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The Transplantation of Human Organs and Tissues Act (THOTA): Law, Practice and Real-World Enforcement in India

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Abstract

India's Transplantation of Human Organs and Tissues Act (THOTA), enacted in 1994 as the Transplantation of Human Organs Act (THOA) and amended in 2011, governs how human organs and tissues may be removed, stored and transplanted. Its twin aims are to make life-saving transplantation possible and to stamp out the organ trade. This paper reviews the law's origins, main provisions, institutions and reforms, then tests it against documented cases, including the Mumbai, Delhi, Hyderabad and Tamil Nadu kidney rackets, and against national statistics and Telangana's Jeevandan programme. It concludes that THOTA has built a credible framework and helped grow deceased-donor transplantation, but that enforcement gaps, heavy reliance on living donors and bottlenecks in brain-stem death certification limit its effectiveness.

1. Introduction

Every year, thousands of Indians with end-stage kidney, liver, heart or lung disease wait for an organ that may never arrive. According to the National Organ and Tissue Transplant Organisation (NOTTO), India's deceased-donation rate remains below one donor per million population, far under the estimated need. Where supply is scarce and patients are desperate, a black market is a predictable result. THOTA is India's answer to both halves of the problem: it creates a lawful route to transplantation and criminalises the trade that grows when that route is too narrow.

"THOTA Act" here means the Transplantation of Human Organs and Tissues Act, 1994, as amended in 2011. This paper uses THOA for the original 1994 version. Sections 2 to 5 cover the law, Sections 6 and 7 real-life cases and data, Section 8 challenges, and Sections 9 and 10 recommendations and conclusions.

2. Background

Organ transplantation began in India in the 1960s and 1970s without a dedicated law. By the early 1990s, reports of poor villagers being induced to sell kidneys and of private hospitals profiting, had become a public scandal, and some cities gained notoriety for "transplant tourism" in which wealthy foreign patients bought organs from poor Indian sellers.

Parliament responded with the 1994 Act. Its objectives, which have stayed constant, are to regulate the removal, storage and transplantation of organs for therapeutic purposes and to prevent commercial dealings. It also recognised brain-stem death as a form of death, which made deceased-donor donation legally possible. Several states enacted their own laws modelled on it.

India's approach sits within a global consensus. The United States passed the National Organ Transplant Act (NOTA) in 1984, creating a national organ-sharing system, a transplant registry and a ban on organ sales. The Declaration of Istanbul (2008) condemned organ trafficking and transplant tourism. THOTA shares the philosophy that donation should be altruistic, regulated and transparent.

Scarcity also shapes the ethics of the debate. Kidney patients can be sustained for years on dialysis, though at heavy financial and personal cost, whereas patients with failing livers or hearts have no comparable long-term substitute and depend on a timely organ. The result is that the most desperate patients, and the poorest donors willing to sell, are drawn towards the same illegal market. A law that only punished the trade, without widening lawful supply, would leave this pressure untouched, which is why THOTA pairs its prohibitions with provisions for deceased donation, swap donation and national allocation networks.

3. Core Provisions

Ban on commercial dealings. Buying, selling or brokering organs, advertising such offers and acting as a middleman are criminal offences. The ban reaches donors, recipients, brokers, doctors and hospitals.

Living donation and the "near relative" rule. Living donation is allowed principally between near relatives. The 2011 amendment widened this to include grandparents and grandchildren alongside spouses, parents, children and siblings. A non-relative donation needs the approval of an Authorisation Committee, which must be satisfied that it stems from affection or attachment and not money. The amendment also recognised "swap" or paired donation, in which two incompatible donor-recipient pairs exchange donors.

Deceased donation. The Act provides for certification of brain-stem death by a board of medical experts, commonly described as a four-member board. Brain-stem death and cardiac death are legally equivalent. The 2011 amendment drew intensive-care hospitals into the process and introduced a duty to ask relatives about donation, later promoted through the 2017 awareness drive "Poochna Mat Bhoolo" ("don't forget to ask").

Hospital registration. Only hospitals registered under the Act may carry out transplants. Registration is granted and monitored by the Appropriate Authority.

