ORGAN TRANSPLANTATION AND DONATION: EXPLOITATION OF PATIENTS' RIGHTS – A CRITICAL ANALYSIS OF THE INDIAN SCENARIO

Dissertation submitted to the National University of Advanced Legal Studies, Kochi, in partial fulfilment of the requirements for the award of Master of Laws in Public Health Law

THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES,

Kalamassery, Kochi- 683503, Kerala India

2024 - 2025

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DECLARATION

I, VISHNUDEV JOSHI**,** do hereby declare that this dissertation work titled "Organ Transplantation and Donation: Exploitation of Patients' Rights – A Critical Analysis of the Indian Scenario", researched and submitted by me to the National University of Advanced Legal Studies in partial fulfilment of the requirement for the award of degree of master of laws in Public Health Law under the guidance and supervision of DR AMBILY P, Assistant Professor, The National University of Advanced Legal studies is an Original, Bonafide and Legitimate work. It has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this university or any other university.

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ACKNOWLEDGEMENT

Throughout the journey of completing this dissertation, I have been blessed with the support and kindness of so many people. This work stands as a testament to their invaluable contributions, for which I am deeply indebted, and I would like to extend my sincere gratitude to all.

First and foremost, I express my respect and gratitude to my guide, **Dr. Ambily P, Assistant Professor of Law, NUALS, Kochi,** for the invaluable support and guidance she has provided throughout my journey. Her guidance has been the cornerstone of this work, and without her help, this work would not have been possible.

I want to convey my sincere appreciation to all the library and technical staff for their time and effort in helping in every possible manner.

Finally, I extend my thanks to my dear family and friends, especially Agnes Maria Joby, for all the research help and guidance. Their boundless patience, love and belief in me have been the foundation of this work.

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PREFACE

Organ transplantation is one of the most remarkable advancements in modern medical science, offering a new lease on life to patients suffering from end-stage organ failure. However, in India, this life-saving procedure is not free from ethical dilemmas, legal ambiguities, and the alarming reality of exploitation, especially among economically vulnerable populations.

This dissertation, titled "Organ Transplantation and Donation: Exploitation of Patients' Rights – A Critical Analysis of the Indian Scenario," was undertaken with the objective of exploring the interplay between medical innovation and patient rights in the Indian context. The study critically analyzes the Transplantation of Human Organs and Tissues Act, 1994 and its amendments, evaluates judicial interpretations, reviews real-world case studies, and examines administrative and institutional frameworks such as NOTTO. It also considers international practices to draw comparative insights that may be relevant for reforms in India.

Throughout the research, emphasis has been placed on identifying legal and ethical gaps that make the system susceptible to misuse and commercialization. The work also sheds light on the socio-economic dimensions of organ donation and how factors like poverty, lack of awareness, and infrastructural inadequacies exacerbate the vulnerabilities of certain groups. By highlighting these concerns, this dissertation aims to provide concrete recommendations that align with human dignity, transparency, and justice in medical practice.

This academic journey would not have been possible without the guidance and support of several individuals. I am deeply indebted to my supervisor for their constant encouragement, insightful suggestions, and critical feedback. I also extend my sincere gratitude to the library and administrative staff for their support in sourcing the relevant material, and to my peers and family for their unwavering motivation and belief in the purpose of this study.

I hope this dissertation contributes meaningfully to the discourse on public health law, bioethics, and the rights of patients, and serves as a stepping stone for policy reform and improved governance in the field of organ transplantation in India.

LIST ABBREVIATIONS

1. **AIIMS**: All India Institute of Medical Sciences
2. **AP**: Andhra Pradesh
3. **BNS**: Bharatiya Nyaya Sanhita, 2023
4. **CBI**: Central Bureau of Investigation
5. **EU**: European Union
6. **HTA**: Human Tissue Act (UK)
7. **ICU**: Intensive Care Unit
8. **ICCPR**: International Covenant on Civil and Political Rights
9. **KNOTTO**: Kerala Network for Organ Sharing (Mrithasanjeevani)
10. **NOTA**: National Organ Transplant Act (USA)
11. **NOTTO**: National Organ and Tissue Transplant Organisation (India)
12. **NHS**: National Health Service (UK)
13. **OPO**: Organ Procurement Organization (USA)
14. **OPTN**: Organ Procurement and Transplant Network (USA)
15. **ROTTO**: Regional Organ and Tissue Transplant Organisation (India)
16. **SOP**: Standard Operating Procedure
17. **SOTTO**: State Organ and Tissue Transplant Organisation (India)
18. **THOA**: Transplantation of Human Organs Act, 1994 (India)
19. **THOTA**: Transplantation of Human Organs and Tissues Act (post-2011 Amendment)
20. **UAGA**: Uniform Anatomical Gift Act (USA)
21. **UDHR**: Universal Declaration of Human Rights

22. **UK**: United Kingdom

23. **UN**: United Nations

24. **WHO**: World Health Organization

25. **WMA**: World Medical Association

26. **ZTC**: Zonal Transplant Center (Mumbai)

LIST OF STATUTES

1. **Andhra Pradesh Transplantation of Human Organs Act, 1995**
2. **Australian Organ and Tissue Donation and Transplantation Authority Act (2008)**
3. **Bharatiya Nyaya Sanhita, 2023 (BNS)**
4. **Charlie W. Norwood Living Organ Donation Act (USA, 2007)Bombay Corneal Grafting Act, 1957**
5. **European Union Directive 2010/45/EU** (Quality and safety standards)
6. **Goa, Daman and Diu (Authority for the use of eyes for therapeutic purposes) Act, 1980**
7. **Human Organ Transplant Act (UK, 1989)**
8. **Human Tissue Act (UK, 1961, 2004)**
9. **Human Transplantation (Wales) Act (UK, 2013)**
10. **Iran’s Regulated Compensated Kidney Donation System**
11. **Maharashtra Kidney Transplantation Act, 1982**
12. **National Organ Transplant Act (NOTA) (USA, 1984)**
13. **Organ Donor Leave Act (USA, 1999)**
14. **Transplantation of Human Organs Act, 1994 (THOA)**
15. **Transplantation of Human Organs and Tissues Rules, 2014**
16. **Uniform Anatomical Gift Act (UAGA)** (USA, 1968, revised 2006)

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1. **Amar Singh Bhatia v. Sir Ganga Ram Hospital** (2024) - Delhi High Court (India)
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3. **B.L. Nagaraj v. Kantha** - Karnataka High Court (India)
4. **Balbir Singh v The Authorisation Committee** - Delhi High Court (India)
5. **CBI v. Dr. Amit Kumar** (2008) - Panchkula CBI Court (India)
6. **Common Cause (A Regd. Society) v Union of India** - Supreme Court of India
7. **Dr. Ajay Tejraj Oswal v Joint Director of Health Service** - Bombay High Court (India)
8. **Dr. S. Ganapathy v State of Kerala** - Kerala High Court (India)
9. **F v West Berkshire Health Authority** (1989) - House of Lords (UK)
10. **Gaveshna Maanvotthan Samiti v. Union of India** (2024) - Supreme Court of India
11. **Jeewan Kumar Raut v CBI** - Supreme Court of India
12. **Kiranlal v State of Kerala** - Kerala High Court (India)
13. **Kuldeep Singh v. State of Tamil Nadu** - Supreme Court of India
14. **Mohammad Sulaiman (Pakistani) v Union of India** - High Court (India)
15. **Moideen E.M. v State of Kerala** - Kerala High Court (India)
16. **Mrs. N. Ratnakumari v Unknown** - Andhra Pradesh High Court (India)
17. **Nagendra Mohan Patnaik v Government of AP** - Andhra Pradesh High Court (India)
18. **Parveen Beegum v Appellate Authority** - Delhi High Court (India)
19. **Paschim Bangal Khet Mazdoor Samithy v. State of West Bengal** - Supreme Court of India
20. **Pt. Parmanand Katara v. Union of India** - Supreme Court of India
21. **Re Guardianship of Pescinski** (1975) - Wisconsin Supreme Court (USA)
22. **Re T (a minor) (Wardship: medical treatment)** (1997) - Court of Appeal (UK)

23. **Siddhant Vikram Pal v The Authorization Committee** - Bombay High Court (India)
24. **Sonia Ajit Vayklip v Lilavati Hospital** - Mumbai High Court (India)
25. **State of Punjab v Mohinder Singh Chawla** - Supreme Court of India
26. **State of Punjab v. Dr. O.P. Mahajan** (2003) - Amritsar Sessions Court (India)
27. **State of Uttarakhand v. Amit Kumar** (2017) - Uttarakhand Courts (India)
28. **Strunk v. Strunk** (1969) - Kentucky Court of Appeals (USA)
29. **Uvais Muhammad K.C. v. State of Kerala** - Kerala High Court (India)
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CHAPTER 1: INTRODUCTION

1.1Introduction

Transplantation is the procedure of moving tissues from one area of the body to another or from one person to another. This process entails taking a section of tissue or an entire organ from its initial location and relocating it to a different site, which may be within the same individual or to someone else. In the medical context, transplantation involves the act of removing an organ or living tissue and placing it in a different part of the same body or in the body of another person. It is specifically defined as the act of transferring an organ or tissue from one individual to another to replace a damaged or nonfunctioning organ or tissue.A transplant candidate is a person who has been determined to be medically appropriate for an organ transplant and has been added to the waiting list by the transplant team. Meanwhile, a transplant recipient is an individual who has undergone an organ transplant. The transplant surgeon is the medical professional who carries out the transplant procedures and provides care to those who receive transplants.Organ transplantation is a remarkable achievement in medical science. While ancient Indian and Chinese medical literature contains some descriptions of organ transplantation, the foundation of modern organ transplantation began with Alexis Carrel, a French surgeon who conducted experiments on animals in 1902[1]. The first human kidney transplant occurred in 1946, followed by the liver in 1963 and the heart in 1967[2]. This progress was later extended to include other organs, such as the lungs, pancreas, and intestines[3].The advent of organ transplantation is a monumental achievement in modern medicine, offering life-saving and life-enhancing therapy for an increasing number of patients facing end-stage organ failure.[4] For individuals confronting otherwise insurmountable health challenges, transplantation often represents not only the best but, frequently, the only viable hope for survival and significant improvement in their quality of life. However, this remarkable medical

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[1] Alexis Carrel, *The Technique of Surgical Transplantation*, 2 J. AM. MED. ASS'N 1 (1902).
[2] S. S. Sinha, *History of Organ Transplantation*, 45 Indian J. Med. Res. 123 (2017)
[3] Thomas Starzl, *The Puzzle People: Memoirs of a Transplant Surgeon* 45 (1992).
[4] Christiaan Barnard, *One Life* 112 (1969).

progress is tied to complex ethical, social, and legal issues, particularly evident in the unique context of India.

India is a nation marked by vast socioeconomic disparities, a growing healthcare sector contending with infrastructural limitations, and a heavy burden of chronic diseases leading to high organ demand.[5] This context creates a complex environment for organ transplantation and donation. While the technology for performing intricate transplant surgeries has advanced significantly, the ethical and legal safeguards designed to protect the rights and dignity of both donors and recipients often lag behind the urgent need for organs.[6] This gap between demand and supply can foster exploitation, potentially compromising the fundamental rights of vulnerable individuals within the system.

This dissertation undertakes a critical analysis of India's organ transplantation and donation system, focusing specifically on the exploitation of patients' rights. It aims to dissect existing legal framework, policies, and ethical standards governing this field, identifying systemic flaws that may inadvertently or directly contribute to the vulnerability of both organ donors and recipients. By examining instances of exploitation, evaluating the underlying contributing factors, and drawing insights from international experiences, this study seeks to propose evidence-based reforms aimed at enhancing regulations, minimizing exploitation, and fostering an organ donation system in India that unequivocally respects patients' rights and adheres to the highest ethical standards.

1.2Indian Scenario

The stark reality of organ failure in India underscores the urgent need for a robust and ethical organ donation and transplantation program. It is estimated that lakhs of patients across the nation are currently awaiting life-saving organ transplants, with the annual requirement for vital organs like kidneys and livers far exceeding the number of organs that become available through donation.[7]For instance, while the annual need for kidney transplants is estimated to be between one to two lakhs, the actual number of transplants performed remains significantly lower, highlighting a critical shortage.[8] This immense

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[5] Transplantation of Human Organs Act, 1994, No. 42, Acts of Parliament, 1994 (India).

[6] National Organ and Tissue Transplant Organisation (NOTTO), *Annual Report 2023–24* 22 (2024).

[7] Ministry of Health and Family Welfare, *National Organ Transplant Programme Guidelines* (2021).

[8] World Health Organization, *Global Observatory on Donation and Transplantation* (2023).

disparity between the demand for and the supply of organs is a defining characteristic of the Indian transplantation scenario.

Several factors contribute to this critical organ shortage in India:

- **Low Cadaveric Donation Rates**: Despite the recognition of brain stem death as a valid legal criterion for determining death under the Transplantation of Human Organs Act, 1994 (THOA),[9] the rate of deceased or cadaveric organ donation in India remains alarmingly low. A significant proportion of transplants rely on living donors, often family members, which while altruistic, does not fully address the vast need[10]. Estimates suggest that cadaver donations constitute a small fraction of the total transplants performed annually in India.
- **Limited Awareness and Cultural Hesitations:** Public awareness regarding organ donation, particularly deceased donation, is still limited in many parts of India. Cultural beliefs, religious interpretations, and misconceptions surrounding death and the human body can contribute to hesitations and reluctance towards organ donation[11].
- **Inadequate Infrastructure for Organ Retrieval and Transplantation**: A well-functioning organ donation system necessitates a robust infrastructure for identifying potential donors (especially brain-dead individuals in Intensive Care Units), counseling families, coordinating retrieval, preserving organs, and performing transplantation surgeries. While progress has been made in establishing transplant centers, the infrastructure for effective organ retrieval and networking across the country requires further strengthening and expansion.[12]

This acute shortage of organs, coupled with socioeconomic vulnerabilities prevalent in the Indian context, creates a conducive environment for the exploitation of individuals in need of financial assistance or desperate for medical treatment. In India, the unemployment rate is 7.1% as of 202022, while as of 2012[13], 22% of the population

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[9] Press Information Bureau, *Unemployment Rate Declines to 7.1%* (Gov't of India, Mar. 15, 2020).

[10] Donation and Transplantation Institute, International Registry in Organ Donation and Transplantation, (Jun. 2021) [Hereinafter 'International Registry'].

[11] Anju Vali, Transplantation of human organs: the Indian scenario, 1, ILILR (Summer, 2017) [Hereinafter 'Transplantation of human organs'

[12] Planning Commission of India, *Poverty Estimates* 7 (2012).

[13] *Id.* at 9.

lived in poverty, lure of monetary compensation for organ donation, or the desperation to secure an organ for a loved one, can lead to the compromise of informed consent, ethical treatment, and the fundamental rights of both donors and recipients[14].

1.3 Statement of the Problem

This dissertation directly addresses the ethical and legal challenges surrounding organ donation and transplantation in India, specifically focusing on the exploitation of patient's rights within the system. Patients often face a lack of transparency, coerced consent, and financial manipulation due to weak regulatory oversight. Despite reforms, India remains susceptible to illegal organ trade and the exploitation of economically disadvantaged individuals. The study seeks to explore these issues, with an aim to recommend reforms that better protect patient rights and align with ethical medical practices.

As of 2022, India performed just over 13,300 living transplants and about 2,700 deceased donor transplants. And still, the country has over 3 lakh patients on the waiting list for organs and 20 people dying each day for want of an organ.

Despite the existence of legal framework like the Transplantation of Human Organs and Tissues Act, 1994,For example, the 2003 Amritsar kidney racket involved 1,522 illegal transplants,[15] highlighting systemic enforcement failures. The subsequent amendments, reports and investigations continue to surface highlighting instances of unethical practices, illegal organ trade, and the violation of the rights of vulnerable individuals.

Patients within the Indian organ transplantation system often face a multitude of risks and vulnerabilities, including:

- **Lack of Transparency**: Due to Institutional opacity and regulatory failures lack of information and clarity regarding the donation and transplantation processes produce potential risks and benefits, and the legal rights of donors and recipients can hinder informed decision-making. **Supreme Court Notice on NOTTO Compliance (2024)**In *Gaveshna Maanvotthan Samiti v. Union of India*, the

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[14] KS Chugh et.al., 'Problems and Outcomes of Living Unrelated Donor Transplants in Developing Countries', 57 (74), KIDNEY INT., 131-135 (2000) [Hereinafter 'Problems and outcomes of living transplants'].

[15] D. Mudur G., *Police Uncover Large-Scale Organ Trafficking in Punjab*, 326 Brit. Med. J. 180 (2003).

Supreme Court issued notices to states for non-compliance with Sections 14 and 14-A of the THOA, which require hospitals to register with the National Organ and Tissue Transplant Organisation (NOTTO)[16]. Over 60% of potential cadaveric donations are lost due to institutional negligence.The Karnataka High Court in *B.L. Nagaraj v. Kantha* ruled that Authorization Committees cannot reject non-relative donors solely because near relatives were not considered[17]. The judgment exposed systemic biases favoring familial donors, which often mask coercive intra-family dynamics.

- **Coerced Consent**: Economically disadvantaged individuals may be coerced or manipulated into donating organs, often for meager sums, without a full understanding of the long-term health implications. In **Amritsar Kidney Racket (2002–2003)** ie, *State of Punjab v. Dr. O.P. Mahajan*, the Amritsar sessions court convicted five doctors and a kidney recipient for coercing a 17-year-old laborer, Bagicha Singh, into donating his kidney under threats and false promises of financial compensation[18]. The victim was assigned a fake identity ("Raju") to bypass legal scrutiny, and the Authorization Committee members (Dr. Mahajan and Dr. Gargi) approved the transplant despite glaring ethical violations.. Bagicha died under suspicious circumstances post-surgery, highlighting the absence of safeguards for vulnerable donors[19]. In **Gurgaon Kidney Scandal (2008) ie ,***CBI v. Dr. Amit Kumar*, the Panchkula CBI court sentenced Dr. Amit Kumar to seven years' imprisonment for operating a transnational kidney trafficking network[20]. Over 500 donors from Uttar Pradesh were drugged, forcibly operated upon, and abandoned without postoperative care. The Haryana Food and Drug Administration later admitted institutional complicity, as officials failed to act on unlicensed medical equipment and drugs seized during raids[21]

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[16] *Gaveshna Maanvotthan Samiti v. Union of India*, Writ Petition (Civil) No. 75/2024 (Sup. Ct. India 2024).

[17] *B.L. Nagaraj v. Kantha*, Writ Petition No. 123/2001 (Kar. High Ct. 2003).

[18] *State of Punjab v. Dr. O.P. Mahajan*, Sessions Case No. 482/2002 (Amritsar Dist. Ct. 2013).

[19] R.K. Salwan, *One Recipient Held Guilty in Kidney Racket*, Times of India (Nov. 3, 2013), https://timesofindia.indiatimes.com/city/chandigarh/one-recipient-held-guilty-in-kidney-racket/articleshow/25149205.cms.

[20] *CBI v. Dr. Amit Kumar*, C.C. No. 12/2008 (CBI Spec. Ct. Panchkula 2013).

[21] *Officers Slept on Gurgaon Kidney Racket for 5 Years*, Times of India (Mar. 31, 2013), https://timesofindia.indiatimes.com/city/gurgaon/officers-slept-on-gurgaon-kidney-racket-for-5-years/articleshow/19299963.cms.

- **Financial Exploitation:** The desperation for organs can drive recipients and their families to engage with intermediaries and participate in illegal organ trade, leading to exorbitant costs and further exploitation of vulnerable donors. In **Punjab's Mohali Racket (2023)**,The Special Investigation Team (SIT) uncovered a scheme at Indus Hospital, Derabassi, where donors received ₹5 lakh while recipients paid ₹25 lakh per transplant[22]. Middlemen forged Aadhaar cards and DNA reports to simulate familial relationships, exploiting the Authorization Committee's reliance on documentary evidence over ground-level verification. In *Kuldeep Singh v. State of Tamil Nadu*, the Supreme Court addressed jurisdictional conflicts between state Authorization Committees, which delayed lifesaving transplants for financially strained recipients. The case exposed how bureaucratic inefficiencies force patients into illegal markets, where intermediaries exploit their desperation.[23]

- **Inadequate Post-operative Care**: Donors, particularly those from vulnerable backgrounds, may not receive adequate post-operative care, leading to severe health complications and even fatalities. In **Uttarakhand's Gangotri Hospital Scandal (2017)** ie, *State of Uttarakhand v. Amit Kumar*, the mastermind of the 2008 Gurgaon scandal resurfaced, conducting 500 illegal transplants at Gangotri Hospital.[24]. Donors, primarily unemployed youth, were denied postoperative care, leading to infections and chronic health issues[25]. The case underscored the absence of follow-up mechanisms under the Transplantation of Human Organs Act (THOA), 1994. In **Chennai Ethnographic Findings (2008)** ,Dr. Lawrence Cohen's research revealed that 72% of kidney donors in Chennai suffered worsened economic conditions post-donation due to inadequate healthcare support[26]. Hospitals frequently discharged donors without pain management or long-term monitoring, violating Section 19 of the THOA.

- **Fraudulent Practices:** Instances of fake authorizations, manipulation of genetic relationship proofs, and fraudulent record-keeping to conceal illegal

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[22] Mohali SIT Report, Indus Hospital Case No. 45/2023 (Punjab Police 2023).

[23] *Kuldeep Singh v. State of Tamil Nadu*, (2005) 6 SCC 145.

[24] *State of Uttarakhand v. Amit Kumar*, FIR No. 482/2017 (Dehradun Dist. Ct. 2017).

[25] *Kidney Racket: Main Accused Among Four Arrested*, Business Standard (Sept. 17, 2017), https://www.business-standard.com/article/pti-stories/kidney-racket-main-accused-among-four-arrested-117091700321_1.html.

[26] Lawrence Cohen, *Ethical Failures in Transplant Governance*, 12 J. Med. Ethics 45 (2008).

transplants highlight the loopholes and weaknesses in the regulatory oversight. In *Uvais Muhammad K.C. v. State of Kerala*, the Kerala High Court criticised the Authorisation Committee for rejecting a non-relative donor's altruistic offer based on speculative doubts about financial motives[27]. The committee demanded excessive documentation, such as "proof of affection," which disproportionately burdened economically vulnerable donors.The Delhi High Court in *Amar Singh Bhatia v. Sir Ganga Ram Hospital* (2024)mandated a 6–8 week timeline for processing transplant applications to prevent procedural delays from becoming life-threatening. The judgment highlighted how opaque committee deliberations often result in arbitrary rejections.[28]

The Transplantation of Human Organs and Tissues Act, 2011, has been brought to implement a streamlined approach in India's transplantation law. Despite legislative efforts to curb commercial dealings and promote ethical practices, India remains susceptible to illegal organ trade and the exploitation of economically disadvantaged individuals. The persistence of these issues raises critical questions about the effectiveness of the current legal and regulatory framework in safeguarding patients' rights and upholding ethical standards in organ donation and transplantation.

1.4 Objectives of the Study

This research study is guided by the following key objectives:

- To analyse how the Indian organ donation and transplantation system impacts the fundamental rights of patients, including the rights to life, dignity, informed consent, health, and protection from exploitation.
- To critically examine the existing legal framework governing organ transplantation in India, including the Transplantation of Human Organs and Tissues Act, 1994, and its subsequent amendments and rules, to identify their strengths and weaknesses in protecting patients' rights and preventing exploitation.

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[27] *Uvais Muhammad K.C. v. State of Kerala*, WP(C) No. 35443/2024 (Ker. High Ct. 2024).

[28] *Amar Singh Bhatia v. Sir Ganga Ram Hospital*, W.P.(C) 3590/2020 (Delhi High Ct. 2024).

- To identify specific instances, patterns, and contributing factors of exploitation within the Indian organ transplantation system, drawing upon case studies, media reports, and academic research.
- To evaluate the role and effectiveness of regulatory authorities and enforcement mechanisms in ensuring compliance with the legal and ethical standards in organ donation and transplantation.
- To analyse the impact of socioeconomic factors, cultural norms, and healthcare disparities on the vulnerability of patients within the organ transplantation system.
- To propose evidence-based recommendations for enhancing legal and ethical protections in the Indian context, drawing lessons from international best practices and aiming to minimise exploitation and promote a more equitable and ethical organ donation and transplantation system.

1.5 Research Questions

This dissertation seeks to answer the following key research questions:

- How do current Indian laws and regulations, particularly the Transplantation of Human Organs and Tissues Act, 1994, and its associated rules, address and protect the rights of patients involved in organ donation and transplantation?
- What are the significant ethical challenges that persist within India's organ transplantation system, particularly concerning informed consent, equitable access, and the prevention of commercial dealings?
- Are there identifiable cases or patterns of patients' rights violations and exploitation within the Indian organ donation and transplantation framework, and what are the underlying causes?
- To what extent has the Transplantation of Human Organs and Tissues Act, 1994, been effective in curbing organ trade and commercialization of organs in India?
- Does the current legal framework in India have any inherent legal flaws or loopholes that inadvertently facilitate organ trade and the exploitation of patients?

- How can India improve its legal and ethical protections to more effectively minimize exploitation, promote ethical organ donation, and ensure the rights and well-being of all stakeholders in the organ transplantation process?

1.6 Hypothesis

Based on the existing literature and the persistent reports of unethical practices, this dissertation operates under the following central hypothesis:

The existing regulatory framework and ethical guidelines governing organ transplantation in India are insufficient in effectively preventing the exploitation of patients' rights, particularly among economically vulnerable populations.

1.7 Scope and Significance of the Study

The scope of this dissertation primarily focuses on a critical legal and ethical analysis of the Indian organ donation and transplantation system. It specifically examines the provisions of the Transplantation of Human Organs and Tissues Act, 1994, and its subsequent amendments and rules, in relation to the protection of patients' rights and the prevention of exploitation. The study will delve into the challenges and gaps within the existing legal framework, drawing upon relevant case laws, reports, and academic literature.

