
LEGAL AND ETHICAL ISSUES IN ORGAN DONATION IN INDIA

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ABSTRACT

This paper carefully looks at the legal and ethical problems about organ donation in India. It focuses on the rules made by THOTA, 1994 (THOTA) and its changes later. It explains important parts about how people give permission (consent), how brain death is confirmed (brain death certification), stopping organ trade and the jobs of the authorities who control these rules. The study shows ongoing problems like very few people donating organs, weak law enforcement, risks of misuse and social and cultural difficulties. It also compares India's system with other countries to find better ideas. The paper ends with suggestions to make laws stronger, teach people more and change policies to make organ donation in India more open, fair and ethical.

Keywords: Organ Donation, THOTA, Informed Consent, Brain Death organ Trafficking

1. INTRODUCTION

Organ donation is a very important medical and kind act where a person (the donor) gives their organs or tissues to another person (the recipient) to help them live better through transplantation. In India organ donation happens both when people are alive and after they have died. After death, donation can happen when brain stem death occurs a fact that is legally accepted in India. Organ donation is very important in India because many people need organs but very few are available. With more people getting diseases like diabetes, high blood pressure (hypertension) and chronic kidney disease, the number of patients needing organ transplants is growing. This makes organ donation very important for the health of the country. Still, India's organ donation rate is very low less than one donor for every million people though it has been slowly getting better in recent years.¹

1.1. Definition and Significance of Organ Donation in India

In India organ donation is controlled by strong laws that explain how organs and tissues can be taken, stored and transplanted. The main law is called THOTA, 1994 which has been changed over time to keep it up to date. Under Section 2 of THOTA, a "human organ" means any part of the body made of tissues that cannot be replaced if taken out. The law explains the difference between living donors who can give things like a kidney or part of their liver and deceased donors, whose organs can be taken after brain stem death or heart death.²

THOTA also says that brain stem death (Section 2(e)) is a legal form of death. This is very important because it allows doctors to take many vital organs from one person who has died this way, saving more lives. This law makes India's rules like those in other countries and has changed how many organs can be donated after death. After natural heart death, only some tissues like cornea, bone, skin and blood vessels can be donated but after brain stem death, up to 37 different organs and tissues can be given, including kidneys, heart, liver and lungs.

Organ donation in India is not only about medicine but also shows values like kindness and helping others. The government runs programs like the National Organ Transplant Program (NOTP) and the National Organ & Tissue Transplant Organisation (NOTTO) to teach people,

¹ Lalitha Mohan and T Thanga Panneer Selvam, "Perspective on organ donation in India: A comprehensive review," 7 *The Journal of Community Health Management* 73–6 (2020).

² *Ibid.*

make donation easier and keep a list of donors and recipients. Even with these efforts, there are still not enough organs which causes long waiting times and many avoidable deaths. This means India needs to keep working on laws, ethics and community support for organ donation.³

1.2. Overview of Legal and Ethical Challenges

The main law for organ donation in India is THOTA and its updates, like the THOTA (amendment), 2011 and THOTR, 2014. The law's goal is to control how organs and tissues are taken and used for treatment and to stop buying and selling organs. Section 3 says organs can only be taken with written and informed permission from the donor or if the donor is dead, from their closest family member. Section 6 allows organs to be taken from bodies that are sent for post-mortem (after death) checks but only with certain rules.⁴

An important part of the law is making Authorization Committees (Section 9) that check cases when the donor is not a close family member, to stop buying and selling organs and forcing people. The law also expanded the meaning of "near relative" in 2011 to include grandparents and grandchildren, so more family members can donate organs. Section 19 of THOTA has strong punishments for buying and selling organs, like jail for up to ten years and fines up to twenty lakh rupees. The law also requires hospitals and tissue banks that do transplants to be registered and inspected (Sections 10 and 14), so only trusted places can do these important operations.

