, switch to alternative therapies, or pass away.

In the absence of a strict regulatory framework, the disparity between the need for transplants and present donor rates encourages the growth of illegal operations. The current legal system leaves room for criminal activity to flourish while making the process extremely drawn out and taxing for regular people. Although there has been significant progress in transplantation in India, there are still many people living with chronic illnesses, which makes access and

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<sup>2</sup> Lancet Regional Health Southeast Asia, 'Organ Transplantation in India: needs a bigger push' (2024)

<sup>3</sup> *ibid*

<sup>4</sup> *ibid*

availability difficult. Therefore, early identification and prevention of chronic illness are crucial aspects of organ transplantation. In the public sector, a robust diagnostics infrastructure will be necessary for early detection and screening. In addition to raising awareness of dead organ donation, there has to be ongoing discussion on the moral and legal implications of organ donation.

### **THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994**

The removal, storage, and transplantation of organs and tissues in India are regulated by the Transplantation of Human Organs and Tissues Act (THOTA) which stipulates that organ donation is only allowed for medical reasons. All transplant centers must comply with this law and submit regular reports to the government detailing all transplant-related activities including case numbers, results, and expenses. Moreover, the public must be able to access these details on a designated website.

The main provisions of the Transplantation of Human Organs Act and the newly passed Gazette by the Government of India include the following:

1. **Eligibility for Living Organ Donation:** The THO Act specifies eligible family members who can donate organs without legal formalities, including parents, siblings, children, spouses, and now grandparents as per the recent Gazette. Documentation proving the relationship is required. Non-related donors must seek special permission from the authorization committee and undergo an interview to demonstrate altruistic motives.
2. **Criteria for Brain Death Declaration:** The Act mandates that brain death be certified by two doctors, with at least one being an expert in neurology nominated by the government. Certifications must be issued six hours apart to confirm brain death.

## **AUTHORITIES**

### **Appropriate Authority<sup>5</sup>**

For this Act, the Central Government and state government shall designate, by notification, one or more officials as Appropriate Authorities for each of the Union territories and states respectively.

### **Functions of Authority**

The Appropriate Authority is responsible for granting and renewing registrations for organ and tissue transplantation, suspending or canceling registrations as necessary, and enforcing standards for hospitals and Tissue Banks. It investigates complaints of violations, inspects Tissue Banks and hospitals periodically to ensure quality in transplantation and follow-up care, and takes appropriate action to address any breaches of the Act.

### **Advisory Committee<sup>6</sup>**

To support the Appropriate Authority, the Central and State Governments must form two-year Advisory Committees. A secretary-level chairperson, two medical experts, a Joint Director-level Member-Secretary from the Health Ministry or Department, two distinguished social workers (one from a women's organization), a judicially experienced legal expert, a representative of an NGO engaged in human rights or organ donation, and a human organ transplantation specialist who is not on a transplant team comprise each committee. The terms and circumstances for appointments shall be determined by the Central Government.

### **Authorization Committee**

The Authorization Committee (AC) ensures that non-relative organ donors are not being exploited for monetary gain. It scrutinizes the joint application from the donor and recipient, conducts interviews to verify genuine intent, and ensures the donor understands the surgery's risks. Hospitals performing over 25 transplants annually can establish their own AC.

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<sup>5</sup> The Transplantation of Human Organs and Tissues Act 1994, s 13

<sup>6</sup> The Transplantation of Human Organs and Tissues Act 1994, s 13A

## AMENDMENTS<sup>7</sup>

The 2011 amendment to THOTA introduced significant changes: tissues were included alongside organs, the definition of "near relative"<sup>8</sup> was expanded to include grandchildren and grandparents, retrieval centers were required to register for organ retrieval from deceased donors, tissue banks also needed registration, swap donation was permitted, and a mandatory inquiry from the attendants of potential donors was instituted.

