
LEGAL REGIME ON ORGAN DONATION AND TRANSPLANTATION IN INDIA: CHALLENGES AND SOLUTIONS

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ABSTRACT

India's organ donation and transplantation landscape is primarily governed by the Transplantation of Human Organs and Tissues Act (THOTA) of 1994 and its subsequent amendments. While THOTA addresses crucial aspects like brain stem death recognition and commercial trade bans, India's organ donation system faces significant challenges, including low deceased donation rates, bureaucratic hurdles, affordability issues, and cultural reservations. The current "opt-in" model, requiring explicit consent, further exacerbates organ shortages and waiting times.

To improve the system, the study proposes several recommendations inspired by international best practices. First, public awareness campaigns are essential to dispel myths and encourage organ donation. Second, investing in transplant coordinator training and hospital infrastructure is crucial for efficient operations. Third, establishing a national registry will streamline data management and ensure ethical practices. Finally, adopting digital platforms can facilitate donor registration and organ allocation.

By implementing these reforms, India can enhance the efficiency, transparency, and accessibility of its organ donation system, potentially increasing organ availability and saving countless lives.

Keywords: THOTA, Organ Donation, Organ Transplantation laws, Opt-in models.

INTRODUCTION

Law and Organ Donation: A Global Perspective

The health of a region is intrinsically linked to the effectiveness of its legal frameworks. Sound legal systems play a crucial role in establishing robust health systems, guaranteeing equitable access to healthcare, and achieving broader health outcomes. The World Health Organization (WHO) has consistently emphasized the importance of law in reaching health-related Sustainable Development Goals (SDGs). The WHO asserts that well-crafted laws are fundamental to establishing robust healthcare systems, ensuring the safety and quality of care, and promoting health equity.¹ Organ transplantation, a medical marvel capable of saving lives, is significantly influenced by the legal and ethical framework governing organ donation. A global organ donor deficit underscores the pressing need for robust legal systems in this area. The WHO estimates that only 10% of the global need for organ transplants is met, a figure partly attributed to inadequate legal support that hinders access to this life-saving procedure.² Recognizing the vital role of legal structures in organ donation, the WHO published “Guiding Principles on Human Cell, Tissue, and Organ Transplantation” to guide member states in establishing ethical and transparent systems. These guidelines stress the need for legal frameworks that promote informed consent, prevent the exploitative practice of organ trafficking, and guarantee fair and equitable organ allocation, ultimately maximizing the benefits of transplantation while upholding ethical principles.³

The Indian Context: A Look at Organ Donation

Like many regions worldwide, India is grappling with an acute shortage of organs for transplantation. Reports from 2017 indicate that India needs approximately 200,000 kidneys, 50,000 hearts, and 50,000 livers annually, but the number of transplants performed falls drastically short of this demand.⁴ Despite the existence of the Transplantation of Human Organs

¹ World Health Organisation, ‘Health Systems Governance’ (who.int28 June 2019) <https://www.who.int/health-topics/health-systems-governance#tab=tab_1> accessed 4 November 2024

² Alyssa Ward and Others, ‘Social, Economic, and Policy Implications of Organ Preservation Advances’ (2018) 23 *Current Opinion in Organ Transplantation* 336, 336-346
https://www.researchgate.net/publication/324701937_Social_economic_and_policy_implications_of_organ_preservation_advances/citations Accessed 04 November 2024

³ World Health Organization, WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (WHO/HTP/EHT/CPR/2010.01, 2010) <https://iris.who.int/bitstream/handle/10665/341814/WHO-HTP-EHT-CPR-2010.01-eng.pdf> accessed 4 November 2024.

⁴ Anju Vali Tikoo, ‘Transplantation of Human Organs: The Indian Scenario’ (2017) 1 *ILI Law Review* 147
<https://ili.ac.in/pdf/paper1017.pdf> accessed 4 November 2024.

and Tissues Act, 1994 (THOTA,1994), aimed at regulating and promoting ethical organ donation practices, India's organ donation rate remains alarmingly low, at less than one per million population.⁵ This is in stark contrast to countries like Spain, with an organ donation rate of approximately 48 per million, compared to 0.08 per Million in India highlighting the potential shortcomings within India's legal framework for organ donation.⁶ The existing legal regime in India, while intended to support and regulate organ donation, is often cited as a factor contributing to these challenges.

Objective of the Study

To critically evaluate the legal framework, ethical considerations, and procedural challenges surrounding organ donation and transplantation in India, with a focus on improving the current consent models, roles of transplant coordinators and Authorization Committees, data management, and international comparisons to enhance the effectiveness and transparency of the system.

Research Questions

1. What is the current legal regime in India vis-à-vis organ donation and transplantation?
2. What are the challenges presented by the legal regime in India to larger adoption of the concept of organ donation and transplantation.
3. What lessons can be learnt from other countries to make the organ donation and transplantation regime efficient and better suited for Indian conditions?

Research Objectives

1. To analyze the key provisions of the Transplantation of Human Organs and Tissues Act of 1994 (THOTA) and its subsequent amendments, examining their role in shaping the organ donation and transplantation landscape in India.

