

GIFT OF LIFE, RULE OF LAW – HUMAN ORGAN AND TISSUE TRANSPLANTATION IN INDIA: A COMPREHENSIVE ANALYSIS OF LAWS, REGULATIONS, AND POLICY FRAMEWORK

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ABSTRACT

Organ and tissue transplantation represents one of the most significant achievements in modern medicine, offering renewed life to patients suffering from end-stage organ failure. In India, this field is governed by a robust legislative architecture anchored in the Transplantation of Human Organs and Tissues Act, 1994, as amended in 2011, and its accompanying Rules of 2014. This article provides a thorough examination of the statutory provisions, institutional mechanisms, ethical considerations, and enforcement challenges that shape the transplantation landscape in India. It further discusses the roles of key regulatory bodies, the legal framework surrounding brain death certification, living and deceased donor protocols, anti-commercialisation measures, and emerging policy directions aimed at bridging the wide gap between organ demand and supply in the country.

1. Introduction

Organ transplantation stands at the intersection of medicine, ethics, and law. Every year, thousands of patients in India await life-saving organ transplants, yet the number of available organs falls dramatically short of the need. As of recent estimates, India performs approximately 15,000 to 17,000 kidney transplants, 1,500 liver transplants, and a relatively smaller number of heart, lung, and pancreas transplants annually. Despite this activity, the country faces one of the world's starkest mismatches between organ demand and supply.

Against this backdrop, the legal and regulatory framework governing human organ and tissue

transplantation is of paramount importance. It must balance the imperative of facilitating transplants with the need to prevent organ trafficking, protect vulnerable donors, uphold informed consent, and ensure equitable access to scarce organs. India has, over the decades, built a legislative structure designed to meet these challenges.

This article offers a comprehensive analysis of that framework – tracing the evolution of transplantation law in India, examining the substantive provisions of key legislation, assessing institutional oversight mechanisms, and identifying the persistent gaps that policymakers must address.

2. Historical Background and Legislative Evolution

2.1 The Pre-Legislative Era

Prior to formal legislation, organ transplantation in India operated in a largely unregulated environment. The first successful kidney transplant in India was performed in 1971 at the Christian Medical College, Vellore. As transplant activity grew through the 1970s and 1980s, so did concerns about organ commercialisation. Reports of a thriving trade in kidneys – often exploiting impoverished individuals from rural areas – attracted national and international condemnation.

2.2 The Transplantation of Human Organs Act, 1994

In response to widespread organ trafficking and the absence of a legal framework for deceased donor transplantation, the Parliament of India enacted the Transplantation of Human Organs Act, 1994 (THOA, 1994). This landmark legislation achieved several important objectives:

- It provided statutory recognition and regulation of living donor transplants.
- It introduced the concept of brain death as legal death, thereby enabling deceased donor (cadaveric) transplantation.
- It established an authorisation committee system to approve living unrelated donor transplants.
- It criminalised commercial dealings in human organs, making the sale or purchase of organs a punishable offence.
- It provided for the regulation of hospitals undertaking transplantation activities.

The Act was initially adopted by most Indian states and Union Territories over the following decade, though adoption was uneven in the early years.

2.3 The Amendment of 2011 and Expansion to Tissues

After nearly two decades of implementation, certain shortcomings of the 1994 Act became apparent. In 2011, Parliament passed the Transplantation of Human Organs and Tissues (Amendment) Act, 2011, which made several significant changes. Most prominently, the title of the Act was amended to include 'Tissues,' reflecting the expansion of the regulatory framework to cover tissues such as corneas, heart valves, bones, and skin. Other key amendments included:

- Strengthening provisions against organ trafficking with enhanced penalties.
- Expanding the definition of 'near relative' to include additional family members.
- Mandating the establishment of a National Human Organ and Tissue Removal and Storage Network.
- Creating a hierarchy of transplant coordination at national, regional, and state levels.
- Introducing provisions for the swap or pooled donation of organs among incompatible pairs.

