

# Legal and Ethical Challenges in Organ Donation: A Critical Study on Aspects of Implementation in India

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## ABSTRACT

Organ donation is an essential part of healthcare, providing a way to save lives by addressing the growing need for organs. It is a life-saving medical practice that raises complex legal and ethical concerns, particularly in India, where regulatory, socio-cultural, and operational challenges hinder its effective implementation. This paper critically evaluates the legal and ethical challenges related to organ donation in India, analysing key legislations such as the Transplantation of Human Organs and Tissues Act, 1994 (THOTA) and its subsequent amendments. Despite the legal framework, issues such as organ trafficking, consent mechanisms, brain death determination, and the lack of robust enforcement mechanisms persist. Ethical concerns, including the exploitation of economically vulnerable individuals, the role of informed consent, and religious or cultural apprehensions, further complicate the organ donation landscape. Additionally, the disparity between organ demand and supply has led to unethical practices, necessitating stricter regulatory oversight and enhanced public awareness. The paper also explores the role of healthcare institutions, the judiciary, and law enforcement in ensuring transparency and preventing commercial organ trade. The current situation in India highlights the need for policy reforms to promote ethical organ donation while maintaining legal safeguards. The study concludes with recommendations for strengthening legal provisions, improving public trust, and increasing organ donation rates through education, streamlined legal processes, and better healthcare infrastructure. By addressing the legal and ethical complexities, India can create a more equitable and transparent organ donation system that upholds human dignity and rights to ensure that more lives can be saved through increased organ donations.

**KEYWORDS:** Organ Donation, Healthcare, Legal Framework, Ethical Concerns, Public Awareness, Policy Reforms.

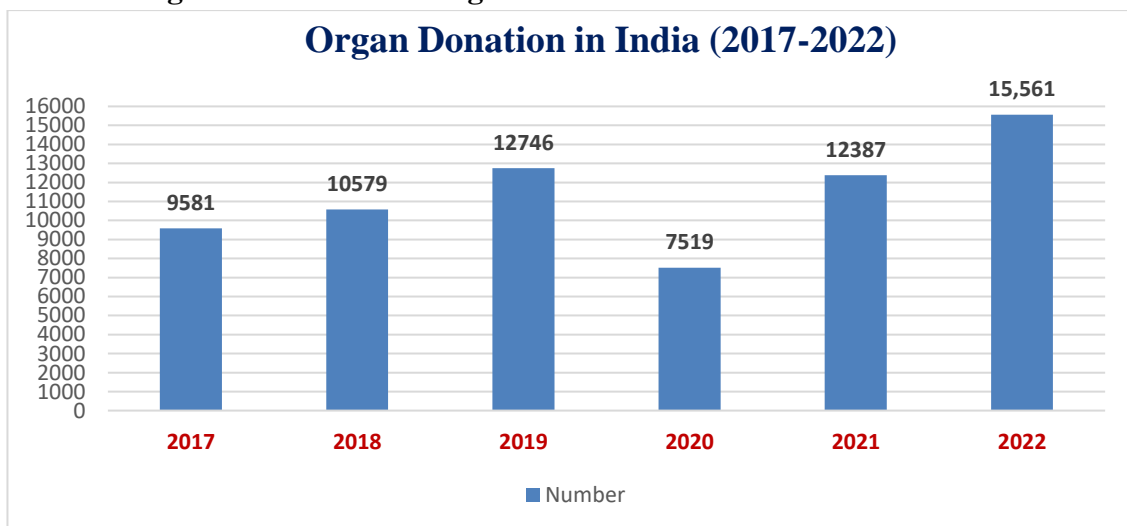
## 1. INTRODUCTION

Organ donation is a medical procedure in which an individual voluntarily donates an organ or tissue for transplantation to an individual experiencing organ failure. It is a critical life-saving intervention that has

transformed modern medicine, offering hope to patients with end-stage organ diseases. The advancement of organ transplant technologies in the 1980s significantly enhanced health outcomes for individuals with non-functioning organs requiring replacement.<sup>1</sup> Although the concept of organ donation is not entirely new, it was once thought to be a myth, in contrast to today.

According to the World Health Organization (WHO), organ donation refers to "the removal of organs or tissues from a living or deceased person, with the purpose of transplantation into another individual in need".<sup>2</sup> There are two categories of Organ donation, living donation, where a healthy individual donates an organ or a part of it (such as a kidney or liver), and deceased donation, where organs are retrieved from a brain-dead or cardiac-dead donor with prior consent or family approval. Despite its medical advancements, organ donation remains a complex issue globally due to legal, ethical, and socio-cultural challenges. Most people cannot afford organ transplantation because of a shortage of organs, the distribution of available organs is inefficient and unfair, and there is a lack of infrastructure and the high cost of transplants also.

**Figure 1: Number of Organ donation in India from 2017- 2022<sup>3</sup>**



Organ donation from living people is more common in India than from deceased people, according to trends. In fact, statistics throughout time show that a growing percentage of organ donations come from living people. Approximately 75% of organ donations in 2016 came from living donors. 6781 of the 9046 documented organ donations were from living donors, while the remaining 2265 came from

<sup>1</sup> History of Organ Donation, Donate Life, <https://www.donatelife.org.in/history-of-organ-donation> .

<sup>2</sup> WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, as endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22. <https://iris.who.int/bitstream/handle/10665/341814/WHO-HTP-EHT-CPR-2010.01-eng.pdf> .