⁵ National Organ and Tissue Transplantation Organisation, Annual Report 2023-24 (Ministry of Health and Family Welfare)

<https://notto.mohfw.gov.in/WriteReadData/Portal/News/858_1_NOTTO_ANNUAL_REPORT__08-05-24_.pdf> accessed 4 November 2024. (NOTTO Annual Report, 2023-24)

⁶ Chris Baraniuk, 'Spain Has a Lesson for the Rest of the World about Organ Donation' (World Economic Forum, 27 June 2018) <<https://www.weforum.org/stories/2018/06/spain-leads-the-world-in-organ-donation-what-s-stopping-other-countries-catching-up/>> accessed 4 November 2024.

2. To identify and critically assess the challenges and barriers within the Indian legal regime that hinder the wider adoption of organ donation and transplantation practices.
3. To compare and contrast the legal and policy frameworks governing organ donation and transplantation in India with those of other countries highlighting best practices, successful strategies, and lessons learned.
4. To propose evidence-based recommendations for reforming the Indian organ donation and transplantation system, drawing on international best practices while considering India's unique socio-cultural and economic context.

Methodology

Given the focus on secondary research, this study will rely on document analysis and comparative legal research:

Document Analysis

- a. Legal Documents: A thorough review of primary legal sources will be conducted, including:

- The Transplantation of Human Organs and Tissues Act of 1994 (THOTA) and its amendments.
- The Transplantation of Human Organs and Tissues Rules of 2014.
- Policy Documents and Reports: This will involve examining policy documents, reports, and guidelines issued by government agencies, such as:

Reports and guidelines from the National Organ and Tissue Transplant Organization (NOTTO).

Ministry of Health and Family Welfare guidelines and annual reports.

Comparative Legal Research

- a. International Legal Frameworks: Study the legal frameworks and policies governing organ donation and transplantation in countries with higher organ donation rates (e.g.,

Spain, Croatia, the United States).

b. Comparative Analysis: A comparison of the Indian system with those of selected countries will include analyses of:

- Consent models (opt-in vs. opt-out).
- The role of transplant coordinators and authorization committees.
- Organ allocation policies and waiting list management.
- Data management systems and the use of technology.

Scope

This essay aims to explore the intersection of law and healthcare, focusing specifically on the role of legal frameworks in organ donation and transplantation in India. By examining the Transplantation of Human Organs and Tissues Act of 1994 (THOTA) and subsequent amendments, this study will analyze the existing legal structures governing organ donation in India, identify the barriers that restrict broader organ donation practices, and evaluate how these issues impact the nation's ability to meet its organ transplant needs. Additionally, a comparative analysis with international models, such as those in Spain and Croatia, will provide insights into successful policies and practices that could be adapted to the Indian context. This scope encompasses the study of primary legal documents, comparative frameworks, and thematic literature review, aiming to propose actionable reforms that address India's unique cultural, economic, and systemic challenges in promoting ethical and efficient organ donation practices.

Literature Review

Research highlights the development, challenges, and complexities within India's organ donation and transplant system. The Indian government has implemented regulations to encourage ethical practices and prevent exploitation, most notably through the Transplantation of Human Organs Act (THOA) of 1994, which provides a legal framework for organ donation, criminalizing commercial trade in organs. This legislation mandates Authorization Committees to oversee donor eligibility and regulate transplantation activities, and all Indian states and

union territories (except Andhra Pradesh and Jammu and Kashmir, which have enacted similar legislation) have adopted the Act.

However, the system faces significant challenges, notably low rates of deceased organ donation. Despite efforts to promote it, the system remains heavily dependent on living donors, with deceased donors comprising only 6% of donations in northern India. Contributing factors include limited awareness of brain death, cultural and religious reservations, and public mistrust in the healthcare system.⁷

Bureaucratic challenges are also a major barrier to efficient organ donation processes. The transplant process involves numerous forms with extensive and often redundant information requirements, creating administrative burdens for healthcare institutions. For example, the application to become a licensed transplant center requires 61 fields, while a Non-Transplant Organ Retrieval Center (NTORC) license application has 49. This bureaucratic load discourages hospitals from joining the donation network.⁸

The complexity of swap transplants presents further challenges. Swap transplants, which involve exchange of donors between incompatible pairs, are hindered by inconsistent documentation requirements across states. For example, one case required verification from four different states, delaying the transplant by seven months according to a speaker at the Symposium on Legal Challenges on transplantation organised by NOTTO.

Additionally, affordability remains a critical issue. While India's transplant infrastructure has advanced, high costs restrict access for lower-income patients. Exploring strategies for equitable access to transplant services is essential to avoid a system that disproportionately benefits wealthier individuals.⁹

In Europe, most countries operate under an opt-out consent model, which presumes consent for organ donation unless an individual opts out. However, studies show that an opt-out system

⁷ Rajesh Panwar and others, 'Why Are We Poor Organ Donors: A Survey Focusing on Attitudes of the Lay Public from Northern India' (2016) 6 Journal of Clinical and Experimental Hepatology 81 <<https://pmc.ncbi.nlm.nih.gov/articles/PMC4963316/>> accessed 4 November 2024

⁸ National Organ and Tissue Transplantation Organisation, 'Symposium on Legal and Ethical Aspects of Organ Donation and Transplantation (19.01.2024)' (YouTube 22 January 2024) <<https://www.youtube.com/watch?v=D-J-k4WizUQ&t=217s>> accessed 4 November 2024 (NOTTO Symposium, 2024)

⁹ The Lancet Editorial, 'Organ Transplantation in India: Needs a Bigger Push' (2024) 21 The Lancet Regional Health - Southeast Asia 100366 <<https://pmc.ncbi.nlm.nih.gov/articles/PMC10866917/>> accessed 4 November 2024

alone does not guarantee higher donation rates, as family refusal remains a significant barrier in countries like Denmark¹⁰. This indicates that changing the consent model alone may not effectively increase donation rates without addressing broader systemic issues.