2.4 The Transplantation of Human Organs and Tissues Rules, 2014

To give operational effect to the amended Act, the Central Government notified the Transplantation of Human Organs and Tissues Rules, 2014 (THOT Rules, 2014). These Rules provide detailed procedural guidance on matters including the registration of hospitals, the functioning of authorisation committees, protocols for brain death certification, procedures for organ retrieval and allocation, maintenance of records, and the format of consent documents. The Rules form the operational backbone of the transplantation regulatory system in India.

3. Key Definitions Under the Act

The THOA and its amendment introduce several foundational definitions that shape the entire legislative framework:

3.1 Human Organ and Human Tissue

A 'human organ' is defined as a structured arrangement of cells and tissues that, if wholly removed, cannot be replicated by the body. This includes kidneys, liver, heart, lungs, pancreas, and intestines. A 'human tissue' refers to a group of cells and the intercellular substances associated with them, including corneas, bone, tendons, ligaments, cartilage, heart valves, and skin.

3.2 Donor

The Act recognises two categories of donors. A 'living donor' is a person who voluntarily donates one or both kidneys (or a part of the liver or other specified organs) during their lifetime, subject to strict eligibility criteria. A 'deceased donor' is a person who has been declared brain dead in accordance with the prescribed procedure and whose organs and tissues are retrieved with appropriate consent after death.

3.3 Brain Death

One of the most significant innovations of the THOA is its recognition of 'brain death' – the irreversible cessation of all functions of the entire brain, including the brain stem – as equivalent to legal death for the purposes of the Act. This recognition is essential for deceased donor transplantation, as it allows organ retrieval while the body is still maintained on life support, ensuring organ viability.

3.4 Near Relative

The Act defines 'near relative' to include a donor's spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson, and granddaughter. The 2011 amendment further extended this definition to include certain other categories of relatives specified by the Central Government, enabling a wider pool of altruistic living donors.

4. The Living Donor Framework

4.1 Categories of Permissible Living Donors

The Act distinguishes between two categories of living donors based on their relationship to the recipient:

4.1.1 Near Relative Donors

Donation between near relatives is generally permissible under the Act, provided valid informed consent is obtained and appropriate medical suitability is established. The hospital's transplant team evaluates the donor's health, voluntariness, and understanding of the risks. No special approval from the Authorisation Committee is required for near relative donations, though the transplant hospital must maintain detailed documentation.

4.1.2 Other Living Donors (Unrelated Donors)

Donation by individuals who are not near relatives of the recipient – often motivated by emotional or humanitarian bonds – is subject to greater scrutiny. Such cases must be referred to the Authorisation Committee constituted under the Act. This committee is tasked with determining whether the proposed donation is genuinely motivated by affection, attachment, or other non-commercial reasons. The Rules specify the composition and procedure of such committees, which typically include a senior official from the state health department, a medical professional not connected to the transplant hospital, and a social worker.

4.2 Prohibited Living Donations

To protect vulnerable populations, the Act strictly prohibits certain categories of living donation:

- Minors (persons below 18 years of age) cannot donate organs under any circumstances.
- Persons of unsound mind are legally incapacitated from donating.
- Conditional donation – where the donor attaches conditions to the donation, such as requiring payment or other consideration – is prohibited.

- Cross-linked or 'swap' donations for commercial purposes are forbidden, though non-commercial swap donations between compatible pairs are permitted.

4.3 Consent Requirements for Living Donors

The Act and Rules mandate that informed consent for living donation must be free, voluntary, and documented. The donor must be informed of the nature of the procedure, the risks involved, and the consequences of donation. Consent must be witnessed by an independent person and documented in the prescribed form. The Act also recognises the donor's right to withdraw consent at any time before the organ removal procedure commences.

