

# INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

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Volume 7 | Issue 2

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2024

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# Human Organ Transplantation in India: Issues and Challenges

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MAITRAYI CHAWLA<sup>1</sup>

## ABSTRACT

*The field of human organ transplantation in India has seen significant growth since the 1970s, particularly with the inception of kidney transplants. Despite advancements in transplant techniques improving health outcomes for patients, there remains a stark imbalance between organ demand and supply, largely due to low cadaver donations influenced by social and ethical factors. This scarcity has led to the proliferation of unethical practices such as organ trafficking and commercial transplants, posing serious violations of individuals' rights and international obligations. The primary legislation governing organ donation and transplantation in India, the Transplantation of Human Organs Act of 1994, aims to regulate these procedures and deter commercial dealings in organs. However, despite its existence, challenges persist, including the limited focus on brain death, inconsistent interpretation and implementation of the law, and inadequate increase in deceased donor numbers.*

*This paper seeks to delve into the multifaceted challenges surrounding organ transplantation in India, aiming to propose reforms to address unethical practices and bolster organ supply. Through a comparative analysis with international frameworks, the study aims to identify best practices and recommend changes to align the Indian legal landscape with global standards. The significance of this study lies in its potential to enhance access to life-saving organ transplants for patients in need, given the substantial gap between demand and availability. Moreover, addressing unethical practices not only upholds fundamental rights but also fulfills India's international obligations. Key challenges include the shortage of deceased donors, complex donation procedures, lack of awareness, and inadequate infrastructure for organ management.*

*By critically examining the existing legal framework and drawing from international experiences, this research aims to pave the way for legislative reforms that regulate unethical practices and promote organ donation in India. Ultimately, the study endeavors to contribute to a more ethical and efficient organ transplantation system that aligns with constitutional principles and international norms, thereby improving healthcare outcomes and safeguarding human rights.*

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<sup>1</sup> Author is a Graduated from NALSAR University of Law, India.

**Keywords:** *Human Organs, Health law, Transplantation of Human Organs Act, 1994, organ donation.*

## **I. INTRODUCTION**

There has been a rise in human organ transplantation (herein after organ transplantation) in India since the 1970s, which was marked by the beginning of kidney transplantations in India. The advancement of organ transplant techniques significantly improved the health prospects of individuals with failing organs, addressing the scarcity dilemma arising from the demand for new organs outstripping their supply. This is because cadaver donations continue to remain low due to various social and ethical issues prevailing in Indian society.<sup>2</sup> Another challenge is finding the exact match for a patient. Moreover, there are multifarious reasons for the scarcity of organs in India.

The disparity between organ demand and availability has spurred unethical activities such as organ trafficking and illicit organ purchases, which defy legal regulations. The brunt of these activities disproportionately affects individuals from disadvantaged socioeconomic backgrounds, constituting a severe infringement upon their right to life as guaranteed by Article 21 of the Indian Constitution.<sup>3</sup> Apart from the Indian constitution, various international instruments recognise the right to health like Article 12 of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), 'Guiding Principles on Human Cell, Tissue and Organ Transplantation' enacted by the World Health Assembly in 2010<sup>4</sup>.

In India, the principal legislation concerning organ donation and transplantation is the Transplantation of Human Organs Act, enacted in 1994. Its objective is to oversee the extraction, preservation, and transplantation of human organs for medical treatment while curbing commercial transactions involving human organs. All states have embraced THOA except Andhra Pradesh, Jammu, and Kashmir, which have similar legislations. This law has undergone amendments over time, with the latest being the introduction of the Transplantation of Human Organs and Tissues Rules in 2014, officially notified on March 27, 2014.<sup>5</sup>

Despite the prevailing legal framework concerning organ transplantation in India, the situation is still very depraved. There has not been any substantial increase in the number of deceased

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<sup>2</sup> The Constitution of India, 1950, Art. 21

<sup>3</sup> International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 999 UNTS 3 (ICESCR) art 12

<sup>4</sup> WHO (Resolution of the World Health Assembly) 'Guiding Principles on Human Cell, Tissue and Organ Transplantation' (May 2010) WHA63.2.

<sup>5</sup> The Transplantation of Human Organs and Tissue Rules, 2014

donors or the reduction of commerce in the organ market. The concept of brain death is also not significantly focused upon. The interpretation and implementation of the act by the authorities and hospitals is also one of the biggest problems prevailing in India. There are many other challenges concerning organ transplantation in India that need attention. Therefore, there is a need to relook into the prevailing legal scenario and develop new laws or substantial changes in the law that are at par with the international standards and the objectives of the Indian constitution.

### **(A) Research Problem**

Organ transplantation rates are increasing in India, but simultaneously, there is a growing disparity between organ demand and availability. This gap has led to a surge in unethical practices within the country, including organ trafficking, commercial transplants from unrelated donors, biased allocation of organs to foreign nationals or affluent individuals, unauthorized organ extraction, and unsanitary surgical conditions. Apart from unethical practices, another big challenge is increasing the supply of organs in India. This is a herculean task, because cadaver donation in India continues to be low due to the socio-religious circumstances prevailing in the country and the lack of awareness among people. This paper aims to understand and analyse the various challenges prevailing in India concerning organ transplantation. Also, it aims to make recommendations to regulate unethical practices about organ transplantation and to increase the supply of organs in India. This will be done through a comparative study with other countries.

### **(B) Significance of study**

Organ transplantation has become an increasingly viable therapeutic solution for individuals enduring chronic illnesses. However, in India, a notable disparity exists between the demand for organs and their availability. Approximately 180,000 individuals experience renal failure annually, yet only around 6,000 renal transplants are performed. Similarly, an estimated 200,000 patients succumb to liver failure or liver cancer each year in India, with 10-15% of them potentially saved through timely liver transplantation. This trend is mirrored in other transplant procedures, such as those involving the heart, kidneys, and cornea. Due to the imbalance of demand and supply, there is a rise in unethical practices in relation to organ transplantation, the trafficking of organs, commercial transplants from unrelated donors, preferential allotment of organs to foreign nationals or rich people, extracting organs without informed consent, unhygienic conditions of surgery, etc. These unethical practices are blatant disregard for the fundamental rights of the victims of these practices as enshrined in the Indian

Constitution. These practices also contravene the international obligations that bind India. Moreover, such practices violate the very inalienable human rights of the people.

Also, there is a shortage of organs in India. The number of deceased donors or cadaver organ donors remains significantly low due to the socio-religious circumstances of Indian society. There are other challenges, like complex procedures involved in donations from unrelated parties, lack of an effective body to manage the storage, collection and transmission of organs, lack of a centralised registry, lack of awareness amongst people, etc.