<sup>3</sup> Kancharla B., Data: Between 2016 & 2021, Four States Accounted For 53% of The Organ Donations Reported from Across the Country, Factly, December 22, 2022. [https://factly.in/data-between-2016-2021-four-states-accounted-for-53-of-the-organ-donations-reported-from-across-the-country/#:~:text=\(Cumulative%20Totals%20%2D%202016%20to%202021\)&text=During%20these%200years](https://factly.in/data-between-2016-2021-four-states-accounted-for-53-of-the-organ-donations-reported-from-across-the-country/#:~:text=(Cumulative%20Totals%20%2D%202016%20to%202021)&text=During%20these%200years) .

deceased donors. The percentage of organs donated by living donors has risen annually, with the exception for 2018. According to statistics, organ donation occurs all around the world, with over three lakh patients on waiting lists and at least 20 people dying every day while waiting for an organ. India has been particularly hard hit by the lack of organ donors, particularly dead donations.

Data from the Health Ministry shows that the number of donors (including the deceased) only increased from 6,916 in 2014 to roughly 16,041 in 2022.<sup>4</sup> According to data from the National Organ Tissue and Transplant Organization, the number of registered patients on the organ transplant waiting list rose from 2,833 in 2021 to 3,275 in 2022.<sup>5</sup>

Delhi had the most organ donations with 11,181 throughout the course of the five-years (2017–2021), with a significant portion of those contributions (10,788) coming from living individuals. As the nation's capital and primary medical center, Delhi contributes to the increased number of transplant procedures performed, which raises the nation's organ donation rate. With almost 10,000 donations over the previous six years, Tamil Nadu comes in second. In comparison to Delhi, the organ donation ratio from living donors and deceased is better with 6900 from live donors and the remaining portion from deceased. The next states with the highest number of organ donations are Maharashtra and Telangana. Approximately 53% of the donations come from these four states. The point is to be noted that these states are home to some of the major cities like Hyderabad, Chennai, Mumbai, Pune etc., and serve as medical centers that draw patients from within the state and all over the country. The presence of hospital infrastructure in these cities is the major reasons for this skew.

In 2017, 9,581 donations were made in total which was greater as compared to the number of 9,046 in 2016. In the years that followed, the numbers increased. However, there was a decline in 2020, with only 7,519 organ donations and 12,746 in 2019.<sup>6</sup> According to news and other sources, the COVID-19 pandemic was the main cause of this fall. Restrictions on travel, hospital infrastructure used to combat the epidemic, etc. have impacted organ transplant procedures in 2020. Close to the pre-pandemic level, the number increased to 12,387 in 2021. In the year 2022, 15,561 organ transplants were performed nationwide. The number of transplants has increased by about 26% annually.

The Government has implemented various measures to increase the number of organ transplants performed nationwide. It is also thought that the numerous pending surgeries from 2020 that were moved to 2021–2022 may be the cause of this larger number in 2022.

Among the states with the highest number of organ donations are Gujarat, Haryana, Bengal, and the other two southern states of Kerala and Karnataka. In the majority of states, the trends follow the

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<sup>4</sup> Perappadan B.S., “Organ shortage continues to cost lives”, The Hindu, August 07, 2023.

<https://www.thehindu.com/sci-tech/health/indias-poor-organ-donation-record-continues-to-cost-lives/article67161978.ece>

<sup>5</sup> Answer of The Hon’ble Minister of State in The Ministry of Health and Family in response to a question in Rajya Sabha, March 2023. [https://sansad.in/getFile/annex/259/AU2358.pdf?source=pqars#:~:text=\(a\)%20to%20\(d\),the%20country%20in%20year%202022](https://sansad.in/getFile/annex/259/AU2358.pdf?source=pqars#:~:text=(a)%20to%20(d),the%20country%20in%20year%202022)

<sup>6</sup> Answer of The Hon’ble Minister of State in The Ministry of Health and Family Welfare in response to a question in Lok Sabha, December 2023. <https://sansad.in/getFile/loksabhaquestions/annex/1714/AU997.pdf?source=pqals> .

general patterns, signifying that the donations made by living donors are proportionately higher than those made by deceased donors.

In 2017, a mere 0.009 % of all those who died in India donated their Organs. If we go through some of the challenges that India faced in Organ donation, then definitely we can say where India stands in this race of organ management.

According to ORGAN INDIA<sup>7</sup>, 2 lakhs of corneal donations are required annually. However, only 50,000 Corneas are donated in India every year. 3 out of 4 people awaiting corneal donation remain visually impaired. Around 5 lakh people need organ transplantation every year and many of them die due to the lack of organs available for transplantation. If we can assume a figure then around 586 Airbuses can be filled by people waiting for organ transplantation. As per the record of NOTTO (National Organ & Tissue Transplantation Organization), 2 lakhs Kidneys, 50,000 hearts & 50,000 Livers as in required in India but the total availability of stock is 1684 Kidneys, 339 Hearts & 708 Livers which is very low as compared to the requirements. Significantly, India's Organ Donation rate is one of the lowest in the world.

India has a dismal record of deceased donors. The nation recorded 250 heart transplants, a total of 761 liver transplants, and 1,589 kidney transplants under the deceased category in 2022. There were only three kidney and pancreas transplants in 2014 and by 2022, there were 22. Conversely, the number of kidney transplants performed using living donors increased from 4,884 in 2014 to 9,834 in 2022. In this category, the number of liver transplants increased from 1,002 to 2,957.<sup>8</sup>

In 2023, India's cadaver donors annual count surpassed the four-digit threshold.<sup>9</sup> According to the National Organ & Tissue Transplant Organization (NOTTO), there were 1,028 deceased donors in 2023 as against 941 in 2022.<sup>10</sup> Transplantation needs are significantly more in demand than they are in supply. Many lives are on the line as they await a miracle—a donated organ—to save them. Donated organs have the potential to save many lives and provide patients with terminal conditions hope and a second opportunity at life.

India has made significant progress in the field of organ donation in the last few decades. The Transplantation of Human Organs and Tissues Act, 1994, prohibits the commercial trade in organs and

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<sup>7</sup> <https://www.organindia.org/>

<sup>8</sup> Data for organ donation and transplantation (2013-2022), National Organ and Tissue Transplant Organisation, Ministry of Health and Family Welfare, Govt. of India.