A comparative study across seven European countries—Germany, Denmark, Austria, Belgium, Spain, Greece, and Slovenia—suggests the need for an assessment model that considers multiple factors beyond consent models.¹¹ For instance, the "Spanish Model" emphasizes the role of well-trained transplant coordinators within hospitals to work with families and guide the donation process, contributing significantly to Spain's high donation rates.¹² Public trust, transparency, and accountability are also crucial, as shown in the World Health Organization (WHO) guidelines that highlight the importance of data collection on transplant outcomes, biovigilance, and ethical allocation.¹³

The WHO advocates for the establishment of expert committees to devise global strategies for organ donation and transplantation, emphasizing that international frameworks and robust local implementation together can optimize donation rates and ethical standards.¹⁴

Data Analysis

Thematic Analysis: After gathering data from the sources above, thematic analysis will be employed to identify key themes, patterns, and recurring challenges within India's organ donation and transplantation regime.

¹⁰ Anja MB Jensen, 'NO! An Anthropological Study of Danish Families Who Refused Organ Donation When Asked at the Hospital' (Conference Paper, ELPAT - Ethical, Legal and Psychosocial Aspects of Organ Transplantation, Rome, April 2016)

https://www.researchgate.net/publication/301683819_NO_An_Anthropological_Study_of_Danish_Families_who_refused_Organ_Donation_when_asked_at_the_Hospital accessed 4 November 2024

¹¹ Harriet Rosanne Etheredge, 'Assessing Global Organ Donation Policies: Opt-in vs Opt-Out' (2021) Volume 14 Risk Management and Healthcare Policy 1985 <<https://pubmed.ncbi.nlm.nih.gov/34012308/>> accessed 4 November 2024

¹² Dallacker M and others, 'Opt-out Defaults Do Not Increase Organ Donation Rates' (2024) 236 Public Health 436

<<https://www.sciencedirect.com/science/article/pii/S003335062400355X#:~:text=The%20veto%20power%20given%20to,over%20the%20opt%2Din%20system.&text=Considering%20expressed%20preferences%2C%20whether%20of,their%20relatives%2C%20overrides%20the%20default.>> accessed 4 November 2024

¹³ Eoin McGrath and others, 'A WHO Remit to Improve Global Standards for Medical Products of Human Origin' (2024) 102(10) Bulletin of the World Health Organization 707

<https://pmc.ncbi.nlm.nih.gov/articles/PMC11418839/> accessed 4 November 2024.

¹⁴ World Health Assembly, Increasing Availability, Ethical Access and Oversight of Transplantation of Human Cells, Tissues and Organs, WHA77.4 (1 June 2024)

https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R4-en.pdf accessed 4 November 2024.

Comparative Framework: A comparative framework will be used to analyze similarities, differences, and best practices between the Indian system and those of other countries.

This methodology will provide a comprehensive understanding of the legal, procedural, and social complexities surrounding organ donation and transplantation in India and will support the formulation of informed recommendations for potential reforms.

THOTA's Main Provisions and Subsequent Amendments

The Transplantation of Human Organs and Tissues Act (THOTA) of 1994 serves as the foundation of India's organ donation and transplantation system. Prior to its enactment, India lacked a comprehensive legal framework, relying on a patchwork of state-specific laws that often applied only to specific organs. The Act established a national system to regulate organ donation and transplantation, striving to promote ethical practices while curbing illegal organ trade. It has been adopted by all states and union territories, except Andhra Pradesh and Jammu and Kashmir, which have their own legislation based on the Act. Since health is a state subject, the Centre first enacted the legislation after a resolution passed by Himachal Pradesh and Goa under Article 252 of the Constitution requesting the Parliament to pass a law on the matter. Later, many states have adopted the legislation.¹⁵

A primary objective of the Act is the prohibition of commercial dealings in human organs. To facilitate legitimate transplants, the Act created a legal mechanism for organ donations from both living and deceased donors. A landmark provision of THOTA was the recognition of brain stem death as a form of legal death. This definition, which allows organ retrieval from brain-dead patients, is crucial for expanding the pool of deceased organ donors.¹⁶

¹⁵ Constitution of India 1950, art 252 accessed 4 November 2024: 252. Power of Parliament to legislate for two or more States by consent and adoption of such legislation by any other State

(1) If it appears to the Legislatures of two or more States to be desirable that any of the matters with respect to which Parliament has no power to make laws for the States except as provided in articles 249 and 250 should be regulated in such States by Parliament by law, and if resolutions to that effect are passed by all the Houses of the Legislatures of those States, it shall be lawful for Parliament to pass an Act for regulating that matter accordingly, and any Act so passed shall apply to such States and to any other State by which it is adopted afterwards by resolution passed in that behalf by the House or, where there are two Houses, by each of the Houses of the Legislature of that State. (2) Any Act so passed by Parliament may be amended or repealed by an Act of Parliament passed or adopted in like manner but shall not, as respects any State to which it applies, be amended or repealed by an Act of the Legislature of that State.”

