

LEGAL AND ETHICAL ASPECTS OF ORGAN DONATION AND TRANSPLANTATION

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Abstract

Organ donation and transplantation present complex legal and ethical challenges that require careful consideration of consent, allocation, regulation, and ethical principles. While legal frameworks provide the structure for organ procurement and transplantation, ethical guidelines safeguard the rights and well-being of donors, recipients, and society as a whole. Continued efforts to strengthen legal protections, enhance ethical standards, and promote public awareness are essential to advancing the field of organ transplantation and ensuring equitable access to life-saving treatments. This paper deals with various legal issues related to legal and ethical aspects of organ donation and transplantation.

1. INTRODUCTION:

“India passed the Transplantation of Human Organ Act (THO) in 1994 with the goal of accelerating the process of organ donation and transplantation. Broadly speaking, the act recognised brain death as a kind of death and outlawed the trade of organs. Solid organ transplants, such as liver, heart, lung, and pancreas transplants, as well as kidney transplants, were made possible by the recognition of brain death. Even with the THO Act, kidney scandals and the organ trade frequently make the news in Indian media. Most of the time, the legislation's provisions have been misused, and its application has been flawed.”¹

“The programmes for deceased donations and living related and unrelated donation have progressively grown alongside one another in a number of states. Organs from deceased donor programmes are used in about one-third of liver transplants, as well as all heart and pancreatic transplants. The dead donor programme has continued at the same rate in these states thanks to a few hospitals and committed non-governmental organisations. In the last fourteen years,

¹ Sunil Shroff, Legal and ethical aspects of organ donation and transplantation, (Indian J Urol. 2009 Jul-Sep), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/>.

1,300 deceased organ transplants have been performed nationwide; the MOHAN Foundation, based in Tamil Nadu and Andhra Pradesh, has enabled 400 of those operations. To address the organ scarcity, developed countries are reassessing the ethics of unrelated programmes, and it seems that there is a drive to make this a legal alternative that is acceptable.”²

“Organ transplantation is among the biggest breakthroughs in medical research to date. While ancient Chinese and Indian medical writings do contain some references of organ transplantation, French surgeon Alexis Carrel laid the scientific groundwork for modern organ transposition in 1902 while conducting animal studies. A human kidney was transplanted in 1946, followed by a liver in 1963 and a heart in 1967. This also occurred in many other organs, including the intestines, pancreas, and lung.”³

2. HISTORY:

“Since kidney transplants were first carried out in India in the 1970s, the country has emerged as a leader in this field on the Asian subcontinent. Transplants have changed over the past forty years, with a new facet of the discipline emerging every ten years. Developing surgical and immune-suppressive abilities took up the first ten years. Over the next ten years, there was a notable rise in the number of transplants carried out as a result of its success. Furthermore, unrelated kidney donations from lower socioeconomic groups started to happen, and organ donation via commerce was acknowledged as a crucial part of the programme.”⁴

After this approval, transplant ethics in India have always been problematic, with several dubious techniques being accepted as standard procedure. It was widely believed, "Why donate when you can buy one?" Western doctors began to criticize the growing number of these exploitative transplants carried out in India over the course of the following 10 years. There were also protests from other Indian sectors. Political pressure led to the government passing the Transplantation of Human Organ Act (THO), which forbade unrelated transplants and permitted deceased donation in situations where brain death occurs.⁵

² Ibid 2.

³ Frederike Ambagtsheer, Coby Annema, John Forsythe, Nichon Jansen and David Paredes, "Ethical and Legal Aspects of Organ Donation and Transplantation", (Frontier partners, April 9 2024), <https://www.frontierspartnerships.org/articles/10.3389/ti.2024.13011/>.

⁴ Sunil Shroff, "Legal and ethical aspects of organ donation and transplantation", (Indian J Urol. 2009 Jul-Sep), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/>.

⁵ Ibid.