[https://notto.mohfw.gov.in/WriteReadData/Portal/News/806\\_1\\_data\\_2022.pdf](https://notto.mohfw.gov.in/WriteReadData/Portal/News/806_1_data_2022.pdf)

<sup>9</sup> Iyer M., "For 1st time, yearly cadaver donations cross 1000 in 2023", The Times of India, January 21, 2024.

<https://timesofindia.indiatimes.com/india/for-1st-time-yearly-cadaver-donations-cross-1000-in-2023/articleshow/107018713.cms#:~:text=India's%20cadaver%20transplant%20programme%20achieved%20a%20significant,the%20deceased%20donation%20programme%2C%20conducting%20two%20do nations.>

<sup>10</sup> Annual Report 2023-2024, Unveiling a Year of Remarkable Achievements, National Organ and Tissue Transplant Organisation, Ministry of Health and Family Welfare, Govt. of India. [https://notto.gov.in/WriteReadData/Portal/News/858\\_1\\_Updated\\_Notto\\_Annual\\_Report\\_\\_08-05-24\\_.pdf#:~:text=Recently%2C%20India%20has%20achieved%20one%20more%20milestone,retrieval%20and%20distribution%20of%20organs%20in%20a](https://notto.gov.in/WriteReadData/Portal/News/858_1_Updated_Notto_Annual_Report__08-05-24_.pdf#:~:text=Recently%2C%20India%20has%20achieved%20one%20more%20milestone,retrieval%20and%20distribution%20of%20organs%20in%20a)

tissues and governs organ transplantation in India. The goal of this act is to establish a thorough legal framework that governs the removal of organs from both living and deceased individuals. However, there are still a lot of difficulties. Therefore, it is necessary to evaluate the operation of the Act and ascertain whether its goals have been achieved. The increasing demand for various organs and the restricted availability led to the emergence of unethical organ transplant practices.

The Government of India is working with the aim of “One Nation, One Policy” for Organ Donation and Transplantation in consultation with the states. In this regard, it has been decided to eliminate the need for a domicile of State residence in order to register patients who need organ transplants from deceased donors. These patients will now be able to register for an organ transplant in any state in the nation. As per the new guidelines, the upper age limit of 65 years for eligibility for registration to receive deceased donor organs has been removed.<sup>11</sup> Now, a person of any age can register to receive a deceased donor organ.

This research critically examines the legal and ethical dimensions of organ donation in India, analyzing the existing framework, identifying gaps, and proposing reforms to strengthen the system. This paper aims to provide recommendations to enhance organ donation policies and promote ethical and legal compliance.

## 1.1. Literature Review

Several studies have examined the legal, ethical, and operational challenges of organ donation in India, highlighting factors influencing donation rates and potential solutions.

### 1.1.1. Legal Challenges

1. **Mathiharan K. (2011)**<sup>12</sup> examines the limitations of the Transplantation of Human Organs and Tissues Act (THOTA), 1994, in curbing organ trafficking, highlighting weak enforcement leading to illegal organ trade and exploitation of vulnerable donors.
2. **Suriyamoorthi S. et al. (2018)**<sup>13</sup> discusses the lack of standardized procedures and medical skepticism surrounding brain death certification in India, leading to delays in organ retrieval.
3. **Shah S.B., Shah B.V. (2018)**<sup>14</sup> highlights issues such as commercialization and coercion affecting living donor transplants, with common occurrences of fake familial relationships and financial inducements in private hospitals.

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<sup>11</sup> Answer of The Hon’ble Minister of State in The Ministry of Health and Family Welfare in response to a question in Rajya Sabha, March 2023. [https://sansad.in/getFile/annex/259/AU2358.pdf?source=pqars#:~:text=\(a\)%20to%20\(d\),the%20country%20in%20year%202022](https://sansad.in/getFile/annex/259/AU2358.pdf?source=pqars#:~:text=(a)%20to%20(d),the%20country%20in%20year%202022)

<sup>12</sup> Mathiharan K., “Ethical and legal issues in organ transplantation: Indian scenario”, *Med Sci Law*, 2011, 51 (3), 134-40. Doi: 10.1258/msl.2011.010134. PMID: 21905567.

<sup>13</sup> Suriyamoorthi S., Shroff S., Navin S., Pathinathan P., Ranjithkumar R., Rajasekar J., “Unique Challenges in the Deceased Donation Programme in India”, *Transplantation*, 2018, 10 (2), S223. DOI:10.1097/01.tp.0000542887.27707.0c.

<sup>14</sup> Shah S.B., Shah B.V., “Legal Aspects of Transplantation in India”, *Indian Journal of Transplantation*, 2018, 12 (3), 169-173. DOI: 10.4103/ijot.ijot\_43\_18.



4. **Lenin B., Butani A. (2023)**<sup>15</sup> This survey finds that a significant portion of the Indian population is unaware of organ donation laws, leading to hesitancy due to fears of organ theft, misuse, or inadequate legal protection.
5. **Das A., Nair R. (2021)**<sup>16</sup> discusses the unequal legal access to organ transplantation between urban and rural populations, with legal documentation, donor registration, and access to transplant centers being more streamlined in metropolitan areas.
6. **Mehta D. et al. (2017)**<sup>17</sup> assessed Organ Transplant law in compatibility with the Right to Health, recommending legislative and policy changes for better compatibility.
7. **Vasanthi R. (2020)**<sup>18</sup> discussed the establishment of NOTTO and its impact on organ donation in India. Analyzing data from 2013–2018, the study highlighted NOTTO's role in regulating organ transplantation, strengthened by the 2011 amendment of THOA 1994.
8. **Subha C. C. (2018)**<sup>19</sup> emphasized the growing gap between organ demand and supply, leading to illegal organ trade despite existing legal frameworks.
9. **Ramesh V., Pal C. (2021)**<sup>20</sup> analyzed data collected by the NOTTO for the WHO-Global Observatory on Donation and Transplantation, noting that kidney transplant waitlists were the longest and India was the only WHO South-East Asia Region country consistently submitting organ donation data from 2013 to 2019.