## PENALTIES UNDER THE ACT

The Act's Section 18<sup>9</sup> penalizes the unapproved removal of human organs or tissues, carrying fines of up to Rs. 20 lakhs or ten years in prison. This section primarily targets medical professionals, who may also face further disciplinary action from the State Medical Council, which may include a three-year suspension for the first offense and permanent removal for subsequent offenses. Regarding the commercial trafficking of organs, Section 19<sup>10</sup> stipulates fines between Rs. 20 lakhs and Rs. 1 crore in addition to a minimum five-year prison sentence that can be extended to ten years. Infractions of other laws are covered by Section 20<sup>11</sup>, which carries fines of up to Rs. 20 lakhs or a maximum five-year jail sentence.

## LEGAL AND ETHICAL CHALLENGES

Despite the legal framework, India still has its sets of struggles with organ donation and transplantation. One of the main challenges is the scarcity of organs, which has resulted in a flourishing black market for organs and illegal organ trafficking.

- i. **Scarcity of Organs:** One of the primary concerns about organ transplantation in India is the scarcity of organs. The demand for organs far surpasses the supply, and this has led to long waiting lists for people requiring transplants. According to the National Health Profile 2018, the demand for organs in India is estimated to be around 500,000 per year, while the supply is less than 10% of this number. Some of the reasons that give rise to organ shortage in India include a lack of organ donor

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<sup>7</sup> The Transplantation of Human Organs and Tissues (Amendment) Act 2011

<sup>8</sup> The Transplantation of Human organs and Tissues Act 1994, s 2(i)

<sup>9</sup> The Transplantation of Human Organs and Tissues Act 1994, s 18

<sup>10</sup> The Transplantation of Human Organs and Tissues Act 1994, s 19

<sup>11</sup> The Transplantation of Human Organs and Tissues Act 1994, s 20

awareness, a lack of a clear certification process for brain death, and a dearth of resources to support deceased organ donation.

- ii. **Commercial Exploitation of Organ Transplantation:** Regardless of THOTA's regulation to prohibit the commercialization of organ transplants, there have been accusations of illegal organ trade and trafficking across the country. The unlawful trade in organs majorly targets individuals who are willing to sell their organs for money.
- iii. **Lack of Transparency and Accountability:** The lack of transparency in the process of organ transplantation in India has given rise to grave concerns regarding its fairness. The organs are distributed based on economic status and connections rather than medical needs. Though a transparent process needs to be encouraged and followed by the authorities, the Act fails to hold the authorities accountable for non-compliance.
- iv. **Lack of awareness:** Even though there are laws regulating organ transplantation in India, the common man is still not aware enough of how imperative the whole process is. The unawareness among people contributes to organ scarcity and poses challenges for people who are in need of organ transplants.
- v. **Inadequacy of Infrastructure:** The inadequacy of organ transplant infrastructure aids in the impediment of healthcare of patients suffering from terminal illnesses. The long waiting lists for organ transplants deter the commencement of the procedure of organ transplant.
- vi. **Religion and cultural barriers:** Besides the challenges arising out of deficiency of the services of authorities or greediness of people giving rise to the illegal selling of organs, there is a substantial role of religious and cultural barriers as well that affect the practice of organ transplantation in India. The religious or cultural values of some communities don't celebrate the idea of organ transplants, resulting in a scarcity of organs.

## LEGAL CHALLENGES

- i. **Interpretation of the term 'Near Relative':** The Act empowers 'near relatives' to donate an organ without obtaining prior approval from the government. There is a diverse opinion as to what comes under the term 'near relatives', whether it should be extended to incorporate friends or non-blood relations or not.