Thus, there is an alarming need to regulate unethical practices in relation to organ transplantation and to promote the supply of organs through various legislative interferences. In this background, there is a need to identify, understand and examine the challenges concerning organ transplantation through the existing legal framework and to fine-tune the laws and policies in such a way as to regulate unethical practices and enhance the supply of organs to smoothen the process of organ transplantation. The researcher has also comparatively analysed the Indian legal framework with that of international instruments and the framework of other countries to examine the best practices in the world and consequently recommend changes in the Indian framework.

### **(C) Review of literature**

#### **1. Galia Assadi, Georg Marckmann, Ralf J. Jox, *Organ Transplantation in Times of Donor Shortage: Challenges and Solution* (Springer et al., 2015)**

The authors provided a lucid explanation of the reasons for the shortage of organ donations and suggested innovative ideas for approaching this problem. The book is essential to gaining fresh perspectives to approach the problem of the shortage of organ donations. The beauty of this book lies in the fact that it also investigates and critically rethinks the numerous ethical and emotional problems that are a part of public discourse around organ donation. However, this book does not focus on the Indian issues and challenges concerning organ donation and transplantation.

#### **2. *Organ Transplant Law: Assessing Compatibility with the Right to Health* (Vidhi Legal, 2017) < <https://vidhilegalpolicy.in/research/organ-transplant-law-assessing-compatibility-with-the-right-to-health/>>**

This report has systematically highlighted the indicators to identify changes needed in the Indian organ Transplant to make it compatible with the international human right to health. This report has critically analysed the Transplantation of Human Organs and Tissues Act, 1994, in the light of its objectives and the above indicators. This report is also very comprehensive in terms of its

recommendations.

**3. A Study of the Deceased Organ Donation Environment in Delhi/NCR (Organ India Archive 2014) < <https://www.organindia.org/wp-content/uploads/2014/11/ORGAN-Research-Report.pdf>>**

This report is very comprehensive, and it highlights the scenario of organ transplantation in India and focuses on the historical trends, challenges and scope for further changes. This report is quintessential in understanding the fundamental issues and challenges prevailing around organ transplantation in India. This report also throws light on the success stories in the field. However, this report makes recommendations while considering the Delhi/NCR region.

**4. Dr Anju Vali Tikoo, 'Transplantation of Human Organs: The Indian Scenario' [2017] 1 ILI Law Review 147**

This article is very comprehensive and deals with the Indian legal scenario. This article points out the various lacunas in the Indian laws about organ transplantation, like the issues of consent, autonomy of the deceased, public policy issues, problems with organ donation and retrieval, etc. The author has also suggested the changes that could be made to these laws. However, this article has yet to discuss international practices about organ transplantation.

**5. Francis L Delmonico, Beatriz Dominquez-Gil, Rafael Matesanz, Luc Noel 'A call for government accountability to achieve self-sufficiency in organ donation and transplantation' [2011] Lancet 378.**

This paper is very lucid, and through this paper, the authors have urged the nations to be self-sufficient in organ transplantation. The paper notes that the needs of each country are different, and these needs must be systematically addressed by their respective legal systems. It is also suggested that end-state organ failures must be prevented through medical strategies. This paper is very general and is normative.

**(D) Objectives of the study**

1. To identify, examine and analyse the various issues and challenges about organ Transplantation in India.
2. To evaluate and critically analyse legal framework and judicial decisions about organ Transplantation in India.
3. To comprehend, comparatively analyse and assess the international practices about organ transplantation.

4. To examine and recommend ways to regulate unethical practices about organ transplantation and promote the supply of organs in India.
5. To identify and suggest measures to reduce the gap between demand and supply of organs in India.

### **(E) Research Questions**

The paper aims to answer the following questions:

1. What are the various issues and challenges concerning organ transplantation in India?
2. How does the Indian legal regime deal with organ transplantation?
3. How do other legal jurisdictions regulate organ transplantation?
4. What changes could be made to the Indian legal system for the regulation of organ transplantation and promotion of the supply of organs in India?
5. What measures could be taken to reduce the gap between demand and supply of organs in India?

### **(F) Research Methodology**

The approach employed for this paper is doctrinal, relying on secondary sources of literature with a descriptive and analytical research design. Initially, the paper will offer a descriptive introduction to the topic, followed by an exploration of issues and challenges in organ transplantation and the regulatory framework in India, drawing from legislation and judicial decisions. Subsequently, it will adopt an analytical stance, comparing the Indian framework with those of other jurisdictions and international bodies. Upon identifying and examining policy gaps, the researcher will conclude by suggesting reforms for an improved legal framework.

Empirical research data collection is optional to achieve the paper's objectives; however, primary sources such as judicial reports, cases, legislation, and statistical data will be extensively used to support arguments. Secondary sources such as law commentaries, journals, reports, and opinions from reputable national and international newspapers will also be consulted.

## **II. ISSUES AND CHALLENGES ABOUT ORGAN TRANSPLANTATION IN INDIA**

Organ Transplantation is one of the unique treatments that offers an efficient solution to many diseases. However, there are various issues in transplantation, the primary issue being the lack of organs for transplantation. These challenges are sometimes the results of poor

implementation of laws and sometimes arise due to the nature of the society that we live in. The shortage of organs may be resolved by tweaking the existing laws and developing a more cohesive legal framework.

### **(A) Complications and Challenges in Organ Transplantation in India**

#### **1. Lack of Supply of Organs**

The supply of organs remains low in India due to various factors. This includes the limited number of cadaver donations in India. There are around 150,000 deaths every year. However, organ donations by the deceased have only been 900.<sup>6</sup>

The laws are in place to promote cadaver donations, but the supply of organs for transplants still needs to grow. This is also in sharp contrast to the present circumstances of India, where, on the one hand, it ranks second in the world, being positioned next only to the USA concerning transplants with donors who are alive. On the other hand, the supply of organs remains stagnant. Facts have shown that India is far behind other nations in organ donations. India has a national deceased donation rate of less than one million population (pmp)<sup>7</sup>

The various factors that contribute to the limited number of organ donations in India are as follows:

- a) Legal Concerns: "In the case of living organ donations (from a living donor to a recipient), if the donor is not related to the patient, the transplant needs to be approved by a state-level committee or hospital committee, including government officials". These lead to delays in the process, which sometimes leads to the death of the individuals in need of transplant.