### 1.1.2. Ethical Challenges

1. **Shroff S. (2020)**<sup>21</sup> This study highlights ethical dilemmas in living organ donations, particularly coercion and financial exploitation, with many poor individuals pressured into donating organs due to economic distress.

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<sup>15</sup> Biplab L.B., Butani A., “Beneath the Surface: Scrutinising India’s Organ Donation Laws and the Dilemmas of ‘Brain-Stem Death’”, Cyril Amarchand Mangaldas, June 22, 2023. <https://corporate.cyrilamarchandblogs.com/2023/06/beneath-the-surface-scrutinising-indias-organ-donation-laws-and-the-dilemmas-of-brain-stem-death/> .

<sup>16</sup> “The Current State of Organ Donation in India and the Case for an Opt-Out System”, liverindia. <https://liverindia.in/the-current-state-of-organ-donation-in-india-and-the-case-for-an-opt-out-system/> .

<sup>17</sup> Mehta D., Saksena N., Mittal Y., “Organ Transplant Law: Assessing Compatibility with The Right to Health”, Vidhi, 2017. [https://vidhilegalpolicy.in/wp-content/uploads/2020/06/171003\\_OrganTransplantsReportFinal.pdf](https://vidhilegalpolicy.in/wp-content/uploads/2020/06/171003_OrganTransplantsReportFinal.pdf) .

<sup>18</sup> Vasanthi R., “Why NOTTO? The National Organ and Tissue Transplant Organisation and Why It Is Crucial to Regulate Organ Donation and Transplantation in India”, *Transplant Proc*, 2020, 52 (10), 2930-2933. Doi: 10.1016/j.transproceed.2020.04.1824. Epub 2020 Jun 27. PMID: 32605769.

<sup>19</sup> Subha C.C., “Sale and transplantation of human organs in India critical evaluation of the legal framework”, <http://hdl.handle.net/10603/325476> .

<sup>20</sup> Ramesh V., Pal C., “Organ Donation and Transplantation in India in 2019”, *Exp Clin Transplant*, 2021, 19 (12), 1313-1321. Doi: 10.6002/ect.2021.0105. Epub 2021 Oct 19. PMID: 34763630.

<sup>21</sup> Sunil S.S., “Organ Commerce - Issues, Challenges and Ethics in Organ Transplantation”, mohanfoundation. <https://www.mohanfoundation.org/organ-donation-transplant-resources/organ-commerce-issues-challenges-ethics-organ-transplantation.asp>

2. **Misha S. (2024)**<sup>22</sup> emphasizes how religious beliefs and cultural norms play a crucial role in low organ donation rates in India, with many individuals fearing violation of religious doctrines or believing in maintaining bodily integrity after death.
3. **NagraL S., Amalorpavanathan J. (2014)**<sup>23</sup> explores ethical concerns in cadaveric organ donation, especially regarding family consent and next-of-kin decision-making, finding that even when individuals register as organ donors, their families often refuse donation due to emotional distress or distrust in the medical system.
4. **Suriyamoorthi S. et al. (2018)**<sup>24</sup> This review raises concerns about the lack of transparency in organ allocation systems in India, finding that wealthy or well-connected patients often receive priority over more deserving candidates, leading to ethical concerns about fairness.
5. **Ehtuish F. A. Ehtuish (2024)**<sup>25</sup> debates whether financial incentives for organ donation should be allowed, discussing the potential for exploitation of the poor and suggesting that non-monetary benefits such as healthcare support or insurance could be ethically acceptable alternatives.
6. **Ahlawat R. et al. (2013)**<sup>26</sup> assessed healthcare workers' attitudes toward organ donation and factors influencing their willingness for self-organ donation after death.
7. **Dhakate N. N. (2021)**<sup>27</sup> focused on deceased organ donation rather than organ donation only. Deceased organ donation is limited to donation after brain death and not after circulatory death, as it is not yet practiced in India, and its barriers to the processes inside the hospital.
8. **Panwar R. et al. (2016)**<sup>28</sup> emphasized that organ donation is a noble, altruistic act with no attached motives. They highlighted the need to understand low organ donation rates in India through a 30-item questionnaire for the public. The survey underscored the influence of family and religious leaders in organ donation decisions.

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<sup>22</sup> Heart of the Matter: Ethical Dilemmas in India's Organ Donation,

<https://stophindudvesha.org/heart-of-the-matter-ethical-dilemmas-in-indias-organ-donation/>

<sup>23</sup> Nagral S., Amalorpavanathan J., “Deceased organ donation in India: where do we go from here?”, *Indian Journal of Medical Ethics*, 2016, 11 (3), p.162. DOI: <https://doi.org/10.20529/IJME.2014.043>.

<sup>24</sup> Navin S., Suriyamoorthi S., Shroff S., “Ethical Dilemmas in Deceased Organ Donation and Allocation – An Emerging Challenge in India”, *Transplantation*, 2018, 10 (2), S221. DOI: 10.1097/01.tp.0000542883.35331.47.

<sup>25</sup> Ehtuish F. A., “Ethics of Organ Donation and Transplantation: Toward Self-Sufficiency”, *Experimental and clinical transplantation*, October 2024 - Supplement - 5, 22 (10), 30-34. [https://www.ectrx.org/detail/supplement/2024/22/10/5/30/0?utm\\_](https://www.ectrx.org/detail/supplement/2024/22/10/5/30/0?utm_)

<sup>26</sup> Ahlawat R., Kumar V., Gupta A.K., Sharma R.K., Minz M., Jha V., “Attitude and knowledge of healthcare workers in critical areas towards deceased organ donation in a public sector hospital in India” *Natl Med J India*, 2013, 26 (6), 322-6. PMID: 25073987.