Penalties. The 2011 amendment stiffened punishment, with imprisonment and heavy fines, and extended liability to medical professionals, whose registration may also be suspended. Secondary sources summarise the figures differently: one reports up to five years' imprisonment and a fine of up to ₹20 lakh for a doctor's first offence, another up to ten years and ₹20 lakh for illegal trade. Readers needing precision should consult the Act's official text.

Who may prosecute. Section 22 bars courts from taking cognisance of an offence except on a complaint by the Appropriate Authority or an authorised officer. This prevents frivolous complaints but creates friction: in the 2016 Delhi racket, police had to write to the Delhi government for permission to add THOTA charges, which was later granted for a supplementary charge sheet.

Tissues and foreign nationals. Since 2011 the Act covers tissues as well as organs, bringing donation of tissues such as corneas under the same regulatory umbrella; India ranks second in the world for corneal transplants. Transplants involving foreign nationals attract particular scrutiny, because transplant tourism was one of the abuses the law was designed to stop. NOTTO reports such transplants state by state, which lets regulators see where they are concentrated and check whether unrelated donor-recipient pairs are being cleared properly.

4. Institutional Framework

The **Appropriate Authority** registers and inspects transplant hospitals, investigates complaints and files prosecutions. **Authorisation Committees** scrutinise non-near-relative living donations, interviewing donors and recipients and checking documents for signs of inducement. The 2011 amendment gave statutory footing to **NOTTO** in New Delhi as the apex body for coordination, data and allocation, working with Regional (ROTTO) and State (SOTTO) organisations in a three-tier structure under the National Organ Transplant Programme. Hospitals must also appoint **transplant coordinators**, who liaise with donor families; as the Jalandhar case shows, this safeguard can itself become a conduit for fraud.

5. Amendments and Reforms

2011 amendment. The most comprehensive change. It extended the law to tissues (hence the new name), widened the definition of near relative, recognised swap donations, strengthened penalties, required ICU hospitals to take part in brain-stem death identification, and gave a statutory base to the national and regional networks.

2014 Rules. The Transplantation of Human Organs and Tissues Rules, 2014 set out forms, committee composition, hospital registration criteria, requirements for foreign nationals and allocation details.

2023 "One Nation, One Policy" changes. The Union Health Ministry modified national guidelines to remove the state-domicile requirement, so patients can register for a deceased-donor organ in any state, and to remove the upper age limit of 65 for registration. These are guideline changes, not statutory amendments, and states were asked to implement them.

State laws. Telangana inherited a 1995 Act from undivided Andhra Pradesh, itself modelled on the 1994 law. In March 2025 its Assembly passed the Telangana Transplantation of Human Organs Bill, 2025 to align state law with the central Act and curb organ trade, and later reports describe the Assembly adopting THOTA itself, a step towards a single national standard.

Other supporting initiatives. Alongside the legal changes, the government introduced an Aadhaar-linked portal in 2023 so that people can pledge organs digitally through identity verification, and the "One Nation, One Policy" effort has aimed to standardise age limits, domicile criteria and registration fees across states. The Ayushman Bharat PM-JAY insurance scheme includes transplants, which reduces the catastrophic cost of surgery for poorer households. These measures matter for the Act's goals because the cheaper and more accessible lawful transplantation becomes, the weaker the case for turning to brokers.

6. THOTA in Practice: Real-Life Cases

A statute is best judged by what happens when people try to evade it. The cases below are drawn from press reports; allegations are not findings, and accused persons are presumed innocent unless convicted.

Mumbai, Hiranandani Hospital (2016). Police were tipped off that the donor and recipient in a scheduled kidney transplant were not close relatives. The man due to receive the kidney was not married to the woman presented as his wife and donor. After a report by the state's health services director, the hospital's chief executive, its medical director and three doctors were arrested. Their lawyers argued the case involved only procedural lapses. It shows that the near-relative rule is the Act's main checkpoint, that fake spousal ties are a classic workaround, and that hospital leadership can face arrest.