Another issue is about the law's main power concerning health. Health is a state subject, and thus, each state's approach while making a law on health differs. This creates problems of uniformity. Health is a part of the state list under entry six under the VII schedule of the Indian constitution.<sup>8</sup> This is as follows: "Public Health and Sanitation, Hospitals and Dispensaries"

- b) Issues linked to Brain Death: There are various issues concerning brain death in India, with the present law being inefficient while dealing with Brain Deaths. Conversion deaths are very low about organ donations, which leads to organ

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<sup>6</sup> Ruhi Kandhari, 'India's Organ Transplant Paradox: World no. 2, but most are living donors' (*The Ken*, 23 Jan 2020) < <https://the-ken.com/story/indias-organ-transplant-paradox/> > accessed 20 November 2020.

<sup>7</sup> Abraham G, Reddy YN, Amalorpavanathan J, Daniel D, Roy-Chaudhury P, Shroff S, *et al.*, 'How deceased donor transplantation is impacting a decline in commercial transplantation-the Tamil Nadu experience' (*PubMed*, 27 April, 2012) < <https://pubmed.ncbi.nlm.nih.gov/22245870/> > accessed 20 November 2020.

<sup>8</sup> The Constitution of India, 1950, Entry 6, List- II, Schedule VII.

wastage. The attitudes of people and medical professionals about brain death are still not developed.

## 2. Lack of Awareness

Lack of availability of adequate information and lack of awareness remains one of the pressing challenges to organ transplants today. There are a variety of NGOs that are working to create awareness amongst people about organ donations. The govt. of India also came up with NOTTO. Still, the circumstances could be more favourable regarding the awareness about organ donation in India. There are a number of individuals who are enthusiastic about organ donations, but their intentions are inhibited by the absence of proper procedures and institutes that could support them in their intentions. There is a necessity for a variety of platforms where individuals can sign up for organ donations and pledge to donate.

## 3. Infrastructural Failures

Organ Transplants are a costly process which makes it out of the reach of the poor people of the country and thus is a violation of their right to health, which has been established as a part of the right to life under Article 21.<sup>9</sup>

It needs to be highlighted that most of the transplants in India are carried out by privately run hospitals. However, India is also one of the destinations known as a hub for organ transplants. Internationally, the Indian healthcare system for human organ transplants is considered cost-effective and efficient.<sup>10</sup> India needs a public health care system at the national level that could also cater to the needs of organ transplants. This is due to the disparity among the populations in terms of their incomes. There are many who are not able to afford the costs of private hospitals, but that should not deprive them of the right to health. Another issue is health insurance; India needs to have a more significant number of health insurance schemes that specifically cater to organ transplantation matters.

In terms of infrastructure, there are lapses as there is a lack of availability of machinery which is necessary for the process of transplants, like ventilators, a lack of skilled professionals for facilitating the process of transplants, and an absence of proper hospitals and organizations across India that cater to transplantation in particular.

Another problem is the need for more efficacious institutional support. There needs to be a well-linked system of organ donation institutions that ensures uniformity around the country. There

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<sup>9</sup> The Constitution of India, 1950, Art. 21.

<sup>10</sup> Jose R, Sachdeva S, 'Keeping an eye on future: Medical tourism' (*PubMed.gov*, July 2010) <<https://pubmed.ncbi.nlm.nih.gov/21031099/>> accessed 20 November 2020.

was no system for adequate counselling of patients who were going for transplants or those donating their organs or are willing to donate them; now, the act has provided for the same.<sup>11</sup> There needs to be trained professionals who imbibe symphonic attitudes and have smooth communication skills, thereby removing the gap between the intentions of individuals and their actual actions with regard to donations.

#### 4. Discrimination between Foreigners and Indian Nationals:

There are various cases that have come to light in recent years that highlight the ways in which distinctions have been carved out between Indians and foreigners in terms of allotment of organs. It has been seen through an enquiry conducted in Tamil Nadu on the instance of the government of the state of Tamil Nadu that brought to light the ways in which preferential allotment was made to the foreign nationals from countries of Africa, Central Asia, the Middle East, etc.<sup>12</sup> The justification given for these actions includes the prevention of organ wastage and the promotion of medical tourism. Even though it is necessary to promote medical tourism, the ways used in the present cases highlight the systematic lapses in India where we are not able to treat our own people at par with others. These cases are not medical tourism but are unethical practices of 'transplant tourism' that are declared unethical by various international instruments such as the World Health Organization, the Declaration of Istanbul, and the Madrid Resolution.

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Reducing these practices demands that better infrastructure be developed by the govt. It is in the spirit of the welfare state.

5. Absence of Centralised Registry: An enabling mechanism in India, in the form of a centralized registry, that smoothens the process of donation and transplantation by coordination between various stakeholders linked to transplants, is absent. This type of centralized institutional framework is required to keep a record of the eligible donors and those who are in need of organs. This type of registry will also ensure that organ allotment is fair and just. Such a registry is in the USA in the form of UNOS.<sup>14</sup>

6. Socio-Religious Circumstances: The lack of organ supply in India could also be

<sup>11</sup> Organ India, 'A study of the Deceased Organ Donation Environment in Delhi/NCR'(2014) <<https://www.organindia.org/wp-content/uploads/2014/11/ORGAN-Research-Report.pdf> accessed 20 November 2020.

<sup>12</sup> S Vijay Kumar, 'Protocol breached in Tamil Nadu organ transplant case, says probe' *The Hindu* (Tamil Nadu, 3 Dec 2013) < <https://www.thehindu.com/news/national/tamil-nadu/protocol-breached-in-tamil-nadu-organ-transplant-case-says-probe/article24852300.ece>> accessed 20 November, 2020.

<sup>13</sup> Vivekananda Jha, 'The Seamy Underbelly of Organ Transplantation in India' *The Wire* (3 Dec 2013) < <https://thewire.in/health/underbelly-organ-transplantation-india> > accessed 20 November, 2020.

<sup>14</sup> C. Rudge, R. Matesanz, 'International Practices of Organ Donation'(BJA, 01 January 2012) <[https://academic.oup.com/bja/article/108/suppl\\_1/i48/237865](https://academic.oup.com/bja/article/108/suppl_1/i48/237865)> accessed 20 November 2020.

attributed to the various cultural and religious beliefs and practices that prevail in Indian society. For instance, the Hindu religion has a firm faith in the concept of life after death, thereby discouraging individuals from donating organs. Other superstitions include compromising with the sanctity of the dead and not being born with an organ.<sup>15</sup>

#### 7. Organ Wastage:

In India, brain deaths are still not recognized as death traditionally. There are many superstitions related to the same. The situation of brain deaths is such that they are not certified in most cases and also go unacknowledged. Due to these issues, it is not possible to harvest tissues from persons who are brain-dead and eligible for donating organs. This results in many organs going to waste, which could have changed the lives of many in need. The data shows that there are approximately 1.5 lakh deaths in a year, and around 2 lakh kidneys, 50,000 hearts and 50,000 livers are required for transplantation every year.<sup>16</sup> This data highlights the stark reality of the way in which precious organs are wasted every year.