<sup>27</sup> Dhakate N.N., ‘Organ Donation Process in India Examining the Key Attributes Challenges Enablers and Success Factors’. <http://hdl.handle.net/10603/457754> .

<sup>28</sup> Panwar R., Pal S., Dash N.R., Sahni P., Vij A., Misra M.C., “Why are we Poor Organ Donors: A Survey Focusing on Attitudes of the Lay Public from Northern India”, *J Clin Exp Hepatol*, 2016, 6 (2), 81-6. Doi: 10.1016/j.jceh.2016.04.001. Epub 2016 Apr 30. PMID: 27493454; PMCID: PMC4963316.

### 1.2. Statement of Problem

Human organ donation and transplantation are considered as an accepted form of treatment nowadays. The only choice for patients with end-stage organ failure is to undergo organ transplantation. Organs can be donated by a live donor or deceased donor (Cadaver donor) after brain death/natural death. In order to reduce the possible risk to the live donor following organ donation, it is quite advisable to transplant organs from a deceased donor.

The organ donation rate is not sufficient enough to meet the demand of organs. So, there lies a gap between the supply and demand of organs, and many patients in the waiting list die due to the unavailability of organs for transplant. According to statistics, nearly 5 lakh people die in India due to a shortage of organs. India is in need of 2,60,000 organs every year i.e. 1,80,000 kidneys for transplant, 30,000 livers, and 50,000 hearts but the organs transplanted annually are only 6,000 kidneys, 1,200 livers, and 15 hearts (DGHS, NOTP). Shortage of organs is regarded as a social issue rather than a medical issue. Generally, people show their unwillingness towards organ donation due to a lack of awareness and knowledge. Also, the unwillingness towards organ donation is spreading in India due to various reasons such as the lack of mechanisms/tools in hospitals for administering organ donation, the high cost of organ transplantation in private hospitals as compared to Government sectors, inadequate facilities in Govt. medicals for carrying out the procedure of organ Retrieving mechanism, improper hospital administration in many states all across India to carry out the process, non-availability of database of organ donation and transplant rates in many states, and inadequate State laws, rules, and regulations available for stringent organ donation process.

### 1.3. Research Methodology

This research employs a doctrinal method to critically analyze the legal and ethical challenges in organ donation in India, with a specific focus on the Transplantation of Human Organs and Tissues Act, 1994 (THOTA) and its practical implementation. The methodology is designed to provide a comprehensive understanding of the issues through a theoretical perspective only.

## 2. Regulatory Framework on Organ Donation

Organ donation is a critical subject of inquiry for medical professionals as well as social scientists. It involves adverse challenges like ethical, cultural as well as legal. To regulate all the concerning issues, a law has been made under the constitution of India and then for the first time The Transplantation of Human Organs Act, 1994 was enacted to curb the challenges faced in Organ Donation.

The main objectives of The Transplantation of Human Organs Act, 1994 are to restrict the commercialization of organs by punishing illegal transplantation of organs and to come up with a comprehensive legal framework for organ donations by living as well as brain-dead donors (facilitating legal transplants). The Act does this by regulating the provision of healthcare services and prescribing administrative and criminal penalties for failing to meet the requirements under the Act. Till the late 1980s, only three states (Maharashtra, Tamil Nadu, and Karnataka) had legally permitted the transplantation of organs from deceased donors. Therefore, a complete law was deemed necessary "to regulate the removal of organs from living as well as deceased persons and transplantation of such organs."

Time and again underlying challenges in the implementation of laws. It has been scrutinized, and evaluated by various committee reports. The L.M. Singhvi Committee Report offered amendments and policy reforms. In order to define this legislation, a committee consisting of legal and medical experts



led by Dr. L.M. Singhvi was established to define and explain several concepts, such as the definition and concept of brain death, the need for separate legislation to deal with brain death and its medical and socio-legal ramifications, the methods whereby the idea of brain death should be used to make human organs available for transplantation, and the precautions that must be taken to prevent its misuse.

In order to encourage the organ donations from living individuals willingly, proper medical services and care should be given to donors. Lastly, the Committee suggested that trafficking in human organs should be banned and declared it a punishable offence as per the ensuing Acts.

### **2.1. The Transplantation of Human Organs and Tissues Act, 1994**

The Transplantation of Human Organs and Tissues Act, 1994 was enacted to govern organ donation and transplantation in India, aiming to prevent illegal organ trade and establish ethical medical practices. Its key objectives include:

- Defining and legalizing brain death as a criterion for organ retrieval.
- Regulating living and deceased organ donation.
- Establishing an authorization committee to scrutinize living donor cases.
- Setting up a punitive framework to curb illegal organ trade.
- Promoting cadaveric (deceased) organ donation through awareness and legal provisions.

On September 27, 2011, the Transplantation of Human Organs (Amendment) Act, 2011 was passed. However, it took effect in January 2014, nearly 3 years later and the notification of Rules pertaining to the amended Act came in the month of March 2014.

### **2.2. The Transplantation of Human Organs (Amendment) Act, 2011**

This act was introduced to address loopholes in the 1994 Act and enhance regulatory oversight. Its salient features include:

#### **Ethical Considerations**

- To prevent commercial exploitation, the definition of "near relatives" was expanded to include grandparents and grandchildren.
- Introduced swap donation provisions for legally permissible organ exchanges between unrelated pairs.

#### **Legal and Operational Provisions**

- Allowed retrieval of organs from a deceased donor without delay, ensuring timely transplantation.
- Made it compulsory for hospitals to register for organ retrieval and transplantation, ensuring transparency.
- Strengthened authorization committees to scrutinize cases of unrelated donors and prevent coercion.

#### **Penal Provisions**

- Increased penalties for organ trafficking, including imprisonment of up to 10 years and fines up to ₹1 crore.
- Imposed stricter punishment for doctors and hospitals involved in illegal organ transplants.