Despite THO legislation, there has been no rise in the trade or number of deceased donors in India to alleviate the organ scarcity. There has never been substantial media discussion or support for brain death. The vast majority of unrelated transplants are being performed with committee approval. The few deceased contributions that are happening are because of the efforts of a tiny number of hospitals or non-governmental organizations (NGOs) that are fervently dedicated to the cause. The government has attempted to tighten the THO act's flaws and halt illicit unconnected contribution operations by introducing numerous legislation in the form of gazettes in response to growing public and media criticism. The interpretation and implementation of the THO act by hospitals and government organizations has been a major factor in its failure.⁶

3. INDIAN ORGANIC DONATION AND TRANSPLANTATION LAWS AND REGULATIONS:

“Transplantation is the process of grafting tissues from one part of the body to another or from one individual to another. It entails taking an organ or a section of tissue out of its natural site and relocating it, either inside the same person or in a different one. Relocating or introducing something from one place or context to another is another meaning of transplanting. Transplantation, as used in medical terminology, is the process of moving a living tissue or organ to a different body or area of the body. Transplantation is the process of replacing a diseased or failed organ or tissue with a new one by moving an organ or tissue from one person to another.”⁷

“By making use of the pool of brain-dead people, fewer unrelated transplants were anticipated to address the organ shortage. Over the past ten years, India's scheme for deceased donation has faced numerous challenges. It has also seen the continuous kidney disputes that plague the process for living donors. Typically, the donor asserted that neither the recipient nor the intermediary had given them the agreed-upon sum. Additionally, organ transplants including the liver, heart, and pancreas from deceased donors were performed.”⁸

⁶ Ibid.

⁷ Dictionary of Organ Donation and Transplantation Terms, 1+1= LIFE METORSHIPNPROGRAM AMERICAN TRANSPLANT FOUNDATION, (Dec. 12, 2018), <http://www.americantransplantfoundation.org/wp-content/uploads/2014/04/Organ-DonationDictionary.pdf>.

⁸ Sunil Shroff, Legal and ethical aspects of organ donation and transplantation, (Indian J Urol. 2009 Jul-Sep), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/>.

“Even though cadaver transplants are a relatively new operation in India, the first attempts to use a kidney from a corpse donor were attempted in Mumbai in 1965. The author describes the physiological and social problems they ran into. Infection, immunological problems, and technical difficulties with engrafting were among the medical complications. The unfavourable reaction from certain medical experts and the general public, however, was harder to handle. The entire process has been called "neo-cannibalism" by some. This affected the cadaver programmes across the country, not just in Mumbai.”⁹

3.1 Transplantation of Human Organs Act, 1994:

The disparity between the supply and demand of organs has widened as a result of the transplantation technology field's rapid advancements. This presents a number of ethical and policy issues for the legal community at large as well as the medical community, which need to be effectively addressed by the state and the legal community in particular. The most important question is: What laws should be put in place to help boost the availability of organs when the supply cannot keep up with demand?¹⁰

The Indian government made the appropriate decision to address the issue of the lack of organ donors as well as the additional challenges faced by patients in need of this amazing new medical technology. Thus, the Transplantation of Human Organs Act⁵ (THOA), which regulated "the removal, storage, and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto," was approved by the President of India on July 8, 1994.¹¹

The cornerstone of Indian law governing organ donation and transplantation is the Transplantation of Human Organs Act (THOA), which was passed in 1994 and revised in 2011. Important clauses consist of:

Authorization: Section 9¹² of THOA prohibits commercial dealings in organs and specifies the conditions under which organs may be removed and transplanted.

⁹ Ibid 9.

¹⁰ Arthur L. Caplan, "Sounding Board: Ethical and Policy issues in the Procurement of Cadaver organs for Transplantation", Dale H. Cowan (ed.), Human Organ Transplantation 272 (1987).

¹¹ Sapna Khajuria and Saugata Mukherjee, ORGAN TRANSPLANTATION : LEGAL FRAMEWORK EXAMINED, (Journal of the Indian Law Institute , APRIL-DECEMBER 1997, Vol. 39, No. 2/4, APRIL-DECEMBER 1997), pp. 299-311, (Indian Law Institute), <https://www.jstor.org/stable/43953275>.

¹² The Transplantation of Human Organs and Tissues Act, 1994, No.42 of the Parliaments 1994 (India) Section 9.

Consent: Section 3¹³ mandates that organ donation must be voluntary and based on informed consent from the donor or their next of kin.

Regulation: The Act establishes National and State Authorization Committees to oversee and regulate organ transplantation activities, ensuring compliance with legal standards and ethical guidelines.