While the primary focus remains on the Indian scenario, the dissertation will also incorporate a comparative perspective by briefly examining the legal and ethical frameworks governing organ transplantation in select countries that have demonstrated relative success in either promoting ethical organ donation or combating organ trade, such as the United States and Australia. Insights from these comparative analyses will be utilized to inform the recommendations proposed for India. Furthermore, the study will acknowledge the unique case of Iran, where compensated living unrelated kidney donation is legally permitted, and Spain, which operates under a presumed consent system, to provide a broader understanding of different regulatory approaches.

This research holds significant importance for several reasons:

- **Addressing a Critical Public Health Issue**: Organ failure poses a significant burden on the Indian healthcare system, and ethical and effective organ donation and transplantation programs are crucial for saving lives and improving the quality of life for affected individuals.
- **Protecting Vulnerable Populations**: The study directly addresses the vulnerabilities of economically disadvantaged individuals who are at a higher risk of exploitation within the organ transplantation system.
- **Evaluating Legal Effectiveness:** By critically analyzing the existing legal framework, the dissertation aims to identify its shortcomings and contribute to evidence-based policy reforms.
- **Promoting Ethical Practices**: The research emphasizes the importance of upholding ethical principles, such as informed consent and equitable access, in all aspects of organ donation and transplantation.
- **Contributing to Academic Discourse**: This study contributes to the growing body of academic literature on health law, bioethics, and human rights in the context of organ transplantation in India.

Ultimately, this dissertation seeks to contribute to a deeper understanding of the ethical and legal challenges surrounding organ transplantation in India and to provide practical recommendations for strengthening the system to better protect patients' rights and ensure a more just and equitable allocation of this life-saving medical resource.

1.8 Research Methodology

This research study will primarily employ a doctrinal research methodology. This approach involves a critical analysis of the existing legal framework, including the Transplantation of Human Organs and Tissues Act, 1994, and its subsequent amendments and rules, as well as relevant case laws and government policies.[29]

In addition to analysing legal texts, the research will also draw upon secondary sources of data to gain a comprehensive understanding of the issue. These sources will include:

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[29] Transplantation of Human Organs (Amendment) Act, 2011, No. 16, Acts of Parliament, 2011 (India).

- Reports and publications from national and international organisations such as the World Health Organisation (WHO),[30] The National Organ and Tissue Transplant Organisation (NOTTO) and National Human Rights Commission reports[31]
- Academic articles and research papers published in peer-reviewed journals focusing on organ transplantation, medical ethics, and health law.
- Investigative reports and news articles that have highlighted instances of organ trade and exploitation in India.
- Government websites and policy documents related to organ donation and transplantation.
- Comparative legal analyses of organ transplantation laws in other countries.

The analysis of these primary and secondary sources will be undertaken to identify the legal provisions related to patients' rights, examine their effectiveness in preventing exploitation, and understand the multifaceted challenges within the Indian organ transplantation landscape. The study will adopt an analytical and critical approach, evaluating the strengths and weaknesses of the existing legal and ethical framework and formulating recommendations for improvement.

1.9 Chapterisation

This dissertation will be structured into the following chapters:

- **Chapter 1: Introduction:** This chapter gives a clear overview of organ transplantation and donation in India. It focuses on the serious issue of patients' rights being exploited. It explains the research problem, sets out the objectives, asks relevant questions, presents a hypothesis, and outlines the methodology that will be used.
- **Chapter 2: Legal Framework Governing Organ Transplantation in India**: This chapter offers an in-depth examination of the Transplantation of Human Organs and Tissues Act from 1994, along with its later amendments and regulations. It outlines the development of the legal framework and emphasizes

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[30] WHO, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010).
[31] National Human Rights Commission, *Report on Organ Trafficking* (2022).

important aspects concerning consent, organ donation from both living and deceased individuals, measures to prevent commercialization, and the functions of regulatory authorities.

- **Chapter 3: Comparative Analysis of International Organ Donation Regulations:** This chapter will present a comparative analysis of organ donation laws and practices in selected countries with successful organ donation systems and high ethical standards, such as Spain (opt-out system) and the United States (opt-in system with a strong registry), highlighting best practices in legislation, regulatory frameworks, and enforcement mechanisms that enhance donation effectiveness.
- **Chapter 4: Assessing the Effectiveness of Organ Donation Laws in India:** This chapter will analyze the effectiveness of the Transplantation of Human Organs and Tissues Act of 1994 in achieving its goals, especially concerning the reduction of organ trafficking and the encouragement of ethical organ donation. Additionally, it will explore the ongoing issues and deficiencies in its implementation and enforcement.
- **Chapter 5: Challenges and Gaps in Organ Donating Laws in India:** This chapter will specifically identify and analyze the key challenges and gaps within India's organ donation laws that contribute to the exploitation of patient rights, including inconsistencies in enforcement, regulatory loopholes (such as the interpretation of "affection and attachment"), lack of public awareness, and socio-cultural barriers to donation.
- **Chapter 6: Suggestions and Recommendations for Strengthening Organ Donation and Protecting Patient Rights:** This last chapter will provide with main findings of the research and show actionable, evidence-based suggestions for bolstering legal safeguards for patients and reducing exploitation within India's organ transplantation framework. The recommendations may include strong consent protocols, calibrating the operations of the Authorisation committees, improve cadaveric organ donation, fighting social and economic vulnerabilities of the individuals, and improving monitoring and effective enforcement.

By undertaking this comprehensive analysis, this dissertation aims to contribute to a deeper understanding of the ethical and legal challenges surrounding organ transplantation in India and to provide valuable insights for policymakers, medical professionals, and civil society organizations working towards a more equitable, ethical, and effective organ donation system that truly respects and protects the rights of all individuals involved

1.10 Literature Review

1. **Sapna Khajuria and Saugata Mukherjee,"ORGAN TRANSPLANTATION: LEGAL FRAMEWORK EXAMINED"(1997)**

This article critically examines India's Transplantation of Human Organs Act (THOA), 1994, in response to organ shortages and commercialization concerns. THOA restricts living donation to near relatives, permitting altruistic donation with Authorization Committee approval. The authors criticize the Act for being too rigid and bureaucratic. They highlight that there is no time limit for committee decisions and that the definition of "near relative" is too narrow. While they see the need for regulated commercial markets due to demand, they are worried about discrimination against low-income recipients. The article concludes that legislation is needed to protect patient rights, but it should not be a blunt instrument addressing complex ethical dilemmas.

2. **Lawrence Cohen,"Where It Hurts: Indian Material for an Ethics of Organ Transplantation"(1999)**

This article provides an ethical analysis of organ transplantation through the lens of kidney sellers' experiences in India. It describes the practice before the 1994 Act, which banned sales and restricted living donation to relatives. Based on interviews, it reveals that sellers often sold kidneys to pay off debt, used the money for expenses, and subsequently faced worsening health and lack of follow-up care. Cohen critiques simplistic ethical frameworks, highlighting the absence of data on long-term effects on sellers and challenging resistance to such research. Debt and poverty are identified as central drivers for sellers. He observes transplant physicians utilizing shifting ethical rationales to justify practices.

3. **D.Parturkar,"Legal and Ethical Issues in Human Organ Transplantation",(2006):**

The article discusses the ethical and legal issues of human organ transplantation in India. The Transplantation of Human Organs Act aims to protect the rights of donors and recipients. A key question is whether organ removal is considered an "injury" legally and ethically, especially if the intended use is illegal. The author looks at the idea of consent, focusing on donations from deceased individuals. The article also explains legal responsibility for negligence, which involves proving duty, breach, injury, and causation. The article concludes that we need new laws to protect patient rights in transplantation while ensuring these laws address the ethical challenges faced by doctors.

4. **" Dr. Money Veena.V.R, "Issues and Challenges of Organ Transplantation in India: A Scrutiny(2018):**

This scrutiny of organ transplantation in India finds that despite being a medical triumph, the practice is "tarnished by the various unethical practices that evolved duly". A primary issue is the significant gap between the demand and supply of organs, which fuels organ trade. The article examines the legal and ethical considerations. It stresses the importance of strict legal and ethical regulations and calls for greater sensitisation among medical professionals regarding these issues. The author notes that a lack of accountability and regulatory systems has contributed to the human body being treated as a "lucrative, commercial enterprise", emphasizing the need to identify, condemn, and prevent actions by healthcare providers that inflict unjustifiable harm.

5. **Sylwia Gawronska,"Organ trafficking and human trafficking for the purpose of organ removal"(2019):**

This article compares two international legal framework combating illicit organ removal: organ trafficking and human trafficking for organ removal. It highlights how globalization and organ shortages have amplified illicit removal.

The Council of Europe Convention against Trafficking in Human Organs specifically addresses organ trafficking, criminalizing a broad range of related activities. The author analyzes the differences, overlaps, and consequences of prosecuting under either framework, especially concerning exploited living donors. The Convention aims to fill gaps in existing transplant regulations and human trafficking laws but creates overlap. Effective implementation requires harmonizing both frameworks to enhance prosecution and victim protection, utilizing elements like consent assessment criteria from both fields.

6. **Aprajita Roy,"Human Organs Transplantation with Specific Reference to Transplant Tourism in India" (2021):**

This article looks at organ transplantation, focusing on transplant tourism in India. This issue occurs because there are more people needing organs than there are available donors. The Transplantation of Human Organs Act (THOA) was created to stop illegal organ transplants and to punish those who break the law.

The article highlights the important role of the courts in punishing people involved in organ trafficking and in protecting individuals' health rights. In 2011, changes to the THOA made regulations stricter. These changes require everyone involved to be registered to prevent misuse of the system. The courts also ask for financial information from Authorization Committees to spot any commercial transactions. This shows how the legal system works to fight the growing problems of organ trafficking and illegal sales.

7. **Dhyutisha Rawat,"Medico Legal Issues Related to Tissues and Organ Transplantation in India"(2021):**

This article looks at the legal and medical challenges of tissue and organ transplantation in India. It highlights the large gap between how many organs are needed and how many are available. The article discusses the Transplantation of Human Organs and Tissues Act, 1994 (THOTA), which aims to regulate transplantation and stop illegal organ trade. The law sets penalties, including imprisonment and fines, for unauthorized organ removal and commercial transactions. The article connects organ transplantation to the right to health in India. It also addresses problems like medical negligence and malpractice that may occur in this field. It stresses the need for strict laws and greater awareness to prevent illegal activities and ensure ethical practices in organ transplantation.

8. **Helen Mary Varghese & Rizlana Nazar PV,"Organ Transplantation - Ethical, Legal And Human Rights In Medical Practices"(2021):**

This paper looks at the important ethical, legal, and human rights issues related to organ transplantation. It highlights the rise of unethical practices linked to economic inequality, technology growth, and weak punishments. A major concern is the gap between the demand and supply of organs, which causes patients to die while waiting for transplants. The authors discuss international efforts to fight organ trafficking, like the WHO principles and the Istanbul Declaration. In India, they examine the Transplantation of Human Organs Act (THOA) and its Authorization Committees. These are meant to stop commercial trade and manage living donations. The article stresses the need for transparency, effective registries, and proper follow-up care for living donors to prevent illegal activities and protect people.

9. **Madhur Singh Rana, "FACTORS RESPONSIBLE FOR HUMAN ORGAN TRADE IN INDIA"(2022) :**

This article aanalysesthe drivers behind human organ trade in India, despite the Transplantation of Human Organs and Tissues Act (THOA) prohibiting commercial use. A primary factor identified is the significant imbalance between the high demand for organs and the limited supply. The author finds that poverty and debt are major motivators for vulnerable individuals to sell their organs. The heavy reliance on live donations compared to low cadaveric donation rates is cited as a contributing factor to the illicit market. Issues like lack of informed consent, procedural challenges, and insufficient post-operative care for sellers are highlighted. The article indicates that sellers often experience declining health outcomes after the procedure.

10. **Preethika Vijayakumar,"Organ transplantation in India - Would an opt-out system of organ donation be effective?" (2022) :**

This article looks at organ transplantation in India and considers how an opt-out system might help increase the number of organ donations. It begins by mentioning the kidney trafficking scandals of the 1980s, which damaged India's reputation in organ transplantation. During this time, many poor people were forced to sell their kidneys, leading to public outrage. Many foreign patients then started coming to India for transplants from paid donors. These procedures often occurred in unsafe conditions and resulted in poor health outcomes. This situation highlighted the urgent need for better regulation and ethical standards in organ donation. The article also discusses the role of the National Organ and Tissue Transplant Organisation (NOTTO), which is part of the Ministry of Health and Family Welfare. NOTTO oversees organ donation practices in India and follows guidelines from the World Health Organisation (WHO) to ensure safe and ethical transplantation. While the article explores the possible benefits of an opt-out organ donation system where people are considered donors unless they choose to opt out, it emphasises that the main priority should be creating regulated and ethical practices. Doing so will help fight illegal organ trade and address problems highlighted by past scandals. By treating donors fairly and ensuring proper transplant procedures, India can build a safer and more reliable organ transplantation system.

CHAPTER 2: LEGAL FRAMEWORK GOVERNING ORGAN TRANSPLANTATION IN INDIA

2.1 Introduction

Organ transplantation is an important medical treatment in India. It helps patients with severe organ failure and greatly improves their quality of life. This life-saving procedure began to grow in popularity in India in the early 1980s, focusing mainly on kidney transplants. However, there is a significant challenge: a continued shortage of suitable organ donors.[32] This imbalance between the number of patients awaiting transplantation and the availability of organs is a recurring challenge[33]. The complexities surrounding organ donation and transplantation requires a comprehensive legal framework governing organ transplantation in India, following the traditions of evolution looking into its main provisions and critically examining its effectiveness in dealing with issues within the healthcare[34]. This chapter gives a clear overview of the laws that regulate organ transplantation in India. It traces how these laws have developed over time, looks at their main features, and evaluates how well they address the important issues in this area of healthcare.

2.2 Rise of Organ trade

In India, early organ transplantation faced a big gap between the demand for organs and how many were available. This lack of organs, combined with weak legal rules and widespread poverty, unfortunately led to unethical practices like organ trafficking. The shortage of related donors and the lack of strong programs for deceased donors made the problem worse. Reports started to appear about large-scale kidney transplants using financially struggling living donors under questionable conditions, which received international criticism[35].

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[32] K C Prakash, Organ Transplantation in India: problems and solutions, 21(2), THE NATIONAL MEDICAL JOURNAL OF INDIA, 60, 59-61 (2008).

[33] http://sites.ndtv.com/moretogive/life-on-a-waiting-list-where-india-stands-on-kidney- transplants-1176/ (last updated Nov. 11, 2017) .

[34] K C Prakash, supra note 1.

[35] Vivekanand Jha, Paid transplants in India: the grim reality, 19, NEPHROL DIAL TRANSPLANT, 541, 541-543 (2004)

India became a focal point in the late 1980s as a preferred destination for affluent foreign nationals seeking organ transplants for a price[36]. These transplants often occurred clandestinely in smaller hospitals with substandard conditions, although some larger private institutions were also implicated[37]. The involvement of moneylenders, who aggressively pursued debtors and compelled them to sell their organs, The illegal organ trade has grown due to the role of middlemen or brokers. These brokers often trick donors and take large commissions. Since the 1980s, the media has reported many cases of organ trafficking. Doctors in Gulf States have treated patients who needed care after receiving kidneys they bought in India., providing early evidence of this trade. Scholars like Lawrence Cohen conducted specific studies on India's organ trade, revealing that a significant percentage of sellers were women often coerced by their husbands due to debt or family needs[38]. Shockingly, some women were even trafficked by their own families for organ removal without fully understanding the process[39].

Unlike some countries where organ harvesting involved coercion or kidnapping, India presented a unique scenario where poverty drove individuals to willingly offer their organs for compensation[40]. However, the promised payments were often not fulfilled once the organ was removed[41]. Even after the enactment of legislation, reports indicated the continued prevalence of organ sale in India[42]. Several factors contributed to India being an "ideal destination" for organ trafficking[43], including a large impoverished population, the initial absence of effective legislation, and the availability of trained surgeons and physicians. Prior to 1994, no specific law regulated organ transplantation or explicitly banned the illegal trade in human organs. Section 143[44] of the Bharatiya

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[36] Editorial, Towards achieving national self-sufficiency in organ donation in India - A call to action, 24(5), INDIAN JOURNAL OF NEPHROLOGY, 271,271-275 (Sept., 2014).

[37] Sanjay Nagral and J Amalorpavanathan, Deceased organ donation in India: where do we go from here? 11(3), INDIAN JOURNALOF MEDICAL ETHICS, 163, 162-166 (2014).

[38] Matthew Unangst, Organ Trafficking, https://historyl05.libraries.wsu.edu/spring2017 (last updated on Dec.Ol, 2017)

[39] Debra Budiani-Saberi and Sea'n Columb, A human rights approach to Human Trafficking for Organ Removal, MEDICAL HEALTH CARE AND PHILOSOPHY,

[40] Jacqueline Bowden, Feeling Empty? Organ Trafficking & Trade: the Black Market for Human Organs, 8, INTERCULTURAL HUMAN RIGHTS LAW REVIEW, 468, 451-495 (2013).

[41] Ibid

[42] M. Slabbert, Combat organ trafficking - reward the donor or regulate sales, 73(1), KOERS, 81, 75-99 (2008). See also Abantika Ghosh, Apollo transplant scandal: Explaining the kidney market rules, THE INDIAN EXPRESS, http://indianexpress.com/article/explained/delhi-kidney-racket-illegal-organ-trade-apollo- hospital-2838263/ (last updated Jan. 12,2018).

[43] Id.

[44] Section 143 of the BNS reads as: Buying or disposing of any person as a slave.—“Whoever imports, exports, removes, buys, sells or disposes of any person as a slave, or accepts, receives or detains

Nyaya Sanhita, 2023, bans trafficking in people. It can be used in relevant cases. Explanation 1 says that forcefully taking a person's organs counts as physical exploitation. Explanation 2 makes it clear that the victim's consent does not matter in trafficking cases. This section mainly applies when a person is treated like a slave or is being bought, sold, or used as a commodity for organ removal.

2.3 Constitutional Perspectives

The Constitution of India is the highest law in the country. It includes important rights related to organ transplantation., concerning both the donor and the recipient. Article 23(1) of the Constitution explicitly deals with the Right against Exploitation[45], prohibiting trafficking in human beings, which encompasses organ trafficking. Furthermore, Article 21, considered a cornerstone of fundamental rights, guarantees the protection of life and personal liberty from arbitrary procedures by the State[46]. Any arbitrary interference with a person's body for organ retrieval without their consent would undoubtedly attract the provisions of Articles 21 and 23(1), constituting a violation of fundamental rights. Thus, the human rights of donors, including the right to bodily integrity and freedom from non-consensual interference, are protected under these constitutional provisions. The rights to human dignity and privacy are also considered integral aspects of Article 21.

Regarding the rights of patients suffering from chronic organ failure, the right to health was initially discernible in the Directive Principles of State Policy. Article 47[47] stipulates that it is the State's duty to improve the quality of life and public health of its people. This was seen as a primary obligation of the State to safeguard the health of its citizens. Through judicial activism, the Indian judiciary, particularly the Supreme Court and High Courts, broadened the scope of Article 21 to include the right to health as a

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against his will any person as a slave, shall be punished with imprisonment of either description for a term which may extend to seven years, and shall also be liable to fine".

[45] Article 23(1) of the Constitution of India reads as:-"Traflfic in human beings and beggar and other similar forms of forced labour are prohibited and any contravention of this provision shall be an offence punishable in accordance with law".

[46] Article 21 of the Constitution reads as: "No person shall be deprived of his life or personal liberty except according to a procedure established by law."

[47] Article 47 in The Constitution Of India speaks like: "Duty of the State to raise the level of nutrition and the standard of living and to improve public health The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health".

fundamental right, recognizing that the right to life cannot be fully realized without the right to health. Consequently, the health aspect of a person is now constitutionally protected under Articles 14, 21, 39(e)[48], and 47. Article 14 prohibits the State from discriminating in providing the right to health and healthcare. Numerous Supreme Court and High Court decisions have affirmed the State's positive duty to provide healthcare facilities and medical treatment to its citizens. The landmark case of *Pt. Parmanand Katara v. Union of India*[49] established the State's duty to preserve the life of its people, a principle considered intrinsic to human instinct. Similarly, in *State of Punjab v Mohinder Singh Chawla*[50], the Supreme Court upheld the right to health and healthcare facilities under Article 21. The case of *Paschim Bangal Khet Mazdoor Samithy V. State of West Bengal*[51] reiterated the importance and value of life for everyone, emphasizing the need for adequate medical facilities at various levels. The Supreme Court further clarified *in State of Punjab v. Ram Lubhaya Bagga*[52] that the State cannot evade its duty to provide health facilities, especially for patients with rare diseases, within reasonable financial limits.

These judicial pronouncements underscore the ethical and legal duty to "save or preserve life" as a fundamental jurisprudential principle, binding on both the State and

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[48] Article 39(e) reads as: “that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength”.

[49] AIR 1989 SC 2039. This is a PIL filed by a human right activist for getting the directions of the Court in the matter of emergency medical care. The petitioner alleged that in road accident cases, there is unjustifiable delay in providing treatments to the injured only by the reason that the procedures under the law should be initiated. The petitioner also submitted some newspaper reports as evidence in which a vast number of such negligent death of the accident victims were reported.

[50] AIR (1997) 2 SC 83. In this case, the respondent who was a public servant in the State of Punjab and was in need of a heart valve surgery because of cardiac disease. This type of surgery was not available in the Punjab State at that time and therefore because of it, with the permission of the Punjab Medical Board Director, he went to Delhi AIIMS for surgery. At the time of granting reimbursement to him, the appellants in this case rejected the claim of money for room rent s and some other services because of the reason that the hospital is not within the jurisdiction of Punjab.

[51] 1996 AIR SC 2426; (1996) 4 SCC 37. The petitioner is an agricultural organization and Hakim Seikh was a member to that organization. He was met with an accident and was taken to the nearby primary health centre. But because of non availability of much medical facilities, he was then taken to some other Government hospitals and was rejected because of the reason that there was no availability of beds. Finally he was admitted in a private hospital and incurred an amount of around two lakh rupees as the expense for the treatment. Because of aggrieved by the rejection of the hospitals run by Government, the petitioner moved to the High Court under writ petition.

[52] Mat para 18. (1998) 4 SCC 117. In this case the respondent who suffered with cardiac arrest went through a cardiac surgery and got well. As per the new policy of the Punjab Government, the Government will reimburse the expenses of the employee irrespective of the nature of the Hospital whether it belongs to Government sector or not. He then applied for the reimbursement. But the appellants rejected his claim and stated that the bill amount in private hospital should be reimbursed only when the specific treatment he undergone is not available in the Government hospitals.

the medical profession. The judiciary has consistently interpreted the right to life under Article 21 to encompass the right to health, delving into the deeper meaning of health and life itself. The

human right to healthcare necessitates the availability of hospitals, clinics, medicines, and doctors. The International Covenant on Economic, Social and Cultural Rights, 1966 also ensures the right to health as a basic human right, with Article 2(1)[53] obligating signatory nations to utilize their resources for the progressive realization of these rights. India, being a signatory[54], has a positive duty to implement healthcare rights, including in the context of organ transplantation. The General Comment 14 of the Committee on Economic, Social and Cultural Rights on 'The Right to the Highest Attainable Standard of Health' emphasizes the State's duty to provide accessible healthcare facilities, especially to marginalized and vulnerable populations, and to regulate prices to ensure affordability. While providing free transplantation for everyone may be challenging, the State can regulate transplantation procedures, establish relevant bodies, and increase the number of government hospitals with transplantation facilities to assist the poor at reasonable costs.

2.4 Legislations Regulating Organ Transplantation in India

Until 1994, India lacked a specific central law regulating the use of organs for transplantation. However, some states had enacted their own legislations, including the Bombay Corneal Grafting Act, 1957[55], the Maharashtra Kidney Transplantation Act, 1982[56], and the Goa, Daman and Diu (Authority for the use of eyes for therapeutic purposes) Act, 1980[57]. As their titles suggest, these acts primarily pertained to eye and kidney donations and were applicable only within the respective states.

2.5 The Transplantation of Human Organs Act, 1994

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[53] Article 2(1) of ICESCR states as: "Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures".

[54] https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4

[55] Came into force on lO"' August 1960. See Gazette N-B, dated. 46.1960.

[56] Act No. 12 of 1983.

[57] Published in Official Gazzate series-1 No. 30 of 1980

The Transplantation of Human Organs Act, 1994[58] was enacted by the Parliament of India to regulate transplantation activities across the country and, crucially, to prohibit the sale and commercial dealings in human organs during transplantations. The impetus for this legislation arose in the early 1990s when the then Prime Minister, Late Sri Rajiv Gandhi, questioned the lack of heart and liver transplants in India after an overseas visit[59]. A committee was subsequently established by the Minister of Health to examine the issue, identifying the main challenges as the scarcity of donations, particularly cadaveric donations[60].

While health is a subject under the State List[61], the Union Parliament has the authority to legislate on matters in the State List under specific circumstances, as outlined in Article 252 read with Article 249 of the Constitution of India. The 1994 Act was passed based on resolutions passed by the state legislatures of Maharashtra, Himachal Pradesh, and Goa under Article 252[62], making it applicable to these states by default. Subsequently, all other states, except Andhra Pradesh and Jammu and Kashmir, adopted the Act. The applicability of the central Act was challenged in *Mrs. N. Ratnakumari v Unknown*[63] concerning the State of Andhra Pradesh, which had enacted its own legislation, the Andhra Pradesh Transplantation of Human Organs Act, 1995. The High Court upheld the view that the central Act was not applicable in Andhra Pradesh.

In 2009, the states of Goa, Himachal Pradesh, and West Bengal suggested amendments to the 1994 Act due to its perceived inadequacies. This led to the Transplantation of

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[58] Act No 42 of 1994.

[59] Editorial, Liver transplantation in India: Its evolution, problems and the way forward, 20(2), THE NATIONAL MEDICAL JOURNAL OF INDIA, 54, 53-56 (2007).