**Although the legislation has regulated aspects of brain death certification, authorization of living donors, and penalties for illegal organ trade, it has inherent lacunae in the following areas:**

- Lack of Awareness and Implementation – Despite legal provisions, there is low public awareness about organ donation, leading to underutilization of deceased donor programs.
- Ethical Concerns in Living Donation – The possibility of coercion and financial incentives in unrelated donor cases remains a challenge.

- Organ Allocation Transparency – The absence of a centralized and publicly accessible allocation system raises ethical concerns about fairness.
- Weak Enforcement Mechanisms – Despite stringent penalties, illegal organ trade persists, through loopholes in donor-recipient verification processes.
- Limited Rural Access – The implementation of the law is urban-centric, leading to inequitable access to transplantation facilities for rural populations.

### 2.3. The Transplantation of Human Organs and Tissues Rules, 2014

The Transplantation of Human Organs and Tissues Rules, 2014 were introduced to operationalize the amendments made in The Transplantation of Human Organs (Amendment) Act, 2011. These rules provide procedural and technical guidance for transplant activities in India and aim to enhance transparency, strengthen regulatory oversight, and curb illegal organ trade.

Salient Features of the 2014 Rules are as follows –

#### Ethical Provisions

- Strengthened the role of Authorization Committees to prevent trafficking of organs and assure that organ donation is voluntary and free from coercion.
- Made it mandatory for medical institutions to establish brain death certification protocols, ensuring ethical organ retrieval from deceased donors.

#### Legal and Operational Provisions

- Established National and State Organ and Tissue Transplant Organizations (NOTTO & SOTTO) to coordinate organ allocation and maintain a national registry.
- Directed hospitals to register for organ transplantation and retrieval to ensure accountability and standardization.
- Streamlined procedures for cadaveric organ donation, reducing bureaucratic delays in organ retrieval.
- Introduced mandatory consent from family members in cases where a donor has not explicitly consented before death.

#### Penal Provisions

- Strengthened penalties for violations, including imprisonment and fines for hospitals, medical professionals, and middlemen involved in illegal organ trade.
- Allowed suspension or cancellation of hospital registrations if they violate transplant regulations.
- Implemented strict documentation and verification of donor-recipient relationships to prevent fraud.

**Although the legislation has regulated the aspects of organ transplant authorization, ethical donor verification, and legal penalties for violations, it has inherent lacunae in the following areas:**

- Inconsistent Implementation Across States – Many states still lack fully operational SOTTO units, leading to gaps in coordination and organ distribution.
- Challenges in Brain Death Certification – The lack of uniform medical training results in delays and discrepancies in declaring brain death.
- Transparency in Organ Allocation – While NOTTO and SOTTO were introduced to streamline allocation, favouritism, and prioritization of high-paying patients remain concerns.

- Ethical Issues in Living Donation – Despite regulations, financial inducements and coercion persist, particularly affecting economically weaker sections.
- Limited Awareness and Public Participation – There is insufficient public knowledge and trust in the organ donation system, resulting in low donation rates.

### **3. Challenges in organ donation**

#### **3.1. Ethical Challenges in Organ Donation**

Absence of detailed information to evaluate hazards- Social norms have been encountered to be deeply embedded in the majority of these live donors. Because of their moral duty to their loved ones, friends, or society, live donors typically choose to donate right away. He/she does not consider the effects of such choices on their life and well-being. Organ donation is sometimes done as a form of atonement for previous transgressions. There isn't a way to follow up with the donations at the moment. It is difficult for donors to precisely evaluate the hazards because there is a lack of detailed information on the post-donation outcomes of these donors.

Gender issues- The donation of organs regime has, in fact, placed the onus of organ donation on living female donors worldwide. These women are under direct or indirect household pressure to save the recipient, and they occasionally worry about social rejection or condemnation from their parents or in-laws if they decline to donate.

Informed consent challenges- Ensuring truly informed consent from organ donors remains a significant challenge, particularly among individuals with limited education or economic dependence. Many donors, especially those from marginalized communities, may not fully comprehend the medical risks, long-term health implications, or legal aspects of donation. In some cases, coercion or financial incentives subtly influence their decisions, undermining the principle of voluntary and well-informed consent. The lack of adequate counseling and awareness further exacerbates it, making it difficult to ascertain whether consent is truly autonomous. In cases where the patient has no living members left behind then the issue arises as to whether the state or any rehabilitation organization has the authority to give consent for organ donation.

Social and familial pressures- In India, family dynamics and societal expectations play a crucial role in organ donation decisions. Donors often feel an implicit obligation to donate their organs to relatives, even if they are not entirely willing. Familial pressure, emotional blackmail, or cultural norms may compel individuals to make donations against their best interests. In some cases, women, particularly daughters-in-law, may face undue pressure to donate organs to male family members, raising ethical concerns about gender-based exploitation. This issue highlights the thin line between voluntary donation and coerced participation.

Ethical concerns in unrelated donations- Unrelated organ donations are often subjected to rigorous scrutiny due to the high risk of financial transactions disguised as altruistic acts. The legitimacy of such donations is frequently questioned, as it is challenging to determine whether the donor is genuinely motivated by humanitarian concerns or influenced by monetary incentives. The strict approval process for unrelated donations, though necessary, often leads to delays and discourages potential donors. Additionally, there are ethical concerns regarding potential exploitation, where financially disadvantaged individuals may be subtly pressured into donating under the guise of goodwill.

Access inequities- Economic disparities significantly impact access to organ transplants in India. Wealthier individuals have greater access to high-quality medical care, legal support, and potential

living donors, whereas economically weaker patients often struggle to find matching donors or afford the transplantation process. This disparity creates an unfair advantage for affluent patients, while those from lower-income backgrounds remain on long waiting lists or resort to illegal means to obtain organs. The lack of a well-established, equitable organ-sharing system further aggravates this problem.