¹⁶ The Transplantation of Human Organs and Tissues Act, 1994, Act No. 42 of 1994, s 2D
https://www.indiacode.nic.in/bitstream/123456789/15433/1/transplantation_of_human_organs_and_tissues_act%2C_1994.pdf accessed 4 November 2024. (THOTA, 1994)

THOTA underwent significant amendments in 2011, further shaping the regulatory landscape. These amendments broadened the Act's scope to encompass tissues, reflecting the growing importance of tissue transplantation. The concept of swap transplantation was introduced, offering an alternative for patients who have willing but incompatible donors. Penalties for those violating the Act, particularly those involved in illegal organ trade, were increased from a from 2 - 7 years of imprisonment to 5-10 years of imprisonment; fines now range from Rs. 20 Lakhs to Rs. 1 Crore as opposed to the previous Rs.10,000 - Rs. 20,000 range.¹⁷ Further, the 2011 amendments explicitly prohibited the removal of organs or tissues from individuals with mental retardation.¹⁸ The amendment of 2011 also expanded the definition of the term 'near relative' to include third generation relationships such as granddaughter and grandmother.¹⁹

Legal Requirements for Donor Consent

Donor consent is a cornerstone of ethical organ donation and transplantation practices. THOTA establishes clear legal requirements to ensure informed and voluntary consent.²⁰ These requirements vary depending on the type of donor: living or deceased.

For living donors, Section 3(1) of THOTA permits the donation of organs or tissues before death, but only for therapeutic purposes. The donor must be at least 18 years old. The Act prioritizes living donations from near relatives of the recipient to minimize the potential for coercion or exploitation.²¹ This is further emphasized in Section 9, which restricts live donations to near relatives unless specific conditions are met.

When the recipient is not a near relative, the donor must apply for approval from an Authorization Committee established at the state or central government level.²² These committees are mandated to conduct thorough inquiries to ensure the donation is voluntary and free from any commercial aspects. The 2011 amendments introduced swap transplantation, permitting organ exchange between two pairs of incompatible donors and recipients. However,

¹⁷ THOTA 1994, s.19

¹⁸ The Transplantation of Human Organs (Amendment) Act, 2011, Act No. 16 of 2011, s 7, <https://mohfw.gov.in/sites/default/files/THOA-amendment-2011%20%281%29.pdf> accessed 4 November 2024.(THOTA 2011 Amendment)

¹⁹ THOTA 2011 Amendment, s.5

²⁰ THOTA 1994, Ch II.

²¹ THOTA 1994, s.9

²² THOTA 1994, sub-s.9(3)

this provision still requires approval from the Authorization Committee, even though no commercial transaction is involved.²³

In cases of deceased donation, Section 3(2) of THOTA empowers individuals to authorize the removal of their organs or tissues after death for therapeutic purposes. This authorization can be given in writing and witnessed before death, using Form 7 under the THOTA Rules of 2014. The individual's driving license can also document this authorization.

If no prior authorization was given, the person lawfully in possession of the deceased's body can authorize organ removal.²⁴ This provision relies on the assumption that the deceased did not express any objections during their lifetime. However, the Act explicitly states that if any near relative of the deceased objects to the donation, their wishes must be respected.

THOTA does not adopt a presumed consent system for deceased donation, unlike countries like Spain. It mandates explicit consent, either from the deceased before death or their family after death. However, concerns remain about the effectiveness of informed consent in deceased donation. Family members might not understand brain stem death, leading to misinterpretations and potential conflicts with the deceased's wishes.

Enforcement of these consent requirements rests with the Appropriate Authority designated in each state or union territory. This authority, established under Section 13 of THOTA, is responsible for overseeing the implementation of the Act and investigating any breaches. The Appropriate Authority can impose penalties, including the suspension or cancellation of hospital registrations, for violations of the consent provisions.²⁵

Roles of Transplant Coordinators and Authorization Committees in India, as per THOTA and THOTA Rules

Section 3(1A) of The Transplantation of Human Organs and Tissues Act, 1994 (THOTA), as amended in 2011, establishes the role of transplant coordinators in hospitals registered for organ removal, storage, or transplantation. Transplant coordinators are required to:

²³ THOTA 1994, sub-s.9(3A)

²⁴ THOTA 1994, sub-s.3(3)

²⁵ THOTA 1994, s.16

- Ascertain from patients admitted to the Intensive Care Unit (ICU), or their near relatives, if the patient had previously authorized organ donation.
- Inform patients or near relatives of the option to authorize or decline organ and tissue donation.
- Notify the Human Organ Removal Centre about the availability of a potential donor.

THOTA Rules, 2014 (Rule 29) outlines the eligibility criteria for transplant coordinators: a medical degree, nursing qualification, or a bachelor's or master's degree in relevant fields such as social work or public health.