Subclause (3), Clause 9 of Chapter II of the THO act states that "human organs shall not be removed and transplanted without the prior approval of the Authorization Committee if any donor authorises the removal of any of his human organs before his death under sub-section (1) of Section 3 for transplantation into the body of such recipient, not being a near relative as is specified by the donor, by reason of affection or attachment towards the recipient or for any other special reasons." This clause has been misapplied or misconstrued by many over the years since the act was passed.¹⁴

Organs for transplantation may come from a deceased or living donor.

Living Donor:

Donor: Near Relative: Transplant (parent, son, daughter, brother, sister, partner, etc.). by switching close relatives who donate in pairs with recipients who aren't matched; Other than donors who are close relatives: With the approval of the authorization committee, such a donor may only give for emotional reasons such as love and connection or for any other special cause.¹⁵

Deceased donor:

Donor after brain stem death: In situations where a patient's brain stem has died and their breathing is assisted by a ventilator, oxygen, fluids, etc. to maintain their heart and other organs functioning, such as those involving victims of auto accidents or other incidents, organ donation is theoretically possible.¹⁶ Donor following cardiac demise (DCD): In India, donating

¹³ The Transplantation of Human Organs and Tissues Act, 1994, No.42 of the Parliaments 1994 (India) Section 3.

¹⁴ Sunil Shroff, Legal and ethical aspects of organ donation and transplantation, (Indian J Urol. 2009 Jul-Sep), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/>, Accessed 1st July 2024.

¹⁵ "Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOS/SOTTOs, http://dghs.gov.in/WriteReadData/userfiles/file/RTI/THOA_NOTP_NOTTO_ROTTO_SOTTO_16-7-2020.pdf",

¹⁶Ibid 16.

tissues is limited to cases of cardiac death. Yet, only a few facilities, such as PGI Chandigarh, have begun DCD.

The Interpretation of Transplant Clinicians: The clinicians question why they should reject any arrangement between the donor and receiver if the law itself contains a provision to assist persons whose own family members decline to donate or those who do not have a suitable or matched donor. To them, all objections are superseded by the recipient's predicament. They contend that it is challenging for them to comprehend what is meant to be genuine affection. They believe that the government AC has the authority to determine who is responsible for finding genuine affection and partnerships.

The interpretation of the authorization committee:

Upon reviewing the relevant legal rules, the AC determines that unless there is a serious oversight or complaint, the recipient and giver should not protest if they pledge affection in front of each other. Additionally, they think that since the doctor submitted the case to the committee, they should confirm the assertions made. Most petitions submitted to the AC are often approved. The majority of unconnected donations happen when the giver publicly declares their genuine love for the recipient.

It outlines who is qualified to give when they are still living without requiring any formal legalities. The family members that are allowed to donate include the mother, father, son, daughter, sisters, and spouse. Recently, grandparents were added to the new Gazette's list of first relations. The earliest relatives are required to provide proof of their relationship, such as court records or DNA tests.¹⁷

In the event that the donor and beneficiary are unrelated, the donor must seek for special permission from the government-appointed authorization committee and show during the interview that the donation was made only with the recipient's best interests in mind. The following standards are applied for defining and declaring brain death: Two certifications are required, six hours apart from medical professionals. Two of them must be from medical professionals nominated by the appropriate government agency, with one certification coming from a neurology specialist.¹⁸

¹⁷ Sunil Shroff, Legal and ethical aspects of organ donation and transplantation, (Indian J Urol. 2009 Jul-Sep), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/>, Accessed 27th September 2024.

¹⁸ Ibid 18.