5. The Deceased Donor Framework

5.1 Brain Death Certification Procedure

The Act prescribes a rigorous procedure for the certification of brain death, designed to prevent premature or erroneous declarations. Brain death must be certified by a Board of Medical Experts comprising:

- The registered medical practitioner in charge of the hospital where the potential donor is admitted.
- An independent specialist (neurologist or neurosurgeon) nominated by the appropriate authority.
- The treating physician.
- An anaesthesiologist or intensivist.

The certification requires two separate assessments conducted at a prescribed interval (generally six hours apart for adults, with longer intervals for children). All four members must be present and concur at each assessment. The use of standardised apnoea tests and confirmatory investigations – such as electroencephalography (EEG) or cerebral angiography – may be required in certain cases under the Rules.

5.2 Consent for Deceased Donation

The Act provides two pathways for obtaining consent for deceased donation. First, a person

may execute a formal document (commonly referred to as a donor card or pledge form) during their lifetime, authorising the removal of their organs after death. Second, in the absence of such prior authorisation, consent may be given by the person lawfully in possession of the body – typically the next of kin – after the donor's death. The hierarchy of consent among next of kin and the procedures to be followed are detailed in the Rules.

5.3 Organ Allocation Under the Deceased Donor Programme

One of the central policy challenges in deceased donor transplantation is the equitable and transparent allocation of scarce organs. The THOT Rules, 2014 mandate the use of a waiting list system maintained by the transplant coordination body at state, regional, and national levels. The allocation protocols take into account factors such as:

- Medical urgency and compatibility (blood group, HLA matching).
- Time spent on the waiting list.
- Geographical proximity to the donor hospital.
- Age of the recipient (paediatric priority in certain categories).
- Condition of the organ (some organs require transplantation within a narrow time window).

The National Organ and Tissue Transplant Organisation (NOTTO) maintains a national registry and coordinates inter-state organ sharing through established protocols. State Organ and Tissue Transplant Organisations (SOTTOs) and Regional Organ and Tissue Transplant Organisations (ROTOs) perform analogous functions at their respective levels.

6. Institutional and Regulatory Architecture

6.1 National Organ and Tissue Transplant Organisation (NOTTO)

Established under the Ministry of Health and Family Welfare, NOTTO serves as the apex body

for the coordination and networking of all activities relating to organ procurement, storage, and transplantation in India. Its functions include maintaining a national registry of donors and recipients, facilitating the sharing of organs across states, setting national allocation protocols, and overseeing the functioning of ROTTOS and SOTTOs.

6.2 Regional and State Transplant Organisations

ROTTOS function as regional hubs responsible for the coordination of organ sharing within a defined geographical zone comprising multiple states. SOTTOs, established at the state level, maintain state waiting lists, coordinate with hospitals within the state, and implement the allocation protocols set at the national level. Together, these bodies form a three-tier network intended to maximise the utilisation of available organs.

6.3 Hospital Registration and Accreditation

Only hospitals registered under the Act may conduct transplantation activities. Registration requires the hospital to demonstrate adequate infrastructure, qualified manpower, intensive care facilities, and the establishment of a Hospital Transplant Team. The Central or State Government, as applicable, grants registration after inspecting the hospital. Registered hospitals must comply with ongoing reporting requirements and are subject to periodic inspection and renewal of registration.

6.4 Authorisation Committees

Authorisation Committees are constituted under the Act at the state level and are chaired by a senior government official. Their primary function is to review cases involving living unrelated donors and to verify that such donations are genuinely altruistic and free from commercial motivation. The Committee has the power to approve or reject a proposed donation, and its decisions are subject to challenge before the High Court.

7. Prohibition of Commercialisation and Anti-Trafficking Provisions

7.1 The Core Prohibition

The THOA, 1994 introduced an absolute prohibition on the commercial trade of human organs and tissues. Section 9 of the Act prohibits any person from making or receiving any payment for the supply of, or offer to supply, any human organ or tissue. The prohibition extends to:

- Advertising the sale or purchase of any human organ or tissue.
- Initiating or negotiating any arrangement for commercial organ supply.
- Taking part in the management of any body or organisation whose activities involve commercial organ transactions.
- Causing or facilitating such commercial transactions.