Section 9 of THOTA mandates the approval of the Authorization Committee for organ transplantation from individuals who are not near relatives of the recipient. The Authorization Committee must hold an inquiry and ensure the applicants comply with all requirements outlined in the Act and its Rules before granting approval for organ removal and transplantation.

According to Rule 11 of THOTA Rules, 2014, a State-level Authorization Committee should be constituted in each state. Hospitals conducting more than 25 transplants annually are required to establish their own Authorization Committees. The composition of both Hospital-based and State-level Authorization Committees is explicitly defined in the Rules. No member of the transplantation team can be part of the Authorization Committee.

Rule 14 of the THOTA Rules, 2014, empowers the Authorization Committee to inform the police if there is suspicion of organ trafficking. This rule aims to prevent the illegal trade of human organs and ensure ethical practices in organ transplantation.

Data Management and Technology in Organ Transplantation in India

The Transplantation of Human Organs and Tissues Act, 1994 (THOTA), as amended in 2011, and the THOTA Rules, 2014, establish a framework for data management in organ transplantation, primarily focusing on the creation of registries.

- Rule 32 of the THOTA Rules, 2014, mandates the establishment and maintenance of the National Registry of Organ Transplants. This registry is tasked with collecting and

compiling data from various sources, including Hospital and State Organ Transplant Registries. Information to be collected includes demographic data about the patient, donor, hospitals, recipient and donor follow-up details, transplant waiting list data, etc.²⁶

- The Rules also prescribe the establishment of Organ Donation Registries and Tissue Registries, with similar data collection requirements. However, these registries have not been effectively implemented in most states, except for Tamil Nadu, Kerala, and Rajasthan.²⁷
- Section 13D of THOTA mandates the creation of a National Human Organs and Tissues Removal and Storage Network. Rule 31 of the THOTA Rules, 2014, further details the functions of this network, including establishing and maintaining an online registry for organ and tissue allocation and networking. This network is envisioned as a digital platform for coordinating organ allocation across the country.²⁸

While the Act and Rules emphasize data collection and registry creation, they offer limited provisions regarding data privacy.

- Rule 21 of THOTA Rules, 2014, mentions data protection and confidentiality as a condition for registering Tissue Banks. This provision mandates using a unique donor identification number and restricting access to donor records.

The Rules also require video recording of the Authorization Committee's interview with potential living donors to ensure transparency and prevent coercion.²⁹

Beyond these limited provisions, the THOTA and its Rules lack comprehensive guidelines on data protection, particularly concerning the use of technology and the sharing of sensitive medical information. This absence of clear data privacy guidelines raises concerns about the

²⁶ Ministry of Health and Family Welfare, Transplantation of Human Organs and Tissues Rules, 2014 (GSR 218 (E), 27 March 2014) Rule 32(1)
https://upload.indiacode.nic.in/showfile?actid=AC_CEN_12_13_00014_199442_1517807323753&type=rule&filename=THOA-Rules-2014.pdf accessed 4 November 2024. (THOTA Rules, 2014)

²⁷ NOTTO Symposium

²⁸ 'Directorate General of Health Services' (Dghs.gov.in2014)
<http://dghs.gov.in/content/1353_3_NationalOrganTransplantProgramme.aspx> accessed 4 November 2024

²⁹ Rule 32, THOTA Rules, 2014

potential misuse of donor and recipient data, particularly in the context of increasing digitalization in the healthcare sector.

Challenges presented by the Legal Regime

Consent Models (Opt-In vs. Opt-Out)

- **Challenges with Opt-In Models:** In India, the Transplantation of Human Organs Act (THOA) of 1994 requires explicit consent from the donor or their family for organ donation. This “opt-in” approach often results in a shortage of organs, as many individuals do not register as donors or families may decline consent after death. This contributes to long wait times and the unfortunate passing of patients in need.
- **Ethical and Legal Concerns with Opt-Out Models:** While an opt-out system (presumed consent) could potentially increase organ availability, implementing such a system in India faces significant ethical and legal obstacles. There are concerns about potential coercion and violation of individual autonomy, particularly given the existing sociocultural context and potential for mistrust in the healthcare system. Additionally, ensuring adequate public awareness and understanding of an opt-out system would be crucial to avoid unintended consequences and maintain public trust.

The Role of Transplant Coordinators and Authorization Committees

- **Overburdened Authorization Committees:** The current legal framework relies on Authorization Committees to vet potential organ donors and approve transplants, which can result in lengthy approval processes.³⁰ Delays are compounded when cases involve individuals from different states, requiring approvals from multiple State Authorization Committees.³¹ These delays can result in missed opportunities for transplantation and increase the risk of patient mortality.

³⁰ THOTA 1994, s.9

³¹ See Transplantation of Human Organs Act 1994, s 9(4)(b); Transplantation of Human Organs Rules 2008, r 6B; Transplantation of Human Organs and Tissues Rules 2014, rr 14, Form 11, and Form 20; and Transplantation of Human Organs Act 1994, s 9(3A). These provisions collectively imply that, in cases involving individuals from different states, approvals from multiple State Authorisation Committees may be required, potentially contributing to delays. For the full text of the 2014 Rules, see Ministry of Health and Family Welfare, Transplantation of Human Organs and Tissues Rules, 2014 (GSR 218 (E), 27 March 2014) https://upload.indiacode.nic.in/showfile?actid=AC_CEN_12_13_00014_199442_1517807323753&type=rule&filename=THOA-Rules-2014.pdf accessed 4 November 2024

- **Resource and Capacity Constraints:** The effectiveness of transplant coordinators in facilitating organ donation is often hampered by a lack of resources, training, and support.³² Many hospitals lack dedicated transplant coordinators, and those that exist may face challenges due to heavy workloads and inadequate funding.