“Establishing an Authorization Committee (AC) and Appropriate Authority (AA) in each State or Union Territory will regulate transplant operations.” Everybody has the following specific roles:

Function of the Authorization Committee (AC): The AC's job is to oversee the authorization procedure for transplants involving recipients and donors who are not first cousins. The committee's main responsibility is to make sure the donor isn't being used to obtain money in exchange for their organ donation.¹⁹

“The application submitted jointly by the donor and recipient is carefully examined, and a face-to-face interview is necessary to confirm to the AC that the donor truly has the intention of donating and that they are aware of the possible dangers associated with the procedure. Notifications of acceptance or rejection are mailed to the relevant hospitals. Section 9 of Chapter II of the THO Act, Subclause (3), governs the decision to accept or reject a donor. The role of Appropriate Authority (AA) is to control the harvesting, storing, and transplantation of human organs. A hospital can only carry out these tasks after receiving an official licence from the relevant authorities. Eye extraction from a donor's dead body is not subject to such regulations, and it is possible to perform the process elsewhere without a licence.”²⁰

“The AA has the authority to inspect and approve hospitals for transplant surgery, enforce hospital standards, carry out routine hospital inspections to assess the standard of transplantation and post-transplant medical care for donors and recipients, suspend or revoke the registrations of hospitals that violate the Act, and look into complaints alleging violations of any of the Act's provisions. A hospital can obtain a licence from the AA for a maximum of five years at a time, with the option to renew it thereafter. Licenses for each organ are needed separately.”

3.2 National Organ and Tissue Transplant Organization (NOTTO)

NOTTO, established under the Ministry of Health and Family Welfare, Government of India, plays a pivotal role in coordinating and monitoring organ donation and transplantation activities across the country. It oversees:

¹⁹ Sunil Shroff, Legal and ethical aspects of organ donation and transplantation, (Indian J Urol. 2009 Jul-Sep), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/>.

²⁰ Ibid 11.

National Registry: NOTTO maintains a national registry of donors and recipients, facilitating equitable distribution of organs based on medical urgency and compatibility.

Policy Formulation: The organization formulates policies and guidelines to promote ethical practices, donor awareness, and transplant coordination among authorized centers.²¹

1. Nagendra Mohan Patnaik And Ors. vs The Government Of A.P. Rep. By Its ... on 12 November, 1996²²

Facts:

The case involved Nagendra Mohan Patnaik and others as petitioners against the Government of Andhra Pradesh. The petitioners were challenging the legality of actions taken by the government related to organ transplantation practices in the state. The case referenced the Transplantation of Human Organs Act, 1994, which regulates organ donation and transplantation in India.

Issues:

1. Validity of Government Actions: Whether the government's actions concerning organ transplantation complied with the provisions of the Organ Transplantation Act.
2. Rights of Patients and Donors: Did the government adequately safeguard the rights of patients needing transplants and the rights of organ donors?
3. Implementation of Regulations: Were there proper guidelines and procedures in place for organ donation and transplantation?

Arguments:

Petitioners' Arguments:

- The petitioners contended that the government had not effectively implemented the Organ Transplantation Act, leading to issues like illegal organ trade and unethical practices.
- They argued that the rights of patients and potential organ donors were being overlooked, resulting in a lack of trust in the organ transplantation system.

²¹ National Organ and Tissue Transplant Organization (NOTTO).

²² W.P. (MD) No. 363 of 2014, M.P. (MD) No. 1 of 2014.

- They sought better regulatory frameworks and more transparency in the organ donation process.

Respondent's Arguments:

- The government defended its actions by stating that it was working within the framework of the Organ Transplantation Act and that necessary measures were being taken to regulate organ transplants.
- It asserted that there were ongoing efforts to promote legal organ donation and prevent illegal activities.
- The government argued that it had established protocols for organ transplantation in line with the Act.

Judgment:

The court assessed the adherence of the government to the provisions of the Organ Transplantation Act. Key points from the judgment included:

1. **Regulatory Compliance:** The court found that there were significant lapses in the enforcement of the Organ Transplantation Act, which needed immediate attention.
2. **Patient Rights:** The judgment emphasized the necessity of protecting the rights of patients and potential donors, advocating for a more transparent and accountable system.
3. **Government Responsibility:** The court directed the government to take proactive measures to enhance the implementation of the Act, ensuring that proper guidelines and ethical practices were in place.
4. **Public Awareness:** It also highlighted the importance of educating the public about organ donation and transplantation to encourage legal practices and discourage illicit activities.

Conclusion:

The ruling underscored the need for effective governance in the area of organ transplantation, reinforcing the principles of ethics and legality. The case served as a reminder of the government's obligation to uphold the rights of individuals while fostering a responsible environment for organ donation and transplantation.