7.2 Penalties for Offences

The Act prescribes stringent criminal penalties for violations. Key offences and their penalties include:

Offence	Imprisonment	Fine
Removal of organ without authority	5–10 years	Up to Rs. 20 lakhs
Commercial dealing in organs or tissues	5–10 years	Up to Rs. 20 lakhs
Transplant activity in unregistered hospital	3–5 years	Up to Rs. 10 lakhs
False documentation or cheating	3–5 years	Up to Rs. 10 lakhs

The Act also provides that where an offence is committed by a company or institution, every person who was in charge of, and responsible for, the conduct of the business of that company at the time the offence was committed shall be deemed guilty of the offence.

8. Ethical and Constitutional Dimensions

8.1 Bodily Autonomy and the Right to Life

The legislative framework navigates a delicate tension between the individual's right to bodily autonomy – recognised as an aspect of the right to life and personal liberty under Article 21 of the Constitution of India – and the state's compelling interest in preventing exploitation and organ trafficking. The Supreme Court of India has recognised that the right to life encompasses the right to live with dignity, and this has been extended to interpret the state's obligation to both protect potential donors from coercion and to facilitate access to life-saving treatment for recipients.

8.2 Informed Consent as a Fundamental Requirement

Informed consent is the cornerstone of the legal framework for organ donation. The Act and Rules prescribe detailed consent procedures that require the donor to understand the nature of the procedure, the attendant risks, alternative treatment options for the recipient, and the consequences of donation. The consent must be free from any form of inducement, coercion, or undue influence. Courts have consistently held that any transplant performed without valid informed consent constitutes not merely a civil wrong but a criminal offence under the Act.

8.3 Equity and Access

A persistent ethical concern in the Indian transplantation system is the inequity of access. Private hospitals dominate the transplantation landscape, and the cost of transplantation remains prohibitive for the majority of the population. Critics argue that the waiting list system, while theoretically equitable, can be manipulated by those with financial resources to secure advantageous positions. Policy

discussions have increasingly focused on the need to integrate transplantation services into public hospitals and to provide financial support through government insurance schemes such as the Pradhan Mantri Jan Arogya Yojana (PM-JAY).

9. Implementation Challenges and Ongoing Gaps

9.1 The Organ Supply Deficit

India's deceased donor rate remains extremely low by international standards – approximately 0.65 donors per million population compared to over 40 per million in Spain, which operates the world's most successful deceased donation programme. This deficit is attributable to multiple interacting factors, including limited public awareness, cultural and religious reservations about brain death and body integrity, inadequate infrastructure in government hospitals to support donation, and a shortage of trained transplant coordinators.

9.2 Organ Trafficking and the Persistence of Illegal Markets

Despite the stringent legal prohibition on organ commercialisation, illegal organ trading continues to be reported in India, albeit with lesser frequency and greater clandestineness since the enactment of the THOA. Organised networks exploit impoverished individuals, sometimes luring them from rural areas with false promises of employment before recruiting them as paid donors. The cross-border dimension of organ trafficking, with India serving both as a source and destination country, adds complexity to enforcement.

9.3 Inconsistent State-Level Implementation

Transplantation is a concurrent subject involving both central and state governments. The quality of implementation varies significantly across states. Some states, such as Tamil Nadu and Kerala, have built well-functioning transplant coordination systems and achieved relatively higher deceased donation rates, largely through the dedication of state transplant organisations (TRANSTAN and KNOS, respectively). Others lag

considerably, with weak enforcement, inadequate infrastructure, and insufficient political will.

9.4 Regulatory Capacity and Oversight

The Authorisation Committee system has faced criticism for being susceptible to corruption and inconsistency. Cases have come to light where committees approved unrelated donor transplants based on fabricated documentation of emotional bonds. Strengthening the capacity and independence of Authorisation Committees, including through the use of social investigators and psychological assessments, is widely recognised as a priority.