8. **Illegal Trade of organs:** The widening wealth gap and technological advancements in today's world have facilitated the commodification of organs, offering a quick and appealing solution for some while posing ethical challenges. In India, this issue is akin to other social problems like child labour and prostitution, exploiting the economically disadvantaged by luring them with financial gains to meet immediate needs. A notable study examining the economic and health impacts of kidney sales in India found that 96% of participants sold their kidneys to alleviate debt, earning an average of \$1070. However, post-surgery, family incomes dropped significantly, pushing many below the poverty line, with a large portion still in debt. Moreover, approximately 86 per cent of participants experienced deteriorating health following nephrectomy.<sup>17</sup>

These are the challenges that continue to prevail in the Indian scenario with respect to organ transplantation. These challenges have both policy and moral dimensions to it. These concerns are difficult to address when the question is about the socio-religious beliefs of people. A legal

<sup>15</sup> Aneesh Srivastava, Anil Mani, 'Deceased Organ Donation and Transplantation in India: Promises and Challenges' (2018)

66 Neurology India 316 < <https://neurologyindia.com/article.asp?issn=0028-3886;year=2018;volume=66;issue=2;spage=316;epage=322;aulast=Srivastava> > accessed 21 November, 2020.

<sup>16</sup> R Jose, Sandeep Sachdeva, 'Keeping an eye on future: Medical Tourism' (*Pubmed.gov*, July 2010) < <https://pubmed.ncbi.nlm.nih.gov/21031099/> > accessed 21 November 2020.

Organ India, 'A study of the Deceased Organ Donation Environment in Delhi/NCR'(2014) <<https://www.organindia.org/wp-content/uploads/2014/11/ORGAN-Research-Report.pdf> accessed 20 November 2020.

<sup>17</sup> Sunil Shroff, 'Legal and Ethical Aspects of Organ Donation and Transplantation' (2009)

Indian Journal of Urology 348 < <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/> > accessed 21 November 2020.

framework in place addresses these issues and challenges to some extent.

### **III. LEGAL FRAMEWORK OF INDIA CONCERNING ORGAN TRANSPLANTATION**

The matter of health is placed under the state list under Entry 6 of the State list in the VII schedule of the Indian constitution.<sup>18</sup> It is mentioned as "Public Health and Sanitation, Hospitals and Dispensaries."

Article 252, read with Article 249 of the Constitution, is a special provision which confer power on the Parliament to legislate for two or more states by consent or by adoption of such legislation by any other state.<sup>19</sup>

The central government, specifically the Ministry of Health and Family Welfare, has the responsibility to look into matters pertaining to the transplantation of organs. The Department of Health and Family Welfare is the department that deals with organ transplants out of the four departments that deal with other matters. The Health Care Directorate General (DGHS) is also attached to the above department's office. It is responsible for giving technical guidance on all issues relating to medical and public health and is active in the delivery of different health programmes. As announced, the ministry has considered steps such as a 50 per cent discount on second-class rail tickets and the provision of lifelong-free diagnostic checks and treatment at the hospital where the organ was donated.<sup>20</sup>

#### **1. National Organ and Tissue Transplant Organization (NOTTO)**

This is a national-level agency set up under the Ministry of Health and Family Welfare of the Directorate General of Health Services and was established in 2011 as mandated by the Transplantation of Human Organs Act (THOA) amendment. This agency is a subdivision of the National Human Organ and Tissue Removal and Storage Network. It was established in Delhi and will grow steadily, including the country's other states and regions. It serves as an apex hub for all India's coordination and networking events, for the procurement and distribution of organs and tissues, for the preservation of the organ registry, and for the enablement of tissue donation and organ transplantation throughout the world.<sup>21</sup>

#### **2. Transplantation of Human Organ Act, 1994:<sup>22</sup>**

The aims of the acts are twofold. One is to provide for the regulation of removal, storage and

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<sup>18</sup> The Constitution of India, 1950, Entry 6, List- II, Schedule VII.

<sup>19</sup> The Constitution of India, Art. 21.

<sup>20</sup> 'About the Ministry' (Mohfw) < <https://main.mohfw.gov.in/> > accessed 15 November 2020.

<sup>21</sup> 'About us'(NOTTO) < <https://www.notto.gov.in/about-us.htm> > accessed 15 November 2020.

<sup>22</sup> The Transplantation of Human Organs and Tissues Act, 1994 (Act 42 of 1994)

transplantation of human organs for therapeutic purposes, and another is to prevent commercial dealings with human organs.

This is the principal law in India governing organ donation and transplantation. The laws for organ donation and transplantation in India were non-existent before the passage of this Act, and malpractices were rampant. Parliament approved the amendment to the Act in 2011, and the laws were notified in 2014 as the Human Organs and Tissue Transplantation Rules 2014.

The features of the act are as follows:

### *Consent and authorisation for donation of organs*

The act envisions two kinds of donors- Deceased donors and Live Donors. The act provides a separate process for each kind of donation.

#### **1. Transplants in case of living donors**

Section 3 establishes the Authority responsible for the extraction of human organs or tissues. It delineates the entity empowered to grant authorization for organ procurement, specifying that such consent for the removal of any organ or tissue from an individual's body must be provided by a living individual.<sup>23</sup> Additionally, two witnesses are required, one of whom is a close relative of the donor. Furthermore, the donor must be of sound mind and at least 18 years old, and the authorization for organ removal for transplantation must be voluntary.<sup>24</sup> The 2014 regulations include an additional provision stating that following the donor's death, consent must be obtained from a close relative or the individual lawfully in possession, even if the donor had previously given authorization before death. The act provides that the consent is to be an informed one, which implies that the donor is to be made aware of all the complications, dangers and effects of the harvesting of organs.<sup>25</sup> Section 3(4) prohibits the removal of organs by any person other than a registered medical practitioner, which is defined in section 2(n)<sup>26</sup> Even the hospital where transplantation is to take place is required to be registered under the act under section 15.<sup>27</sup>

Living donations:

- a) Related: In circumstances where an individual wishes to donate to near relatives while he is alive, the act mandates the approval of the Authorisation Committee.<sup>28</sup>

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<sup>23</sup> The Transplantation of Human Organs and Tissues Act, 1994, s. 3

<sup>24</sup> The Transplantation of Human Organs and Tissues Act, 1994, s. 2(f)

<sup>25</sup> The Transplantation of Human Organs and Tissues Act, 1994, s. 12

<sup>26</sup> The Transplantation of Human Organs and Tissues Act, 1994, s. 3

<sup>27</sup> The Transplantation of Human Organs and Tissues Act, 1994, s. 15

<sup>28</sup> The Transplantation of Human Organs and Tissues Rules 2014, Rule 18

- b) Non-related: In cases where donations are to be made to non-related recipients, certain conditions are provided under s—9 (3) of the act and after the approval of the Authorisation Committee.