- ii. **Prohibition of monetization of organs:** Selling of organs for transplantation is prohibited by the Act, nevertheless, there have been innumerable instances of organ trafficking and commercialization.
- iii. **Procedural Challenges:** The Act outlines various procedures to be adhered to during the process of transplantation. The procedure is aimed to guarantee the safety of both donor and recipient. However, it has been questioned based on the procedure being stringent or onerous.
- iv. **Consent of Organ Donation:** To initiate the process of organ transplantation, the Act demands informed consent of the donor and his family. Still, there have been cases where the validity of the consent has been questioned, majorly when the donor is deceased.
- v. **Punishment of violations:** Though the Act imposes severe penalties on the people who violate any provisions, it has been observed that these penalties don't suffice to mitigate the practices of illegal organ trade.

### ADDRESSING THE BLACK MARKET FOR ORGAN TRAFFICKING

Black market organ transfer results from a severe mismatch in supply and demand. The number of patients on the waiting list for organ transplants far exceeds the number of organs being donated.

The traffickers target those in desperate financial situations, with limited options, often poor or undocumented immigrants. They might be facing crushing debt, extreme poverty, or a situation where they feel like they have no other choice. Traffickers may use false promises or manipulate situations. They might undermine the risks of surgery or overestimate the financial compensation. In some cases, they might resort to threats or violence. Donors are offered a small fraction of the actual price paid by the recipient. They are not given proper post-operative care, and their health concerns are often ignored. Poverty and lack of social safety nets push some individuals to sell organs, despite potential health risks, to meet basic needs or pay off debts. Inadequate resources or corruption within law enforcement can make it difficult to track down and dismantle trafficking rings.

The THOTA statute makes it unlawful to buy and sell organs in India. The goal of this is to stop the use and sale of organs. Iran is an exception, where people are able to lawfully purchase



and sell organs while being closely supervised by the government. But there are still worries about possible exploitation and coercion.

### **How does it work?**

#### **Brokers and Traffickers**

Within the clandestine realm of organ trafficking, traffickers and brokers serve as vital middlemen, connecting wealthy recipients willing to pay extravagant rates for organs with potential donors, many of whom come from underprivileged and marginalized groups. These middlemen take advantage of the desperate situations of the poor by giving them a small portion of the organs' eventual sale price. The brokers and traffickers work within a murky network with almost no ethics or transparency, which feeds the cycle of abuse and exploitation even further.

#### **Coercion as well as Abuse**

Exploitation and coercion are often used by organ traffickers all over the world to manipulate poor people or those who are below the poverty line to intimidate them into donating their organs for a meagre price. They may use manipulation, undue influence, and threats to intimidate their loved ones. Potential contributors are deceived by making false financial promises only later to not fulfill them. Although traffickers make enormous amounts of money by selling off these organs on the black market. The lack of support and legal options available to donors makes them more vulnerable to such practices.

#### **Unsafe Practices**

The surgeries involved in organ trafficking are usually executed in an unhygienic manner because of their furtive manner. The lives of donors are often put at risk due to the absence of post-operative care and observation by doctors. These procedures are performed by inexperienced and unskilled people, hence increasing the risk of life-threatening illnesses, infections, and even death of donors.

### **TRANSPLANT TOURISM**

Transplant tourism involves the practice of traveling outside of one's own country to obtain organ transplant services, most commonly for the transplantation of the kidney, liver, or cornea.

Emotionally or biologically linked individuals who have traveled across international borders to receive an organ transplant in a nation with advanced or more easily available transplantation services may lawfully engage in legal transplant tourism.

Although not all organ-related medical tourism is unlawful, the phrase "transplant tourism" refers to the commercialism that fuels the illicit organ trade. For instance, in certain situations, both the organ recipient and donor go to a nation with sufficient infrastructure to carry out legal surgery. In some situations, a recipient journeys overseas to obtain a relative's organ. Because transplant tourism includes the movement of healthy organs in one direction, it depletes the areas where organs are purchased, which is concerning. The process can be opaque, making it difficult to verify informed consent and fair compensation for donors.