Organ Allocation Policies and Waiting List Management

- **Lack of a Unified National Waiting List:** While NOTTO maintains a National Registry, there is no centralized, transparent national waiting list for organ transplantation. Instead, organ allocation often occurs at the state or regional level, leading to inconsistencies and potential inequities in organ distribution.³³ A unified national system would improve transparency, fairness, and efficiency in organ allocation.
- **Complexities of Interstate Organ Transplants:** The requirement for No Objection Certificates (NOCs) from the state of domicile for interstate organ transplants adds administrative burdens and delays.³⁴ While recent legal interpretations have clarified that NOCs are not mandatory for related transplants in some states, challenges persist, especially for unrelated and swap transplants. This can deter patients from seeking transplants across state lines and limit access to organs.

In *Kuldeep Singh v. State of T.N.*, both the donor and recipient were from Punjab, but the transplant was scheduled to take place in Tamil Nadu. The court ruled that the Authorization Committee of Punjab, the domicile state of both the donor and recipient, had the authority to issue approval for the transplant. Once Punjab's committee granted approval, it could then be forwarded to Tamil Nadu for the necessary action, establishing that domicile state authorization is primary in such cases.³⁵

In *Dr. J. Kaja Moinudeen v Authorization Committee*, the petitioner, a doctor in Tamil Nadu with chronic kidney disease, faced issues when Tamil Nadu hospitals refused a kidney transplant from an unrelated donor. Seeking treatment in Kerala, he was informed he needed a

³² *ibid*

³³ NOTTO Annual Report, 2023-24

³⁴ Ministry of Health and Family Welfare, Transplantation of Human Organs (Amendment) Rules, 2008 (GSR 571(E), 31 July 2008) Rule 6B
[https://upload.indiacode.nic.in/showfile?actid=AC_CEN_12_13_00014_199442_1517807323753&type=rule&filename=4Transplantation%20of%20Human%20Organs%20\(Amendment\)%20Rules,%202008.pdf](https://upload.indiacode.nic.in/showfile?actid=AC_CEN_12_13_00014_199442_1517807323753&type=rule&filename=4Transplantation%20of%20Human%20Organs%20(Amendment)%20Rules,%202008.pdf)
accessed 4 November 2024.

³⁵ AIR 2005 SC 2106

No Objection Certificate (NOC) from Tamil Nadu. The court ruled that under Section 9(3) of the THOT Act, unrelated donors are permitted, and an NOC was unnecessary per the 2014 THOT Rules. This decision underscored that hospitals cannot refuse transplants solely based on the donor's lack of relation, emphasizing that the domicile state's Authorization Committee should evaluate and approve the case. This ruling reinforced the need for consistent application of the law to prevent patients from facing unnecessary delays due to misunderstandings of transplant regulations.³⁶

Data Management Systems and the Use of Technology

- **Need for a Robust National Registry:** The existing National Registry lacks real-time data on organ availability, waiting lists, and transplant outcomes. This limits the ability to effectively manage organ allocation, monitor transplant activity, and ensure accountability.³⁷
- **Leveraging Technology for Improved Efficiency:** While technology offers significant potential to streamline transplant processes, its adoption in India's organ transplant system remains limited. Integrating digital platforms for donor registration, consent management, organ allocation, and data sharing could significantly enhance efficiency, transparency, and accessibility.³⁸

Forms required for various processes are often excessively detailed, creating administrative burdens that deter participation and slow down potentially life-saving procedures.

Lengthy Forms Discourage Participation

The sheer length of some forms poses a major challenge. The form for NTORC (Non-Transplant Organ Retrieval Centre) licenses requires completion of 49 fields, while the form for transplant centres has 61 fields. This can be daunting for healthcare institutions, especially smaller ones with limited administrative staff. The time and resources needed to accurately

³⁶ 2023 SCC OnLine Mad 6339.

³⁷ Bindu Shajan Perappadan, 'Organ Shortage Continues to Cost Lives' (The Hindu 5 August 2023) <<https://www.thehindu.com/sci-tech/health/indias-poor-organ-donation-record-continues-to-costlives/article67161978.ece>> accessed 4 November 2024

³⁸ Vinay Kesri, Government Stewardship for Health Care: A Scoping Review of Regulatory Frameworks for Health Care Providers (Asian Development Research Institute (ADRI) Working Paper, 2018) <https://www.adriindia.org/images/paper/1557397184GovernmentStewardshipForHealthCare.pdf> accessed 4 November 2024.

complete these forms can discourage hospitals from participating in the organ donation and transplant network.³⁹

Form 3 and Inconsistencies Across States

Form 3, required for swap transplants, serves as an example of the problems caused by inconsistent requirements across states. While the rules allow for merging Forms 1, 2, 3, and 11, different states have varying document demands, with some requiring all listed documents while others accept only two.⁴⁰

This lack of uniformity can lead to delays and confusion, making the swap transplant process more complicated than it needs to be.