*“...as is specified by the donor by reason of affection or attachment towards the recipient or any other special reasons.....”*<sup>29</sup>

Who is a relative is defined under section 2(i)-

*“near relative means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter”*<sup>30</sup>

Foreign Nationals: For donation to foreign nationals, the act only permits donation to relatives near them; there is, however, a requirement of approval from the authorisation Committee of the hospital, district or state.<sup>31</sup>

These terms, like 'affection or attachment', have remained contentious as a number of illegal transplants are happening in the garb of these terms. What is 'affection' or 'attachment' is ambiguous and subject to interpretation. This clause is ambiguous for most stakeholders. The weightage of evidence that needs to be considered is also different in different states. AC applications are generally approved. The highest amount of unrelated donations happens when the donor shows genuine love for the beneficiary before the AC. In Tamil Nadu, between 1995 and 2002, some 5,000 cases with refuse rates of less than 5% were interviewed by the AC. In another memo released by the Tamil Nadu Health Ministry, it was reported that 1,559 unrelated transplants from 1,868 requests submitted from January 2000 to May 2002 were authorized.<sup>32</sup>

## 2. Deceased Donations

In circumstances where the potential donor dies before death, an obligation is imposed upon the registered medical practitioner (RMP) in consultation with the transplant coordinator to discover whether the deceased gave consent for the donation of their organ before death.<sup>33</sup>

If consent is not given, then a duty is cast upon the RMP to make the near relative aware of the option to authorise or decline the donation of organs or tissues.<sup>34</sup> The authorisation in such cases can be given by any person who is in lawful possession of the body of the deceased by

<sup>29</sup> The Transplantation of Human Organs and Tissues Act, 1994, s. 9(3)

<sup>30</sup> The Transplantation of Human Organs and Tissues Act, 1994, s. 2(i).

<sup>31</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 9(1)(1A).

<sup>32</sup> Sunil Shroff, 'Legal and Ethical Aspects of Organ Donation and Transplantation' (2009)

Indian Journal of Urology 348 < <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/> > accessed 21 November 2020.

<sup>33</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 3(1)(1A)(i).

<sup>34</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 3(1)(1A).

satisfaction of two conditions.<sup>35</sup>

- (a) The potential donor did not raise any objection to the donation of organs prior to death.
- (b) There is no objection by the near relatives as to donation.

The act also provides that the organ and tissue donation of deceased minors could also be made by authorisation of parents.

The implementation of the act has been faulty, and there has also been an abuse of the provisions of the act. There are issues with respect to deceased donations as the provision seems to be oppressive for the deceased donor as even after his authorisation while he was alive, the consent of the relatives overrides his consent, thereby rendering the choice made by the deceased superficial. This provision also undermines the autonomy of an individual. This further reduces the chances of deceased organ donation in India.

### **3. Brain Death:**

'Brain-stem death' is defined as 'the stage at which all functions of the brain-stem have permanently and irreversibly ceased.'<sup>36</sup>

This is one of the contentious provisions under the act. The act provides that allows the extraction of organs from persons who are brain-dead. This requires a declaration by the Board of Medical Experts as to "brain-stem death".<sup>37</sup> The following conditions are used as the definition of brain death and its statement - brain death: two doctors must be licenced for a span of 6 hours except for two of them, and the government's competent authority must appoint two of these doctors, one being a neurology specialist.<sup>38</sup>

If the family rejects such a donation, however, an additional issue can occur. Although 'brain death' is appropriate for organ donation under the Act, the individual is still not considered 'dead' before cardiac arrest or 'cardiac death' has occurred. This is because, although the Act describes death as 'brain death', the term 'death' has been defined differently under the Indian Penal Code, 1860 ("IPC"). In IPC, death means 'the death of a human being.'<sup>39</sup>, unless the contrary appears from the context and in the Registry of Births and Deaths Act, 1969, 'Death' is when 'permanent disappearance of all evidence of life at any time after live-birth has taken

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<sup>35</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 3(3).

<sup>36</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 2(d).

<sup>37</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 3.

<sup>38</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 3.

<sup>39</sup> The Indian Penal Code, 1860, s 46.

place.<sup>40</sup> Even if 'brain death' may have happened, it is then technically not appropriate to detach the patient from the ventilator and withhold treatment until the 'cardiac death' of the patient as the individual is alive even though with the help of a life support system.

#### **4. Prohibition of illegal activities such as organ donation**

Section 9 aims to prohibit illegal practices with respect to organ donation. It forbids any such transaction, including offers to supply any human organs for payment and making or receiving any payment for the supply of any human organs. Clause 1 of section 9 prohibits the removal of an organ or tissue from a donor who is alive except in cases where the donor is a near relative of the recipient. The other types of removal of organs or tissues include these kinds of removal from the body of a minor and those of mentally challenged individuals if they are alive.<sup>41</sup>

This section is problematic because it carves out a class of persons who do not have near relatives or willing and altruistic donors and thus are excluded from taking the organs from them when they are alive and do not have altruistic donations. This is a refutation of the right to health of the people who belong to this class.

#### **5. Authorities**

Transplant Coordinators: These are to be established under s. 14(4) of the act. These coordinators are enable authorities for the registration of hospitals that are indulged in transplants and activities incidental to transplants. These authorities also inform the relatives of brain-dead individuals about their options to donate organs and to create awareness about organ donation. These transplant coordinators need to be adequately established.

Regulation of transplant operations by the establishment, in each State or Union territory, of an Authorisation Committee (AC) and Appropriate Authority (AA). Each one has the following specified role:

Function of Authorization Committee (AC).- The object of this Authorization Committee (AC) is to control, rather than a first relative, the mechanism by which transplants are allowed to be accepted or denied. The committee's primary responsibility is to make sure that the donor is not used to donate its organ in the money. The receiver and donor joint requests are reviewed, and a personal interview is necessary in order to provide the AC with the valid reasons for donation and to guarantee. Make sure the donor knows the surgery's likely complications. The acceptance or denial information is forwarded to the appropriate hospitals by mail. Subclause (3), Clause 9

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<sup>40</sup> The Registration of Births and Deaths Act, 1969, s 2(b).