1.3. Objectives of the Study

1. To critically examine the legal framework governing organ donation in India, with a focus on THOTA, 1994 its amendments and relevant rules.
2. To analyse the ethical issues arising in organ donation, including informed consent, autonomy, exploitation and cultural challenges and to assess how these are addressed within the existing legal regime.

³ available at: <https://notto.mohfw.gov.in/> "NOTTO : National Organ & Tissue Transplant Organisation, "No Title."

⁴ available at: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1842747> "Transplantation of Human Organs & Tissues Act (THOTA), 1994 provides for regulation of removal, storage and transplantation of human organs & tissues for therapeutic purposes, "No Title."

3. To identify and evaluate the operational and procedural challenges in the implementation of organ donation laws, such as brain death certification, regulatory oversight and organ allocation mechanisms.

4. To compare India's legal and ethical approach to organ donation with international standards and practices and to propose recommendations for strengthening the Indian system in light of global best practices.

1.4. Research Methodology

This study adopts a doctrinal research methodology which involves systematic analysis of primary legal sources such as statutes, rules and judicial decisions, as well as authoritative secondary materials like legal commentaries and scholarly articles.

2. HISTORICAL BACKGROUND

The evolution of organ donation and transplantation in India is rooted in both ancient and modern medical history. References to surgical reconstruction using donor tissue can be traced back to the era of Sushruta, the renowned ancient Indian surgeon, whose pioneering work in the reconstruction of deformed noses using tissue from other parts of the body laid an early foundation for transplantation concepts. While these ancient techniques were not organ transplants in the modern sense, they demonstrated a sophisticated understanding of anatomy and surgical innovation that would inspire future generations.⁵

India's journey into modern organ transplantation began in earnest in the mid-20th century, paralleling global advances in the field. The first significant milestone was achieved at KEM Hospital, Mumbai, in the mid-1960s where Dr. P. K. Sen and his team attempted the earliest kidney transplants using deceased donors. Although these initial procedures were fraught with challenges and did not succeed, they marked a crucial step forward and provided valuable insights for subsequent efforts. The real turning point came on 2nd February 1971 when the Christian Medical College (CMC), Vellore, performed the first successful live donor renal transplant in India, led by Dr. M. Mohan Rao and his team. This achievement not only demonstrated the feasibility of transplantation in the Indian context but also set a precedent for

⁵ 2025). delhicentreadvanceurology@gmail.com, "9 Point Evolution of Organ Transplantation in India: A Journey Through Time - Dr Arif Akhtar - Expert Urologist in Gurgaon" delhicentreadvanceurology@gmail.com, 2023 available at: <https://drarifakhtaruology.com/evolu>, "No Title."

other institutions to follow, gradually expanding the scope of organ transplantation across the country.⁶

3. LEGAL FRAMEWORK GOVERNING ORGAN DONATION 3.1. THOTA, 1994 and Amendments

The main law that controls organ donation and transplantation in India is THOTA, 1994. This law was made to control how human organs and tissues are taken out, stored and transplanted to help people get better. It also stops people from selling organs and tissues for money. Most Indian states accepted this law, except the old State of Jammu & Kashmir and Andhra Pradesh which made their own laws. THOTA was made because there were many cases of illegal organ selling and India needed one clear law to make organ transplants safe and fair.⁷

In 2011, the law was changed and the changes came into effect in 2014. These changes made the law cover tissues as well as organs. The meaning of “near relative” was made bigger to include grandparents and grandchildren. The law also allowed swap donation where two donor-recipient pairs exchange organs. The penalties for breaking the law became stronger. THOTR, 2014 explained how things should work, like making centres to collect organs, tissue banks and requiring transplant coordinators in hospitals that are registered.⁸

THOTA was very important because it also legally accepted brain stem death as a kind of death (Section 2(e)). This lets doctors take many organs from a person who has died this way before their heart stops, making more organs available for transplant. The law and its changes still guide organ donation and transplantation in India in a safe and fair way.