Form 21 and Challenges with Foreign Nationals

Form 21, designed for foreign nationals involved in transplants, poses specific issues with document verification. Embassies often lack the capacity or willingness to thoroughly check the documents submitted, potentially opening the door to fraudulent activities.⁴¹ There is a need for improved international collaboration and stricter verification mechanisms to address these concerns.

Building a Robust Organ Donation and Transplantation System in India: A Comparative Approach to Reform

International Legal Frameworks

High-donation countries demonstrate a commitment to organ donation reflected in their laws and healthcare structures. Spain, often lauded for its world-leading donation rates, operates under a system often misconstrued as a pure opt-out framework.⁴² While legislation since 1979 allows for presumed consent, the real turning point came in 1989 with the implementation of the "Spanish Model". This model emphasizes a multi-faceted approach that includes trained

³⁹ NOTTO Symposium, 2024

⁴⁰ Sunny B Shah and Bharat Vallabhdas Shah, 'Legal Aspects of Transplantation in India' (2018) 12(3) Indian Journal of Transplantation 169, https://journals.lww.com/ijjt/fulltext/2018/12030/legal_aspects_of_transplantation_in_india.4.aspx accessed 4 November 2024.

⁴¹ NOTTO Symposium, 2024

⁴² Aser García Rada, 'Spain Remains World Leader in Organ Donation for 32 Consecutive Years' [2024] BMJ <<https://www.bmj.com/content/384/bmj.q175>> accessed 4 November 2024.

transplant coordinators in hospitals to identify potential donors and engage with families. This proactive, organized system, combined with strong public trust, has been instrumental in Spain's success.⁴³

The US, with its opt-in system, highlights the importance of a centralized, transparent system. The Organ Procurement and Transplantation Network (OPTN), a national system, manages the allocation process and maintains a robust database for accountability. Organ Procurement Organizations work regionally within this framework to coordinate recovery and allocation.⁴⁴ While effective in many aspects, the US system grapples with inconsistencies in consent practices across states, sometimes leading to family overrides of the deceased's registered wishes.

Croatia, like many European nations, utilizes an opt-out or presumed consent model. This approach, assuming consent unless explicitly refused, aims to expand the potential donor pool.⁴⁵ However, recent studies suggest that simply switching to opt-out may not be a "magic bullet". Factors such as clear legal criteria, public awareness, and healthcare system capacity play a significant role in effectiveness.

Comparative Analysis

Consent Models

India, operating under an opt-in framework, faces challenges unique to its socio-cultural context. Explicit consent, whether from the individual or family, is required, but cultural sensitivities surrounding death and limited awareness regarding organ donation hinder donation rates. Switching to an opt-out model might seem appealing, but the evidence is not clear-cut. Studies reveal that family intervention often supersedes presumed consent, regardless of the model. One study showcases estimated retrieval rates under different scenarios, highlighting the influence of family dynamics. In countries like Denmark, family refusal

⁴³ Ibid

⁴⁴ Eric Perakslis, Brian McCourt and Stuart Knechtle, 'Reimagining the United States Organ Procurement and Transplant Network' (2023) 2 *Frontiers in Transplantation*
<<https://pmc.ncbi.nlm.nih.gov/articles/PMC11235254/>> accessed 4 November 2024.

⁴⁵ Joan Costa-Font, Caroline Rudisill and Maximilian Salcher-Konrad, "'Relative Consent' or 'Presumed Consent'?" *Organ Donation Attitudes and Behaviour* (2020) 22 *The European Journal of Health Economics* 5
<<https://pmc.ncbi.nlm.nih.gov/articles/PMC7822792/>> accessed 4 November 2024.

remains a primary obstacle, even in an opt-out system.⁴⁶

Transplant Coordinators and Authorization Committees

Transplant coordinators are critical in streamlining the donation process, acting as a link between potential donors and recipients. Spain's success underscores the importance of well-trained coordinators embedded within hospitals, enabling timely identification and sensitive communication with families.⁴⁷ In the US, specialized Organ Procurement Organizations manage the logistical and ethical complexities of organ recovery, working in sync with the OPTN for nationwide coordination.

India's transplant coordination infrastructure is developing but often faces resource and personnel constraints. To bolster the system, investing in specialized training programs and expanding the network of transplant coordinators should be prioritized. This approach can enhance procurement efficiency and offer much-needed support to families during a difficult time. Steps in that direction have been taken recently by the governments.⁴⁸

Authorisation committees tasked with upholding ethical standards and ensuring transparency also differ internationally.⁴⁹ In Spain, these committees play a crucial role in maintaining trust and accountability throughout the process. India can learn from this model by empowering its authorization committees, promoting transparency in their decisions, and fostering a culture of accountability.

