



## **Evolving Jurisprudence on Organ Transplantation in India: An Analytical Study of the Transplantation of Human Organs and Tissues Act**

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### **Abstract**

**Background:** Organ transplantation is a great advancement in modern medicine; it functions within a sensitive legal and ethical framework that seeks to balance the protection of fundamental human rights with medical needs. In India, this regulatory system is essentially founded upon the landmark legislation known as the Transplantation of Human Organs and Tissues Act (THOTA), 1994.

**Aim:** The aim is to critically analyze the legal development, basic provisions, and practical challenges of THOTA and its amendments, with a core focus on ethical, procedural, and regulatory perspectives.

**Methods:** We conducted a detailed descriptive and analytical review, scrutinizing primary sources such as THOTA, its amendments, and related rules, along with secondary literature from various legal, medical, and bioethical journals. The study examines, in depth, the structure, procedures, and practice of the law.

**Results:** THOTA established key milestones, such as the recognition of brain-stem death and a national allocation system. However, major gaps persist: inadequate infrastructure, low deceased-donor rates, and vulnerabilities to organ trafficking.

**Conclusion:** Although THOTA provides a robust legal framework, systemic limitations seriously impede its practical application. Requirements to optimize ethical and effective organ transplantation in India include better infrastructure, digital integration, public awareness, and standardization of procedures.

**Keywords:** Brain Death, Ethics, India, Organ Donation, Organ Transplantation, Transplantation of Human Organs and Tissue Act.

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## INTRODUCTION

Organ transplantation is one of the greatest medical advances of the 20th century, offering a realistic chance of recovery for people with end-stage organ failure. Once an experimental operation, it is now a common life-saving procedure. However, the entire practice of organ transplant raises a number of moral and legal questions regarding what exactly qualifies as death, consent, the commercialization of the human body, and the equitable distribution of such a priceless, life-giving resource [1]. It is crucial that the act of saving a life itself be founded on values that uphold the rights and dignity of both the donor and the recipient.

Organ donation is the selfless act of donating one's organs or tissues for transplantation to a person in dire need thereof. One of the most striking examples of medical altruism is the transformation of grief over death into the chance to preserve another life. Globally, organ transplantation has become a vital, life-saving treatment for patients with end-stage organ failure; however, the gap between supply and demand is growing. Awareness of and rates of cadaveric donation remain critically low in India, underscoring the need for robust ethical standards and practical legislative measures — both to protect against exploitation and commercialization and to promote voluntary donation.

With the passage of the Transplantation of Human Organs and Tissues Act, or THOTA, in 1994, India's legal response to these issues took a tangible form. This act was historic because it established a formal system for transplants while explicitly forbidding their commercialization [2]. The 2011 and 2014 amendments to this Act, along with the establishment of the associated Rules, have strengthened the Act's regulatory mechanisms and expanded its scope [3,4].

Despite the existence of this progressive law, the demand for organs in India remains alarmingly higher than their availability. It is estimated that,

every year, more than 200,000 people require a kidney transplant, but only about 7,500 procedures actually take place. Concerning liver transplants, the demand is approximately 80,000 annually, yet only around 2,000 are performed [5]. This glaring gap between demand and availability underscores the vital necessity not just of having laws, but also of ensuring their effective implementation. In this article, we explore the legal complexities of THOTA, evaluate its effectiveness, and pinpoint the ongoing medicolegal hurdles holding India back from achieving its full potential in the field of organ transplantation.

## THE LEGAL EVOLUTION: THOTA AND ITS AMENDMENTS

In India, the period before THOTA was marked by a lack of regulation, featuring inconsistent practices and increasing concerns regarding "kidney scams" and the exploitation of economically disadvantaged individuals ([A3.1] [A3.2]6). Consequently, THOTA was enacted in 1994 to establish a thorough legal framework with multiple foundational goals: to oversee the removal, storage, and transplantation of human organs; to acknowledge brain-stem death; to combat commercial trafficking; and to maintain the ethical standards of altruism and voluntary donation.