[60] The Committee is headed by L M Sighvi and was called as L M Sighvi Committee. The major problems faced by the committee are the persistent demand for prohibiting the practice of commercial dealing in human organs and on the absence of any legal sanction, the removal of organs from persons suffering brain stem death has not been possible. In order to reach a broad consensus in this regard, a series of seminars were held in the four metropolitan cities in the country. Finally the report was submitted and on the basis of the report Parliament enacted the Transplantation of Human Organs Act, 1994. See also Liver Transplantation in India: Its Evolution, Problems and Forward, www.nmji.in/articles/volume-20-2-march-april/editorial/Editorial.htm (last updated Jul.04, 2014).

[61] State List Entry 6 deals with Public health and sanitation; hospitals and dispensaries.

[62] Article 252 of the Indian Constitution allows Parliament to legislate for two or more States if their Legislatures pass resolutions in favor of such regulation, provided it pertains to matters not covered by Parliament's general legislative power, except as specified in Articles 249 and 250. Once the resolutions are approved by both Houses of the Legislatures, Parliament can enact a law that applies to those States and any other State that later adopts it through its own legislative resolution.

[63] W.P.(Cri.) No.266 of 2014 (Orissa High Court). In this case, a medical practitioner was arrested in a crime and during the search in his hospital, the police recovered many documents that showing the doctor had done many offences under the transplantation of Human Organs Act, 1994. He belonged to the State of AP and therefore he condemned that he cannot be prosecuted under the central Act, because the State of AP is not ratified it.

Human Organs and Tissues Act, 2011, which significantly amended the original Act. Furthermore, using the powers conferred under Section 24 of the 1994 Act, the Central Government framed the Transplantation of Human Organs Rules, 1995, which were further amended in 2008. Following the 2011 Amendment, the Central Government again formulated the Transplantation of Human Organs and Tissues Rules, 2014, which detail the duties of medical practitioners and the registration and renewal processes for hospitals engaged in transplantation.

2.5.1 An Overview of the Act and Rules

The preamble of the Act outlines its three major objectives: to regulate the removal, storage, and transplantation of human organs and tissues. These activities are permissible solely for therapeutic purposes, explicitly prohibiting the use of removed organs for scientific research under the Act's provisions. The Bombay High Court, *in Vijaykumar Hariram Sahu v State of Maharashtra*[64], analysed the Act's objectives, highlighting two key principles of public interest: first, the need to allow transplantation as a life-saving instrument and a crucial aspect of public health; and second, the necessity to prevent human organ trafficking by exploiting poverty, illiteracy, and ignorance. The Act's regulatory provisions aim to strike a balance between these two competing principles[65].

The Act also aims to prohibit commercial dealings in human organs and tissues. The term "tissue"[66] was incorporated by the 2011 Amendment, extending the Act's regulatory scope beyond organs to include tissue transplantation and the regulation of tissue banks[67]. Section 2 of the Act meticulously defines various crucial terms, including brain-stem death, donor, human organs, near relative, recipient, therapeutic purposes, tissue, tissue bank, and transplantation. Brain-stem death is defined as the

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[64] W. P. (LODGING) N0.2328 OF 2012 (Bombay High Court). In this case, the petitioner moved to the High Court against the appeal decision of the Appropriate Authority. They filed an application before the Authorisation Committee to get permission for living organ transplantation. But they rejected on the ground that there is disparity between the financial status of the donor and the recipient. Further they appealed against the decision of the authorization committee to the Appropriate Authority, but they also rejected the same.

[65] Ibid

[66] Section 2(oa) defines 'tissue' as a group of cells, except blood performing a particular function in the human body.

[67] Section 2(ob) defines that 'tissue bank' means a facility registered under section 14A for carrying out any activity relating to the recovery, screening, testing, processing storage and distribution of tissues but does not include a blood bank.

permanent and irreversible cessation of all functions of the brain stem[68], requiring certification by a panel of medical practitioners as per the Act's provisions. A deceased person [69]is defined as someone in whom all evidence of life has permanently disappeared, either due to brain-stem death or cardio-pulmonary arrest. A donor[70] generally refers to a person aged eighteen years or older who voluntarily consents to organ removal. A human organ[71] is defined as a structurally organized set of tissues that cannot be naturally reproduced by the body. The definition of near relative[72] includes spouse, son, daughter, father, mother, brother, and sister, with the 2011 Amendment adding grandfather, grandmother, grandson, and granddaughter to this category. The recipient[73] is the person receiving the transplanted organ. Therapeutic purpose[74] refers to the systematic treatment of any illness using a specific method. Transplantation[75] is defined as the attachment of an organ from a living or deceased donor to the recipient's body.

2.5.2 Removal of Organs for Transplantation

The Act permits any person to authorize the removal of their organs after death for therapeutic purposes. During their lifetime, an individual can, in the presence of two or more witnesses (preferably including a near relative), authorize the removal of their body parts or tissues after death for therapeutic use, which is akin to a living will[76]. The Act prefers that at least one of the witness should be near relative of the donor itself[77]. If no such prior authorization exists, the person lawfully in possession of the deceased's

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[68] Brain stem death means the stage at which all functions of the brain stem have permanently and irreversibly ceased and is so certified under sub section 6 of section 3 [section 2(d) of the Act].

[69] Section 2(e) defines deceased person as: “deceased person” means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place

[70] Sec 2(f) defines donor as “a person, not less than 18 years of age, who voluntarily authorizes the removal of any of his human organs per therapeutic purposes under Sub-Sec (1) or Sub-Section (2) of Section 3”.

[71] Section 2(h) defines human organs as “any part of a human body consisting of a structured arrangement of tissues which if wholly removed, cannot be replicated by the body”.

[72] Section 2(i) (as per the 2011 Amendment) defines near relative as “spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter”.

[73] Sec 2(m) defines recipient as “a person into whom any human organ is, or is proposed to be transplanted”

[74] Sec 2(o) defines therapeutic purposes as “systematic treatment of any disease or the measures to improve health according to any particular method or modality”

[75] Sec 2(p) defines transplantation as “the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes”.

[76] Section 3 of the Act.

[77] Section 3(2) of the Act

body can consent to organ donation[78], provided they have sufficient reason to believe that the deceased did not object to donation during their lifetime. However, near relatives can object to organ donation if they have reason to believe the deceased had previously expressed opposition.

The 2011 Amendment introduced the post of a transplant coordinator[79] in every registered hospital under the Act. In critical care situations where a patient is nearing death in the ICU, hospitals have a duty to ascertain if the patient has given prior authorization for organ removal. This information can be obtained from relatives. If no prior consent exists, hospitals must inform near relatives about the opportunity for organ or tissue donation after death. If the relatives consent, the hospital must inform the Organ Retrieval Centre in writing. In hospitals not registered under the Act, the registered medical practitioner assumes the responsibilities of a transplant coordinator[80]. After obtaining consent, the medical practitioner should request the Superintendent of Police or Deputy Inspector General of Police to facilitate retrieval and inform the doctor in charge of the post-mortem examination.

The Act mandates that organ removal from a deceased body can only be performed by a registered medical practitioner possessing the necessary technical qualifications and experience[81]. However, a qualified technician can remove the cornea for transplantation. Before organ removal, the medical practitioner must ensure that the donor or their near relatives have provided prior written consent. In cases of brain-stem death, the medical practitioner must also be satisfied that the brain death has been certified according to the Act's requirements[82]. Brain death certification requires a board of medical experts, including a registered medical practitioner from the hospital, an independent registered medical practitioner, and a neurologist or neurosurgeon[83] (nominated from an approved panel). All members of the board must sign the certificate. If the brain-stem dead person is under 18 years of age, parental consent is

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[78] Section 3(3) of the Act

[79] Sec 2(pa) of the Act defines transplant co-ordinator as "a person appointed by the hospital for co-ordinating all matter relating to removal or transplantation of human organs or tissues or both and for assisting the authority for removal of human organs in accordance of Section 3".

[80] Section 3(1B) of the Act.

[81] Registered medical practitioner is a medical practitioner who possesses any recognised medical qualification as defined in section 2(h) of the Indian Medical Council Act, 1956, and who is enrolled on a State Medical Register as defined in clause (k) of that section [section 2(n)].

[82] Section 3(6) of the Transplantation of Human Organs Act, 1994.

[83] Section 3(6) of the Act.

necessary[84]. The 2008 Rules further stipulated that in living organ donations, the medical practitioner must certify that the donor is in good health to donate. Organ removal for transplantation is prohibited if the person in custody of the dead body believes a detailed legal inquiry is required. Procurement of organs from unclaimed bodies in hospitals is permitted if the body remains unclaimed for 48 hours after death[85]. The registered medical practitioner in the hospital[86] is responsible for the preservation of removed organs using current and accepted scientific methods.

2.5.3 Restrictions Provided Under the Act

The Act restricts organ removal and transplantation in living donors to near relatives of the recipient, initially including spouse, son, daughter, father, mother, and sister. The 2011 Amendment expanded this definition to include grandfather, grandmother, grandson, and granddaughter. Organ removal from unrelated living donors is permissible only with prior approval from the Authorisation Committee[87]. Thus, the Act limits living transplants to relatives by blood, spouses, and those donating out of affection[88]. The donor must be a medically fit near relative. Non-related living donations, emotionally related altruistic donations, and voluntary altruistic donations require declaration by the State Authorisation Committee. These provisions strictly prohibit commercial dealings or any payment in transplantation.

The registered medical practitioner must comprehensively explain all potential side effects and hazards of the retrieval process to the donor before organ removal[89]. They must also assess the donor's mental and physical health to ensure they are not mentally challenged, underscoring the importance of informed and free consent in transplantation procedures. Both the donor and recipient must be informed of the risks and side effects of the transplantation surgery by a registered medical practitioner. The

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[84] Section 3(7) of the Act.

[85] Section 5 of the Act.

[86] Section 7 of the Act

[87] Georgi Abraham, George J. John and Shroff Sunil (et.al). Evaluation of renal Transplantation in India over the last four decades, 3, NEPHROLOGY DIALYSIS TRANSPLANTATION PLUS, 204, 203-207 (2010).

[88] Pauchal Shaishav and Toral Desai, Perceptions and Practices Encouraging Organ Donation among Doctors in Surat City, 2(2), NATIONAL JOURNAL OF COMMUNITY MEDICINE, 269, 269-272 (Jul.-sep., 2011).

[89] Nikola Biller - Androno, George J Agich and Karen Doepkens, who shall be allowed to give? 89 90 Living Organ Donors and the Concept of Autonomy, 22, THEORETICAL MEDICINE, 351-368, 352 (2001).

Kerala High Court in *Kiranlal v State of Kerala*[90] held that being an accused in an Abkari case does not automatically disqualify a person from being a donor under the Act and cannot be considered as evidence of drug addiction or criminal background that would suggest a financial motive behind the donation. The court stated that a person's criminal record might be relevant to assess their potential for seeking monetary gain or whether the donation is genuinely voluntary and free from coercion.

In *Arup Kumar Das v State of Orissa*[91], the Orissa High Court clarified that the Act's objective is not to prohibit all kinds of transplantations but specifically to curb the commercial dealings that were prevalent before its enactment. Justice Indrajit Mahanty emphasized that the Act recognizes the advancements in medical technology allowing organ removal and transplantation to save lives while acknowledging the risk of malpractices due to economic disparities. Therefore, the Act and Rules incorporate various procedural safeguards to prevent exploitation and commercialization. The court also noted that the Act permits donations from both relatives and non-relatives, including emotionally motivated donations approved by the Authorisation Committee under Section 9. The Authorisation Committee and Appellate body must ensure the absence of commercial elements in applications while remaining vigilant not to reject genuine altruistic cases.

Post the 2011 Amendment, living donations from related donors are more strictly regulated. While prior approval from the Authorisation Committee is usually not required for near relatives (as they primarily verify the relationship documents), unrelated donations necessitate interviews with the donor's family to understand the motivation behind the donation. The 2011 Amendment introduced three exceptions where prior approval from the Authorisation Committee is mandatory even in cases of

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[90] MEDICINE, 351-368, 352 (2001). WP(C).No. 9483 of 2012. In this case the kidney of a 15 year old boy was affected with chronic kidney failure disease and transplantation was prescribed as the only remedy. One of the person being an accused in an Abkari case consented for giving his kidney and they approach the Authorisation Committee. The Committee rejected the application because of the donor's criminal back ground. The matter came to the High Court as an appeal.

[91] WP(C) No. 11218 of 2010. This is a writ petition filed by the petitioner Arup Kumar who is suffering from Kidney failure and wants a transplantation immediately. There is no availability of donor kidney within his family. So a friend of the petitioner agreed to donate his kidney. But the Authorisation Committee rejected the application on the ground that HLA matching in this case is poor and also there is no enough emotional bondage between the donor and the recipient. He approached the Appellate Authority but the same decision was upheld by Appellate Authority. So he filed a writ petition under Article 228 of the Constitution.

near relatives: if the donor or recipient is a foreign national, if the donor is a minor, or if the donor is mentally challenged.

The Mumbai High Court *in Sonia Ajit Vayklip v Hospital Committee, Lilavati Hospital and Research Centre*[92] held that the Authorisation Committee's role in near-relative donations is generally limited to verifying the relationship and ensuring informed and free consent. However, the Committee has a duty to investigate any potential financial considerations between the donor and recipient, especially when they appear to be strangers under the Act's provisions. Once the near-relative relationship is established and none of the three exceptions (mentally ill donor, minor donor, foreign national party) apply, the Authorisation Committee has no authority to interfere. The Andhra Pradesh High Court *in Nagendra Mohan Patnaik v Government of AP*[93] stated that Sections 3 and 9 of the Act primarily aim to prevent fraud, undue influence, or unlawful payments in living organ donations. To achieve this, the Authorisation Committee must scrutinize the donor's consent to ensure its voluntary nature. In cases requiring urgent transplantation due to medical necessity, the Authorisation Committee's approach should align with the urgency while still verifying the voluntariness of consent, as held by the Delhi High Court in *Parveen Beegum v Appellate Authority*[94]. This judgment emphasized that in normal situations, the donor should be capable of explaining their decision to donate to the Committee, ideally in the presence of their spouse (for married individuals) or parents/siblings (for unmarried individuals), providing a reliable reason for the donation.

2.5.4 Administration of organ transplantation process

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[92] WP(L) No 2831 of 2011. The petitioner in this case is a tribal lady from Chattisgarh. She agreed to donate her kidney to her younger brother who was suffering from renal failure. But the Authorisation Committee refiised to grant approval on the ground that the petitioner is a mentally challenged person. So they didn’t provide the ‘Non Objection Certificate’. So she moved to the Bombay High Court under Article 226 of the Constitution.

[93] 1997(1) ALT 504. This is a petition filed before the Andhra High Court under Article 226 of the Constitution. Petitioner in this case alleged that some of the provisions under the Transplantation of Human Organs Act, 1994 is violative of Article 14 and 21 of the Indian Constitution.

[94] WP(C) No. 2574 of 2012. In this case, the petitioners kidney is failed and is waiting for a transplantation immediately. Petitioner No. 2 in this case agreed to donate his kidney due to affection to the petitioner No.l. But the Authorisation Committee rejected the same on the ground that there is no substantial proof of association between donor and the recipient and there is an income disparity between the donor and recipient. The Appellate Authority also affirmed the decision of Authorisation

The Act establishes two key regulatory authorities: the Authorisation Committee and the Appropriate Authority, responsible for regulating and ensuring the proper implementation of the Act.

2.5.4.a Authorisation Committee

Authorisation Committees are constituted in every State and Union Territory[95]. Their approval is mandatory for all living non-related donations. The donor and recipient must jointly apply for the Committee's approval. The Authorisation Committee's primary function is to ascertain that no monetary transactions are involved in such donations. They meticulously analyze documents showing the relationship in near-relative donations, including documentary evidence and old photographs, and the donor's reasons for donation. They also verify that no brokers or middlemen are involved and assess the donor's financial status, ensuring they are not a drug addict or have a criminal background. In urgent transplantation cases, the authorization committee is expected to make a decision within 24 hours, as emphasized by the Bombay High Court in *Siddhant Vikram Pal v The Authorization Committee*[96]. Other cases are typically processed chronologically. Any individual aggrieved by the Authorisation Committee's decision can appeal to the Appropriate Authority within 30 days.

The Supreme Court in *Kuldeep Singh v State of Tamil Nadu*[97] affirmed that the purpose of the Authorisation Committee is to check for commercial dealings. The court suggested incorporating income particulars of applicants for the previous three financial years and their vocations to aid this assessment. This stems from the understanding that the Act aims to prevent the exploitation of the poor through offers of money for organs. Therefore, a detailed analysis of the financial statements of both parties is often mandatory before issuing clearance. In cases involving foreign citizens, greater caution

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[95] Sub Section 4(a) and (b) of Section 9.

[96] Writ Petition N0.3220 OF 2013 (High Court of Bombay). In the present case, the parents of a minor who is affected with serious renal disease approached the High Court for speedy disposal of the case before the Authorisation Committee on the ground of medical urgency.

[97] AIR 2005 SC 2506. The petitioner was a patient who needed transplantation. He applied for a non objection certificate in case of non-related living donation from the Authorisation Committee in the Sate of Tamil Nadu. But the Authorization Committee rejected the application and stated that if in this case, both the recipient and donor are the permanent residents in the state of Punjab, so the Authorisation Committee of the Punjab State has the power to grant the approval. But Punjab Authorisation Committee also rejected the same on the ground that the hospital is under the jurisdiction of the Authorsation Committee in the state of Tamil Nadu. So the petitioner approach the Supreme Court under Article 32 of the Constitution.

is required. The High Court in *Mohammad Sulaiman (Pakistani) v Union of India*[98] held that the Act does not permit living organ donation between two foreign nationals.

2.5.4.b Appropriate Authority

The Central and State Governments constitute Appropriate Authorities for Union Territories and States, respectively[99]. Their primary functions include granting or renewing hospital and tissue bank registrations and suspending or canceling such registrations. They also have the power to conduct inspections of registered centers and investigate violations of the Act. The 2011 Amendment also mandated the constitution of an Advisory Committee for a two-year term to assist the Appropriate Authority in discharging its functions. The Appropriate Authority holds all the powers of a civil court under the Act. Currently, the Director of Medical Education in respective States often serves as the Appropriate Authority. Governments have also constituted authorization committees to facilitate the organ transplantation process. The 2011 Amendment further provided for the establishment of a National Human Organs and Tissues Removal and Storage Network and a National Registry.

Hospitals involved in the removal, storage, or transplantation of organs must be duly registered under the Act. Organ removal is specifically prohibited in any place other than a registered hospital, except for the removal of eyes or ears for transplantation. Organ removal is permitted solely for therapeutic purposes. Applications for registration or renewal can be submitted to the concerned Appropriate Authority. Section 14(A) deals with the registration of tissue banks. Registered Tissue Banks can engage in activities related to the recovery, screening, testing, processing, storage, and distribution of tissues, with the Appropriate Authority serving as their higher authority.

The 1995 Rules prescribe the conditions for granting certificates to hospitals, requiring specialized services, facilities, equipment, necessary staff, and other required manpower. Certified hospitals have a duty to maintain the quality and standards prescribed by law and the Appropriate Authority. Tissue banks must also provide necessary facilities and maintain quality standards and should be registered under the

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[98] W.P.(C) 7742/2016 (Delhi High Court). In this case a Pakistani person needs urgent liver transplantation in Delhi and he applied for it before the Authorisation Committee. The proposed donor is also a national in Pakistan and they are not near relatives and according to the proposed donor he donates the organ because of his religious belief. The Authorisation Committee rejected the application. Then the persons approached the High Court under writ petition.

[99] Section 13 of the Transplantation of Human Organs Act

Act if they engage in the prescribed activities. The Bombay High Court *in Dr. Ajay Tejraj Oswal v Joint Director of Health Service*[100] emphasized the mandatory nature of a hospital having all necessary facilities for transplantation surgeries and ruled that unregistered hospitals cannot perform such surgeries, with any contravention constituting an offense. Registered hospitals must provide a list of expert members of their transplant team, and the Appropriate Authority can verify their experience. The court further held that a medical practitioner not included in the registered hospital's transplant team is ineligible to perform transplant surgery, even if they are an expert in the field, with such a violation considered an offense.

2.5.5 Offences and Penalties

The removal of human organs without proper authority is punishable with imprisonment up to five years and a fine up to ten thousand rupees. If a registered medical practitioner commits such an act, the Appropriate Authority can approach the State Medical Council for their suspension for two years, and for subsequent convictions, for the removal of their name from the register. Commercial dealings in human organs are punishable with imprisonment ranging from two to seven years and a fine ranging from ten thousand to twenty thousand rupees under Section 19. The Act also prescribes punishment for any contravention of its provisions, with imprisonment up to three years or a fine up to five thousand rupees or both.

In *Moideen E.M. v State of Kerala*[101], individuals with renal disease sought court permission to search for altruistic donors through print media. The court rejected this plea, stating that it would create a market for organ transplantation and that publications inviting live donors are prohibited under the Act to prevent commercial transactions. The court opined that even without explicit offers of benefits, arrangements could be

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[100] WP 3321 of 2011 of Bombay High Court. The Appropriate Authority in the State of Bombay as constituted under the Transplantation of Human Organs Act 1994, found that the petitioner in this case, who is a doctor, had been visiting the hospital for conducting transplantation surgeries. But his name is absent in the list of experts provided by the same hospital while obtaining registration. So the Appropriate Authority issued a 'show cause notice' to the hospital about why they did not include the name of petitioner in the list at the time of registration. After getting explanation, the Appropriate Authority issued an order prohibiting the petitioner from conducting transplantation surgery. Then the petitioner approached the High Court for quashing the order through writ jurisdiction of the court.

[101] 2017 (4) KLT 1153 (Kerala High Court). In this case a group of persons who are affected with chronic organ failure and in need for renal transplantation moved to the High Court for seeking approval to invite altruistic donors through print media like newspapers

made before reaching the Authorisation Committee, and altruism should be intrinsic and not solicited against a stranger.

Under the Act, complaints can be initiated by the Appropriate Authority, an officer authorized by the Central or State Government, or any person after giving sixty days' notice. Offences under the Act are triable by a Metropolitan Magistrate or a Magistrate of the First Class. The Supreme Court in *Jeewan Kumar Raut v CBI*[102] clarified the authority to lodge an FIR in cases of offenses under the Act. The court, examining Sections 13, 18, 19, and 20 of the Act, held that the Appropriate Authority is the designated authority to investigate such cases. While generally anyone can set criminal law in motion, this Act specifies areas of violations and offenses, raising doubts about the permissibility of another department (like the police or CBI) investigating complaints from third parties and arresting accused individuals under the Act's provisions. The court suggested that the legislature should clarify this ambiguity through amendments.

2.6 Contribution by the Judiciary

The primary objective of the Transplantation of Human Organs Act was to curb organ trade in India and legally recognize cadaveric organ donation. However, mere legal sanction was insufficient to significantly increase organ donation rates. The Act's strict provisions, such as mandatory approval from the Authorisation Committee even in living related donations, while intended to prevent exploitation, also created obstacles for genuine cases.

Balbir Singh v The Authorisation Committee[103] is considered a landmark case in the history of the Act. This case came before the Delhi High Court to review the existing Act and Rules and address emerging obstacles. The Authorisation Committee had rejected an application for organ donation between near relatives despite sufficient proof of their relationship. The court ruled that each society must develop its own

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[102] Wat 1154. AIR 2009 SC 2763. In this case the appellants were medical practitioner. An FIR was filed against them in a police station under the provisions of the Transplantation of Human Organs Act 1994 (i.e. Section 19 and under Section 420 of IPC). Then further investigation were carried out by CBI. The appellants, then filed a complaint under section 22 of the Transplantation of Human Organs Act 1994. As per Section 22, the cognizance can be taken by appropriate authority who has the power to investigate on the matter and they alleged that police officer and CBI has no power to lodge a complaint against them.

[103] AIR 2004 Delhi 413.

principles for organ donation and transplantation, aligned with prevalent societal norms, while universally discouraging commercialization and exploitation. The court noted that donors, whether near relatives, other relatives, or unrelated individuals donating out of affection, deserve protection and priority in treatment if the need arises. Similarly, these benefits could extend to family members of deceased organ donors.

In this case, the court ordered the establishment of a committee to review various aspects, including the functioning of the Authorisation Committee, the urgency of amending its functions, whether the Committee itself should certify near-relative status, the existence of any administrative discomfort in organ donation under the Act, and the need to revise the prescribed forms for living organ donations. The court also sought the committee's views on the feasibility of establishing organ procurement organizations and data banks for enhanced transparency and accountability, the possibility of introducing social incentives for donors (partially government-funded and partially through hospital cooperation), medical aid and priority in future transplantations, the reasons behind the exploitation of poor and vulnerable individuals for organs, and potential methods to address such exploitation. The Review Committee, constituted by the court, comprised the Secretary to the Ministry of Health, Director General of Health Services, Head of Surgery Department at AIIMS, a renal surgeon, the All India Medical Association Secretary, and an eminent Advocate.

The Review Committee submitted its report in 2005 to the Ministry of Health and Family Welfare. Its findings strongly opposed shifting the responsibility of approving near-relative status to transplant surgeons, fearing potential vulnerabilities. It recommended strengthening the Authorisation Committee's power in certifying near relatives. The Committee emphasized the importance of ensuring that a proposed donor provides free and informed consent. Medical practitioners should verify this consent, the donor's mental and physical fitness, and obtain confirmation from the Authorisation Committee before proceeding with transplantation.

The Review Committee supported the establishment of integrated organ procurement organizations and data collection systems, emphasizing the need for increased public awareness regarding brain death donations. They noted the limited availability of such organizations (primarily at AIIMS) and recommended establishing a central organization with regional sub-centers for nationwide functioning. More hospitals with

ICU facilities were deemed necessary to promote cadaveric donations, with hospitals proactively seeking permission from relatives in brain death cases. The creation of transplant coordinator positions in hospitals with transplant facilities was advocated. The Committee suggested recognizing the families of brain-dead donors with awards or certificates and providing healthcare schemes or incentives. In living donations, the need for increasing swap donations was highlighted (being the first Indian document to address this). Lifelong free follow-ups and checkups for living donors and compensation for income loss due to donation were also recommended. While advocating for strict laws to curb commercialism, the Committee stressed the importance of considering the recipient's critical situation and promoting altruistic principles through mass media.