2. Dr. Upendra Kumar v. State Of Maharashtra.²³

The petitioner filed a Criminal Revision Petition to call for the records relating to the impugned order dated 16.08.2019 passed by the learned Judicial Magistrate No.1, Dharmapuri in CrI.M.P.No.4289 of 2017 in C.C.No.132 of 2007. The petitioner sought to examine the correctness of the findings therein and to set aside the same and discharge the petitioner from the said case.

The respondent police registered the case in Crime No.28 of 2013. Challenging the said order, the petitioner filed the present Revision. The learned Magistrate overlooked the clear and specific findings of this Court in the above referred to judgment. Even in the FIR registered in Crime No.28 of 2013, the name of the petitioner was not found and subsequently arrayed as A-5 in the charge sheet. The petitioner having already challenged the FIR in Crime No.29 of 2013 and orders having been passed by this court, prohibiting investigation by the respondent police, the present Final Report filed by the respondent Police in crime No.28 of 2013 implicating the petitioner also as an accused is thoroughly illegal and tainted with malafides. Therefore, the trial court failed to look into the legal provisions and also the judgment of the Division Bench of this court referred to supra and wrongly dismissed the petition and stated that there is no bar under Section 13(3) (iv) of the TOHO to register and investigate the case for offence under IPC.

However, in regard to the clear-cut ingredients of Section 22 of the TOHO and Tissues Act, the police is forbidden to file its report after completion of investigation. The learned counsel for the petitioner submitted that the petitioner was not involved in any offence and prima facie, no material is against the petitioner. Though the case was registered based on information sent by the Authorisation Committee, the respondent police helped the committee to arrive at prima facie case and that the appropriate authority has to file the complaint and not the respondent police. However, the State Appropriate Authority, Human Organ Transplantation Act, 1994, can file a complaint against the petitioner herein in the manner known to law. However it is for the Appropriate Authority to file complaint against the petitioner in the manner known to law.

²³ Writ Petition No. 2903 of 2013.

4. ETHICAL DIMENSIONS OF ORGAN TRANSPLANTATION:

It is indisputable that the foundations of ethics are derived from philosophical and theological creeds. Additionally, ethics is culture- and time-specific, and it may need to be further adjusted to meet the demands of a country's diverse ethnic groups. These empirical facts must be taken into consideration for a set of moral standards to be deemed acceptable.

Ethical Considerations:

1. Autonomy and Informed Consent

Respecting the autonomy of donors and recipients is fundamental to ethical organ donation practices. Donors must provide informed consent, understanding the risks and benefits of donation, without coercion or undue influence. Recipients, on the other hand, must be fully informed about the transplantation procedure, including potential risks and long-term implications.²⁴

2. Equity and Justice

Ensuring fairness and justice in organ allocation is essential to ethical transplantation. Allocation systems should prioritize medical need and clinical criteria rather than socioeconomic status, race, or other non-medical factors. Ethical guidelines promote transparency and accountability in the allocation process to mitigate disparities and promote trust in the system.²⁵

3. Avoiding Exploitation and Commercialization

Efforts to prevent exploitation and commercialization of organ donation are critical ethical considerations. Organ trafficking, where organs are illegally bought or sold, undermines ethical principles and poses serious risks to donors and recipients alike. Ethical guidelines and legal frameworks aim to prohibit such practices and promote altruistic donation based on humanitarian principles.²⁶

4. "Helping many people who are in critical condition is the aim of organ donation and transplantation. A method or course of action is justifiable under the concept of utility if it

²⁴ The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, Participants in the International Summit on Transplant Tourism and Organ Trafficking Convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey, (April 30 through May 2, 2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571160/>.

²⁵ The American Society of transplant Surgeons (ASTS) Code of Ethics.

²⁶ The Council of Europe's Convention against Trafficking in Human Organs

advances the aggregate net good to the same extent—if not more—than any other course of action. When it comes to the distribution of organs, the concept of utility—which incorporates the moral precepts of beneficence (do well) and non-maleficence (do no harm)—specifies that the distribution should aim to maximise the anticipated net amount of overall benefit.”²⁷

5. JUSTICE:

The National Organ Transplant Act (NOTA) specifically identified the need for "equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centres and among patients medically qualified for an organ transplant" when it mandated the formation of the Task Force on Organ Procurement and Transplantation.²⁸ Justice in this sense refers to the fair distribution of the benefits and drawbacks of an organ procurement and allocation programme.