3.2. Key Provisions: Regulation of Living and Deceased Donation, Brain Death, Consent and Prohibition of Organ Sale THOTA and its changes have important rules to make sure organ transplants are done safely, fairly and clearly:

Regulation of Living and Deceased Donation:

The law says there are two types of donors: living and deceased. Living donors must be “near

⁶ P. Madhusoodanan, “Organ transplantation in India: Indian scenario and perspectives for the Armed Forces,” 63 *Medical Journal Armed Forces India* 2–4 (2007).

⁷ Ashok K. Taneja et al., “Organ Transplantation in India: Medical, Legal, and Ethical Nuggets,” 73 *Journal of Association of Physicians of India* 92–9 (2025).

⁸ *Ibid.*

relatives” as explained in Section 2(i) which includes husband or wife, parents, brothers and sisters, children, grandparents and grandchildren. If a person wants to donate from outside this group, they must get permission from an Authorization Committee (Section 9). This is to make sure donations happen with free will and no money involved. Swap donations where two donor-recipient pairs swap organs are allowed if rules are followed.⁹

Brain Death:

A very important part of THOTA is that it legally accepts brain stem death as death (Section 2(e)). This means organs can be taken from a person who has died this way before their heart stops which helps save more lives. A board of medical experts must confirm brain stem death. If a neurologist is not available, an anaesthetist or intensivist can confirm it, as long as they are not part of the transplant team.¹⁰

Consent: The law requires written and informed permission from the donor or, if the donor has died, from their closest family (Sections 3 and 5). For brain stem death, the family’s consent is needed and hospitals must ask families in intensive care units if they want to donate organs.

Prohibition of Organ Sale:

THOTA strictly stops any buying or selling of human organs and tissues. Section 19 says that people who break this law can get jail time up to ten years and pay fines up to twenty lakh rupees. The law also stops organ donation from children and mentally challenged people unless special rules are followed (Section 9 as changed).¹¹

Registration and Regulation of Hospitals:

Only hospitals registered under THOTA can do organ and tissue transplants. The law requires hospitals and tissue banks to register, get inspected often and follow rules (Sections 10 and 14).¹²

National and State Networks: The law and government programs have created networks to

⁹ “organ-trafficking-in-india-a-legal-and-ethical-analysis,” <https://theamikusqraie.com>.

¹⁰ *Ibid.*

¹¹ *Organ Transplantation in India*,” *Organ India*, 2022 Available at: <https://www.organindia.org/organ-transplant-laws-made-easy>.

¹² *Ibid.*

manage organ collection and sharing. These include the national (N.O.T.T.O), Regional (ROTTOS) and State (SOTTOs) groups, plus a national list of donors and recipients.

3.3. Role of Authorization Committees and Appropriate Authorities These two groups help run and watch over organ donation under THOTA: **Authorization Committees:** These groups work at the state and hospital levels to check and approve organ donations from unrelated living donors and foreign nationals (Section 9). They make sure the donation is real, free and not because of money or pressure. They can approve swap donations and donations from minors or foreign nationals but only with strict rules. Since 2011 it is required to get permission before donating if the donor or recipient is from another country.

Appropriate Authorities: Appointed by central and state governments, these authorities register, inspect and regulate hospitals and tissue banks that do organ transplants (Sections 13 and 14). They investigate complaints, make sure rules are followed and start legal action against rule breakers. They play a key role in keeping ethical standards and following the law during the transplant process.

3.4. Case Laws

Vikash Kumar v. Union of India¹³ In this case, the Supreme Court talked about organ transplantation for a minor with a rare disease. The Court said it is very important to follow all the rules in THOTA carefully especially about getting consent and the role of the Authorization Committee. The judgment said the donor's welfare especially if the donor is a minor, must be the most

R. Rathinam v. Union of India¹⁴ The Madras High Court looked at the law about brain stem death certification and taking organs from dead donors. The Court said brain stem death, as recognized by THOTA, is legal. It also said that the medical board must give proper certification as required by the Act. This supports the legal rules for organ donation after death in India.

State of Tamil Nadu v. K. Balu¹⁵ This case was mainly about rules for liquor shops near highways but it is often used when talking about public health and the government's duty to

¹³ *Vikash Kumar v. Union of India*, (2013) 10 SCC 94,.