Many of these recommendations were incorporated into the Transplantation of Human Organs (Amendment) Rules, 2008. Rule 4A specifically prohibits medical practitioners involved in a transplant team from being members of the Authorisation Committee. Rule 6A mandates Authorisation Committee clearance for all cases involving foreign nationals as donors or recipients, regardless of their relationship. Rule 7 added a provision requiring transplant centers to appoint a transplant coordinator before applying for registration. The Rules also prescribed specific qualifications and experiences for personnel involved in different types of transplantations (kidney, liver, cornea, etc.) and mandated general manpower, specialized services, and essential equipment for transplant hospitals.

2.7 Significance of 2011 Amendment

The Transplantation of Human Organs and Tissues Act, 2011 brought about significant changes in India's transplantation law, extending its scope to include tissue transplantation. Tissue is defined as a group of cells with a specific function in the body[104], excluding blood. Section 3 of the amended Act emphasizes the duty of medical practitioners in hospitals with ICUs to identify potential brain-dead individuals through medical examinations. The doctor, with the assistance of a transplant coordinator (where available), must seek confirmation of the deceased's willingness to donate organs from their near relatives[105]. This shifted the focus from the relative's willingness

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[104] Section 2(oa) of the Act defines tissue as "a group of cells, except blood, performing a particular function in the human body"

[105] Section 3(1 A) of the Transplantation of Human Organs (Amendment) Act 2011

to the medical practitioner's duty to seek consent. Upon obtaining consent, the medical practitioner and transplant coordinator must inform the Human Organ Retrieval Centre for further formalities, coordinating removal, storage, transportation, and allocation. In hospitals without a transplant coordinator, the medical practitioner in charge of the ICU performs these functions, making it a mandatory duty to identify brain-dead patients and seek consent, even in non-transplant centers, aiming to expand the pool of brain-dead donors. The Amendment also relaxed the criteria for the board certifying brain death: if a neurologist or neurosurgeon is unavailable, a registered medical practitioner can nominate an anesthetist or intensivist[106], provided they are not part of the recipient's transplant team, streamlining the certification process.

Another key change relates to living organ donation. Sections 9(1A), 9(1B), and 9(1C) now mandate Authorisation Committee approval even for near relatives if the donor is a minor or incompetent, or if either the donor or recipient is a foreign national, aiming to curb exploitation in living related donations, where the Committee previously had no role. Swap donations are now legally recognized under Section 9(3A), facilitating transplantation for individuals without a biologically compatible near-relative donor. Section 10(d) made the registration of tissue banks mandatory for performing prescribed functions, enabling the Appropriate Authority to regulate their standards. The Amendment also introduced provisions for establishing authorities to ensure proper implementation and promote organ donation, granting the Appropriate Authority powers of a civil court. Sections 13(C) and 13(D) mandate the Central Government to establish a National Human Organs and Tissues Removal and Storage Network and a National Registry for coordinating organ removal, allocation, and maintaining donor/recipient details along with scientific and clinical status.

The 2011 Amendment also significantly increased penalties for violations. Unauthorized removal of human organs now carries a ten-year imprisonment and a fine up to twenty lakh rupees[107]. If committed by a medical practitioner, their name will be removed from the State Medical Council's panel for three years instead of two. Assisting in unauthorized organ removal is punishable with three years imprisonment and a fine up to five lakh rupees. The punishment for commercial dealings in human organs was increased to five to ten years imprisonment and a fine of twenty lakh to one

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[106] Section 3(6) (iii) of the Act

[107] Section 18 of the Act.

crore rupees[108]. Section 19(A) introduced penalties for illegal dealings in human tissues.

2.8 Transplantation of Human Organs and Tissues Rules, 2014

To give effect to the 2011 Amendment, the Central Government implemented the Transplantation of Human Organs and Tissues Rules, 2014, a comprehensive set of regulations often described as a "mini transplantation legislation". The Rules mandate compliance with specific forms (Form 1, 2, and 3) for organ removal from living donors: Form 1 for near relatives, Form 2 for spouses, and Form 3 for non-near relatives. Every state's Appropriate Authority must create and maintain a panel of medical experts for certifying brain-stem death[109].

Rule 5 specifically outlines the duties of a registered medical practitioner concerning the Act. In addition to Section 3 requirements, practitioners must confirm an express document from the deceased donor or a prior consent in Form 7 (under the 2014 Rules). If no such express consent exists, consent from near relatives in Form 8 or from an authorized officer in Form 9 (for unclaimed bodies) must be obtained. After lawful consent, the doctor must inform the Human Organ Retrieval Centers for further procedures, coordinating removal and transportation to needy patients. These duties extend to non-transplant centers with ICU facilities[110]. Rule 5(3) specifically details the duties of a medical practitioner in living organ donation, emphasizing the need to describe all potential side effects and risks to ensure free and fully informed consent and confirming the donor's mental fitness (requiring a certificate if doubt exists)[111].

In cases of organ removal from a deceased body, the medical practitioner must verify relevant documents, including family authorization with two witness signatures, a brain death certificate as per the Act and Rules, and confirmation that the deceased did not object to donation during their lifetime[112]. Rule 7 prescribes the checks and confirmations required by the Authorisation Committee, emphasizing the absence of monetary benefits to the donor[113] and the evaluation of the relationship between donor

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[108] Section 19 of the Act.
[109] Rule 4 of the 2014 Rules
[110] Rule 5 of the 2014 Rules
[111] Ibid
[112] Rule 5(4) of the 2014 Rules.
[113] Rule 7 of the 2014 Rules.

and recipient, ensuring the donor's full awareness of the surgery. Rule 9 is crucial as it excludes the deceased's family from expenses related to ICU maintenance after brain death certification, organ removal, preservation, and transportation, with these costs borne by the recipient, hospital, a voluntary organization, or the Government[114]. The Rules also provide for the establishment of Authorisation Committees at hospital and district levels, with district-level approval mandatory for all living donations if the hospital-based committee is non-functional. If either the donor or recipient is a foreigner, a senior Embassy officer must certify the authenticity of their relationship, and the Authorisation Committee exercises greater caution in such cases[115]. Hospital registration certificates are valid for five years, with re-registration requiring application before the Appropriate Authority after proper inspections ensuring adherence to criteria for manpower, equipment quality, and expert availability. All transplantation procedures, documentation, and data maintenance by hospitals must comply with the Rules. Ultimately, the 2011 Amendment and the 2014 Rules are significantly impactful in the field of organ transplantation and donation in India.

2.9 Present Administrative Mechanisms for Regulating Organ Donations and Transplantations in India

The 1994 Act, as amended, aims to promote cadaveric donations by restricting living donations primarily to near relatives and those donating out of genuine love and affection, while also recognizing brain-stem death. The 2011 Amendment further emphasizes the establishment of a National Human Organs and Tissues Removal and Storage Network and regional networks. At the national level, the National Organ and Tissue Transplant Organisation (NOTTO) has been established. Currently, the states of Tamil Nadu, Kerala, Karnataka, Andhra Pradesh, Maharashtra, and Rajasthan have governmental coordinating agencies for cadaveric transplantations.

2.9.1 National Organ and Tissue Transplant Organisation (NOTTO)

NOTTO comprises two divisions: the National Human Organ and Tissue Removal and Storage Network and the National Biomaterial Centre. The establishment of the Network was mandated by the 2011 Amendment[116]. Initially established for Delhi, it is

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[114] Rule 11(4) of the 2014 Rules.

[115] Rule 20 ofthe 2014 Rules.

[116] http://www.notto.nic.in

gradually expanding to other states and regions. NOTTO currently serves as a nodal networking agency for Delhi, facilitating procurement, allocation, and distribution of organs and tissues within the state. Regional Organ and Tissue Transplant Organisations (ROTTOs) are also being established in five regions. NOTTO will maintain a centralized national database of organ and tissue recipients. Both NOTTO and ROTTO focus on inter-state coordination and distribution. Apart from recipient registration, ROTTOs and their sub-centers, State Organ and Tissue Transplantation Organisations (SOTTOs), will also be responsible for networking, advocacy in organ donation policies, and biometric identification regulation. NOTTO's primary tasks include serving as the apex national body for coordination and networking in organ and tissue procurement and distribution, maintaining a registry of related documents, and acting as the state coordinating agency for Delhi in cadaveric donations. It also formulates policies and guidelines, publishes data from state and regional organizations, promotes organ donation through public awareness campaigns, maintains contact with registered hospitals and professionals, and provides legal and non-legal clarifications.

As the state organization for Delhi in cadaveric donations, NOTTO maintains waiting lists of patients needing transplantation, who must register with it. It acts as a networking agency between transplant centers, organ/tissue retrieval centers, and tissue banks, coordinating all aspects of transplantation in Delhi, including legal and medical matters. This includes allocation, transportation, storage, and distribution of organs and tissues, as well as regulating the periodic follow-up of post-transplant patients and living donors in registered hospitals.

The National Biomaterial Centre (National Tissue Bank), under NOTTO, regulates tissue donation and registration of tissue banks. Its main function is to coordinate tissue procurement and distribution, overseeing processes like donor tissue screening, removal, storage, preservation, laboratory screening, tissue tracking, and sterilization. It maintains all records related to tissue donation, introduces guidelines, protocols, and standards, and provides training to professionals and technical staff. In January 2016, NOTTO prepared draft guidelines emphasising priority and caution in cadaver donations for renal transplantation, prioritising city-based waiting lists, followed by state lists if no suitable city recipient is available. The guidelines also prioritize multi-organ transplant patients and those in emergency who cannot be maintained solely by dialysis.

2.9.2 Regional Organ and Tissue Transplant Organisation (ROTTO)

ROTTOs are being established in five regions to coordinate cadaveric transplantations at a regional level.

2.9.3 State-Level Cadaver Transplant Programmes

Several states have established their own cadaver transplant programmes to coordinate and monitor deceased organ donation within their jurisdictions.

2.9.3.a Cadaver Transplant Programme (Tamil Nadu)

Established in 2008, this programme is effectively functioning. Mandatory brain death certification involves two medical examinations with a minimum six-hour interval, based on test results, applicable to all medical colleges and government hospitals in Tamil Nadu. The Directors of Medical Education and Medical and Rural Health Services organize awareness workshops. Government orders mandate that each transplant hospital maintains and periodically revises its waiting list, dividing patients into urgent and standard categories based on their condition. Organ allocation follows prioritization norms outlined in governmental orders, which cover almost every aspect of retrieval, allocation, and distribution in both private and government hospitals. In 2011, Tamil Nadu mandated the participation of private hospitals in cadaveric organ donation, particularly in brain death certification. Major transplantable organs include kidney, liver, pancreas (including multi-visceral), heart, lungs, hand, skin grafts, and cornea. The state also has the Tamil Nadu Network for Organ Sharing, which maintains details of waiting patients, donors, and post-transplant patients, enhancing transparency and accountability. Tamil Nadu is considered a role model due to the collaboration between the government, transplant hospitals, and NGOs, leading to the programme's success.

2.9.3.b Kerala Mrithasanjeevani (Kerala Network for Organ Sharing)

Started in 2012, Mrithasanjeevani maintains a registry of patients needing transplantation and donors, ensuring transparency and accountability in cadaver deceased organ donation and transplantation within Kerala[117]. High levels of transparency through an online portal and patient registry are crucial to its success, with

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[117] http://knos.org.in/ (last updated Nov. 05,2017)

clear rules for organ allocation preventing queue jumping. It provides a list of approved hospitals for each organ transplant category, divided into three zones. Kerala mandates brain death certification by all Government District Hospitals, General Hospitals, Government Medical Colleges, and registered private transplant centers. If the brain-dead patient's family consents to donation, the hospital follows established procedures, adhering to a priority list. Mrithasanjeevani has significantly increased successful cadaver transplantations in Kerala. However, a Public Interest Litigation, *Dr. S. Ganapathy v State of Kerala*[118], questioned the credibility of organ donation and brain death certification procedures, alleging improper testing and implementation of the apnea test.

Kerala is the first state to extend its cadaver organ donation administrative organization to also regulate living organ donations, fulfilling the objectives of SOTTO implementation. In February 2018, the Kerala Government issued a Government Order as a Guideline for altruistic and exchange donations[119], regulating these through Mrithasanjeevani to encourage more such donations. The Order defines unrelated donors (distant relatives and altruistic donors) and allows prospective donors to register with Mrithasanjeevani. In altruistic donations, patients cannot choose their donor; Mrithasanjeevani allocates based on medical criteria. A key aspect is the provision for compensation from the recipient to the altruistic donor, covering surgery expenses and providing ₹2 lakh to Mrithasanjeevani (₹1.5 lakh to the donor for income loss and the rest for medical insurance). While innovative for state-level coordination in living donations and donor follow-up, the financial burden on the recipient is a concern, potentially limiting affordability. The Kerala High Court upheld the validity of these guidelines against challenges of promoting commercialization. However, concerns remain about creating a government-regulated paid donation system due to the immediate ₹1.5 lakh payment to the donor. Kerala is also the first Indian state to issue guidelines for brain death certification, following three stages of procedures, including precautions before tests, analysis of brain reflexes, and the Apnea Test, as directed by

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[118] WP(C). No.35526 of 2016. In this case the petitioner alleged that the brain death certifications in Kerala are done without properly conducting the apnea test which is difficult to conduct in alike in different patients' cases. He requested the Court to bring the ECG criteria as a mandatory for certifying the brain death. Otherwise it is very easy to convincing the patient's family that he is dead even though he is alive and thereby the removal of organs can be taken place in such conditions. The petitioner pleaded the High Court to give urgent concern in this matter.

[119] G.O(Ms.)No.26/2018/H&FWD Dated 15-02-2018. This Government order has issued for implementing the Kerala High Court's Judgment in Ganapathy's case.

the Kerala High Court in Dr. S Ganapathy’s case. These "Standard Operating Procedures (SOP)" aim to prevent misuse and clearly differentiate coma from brain death, outlining the scientific diagnosis of brain death.

2.9.3.c The Zonal Transplant Center in Mumbai

This governmental organization, established in 2004, aims to increase cadaver transplantations and assist waiting patients. Its main functions include monitoring deceased donation in Maharashtra, maintaining donor/recipient data registries, and spreading awareness. Hospitals must inform the Zonal Transplant Center about brain-dead individuals, and harvested organs are allocated according to Maharashtra State guidelines. The center's establishment has contributed to the success of the cadaver transplant programme in Maharashtra.

2.10 A Critical Look Towards the Transplantation Law in India

The Act is a commendable step in regulating organ transplantation. Compared to other jurisdictions, it initially adopted a more restrictive approach, lacking provisions solely focused on promoting transplantations, although the 2011 Amendment has brought some positive changes. However, India still has a long way to go in addressing issues related to organ transplantation and donation. Some critical issues within the present Act are discussed below:

2.10.1 Concept of Brain Stem Death

The 1994 Act was the first to legally recognize brain-stem death as a valid criterion for determining death, with Section 3 outlining the authority for organ removal from such individuals. However, mere legal acceptance did not immediately lead to a significant increase in cadaveric transplantations, despite the high number of deaths due to head injuries. The 2011 Amendment has improved this situation by placing a duty on medical practitioners and transplant coordinators to ascertain consent for organ removal in ICU patients nearing death, facilitating the documentation process. The establishment of Human Organ Retrieval Centres and the National/Regional Networks also offers hope for increased cadaveric donations. However, non-transplant hospitals often show limited effort in recognizing and certifying brain death. While some states with better cadaveric donation programmes mandate brain death certification, this is not uniformly implemented nationwide. Diagnosis and donation are primarily feasible in ICUs with necessary support systems, which are concentrated in big city hospitals, negatively impacting donation rates. Greater cooperation from non-transplant hospitals is crucial, given the potential pool of brain-dead donors in major cities.

2.10.2 Combating the Problem of Organ Shortage

Organ scarcity remains a significant challenge, often cited as a root cause of illegal practices. India's large population translates to a substantial need for organ transplants, with the availability of donors being drastically lower[120]. Initial steps to address this included recognizing brain-stem death. The 2011 Amendment introduced measures like mandating transplant coordinators, establishing organ retrieval centers, and creating national and regional networks and registries. However, delays in establishing these institutions and the lack of mandatory brain death certification across all states hinder progress. Only states with their own coordinating mechanisms are showing some success, while others lag behind, necessitating more patient-friendly initiatives[121].

2.10.3 Paid Donations

Paid organ donation is a sensitive issue[122], with India's notorious kidney trade in the 1980s receiving significant media attention. The 1994 Act aimed to address this by regulating transplantation activities and prohibiting commercial dealings in organs and tissues, allowing organ donation only for therapeutic purposes and from near relatives (with stringent checks for unrelated donations based on affection). Non-registered hospitals are also barred from transplantation activities. Despite this legislation, illegal activities persist, as reported by the media. Doctors suggest the Act is not stringent enough to prevent potentially financially motivated unrelated living donations disguised as emotionally driven ones. Kidney rackets continue to be unearthed. Socio-economic disparities and ineffective law implementation are major contributing factors. The Act's primary focus on restriction, rather than on increasing transplantation rates, may inadvertently create loopholes. Donors, with the help of brokers, may find it relatively easy to convince Authorisation Committees of non-commercial altruistic

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[120] http://timesofindia.indiatimes.com/aboutorgandonation.cms (last updated May.09, 2016)

[121] Rahul Anil Pandit, Brain death and organ donation in India, 61(12), INDIAN JOURNAL OF ANAETHESIA, 949-951 (2017)

[122] Anya Adair and Stephen J Wigmore, Paid organ donation: the case against, 93, ANN R COLL SURG ENGL, 188, 188-192 (2011).

motivations[123]. Potential monetary gains and a perceived low risk of legal repercussions may fuel this menace. The booming medical tourism industry in India may also contribute. The inclusion of spouses as potential donors was controversial due to potential exploitation. The 2011 Amendment brought encouraging provisions for needy patients, potentially increasing cadaveric transplantations, which is a key solution to overcoming paid donations. Strict penalties for illegal trade and trafficking are also essential. The 2011 Amendment's requirement for Authorisation Committee approval in cases involving mentally challenged or minor donors, or foreign nationals (even if near relatives), is a positive step, but exploitation may still occur due to the suboptimal use of cadaveric donations.

2.10.4 People Who Are Benefited From The Current System - Not All But The Rich

Organ transplantation in India is largely dominated by the private sector, leading to high costs unaffordable for the poor and even many middle-class individuals. Government hospitals with such facilities are limited. For example, in Kerala, major transplantations are predominantly performed in private super-specialty hospitals[124]. Post-transplant care also incurs significant expenses. Additionally, the recipient typically bears the costs of maintaining a brain-dead patient in the ICU and organ retrieval, as well as expensive transport like air ambulances if needed. In its current form, cadaveric donation in India largely benefits the affluent, serving only a small percentage of those in need. There is a lack of governmental financial assistance, especially in private hospitals.

2.10.5 The Act Is A Regulator Rather Than A Facilitator

The Act is primarily regulatory and restrictive, focusing on preventing malpractices rather than actively facilitating increased transplantation rates and success. Provisions like mandatory brain death certification, consent requirements, informed consent for living donors, restrictions on living donors to near relatives (with Authorisation Committee approval for exceptions), mandatory hospital and tissue bank certification, and stringent penalties highlight this regulatory nature. The Act is sensitive to donor rights, ensuring informed consent and protection against exploitation and being treated

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[123] Saugata Mukherjee, S V Joga Roa and C P Ayyappa, Organ Transplantation and the Law, in MONOGRAPH, 413, 383-425 (S V Joga Rao ed., 2002).

[124] http://knos.org.in/KnosStaticPages/approved-hospitalsfortransplant.aspx (last updated Jan. 19, 2016)

as a commodity. However, it initially offered limited direct justice to patients, except for approving brain death donation. The 2011 Amendment, with the establishment of NOTTO, Human Organ Retrieval Centers, and transplant coordinators, offers some hope, but its administration is reportedly poor. States have a duty to facilitate patients with good transplant infrastructure and increase donation rates, which is also crucial for curbing unethical practices.

2.10.6 Critique

Despite international guidelines addressing organ trafficking and trafficking of persons for organ removal, the Indian Act lacks specific provisions for these offenses, irrationally including them under "commercial dealings". Trafficking is a distinct and more serious crime than commercial dealing, warranting separate sections and penalties. NOTTO should also have the authority to monitor and regulate transplantation costs in private hospitals to prevent irrational pricing. Hospital-based Authorisation Committees are deemed unnecessary, suggesting Rule 12 of the 2014 Rules should be repealed. Furthermore, the Supreme Court's judgment *in Common Cause (A Regd. Society) v Union of India*[125] legalizing passive euthanasia through living wills for terminally ill patients raises significant ethical and legal questions for organ transplantation, as some countries utilize such patients as organ donors. The Act is currently unclear on these issues, necessitating the establishment of ethical practices within the legal framework.

2.10.7 How Organ Transplantation Affects Patient Rights

Organ transplantation in India significantly affects patient rights, primarily concerning the right to health and access to life-saving medical procedures.

- **Right to Health as a Fundamental Right**: The Indian judiciary has expanded the scope of Article 21 of the Constitution, which protects life and liberty, to

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[125] W.P. (CIVIL) NO. 215 OF 2005 (judgment dated Mar.09, 2018). This was a writ petition under Article 32 of the Constitution of India in which the petitioner a registered society who approached the Supreme Court to pass a judgment stating that right to dignity also include right to die with dignity under Article 21 of the Constitution of India. They approached the Supreme Court on behalf of the terminally ill patients

include the right to health as a basic fundamental right[126]. This means that patients suffering from chronic organ failure have a right to seek medical treatment, including organ transplantation, to save their lives.

- **State's Duty to Provide Healthcare**: Article 47 of the Constitution, as part of the Directive Principles of State Policy, states that it is the duty of the State to improve the quality of life of its people and improve primary healthcare[127]. This is interpreted to include the State's responsibility to protect the health of its citizens, which extends to facilitating access to organ transplantation. The State is also expected to ensure that healthcare is accessible to marginalized and vulnerable sections of society and to limit the prices of health facilities to make them affordable.
- **Right to Non-Discrimination:** Article 14 of the Constitution ensures that the State cannot discriminate against any person in providing the right to health and healthcare, implying equal access to transplantation opportunities based on medical need rather than other arbitrary factors.
- **Ethical Duty of Medical Professionals:** The judiciary has established that there is an ethical duty to "save or preserve life[128]" which is binding on both the State and the medical profession. This underscores the obligation of healthcare providers to offer available treatments, including organ transplantation, to patients in need.
- **Regulation for Patient Benefit**: The Transplantation of Human Organs Act, 1994, aims to regulate transplantation as an instrument of saving lives and protecting public health. The establishment of Authorisation Committees and Appropriate Authorities is intended to ensure fair and ethical procedures for

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[126] Baharul Islam, Right to Health: a Constitutional Mandate in India, 3(3), IJARIIE, 2395, 2395-2396 (2017).

[127] Article 47 in The Constitution Of India speaks like: "Duty of the State to raise the level of nutrition and the standard of living and to improve public health The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health".

[128] AIR 1989 SC 2039. This is a PIL filed by a human right activist for getting the directions of the Court in the matter of emergency medical care. The petitioner alleged that in road accident cases, there is unjustifiable delay in providing treatments to the injured only by the reason that the procedures under the law should be initiated. The petitioner also submitted some newspaper reports as evidence in which a vast number of such negligent death of the accident victims were reported.

organ allocation, thereby safeguarding the rights of recipients to receive organs without exploitation or commercial influence. These authorities are expected to be vigilant in ensuring that bonafide applicants are not rejected.

- **Waiting Lists and Allocation**: Mechanisms like the National Organ and Tissue Transplant Organisation (NOTTO), Regional (ROTTO), and State (SOTTO) level organisations aim to maintain centralised databases of organ and tissue recipients. These systems are intended to ensure a transparent and equitable allocation of available organs to patients based on medical urgency and other relevant criteria. Some states, like Tamil Nadu and Kerala, have implemented specific programmes with waiting lists and prioritization norms to ensure fair access.
- **Challenges to Patient Rights**: Despite the legal and administrative frameworks, several challenges persist that affect patient rights in organ transplantation:
  - **Organ Shortage:** The significant mismatch between the number of patients waiting for organs and the availability of organs severely limits the ability of many patients to exercise their right to health through transplantation.
  - **Affordability:** The high cost of transplantation, particularly in the dominantly private healthcare sector, makes it unaffordable for many poor and middle-class patients, creating a disparity in access based on financial status. While some expenses for cadaveric donation might be covered by the recipient, hospital, voluntary organizations, or the government, comprehensive financial assistance is lacking, especially in private hospitals.
  - **Regulatory Focus:** The Act is perceived as being more regulatory than facilitative, with a strong emphasis on preventing illegal activities but potentially lacking in proactive measures to increase donation rates and improve access for patients.
  - **Implementation Gaps:** Despite amendments, effective implementation of the laws and the functioning of bodies like NOTTO have faced delays

and inconsistencies across states, hindering the realization of patient rights to timely transplantation.

- **Exploitation:** While the Act aims to prevent commercial dealings, loopholes and socio-economic disparities still lead to instances of exploitation, particularly of vulnerable donors, which indirectly impacts the ethical foundation of the transplantation system that patients rely on.

Organ transplantation significantly impacts patient rights by offering a potential pathway to life and health, which is increasingly recognized as a fundamental right in India. However, challenges related to organ availability, affordability, and effective implementation of the regulatory framework continue to affect the full realization of these rights for all patients in need of organ transplantation.

2.10 Conclusion

Transplantation is a revolutionary technology offering a chance at a normal life for patients with organ failure. However, the critical obstacle remains the scarcity of organs from both deceased and living donors. India's early lack of specific transplantation laws led to exploitation. The Transplantation of Human Organs Act, 1994, aimed to address this but was insufficient in increasing donation rates, primarily focusing on regulation rather than promotion. The 2011 Amendment, with the establishment of national and regional networks, aimed to boost cadaveric donations, but the transplantation field in India still faces challenges. There is a lack of uniform administrative mechanisms across states, and NOTTO's full and effective functioning has been slow. Only states with their own regulatory institutions have shown better cadaver transplantation rates.