6. RESPECT TOWARDS INDIVIDUALS:

Respect for humans is the third ethical guideline offered by the Belmont Report. According to this theory, persons should be respected and considered "ends in themselves," not only as means to an end. This idea upholds the moral standards of integrity and loyalty to agreements made. Above all, respect for humans includes the idea of honoring individuality.²⁹

In the 1990s, the Ethics Committee recommended that policies make an effort to give equal weight to conflicting ethical opinions in order to balance them. That still appears to be a reasonable compromise. Consequently, it is intolerable for an allocation policy to be restricted to maximizing the total medical benefit at the expense of justice in the distribution of that benefit, or conversely, to be restricted to advancing justice at the expense of the total medical benefit. It's possible for one group to value one principle more than another.³⁰

The country's technical developments, the growing middle class, the lack of a federal health insurance scheme, and the growing wealth divide all contribute to the commoditization of organs, making it a quick, simple, and attractive commercial enterprise for some and a cure for

²⁷ U.S. Department of health and human services, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-in-the-allocation-of-human-organs/>

²⁸ U.S. Department of health and human services, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-in-the-allocation-of-human-organs/>

²⁹ supra note 25.

³⁰ supra note 25.

others. Many middle-class or upper-class affordable families commonly hear the general objection, "Why donate and take any risks when you can buy a kidney?" This remains valid even in cases when there are healthy relatives who are able to give. The organ trade has a societal component in India, much like child labour and prostitution do.

5. TRADE OF HUMAN ORGANS:

Even after the THOA was passed to prohibit the sale of human organs for profit, more and more scandals involving doctors and other kidney trade participants have surfaced on a regular basis in all of India's states, demonstrating the inadequacy of the current regulatory framework in stopping the organ trade.

"The commercialization of kidneys is as common now as it was prior to the implementation of the Act and the current regulatory system is incapable of preventing it," according to a study titled "Implementation of the THOA" by Dr. VR Muraleedharan and S. Ram Prasad from the Centre for Sustainable Development, Indian Institute of Technology, Chennai. The investigation found that patients with end-stage renal disease often married women for their kidneys and afterward divorced them; they also often gave donors bogus addresses and used proxy donors to get authorization committee clearance for unrelated transplants.³¹

"The analysis concludes that the primary problem is that the Authorization Committee needs to justify rejecting an unrelated donation but not approving it. It further asserts that a number of medical professionals and hospitals have allowed middlemen to operate openly on their grounds, which has aided in the rapid commercialization of kidneys. It goes on to say that many kidney donors are genuinely in poor health and shouldn't have been allowed to donate their organs, and that these detrimental, profit-driven strategies have also undermined medical standards for matching donors and receivers."³²

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³¹ Karunakaran Mathiwaran, 'Ethical and Legal Issues in Organ Transplantation: Indian Scenario' (2011) 51 Med Sci & L 134.

³² supra note 29.

organs, and that these detrimental, profit-driven strategies have also undermined medical standards for matching donors and receivers.”³³

Most proposals submitted to the Authorization Committee are often approved. The majority of unrelated contributions happen when a donor appears before the Authorization Committee and declares their genuine love for the receiver. “Between 1995 and 2002, the Tamil Nadu Authorization Committee considered nearly 5000 cases, rejecting less than 5% of them. In a separate memo, the Tamil Nadu Department of Health stated that, of the 1868 applications received, 1559 unrelated transplants had been accepted between January 2000 and May 2002. The circumstances in Tamil Nadu are similar to those in other Indian states where transplants are performed.”