¹⁴ *R. Rathinam v. Union of India*, AIR 1999 Mad 340,.

¹⁵ *State of Tamil Nadu v. K. Balu*, (2017) 2 SCC 281,.

make strong rules. The Supreme Court's comments about the need for good enforcement of laws have been used in talks about enforcing THOTA and stopping organ trafficking.

Dr. Suchitra Srivastava v. Chandigarh Administration¹⁶ This case was mostly about reproductive rights. The Supreme Court's explanation of the right to autonomy and informed consent has helped to understand the consent rules under THOTA especially in cases with vulnerable donors.

4. ETHICAL ISSUES IN ORGAN DONATION

4.1. Informed Consent: Autonomy and Voluntariness Informed consent is very important in ethical organ donation. It is written in Section 3 of THOTA, 1994. The law says that no human organ or tissue can be taken from a living donor without their clear and voluntary written consent. For organs from someone who has died, permission must come from the closest family member or a person allowed by law to act for the donor. Section 12 says that registered medical practitioners must explain the procedure and its effects to the donor or family in a way they can understand. But in India, there are still problems because many people have different levels of health knowledge, speak different languages and do not get enough counselling. Making sure consent is truly informed and voluntary is very hard in poor communities where people may be pushed or not fully understand, risking their freedom to choose.

4.2. Exploitation and Vulnerability of Donors

THOTA tries to protect people who are vulnerable from being taken advantage of by controlling who can donate and how. Section 9 limits living donations mostly to "near relatives" (like spouse, parents, brothers, sisters, children, grandparents and grandchildren). If someone not related wants to donate, an Authorization Committee must approve it. These rules try to stop pressure or bribery especially among poor people. But there are still cases where vulnerable people are tricked or forced to donate, sometimes with false promises or money offers which is a serious worry. The law has stronger punishments for organ trading (Section 19), showing how serious exploitation is. Still, because of weak enforcement, exploitation keeps happening

¹⁶ *Dr. Suchitra Srivastava v. Chandigarh Administration*, (2009) 9 SCC 1,.

especially to people with less money or education.¹⁷

4.3. Organ Trafficking and Commercialization

Sections 18 and 19 of THOTA say clearly that buying or selling human organs and tissues is illegal. It is a crime to pay or receive money for organ donation. Section 19 says people caught doing this can be jailed for up to ten years and fined up to twenty lakh rupees. Even with these strict laws, illegal organ markets still work by using fake documents and tricks. Authorization Committees check if unrelated donations are real but sometimes people lie about being related to hide organ sales. This problem harms the trust and fairness of the organ transplant system.¹⁸

4.4. Emotional Coercion and Familial Pressures

In India, family and culture often make it hard to see emotional pressure but it happens a lot. Section 3 of THOTA says all donations must be voluntary but the law does not clearly explain family pressure. People may feel they have to donate to family because of duty, honour or feelings, even if they don't want to. Authorization Committees try to make sure donations are voluntary but it is hard to tell if consent is real or because of pressure. This is especially true in living donations where the donor's mental health must be carefully protected.¹⁹

4.5. Religious, Cultural and Social Considerations

Religious and cultural beliefs strongly affect how people in India think about organ donation. Most religions do not forbid organ donation but wrong ideas about respecting the body, brain death and what happens after death stop some people from donating. THOTA does not talk about religion directly but these beliefs affect how the law is followed. Public education and working with religious leaders are important to clear up wrong ideas and encourage donation. Social stigma and lack of knowledge make the problem bigger, so it is important to include

¹⁷ PIB Delhi, "Transplantation of Human Organs & Tissues Act (THOTA), 1994 provides for regulation of removal, storage and transplantation of human organs & tissues for therapeutic purposes" *Ministry of Health and Family Welfare*.

¹⁸ available at: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1842747> "Transplantation of Human Organs & Tissues Act (THOTA), 1994 provides for regulation of removal, storage and transplantation of human organs & tissues for therapeutic purposes, "No Title."