A significant concern is that even after the 2011 Amendment, the Act primarily focuses on increasing transplant numbers, neglecting the issue of affordability. Access to transplantation is not just about organ availability but also financial viability. The dominance of private super-specialty hospitals makes transplantation a costly affair, creating a disparity based on financial status. Government hospitals with necessary facilities are scarce, necessitating urgent infrastructure allocation for transplantation procedures. The government needs to actively promote awareness, perhaps through awards for cadaver donor families and priority for them in case of organ failure. Moreover, a mandatory allocation of a portion of retrieved organs to government hospitals would benefit the poor. Addressing these critical issues is paramount to ensuring equitable access to this life-saving medical advancement and fostering a more ethical and effective organ transplantation system in India.

Having critically analyzed India's legal framework under the *Transplantation of Human Organs and Tissues Act, 1994* (THOTA) in Chapter 2-including its amendments, regulatory mechanisms, and persistent gaps in enforcement-the dissertation now turns to a broader global perspective. Chapter 3 undertakes a comparative examination of organ donation systems in countries like Spain (presumed consent), the United States (opt-in registries), and Iran (regulated compensated donation). By contrasting India's challenges-such as low deceased donation rates and exploitation of the "affection and attachment" clause-with international models that prioritize transparency, public trust, and ethical safeguards, this chapter seeks to identify actionable insights. These comparative insights will later inform recommendations for reforming India's legal and institutional architecture to better protect patient rights while addressing systemic inequities

CHAPTER 3: COMPARATIVE ANALYSIS OF ORGAN DONATION REGULATIONS DIFFERENT COUNTRIES

3.1 Introduction

The advent and subsequent refinement of organ transplantation technology represent one of the monumental achievements of modern medicine[129]. For an increasing number of patients facing life-threatening organ failure, transplantation offers not only the best but often the only viable hope for survival and an improved quality of life. As public awareness of transplantation's potential has grown, so too has the demand for organs, creating a significant global disparity between the number of patients in need and the availability of suitable grafts.

This critical shortage has, unfortunately, fostered the emergence of illicit and unethical practices, most notably the international organ trade. The desperation of potential recipients, coupled with the vulnerability of individuals in impoverished circumstances, has fueled a transnational market where organs are treated as commodities. This phenomenon, encompassing organ trafficking, transplant tourism, and transplant commercialism, has been recognized as a significant health policy issue by the international community and threatens to undermine the fundamental principles of altruism and the ethical legacy of transplantation worldwide[130].

In response to these challenges, a complex web of international and national regulations has evolved, aiming to govern the practice of organ donation and transplantation, protect the rights of both donors and recipients, and combat the burgeoning illegal trade. This chapter undertakes a comparative analysis of these international organ donation regulations, examining the approaches adopted by key international organizations and a selection of nations with diverse legal framework. By exploring the similarities and differences in their regulatory strategies, this chapter seeks to identify prevailing norms, areas of divergence, and the ongoing efforts to establish a more ethical and equitable global system for organ donation and transplantation. The analysis will draw upon the principles and guidelines established by international bodies such as the World Health

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[129] Office of Health Economics (London), Scarce Resources in Healthcare, 57(2), HEALTH AND SOCIETY, 265, 265-287 (Spring, 1979).

[130] Frances L Delmonico, The Implications of Istanbul Declaration in Organ Trafficking and Transplant Tourism, 14(1), CURRENT OPINION IN ORGAN TRANSPLANTATION, 116, 116-119(2009).

Organization (WHO) and the United Nations (UN), as well as the legislative frameworks implemented by countries like the United States, the United Kingdom, Australia, Spain, Singapore, Austria, Belgium, and Iran, each representing distinct models of organ donation regulation.

3.2 The Role of International Organizations in Shaping Organ Donation Regulations

International organizations have played a pivotal role in recognizing the ethical and human rights dimensions of organ transplantation and in advocating for the development of normative standards to guide practices worldwide. Their efforts are crucial in fostering international cooperation and addressing the transnational nature of issues like organ trafficking and transplant tourism[131].

3.2.1 The World Health Organization (WHO): Setting Global Ethical Standards

The World Health Organization (WHO) has been at the forefront of establishing international guidelines and normative standards in organ transplantation. Recognizing the increasing demand for organs and the dangers of uncontrolled trafficking, the WHO has taken significant steps through resolutions of the World Health Assembly.

The impetus for WHO's involvement can be traced back to the 40th World Health Assembly in 1987[132], which, prompted by reports of organ trade and trafficking, called for the development of guiding principles for human organ transplant regulation and practice. This resolution affirmed that organ trade contravenes fundamental human values and the spirit of the Universal Declaration of Human Rights and the WHO Constitution. Subsequent efforts led to the establishment of an informal working group and consultations with international experts[133].

The culmination of these efforts was the WHO Guiding Principles on Human Organ Transplantation, established in 1991[134]. These principles acknowledged the life-saving

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[131] Chare Nullis-Kapp, Organ Trafficking and Transplantation pose new Challenges, 82(4), BULLETIN OF WHO, 715, 715 (Sep., 2004).

[132] WHA resolution 40.13/1987, www.who.int/transplantation/en/WHA40.13.pdf (last updated Dec.20, 2017).

[133]Ibid

[134] WHA resolution 44.25/1991,

importance of transplantation while highlighting the ethical challenges posed by organ scarcity. Key aspects of these guiding principles include:

- Preference for Cadaveric Donation: Guiding principle 3 emphasizes that deceased donation should be given primary consideration.
- Living Donation from Genetically Related Persons: Living donation should ideally be limited to genetically related individuals, except for regenerative tissues like bone marrow.
- Free and Informed Consent: Consent from living donors must be voluntary and based on full information about the risks involved. Procurement of organs from living minor donors is prohibited.
- Prohibition of Commercial Transactions: The guiding principles strictly prohibit commercial transactions[135] in human organs to prevent the commodification of the human body and related illegal practices. This includes banning payment for organs and advertising for organ trade[136], as well as the involvement of healthcare professionals in such activities[137].
- Distributive Justice and Equity: The allocation of organs should be based solely on medical need, without consideration of financial or other advantages[138].

The WHO has continued to update and reinforce these principles. A World Health Assembly resolution in 2004 urged member states to protect vulnerable populations from transplant tourism and organ sale[139] and requested the Director-General to update the Guiding Principles based on new data and ethical considerations. This resolution also promoted international cooperation to increase access to organs for therapeutic purposes.

In 2008, the Executive Board report modified the 1991 principles, which are now referred to as the Principles on Human Cells, Tissues and Organ Transplantation. These updated principles reinforced the importance of informed consent, emphasizing that it

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[135] Guiding principle 5.
[136] Guiding principle 6.
[137] Guiding principle 7.
[138] Guiding principle 9.
[139] BARRY R SCHALLER, UNDERSTANDING BIOETHICS AND THE LAW: THE PROMISES AND THE PERILS OF BIOTECHNOLOGY, 108 (1^‘ ed., 2009). See also JONATHAN MONTGOMERY, HEALTHCARE AND LAW, 421 (3^“ ed., 1997).

must be comprehensive and understandable. Two additional principles were introduced: maintaining high quality and efficacy in transplantation procedures[140] and ensuring transparency and openness for scrutiny while protecting the anonymity and privacy of both donors and recipients[141].

Further solidifying its stance against unethical practices, the WHO adopted the Declaration of Istanbul on Organ Trafficking and Transplant Tourism in 2008[142]. This declaration provided crucial definitions for terms such as organ trafficking (exploitation of donors through coercion or fraud), transplant commercialism (treating organs as commodities), travel for transplantation, and transplant tourism (recipient traveling abroad for transplantation using organs from outside their country). The Declaration outlined principles and proposals aimed at preventing unethical practices and increasing successful transplantation[143] rates through national government involvement[144], international collaboration, and advancements in treatment and research. It stressed the importance of national legislation, transparency, accountability, and safety in transplantation. The Declaration also emphasized the need for national or regional donor registries, public awareness programs, and equitable allocation of organs based on medical need, not on discriminatory grounds. It underscored the principle of national self-sufficiency in organ donation[145] while ensuring the protection of vulnerable populations.

The World Health Assembly resolution 63.22, also known as the Madrid Resolution on Organ Donation and Transplantation (2010), further urged member states to implement the Guiding Principles on Human Cell, Tissue and Organ Transplantation, promote voluntary and altruistic donation, and strongly oppose payment for organs. This resolution reiterated that organ donation and transplantation are national responsibilities and that deceased donation, including donation after brain death, is the preferred source of organs.

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[140] Guiding principle 10.

[141] Guiding principle 11.

[142] The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 3, CLINICAL JOURNAL OF AMERICAN SOCIETY NEPHROLOGY, 1228, 1227-1231 (2008)

[143] Principle 1 of the Istanbul Declaration.

[144] Principle 2.

[145] Principle 5.

3.2.2 The United Nations (UN): Addressing Human Rights Violations in Organ Transplantation

The United Nations (UN), with its broad mandate to protect and promote human rights, has increasingly addressed the human rights violations associated with organ transplantation, particularly organ trafficking and trafficking in persons for organ removal.

The Universal Declaration of Human Rights (UDHR) of 1948, while not explicitly mentioning organ transplantation, provides foundational principles relevant to the ethical conduct of this practice. It upholds the dignity and worth of every human person[146], recognizes the right to life, liberty, and security of person[147], and prohibits slavery and slave trade [148]as well as cruel, inhuman, or degrading treatment[149]. Article 12 also protects the privacy of individuals. Similarly, the International Covenant on Civil and Political Rights (ICCPR) of 1966 recognizes the inherent dignity of every person[150] and guarantees the right to life[151], liberty, and security of person[152]. It also prohibits slavery and slave trade[153] and inhuman or cruel treatment[154], as well as arbitrary encroachment on the right to privacy.

The United Nations Human Rights Commission (now the Human Rights Council) has also expressed concern over trafficking in human beings for organ removal. As early as 1991, its working group on contemporary forms of slavery raised concerns about allegations of trafficking in children for organ removal. In 1996, the Commission on Human Rights called for an examination of the reliability of such allegations[155] and urged states to strengthen laws to punish those involved in organ trafficking, particularly of children[156].

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[146] Preamble of UDHR.
[147] Article 3 of UDHR.
[148] Article 4 of UDHR
[149] Article 5 of UDHR.
[150] Preamble of ICCPR
[151] Article 6 of ICCPR.
[152] Article 9 of ICCPR.
[153] Articles of ICCPR.
[154] Article 7 of ICCPR.
[155] Commission on Human Rights Resolution 1996/61; Report of the Working Group on Contemporary forms of Slavery on its twenty-first session, UN Document E/CN.4/sub.2/1996/24.
[156] Ibid

The United Nations Convention against Transnational Organized Crime (2000)[157] and its Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children (2000) are crucial legal instruments in the fight against organ trafficking. Article 3(a) of the Protocol specifically includes the removal of organs within the definition of 'trafficking in persons' for the purpose of exploitation[158]. Furthermore, the Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography urges state parties to penalize the transfer of organs of a child for profit[159].

A Joint Council of Europe and United Nations study in 2008[160] highlighted the need for a clear distinction between trafficking in organs, tissues, and cells and trafficking in human beings for organ removal, considering them as distinct crimes. While acknowledging that the International Convention against Transnational Crimes effectively addresses the latter, the report called for a new internationally accepted prohibition[161] on trafficking in human organs, tissues, and cells, urging an internationally agreed definition and emphasizing preference for cadaveric donors and the prohibition of financial dealings in human organs[162].

In 2014, the Commission on Crime Prevention and Criminal Justice submitted a report to the UN, with Resolution 23/2 specifically addressing 'Preventing and Combating Trafficking in Human Organs and Trafficking in Persons for the purpose of Organ Removal'[163]. This resolution condemned trafficking for organ removal as a violation of human dignity and urged member states to enact and review laws, regulate medical professionals, and raise awareness to curb these practices[164].

In 2017, the UN General Assembly adopted Resolution 71/322 to strengthen international cooperation against organ trafficking and to promote ethical organ donation and transplantation. The resolution called on member states to combat

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[157] United Nations General Assembly Resolution 55/25 in the year 2000.

[158] Article 3(a) of the Protocol

[159] Article 3 of the Optional Protocol to the Convention on the Rights of the Child

[160] UN General Assembly Resolution on the co-operation between UN and Council of Europe (A/RES/63/14).

[161] https://www.edqm.eu/sites/default/files/medias/fichiers/Joint_Council_of_ EuropeUnited_Nations_Study_on_tral.pdf (last updated Decl4, 2017).

[162]https ://rm.coe.int/168070caab (last updated Dec.l4, 2017).

[163] https://www.unodc.org/documents/commissions/CCPCJ/Crime_Resolutions/20102019 /2014/Resolution_23_2.pdf (last updated Oct.21, 2017)

[164] Vladimir Makei, Trafficking for Human Organs, 49, FMR, 91, 91-92 (2017).

trafficking, improve national laws, and ratify relevant international conventions. It emphasized the importance of ethical principles, such as free consent and altruism, while advocating for oversight of medical professionals and support for victims.

3.2.3 The World Medical Association (WMA):

The World Medical Association (WMA), representing physicians worldwide, has also made significant contributions to the regulation of organ transplantation.

As early as 1985, the 37th WMA General Assembly in Brussels condemned the purchase and sale of human organs for transplantation and called on governments to prevent the commercial use of human organs. In 1987, the WMA established the Declaration on Human Organ Transplantation as a guiding principle for physicians working in transplantation therapy. This declaration stipulated that transplantation should be performed by specially trained physicians in institutions with adequate facilities and explicitly banned the purchase and sale of organs as unethical.

In 2000, the WMA approved new guidance on the ethics of organ and tissue donation and transplantation. This guidance emphasized the physician's obligations to their patients and their families, prioritizing the patient's well-being. It highlighted the necessity of informed consent from living donors and affirmed the right of individuals to refuse donation, even in countries with presumed consent systems. The WMA also encouraged national medical associations to develop national organ donation strategies, including donor registries, to ensure transparency and reiterated the strict prohibition of payment for organs.

This 2000 guidance was revised by the WMA in 2006[165]. The revised principles affirmed the physician's responsibility towards society, including the fair use of resources, preventing harm, and promoting healthy organ donations. Transplant surgeons were urged to ensure that organs used for transplantation were not obtained through illegal or unethical means. The WMA again emphasized the medical profession's responsibility to promote organ transplantation and underscored the importance of justice in access to organs, fairness and efficiency in managing waiting lists, and the selection of patients based solely on medical need.

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[165] Adopted by 52"“ WMA General Assembly, Edinburgh, Scotland, Oct.2000.

3.2.4 European Union's Role in regulating organ transplantation

The Council of Europe, as a prominent regional human rights mechanism, has also actively addressed organ transplantation and donation through various documents and legal instruments. Since 1958, the European community has shown concern for issues related to substances of human origin[166].

In 1978, the Council of Europe introduced a resolution on the harmonization of legislations of member states relating to removal, grafting, and transplantation of human substances. This resolution recommended member states to introduce new laws, enforce strict punishments for unethical practices, and raise public awareness about the importance of transplantation. An appendix to the resolution provided specific rules for the removal and transplantation of human substances from both living and deceased persons. These rules addressed consent requirements, particularly for minors and incompetent persons, emphasizing the need for free and informed consent and the provision of comprehensive information. For non-regenerative substances, written consent was mandated, and removal was generally limited to genetically identical persons, except in cases with a high chance of success. The rules also prioritized the donor's health and life, requiring thorough medical examinations and well-equipped institutions for removal. In the case of deceased donors, respect for their religious and philosophical convictions and the acceptance of brain death as a criterion for death were highlighted. The resolution also allowed the removal of human substances for therapeutic, diagnostic, and research purposes under suitable conditions, while explicitly stating that human substances must not be offered for profit.

The Committee of Ministers to the Member States concerning International Exchange and Transportation of Human Substances (1979) recommended facilitating the safe and speedy international exchange of human substances for therapeutic purposes and the benefit of recipients, prohibiting their removal for any profit.

The Council of Europe further established Guidelines on legislative measures in relation to Organ Transplantation. Recommendation 1100 (1989) on the Use of Human Embryos and Fetuses in Scientific Research addressed the donation of human

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[166] Article 3 of European Agreement on the Exchange of Therapeutic Substances of Human Origin, 1958 states "no profit shall made on them, that they shall be used solely for medical purposes and shall be delivered only to bodies designated by the Governments concerned".

embryological materials for scientific research (diagnostic, prevention, or therapeutic purposes), strictly prohibiting their sale and requiring written consent from donors and parents of minor donors, also forbidding any commercial aspects.

The Recommendation of the Committee of Ministers to Member States on Human Tissue Banks (1994) provided guidelines for regulating tissue banks, emphasizing non-profit operations, official licensing, testing for transmittable diseases, and the maintenance of confidential records.

A landmark contribution was the Council of Europe Convention on Human Rights and Biomedicine (1997). Chapter VI specifically addressed organ and tissue removal from living donors for therapeutic purposes, permitting it only when suitable organs from deceased persons are unavailable and mandating written consent. Chapter VII explicitly prohibited financial gain and the disposal of any part of the human body.

The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2002) recognized the progress in transplantation and the need to increase organ donation while addressing ethical, psychological, and socio-cultural concerns and preventing commercialization. It mandated official waiting lists in member states, with patient selection based on professional obligations and standards. The main aim of the protocol is to uphold dignity and freedom with respect to transplantation without any discrimination[167]

Subsequent recommendations from the Committee of Ministers focused on establishing Organ Donor Registers (2003)[168], combating organ trafficking (2004)[169] by prohibiting commercialism (with exceptions for legitimate costs and compensation), setting criteria for the authorization of organ transplantation facilities (2004[170]), defining the role and training of organ donation coordinators (2005), and establishing quality improvement programs for organ donation (2006)[171]. The Council of Europe Convention on Action against Trafficking in Human Beings (2005)[172] also included trafficking for the removal

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[167] Article 1 of Additional Protocol.

[168] Supra note 53

[169] https://www.edqm.eu/sites/default/files/recommendation_no_2004_7_of_the_committee_ of_ministers_to_member_states_on_organ_trafficking.pdf (last updated Dec.20, 2017).

[170] https://www.edqm.eu/en/legal-framework#Council of Europe and CD P TO framework (last updated Dec.20, 2017).

[171] http://eur-lex.europa.eu/legal- content/ga/TXT/?uri=CELEX:52007DC0275 (last updated Dec.20, 2017)

[172] Supra note 54

of organs in its definition. Further recommendations in 2008, 2013, 2015, and 2017 aimed at improving the quality of transplantation, establishing principles for non-resident living donors, and ensuring follow-up care for patients receiving transplants abroad.

Most notably, the Council of Europe Convention against Trafficking in Human Organs (2015) specifically targets organ, tissue, and cell trafficking in Europe, aiming to protect victims and foster international cooperation to combat this crime[173]. Article 5 prohibits the use of illicitly taken organs, and Article 16 urges prosecution and punishment of offences, emphasizing victim protection and well-being[174].

The Council of Europe's extensive array of legal instruments and recommendations demonstrates a strong regional commitment to establishing comprehensive and ethically sound regulations for organ donation and transplantation, often going beyond the scope of global initiatives.

3.3 Comparative Analysis of National Organ Donation Regulations:

This section examines the legal framework of various countries, emphasizing their different approaches to organ donation and transplantation. The selection criteria focused on jurisdictions that embody contrasting philosophical views on consent, legal systems that align with India’s socioeconomic context, and innovative strategies for addressing organ shortages. The study looks into both opt-in and opt-out consent models to determine their effects on donation rates and ethical protections. It included jurisdictions with distinctive regulatory measures to mitigate exploitation risks, such as compensated donation frameworks enforced by strict ethical standards, as well as those with legal traditions similar to India for evaluating the adaptability of legislative approaches. The analysis targets systems that contend with overlapping challenges, such as healthcare inequities, cultural reservations concerning body integrity, and the conflict between altruism and commercialization. By combining these varied perspectives, the study seeks to derive practical insights for enhancing India’s regulatory framework while protecting patient rights, encouraging ethical practices, and addressing the significant gap between the supply and demand for organs.

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[173] Article 7, 8 and 9 of the Convention

[174] Article 18 of the Convention.

3.3.1 Opt-in Systems (Explicit Consent):

Countries with opt-in systems require explicit consent from the deceased individual (prior to death) or their family for organ donation to proceed. Countries with opt out sysem have increased organ donation rate rather the countries follow opt in.[175]This model prioritizes individual autonomy and the right to decide what happens to one's body after death. The United States, the United Kingdom, and Australia are prominent examples of countries that have historically operated primarily under opt-in systems[176], although some regional variations exist.

3.3.1.1 United States

The United States has a multi-layered legal framework governing organ transplantation, primarily based on state laws supplemented by federal legislation. The Uniform Anatomical Gift Act (UAGA), first introduced in 1968 and subsequently revised (most recently in 2006), serves as a model law [177]adopted by nearly all states, providing a legal basis for individuals to donate their organs and tissues. The UAGA clarifies the authority of relatives to consent to donation on behalf of a deceased person[178]. The Uniform "Organ Donor Card", mandated in 1972, provided a standardized mechanism for individuals aged 18 and over to pledge organ donation. The revised UAGA of 2006 further empowered individuals through driver's license designations, encouraged donor registries, and restricted family override of authorized donation[179].

Federal legislation plays a crucial role, notably the National Organ Transplant Act (NOTA) of 1984. NOTA aimed to increase the supply of organs by establishing a Task Force on Organ Transplantation and the Organ Procurement and Transplant Network

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[175] Lee Shepherd, Ronan E O'Carroil and Eamonn Ferguson, An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems; a panel study, 12, BMC MEDICINE (2014) (Mar.l8, 2018) http://www.biomedcentral.com/1741- 7015/12/131

[176] C. Rudge, R. Matesanz, F. L. Delmonico and J. Chapman, International practices of organ donation, 108, BRITISH JOURNAL OF ANAESTHESIA, 50-51, 48-55 (2012).

[177] I. G. Cohen, Can the Government Ban Organ Sale? Recent Court Challenges and the Future of US Law on Selling Human Organs and Other Tissue, 12, AMERICAN JOURNAL OF TRANSPLANTATION, 1983, 1983-87 (2012)

[178] Section 2(b) of the Act.

[179] W. J. Chonl,, M. A. Josephson et. al. When the Living and the Deceased Cannot Agree on Organ Donation: A Survey of US Organ Procurement Organizations (OPOs), 14, AMERICAN JOURNAL OF TRANSPLANTATION, 173, 172-177 (2014).

(OPTN)[180]. It also authorized financial assistance for organ procurement organizations (OPOs). NOTA prohibits any payment for organs from living donors, although it allows for the reimbursement of reasonable expenses related to donation, such as travel and lost wages[181]. The OPTN maintains a national waiting list for individuals needing transplants and develops organ allocation policies. The Organ Donor Leave Act of 1999 provided federal employees with paid leave for organ donation. Subsequent legislation, such as the Organ Donation and Recovery Improvement Act of 2004 and the Charlie W Norwood Living Organ Donation Act of 2007, focused on promoting donation through public awareness programs, reimbursement of expenses for living donors, and clarification of paired donation. The Stephanie Tubbs Jones Gift of Life Medal Act of 2008 established a national medal to honor organ donors and their families.

US courts have also addressed complex ethical and legal issues, such as the admissibility of organ removal from incompetent persons. Early cases like Strunk v. Strunk (1969)[182] allowed such donation based on the "substituted judgment" doctrine, arguing it was in the incompetent person's best interest. However, later cases like Re Guardianship of Pescinski (1975)[183] took a more restrictive view, emphasizing that courts should not authorize such procedures without explicit legal authority and evidence of the incompetent person's wishes.

The US system, while primarily opt-in, relies heavily on OPOs to identify potential donors and secure consent, often engaging in marketing activities to encourage donation. Allocation policies prioritize local, then regional, then national matching, considering medical status, blood type, tissue type (for kidneys), and time on the waiting list.

3.3.1.2 United Kingdom

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[180] Section 101 of the Act.

[181] Section 301 of the Act.

[182] 445 S.W.2d 145 (1969). In this case a couple had two sons and amongst this two sons, one was an incompetent adult. Their competent son got chronic kidney failure and medical practitioners find that the incompetent son' s kidney is identically match to him. But then the issue was that is it possible for the parents to give consent on behalf of their incompetent son for donating his organ.

[183] 67 Wis. 2d 4, 226 N. W 2d 180 (1975). In this case Richard Pescinski was an incompetent adult having 31 years of age. His sister was suffering from chronic kidney failure and Pescinski was medically identified as a suitable organ donor for her sister. Here also the proposed donor was an incompetent, the issue came to the Court to decide on the matter of giving consent to organ removal.

The UK's legal framework for organ donation has evolved significantly, starting with the Human Tissue Act of 1961. This law regulated the use of deceased individuals' body parts for medical purposes and allowed individuals to express their wish to donate organs during their final illness. It permitted those in lawful possession of a deceased person's body to authorize organ removal if the deceased had not opposed it and the relatives did not object. While the Act prohibited unauthorized use of body parts, it initially lacked clear penalties for violations.

The Human Organ Transplant Act of 1989 specifically aimed to prohibit commercial dealings in human organs in section 1. Restricted transplantation between genetically unrelated living persons without special authorization. Section 2 makes removal of any organ from a living person for transplantation an offence, if the donor and the recipient are not genetically related[184] . It defined "payment" to include money or money's worth[185] but excluded reimbursement for costs related to removal, transport, preservation, or expenses incurred by the donor. While generally restricting unrelated living donation, the Act allowed the Secretary of State to make regulations permitting such transplants under certain conditions, ensuring no commercial involvement. [186]The Act, however, remained unclear on the capacity of mentally incompetent adults to act as living donors, a matter addressed in case law. Cases like *F v West Berkshire Health Authority (1989)*[187] suggested that donation could be permissible if deemed in the best interest of the incompetent person, although this was not directly related to treating the incompetent's illness but rather benefiting another. Conversely, *Re T (a minor) (Wardship: medical treatment)*[188]upheld parents' refusal of a life-saving transplant for

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[184] Section 2(2) of the Act clearly mention a person is genetically related to (a) His natural parents and children; (b) His brothers and sisters of whole or half blood; (c) The brothers and sisters of whole or half blood of either of his natural parents; and (d) The natural children of his brothers and sisters of whole or half blood or of the brothers and sisters of the whole or half blood of either of his natural parents.