Coercion and exploitation of Donors- Living donors, especially from economically weaker sections, face coercion and undue influence, leading to non-voluntary donations. Cases of organ trafficking and black-market transactions expose the vulnerability of poor individuals who are pressured into donating organs for financial compensation.

### **3.2. Legal Challenges in Organ Donation**

Regulatory limitations- While THOTA was enacted to prevent organ commercialization and regulate transplantation, its rigid provisions have struggled to keep pace with evolving medical and ethical challenges. The Act does not provide clear guidelines for altruistic donations, where individuals voluntarily donate organs to non-relatives without financial incentives. Additionally, cross-border organ donation remains a grey area, as India's legal framework does not effectively address scenarios where foreign recipients seek organ transplants in the country. The absence of legal provisions accommodating these complex cases restricts the availability of potential donors.

Illegal organ trade- Despite stringent laws prohibiting organ sales, illegal organ trafficking remains a pressing issue in India. Vulnerable socio-economic groups are often coerced or deceived into selling their organs through middlemen who exploit legal loopholes. Organ trafficking networks thrive due to inadequate enforcement of THOTA, weak monitoring mechanisms, and corruption. The persistent demand-supply gap in organ transplantation further fuels this illicit trade, making it challenging for authorities to eliminate black-market activities.

Weak implementation and monitoring- Despite the legal safeguards outlined in THOTA, enforcement remains inconsistent at the ground level. Weak monitoring mechanisms allow unethical practices such as organ trafficking, coerced donations, and falsified consent documents to persist. Many hospitals and regulatory authorities lack the resources or commitment to conduct thorough investigations, making it easier for illicit transactions to go undetected. The absence of a centralized, transparent database for tracking living organ donations also contributes to weak oversight, allowing loopholes to be exploited.

Issues with "authorization committees"- Authorization Committees play a crucial role in approving organ donations, particularly in cases involving unrelated donors. However, inefficiencies within these committees have led to unnecessary delays in scrutinizing applications. The slow processing of approvals significantly impacts patients in urgent need of transplants. Additionally, the overcautious approach of healthcare institutions, aimed at preventing illegal trade and organ trafficking, has resulted in rigid scrutiny, often discouraging legitimate donors. The lack of standardized and transparent procedures has further exacerbated the inefficiencies within these committees.

Brain death determination- Determining brain death in organ donation presents challenges due to the complex and subjective nature of assessing irreversible brain function loss. Variations in medical practices, legal definitions, and the potential for misdiagnosis can complicate the process, raising ethical and legal concerns about the timing and accuracy of the determination.

Consent- Consent poses a substantial legal challenge in organ transplantation mostly due to social stigma, economic inequality, and existing loopholes in the legal framework in India.

### **3.3. Other Challenges in Organ Donation**

Infrastructural and manpower issues in the Government Sector – Government hospitals lack the infrastr-

ucture and workforce necessary to perform transplant procedures. There are about 250 transplant centers in India, the majority of which are located in private hospitals. As a result, private hospitals do around 90% of transplant procedures. Additionally, there is a shortage of transplant surgeons. Particularly at government hospitals, this results in a lengthy waiting list for transplant procedures. While awaiting his turn for treatment, a man who had gotten funding for kidney transplant surgery from the Prime Minister's Office passed away.<sup>29</sup>

**Bureaucratic hurdles-** The requirement for Authorization Committee approval for unrelated living donors adds to the bureaucratic complexity of organ donation in India. The verification process, often involving extensive paperwork and multiple levels of scrutiny, results in prolonged delays. Genuine donors, motivated by personal relationships or humanitarian reasons, frequently face obstacles in obtaining swift approvals. These procedural delays not only frustrate donors but also jeopardize the lives of patients awaiting transplantation. Furthermore, the complex and often inconsistent decision-making process of these committees discourages many willing donors from coming forward.

#### 4. Judicial Approach

The judiciary has addressed both ethical and legal challenges to some extent and suggested measures to ensure transparency, efficiency, and fairness in the organ donation process. Several judicial pronouncements have shaped the legal landscape of organ donation in India, reinforcing the principles of autonomy, informed consent, and regulatory compliance. In *Neha Devi v. Govt. NCT Delhi (2022)*<sup>30</sup> the Delhi High Court upheld the right to bodily autonomy and privacy in organ donation, ruling that a spouse does not have a controlling right over the donor's decision and emphasizing that only free and informed consent is required. The court relied on verdict of *Common Cause v. Union of India (2018)*<sup>31</sup> and clarified that Rules 18 and 22 of the Transplantation of Human Organs and Tissues Rules, 2014, do not mandate spousal consent but require independent confirmation of the donor's choice. In *Kuldeep Singh & Another v. State Of Tamil Nadu & Ors (2005)*<sup>32</sup>, the Supreme Court ruled that organ donors and recipients must seek approval from the Authorization Committee in their home state to assess the donor's true intent. The court emphasized that the burden of proving the donation is motivated by love and affection lies on the applicants. In the case of *Deepa P.M. & Anr. v. State of Kerala & Ors*<sup>33</sup>, the Kerala high court held that the intention behind organ donation cannot be distrusted merely because of the poor economic standing of the donor. It affects individual dignity. In the case of *Sanjay Yogi Goel v. Union of India & Ors*<sup>34</sup>, on the question of the legality of a proposed organ donation by the mother-in-law of the patient's son, the Delhi High Court noted that the attribute of human love and affection cannot be ignored and only if it is carried out for financial or commercial gain with motive, such an exchange

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<sup>29</sup> Verma L., "Santosh Kumar, who got PMO funds for kidney transplant, dies on waitlist", The Indian Express, July 7, 2015. <https://indianexpress.com/article/india/india-others/33-yr-old-who-got-pmo-funds-for-kidney-transplant-dies-on-waitlist/>

<sup>30</sup> W.P (C) 8671/2022, decided on 30.05.2022, The High Court of Delhi (India).