6. GAPS IN THE THOA

“The primary cause of the continued legal immunity granted to the trade in human organs is the misuse of Section 9(3) of the Act. No human organ extracted from a donor before his death may be transplanted into a recipient unless the donor is a close relative, as that term is defined under Section 2(1) of the THOA as a husband, son, daughter, parent, mother, brother, or sister. The Act's Section 9(1) makes this very clear. However, Section 9(3) of the Act states that if a donor is attached to the recipient or has other special circumstances, he or she may consent to the removal of organs before his or her death with the authorization committee's approval.”³⁴

“However, the Authorization Committee is neither equipped nor authorised to verify on its own the accuracy of the information that the donor and beneficiary have provided. The Authorization Committee's weaknesses include the way it is put together, the fact that its operations are not documented, the fact that it cannot halt commercial transactions, the fact that it cannot verify the relationship between a donor and a beneficiary, and the fact that it lacks staff to carry out its counseling responsibilities. The Authorization Committee often conducts a cursory inquiry in these situations to see if the donor and recipient have met with all Act requirements.¹⁰ Additionally, even though the Act permits live unrelated donors, it does not provide for their access to high-quality postoperative treatment or financial security.”³⁵

³³ supra note 29.

³⁴ Karunakaran Mathiharan, 'Ethical and Legal Issues in Organ Transplantation: Indian Scenario' (2011) 51 Med Sci & L 134.

³⁵ supra note 32.

“In response to several protests, a number of state governments issued directions to speed the implementation of the THOA. To evaluate the donors' health, the Tamil Nadu government, for instance, ordered private hospitals allowed to conduct kidney transplants to bring in their donors one to three months following the procedure in October 2003. All the same, it remains silent on the incapacity of the Appropriate Authority to sufficiently supervise the licenced facilities, some of which frequently carry out kidney transplants on patients who have been granted authorization by the Authorization Committee. Instead, the onus will now be on the hospitals and the donors, or the impoverished "sellers," to hasten the THOA's execution.”³⁶

Likewise, in *Kuldeep Singh v. State of Tamil Nadu*³⁷, the Indian Supreme Court issued the same rulings: The applicants' income details for the previous three fiscal years and their occupations must be provided to all Authorization Committees in accordance with this ruling. An administrative official on the Committee would enable more effective decision-making, as the Committee must determine whether transplantation is medically necessary and whether the necessary ingredients are present or absent under Subsection (3) of Section 9 of the Act;³⁸

It would be acceptable for the legislature to change the regulations in accordance with this, making it mandatory to disclose salaries and occupations for a certain number of prior fiscal years let's say three years by statute. This would make it easier for the Authorization Committees to determine whether or not there is any commercial interaction. Despite the actions taken by certain state governments to stop the selling of human organs, reports of these heinous practices come from all states.³⁹

Similar to the UK, India now has an "opt-in" system for organ donation, whereby prospective donors signal that they are willing for their organs to be removed at death or in the event of brain dead for transplantation. It was proposed that a presumed consent (or "opt-out") system be implemented in the UK because the current system did not result in an increase in the supply of organs. A system like this would presume that every adult would want to donate unless they had expressed a preference while they were still living. In the UK House of Commons, an opt-

³⁶ supra note 32.

³⁷ *Kuldeep Singh v. State of Tamil Nadu* AIR 2005 SUPREME COURT 2106.

³⁸ Karunakaran Mathiharan, 'Ethical and Legal Issues in Organ Transplantation: Indian Scenario' (2011) 51 Med Sci & L 134.

³⁹ supra note 35.

out mechanism was discussed during the Human Tissue Bill's report stage. But the members didn't accept it.⁴⁰

REMEDIES:

“Ideally, it would be illegal to accept any form of unrelated living donor. Should that prove unfeasible, legislators, members of civil society and medical professionals ought to reconsider the efficacy of implementing regulated, incentive-based organ donation as a means of augmenting the organ supply. Instead of being outlawed, the trade in organs ought to be controlled.”

It is possible to form a committee made up of members of the government, court, medical community, and well-known members of civil society who have the legal authority to carry out the rule and have the ability to impose penalties:

1. To determine the appropriate amount to be given to the donor;
2. To confirm that the donor has received the funds and assist them in investing them appropriately;
3. To keep an eye on the donor's receipt of standard postoperative care and sufficient, ongoing follow-up;
4. To supervise the fair distribution of organs without regard to caste, community, or financial status.

“It doesn't need to be emphasized that the lack of human organs is leading to unnecessary pain and deaths. Each year, thousands of people who may have been saved by their organs are buried or cremated. Similar to this, hundreds of people suffer or pass away each year while waiting for organs from potential donors who are willing to sell their organs.”