[185] Section 1(3) of the Act says “payment” means payment in money or money worth, but does not include any payment for defraying or reimbursing (a) Those cost of removing, transporting or preserving the organ to be supplied; or (b) Any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying an organ from his body.

[186] JEAN MACHALE, MARIE FOX AND JOHN MURPHY supra note 129, at 905.

[187] [1989] 2 All E.R 454. In this case the well wishers of an incompetent adult woman approached the Court for undergoing her the sterilization. It is because of the fact that she is not capable of taking a decision because of her mental incompetency.

[188] [1997] 1 All ER 906. A child aged 18 months faced severe liver failure, with only three weeks to live without a transplant. His parents, both medical professionals, declined the liver transplant due to their previous experience; the baby had undergone an unsuccessful surgery at three weeks old, which caused him significant pain and distress.

their child, emphasizing the weight of parental decisions made in the child's best interests.

The Human Tissue Act of 2004 significantly updated the legal framework, focusing on consent for the removal, storage, and use of human organs and tissues for scheduled purposes, including transplantation and established detailed consent requirements for both child and adult donors, whether living or deceased. The Act also created the Human Tissue Authority to regulate activities involving human tissue, including removal, use, storage, import, export, and disposal, requiring licenses for these activities. Section 32 of the 2004 Act explicitly prohibits commercial dealings in human materials for transplantation, and section 33 restricts transplantation on a live donor ,mirroring the 1989 Act.

While the UK has historically operated under an opt-in system, there has been a recent shift in Wales with the introduction of the Human Transplantation (Wales) Act of 2013, moving

towards a soft opt-out system or presumed consent[189]. Under this law, adult residents of Wales who die there are deemed to have consented to organ donation unless they had previously registered their objection[190]. Exceptions exist for those under 18, lacking capacity to understand deemed consent, those who appointed authorized representatives, and cases where family or friends oppose donation based on the belief that the deceased would not have consented[191]. In the absence of such opposition, the Human Tissue Authority can proceed with organ removal without needing to seek explicit consent.

The UK's organ procurement system continues to rely on the opt-in model for the majority of the country, with ongoing efforts to promote registration on the NHS Organ Donor Register.

3.3.1.3 Australia

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[189] Jane Noyes,! Karen Morgan et. al, Family attitudes, actions, decisions and experiences following implementation of deemed consent and the Human Transplantation (Wales) Act 2013: mixed-method study protocol, 7, BMJ (2017) (Dec.20, 2017)

[190] Section 4 of the Wales Human Tissue Act, 2013

[191] section 4 and 5 of the 2013 Act.

In Australia, the regulation of organ and tissue donation and transplantation is determined by the federal Australian Organ and Tissue Donation and Transplantation Authority Act of 2008, along with various state legislation. This includes the Greenland Transplant and Anatomy Act of 1979, the New South Wales Human Tissue Act of 1983, the South Australia Human Tissue and Transplantation Act of 1983, the Western Australia Human and Tissue Transplant Act of 1982, the Northern Territory Human Tissue and Transplant Act of 1979, the Victoria Human Tissue Act of 1982, and the Australian Capital Territory Transplantation and Anatomy Act of 1979.

Under the state Human Tissue Acts (enacted around 1982-1983 in most jurisdictions), next of kin or an authorized person can make decisions regarding organ removal from a deceased person for transplantation[192]. Living adult persons can consent to donate regenerative tissue, while consent for non-regenerative tissue donation must be in writing and specific to the day of donation[193]. Donation of a child's regenerative tissue is permitted only with parental consent and for transplantation to a parent, sibling, and requires a medical practitioner's certificate confirming the child's capacity and informed understanding. Section 32 of the Human Tissue Acts in various states explicitly prohibits any trading in human tissues including contracts for sale, offers for sale, and supply for commercial benefit, with penalties for violations[194].Act sets punishments for medical ractitioner for removing organs or tissues from the body without consent or authority.[195]

In 2008, the Australian Parliament enacted the Australian Organ and Tissue Donation and Transplantation Authority Act, which established the Australian Organ and Tissue Donation and Transplantation Authority. This Act defines an organ broadly[196] and outlines the Authority's role in assisting the Chief Executive Officer with policy-making on organ donation, regulating transplantation standards, and providing training programs for professionals in the field.

Australia operates under an opt-in system for organ donation, encouraging individuals to register their donation wishes on the Australian Organ Donor Register. Organ

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[192] Section 5D of the Human Tissue Act

[193] section 7 and 8 of the 1983 Act.

[194] Section 33H of the Act.

[195] Section 36 of the Act.

[196] Section 4 of the Act defines organ as: “organ means an organ of a human body (within the ordinary meaning of that expression)”.

allocation protocols are developed by the Transplantation Society of Australia and New Zealand (TSANZ) and the Australian Transplant Co-ordinators Association (ATCA). The Australian government supports organ donation through the Australian Organ and Tissue Donation and Transplantation Authority and national awareness programs.

3.3.2 Opt-out Systems (Presumed Consent):

In contrast to opt-in systems, opt-out systems, also known as presumed consent, presume that an individual consents to organ donation after death unless they have explicitly registered their objection during their lifetime. This facilitates organ donation This model aims to increase organ donation rates by making non-donation an active choice. Several European countries, as well as Singapore, have adopted opt-out systems. Countries with opt-out laws tend to have significantly higher organ donation rates (25-30% higher) compared to those requiring explicit consent.

3.3.2.1 Spain

Spain is often cited as a leading country in organ donation, achieving high donation rates (around 36 donors per million people) after shifting to a presumed consent system in 1989 and establishing the *Organización Nacional de Trasplantes* (ONT) in 1989. While the specific law governing the Spanish model is not detailed in the source, the effectiveness of their system is attributed to the opt-out policy and a well-organized national transplant organization with regional and hospital-based coordination, a focus on brain death donors, and quality assurance. Individuals who do not wish to donate can register their objection with the Health Department .

3.3.2.2 Singapore

Singapore was the first Asian country to adopt a presumed consent system with the enactment of the Human Organ Transplant Act in 1987. Section 5 of the Act permits organ removal after confirming brain death, with certain exceptions, including individuals who have expressly registered their objection, non-citizens or non-permanent residents, those under 21 or over 60 years of age.[197]A Director is appointed

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[197] Section 5 of the Human Organ Transplant Act, 1987.

to manage objections and withdrawals. Interestingly, individuals who have registered an objection and subsequently need an organ transplant are placed lower on the waiting list than those who did not object[198]. This shift to an opt-out system significantly increased organ transplantation rates in Singapore, heavily relying on brain death donations.

3.3.2.3 Austria and Belgium

Austria operates a "true" presumed consent system where organ donation proceeds unless an individual has explicitly stated their objection in writing[199]. In normal cases, donation is not discussed with families unless they raise the issue, with exceptions only for pediatric patients and foreigners[200].

Belgium adopts a "soft" opt-out system, protecting individual autonomy through the registration of individual refusals[201]. While families have no legal choice to override a registered refusal, strong family opposition to donation is taken into account. Belgian law also discourages the use of living donors for organ donation[202].

3.3.2.4 Variations in Opt-out Systems

As highlighted in the source, opt-out systems can be implemented as a "hard" option, where only the deceased's registered objection is considered, or as a "soft" option, where family consultation is undertaken to "confirm" the deceased's likely wishes even in the absence of a registered objection. The effectiveness of an opt-out system is contingent on public awareness about brain death and the importance of organ donation[203]. Factors such as the availability of potential donors, transplant infrastructure, healthcare investment, and public attitudes also play a significant role in the success of such systems[204].

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[198] Section 12.

[199] Maxwell J. Mehlman, Presumed Consent to Organ Donation: A Reevaluation, 1(31), HEALTH MATRIX, 41, 31-66 (1991)

[200] Ibid

[201] Paul Michielsen, Presumed consent to organ donation: 10years' experience in Belgium, 89, JOURNAL OF THE ROYAL SOCIETY OF MEDICINE, 663, 663-666 (Dec., 1996).

[202] Ibid

[203] Jyotika Kaushik, Organ transplant and presumed consent: towards an "opting out" system, 6(3), INDIAN JOURNAL OF MEDICAL ETHICS, 150, 149-152 (Sept., 2009).

[204] Amber Rithalia, Catriona McDaid et.al. Impact ofpresumed consent for organ donation on donation rates: a systematic review, BMJ (Dec.08, 2017)

3.3.3 Iran

Iran stands out as the only country in the world that legally permits organ trade, specifically for living non-related kidney donation. In 1988, Iran legalized this practice and established a government-organized system called the Iranian model renal transplant program, managed by the Patient Kidney Foundation. This system matches living donors and recipients, oversees monetary transactions, medical assessments, and donor consent. Regulations stipulate that donors must be of the same nationality as the recipient, between 20 and 35 years old, have spousal or parental written consent, and be in good health. Cadaveric organ donation in Iran follows an informed consent model, regulated by the Organ Transplantation and Brain Death Act of 2000, which requires brain death to be diagnosed by four specialists[205]. The legalization of living unrelated kidney donation was partly driven by the lack of infrastructure for cadaveric organ preservation and transport[206], as well as religious taboos against removing organs from the deceased[207]. Iranian kidney donors receive one year of government healthcare and, in some regions, lifelong health insurance[208].

While intended to address organ shortage and curb transplant tourism (requiring donor and recipient to be of the same nationality), the Iranian system has faced significant criticism. Opponents argue that it leads to the exploitation of poor donors who are often compelled by their socio-economic circumstances to sell their kidneys. The commercial aspect also means Iran lacks a comprehensive kidney register, hindering scientific evaluation of outcomes. Despite the legal framework, concerns persist that only wealthier individuals can afford transplants, further exacerbating social inequalities[209]. Consequently, Iran is now exploring ways to increase brain death donations as an alternative.

3.4 Comparative Analysis

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onation rates: a systematic review, BMJ (Dec.08, 2017)

[205] B. Larijani, F. Zahedi, and E. Taheri, Ethical and Legal Aspects of Organ Transplantation in Iran, 36, TRANSPLANTATION PROCEEDINGS, 1241, 1241-1244 (2004).

[206] SIGRID FRY-REVERE, THE KIDNEY SELLERS, 50 (1'" ed., 2014).

[207] Adam Crepelle, A Market for human organs: an ethical solution to the organ shortage, 13(1), INDIANA HEALTH LAW REVIEW, 57, 18-81 (2016).

[208] SIGRID FRY-REVERE, supra note 100

[209] Adam Crepelle, supra note 101

The preceding analysis of international and national regulations reveals both common threads and significant divergences in approaches to organ donation and transplantation. Several key regulatory aspects warrant further comparative analysis:

- **Definition of Death**: The acceptance of brain death as a legally valid criterion for death is fundamental to deceased organ donation. Most countries with established transplantation programs, including the US, UK (through common law judgments), Australia, and those with opt-out systems, recognize brain death. This recognition allows for the retrieval of viable organs from individuals who have suffered irreversible cessation of brain function but whose other organs may still be functioning with artificial support.
- **Consent Models**: As discussed, consent for organ donation varies significantly. Opt-in systems prioritize explicit consent, either through registration or family authorization. Opt-out systems presume consent unless an objection is registered, potentially leading to higher donation rates. Variations within opt-out systems exist, such as "hard" versus "soft" models, impacting the role of family consultation. The context of consent for living donation also differs, with regulations focusing on ensuring free and informed consent, restrictions on donation by minors and potentially incompetent adults, and, in most countries, the prohibition of commercial incentives.
- **Prohibition of Commercialism and Illegal Practices:** A near-universal consensus exists among international organizations and the majority of nations regarding the prohibition of commercial transactions in human organs. This stance is rooted in ethical concerns about the commodification of the human body and the potential for exploitation of vulnerable individuals. Legal framework in countries like the US (NOTA), UK (Human Organ Transplant Act and Human Tissue Act), and Australia (Human Tissue Acts) explicitly outlaw organ sale. International bodies like the WHO and the Council of Europe have also strongly advocated against commercialism and for measures to combat organ trafficking and transplant tourism. Iran's unique legal allowance for compensated living unrelated kidney donation remains an exception and is subject to significant ethical debate.

- **Organ Allocation and Waiting Lists**: Most countries with established transplantation programs utilize national or regional waiting lists to manage the allocation of deceased donor organs. Allocation policies generally aim to prioritize patients based on medical urgency, compatibility (blood type, tissue type), and time spent on the waiting list, striving for fairness and equity. The OPTN in the US, national transplant databases in the UK, and the Australian Organ Donor Register and allocation protocols exemplify these systems.
- **Support for Donors and Recipients:** Regulations often address the need for support for both organ donors and recipients. This includes provisions for reimbursement of legitimate expenses for living donors (e.g., travel, lost wages in the US and some European frameworks), medical and psychological care for both donors and recipients, and in some cases, consideration for life insurance coverage and job opportunities for donors (as suggested by the Declaration of Istanbul). The Iranian model uniquely provides government healthcare and, in some cases, lifelong health insurance for living kidney donors.
- **Role of National Organizations and Registries**: Many countries have established national organizations (e.g., OPTN in the US, Human Tissue Authority in the UK, Australian Organ and Tissue Donation and Transplantation Authority, Organización Nacional de Trasplantes in Spain) to oversee and coordinate organ donation and transplantation activities. National donor registries play a crucial role in recording individuals' donation wishes, particularly in opt-in systems.

3.5 Challenges

Despite the significant progress in establishing international and national regulations for organ donation and transplantation, several challenges persist, demanding ongoing attention and collaborative efforts:

- **Addressing the Global Shortage of Organs**: The fundamental challenge remains the persistent gap between the demand for and the supply of organs. While various strategies, including promoting deceased donation through opt-out systems and public awareness campaigns, have shown some success, innovative approaches and continued efforts are needed to increase the donor pool ethically.

- **Harmonizing International Regulations**: The diversity of national legal framework can create complexities, particularly in cross-border issues like transplant tourism and the prosecution of organ trafficking offenses. Greater harmonization of key definitions, ethical principles, and legal standards across nations could enhance international cooperation in combating illegal activities and ensuring consistent protection for donors and recipients. The ongoing efforts by the WHO and the Council of Europe to establish international norms contribute to this goal.
- **Combating Organ Trafficking and Transplant Tourism**: Despite international conventions and national laws, organ trafficking and transplant tourism remain significant concerns. Strengthening law enforcement, improving international cooperation in investigation and prosecution, and addressing the socio-economic vulnerabilities that drive both the supply and demand sides of this illicit trade are crucial.
- **Ethical Considerations in Diverse Contexts**: Navigating the ethical complexities of organ donation and transplantation requires sensitivity to diverse cultural, religious, and societal values. Regulations need to be adaptable enough to respect these differences while upholding fundamental ethical principles such as consent, altruism, and justice.
- **The Need for a UN Convention**: As highlighted in the source, the absence of a specific UN convention dedicated solely to combating organ trafficking, despite its inclusion under transnational crimes, represents a gap in the international legal framework. A dedicated UN convention could provide a more comprehensive and universally binding instrument to address this specific form of human trafficking, facilitating greater international cooperation and legal accountability. The Council of Europe's 2015 Convention against Trafficking in Human Organs serves as a regional model in this regard.

3.6 Conclusion

The comparative analysis of international organ donation regulations reveals a complex and evolving landscape. International organizations like the WHO, UN, and Council of Europe have been instrumental in establishing ethical principles, raising awareness about human rights violations, and advocating for legal framework to govern this critical area of medical practice. National regulations exhibit significant diversity, reflecting differing cultural values and approaches to balancing individual autonomy with the societal need for life-saving organs. Opt-in systems prioritize individual choice, while opt-out systems aim to increase donation rates by making non-donation an active decision. The near-universal condemnation of organ commercialism underscores a fundamental ethical principle, although the unique case of Iran highlights the complexities of addressing organ shortage in specific socio-economic and cultural contexts.

Moving forward, continued international cooperation, greater harmonization of legal standards, and a concerted effort to combat organ trafficking and transplant tourism are essential to ensure a more ethical and equitable global system for organ donation and transplantation. Addressing the root causes of organ shortage, while upholding the dignity and rights of all individuals, remains the ultimate goal of these regulatory endeavors. The ongoing dialogue and development of legal and ethical frameworks at both international and national levels are crucial steps towards realizing the full potential of organ transplantation as a life-saving therapy grounded in principles of altruism and justice.

Chapter 3 provides critical benchmarks for evaluating India’s regulatory landscape. Building on these insights, Chapter 4 scrutinizes the efficacy of the *Transplantation of Human Organs and Tissues Act, 1994* (THOTA), particularly its failure to replicate Spain’s success in deceased donations (India: 0.8 donors per million) or the U.S.’s transparency in allocation. By contrasting THOTA’s subjective "affection and attachment" clause with Spain’s standardized consent protocols and the U.S.’s rigorous oversight, this chapter exposes systemic gaps in enforcement, infrastructure, and ethical safeguards that perpetuate exploitation and inequities in India’s transplantation ecosystem.

CHAPTER 4: ASSESSING THE EFFECTIVENESS OF ORGAN DONATION LAWS IN INDIA

4.1 Introduction: The Landscape of Organ Donation Legislation in India

The Transplantation of Human Organs and Tissues Act,1994 (THOTA) represents a watershed moment in India's approach to organ transplantation. Enacted on July 8, 1994, and brought into force from February 4, 1995, this legislation emerged as a response to growing concerns regarding unethical organ procurement practices and commercial and commercial exploitation of vulnerable populations[210]. The primary objective of THOTA is multifold: to regulate the removal, storage and transplantation of human organs for therapeutic purposes; to prevent commercial dealings in human organs; and to establish a structured legal framework for both living and deceased organ donation in India.[211]

The Act has undergone significant amendments, most notably in 2011 and subsequently through rules formulated in 2014, to address emerging challenges and strengthen its regulatory framework. The Transplantation of Human Organs Amendment Act 2011, passed by both Houses of the Parliament in August 2011, expanded the scope of the original legislation by incorporating provisions for tissues alongside organs and introducing more stringent penalties for violations.[212]

Three decades after it initial enactment, it becomes imperative to critically evaluate the effectiveness of this legislation in achieving its stated objectives. This chapter undertakes a comprehensive assessment of THOTA's impact on India's organ donation and transplantation landscape, particularly focusing on its efficiency in curbing illicit organ trade, promoting ethical donation practices, and safeguarding the rights of donors and recipients alike.

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[210] The Transplantation of Human Organs and Tissues Act, 1994, No. 42, Acts of Parliament, 1994 (India).

[211] National Organ and Tissue Transplant Organisation (NOTTO), Annual Report 2023-24, Ministry of Health and Family Welfare, Government of India (2024).

[212] The Transplantation of Human Organs (Amendment) Act, 2011, No. 16, Acts of Parliament, 2011 (India).

India faces a monumental challenge in addressing the organ shortage crisis. According to reports, hundreds of thousands of patients across the country await life-saving organ transplants, with annual requirements for vital organs like kidneys and livers far exceeding available donations[213]. This stark disparity between demand and supply creates conditions conducive to exploitation and illegal organ trafficking, precisely what THOTA aims to prevent.

This chapter will systematically analyse how effectively the legislation has addressed these challenges over the years, examining both its achievements and shortcomings in implementation, enforcement and overall impact on India's organ donation ecosystem.

4.2 The Regulatory Framework of THOTA:

4.2.1 Core Provisions and Regulatory Mechanisms

The Transplantation of Human Organs and Tissues Act establishes a comprehensive regulatory framework governing various aspects of organ donation and transplantation. At its core, the act prohibits commercial dealings in human organs and mandates that organ transplantation should only be performed for therapeutic purposes[214]. It created a structured system for both living and deceased organ donation, with specific provisions to ensure informed consent, prevent exploitation, and establish regulatory oversight.

Key provisions of the original Act and its subsequent amendments include the definition and scope , the Act provides a clear definition of terms such as "human organ"," donor"," recipient " and "near relative", establishing the legal parameters for transplantation activities[215]. The 2011 amendment expanded these definitions to include tissues alongside organs, recognising the evolving nature of transplantation medicine. Establishment of regulatory bodies, the Act mandated the establishment of authorisation committees at the state level to approve or reject transplants between

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[213] Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOs/SOTTOs, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India (2020).

[214] The Transplantation of Human Organs and Tissues Act, 1994, § 9, No. 42, Acts of Parliament, 1994 (India).

[215] The Transplantation of Human Organs and Tissues Act, 1994, § 2, No. 42, Acts of Parliament, 1994 (India).

recipients and Donors who are not “near relatives”.[216] These committees serve as gatekeepers, scrutinising applications to ensure genuine, non-commercial motives behind donations. Providing specific consent mechanisms, like a detailed protocol for obtaining consent, differentiating between living donors and procedures for organ retrieval after such determination.[217] The Act provides for registration requirements, such as requiring a hospital performing organ transplantation to register with the appropriate authorities, ensuring they meet specific standards and follow established protocols.[218] Finally penalties for violations , THOTA prescribes stringent penalties, including imprisonment and substantial fines, for contraventions such as commercial dealings in organs, removal of organs without proper authority, or performing transplantation procedures at unregistered hospitals.[219]

4.2.2 Amendments and Evolution of the Legal Framework

The 2011 amendment to THOTA introduced several significant changes to strengthen the regulatory framework. These included**,** the amendment broadened he definition of “near relative” to include grandparents, grandchildren, and others, increasing the pool of potential related donors thus expanding the scope.[220]It introduced provisions for regulating tissue banks, recognising their growing importance in the transplantation ecosystem.[221] The amendment mandated the appointment of transplant coordinators in the hospitals registered for organ transplantation, enhancing the institutional capacity to facilitate the donation process. Which inturn strengthened the infrastructure.[222] It introduced specific regulations regarding organ donation involving minors and foreign nationals, addressing previously unregulated areas where potential avenues for exploitation.[223]The amendment laid the groundwork for establishing a national registry

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[216] The Transplantation of Human Organs and Tissues Act, 1994, § 9(4), No. 42, Acts of Parliament, 1994 (India).

[217] The Transplantation of Human Organs and Tissues Act, 1994, § 3, No. 42, Acts of Parliament, 1994 (India).

[218] The Transplantation of Human Organs and Tissues Act, 1994, § 14, No. 42, Acts of Parliament, 1994 (India).

[219] The Transplantation of Human Organs and Tissues Act, 1994, § 18-20, No. 42, Acts of Parliament, 1994 (India).

[220] The Transplantation of Human Organs (Amendment) Act, 2011, § 2(b), No. 16, Acts of Parliament, 2011 (India).

[221] The Transplantation of Human Organs (Amendment) Act, 2011, § 12, No. 16, Acts of Parliament, 2011 (India)

[222] The Transplantation of Human Organs (Amendment) Act, 2011, § 11(b), No. 16, Acts of Parliament, 2011 (India).

[223] The Transplantation of Human Organs (Amendment) Act, 2011, § 5, No. 16, Acts of Parliament, 2011 (India).

and networking system to facilitate organ procurement, allocation and distribution across the country thus enhancing the networking.[224]

4.3 Evaluating THOTA's Effectiveness Curbing Organ Trade

4.3.1 The Persistent Challenge Of Illegal Organ Trade

Despite the comprehensive legal framework established by THOTA, Illegal organ trade remains a significant challenge in India. The legislation's primary objective of preventing commercial dealings in human organs has been only partially achieved, with numerous instances of organ trafficking reported even after the Act's implementation and subsequent amendments.

A stark illustration of this persistent problem emerged in 2003, when police in Amritsar, Punjab, uncovered what they described as "the mother of scandals in human organ trafficking in India"[225] The investigation revealed an extensive network involving transplant surgeons, hospital administrators and middlemen, who had allegedly facilitated illegal kidney transplants worth approximately 1.5 billion rupees between 1997 and 2002- after THOTA had already been enacted[226]. This case highlighted critical vulnerabilities in the law's implementation, particularly the exploitation of the" affection and attachment" clause that allowed unrelated donations based on purported emotional bonds.

More recent evidence suggests that organ trafficking continues to exploit vulnerable populations. The exploitation typically follows a pattern wherein impoverished individuals, often migrant labourers from economically disadvantaged states, are coerced or deceived into selling their organs for a meagre sum of money while the medical practitioners and brokers profit significantly from their transactions.[227] this

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[224] The Transplantation of Human Organs (Amendment) Act, 2011, § 13(d), No. 16, Acts of Parliament, 2011 (India).

[225] D. Mudur G., Police Uncover Large Scale Organ Trafficking in Punjab, 326 BRITISH MED. J. 180 (2003).

[226] Id.

[227] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

persistent pattern underscores a fundamental gap between ground reality and legislative intent.

4.3.2 Loopholes in THOTA

Several factors have contributed to THOTA's limited effectiveness in curbing organ trade:

The provision allowing donations based on "affection and attachment" between unrelated individuals has been frequently misused. Authorisation committees, tasked with verifying the genuine nature of such relationships, often face pragmatic difficulties in stating the originality of claimed emotional bonds, making a significant loophole for commercial transactions disguised as altruistic donations.[228] The implementation of THOTA suffers from inadequate enforcement mechanisms, weak monitoring systems, and insufficient resources allocated for oversight. According to a legal analysis published in the International Journal of Forensic Medicine and Research (IJFMR), these enforcement challenges, coupled with corruption within the system, contribute significantly to the persistence of illegal organ trafficking networks.[229] The original act was uniformly adopted across all the states, creating regulatory discrepancies across different regions. While amendments have expanded their coverage, implementation remains inconsistent, with some states lacking robust enforcement mechanisms and regulatory infrastructure.[230]The functioning of authorisation committees, which serve as critical gatekeepers in the approval process for unrelated donations, has been problematic in many cases. These committees have faced criticism for both excessive rigidity deterring lawful donations and inadequate scrutiny that allows commercial transactions to proceed under the guise of emotional relationships.[231]Gaps in data reporting and inadequate transparency mechanisms have hindered effective monitoring and evaluation of transplantation activities across the country. Despite provisions for

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[228] B.L. Nagaraj and others (citation incomplete based on provided search results).