Delhi (2016). The crime branch arrested five people, including the personal secretaries of a neurologist at a major private hospital. An informant posing as a donor recorded the process with hidden devices. The racket allegedly lured poor people from several states to sell kidneys. Police filed a thousand-page charge

sheet against 17 accused, including the alleged kingpin, hospital staff, donors and some recipients. The hospital denied wrongdoing. The case shows the value of undercover evidence and the Section 22 sanction hurdle.

Delhi-NCR (2019). A victim's complaint to Uttar Pradesh Police exposed what was described as an international kidney racket run through a chain of middlemen. More than a dozen people were arrested, including the chief executive of a hospital, and another leading NCR hospital was served a notice for alleged violations of the Act. It showed that large corporate hospitals are not immune from scrutiny.

Gurugram (2023). Legal commentary describes a racket in which middlemen arranged Indian donors by falsely establishing relationships with recipients. About a dozen people were reportedly arrested, including hospital staff, middlemen and fake donors, and attention fell on the hospital's due diligence and the Authorisation Committee's verification role. Allegations of institutional negligence remain allegations until proven in court.

Visakhapatnam (2023) and Hyderabad's Alakananda Hospital (2025). In 2023 a victim alleged his kidney was removed illegally at a hospital in Pendurthi, leading to more than ten arrests. In January 2025, officials inspecting Alakananda Hospital in Saroor Nagar, Hyderabad, found two donors from Tamil Nadu and two recipients who had already been operated on. The hospital lacked authorisation to perform kidney transplants and was sealed. Nine people were arrested, including two doctors, one of them the managing director, and the health minister handed the probe to the CID. A Chennai-based doctor, who had earlier been arrested in the Visakhapatnam case, was later arrested for allegedly performing illegal transplants for about two years. It is a textbook case of outright violation of the registration rule and of repeat offending across states.

Namakkal, Tamil Nadu (2025). Allegations of a thriving kidney-sales racket, with six victims from Pallipalayam suspected of having "donated" organs, led the health department to suspend all treatment except dialysis at a private hospital in Erode and to issue a show-cause notice to a hospital in Tiruchy. The case shows how brokers target low-income communities and the regulatory tools available short of prosecution.

Jalandhar, Punjab. A special investigation team arrested several people linked to a private kidney hospital, including a receptionist-cum-coordinator who emerged as a key accused. Police noted that a coordinator is expected to hold a graduate degree, and said the hospital owner had not been given a clean chit.

Several patterns recur: forged relationships, brokers who exploit poverty and move donors across states, support staff who link brokers and surgeons, repeat offenders, and procedural friction that dilutes deterrence.

Read together, the cases fall into three broad patterns of offence. The first is documentary fraud, where forged marriage certificates, affidavits and family records are used to pass the near-relative test, as alleged in Mumbai and Gurugram. The second is the unauthorised transplant, where a hospital simply operates without registration, as in Hyderabad. The third is exploitation of the donor through deception or pressure, as in the Visakhapatnam complaint that a kidney had been removed illegally. Each pattern calls for a different safeguard: better verification, tougher inspection and registration control, and protection for victims who come forward. The regulatory responses seen in Tamil Nadu, such as suspending services and issuing show-cause notices, also show that administrative action can move faster than criminal trials and can be an effective first line of deterrence.

7. Data and a Success Story

NOTTO's figures show where the framework has delivered. India carried out 18,378 transplants in 2023 and ranks third in the world. Kidney transplants numbered 13,426, liver 4,491, heart 221, lung 197 and pancreas 27. India crossed 1,000 deceased donors in a single year for the first time, and deceased-donor transplants rose from 837 in 2013 to 2,935 in 2023. Tamil Nadu led in 2023 with 595 deceased-donor transplants, followed by Telangana (546), Karnataka (471), Maharashtra (426) and Gujarat (421).

Telangana's Jeevandan programme was ranked first in the country for 2024, with 188 brain-dead donors, 725 lives saved and 4.88 donations per million population against a national average of about 0.8. The same state ran one of the country's most visible enforcement efforts in the Alakananda case, showing that law and administration work together.