¹⁹ Raj K. Mani et al., "Indian Society of Critical Care Medicine and Indian Association of Palliative Care Expert Consensus and Position Statements for End-of-life and Palliative Care in the Intensive Care Unit," 28 *Indian Journal of Critical Care Medicine* 200–50 (2024).

respect for culture in legal and ethical rules.²⁰

5. OPERATIONAL AND PROCEDURAL CHALLENGES

5.1. Determination and Certification of Brain Death

Section 2(e) of THOTA legally says that brain stem death is a kind of death. This allows doctors to take many organs from people who have died this way. The law says a group of medical experts must say a person has brain stem death before organs can be taken. This group must have a neurologist or if none is available, an anaesthetist or intensivist who is not part of the transplant team. But many people, even some doctors, do not understand brain death well. This causes delays and missed chances to get organs. The law also says hospitals must ask families of patients in intensive care about organ donation. Problems like poor training, no clear rules and doubt about brain death diagnosis make this hard.²¹

5.2. Gaps in Enforcement and Regulatory Oversight

THOTA sets up Appropriate Authorities in states and the central government (Sections 13 and 14). These groups check and control hospitals and tissue banks that do transplants. Authorization Committees look carefully at donations that are from unrelated people or foreign nationals (Section 9). But enforcement is not the same in every state. Some authorities do not have enough resources or power to check well. Problems in paperwork and weak checks let illegal organ deals happen and hurt the system's honesty. Scandals and news reports show there is a need for stronger rules, regular checks and more openness about how these authorities work.²²

5.3. Disparity Between Organ Demand and Supply

Even with laws and organizations in place, India does not have enough organs for transplants. Most organs come from living donors and very few come from people who have died. THOTA

²⁰ Britzer Paul Vincent et al., "Barriers and Facilitators Towards Deceased Organ Donation: A Qualitative Study Among Three Major Religious Groups in Chandigarh, and Chennai, India," 63 *Journal of Religion and Health* 4303–22 (2024).

²¹ *Ibid.*

²² "Legality Simplified, 'Supreme Court Case Prompts Inquiry on Organ Transplant Advisory Committees - Legality Simplified' Legality Simplified - Legal Compliance Business Solutions, 2024 available at: <https://www.legalitysimplified.com/supreme-court-case-pro>," Legality Simplified, "Supreme Court Case Prompts Inquiry on Organ Transplant Advisory Committees - Legality Simplified" Legality Simplified - Legal Compliance Business Solutions, 2024 available at: <https://www.legalitysimplified.com/supreme-court-case-pro>.

and its changes set up a National Registry for Transplant and a N.O.T.T.O to help share organs fairly. But the difference between how many organs are needed and how many are available is still very big. This causes long waiting lists and some patients turn to illegal organ markets. Fixing this problem needs not just better laws but also more public awareness, better hospital facilities and rewards for families who donate organs after death.²³

5.4. Transparency and Accountability in Organ Allocation

Being open and responsible in giving organs to patients is very important to keep public trust and fairness. THOTA requires all hospitals and tissue banks doing transplants to register (Sections 10 and 14). It also sets up national and state lists to keep track of donations and who gets organs. But people worry about unfairness, cheating with waiting lists and weak checks in some places. When data is not clear or decisions are hidden, people lose trust in the system. To fix this rule must be followed strictly, regular checks must happen and independent observers should watch the organ allocation process. The law also creates advisory committees to help and guide the Appropriate Authorities, supporting responsibility.²⁴

6. COMPARATIVE PERSPECTIVES A comparison of organ donation laws and practices in different countries shows big differences in legal rules, consent systems and results. Most countries agree on the ideas of kindness giving by choice and no buying or selling of organs. But the way they make rules and follow them is very different which affects how many donations happen and the ethics involved.