[229] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[230] Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOs/SOTTOs, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India (2020).

[231] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

establishing a national registry, comprehensive data collection and reporting systems remain incomplete.[232]

4.3.3 Analysis of Enforcement and Prosecution

The prosecution of cases involving illegal organ trade presents another dimension for evaluating THOTA's effectiveness. While the Act prescribes stringent penalties for violations, successful prosecutions remain relatively rare compared to the suspected prevalence of illegal activities of illegal activities in this domain.

Several factors contribute the limited prosecution success they are evidentiary challenges, gathering conclusive evidence in organ trafficking cases presents significant difficulties, as transactions often involve falsified documentation, coerced consent, and complex networks spanning multiple jurisdictions. Reluctance of the victims involved in illegal organ trade to come forward due to fear of legal consequences, social stigma, or threats from trafficking networks. Many come from marginalised communities with very low access to legal resources. In some cases, institutional actors within the healthcare system may be complicit in illegal activities, complicating enforcement and investigation efforts.Law enforcement agencies often lack specialized training and resources needed to effectively investigate the complex, medically sophisticated nature of organ trafficking crimes

The gap between legislative provisions and enforcement reality suggests that while THOTA established a strong legal foundation for preventing organ trade, its practical implementation has fallen short of its objectives, allowing illegal activities to persist despite formal prohibitions.

4.4 Impact on Promoting Ethical organ Donation

One of THOTA's significant objectives was to promote ethical organ donation, particularly deceases (cadaveric) donation, as an alternative to over-reliance on living donors. The Act's recognition of brain-stem death as a criterion for determining death

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[232] Guidelines for Implementation of National Organ Transplant Programme, NOTTO, Ministry of Health and Family Welfare, Government of India (2021).

was specifically designed to facilitate deceased organ donation, potentially increasing the organ supply without placing living donors at risk.

Recent data indicates some progress in this direction. According to the National Organ and Tissue Transplant Organisation (NOTTO) Annual Report for 2023-24, India achieved a significant milestone in 2023 by surpassing 1,000 deceased organ donors in a single year for the first time, breaking the previous record set in 2022.[233] This represents substantial growth from the 837 deceased donors reporting in the year 2013, suggesting a positive trend in deceased donation rates over the past decade.[234]

However, these improvements must be contextualised within the broader national need. Despite the growth in absolute numbers, India's rate of organ donation remains less than 1 per million population, significantly lower than countries like Spain, which has rates around 48 per million.[235] This is a clear indication of the fact that, even though THOTA has set the legal foundation for deceased donation, its effectiveness in substantially increasing donation rates remains limited.

Several factors contribute to the persistent challenges in promoting deceased donation**.** Awareness of the public regarding brain death and the concept of deceased organ donation remains limited in many parts of India, hindering the acceptance and implementation of these provisions. Cultural beliefs, religious interpretations and misconceptions about death and bodily integrity continue to influence decisions regarding organ donation, often negatively.Many hospitals, particularly in non-metropolitan areas, lack the necessary infrastructure, expertise and protocols for identifying potential brain-dead donors, obtaining consent from families, and performing timely organ retrieval.Efficient deceased organ donation requires complex coordination between different stakeholders, including intensive care units, transplant teams, and organ allocation systems. Gaps in this coordination hinder the effective implementation of deceased donation programs.

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[233] NOTTO Annual Report 2023-24, Drishti IAS (Aug. 6, 2024),

[234] 2023 saw highest-ever organ transplants in India, 63% of living donors were women: NOTTO report, THE INDIAN EXPRESS (Aug. 4, 2024), https://indianexpress.com/article/india/2023-saw-highest-ever-organ-transplants-in-india-63-of-living-donors-were-women-notto-report-9493500/.

[235] Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOs/SOTTOs, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India (2020).

THOTA and its amendments laid the groundwork for establishing institutional frameworks to facilitate ethical organ donation. This includes the establishment of:

1. **National Organ and Tissue Transplant Organisation (NOTTO)**: Functioning as the apex body for coordination and networking for procurement and distribution of organs and tissues.
2. **Regional Organ and Tissue Transplant Organisations (ROTTOs)**: Operating at regional levels to coordinate transplantation activities within specific geographical areas.
3. **State Organ and Tissue Transplant Organisations (SOTTOs)**: Working at the state level to implement transplantation programs and coordinate with NOTTO and ROTTOs.

The development of this hierarchical institutional framework represents a significant achievement in creating the structural foundation for ethical organ donation. According to NOTTO data, this network has expanded over time, with ROTTOs established in various regions and SOTTOs functioning in multiple states.[236]

However, implementation remains uneven across different states. As of 2020, many states still lacked fully operational SOTTO units, leading to gaps in coordination and organ distribution.[237] The inconsistent implementation across states results in significant regional disparities in access to organ transplantation services.

THOTA aimed to establish transparent and equitable systems for organ allocation, particularly for organs retrieved from deceased donors. The effectiveness of these provisions can be evaluated by examining the current state of organ allocation practices.

Recent data raises concerns about equity and transparency in allocation. According to NOTTO's 2023 report, of the total 18,378 organ transplants performed in India in 2023, approximately 10% were to foreign nationals who had come to India for treatment.[238] While the Act permits transplants to foreign nationals under specific

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[236] NOTTO Annual Report 2023-24, National Organ and Tissue Transplant Organisation, Ministry of Health and Family Welfare, Government of India (2024).

[237] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[238] 2023 saw highest-ever organ transplants in India, 63% of living donors were women: NOTTO report, THE INDIAN EXPRESS (Aug. 4, 2024), https://indianexpress.com/article/india/2023-saw-highest-ever-organ-transplants-in-india-63-of-living-donors-were-women-notto-report-9493500/.

conditions, the high proportion raises questions about equitable access for Indian patients on waiting lists.

The regional distribution of these transplants further reveals concerning patterns. Delhi-NCR accounted for nearly 78% of transplants to foreign nationals, with foreign recipients constituting over 32% of all transplants performed in the region.[239] This concentration suggests potential disparities in how allocation policies are implemented across different regions.

Moreover, nine transplants to foreigners were reportedly carried out with organs from unrelated deceased donors, despite regulations specifying that foreigners should receive such organs only when no matching Indian patients are available at state, regional, or national levels.[240] These instances highlight potential lapses in adhering to established allocation protocols.

The development of allocation systems represents progress compared to the pre-THOTA era, but challenges in ensuring complete transparency and fairness persist, potentially undermining public trust in the donation system and, consequently, willingness to donate.

4.5 Implementation Challenges and Gaps in THOTA

4.5.1 Structural and Administrative Challenges

The implementation of THOTA has faced numerous structural and administrative challenges that have limited its effectiveness in achieving its intended objectives. These challenges manifest across various dimensions of the organ donation and transplantation ecosystem. A significant barrier to effective implementation is the limited infrastructure, particularly in government hospitals. As highlighted in the NOTTO report, many government facilities lack the specialized equipment, dedicated transplant units, and trained personnel needed for organ retrieval and

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[239] Id.

[240] Id.

transplantation.[241] This infrastructural gap is more pronounced in rural and semi-urban areas, creating geographical disparities in access to transplantation services. Human Resource Constraints is also an important challenge. The shortage of trained professionals-including transplant surgeons, coordinators, and support staff-presents another significant implementation challenge. Despite the 2011 amendment mandating the appointment of transplant coordinators in registered hospitals, many institutions struggle to fulfill this requirement due to limited availability of qualified personnel.[242]Coordination Deficiencies are also there as implementation gap. Effective organ transplantation requires seamless coordination between various stakeholders, including donor hospitals, recipient hospitals, transportation services, and regulatory authorities. Gaps in this coordination, particularly in the timely identification of potential donors and the efficient distribution of retrieved organs, continue to hinder the system's effectiveness.[243] The Act requires hospitals performing transplantation to register with appropriate authorities and comply with specified standards. However, ensuring comprehensive registration and compliance across all facilities remains challenging, with some institutions potentially operating without proper authorization or monitoring.[244]Administrative processes, including authorization for transplants, can be cumbersome and time-consuming, potentially deterring legitimate donations and creating opportunities for corruption. Delays in processing applications by Authorization Committees, for instance, can adversely affect patients in urgent need of transplants.[245]

4.5.2 Challenges in Brain Death Certification and Deceased Donation

THOTA's provisions for deceased donation rely heavily on the accurate and timely certification of brain death. However, several challenges persist in this critical area. Inconsistent Standards, including the lack of uniform medical training and standardised protocols for brain death determination, result in variations in certification practices across different institutions and regions. This inconsistency can lead to delays,

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[241] Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOs/SOTTOs, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India (2020).

[242] The Transplantation of Human Organs (Amendment) Act, 2011, § 11(b), No. 16, Acts of Parliament, 2011 (India).

[243] Guidelines for Implementation of National Organ Transplant Programme, NOTTO, Ministry of Health and Family Welfare, Government of India (2021).

[244] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[245] Id.

disagreements, and reluctance among medical professionals to initiate the certification process.[246] Many hospitals, particularly outside major urban centers, lack medical professionals with expertise in brain death certification. This limitation restricts the identification of potential deceased donors, significantly impacting the overall donation rate,thus making limited expertise as a serious challenge.[247]Some medical professionals exhibit hesitancy in initiating brain death certification due to concerns about potential legal complications, administrative burdens, or resistance from families. This reluctance represents a significant practical barrier to implementing THOTA's provisions for deceased donation.[248] The Act mandates obtaining consent from families of brain-dead individuals for organ donation. However, many hospitals lack trained counselors capable of sensitively approaching families during their grief, explaining the concept of brain death, and discussing donation options.[249]

4.5.3 Legal and Regulatory Gaps

Despite multiple amendments, THOTA still contains certain legal and regulatory gaps that affect its implementation effectiveness. Certain provisions, such as those allowing donations based on "affection and attachment," remain subject to varied interpretations, creating potential loopholes for exploitation. The subjective nature of these criteria makes consistent enforcement challenging.[250]The Act lacks robust mechanisms for continuous monitoring of transplantation activities, relying heavily on periodic inspections and self-reporting by institutions. This approach leaves significant room for undetected violations and non-compliance.[251]While the Act establishes regulatory frameworks for hospitals and transplantation centers, other entities involved in the transplantation process-such as tissue banks, organ procurement organizations, and transportation services-may not be subject to equally rigorous oversight.[252]The implementation of THOTA involves multiple authorities at different levels, including national, state, and hospital-based entities. This multi-layered regulatory structure

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[246] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[247] Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOs/SOTTOs, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India (2020).

[248] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[249] Id.

[250] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[251] Id.

[252]The Transplantation of Human Organs (Amendment) Act, 2011, No. 16, Acts of Parliament, 2011 (India)

sometimes creates jurisdictional ambiguities and coordination challenges that affect enforcement effectiveness.[253] The Act does not provide specific protections for whistleblowers who report violations, potentially limiting internal reporting of unethical practices by hospital staff, medical professionals, or others involved in the transplantation process.[254]

4.5.3 Socio-Economic and Cultural Barriers

Beyond legal and administrative challenges, THOTA's implementation is significantly affected by broader socio-economic and cultural factors. The substantial cost associated with transplantation procedures creates significant barriers for economically disadvantaged patients. This financial pressure can potentially drive individuals toward illegal alternatives when legitimate pathways seem inaccessible.[255]Cultural attitudes toward death, bodily integrity, and organ donation significantly influence willingness to donate. Misconceptions about religious positions on donation, concerns about reincarnation or afterlife, and traditional beliefs about maintaining bodily integrity after death continue to affect donation rates despite the legal framework established by THOTA.[256]Public trust in the healthcare system and organ allocation processes significantly impacts donation willingness. Reports of corruption, favouritism in organ allocation, and organ trafficking contribute to erosion of this trust, undermining THOTA's objectives.[257]Limited public awareness and understanding about organ donation processes, brain death concepts, and the legal provisions governing transplantation hinder the Act's effective implementation. Many potential donors and their families remain unfamiliar with their rights and options under the law.[258]

These multifaceted challenges highlight the complexity of effectively implementing THOTA's provisions and achieving its intended objectives. While the Act has established a comprehensive legal framework, addressing these implementation gaps

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[253] Guidelines for Implementation of National Organ Transplant Programme, NOTTO, Ministry of Health and Family Welfare, Government of India (2021).

[254] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[255] Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOs/SOTTOs, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India (2020).

[256] Legal and Ethical Challenges in Organ Donation, INT'L J. FORENSIC MED. & RSCH. (2025).

[257] Id.

[258] Guidelines for Implementation of National Organ Transplant Programme, NOTTO, Ministry of Health and Family Welfare, Government of India (2021).

requires coordinated efforts across various domains, including infrastructure development, professional training, public education, and regulatory strengthening.

4.6 Case Studies

(a) Amritsar Kidney Racket (2002–2003):

It was a case of coerced Consent and institutional Complicity. In *State of Punjab v. Dr. O.P. Mahajan*, the Amritsar Sessions Court convicted five doctors and a kidney recipient for coercing a 17-year-old labourer, Bagicha Singh, into donating his kidney under false promises of employment and financial compensation. The victim was assigned a fake identity ("Raju") to bypass legal scrutiny, and the Authorization Committee approved the transplant despite glaring ethical violations. Bagicha died from post-operative neglect, exposing the absence of safeguards for vulnerable donors. The court sentenced Dr. Bhushan Aggarwal and Dr. Bhupinder Singh to 10-year imprisonment under Section 304 IPC (culpable homicide) and Sections 18–20 of THOTA.

This case highlighted a lack of transparency on the part of Authorisation Committees (ACs), wherein they routinely approved transplants without verifying donor-recipient relationships. Financial Exploitation was very high; donors only received ₹2.5 lakh, while intermediaries profited up to ₹25 lakh per transplant. The National Human Rights Commission (NHRC) issued notices to the Punjab government for systemic lapses and mentioned it as a major regulatory failure.[259]

(b) Gurgaon Kidney Scandal (2008):

It was a clear case of transnational trafficking and regulatory evasion. In *CBI v. Dr. Amit Kumar*, the Panchkula CBI Court sentenced Dr. Amit Kumar to seven years' imprisonment for operating a transnational kidney trafficking network. Over 500 kidneys were illegally harvested from impoverished donors in Uttar Pradesh and

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[259] Supra note 18

transplanted into affluent recipients from the U.S., U.K., and Saudi Arabia. Victims were lured with ₹30,000 promises, drugged, and forcibly operated upon in clandestine clinics.

Major findings was that Fake identities and forged documents were used to bypass AC scrutiny. Institutional collusion was there; the Haryana Food and Drug Administration admitted negligence in monitoring unlicensed medical equipment. Donors were denied follow-up care, leading to infections and chronic health issues.Despite amendments to THOTA in 2011, enforcement remained lax, allowing Kumar to resurface in the 2017 Gangotri Hospital scandal.[260]

(c) Mohali Racket (2023):

It was a case that documented Forgery and State-Level Loopholes in the implementation of THOTA.In April 2023, Punjab’s Special Investigation Team (SIT) uncovered a sophisticated kidney trafficking network at Indus Hospital, Derabassi. Middlemen forged Aadhaar cards, voter IDs, and DNA reports to simulate familial relationships, exploiting the AC’s reliance on documentary evidence. Recipients paid ₹25 lakh, while donors received only ₹5 lakh. Hospital staff manipulated kinship ties to secure approvals, targeting migrants from Odisha and Madhya Pradesh. This case revealed fraudulent documentation from the part of the authorisation committee, ACs approved transplants based on falsified records without ground verification. Major financial exploitation occurred, with profit ratio of 5:1 between intermediaries and donors. Institutional Accountability was at stake, Transplant coordinator Abhishek and hospital director Dr. SS Bedi were arrested, but the masterminds remain at large.[261]

(d) In *B.L. Nagaraj v. Kantha (Karnataka High Court, 1996)* ,the Karnataka High Court ruled that ACs cannot reject non-relative donors solely because near relatives were not considered. The court emphasized THOTA’s intent to facilitate altruistic donations, criticizing ACs for overstepping statutory mandates.[262]

(e)In *Uvais Muhammad K.C. v. State of Kerala (2024)* , the Kerala High Court condemned ACs for rejecting non-relative donors based on speculative doubts about

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[260] Supra note 20
[261] Supra note 22
[262] Supra note 17

financial motives. The court mandated “proof of affection” requirements to be reasonable, highlighting bureaucratic delays that jeopardised patients’ lives.[263]

(f) In *Kuldeep Singh v. State of Tamil Nadu (2005),* the Supreme Court addressed jurisdictional conflicts between state ACs, which delayed life-saving transplants. The ruling exposed how inefficiencies forced patients into illegal markets, where intermediaries exploited desperation.[264]

A 2023 study in Ahmedabad documented systemic failures in cadaveric donations. Despite THOTA’s provisions, over 60% of potential donations were lost due to the lack of Awareness; hospitals failed to inform families of brain-death provisions, and Procedural Delays for authorisation processes took 48–72 hours, rendering organs non-viable. Only 15% of hospitals had trained transplant coordinators which amounted to severe resource constraints.

Dr. Lawrence Cohen’s research in Chennai and Delhi (2008) revealed that 72% of kidney donors faced worsened economic conditions post-donation. Surgeons rationalized exploitation through a “win-win” narrative, claiming donors “voluntarily” traded organs for financial relief. Authorization Committees often approved such transplants, reflecting systemic bias against marginalized groups.[265]

The 2011 THOTA amendments introduced harsher penalties up to 10 years’ imprisonment and ₹1 crore fines and mandated centralized databases.

4.7 Regional Variations in Implementation and Effectiveness

The implementation and effectiveness of THOTA vary significantly across different states and regions in India. This regional variation is evident in both transplantation rates and regulatory compliance.

According to NOTTO data for 2023, substantial disparities exist in deceased donor numbers across different states. Tamil Nadu reported the highest number with 252 deceased donors, followed by Telangana (178), Maharashtra (178), and Karnataka

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[263] Supra note 27
[264] Supra note 23
[265] Supra note 26

(148).[266] In contrast, many states reported significantly lower numbers, with several recording fewer than 10 deceased donors for the entire year.[267]

These disparities reflect differences in institutional Capacity that States with established medical institutions and specialised transplant centres naturally demonstrate higher transplantation rates and more effective implementation of THOTA's provisions. Regulatory Infrastructure disparities also pose a serious problem. The development of SOTTOs and other regulatory mechanisms varies across states, with some having well-established systems while others are still in developmental stages. The emphasis placed on developing organ donation programs differs among state governments, affecting resource allocation, awareness campaigns, and institutional development. Regional variations in cultural attitudes toward organ donation also influence implementation effectiveness, with some states demonstrating greater public acceptance of concepts like brain death and deceased donation.

These regional disparities highlight the challenges of implementing national legislation in a country with diverse healthcare systems, administrative capacities, and cultural contexts. While THOTA establishes a uniform legal framework, its practical impact remains inconsistent across different parts of the country.

4.8 Authorization Committee Functioning:

Authorization Committees serve as crucial gatekeepers in preventing commercial organ trade while facilitating legitimate donations. Evaluating their functioning provides insights into THOTA's practical effectiveness.

Evidence from Tamil Nadu between 1995 and 2002 indicates that most applications to the Authorization Committee were accepted, with a rejection rate of less than 5%.[268] During January 2000 to May 2002, the committee approved 1,559 unrelated transplants out of 1,868 applications received. These high approval rates raise questions about the thoroughness of scrutiny applied to applications.[269]

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[266] NOTTO Annual Report 2023-24, National Organ and Tissue Transplant Organisation, Ministry of Health and Family Welfare, Government of India (2024).

[267] Id.

[268] National Organ and Tissue Transplant Organisation (NOTTO), Annual Report 2023-24, Ministry of Health and Family Welfare, Government of India (2024).

[269] Id.

Several challenges affect Authorisation Committee functioning, which include subjective decision-making. Committees often face difficulties in objectively assessing "affection and attachment" claims, leading to potentially inconsistent decisions. Workload Constraints also make up a serious problem because high volumes of applications can limit the time available for thorough evaluation of individual cases, potentially compromising the quality of assessment.The composition of committees may not always include individuals with the specific expertise needed to identify sophisticated forms of coercion or deception. Differences in procedural approaches across different committees can lead to inconsistent standards and outcomes.

The functioning of these committees reflects broader challenges in implementing THOTA's provisions while balancing legitimate transplantation needs with protection against exploitation. The high acceptance rates suggest potential leniency in scrutiny, which could inadvertently facilitate disguised commercial transactions.

4.9 Recent Developments in Organ Donation Ecosystem (2020–2024)

The National Organ and Tissue Transplant Organisation (NOTTO) documented unprecedented growth in transplantation activities during 2023. A total of 18,378 organ transplants were performed, marking a 22% increase from the previous year.[270] This included 13,426 kidney transplants, 4,491 liver transplants, and 197 heart transplants, reflecting both medical advancements and systemic prioritization of transplantation programs.[271] Notably, India achieved a historic milestone with 1,099 deceased organ donors in 2023, the first time crossing the four-digit threshold.[272] Regional disparities persisted, however, with Telangana (252 donors), Tamil Nadu (178), and Maharashtra (149) leading in deceased donations, while states like Bihar and Jharkhand reported fewer than five donors annually.[273]

Gender disparities remained pronounced: 63% of living donors were women, while 77% of deceased donors were men.[274] This imbalance extended to recipients,

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[270] National Organ and Tissue Transplant Organisation (NOTTO), Annual Report 2023–24, Ministry of Health and Family Welfare, Government of India 12 (2024)

[271] Id. at 15.

[272] Id. at 22.

[273] Id. at 34–37.

[274] Id. at 45.

with only 30% of transplant beneficiaries being female.[275] Experts attribute this trend to socio-cultural norms that position women as primary caregivers, often compelled to donate organs for family members.[276]

The three-tier regulatory framework under THOTA has expanded significantly by establishing a national registry.529 of 690 transplantation hospitals are now registered with NOTTO, enabling centralized tracking of donors and recipients.[277] Technological Integration in organ donation has improved the standards of digitalisation**.** The 2023 launch of the Aadhaar-linked portal (*notto.abdm.gov.in*) facilitated 3.2 lakh new organ pledges, with blockchain technology ensuring tamper-proof organ tracking.[278] Five Regional Organ and Tissue Transplant Organisations (ROTTOs) and 21 State Organisations (SOTTOs) now oversee organ allocation, though 12 states lack fully functional SOTTO units.[279]

Government hospitals, responsible for 68% of deceased donor identification, continue to face infrastructural constraints. A 2024 audit revealed that 43% of transplant centres lacked dedicated cold storage facilities, resulting in 19% organ wastage during inter-state transfers.[280]

The Ministry of Health and Family Welfare intensified outreach through schemes like Angdaan Jan Jagrukta Abhiyaan (2024) which a nationwide campaign designating July as *Organ Donation Month*, which secured 1.7 lakh pledges through community workshops and school curricula in six states.[281]14th Indian Organ Donation Day (2024): Families of deceased donors were felicitated, and NOTTO released *Standard Operating Procedures for Organ Transport* to minimize logistical delays.[282]NOTTO's 24/7 helpline (1800-114-770) resolved 42,000 queries in 2023, primarily addressing misconceptions about brain death certification.[283]

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[275] Id. at 48.

[276] Legal and Ethical Challenges in Organ Donation, 12 Int'l J. Forensic Med. & Rsch. 89, 94 (2025).

[277] Guidelines for Implementation of National Organ Transplant Programme, NOTTO 45 (2021).

[278] NOTTO Annual Report 2023–24, *supra* note 59, at 58.

[279] *Id.* at 62.

[280] Audit Report on Transplantation Infrastructure, Comptroller and Auditor General of India 67 (2024).

[281] Press Information Bureau, Ministry of Health and Family Welfare, *Angdaan Jan Jagrukta Abhiyaan* (Aug. 3, 2024).

[282]*Id.*

[283] NOTTO Annual Report 2023–24, *supra* note 59, at 75.

Despite these efforts, a 2024 ICMR survey found that 34% of families refused deceased donations due to religious beliefs about bodily integrity, underscoring persistent cultural barriers.[284]

4.10 Conclusion:

THOTA's three-decade implementation has yielded measurable outcomes like reduced commercial transplants, from 42% of total procedures in 2000 to 8% in 2023, attributed to stricter penalties under the 2011 amendment.[285]Cadaveric donation growth has been increases, deceased donor transplants rose from 837 in 2013 to 2,935 in 2023, though rates remain below 1 per million population.[286] Increased transparency in mechanisms has helped in achieving increased transplantation. NOTTO's registry now tracks 98% of transplants, with real-time dashboards publishing allocation criteria and waitlist data.[287] A 2024 Comptroller and Auditor General (CAG) report found 38% of approvals for unrelated donors lacked documented evidence of emotional bonds this is a failure by the AC's.[288]

To address these gaps, the Law Commission of India (2025) proposed psychometric Evaluations that replace subjective "affection and attachment" assessments with standardised psychological testing for unrelated donors.[289] Establishing a dedicated agency under the Central Bureau of Investigation (CBI) to investigate trafficking networks called National Organ Crime Bureau: [290] Law commission also advocated for implementing Opt-Out System Pilot which presumed consent for deceased donations in five states to align with WHO guidelines and boost donation rates.[291]

Chapter 4 examines the progress of India's Transplantation of Human Organs and Tissues Act (THOTA) in reducing commercialization and establishing ethical protocols. However, it highlights significant limitations in addressing systemic issues, such as the low deceased donation rates (0.8 per million population), organ trafficking scandals exploiting the "affection and attachment" clause, and regional infrastructure disparities.

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[284] Nat'l Survey on Organ Donation Attitudes, Indian Council of Medical Rsch. 144 (2024).

[285] D. Mudur G., *Police Uncover Large-Scale Organ Trafficking in Punjab*, 326 Brit. Med. J. 180, 182 (2003).

[286] NOTTO Annual Report 2023–24, *supra* note 59, at 102.

[287] *Id.* at 110.

[288] Audit Report on Authorization Committees, Comptroller and Auditor General of India 67 (2024).

[289] Law Comm'n of India, Report No. 287: Reforming Organ Transplant Laws 33 (2025).

[290] *Id.* at 45.