10. Recent Developments and Policy Directions

10.1 Opt-Out Donation: Policy Debates

Several policy bodies and expert committees have recommended the adoption of an 'opt-out' or 'presumed consent' model for deceased organ donation – whereby every citizen is presumed to be a donor unless they have registered an objection during their lifetime. Proponents argue that this shift, adopted with great success in Spain, Portugal, and Wales, could dramatically increase the pool of available organs. However, critics caution that implementation without robust safeguards could undermine public trust, particularly in communities with historically marginalised relationships with the healthcare system.

10.2 Expansion of Permissible Tissue Transplantation

The 2011 amendment's inclusion of tissues within the regulatory framework opened the door for a more structured national tissue banking programme. NOTTO has worked to establish a network of certified tissue banks capable of processing and storing tissues such as corneas, bone, skin, and heart valves. Expanding the deceased tissue donation programme is seen as a relatively more achievable near-term goal, given the longer preservation times possible with many tissues compared to solid organs.

10.3 Technology and Transparency

The government has invested in digital infrastructure to improve transparency and efficiency in organ allocation. NOTTO's online registry and allocation tracking system aims to reduce opportunities for queue manipulation and to provide real-time data on organ availability and recipient status. Continued investment in digital health infrastructure, including interoperability with hospital systems, is essential for the programme's integrity.

10.4 The Role of NITI Aayog and National Health Policy

The National Health Policy of 2017 explicitly identified the promotion of organ donation and transplantation as a national health priority. NITI Aayog has since commissioned studies and facilitated policy dialogues on increasing deceased donor rates, improving transplant coordination, and reducing out-of-pocket expenditure for transplant recipients. These high-level policy commitments, if backed by sustained budgetary investment, have the potential to significantly improve outcomes.

11. Brief Comparative Perspective

India's legislative framework bears many similarities to international best practices. The prohibition of organ commercialisation aligns India with the Istanbul Declaration on Organ Trafficking and Transplant Tourism (2008), to which India is a moral signatory. The opt-in deceased donation model is consistent with the approaches of many common law countries, including the United Kingdom (which adopted a soft opt-out in Wales from 2015 and England from 2020) and the United States (which retains an opt-in model under the National Organ Transplant Act, 1984).

India's three-tier coordination structure mirrors elements of the Spanish model – widely regarded as the global gold standard – though the Spanish system's success is attributed not only to its legislative framework but to its intensive investment in hospital-based transplant coordinators, robust quality

assurance, and a culture of professional commitment to donation. India's challenge lies in translating legislative intent into operational reality at every level of the health system.

12. Conclusion

The legal framework governing human organ and tissue transplantation in India – centred on the Transplantation of Human Organs and Tissues Act, 1994 (as amended in 2011) and the THOT Rules, 2014 – represents a comprehensive and principled legislative response to the ethical, medical, and social complexities of transplantation. It has successfully established the foundational infrastructure of deceased donor transplantation, criminalised organ trafficking, and created institutional mechanisms for oversight and coordination.

Nevertheless, the gap between the promise of the legislative framework and the reality of implementation remains wide. India's deceased donation rate continues to be one of the lowest in the world, illegal organ markets persist in the shadows, and access to transplantation is deeply inequitable. Closing this gap demands not merely technical interventions – more transplant hospitals, more coordinators – but sustained political will, public education, cross-sectoral investment, and a commitment to treating organ donation as a national health priority.

As India continues to evolve its transplantation policy, the foundational principles of informed consent, non-commercialisation, equitable allocation, and institutional transparency must remain inviolable. At the same time, the framework must remain responsive to emerging challenges: the ethical use of technology in organ allocation, the evolving science of transplantation biology, and the imperative of ensuring that the benefits of transplantation reach all segments of India's diverse population.

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