Many attractive elements lead to the emergence of transplant tourism. Age, diabetes, and hypertension have all contributed to a notable rise in end-stage chronic kidney disease worldwide, which has created an imbalance between the demand and supply for donor kidneys. When medical reasons or worries of dying while waiting prevent patients from being placed on their country's transplant waiting lists, they frequently turn to foreign countries in search of organs. People in developing nations frequently travel abroad for treatment since there are frequently insufficient dialysis facilities, programs for deceased donors, and surgical transplantation treatments available. Even among blood relatives, organ donation is discouraged in some countries due to cultural restrictions. Moreover, growing wealth disparity fuels a black market for transplant tourism that is made more difficult to police by international regulations.

## **INTERNATIONAL REGULATION OF ORGAN DONATION**

This issue has an international component even if organ donation is governed at the national level. Guidelines and suggestions for the morally righteous and secure practice of organ donation and transplantation have been produced by international organizations including the **United Nations (UN)** and the **World Health Organisation (WHO)**.

In the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, international organizations issued guidelines for health officials and policymakers around the world to address organ trafficking and transplant tourism. Patients traveling abroad to purchase organs from poor and vulnerable people is known as transplant tourism. These patients are frequently from wealthy nations. These international agreements provide a framework for national

cooperation and collaboration protecting organ donation and transplantation practices from unethical and secretive practices.

Organ Procurement and Transplantation Network is a federal agency, operated by a non-profit corporation called the United Network for Organ Sharing. Organ allocation policies are delegated to OPTN's board of directors, which includes transplant specialists, patients, their families, hospitals, organ procurement organizations, and members of the public.

### **ORGAN SHORTAGE: A GLOBAL ISSUE**

The growing disparity between high demand and limited supply of kidneys in the United States has prompted many patients to seek transplants in countries with lax regulatory mechanisms, including India, Iran, China, Pakistan, the Philippines, Brazil, Turkey, Moldova, Ukraine, Russia, Bulgaria, and Romania. The World Health Organization (WHO) has emphasized that the human body and its parts cannot be the subject of commercial transactions and has continuously emphasized that the sale of organs violates both its own constitution and the Universal Declaration of Human Rights. If there is any suspicion of commercial transactions, the World Health Organization recommends doctors not proceed with transplanting organs. Representatives from the international transplant community recently described "transplant commercialism" as the use of organs as commodities that exploit the underprivileged for the profit of the wealthy, during a meeting in Istanbul.

In India, the rate of deceased donation is incredibly low because of taboos related to culture and religion. To address the shortage of organs and stop the unlawful trade, it is imperative to investigate and promote organ donation after death. Alternatives like swapping or exchanging donors for living transplants should also be promoted. Given the substantial advantages of transplants, including increased life expectancy and better patient quality of life, addressing organ scarcity is imperative. For example, compared to dialysis, kidney transplantation dramatically improves patient survival. Moreover, organ transplants are life-saving therapies for those suffering from terminal liver, heart, or lung illnesses, underscoring the significance of raising the organ donation rate.

### **SCOPE OF DECEASED DONATION PROGRAM**

In India, more than 120 transplant centers carry out between 3,500 and 4,000 kidney transplants per year. Of these, four centers execute between 150 and 200 liver transplants annually; several

of them also do the occasional heart transplant. About fifty liver transplants per year are from deceased donors, the remaining liver transplants are from living donors, and 100 heart transplants have been successfully completed to date. Deceased organ donation is significantly increased by fatal traffic accidents and other causes of brain death, such as subarachnoid hemorrhage and brain tumors. Dependency on living donors may be significantly decreased if 5–10% of these deceased patients become organ donors, which would help not only with kidney transplants but also with liver, heart, pancreatic, and lung transplants.

India's networks for organ sharing and deceased donation have seen several remarkable achievements. Through the MOHAN Foundation's Organ Sharing Network, hospitals in Hyderabad and Tamil Nadu successfully shared approximately 450 organs between 2000 and 2008. The Gujarati Jain community has shown promise for a strong deceased donation program lately by extending their support for eye donation to solid organ donations. If these programs were set up correctly, they could cover the majority of the need for liver, kidney, and heart transplants.