<sup>41</sup> The Transplantation of Human Organs and Tissues Act 1994, s. 9.

of Chapter II of the THO Act regulates the decision to approve or deny a donor.

Appropriate authority function (AA): The purpose of the body is to ensure that human organs are preserved, processed, and transplanted. These operations should only be performed at a hospital after the authority has been approved. The removal of eyes from a deceased donor's body cannot and does not require licensing procedures from such a jurisdiction at other places. The AA has the authority to audit and issue hospital registrations for transplant procedures, meet appropriate requirements for hospitals, execute routine hospital checks to determine the consistency of transplantation and medical follow-up services for donors and patients and cancel or revoke the registration.

The AA grants a hospital license for a term of 5 years, and after that period, it will extend a hospital license. A separate license is required for each organ.

## 6. Punishments

In compliance with Section 18 of this Act, any person with the authority to extract the human organ/tissues can be sentenced to imprisonment of up to 10 years and to a fine which can cover Rs. 20 lakhs. If the individual is a medical practitioner, the AA shall report his/her name to the State Medical Council for reasonable acts, which include the removal of his/her name for the first offence from the council's registry for three years and eventually delete it permanently, if he/she commits an offence.

In compliance with Section 19, if anybody has any role in the Trade in human organisations, the individual may be punished with a sentence not less than five years in jail but may expand to 10 years and also be liable for a fine not less than Rs. 20 lakhs, but extendable to Rs. 1 crore.

In compliance with Section 20. When anyone breaches some other clause of this Act, they will be sentenced to imprisonment for a term which can extend to 5 years or with a fine which may extend to Rs. 20 lakhs.

The problem has been how to use sub-clause (3), Clause 9 of Chapter II of the THO act, and how to protect the abusive element of the word affection. In 1997, Dr. M.K. Mani, a prominent Nephrologist in Chennai, summarized the above very well when he wrote: "*The stalwarts of the unrelated live donor program continue to do as many transplants as they did before the Legislative Assembly of Tamil Nadu adopted the Act. What is more, they do them with the seal of approval from the Authorization Committee and are, therefore, a delighted lot. The law, which was meant to prohibit commercial dealings in human organs, now provides protection*

for those very commercial dealings." Dr Mani's article is titled 'The Law is an Ass'.<sup>42</sup>

The law is not able to protect those who are at the bottom of the social hierarchy.

#### IV. JUDICIAL DECISIONS AS TO ORGAN TRANSPLANTATION

In *Sadhana Bhardwaj v. The Department of Health and Family Welfare*<sup>43</sup>, approval is compulsory only at the place of the intended transplant and not at the state of domicile of the donor or recipient. Other HCs have reiterated this position as well.

In *Mukesh Gandhi v. Deputy Secretary (Health)*, the question was with respect to procuring the organ from other states. It was held by the Gujarat HC that there is no express prohibition under the act on the procurement of organs from one state to another.<sup>44</sup>

The way in which authorisation or rejection for organ transplants is made has been an issue of contention. The question arises of how love and affection or special reasons are to be proven. In *Kuldeep Singh v. State of Tamil Nadu*<sup>45</sup>, this question arose: Who will discharge the burden to prove love and affection? The court decided that the applicant bears this burden.

*"The burden is on the applicants to establish the real intent by placing relevant materials for consideration of the Authorisation Committee. Whether there exists any affection or attachment or special reason is within the special knowledge of the applicants, and a heavy burden lies on them to establish it. Several relevant factors like a relationship, if any (need not be near relationship for which different considerations have been provided), period of acquaintance, degree of association, reciprocity of feelings, gratitude and similar human factors and bonds can throw light on the issue."*

This position has now been settled by the guidelines laid down in the 2014 Rules.<sup>46</sup>

With respect to ruling out the transplants for commercial purposes, the HCs have had different approaches. Some HCs have higher evidentiary requirements than others.

In *Anees Ahmed v. State of U.P.*<sup>47</sup>, the requirement of an express finding with respect to the commercial nature of the transaction was laid down.

In *Poonam Gupta v. State of Punjab*<sup>48</sup>, the chances of commercial transactions were found due

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<sup>42</sup> MK Mani, 'Making an Ass of the Law. Letter from Chennai' (*Pub Med. Gov*, October 1997) <<https://pubmed.ncbi.nlm.nih.gov/9401388/>> accessed 21 November 2020.

<sup>43</sup> 184 (2011) DLT 150.

<sup>44</sup> *Mukesh Gandhi v. Deputy Secretary (Health)*, AIR 2009 Guj 7.

<sup>45</sup> (2005) 11 SCC 122.

<sup>46</sup> The Transplantation of Human Organs and Tissue Rules, 2014, Rule 7(3).

<sup>47</sup> 2012 SCC OnLine All 4427.

<sup>48</sup> 2009 SCC OnLine P&H 4572.

to the absence of the establishment of a clear relationship between the parties, and the relatives of the recipient also did not show interest in donating organs.

In *Pawan Anand v. Director General of Health Services*, the basis for the dismissal of the application to approve a transplant was the financial disparity between the donor and recipient.

Any person aggravated by the order of the AC can prefer an appeal to the State Government within 30 days of issuing the order. In *B.L. Nagaraj et al. vs Kantha et al.*, the prospective recipient submitted an appeal in writing before the Karnataka High Court against an ordinance of the AC refusing an association donation application by the recipient's counsel on the basis that nearby family members were not called donors. In compliance with the High Court's formal request.<sup>49</sup>

*"There is no provision in the Act that prohibits the person who is not a 'near relative' by definition from donating his kidney merely because the 'near relative' has not been considered as a donor by the family for kidney transplantation. The Committee has misdirected itself in this regard while refusing permission to the petitioners."*<sup>50</sup>

*"The Committee would ascertain from the second petitioner whether she would be donating the kidney out of 'affection and attachment'. The donor's relationship with the recipient, period of acquaintance and the degree of association, reciprocity of feelings, gratitude and other human bonds are some of the factors that would sustain 'affection and attachment' between two individuals. The committee has to ensure that the human organ does not become an article of commerce. The main thrust of the act is against commercial dealings in human organs."*<sup>51</sup>

Thus, the law still has certain loopholes, which leads to confusion and opens up the scope for judicial interpretation. Such problems need to be cured to ensure that the law is specific. The basis on which the appropriate authority is to make a decision needs to be mentioned clearly to ensure uniformity. The certainty in the law will ensure that there is uniformity in the country, which will ensure equality of treatment in various circumstances. Certainty in-laws will also ensure that the process of organ transplant is fast-paced and efficacious.