In India, THOTA, 1994 has an opt-in system. This means donors or their families must say “yes” clearly before donation. Living donations are allowed only from close family members and donations from others are carefully checked by Authorization Committees. The law forbids buying and selling organs (Sections 18 and 19), requires transplant centres to be registered (Sections 10 and 14) and needs certification of brain stem death (Section 2(e)). Even with these rules, India still faces problems like very few donations from deceased donors, weak law enforcement and illegal organ trade.

Many European countries, like Spain and England, use opt-out (presumed consent) systems to

²³ Promod Kohli² Ashok K Taneja^{1*} et al., “Organ Transplantation in India: Medical, Legal, and Ethical Nuggets” *JAPI*.

²⁴ “NAMS task force report on Organ donation and transplantation,” 60 *Annals of the National Academy of Medical Sciences (India)* 71–87 (2024).

increase donations. Here, all adults are considered donors unless they say “no” clearly. Spain, known as a world leader, uses presumed consent with strong public education, simple paperwork and legal support to respect donor wishes. This helps Spain have many more donations compared to opt-in countries like England. England changed to presumed consent in 2020 but still has fewer donations because of more complex rules and less support.²⁵

The United States has an opt-in system, controlled by the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS). People in the US can register as donors through state lists, driver’s licenses or donor cards. The National Organ Transplant Act stops the buying and selling of organs and makes sure organs are given fairly based on medical need. The US system has many living donors, good checks and clear rules but like India it still has fewer organs available than needed.²⁶

At the European Union level, the EU Directive on the quality and safety of human organs intended for transplantation sets shared rules. It forbids organ sales and makes sure safety and quality are high in member countries. The Directive allows both opt-in and opt-out systems as long as ethics and donor freedom are respected.²⁷

7. CONCLUSION

The laws and rules about organ donation in India have changed a lot since THOTA, 1994 was made. It was made stronger by the Amendment Act of 2011 and THOTR, 2014. These laws created a full set of rules for removing, storing and transplanting human organs and tissues. They have strong rules about getting permission (consent), proving brain stem death and stopping organ buying and selling (Sections 2(e), 3, 9, 18 and 19). The law now includes more family members in the “near relative” group, allows swap donations and has tougher punishments for breaking the rules. The National (NOTTO) was made, along with Regional (ROTTOS) and State (SOTTOs) groups, to organize how organs are collected, given to patients and tracked.

Even with these good changes, India still has big problems. The number of organ donors is

²⁵ Chris Baraniuk, “Chris Baraniuk, ‘Spain has a lesson for the rest of the world about organ donation’ World Economic Forum, 27 June 2018.”

²⁶ Hrsa, “OPTN : Organ Procurement and Transplantation Network” *U. S. Department of Health and Human Services* 23 (1999).

²⁷ C. Rudge et al., “International practices of organ donation,” 108 *British Journal of Anaesthesia* (2012).

very low, less than one donor per million people⁸. Problems with following the law, differences between regions, low public knowledge and cultural beliefs stop the law from working well. There are also delays in brain death certification, not enough good hospitals and equipment and not enough skilled workers to collect and transplant organs on time and in a good way. Illegal organ trade and taking advantage of poor people is still a big risk, so careful watching and public trust are very important. The laws match international rules but to work well they need strong actions, following ethics and changes to handle new problems.

8. RECOMMENDATIONS

To make organ donation and transplantation better in India, some important steps are suggested.

First government hospitals need better facilities like special transplant ICUs, new organ-saving technology and clear ways to collect and move organs quickly to stop delays and waste.

Money matters should be fixed, including adding all major organ transplants to national health programs like Ayushman Bharat, with help to pay for lifelong medicines that stop organ rejection.

To fix the lack of skilled workers, hospitals should hire and keep transplant experts, stop moving them often and give good training in organ collection and transplant surgery.

For rules it's important to strictly follow Sections 18 and 19 of THOTA to stop illegal organ trade and hospitals should have regular checks and clear reports to keep honest work.

Lastly, the government should think about changing to a presumed consent (opt-out) system, like some successful countries have but make sure people's choice and freedom are fully protected.

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