Yet roughly 85 per cent of Indian transplants still come from living donors, while developed countries draw 70 to 80 per cent from deceased donors. Reliance on living donation creates the opening that rackets exploit, because those transplants depend on donor-recipient verification that fraudsters forge. NOTTO also reports transplants to foreign nationals concentrated in certain states, including Rajasthan (116) and West Bengal (88), a category regulators watch because of the history of transplant tourism.

The longer-run trend is nonetheless upward. Total transplants rose from 4,990 in 2013 to 15,561 in 2022 and reached 18,378 in 2023, more than tripling over a decade, with kidney transplants accounting for most of them. Deceased donors supplied nearly 17.8 per cent of all transplants in 2022. The challenge is therefore less about starting a deceased-donation system than about scaling it, and the gap between the strongest states and the rest suggests that administration, training and public trust matter as much as the text of the law.

8. Challenges

Verification is hard. Authorisation Committees work from documents and short interviews. Skilled brokers coach donors and forge records, so the system leans heavily on hospital honesty.

Brain-stem death bottlenecks. Analysts say certification is a bottleneck: the board requirement, and the rule that certain certifying doctors be approved by the Appropriate Authority, are described as bureaucratic hurdles. Commentators recommend allowing identification, certification and retrieval in all ICU-equipped hospitals and requiring certifying doctors to be registered specialists. The national deceased-donation rate is about 0.77 per million.

Enforcement. The Section 22 sanction requirement, slow trials and the difficulty of proving what happened in an operating theatre mean convictions are rarer than arrests, and defences of "procedural lapses" blur paperwork errors and deliberate fraud.

The donor's dilemma. The Act penalises vulnerable donors as well as brokers, which may deter victims from coming forward. Some bioethicists favour regulated compensation or non-cash benefits; the dominant international view, reflected in the Declaration of Istanbul, opposes commerce in organs. This paper takes no side but notes that the debate shapes enforcement.

Uneven state implementation. Health is largely a state subject, and the 2023 guideline changes had to be adopted state by state.

Awareness and public trust. Deceased donation depends on families agreeing at a moment of grief, and on trust that organs will be allocated fairly. Repeated racket exposures involving well-known hospitals risk eroding that trust, which is one reason transparent allocation and visible enforcement are not just punitive measures but also support for voluntary donation. The 2017 "Poochna Mat Bhoolo" campaign

and digital pledge portals show attempts to build that culture, but the national rate of under one donor per million shows how far there is to go.

9. Recommendations

1. **Strengthen verification** with investigative support, digital identity and family-record checks, standard interview protocols and audit trails for non-near-relative donations.
2. **Reform brain-stem death procedures** so certification and retrieval can happen in all ICU-equipped hospitals, keeping qualified-specialist safeguards.
3. **Expand deceased donation** through trained coordinators, state allocation systems modelled on Telangana and Tamil Nadu, and sustained awareness campaigns.
4. **Streamline prosecution** by reviewing Section 22 and considering specialised courts for organ-trade offences.
5. **Protect vulnerable donors** by distinguishing organisers from exploited donors in charging, and by providing follow-up care.
6. **Harmonise state laws** and implement the 2023 reforms fully.
7. **Publish hospital-wise transplant data**, including foreign-national transplants, to detect anomalies early.

10. Conclusion

THOTA reconciles two goals that can pull apart: expanding access to life-saving transplants and preventing the exploitation of the poor. The statistics show rapid growth and state success stories such as Telangana. The case files, from Mumbai and Delhi in 2016 to Gurugram, Visakhapatnam and Hyderabad more recently, show the same methods of forged relationships, brokers and compliant staff recurring. Enforcement alone cannot solve a shortage. As long as patients wait years and most transplants rely on living donors, there will be an incentive to cheat. The most durable protection against trafficking is a well-run deceased-donation system that supplies enough organs to make the black market unnecessary, backed by swift and credible prosecution.

Several questions remain for future research. Public data on convictions under the Act, as distinct from arrests, is thin, and a systematic study of how many cases end in conviction, and how long they take, would show whether deterrence is working. Studies of donor outcomes and of how Authorisation Committees actually decide would also help refine the verification process. Without such evidence, debates about whether the law is too strict or too lenient tend to rest on anecdote and on the most sensational cases.

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