## **V. INTERNATIONAL FRAMEWORK WITH RESPECT TO ORGAN TRANSPLANTATION**

### **(A) Declaration of Istanbul**

This declaration is based on the principles of the Universal Declaration of Human Rights. The primary focus of this declaration was to further donations and transplants across the globe

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<sup>49</sup> B.L. Nagaraj and Ors. v. Dr. Kantha and ors, AIR 1996 Kant 82.

<sup>50</sup> Ibid.

<sup>51</sup> Ibid.

through international alliances. This declaration also focused on the way in which people with low incomes are exploited for the purpose of organ transplantation. Through this declaration, the countries and organizations were urged to have stringent laws forbidding these unethical practices to have accountability and also to ensure equitable sharing of the benefits of transplantation.<sup>52</sup>

### **(B) The Madrid Resolution on Organ Donation and Transplantation**

This resolution urged the significance of organ donation and transplantation and how these must be considered as a responsibility and part of the wellbeing of people. This resolution also highlights the nation's need to invest in the development of a healthcare system on the basis of its own resources. It is to be obtained for the population in that country and, where appropriate, through regional or international supervision and ethical cooperation. Action should start (1) locally; (2) be based on broader public-health policies that both reduce the burden of the illness on the population and make organ transplants more available; (3) enhance the cooperation between stakeholder groups involved; and (4) work on the basis of the guidance of WHO and the Declaration.<sup>53</sup>

The aim is to have a comprehensive framework that addresses the worldwide challenges caused by the growing health concerns amongst the population across the world and also to address the scarcity of organs.

### **(C) Guiding Principles on Human Cell, Tissue and Organ Transplantation**

These principles were endorsed by the World Health Assembly and came into effect in 2010. These principles have provided aid to legislation and policies across the world regarding organ transplants across the world. These principles aimed at providing an 'orderly, ethical and acceptable framework' for organ transplants.<sup>54</sup>

## **VI. LAW AND POLICIES AROUND THE GLOBE WITH RESPECT TO ORGAN TRANSPLANTATION**

### **(A) United States Of America**

In the USA, the National Organ Transplant Act (NOTA). This act led to the establishment of

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<sup>52</sup> 'The Declaration of Istanbul on Organ Trafficking and Transplant Tourism' (2018) 103 *Transplantation* 218 <[https://journals.lww.com/transplantjournal/Fulltext/2019/02000/The\\_Declaration\\_of\\_Istanbul\\_on\\_Organ\\_Trafficking.3.aspx](https://journals.lww.com/transplantjournal/Fulltext/2019/02000/The_Declaration_of_Istanbul_on_Organ_Trafficking.3.aspx)> accessed 21 November, 2020.

<sup>53</sup> 'The Madrid Resolution on organ donation and transplantation: National responsibility in meeting the needs of patients, guided by the WHO principles' (*Pubmed*, 2011) <<https://pubmed.ncbi.nlm.nih.gov/21633281/>> accessed 21 November 2020.

<sup>54</sup> WHO (Resolution of the World Health Assembly) 'Guiding Principles on Human Cell, Tissue and Organ Transplantation' (May 2010) WHA63.2.

the Organ Procurement Transplantation Network (OPTN).<sup>55</sup> The federal contracts by OPTN have been granted to the United Network for Organ Sharing (UNOS) since 1986. OPTN is based on a public-private partnership model and links all professionals involved in the U.S. donation and transplantation system. It aims to maximize transplantation number and access, enhance transplantation survival rates and encourage patient protection and effective system management. The Medicare and Medicaid Services Center (CMS) asks hospitals to classify and submit to the local recruitment organism all possible organ contributors (OPO). In order to classify these patients who should be classified as one of the CMS-managed success metrics, the word "imminent death" was used. Hospitals work closely with OPOs to detect impending deaths by typically establishing explicit objective health requirements for contacting OPOs. For this reason, the company functions.

This is a very efficient and advanced setup that enables the efficiency and effectiveness of organ donation and organ transplantation. This system optimises the process of transplantation by identification of the potential donors. At present, 90% of the organ donors who are deceased are from those who are declared brain dead. This highlights the efficiency of the framework in the USA.<sup>56</sup>

### **(B) Australia**

In Australia, the Australian Organ and Tissue Authority is responsible for coordinating organ donation and transplantation. There is a Human Tissue Act<sup>57</sup> in Australia, which governs organ and tissue donation, along with specific guidelines issued by the National Health and Medical Research Council (NHMRC). These guidelines lay down the appropriate ethical standards for organ transplants and donations.<sup>58</sup>

The interlinking of all these state-level efforts has really boosted the growth of organ donation and transplants in Australia. Australia has Donate Life, which has developed national organ allocation guidelines, promotes the treatment of donor families and has developed particular strategies such as the national contributions following the Cardio-death protocol and national pairing kidneys, and has developed a network of trained patient intensifiers and nursing experts to offset the hospital expenses of prospective donors. The findings are now significant, and the donation rate is increasing to the highest rate ever (30% last year). Australia's experiences are significant in teaching us how the community's strong motivator of a legislative impetus, the

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<sup>55</sup> National Organ Transplantation Act, 1984, 98 Stat. 2339.

<sup>56</sup> C. Rudge, R. Matesanz, 'International Practices of Organ Donation'(BJA, 01 January 2012) <[https://academic.oup.com/bja/article/108/suppl\\_1/i48/237865](https://academic.oup.com/bja/article/108/suppl_1/i48/237865)> accessed 20 November 2020.

<sup>57</sup> Human Tissue Act 1983

<sup>58</sup> 'Organ Donation'(QUT) <<https://end-of-life.qut.edu.au/organ-donation>> accessed 21 November 2020.

need for a well-thought-out and consulted action plan, national commitment emanating from the Prime Minister, a divergence from the voluntarism of the transplant units moving for reform that removes the vital role played by professionals and the significance of investment in the National Authority.<sup>59</sup>

### **(C) European Union**

A very comprehensive framework has been developed by the Council of Europe that addresses the various challenges and issues with respect to organ transplantation. The significant conventions as to organ donation and organ transplant are as follows:<sup>60</sup>

#### **a. The Convention against Trafficking in Human Organs and its Explanatory Report**

This convention was adopted on July 9, 2014, and it defines the various activities that form "trafficking in humans" and 'illicit removal of organs,' which means extraction without the gratis, informed and special consent of a living donor; removing from a late donor other than allowed by domestic law; removal where a living donor (or a third party) has obtained financial gain or benefit from the offered or received by a third party;

#### **b. Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin**

It came into force on May 1, 2006. The object of this Additional Protocol is to protect the privacy and identity of each person and guarantee respect for their reputation and other fundamental rights and freedoms in the transplantation of human organs and tissue without discrimination.