Organ Allocation and Waiting List Management

⁴⁶ Anja MB Jensen, 'NO! An Anthropological Study of Danish Families Who Refused Organ Donation When Asked at the Hospital' (Conference Paper, ELPAT - Ethical, Legal and Psychosocial Aspects of Organ Transplantation, Rome, April 2016)

https://www.researchgate.net/publication/301683819_NO_An_Anthropological_Study_of_Danish_Families_who_refused_Organ_Donation_when_asked_at_the_Hospital accessed 4 November 2024

⁴⁷ Víctor Fernández-Alonso and others, 'Facilitators and Barriers in the Organ Donation Process: A Qualitative Study among Nurse Transplant Coordinators' (2020) 17 International Journal of Environmental Research and Public Health 7996 <<https://pmc.ncbi.nlm.nih.gov/articles/PMC7662326/>> accessed 4 November 2024.

⁴⁸ Bindu Shajan Perappadan, 'Health Ministry Directs States, Medical Institutions to Create Permanent Posts for Transplant Coordinators' (The Hindu 15 October 2024) <<https://www.thehindu.com/scitech/health/health-ministry-directs-states-medical-institutions-to-create-permanent-posts-for-transplant-coordinators/article68756531.ece>> accessed 4 November 2024.

⁴⁹ Simon Streit and others, 'Ten Lessons from the Spanish Model of Organ Donation and Transplantation' (2023) 36 Transplant International <<https://pmc.ncbi.nlm.nih.gov/articles/PMC10249502/>> accessed 4 November 2024.

Fair and transparent organ allocation policies are essential to ensuring equitable access to life-saving transplants.⁵⁰ The US OPTN system, with its centralized waiting list, stands as a model for best practices. Prioritization based on medical urgency, compatibility, and geographic proximity minimizes bias and promotes fairness.

India faces hurdles with transparency and consistency in its allocation system, leading to regional disparities and unequal access. A potential solution lies in transitioning to a standardized national waiting list managed by a central body. Utilizing technology to improve organ matching and allocation based on medical need and compatibility can further enhance equity and patient outcomes.

Data Management and Technology

Robust data management is crucial for tracking outcomes, managing waiting lists, and ensuring transparency. The US OPTN database showcases the power of technology in facilitating data-driven decisions and accountability.

India currently contends with fragmented data collection and management, hindering accurate assessment and improvement efforts. A comprehensive national registry for organ donation and transplantation can address this issue. Integrating digital platforms can streamline processes, enhance data sharing and transparency, and improve overall system performance.

Recommendations for India

Based on global best practices and considering India's specific context, the following actionable recommendations are proposed:

- **Public Awareness and Trust Building:** Launching a nationwide public education campaign is vital to address cultural perceptions and misconceptions about organ donation. Collaborating with religious leaders and community influencers can help overcome cultural barriers and increase understanding and acceptance of organ donation. Educational initiatives should focus on demystifying the process, highlighting the life-saving impact of transplantation, and emphasizing the altruistic nature of

⁵⁰ Eline M Bunnik, 'Ethics of Allocation of Donor Organs' (2023) 28 Current Opinion in Organ Transplantation 192 <<https://pmc.ncbi.nlm.nih.gov/articles/PMC10155689/>> accessed 4 November 2024.

donation.

- **Investing in Human Resources and Infrastructure:** To support the growing need for transplants, India needs to expand its pool of trained professionals. This includes investing in specialized training programs for transplant coordinators and other healthcare personnel involved in the donation and transplantation process. Equally important is the need to strengthen the logistical infrastructure for organ preservation and transportation, ensuring the timely and safe delivery of organs to recipients.
- **Strengthening Transparency and Accountability:** A crucial step towards building public trust is enhancing transparency and accountability within the system. This can be achieved by establishing a centralized national registry for data collection, analysis, and public reporting. Furthermore, empowering authorization committees to enforce ethical guidelines and ensure compliance will further strengthen the system's integrity and public confidence.
- **Leveraging Technology:** Embracing technological advancements can significantly improve efficiency, transparency, and access. Implementing digital platforms for donor registration, educational resources for healthcare professionals, and data analytics tools can streamline processes, enhance communication, and promote data-driven decision-making. Additionally, exploring the use of organ perfusion technology to improve organ quality and viability can further expand the pool of available organs.

Conclusion

India has a unique opportunity to transform its organ donation and transplantation system by learning from international best practices while remaining sensitive to its socio-cultural context. The focus should be on building a system that is not only efficient and effective but also equitable and ethical. Implementing a multi-pronged approach that encompasses public awareness, infrastructure development, transparency, and technological integration will be critical in achieving this goal. First, ethical, religious, and emotional barriers deter organ donation, and public awareness campaigns should respectfully address these, including by involving faith leaders to help dispel myths. Learning from successful regional models, such as those in Tamil Nadu and Maharashtra, can provide national guidelines for legal and logistical processes like obtaining police clearances and conducting autopsies. Equitable access is

essential, given the high proportion of transplants in the private sector. Policy interventions, like allocating organs for public hospitals or requiring a certain percentage of free transplants in private facilities, could make transplants more accessible. Transparent data is also critical; a national registry with mandatory reporting from all transplant centers would help improve system effectiveness. Professional organizations like the Indian Medical Association should actively advocate for ethical practices and integrate brain death education into medical curricula. Finally, piloting an opt-out system for corneal donations in high-performing states could set the groundwork for broader organ donation initiatives. With these comprehensive strategies, India can foster an ethical and sustainable organ donation system for all.

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