<sup>31</sup> (2018) 5 SCC 1 (India).

<sup>32</sup> AIR 2005 SC 2106 (India).

<sup>33</sup> 2023 LiveLaw (Ker) 761 (India).

<sup>34</sup> W.P. (C) 2792/2017, judgement on 01.05.2017, The High Court of Delhi (India).



would be bad in law. In *Jillet K.T. & Another v. State of Kerala & Others (2024)*<sup>35</sup>, the Kerala High Court directed the State Government to establish Hospital-Based Authorization Committees to expedite decisions on organ donation applications, emphasizing that the absence of photographs featuring the donor and recipient should not be grounds to reject a donor's claim of voluntary organ donation. Last but not least, in the case of *Amar Singh Bhatia & Anr. v. Sir Ganga Ram Hospital & Ors. (2024)*<sup>36</sup>, The Delhi High Court prescribed specific timelines for various steps in the organ transplantation process, highlighting that delays due to the absence of fixed timelines defeat the purpose of the statutes governing organ donation.

These judgments collectively highlight the importance of transparency, ethical compliance, and the protection of vulnerable individuals in organ donation practices.

## 5. Conclusion and Suggestions

Organ donation is a vital part of healthcare, offering a chance to save lives, but in India, it faces many challenges. The Transplantation of Human Organs and Tissues Act, 1994 (THOTA) provides a basic legal framework, but its implementation has been difficult. Problems such as weak enforcement, lack of public awareness, and illegal organ trade make it hard to achieve the goals of the law. Ethical concerns like ensuring informed consent and fairly distributing organs also add to the complexity of the issue. However, over the years, significant changes in attitude, awareness, and perspective towards Organ Donation have been noticed but; the implementation of the law is still a problem which continues till now. Organ donation must always be a voluntary act.

To make organ donation more effective and fairer, these challenges need to be addressed in a comprehensive way. This includes stricter enforcement of the law, campaigns to educate the public, and clear processes for organ distribution. Collaboration between the government, hospitals, and NGOs is crucial to build trust and encourage more people to participate in organ donation. By resolving these issues, India can create a fair and efficient organ donation system that saves more lives and benefits everyone.

- Strengthening the Legal Framework by suitably amending and addressing the loopholes and by introducing clearer, stricter penalties for violations, ensuring better deterrence against illegal organ trade.
- Enhancing a robust enforcement mechanism with independent oversight bodies to monitor compliance with organ donation and transplantation regulations.
- Launching nationwide Public Awareness Campaigns to educate people about the need for organ donation, and societal myths, and promote a culture of voluntary donation.
- Ensure that healthcare professionals receive adequate ethical training on ethical issues, including; a) obtaining informed consent and; b) addressing family concerns sensitively.
- Improving Infrastructure and Accessibility by increasing the number of organ retrieval and transplantation centers, particularly in rural areas, to reduce inequities in access.
- Implement an integrated digital registry for organ donors and recipients to ensure transparency and fairness in organ allocation.

<sup>35</sup> 2024 LiveLaw (Ker) 641 (India).

<sup>36</sup> 2024 SCC OnLine Del 30 (India).

- To Study and adapt successful global models, such as Spain's presumed consent system, to the Indian socio-cultural context, encouraging a shift toward an opt-out system.

By implementing these reforms, India can address the existing legal and ethical challenges in its organ donation system. These measures will help build public trust, encourage higher rates of organ donation, and ensure a fair and efficient framework that saves more lives.

## REFERENCES

1. Kancharla B., Data: Between 2016 & 2021, Four States Accounted For 53% of The Organ Donations Reported from Across the Country, Factly, December 22, 2022.
2. Mathiharan K., "Ethical and legal issues in organ transplantation: Indian scenario", *Med Sci Law*, 2011, 51 (3),134-40.
3. Suriyamoorthi S., Shroff S., Navin S., Pathinathan P., Ranjithkumar R., Rajasekar J., "Unique Challenges in the Deceased Donation Programme in India", *Transplantation*, 2018, 10 (2), S223.
4. Shah S.B., Shah B.V., "Legal Aspects of Transplantation in India", *Indian Journal of Transplantation*, 2018, 12 (3),169-173.
5. Mehta D., Saksena N., Mittal Y., "Organ Transplant Law: Assessing Compatibility with The Right to Health", *Vidhi*, 2017.
6. Vasanthi R., "Why NOTTO? The National Organ and Tissue Transplant Organisation and Why It Is Crucial to Regulate Organ Donation and Transplantation in India", *Transplant Proc*, 2020, 52 (10), 2930-2933.
7. Nagral S., Amalorpavanathan J., "Deceased organ donation in India: where do we go from here?", *Indian Journal of Medical Ethics*, 2016, 11 (3), p.162.
8. Ramesh V., Pal C., "Organ Donation and Transplantation in India in 2019", *Exp Clin Transplant*, 2021, 19 (12), 1313-1321.
9. Navin S., Suriyamoorthi S., Shroff S., "Ethical Dilemmas in Deceased Organ Donation and Allocation – An Emerging Challenge in India", *Transplantation*, 2018, 10 (2), S221.
10. Ehtuish F. A., "Ethics of Organ Donation and Transplantation: Toward Self-Sufficiency", *Experimental and clinical transplantation*, October 2024 - Supplement - 5, 22 (10), 30-34.
11. Ahlawat R., Kumar V., Gupta A.K., Sharma R.K., Minz M., Jha V., "Attitude and knowledge of healthcare workers in critical areas towards deceased organ donation in a public sector hospital in India", *Natl Med J India*, 2013, 26 (6), 322-6.
12. Panwar R., Pal S., Dash N.R., Sahni P., Vij A., Misra M.C., "Why are we Poor Organ Donors: A Survey Focusing on Attitudes of the Lay Public from Northern India", *J Clin Exp Hepatol*, 2016, 6 (2), 81-6.