To further public policy and morals, legislatures worldwide have purposefully limited or outright banned access to these organs. To increase the organ supply, it is also necessary to investigate the prospect of offering appropriate compensation to living unrelated donors and the legal heirs of brain-dead individuals whose organs can be extracted for transplantation.

⁴⁰ supra note 35.

INDIA'S CONSTITUTION AND THE RIGHT TO HEALTH:

There are provisions in the Constitution that safeguard everyone's right to the highest standard of bodily and mental health. According to Article 21 of the Constitution, everyone has the right to have their life and personal freedom protected. The Supreme Court holds that the right to live with human dignity, which is protected by Article 21 and derives from the prescriptive principles of state policy, includes the right to maintain one's health. India has ratified both of these accords in addition to the International Covenant on Economic, Social, and Cultural Rights. The Supreme Court declared that international law must be followed while interpreting Article 21 of the Indian Constitution in relation to human rights.⁴¹

“In *Paramanand Katara v. Union of India*⁴², the Supreme Court observed that the State is obligated by Article 21 of the Constitution to safeguard human life. Regardless of whether the patient is a criminal or an innocent person covered by social justice laws, it is the responsibility of those in charge of the community's health to preserve life in order to protect the innocent and punish the guilty. Article 21 uses language that is disparaging. But because of its creative reading of Art. 21 in several cases, the Supreme Court has come to impose an affirmative obligation on the state to ensure that the individual abettor enjoys his life and dignity.”⁴³

Inequitably, the Act of 2021 limits its application solely to married heterosexual couples, leaving out foreign nationals, single parents, cohabiting couples, and homosexual couples on the basis of their marital status, nationality, and sexual orientation. limiting the unjustly disadvantaged group's capacity to enjoy their right to reproductive autonomy—that is, the freedom to choose their own childbirth procedures—as established in *B.K. Parthasarathi v. Andhra Pradesh Govt.*⁴⁴, based only on a person's sex, marital status, and nationality, it unjustly denies gay couples, live-in couples, single parents, and foreigners the ability to use surrogacy as a method of starting a family.

⁴¹ Money Veena V. R., 'Issues and Challenges of Organ Transplantation in India: A Scrutiny' (2018) 1 Int'l JL Mgmt & Human 37.

⁴² *Paramanand Katara v. Union of India*, 1989 AIR 2039, 1989 SCR (3) 997

⁴³ *Supra* note 32

⁴⁴ *B.K. Parthasarathi v. Govt. of Andhra Pradesh* 2000(1) ALD199.

7. CONCLUSION:

Organ donation and transplantation present complex legal and ethical challenges that require careful consideration of consent, allocation, regulation, and ethical principles. While legal frameworks provide the structure for organ procurement and transplantation, ethical guidelines safeguard the rights and well-being of donors, recipients, and society as a whole. Continued efforts to strengthen legal protections, enhance ethical standards, and promote public awareness are essential to advancing the field of organ transplantation and ensuring equitable access to life-saving treatments.⁴⁵

It is a reality that most regions of the nation engage in some type of organ trading or sale. While there may be a few cases of genuine charity, poverty and debt play a major role in the majority of other situations involving unrelated live donors. After selling the organ, the proceeds will be used to settle the donor's obligations, and the donor's health will progressively deteriorate. The impoverished family will eventually find themselves back in the same predicament with debt. In some situations, there may not be enough money to cover the costs of the procedure, even while family members are prepared to give their organs.

Social problems including child labour, the dowry system, child marriage, etc. still exist in our nation. The problems persist in one form or another despite the numerous laws that aim to restrict or outlaw all of these. Similarly, although the government is introducing an increasing number of regulations and changes to enforce the stricter application of the laws governing organ transplantation, the problems pertaining to the trade or sale of organs persist.

More regulations are being implemented by the government to guarantee accountability on the part of hospitals and doctors. In any case, increasing public awareness of organ donation is urgently needed. Organs are in greater demand than ever before, but every day a significant number of people die in accidents. The lack of organs may be somewhat addressed if these organs could be transplanted. The selling or commercialization of organs can be curtailed if the public is made aware of the need for organ donation.

⁴⁵ Organ Procurement and Transplantation Network (OPTN). (<https://optn.transplant.hrsa.gov/>)

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