The THOTA (Amendment) Act, 2011, was a crucial step in addressing the loopholes and practical issues that arose during the initial rollout of the Act. Among the key updates was the broadening of the Act's scope to encompass human tissues and cells, which helped close the regulatory gap for transplants involving tissues such as corneas, heart valves, skin, and pancreatic islets. The amendment also made the authorization process more efficient by empowering hospital-based authorization committees to speed up approvals for living donations, cutting down on bureaucratic delays. It also clarified and expanded the definition of 'near relative' to include grandchildren and grandparents, thereby aiming to curb fraudulent relationship claims. Additionally, it

introduced tougher penalties for violations, including steeper fines and longer prison sentences, to serve as a stronger deterrent against organ trafficking [3].

The Transplantation of Human Organs and Tissues Rules, 2014, operationalized the amendments by providing detailed procedural protocols. The Rules were also instrumental in establishing the National Organ and Tissue Transplant Organisation (NOTTO), with its Regional (ROTO) and State (SOTTO) level organizations, to create a cohesive national network for organ procurement and distribution [4].

### **CORE LEGAL PROVISIONS AND PROCEDURAL MANDATES**

#### *The Standard of Brain-Stem Death*

THOTA's acknowledgement of brain-stem death is of particular significance as it is a first for Indian legislation. It illustrates how Indian law is slowly gaining pace with contemporary medical science, as it now allows for the irreversible cessation of brain-stem function to be legally defined as death. While this law facilitates the retrieval of vital organs from heart-beating donors [2], it stipulates specific rules for certification, documentation, and completion of Form 10 [4, 7] by a minimum of four doctors, with two sets of approvals separated by at least six hours.

Although the legal challenges may appear overwhelming, the first-world nature of these obstacles may be a blessing in disguise. In interviews, officials of the Union Health Ministry have repeatedly cited the "poor identification and certification of cases of brain-stem death" as one of the most significant barriers to the low, and still-declining, rate of deceased donations in India, which remains below one donor per million population [5]. Unfortunately, the challenges are somewhat paradoxical. To the dismay of many, a belief seems to persist among a cohort of the medical profession that brain-stem death should only be declared in cases involving the withdrawal of life support for the purpose of organ harvest.

This leads to the unilateral extension of life support for families who have not made such a decision. The result is ethical dilemmas and an excess of inconsistent death declarations [1,8].

Allegations of serious misconduct have raised eyebrows and led to judicial scrutiny. In 2025, the Supreme Court took up a petition that challenged the constitutional validity of the brain-stem death definition under THOTA, with claims that vulnerable patients were being declared dead prematurely with the aim of organ harvesting. While the Bench, made up of Justices Surya Kant and Joymalya Bagchi, upheld the legislative definition and chose not to second-guess Parliament, they did recognize the gravity of the malpractice allegations and permitted a deeper, fact-specific investigation [4,9]. This judicial episode highlights a significant tension: although the legal definition holds up constitutionally, the system is still vulnerable to abuse. It emphasizes the urgent need for transparent data, independent audits, and strict enforcement to ensure adherence to protocols in both spirit and practice.

#### *Living Donation: Preserving Altruism*

THOTA sets up a clear hierarchy for living donors. The first group consists of close relatives, including spouses, parents, siblings, children, grandparents, and grandchildren. Any donations from this group must be backed by genetic or documentary proof of their relationship, along with a thorough medical evaluation to ensure compatibility and the donor's safety [8].

The law also puts in place strict safeguards for living donations from outside this circle. Such donations are only approved if they stem from "affection and attachment" or for "special reasons", and require the approval of the Authorization Committee. This committee, whether at state or hospital level, plays a crucial role in ensuring that any donation is truly voluntary, free from any pressure, financial incentives, or undue influence. It conducts separate and joint interviews with both

donor and recipient to evaluate their motivations and ensure their full comprehension of the risks involved [4]. Additionally, a mandatory "cooling-off period" ensures sufficient time for the donor to reconsider their decision.

#### *Deceased Donation: The Crucial Pathway*

Deceased donation is a complex, multi-step process requiring careful coordination. It begins in the ICU, where potential donors are identified, followed by certification of brain-stem death by a designated medical board, after which the next-of-kin are approached for consent. Once such certification is in place, organ retrieval cannot proceed without consent from the deceased's next-of-kin.