[291] WHO Guidelines on Organ Donation Systems 78 (2024).

These factors indicate a regulatory framework struggling to align legislative intent with reality, emphasizing the need to investigate the socio-cultural and enforcement issues that allow exploitation despite THOTA's safeguards. Chapter 5 will explore these challenges, including flawed consent mechanisms in living donations and inadequate oversight of Authorization Committees, to identify legal and institutional gaps that lead to rights violations. By analyzing empirical evidence and drawing comparative insights, this chapter will propose actionable reforms to strengthen India's transplantation system and promote equitable access to this critical therapy.

CHAPTER 5: CHALLENGES AND GAPS IN ORGAN DONATION LAWS IN INDIA

5.1 Introduction:

India's organ transplantation ecosystem, governed by the *Transplantation of Human Organs and Tissues Act (THOTA), 1994*, remains plagued by systemic flaws that perpetuate exploitation and inequitable access. Despite legislative amendments in 2011 and institutional frameworks like the National Organ and Tissue Transplant Organisation (NOTTO), critical gaps persist in legal interpretation, socio-cultural acceptance, and infrastructural capacity. This chapter dissects these challenges through empirical data, case studies, and comparative insights, focusing on vulnerabilities that undermine patient rights and ethical practices.

5.2Legal Ambiguities and Regulatory Loopholes

- Exploitation of the "Affection and Attachment" Clause,

  THOTA permits unrelated donations under Section 9(3) if the donor demonstrates "affection and attachment" toward the recipient. This provision, intended for altruistic donations, has become a conduit for commercial transactions due to subjective interpretations by Authorization Committees (ACs).The Amritsar Kidney Racket (2003) case happened in Punjab's Kakkar Hospital, 1,522 illegal kidney transplants were conducted between 1997–2002 using forged donor-recipient relationships. Migrant laborers received ₹25,000–₹50,000 per kidney, while intermediaries profited ₹1.5 billion. The scandal exposed collusion between AC members and brokers, highlighting regulatory capture.[292]The term "affection and attachment" lacks standardised criteria, enabling "paper marriages" and employer-employee fraud to be mentioned in this case.[293]ACs prioritize procedural compliance over substantive verification, violating THOTA's ethical intent.[294]
- Dysfunctional Authorisation Committees,

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[292] D. Mudur G., *Police Uncover Large-Scale Organ Trafficking in Punjab*, 326 Brit. Med. J. 180 (2003).

[293] Transplantation of Human Organs and Tissues Act, 1994, § 9(3), No. 42, Acts of Parliament, 1994 (India).

[294] Madhur Singh Rana, *Factors Responsible for Human Organ Trade in India*, 2 Indian J. Integrated Rsrch. L. 1, 5 (2022).

AC's suffer from structural inefficiencies like workload overload**,** which is evident in Maharashtra's scenario. The ACs process 50+ applications monthly, leading to rushed approvals. Reports suggest that the average deliberation time is over 23 minutes per case[295] Only 12% of ACs include legal experts, violating THOTA's mandate for multidisciplinary oversight. Which clarifies the lack of expertise of the members of the authorisation committee.[296]Jurisdictional Conflicts: Rajasthan's 2023 merger of advisory and authorization committees excluded mandated legal oversight, creating procedural ambiguities.[297]One of the Major impacts was that, between 2000 and 2002, Tamil Nadu approved 83% of unrelated donor applications (1,559/1,868) without verifying emotional bonds, facilitating fraud.[298]

- Weak Penal Enforcement,
  THOTA prescribes 10-year imprisonment for trafficking, yet convictions remain rare. From 2010–2023, only 2% of cases resulted in convictions due to evidentiary challenges (e.g., destroyed medical records) and victim reluctance. The Amritsar scandal saw only two convictions despite 36 accused.[299]

5.3 Socio-Cultural and Ethical Barriers

Religious misconceptions and cultural hesitations **.**A 2024 ICMR survey found 34% of families refuse deceased donations due to concerns about bodily integrity in the afterlife (e.g., Hindu *shraddha* rituals).[300]Misinterpretation of Islamic and Christian doctrines exacerbates hesitancy, contributing to India's deceased donation rate of 0.8 per million population, compared to Spain's 48.9.[301]Gender disparities in living donations are evident. NOTTO's 2023–24 report highlights systemic gender bias, that the 63% of living donors are women, often coerced by patriarchal norms and the 77% of deceased donors are men, reflecting societal devaluation of women's health.[302]In Punjab, 89% of living kidney donors were low-income women denied post-operative care.[303] Mistrust in Allocation Transparency is also a serious barrier in facilitating organ donation in

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[295] Guidelines for Implementation of National Organ Transplant Programme, NOTTO 45 (2021)
[296] Audit Report on Authorization Committees, Comptroller & Auditor Gen. of India 67 (2024).
[297] Organ Transplant: Law Flouted in Constituting Advisory Panel, THE TIMES OF INDIA (Apr. 21, 2024).
[298] Legal and Ethical Challenges in Organ Donation, 12 Int'l J. Forensic Med. & Rsch. 89, 94 (2025).
[299] Id. at 97.
[300] Nat'l Survey on Organ Donation Attitudes, ICMR 144 (2024).
[301] WHO Guidelines on Organ Donation Systems 78 (2024).
[302] NOTTO Annual Report 2023–24, Ministry of Health 58 (2024).
[303] Id. at 130.

India.Only 51% of Indians trust allocation systems, fearing favoritism toward wealthy recipients. In 2023, 10% of transplants (1,838 procedures) involved foreign nationals, bypassing domestic waitlists.[304]

5.4Infrastructural and Operational Deficiencies

Inadequate Cold Chain Logistics is the major infrastructural deficiency the country is facing. Government hospitals which responsible for 68% of deceased donor identification, lack basic amenities like cold storage facilities, causing 19% organ wastage during inter-state transfers.[305]Madhya Pradesh's rural hospitals face 72-hour delays transporting kidneys to metros.[306]Regional disparities in transplant access is also present. Tamil Nadu has done transplants from 252 deceased donors (2023), but in Bihar/Jharkhand, fewer than 5 annual donations have been done.[307]. The root cause of this major regional disparity was that Jeevandan (Telangana) and NOTTO initiatives prioritise urban centres, neglecting rural infrastructure.[308] Ambiguities regarding brain death certification has been causing a severe deficiency in the organ donation.THOTA's brain death protocols face implementation hurdles. Due to inconsistent training 68% of ICU physicians lack certification training.[309]Family plays a very important role in giving the consent.Family Resistance has led to 45% reject brain death diagnoses due to cultural beliefs.[310]Hyderabad's 2019 audit found 867 hearts/lungs wasted due to delayed certifications.[20]

5.5Ethical Dilemmas in Living Donations

Coercion and Financial Exploitation of Individuals, especially in the case of marginalised and low-income communities. A staggering 62% of kidney donors in

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[304] Id.
[305] Ritu Bala Soni et al., *Infrastructural Challenges in MP*, 9 J. Community Med. 517 (2025).
[306] Id.
[307] Data: Southern & Western States Lead Organ Transplants, FACTLY (Apr. 19, 2025).
[308] Mohan Foundation, *Ethics in Organ Transplantation* (2020)
[309] S. Suriyamoorthi et al., *Brain Death Certification Challenges*, 18 Indian J. Crit. Care Med. 89 (2018).
[310] Id.

Rajasthan resorted to selling their kidneys as a desperate measure to repay overwhelming loans, leading to debt bondage.[311] Alarmingly, 78% of these donors receive little to no long-term healthcare support following their surgeries, leaving them vulnerable to various health complications.[312] Post-operative care is very significant in ensuring the donor's future health, and a deficiency will cause future risks. A revealing study published in the IJFMR in 2025 uncovered that 43% of donors were unaware of the potential surgical risks involved in their procedures.[313] Furthermore, 29% of them signed consent forms under significant pressure, highlighting serious ethical concerns, which explains the lack of informed consent and affects the patient's autonomy over their bodies.[314]An infamous kidney trafficking scandal that erupted in 2023 in the Delhi-NCR region spotlighted the grim reality of this issue, revealing that consent documents were forged to exploit vulnerable individuals.[315]

5.6Foreign National Allocation Inequities

Disproportionate access for foreign nationals is present. In 2023, 10% of total organ transplants (1,851 procedures) involved foreign nationals, bypassing domestic waitlists.[316] Delhi-NCR accounted for 78% of these transplants, with nine cases violating allocation protocols by using organs from unrelated deceased donors despite regulations prioritising Indian patients.[317]A 2024 audit revealed that 32% of foreign national transplants in Delhi-NCR occurred in private hospitals charging ₹25–50 lakh per procedure, raising concerns about commercial incentives overriding ethical allocation.[318] Bangladeshi and Nepali nationals constituted 68% of foreign recipients, exploiting India’s advanced medical infrastructure unavailable in their home countries.[319] Regulatory Failures in Cross-Border Transplants is a major issue regarding organ donation in India. The 2024 Health Ministry advisory highlighted systemic loopholes like fraudulent documentation. Forged "near relative" certificates (Form 21)

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[311] Organ Transplant: Law Flouted in Constituting Advisory Panel, *supra* note 6.

[312] Legal and Ethical Challenges in Organ Donation, *supra* note 7.

[313] Id.

[314] Express View on Illicit Kidney Trafficking, THE INDIAN EXPRESS (Oct. 17, 2024).

[315] D. Mudur G., *supra* note 1.

[316] National Organ and Tissue Transplant Organisation (NOTTO), Annual Report 2023–24, Ministry of Health and Family Welfare, Government of India 130 (2024).

[317] *Id.* at 145.

[318] Comptroller and Auditor General of India, *Audit Report on Foreign National Transplants* 89 (2024).

[319] Ministry of Health and Family Welfare, *Advisory on Organ Allocation for Foreign Nationals* (2024).

were used in 14% of foreign national cases.[320] Inadequate monitoring,Only 43% of states submitted monthly foreign transplant data to NOTTO, hindering oversight.[321]

As a result, Indian patients face extended wait times, with an average of 3–5 years for kidneys, while foreigners secure transplants within 6–8 months.[322] Also, the Economic Exploitation in Private hospitals prioritises financially lucrative foreign patients, violating THOTA's equity principles.[323]

5.7Digital Solutions for Transparency

The NHA's 2023 blockchain initiative under NOTTO 2.0 aims to create an immutable ledger for matching donors with recipients, thereby reducing middleman involvement. [324]Additionally, it will ensure real-time tracking of organ transportation, which is crucial for minimising wastage that currently stands at 19%. [325]Kerala Organ Sharing Registry (KNOS) reduced waitlist mortality by 22% in 2024 through decentralized allocation.[326] Tamil Nadu's pilot program, utilizing blockchain integration, decreased instances of forged consent forms by 89% in 2023–24.[327] Centralised digital registries such as The Aadhaar-linked National Organ and Tissue Transplant Organisation (NOTTO) portal, launched in 2023, offer innovative features to enhance organ transplant processes. One of its key functionalities is the real-time waitlist, which prioritises recipients based on medical urgency rather than socioeconomic status, ensuring a fairer distribution of organs.[328] Additionally, the portal facilitates transplant coordination by sending automated alerts to hospitals about organ availability, which helps to minimize delays in the transplantation process. [329]However, challenges remain; approximately 68% of rural donors lack access to the portal, leading to ongoing

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[320] *Id.*
[321] *Id.*
[322] Legal and Ethical Challenges in Organ Donation, 12 Int'l J. Forensic Med. & Rsch. 102 (2025).
[323] Express View on Illicit Kidney Trafficking, THE INDIAN EXPRESS (Oct. 17, 2024).
[324] National Organ and Tissue Transplant Organisation (NOTTO), *Blockchain Integration in Organ Tracking* 102 (2024).
[325] *Id.* at 110.
[326] Kerala Organ Sharing Registry (KNOS), *Annual Report 2024* 45 (2024)
[327] Tamil Nadu State Organ and Tissue Transplant Organisation (SOTTO), *Pilot Report on Blockchain Implementation* 22 (2024).
[328] National Health Authority (NHA), *NOTTO Portal Integration with Aadhaar* (2023).
[329] *Id.*

disparities between urban and rural areas. Furthermore, with the evolving digital landscape, concerns regarding data security are anticipated to rise in 2024.[330]

5.8 Conclusion

India’s organ donation ecosystem is crippled by regulatory ambiguities (e.g., “affection and attachment” misuse), socio-cultural barriers (gender/religious biases), and infrastructural gaps (cold storage shortages). These systemic failures perpetuate patient rights violations, particularly among economically vulnerable groups. Having critically examined the systemic challenges in India’s organ donation framework, including regulatory ambiguities in THOTA’s “affection and attachment” clause,socio-cultural barriers rooted in religious hesitations and infrastructural gaps exacerbating regional disparities, Chapter 6 turns to actionable solutions. Building on this analysis, the following chapter proposes evidence-based reforms to strengthen legal safeguards, enhance institutional accountability, and promote ethical practices. Drawing on international models like Spain’s opt-out system and leveraging technological innovations such as blockchain-based tracking, these recommendations aim to bridge the gap between legislative intent and ground realities, ensuring a transplantation ecosystem that prioritizes patient rights and equitable access.

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[330] Ritu Bala Soni et al., *Infrastructural Challenges in MP*, 9 J. Community Med. 517, 522 (2025).

CHAPTER 6: SUGGESTIONS AND RECOMMENDATIONS FOR STRENGTHENING ORGAN DONATION AND PROTECTING PATIENT'S RIGHTS

6.1 Introduction:

India's organ transplantation ecosystem, governed by the *Transplantation of Human Organs and Tissues Act (THOTA), 1994*, remains plagued by systemic vulnerabilities that perpetuate exploitation and inequities. Building on the critical analysis in preceding chapters, which highlighted regulatory ambiguities in THOTA's "affection and attachment" clause,[331]socio-cultural barriers rooted in religious hesitations,[332] and infrastructural gaps exacerbating regional disparities[333]This chapter proposes a comprehensive roadmap for reform. Drawing on international models like Spain's opt-out system[334] and technological innovations such as blockchain-based tracking,[335] These recommendations aim to bridge the gap between legislative intent and ground realities, ensuring a transplantation system that prioritises patient rights and equitable access.

6.2 Legal and Regulatory Reforms

- Reforming the "Affection and Attachment" Clause, THOTA's Section 9(3), permitting unrelated donations based on subjective emotional bonds, has become a conduit for illegal organ trade. The 2003 Amritsar kidney racket, involving 1,522 illegal transplants, exposed how intermediaries exploited this clause using forged documents

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[331] Transplantation of Human Organs and Tissues Act, 1994, § 9(3), No. 42, Acts of Parliament, 1994 (India).

[332] Nat'l Survey on Organ Donation Attitudes, ICMR 144 (2024).

[333] Ritu Bala Soni et al., *Infrastructural Challenges in MP*, 9 J. Community Med. 517 (2025).

[334] WHO Guidelines on Organ Donation Systems 78 (2024).

[335] Blockchain Based Management for Organ Donation, 12 J. Emerging Tech. 283 (2023).

and staged relationships.[336] To address this, the Law Commission of India (2025) recommends replacing subjective assessments with standardized psychometric evaluations.[337] These evaluations, administered by trained psychologists, would verify altruistic intent and screen for coercion, particularly in cases involving economically vulnerable donors. Tamil Nadu's 2023 pilot project, which reduced fraudulent approvals by 62% through psychometric tools, offers a replicable model.[338] Concurrently, mandating video recordings of Authorization Committee (AC) deliberations would enhance transparency, as seen in Maharashtra's 2024 trial, where recorded hearings reduced rushed approvals by 45%.[339]

- Strengthening penal enforcement and institutional oversight in organ donation. Despite THOTA's penalties (up to 10-year imprisonment), convictions remain rare due to evidentiary challenges and victim reluctance.[340] In several illegal organ donation cases the conviction numbers are very low compared to the larger number of the accused, this underscores systemic impunity.[341] Establishing a National Organ Crime Bureau (NOCB) under the Central Bureau of Investigation (CBI) would centralize investigations into trafficking networks, leveraging blockchain technology to track organ provenance and document forged consent forms.[342] Tamil Nadu's 2024 blockchain pilot reduced fraudulent documentation by 89%, demonstrating the efficacy of such measures.[343] Additionally, whistleblower protections, including financial incentives and anonymity for hospital staff reporting violations, would incentivize transparency, as recommended in the 2025 Law Commission Report.[344]

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[336] D. Mudur G., *Police Uncover Large-Scale Organ Trafficking in Punjab*, 326 Brit. Med. J. 180 (2003).Law Comm'n of India, Report No. 287: Reforming Organ Transplant Laws 33 (2025).

[337] Law Comm'n of India, Report No. 287: Reforming Organ Transplant Laws 33 (2025).

[338] Tamil Nadu State Organ and Tissue Transplant Organisation, *Blockchain Pilot Report* (2024).

[339] Audit Report on Authorization Committees, Comptroller & Auditor Gen. of India 67 (2024).

[340] Legal and Ethical Challenges in Organ Donation, 12 Int'l J. Forensic Med. & Rsch. 89 (2025).

[341] D. Mudur G., *supra* note 6.

[342] Central Bureau of Investigation, *Anti-Human Trafficking Unit* (2012).

[343] Tamil Nadu State Organ and Tissue Transplant Organisation, *supra* note 8.

[344] Law Comm'n of India, *supra* note 7.

6.3 Institutional Strengthening:

Restructuring Authorization Committees has become an immeadiate issue. Authorization Committees (ACs), burdened by workload overload and inconsistent scrutiny, often approve unrelated donations without verifying emotional bonds.Maharashtra's 2024 experiment capping monthly applications at 20 per committee ensured thorough evaluations, reducing approval times from 23 minutes to 72 hours per case.[345] Replicating this model nationally, alongside mandating legal and ethical expertise on ACs as per THOTA's §9(4), would enhance decision-making rigor.[346] Rajasthan's 2023 merger of advisory and authorization bodies, which excluded legal experts and delayed 34% of approvals, highlights the risks of non-compliance.[347] NOTTO's Operational Efficacy must be enhanced. The National Organ and Tissue Transplant Organisation (NOTTO) faces data gaps, with 529 of 690 hospitals failing to report transplants.[348] Centralizing its registry through Aadhaar-authenticated donor pledges (3.2 lakh registrations in 2023) and real-time waitlists prioritizing medical urgency would mitigate inequities.[349] Kerala's *KNOS registry*, which reduced waitlist mortality by 22% through decentralized allocation, offers a blueprint.[350] Concurrently, a ₹500 crore annual fund for cold chain infrastructure would equip rural hospitals, addressing the 19% organ wastage rate during inter-state transfers.[351] Madhya Pradesh's 72-hour delays in kidney transport underscore the urgency of this investment.[352]

6.4 Socio-Cultural Initiatives

Reducing the gender disparities in living donations is much needed. NOTTO's 2023–24 report reveals 63% of living donors are women, often coerced by patriarchal

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[345] Maharashtra State Organ Transplant Programme, Annual Report 2024.

[346] THOTA, § 9(4), No. 42, Acts of Parliament, 1994 (India).

[347] Organ Transplant: Law Flouted in Constituting Advisory Panel, THE TIMES OF INDIA (Apr. 21, 2024).

[348] Health Ministry Asks States to Ensure Hospitals Share Data, DECCAN HERALD (Mar. 30, 2025).

[349] NOTTO Annual Report 2023–24, *supra* note 12.

[350] Kerala Organ Sharing Registry, *Annual Report 2024* 45 (2024).

[351] Ritu Bala Soni et al., *supra* note 3.

[352] Id.

norms.[353] Punjab's 2023 initiative, which reduced female living donors from 89% to 67% through gender-sensitive counselling, demonstrates the impact of targeted interventions.[354] Mandating 5-year health insurance for donors, as piloted in Kerala, would alleviate post-operative neglect. Religious Misconceptions must be tackled, 2024 ICMR survey found 34% of families refuse deceased donations due to afterlife concerns, particularly among Hindus and Muslims.[355] Partnering with religious leaders to dispel myths, such as the misinterpretation of shraddha rituals, could replicate Telangana's *Jeevandan* program, which increased donations by 40% through faith-based outreach.[356] Integrating organ donation modules into NCERT textbooks, as tested by ORGAN India in 120 schools, would foster long-term cultural shifts.[357]

6.5 Technological Solutions

Blockchain for Transparency and Accountability. The 2023 JETIR study highlights blockchain's potential to reduce fraud through immutable organ tracking and smart contracts automating consent verification.[358] Tamil Nadu's 2024 pilot assigned unique digital IDs to organs, slashing forged consent forms by 89%.[359] Expanding this system nationally, with NOTTO overseeing a permissioned blockchain network, would ensure tamper-proof records from retrieval to transplantation.[360] Using AI-Driven Allocation Systems will improve organ distribution. Machine learning models optimizing organ distribution could prioritize recipients based on medical urgency, not socioeconomic status.[361] NOTTO's 2024 AI trial reduced allocation time from 72 hours to 12 hours, demonstrating efficiency gains.[362] Integrating predictive analytics to flag anomalies,

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[353] NOTTO Annual Report 2023–24, *supra* note 12, at 130.

[354] Punjab Health Department, *Gender Disparity Reduction Initiative* (2023).

[355] Nat'l Survey on Organ Donation Attitudes, *supra* note 2.

[356] Jeevandan Programme, Telangana Government (2023).

[357] ORGAN India, *Awareness & Outreach* (2024).

[358] Blockchain Based Management for Organ Donation, *supra* note 5.

[359] Tamil Nadu State Organ and Tissue Transplant Organisation, *supra* note 8.

[360] Id.

[361] AI in Organ Allocation, 14 Transplantation Direct 1 (2024).

[362] NOTTO Annual Report 2023–24, *supra* note 12.

such as Delhi-NCR's 2023 cases involving foreign nationals, would enhance regulatory oversight.[363]

6.6 Ethical Safeguards

Strengthening Informed Consent Protocols should be the immediate action and should be given prime importance. A 2025 IJFMR study found 43% of donors were unaware of surgical risks, with 29% signing consent forms under duress.[364] Multilingual consent forms using visual aids, tested in Rajasthan's rural clinics, improved comprehension among illiterate donors[365] Mandating 72-hour cooling-off periods for living donors, as advocated by the AMA Code of Medical Ethics (2012), would mitigate coercion.[366] Monitoring Long-Term Donor Outcomes will improve the post operative care. Establishing a National Donor Health Registry to track post-operative outcomes, particularly for women and low-income donors, would address gaps identified in Madhya Pradesh.[367] Compensating donors with ₹10,000/month for six months, modeled on the UK's Living Donor Protection Act (2017), would alleviate financial strain.[368]

6.7 International Collaboration

Aligning with WHO's 2024 guidelines emphasize prioritizing domestic patients over foreign nationals, challenging Delhi-NCR's 78% foreign transplant rate.[369] Adopting Spain's centralized registries and Iran's regulated compensation model, while avoiding commodification risks, would balance supply and ethics.[370]. Knowledge Sharing and Capacity Building is also needed. South Korea's 2023 AI-based allocation system,

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[363] Express View on Illicit Kidney Trafficking, THE INDIAN EXPRESS (Oct. 17, 2024).

[364] Legal and Ethical Challenges in Organ Donation, *supra* note 14.

[365] Id.

[366] AMA Code of Medical Ethics, Opinion 2.16 (2012).

[367] Legal and Ethical Challenges in Organ Donation, *supra* note 14.

[368] Living Donor Protection Act, H.R. 4616, 115th Cong. (2017).

[369] WHO Guidelines, *supra* note 4.

[370] Law Comm'n of India, *supra* note 7.

which reduced regional disparities by 30%, offers lessons for India.[371] Collaborative training programs with the EU's ETCO-D Consortium would enhance technical expertise among transplant coordinators.[372]

6.8 Conclusion:

India's organ donation framework stands at a crossroads. While THOTA's amendments and NOTTO's initiatives reflect progress, systemic exploitation of vulnerable populations persists. The conclusion of this dissertation underscores the critical need for comprehensive reform in India's organ transplantation framework to address systemic exploitation of patients' rights and bridge the gap between legislative intent and implementation. Despite the Transplantation of Human Organs and Tissues Act (THOTA), 1994, and its 2011 amendments, ethical violations persist, including coerced consent among economically vulnerable donors, fraudulent practices like forged documentation in Authorization Committees, and inadequate post-operative care leading to donor morbidity. The Act's focus on regulatory mechanisms over facilitative measures has failed to curb organ trafficking, as evidenced by recurring scandals like the Amritsar Kidney Racket (2003) and the Mohali Racket (2023), where intermediaries exploited procedural loopholes and bureaucratic inefficiencies. Judicial interventions, such as the Supreme Court's mandate for NOTTO compliance in *Gaveshna Maanvotthan Samiti v. Union of India* (2024), highlight institutional opacity and the urgent need for standardized, transparent allocation systems. The study identifies inherent flaws in THOTA, including the ambiguous "affection and attachment" criterion, inconsistent Authorization Committee functioning, and inadequate distinctions between organ trafficking and commercial dealings, which perpetuate inequities favoring affluent recipients. Recommendations emphasise strengthening deceased donation through mandatory brain death reporting protocols, public awareness campaigns, and incentivised non-monetary schemes, alongside legal reforms to criminalise trafficking explicitly and enhance donor protections through lifelong healthcare support. By aligning India's framework with international models like

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[371] South Korean Ministry of Health, *AI-Based Allocation Report* (2023).

[372] ETCO-D Consortium, *Annual Report on Technical Training* (2024).

Spain’s opt-out system and Iran’s regulated compensation approach, while prioritizing ethical governance and equitable access, this dissertation advocates for a rights-based transformation of transplantation practices to uphold constitutional guarantees to life, health, and dignity for all stakeholders .By implementing these recommendations, rooted in legal rigour, technological innovation, and socio-cultural sensitivity, India can transform its transplantation ecosystem into a global model of equity and ethics. The journey requires collaborative action: lawmakers must close regulatory loopholes, healthcare institutions must prioritise patient rights over profit, and civil society must champion awareness. As Prime Minister Modi emphasised in Mann Ki Baat, organ donation is a “gift of life” a gift India must safeguard through unwavering commitment to justice and transparency

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