#### **c. The Convention on action against trafficking in human beings and its Explanatory Report**

It came into effect on February 1, 2008, and the aim is to look into human trafficking with the objective of organ removal.

#### **d. Convention for the Protection of Human Rights and Fundamental Freedoms**

It is an international treaty for the protection of European human rights and freedoms. The

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<sup>59</sup> C. Rudge, R. Matesanz, 'International Practices of Organ Donation'(BJA, 01 January 2012) <[https://academic.oup.com/bja/article/108/suppl\\_1/i48/237865](https://academic.oup.com/bja/article/108/suppl_1/i48/237865)> accessed 20 November 2020.

<sup>60</sup> Council of Europe 'Agreements and Conventions'<<http://193.164.228.37/en/agreements-conventions-1514.html>> accessed 21 November 2020.

Council of Europe created it in 1950 The Council of Europe created it in 1950

**e. Oviedo Convention: Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine**

This international document is the first legally binding text to uphold human dignity, rights, and freedoms by a set of standards and restrictions against the exploitation of biological and medical developments. It was entered into force on 1 December 1999.

## **VII. RECOMMENDATIONS AND CONCLUSION**

### **(A) Recommendations**

#### **a. Awareness Building**

There is a need for awareness-building programs. It is high time that our govt. It focuses on investing in such kinds of programs to develop understanding amongst the people and to address and make people understand the necessity of donating organs. It is also very essential that the various myths around organ donation be removed. There is a need to call for public meetings to create awareness in schools and universities with respect to organ transplantation. One of the significant things that could be done is to increase celebrity involvement in these kinds of programs. Also, the effective use of social media and other kinds of communication channels needs to be used to address the myths around organ donation. Another step that has to be taken is to create awareness amongst the poor and vulnerable and the affected areas about what the law is and how organ trafficking is punishable. This is a much-needed step to ensure that the vulnerable sections are not exploited.

#### **b. Brain Death**

Brain Death has been one of the contentious issues under the act. There is a need to have a harmonised definition of brain death across various laws. There are many complications in the cases of brain death as the individual cannot be considered dead due to different definitions in different acts like the Registration of Births and Deaths Act, 1969 and the IPC. The consequence of these irregularities is that an ambiguity is there about what organs can be harvested and what not from the body of a brain-dead person. While framing the criteria for death, the focus may be on WHO's 'Clinical Criteria for the Determination of Death'. It prescribes that while creating a formula for the determination of death in cases other than Cardiac Arrest, factors that need to be kept in mind are as follows: “(1) the basic requirements that must exist for triggering the algorithm, (2) the clinical examination and diagnosis; and (3) confirmatory testing to ensure irreversibility.” India must keep these guidelines and the best practices of other countries in

mind while taking steps for the formulation of the criteria for death.<sup>61</sup>

*c. Infrastructural Developments and accessibility to organ transplantation*

This is one of the most vital steps that needs to be taken. It must be remembered that there is equitable sharing of organs and unethical practices with respect to organ donations have been abolished. India is a welfare state, and there is an immediate need to focus on developing the infrastructure to ensure that there are efficient and effective health professionals, developing quality hospitals, ensuring efficacious post-operative care, etc. These are some of the steps that are needed for the hour.

There is also a need to ensure that organ transplants are accessible to all. This issue arises because 95% of organ transplants still happen in private hospitals.<sup>62</sup> India has recognized the right to health as a fundamental right under the purview of Article 21. This casts a responsibility on the state that all individuals are able to have this right. However, in reality, many are not able to access the facility for organ transplants due to the higher costs involved. It must be kept in mind that fundamental rights are equal for all, including those at the bottom of the social hierarchy. Thus, their needs must also be kept in mind. India, being a welfare state, must make investments in healthcare so as to ensure an equitable organ transplantation program. States like Tamil Nadu are providing kidney, liver and heart transplants free of cost in Tamil Nadu.<sup>63</sup>

*d. Health Insurance*

India still needs to improve in this aspect; only a part of the population has health insurance. Health insurance plans need to be developed while explicitly keeping in mind the need for organ transplantation to cover the high costs of organ transplantation.

**(B) Conclusion**

There is a scarcity of organs across the world due to various factors. Organ transplantation is unique—a recipient can only undergo a transplant by offering the organ in life or after death. However, those benefiting individuals cannot reap the drastic health effects of transplanting (highlighted by the extremely promising findings, at least in the short- to medium-term). There is demand worldwide to expand the amount of available organs, and systematic transplant

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<sup>61</sup> World Health Organisation, 'Clinical Criteria for the Determination of Death: WHO Technical Expert Consultation' 7 (2017) <<http://apps.who.int/iris/bitstream/10665/254737/1/WHO-HIS-SDS-2017.5-eng.pdf>> accessed 21 November 2020.

<sup>62</sup> Sanjay Nagral, 'Who gives, who lives India's organ transplant system continues to favour the rich' *The Daily Telegraph* (09 May 2018) <<https://scroll.in/pulse/878100/who-gives-who-lives-indias-organ-transplant-system-continues-to-favour-the-rich>> accessed 21 November 2020.

<sup>63</sup> Preeti Nair, 'Organ is Free, Transplant Cost is Problem' *Times of India* (5 September 2016) <<http://timesofindia.indiatimes.com/life-style/health-fitness/health-news/Organ-is-free-transplant-cost-is-problem/articleshow/54014378.cms>> accessed 21 November 2020.

programming has been initiated in several countries. In countries where there is a substantial proportion of the population under the poverty line and ineffective regulatory authority, strong demand for organs has brought about commodification. In India, a substantial amount of tragic road crashes have made the potential for deceased contributions, and the reservoir remains untapped. Few hospitals and dedicated NGOs have demonstrated the likelihood of a deceased donation in the region.

The focus of the researcher was to understand and analyse the various challenges prevailing in India with respect to organ transplantation, make recommendations to regulate unethical practices in relation to organ transplantation, and increase the supply of organs in India. This will be done through a comparative study with other countries. The first hypothesis proved that the legal framework in India in relation to organ transplantation needs to be revised to deal with the growing challenges posed by the widening gap between the demand and supply of organs, as there are many issues in the law that need to be removed. The law is also not able to meet the demands of the changing times. The second hypothesis is that there is a need for a more coherent legal system by effecting changes in the present legal system. The researcher has highlighted the areas in which changes are required and has also recommended the ways in which those challenges could be affected.

We in India must create a level playing field that is open and not hierarchical. It would be a long and daunting process, which can also lead to a broader struggle to build a state-of-the-art and affordable healthcare system for everyone.

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