Although individuals in India may voluntarily pledge their organs during their lifetime through donor cards or official registries, the practical implementation of organ retrieval still depends on the consent of their next-of-kin. This situation creates an ethical tension between individual autonomy, which supports the donor's expressed wish to donate, and family authority, which frequently determines the final decision in practice. In many cases, families decline donation despite the deceased having registered as an organ donor, due to emotional distress, cultural considerations, or lack of awareness regarding the donor's intentions. Therefore, trained transplant coordinators play a vital role in counselling families and facilitating informed decision-making during this sensitive period [10].

When we talk about the "cooling-off" period for living donations, it's important to really examine its protective purpose against the risk of undue influence. This period is intended to allow donors time to reflect and to avoid hasty decisions. However, delays in authorization committee meetings can extend this period significantly. Data from hospital transplant reports show that these committees typically approve most cases, with rejections or deferrals being quite uncommon [2,5].

Such a high approval rate raises questions as to whether the process is genuinely thorough or merely a bureaucratic formality. Some experts have noted that "altruistic donations" from individuals outside the immediate family often face much lower approval rates, suggesting that committees may be more cautious regarding non-familial situations [6]. Nonetheless, there remains a lack of comprehensive outcome data from authorization committees across India, making it difficult to assess whether these cooling-off periods truly safeguard donors or if the delays might inadvertently lead to undue influence due to prolonged interactions between donors and potential recipients.

After obtaining consent and the necessary regulatory approvals, donor information is entered into the National Organ and Tissue Transplant Organisation (NOTTO) allocation network. This system ensures that organs are distributed transparently, prioritizing medical urgency, compatibility, and waiting time over socioeconomic status.

#### *Prohibitions and Penalties*

At the heart of THOTA's ethical approach is a strict ban on the commercial trade of human organs. Sections 18, 19, and 19A of the Act prohibit the buying, selling, or brokering of organs, as well as advertising for such activities. The penalties are quite harsh, with potential prison sentences of up to 10 years and fines that can reach ₹20 lakhs [3]. These rules are designed to safeguard the poor and vulnerable from being exploited and to reinforce the idea that the human body should never be treated as a commodity.

### **INSTITUTIONAL INFRASTRUCTURE AND REGULATORY BODIES**

*The implementation of THOTA relies on a multi-layered institutional framework:*

At the top of this structure is the National Organ and Tissue Transplant Organisation (NOTTO), which oversees the national waiting list, develops

policies, and raises awareness about organ donation. Below NOTTO sit the Regional and State Organ and Tissue Transplant Organisations (ROTO and SOTTO), which handle organ matching and transportation while ensuring that state-level practices align with national guidelines. On the hospital front, authorization committees carefully review living donations from individuals who are not close relatives, to confirm that such donations are voluntary and to prevent any commercial transactions. Additionally, state-appointed Appropriate Authorities oversee the licensing of transplant centers, conduct inspections, and ensure that the Act is enforced, including penalties for any violations. This structured approach, from national policy to local enforcement, is designed to promote accountability and transparency throughout India's transplantation system.

### **PERSISTENT CHALLENGES AND MEDICOLEGAL DILEMMAS**

Despite its comprehensive nature, the THOTA framework faces significant challenges. The most glaring issue is the sizeable gap between would-be organ recipients and the number of organs actually available, such scarcity fueling the very black market that the law was designed to eliminate [5]. India's deceased donation rate remains stubbornly low at around 0.8 per million population, a far cry from Spain's 49.6 or the USA's 38 [12]. The reasons for this include a poor understanding of brain death, cultural beliefs that create hesitation, and a lack in many hospitals of the infrastructure to identify and maintain potential donors.

This chronic organ shortage invites exploitation. There are persistent reports of wealthy individuals bypassing waiting lists by exploiting the poor through fraudulent "affection" claims or outright cash deals, sometimes with doctors turning a blind eye [13]. Meanwhile, bureaucratic delays and poor coordination between hospitals and the NOTTO network mean opportunities are missed, leaving grieving families frustrated [14]. Different

authorization committees also interpret the vague standard of "affection and attachment" inconsistently, creating uncertainty and room for arbitrariness [3,6].