India's program for deceased donation has plenty of space to develop. In addition to strengthening hospital programs through improved infrastructure, which includes training for transplant coordinators and other medical staff, more public awareness campaigns can debunk myths and encourage donations. Donations to the families of contributors who have passed away may inspire morally upright giving. Although it is ideal to donate from a deceased person there are programs for ethical living donors that can cover the shortfall. The organs can be made accessible through investing in methods of preserving organs and researching laws pertaining to presumed consent. These actions can strengthen India's donation program.

### **INCREASING AWARENESS AND PROMOTING VOLUNTARY ORGAN DONATION**

An extreme lack of organs for transplantation is a problem for India. Though the number of persons with end-stage organ failure is estimated to be over a million, only a small number of transplants are carried out each year. There is no doubt that the demand for organs exceeds the supply. And there's no getting away from the hard truth.

Therefore, raising awareness for organ donation is the only way out of this gloomy situation. The possibility that organs will become accessible to save lives increases with the number of

possible donors. Regretfully, not many Indians are aware of organ donation or how they might be able to assist others once they pass away. Below are a few strategies:

### **Campaigns for Organ Donation**

There are various ways to organize organ donation campaigns to promote awareness and encourage people to register.

Tie-ups with hospitals and non-profit organizations- Seminars, workshops, and educational awareness programs can be organized with the help of NGOs in such places, which will result in motivating people.

Public Events- A lot of social events including marathons can be planned with information booths to raise awareness about organ donation.

Social Media Engagements with Celebrities- Collaborations with influencers or celebrities having enormous followings can be put to use to reach a larger audience for this cause.

### **Registration of Organ Donors**

Simple Registration: Ensure that it is simple and easy to navigate both the online and offline donor registration processes. Promote websites like the NOTTO website that offer easy online registration.

Organ Donor Registration: Offer Driver's license applicants the opportunity to register as organ donors.

Hospital Registration: When a patient is admitted to the hospital, provide options for registering as an organ donor.

Public service announcements: During prime-time television and public radio public service announcements should be used to encourage registration.

A calculated move to promote awareness and acceptance of organ donation from an early age is the inclusion of organ donation education in the school curriculum. The aim of this initiative is to create modules that are suitable for students' ages and can be easily integrated into current educational frameworks. The goal is to provide students with thorough, precise, and compassionate information regarding organ donation. By putting these strategies into practice

India may create a more informed and supportive environment for willing organ donation. This will ultimately lead to a wider donor pool and save a large number of lives.

## **CONCLUSION**

Regulating the process of organ donation is a complex and intricate issue involving numerous stakeholders on both national and international fronts. The foremost issues that require undivided attention include the shortage of organs for transplantation, the difficulties caused by organ trafficking, inequalities in access to organ donation, evolving trends in organ donation practices, problems related to data privacy, and ethical considerations in research. To mitigate these challenges, there is a need for public awareness campaigns, robust legal and regulatory frameworks, and fostering ethical discourse.

By making collaborative efforts to scale up the regulation of organ donation, we can make sure the whole process is ethical, transparent, and safe, consequently saving lives and improving health outcomes for those awaiting transplants. All stakeholders, involving governments, civil society organizations, donors, medical professionals, recipients, and international entities like the World Health Organization and the United Nations play a significant role by putting collective efforts and showcasing cooperation to ensure successful regulation of organ transplantation.

To conclude, there is light at the end of the tunnel. Organ donation and transplantation in India are growing, and adopting some measures to mitigate challenges will increase the rate of organ donation and make transplantation more accessible to the public. Through these concerted efforts, we can play a crucial role in ensuring that organ donation continues to save lives and improve health outcomes for individuals and communities worldwide.