What can India learn from countries with higher donation rates? Although Spain's 'opt-out' law helps to achieve higher rates of organ donation, this is not the real driver of its success—in practice, Spanish families are always consulted. The real reason lies elsewhere: Spain has created a nationwide network of hospital-based transplant coordinators. These are not bureaucrats but ICU doctors and nurses already working in the hospital, trained to spot potential donors early and approach families with genuine sensitivity [1,5].

The United Kingdom offers another lesson. It recently transitioned to a "soft opt-out" system, but again, families are still consulted [2,8]. What aids the UK's success rate is its specialist nurses: skilled professionals who support families through one of the most difficult moments of their lives. The UK system also tracks all donation-related activities through audits, publishing annual reports that help hospitals improve continuously [2,6].

However, India cannot simply copy these models. Spain's system developed over decades in the setting of universal healthcare, where trust in institutions runs high [1,3]. India's reality is different: most hospitals lack dedicated coordinators, ICU beds are unevenly distributed, and cultural mistrust of healthcare runs deep in many communities. Amending the law alone, without honestly confronting these ground-level realities, will yield limited results. India requires sustained, long-term effort to build institutional trust, train professionals, and develop systems that function equitably across all levels of healthcare.

### **DISCUSSION**

The evolution of India's organ transplantation law reflects a balance between medical innovation, ethical duty, and social equity. The Transplantation of Human Organs and Tissues Act (THOTA) has introduced the concept of brain-

stem death, outlawed organ trafficking, and established regulatory bodies such as NOTTO, while aligning the country's national standards with global ethical practices. Nonetheless, challenges persist — including inconsistent implementation, donor shortages, and regional inequalities — alongside pressing ethical dilemmas surrounding consent and donor vulnerability. By taking cues from Spain and the UK, India can enhance coordination, education, and awareness to close the gap between the law and its real-world application, ensuring that THOTA truly serves its humanitarian and ethical goals.

### **RECOMMENDATIONS FOR A ROBUST FUTURE**

To fortify India's organ transplantation system, a multi-pronged strategy is essential:

1. The government and the medical community must launch sustained, multilingual campaigns to demystify brain death, address cultural and religious concerns, and promote organ donation as a life-saving act of altruism [15].
2. Investment is needed to equip more public and private hospitals with certified transplant coordinators, dedicated ICU beds for donor maintenance, and streamlined processes for swift certification and allocation.
3. The NOTTO registry must be transformed into a real-time, seamlessly integrated digital platform that connects all hospitals, tracks organ availability from identification to transplantation, and ensures absolute transparency in allocation.
4. Developing national guidelines with clearer, more objective criteria for authorization committees can help reduce ambiguity and ensure more uniform decision-making.
5. Collaborations with non-governmental organizations can be highly effective for counselling grieving families—a critical and often overlooked step in the donation process [10].

### **CONCLUSION**

The law governing transplantation of human organs and tissues in India, passed in 1994, shows

that the country is serious about improving medical care while upholding ethical and legal rules. This law was a significant step forward, introducing the concept of brain-stem death into Indian law and creating a system to address the complicated issues associated with this field of medicine. A particularly positive aspect of the law is that it strikes a balance between saving lives through facilitating transplants, and protecting others from being exploited.

Nonetheless, any law is only as strong as its real-world impact. Turning legal language into everyday action is a tough process, beset by obstacles—cultural, logistical, and socioeconomic. The persistent, significant gap between the demand for organs and their supply is not only a medical problem; it also reflects social and ethical issues. To close this gap requires more than just following rules; we need a genuine cultural shift, placing greater value on kindness and social responsibility. By building stronger systems, being more transparent, and continuously educating the public on this issue, India can improve its organ transplantation system. The end goal should be to create a society where the gift of life is given freely and received with gratitude, living up to the full promise of the Transplantation of Human Organs and Tissues Act.

### **CONFLICT OF INTEREST**

None

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