

**ORGAN TRADE IN INDIA:
A CRITICAL ANALYSIS OF THE
TRANSPLANTATION OF HUMAN ORGANS AND
TISSUES ACT, 1994**

A Dissertation submitted to the National University of Advanced Legal
Studies, Kochi in partial fulfilment of the requirements for the award of
LL.M Degree in Public Health Law



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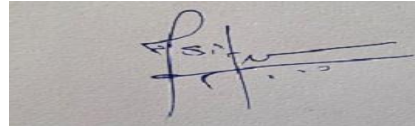
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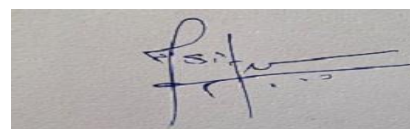
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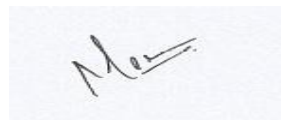
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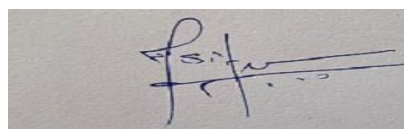
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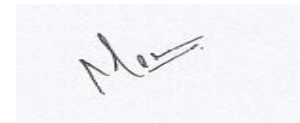
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DECLARATION

I declare that this dissertation titled **ORGAN TRADE IN INDIA: A CRITICAL ANALYSIS OF THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994** researched and submitted by me to the National University of Advanced Legal Studies in partial fulfilment of the requirement for the award of the Degree of Master of Laws in Public Health Law, under the guidance and supervision of Dr. Asif E, is an original, bona-fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.



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LIST OF ABBREVIATIONS

AIR	All India Reporter
CBI	Central Bureau of Investigation
CETS	Council of Europe Treaty Series
CLT	Cuttack Law Times
COFS	Coalition for Organ-Failure Solutions
Cth	Commonwealth
ed.	Edition
GSR	General Statutory Rules
HTOR	Human Trafficking for Organ removal
ILR	Indian Law Report
IPC	Indian Penal Code
MoHFW	Ministry of Health and Family Welfare
NCR	National Capital Region
NGO	Non-Governmental Organisation
NOTA	National Organ Transplant Act, 1984
NOTTO	National Organ and Tissue Transplant Organisation
NSW	New South Wales
NT	Northern Territory
ONT	Organizacion Nacional De Transplantes
OPTN	Organ Procurement and Transplantation Network
pmp	Per million population
Q & A	Question and answer
Qld	Queensland
SA	South Australia
SCC	Supreme Court Cases
Tas	Tasmania
THOTA	Transplantation of Human Organs and Tissues Act, 1994
UAGA	Uniform Anatomical Gifts Act, 1968
UK	United Kingdom

USA	United States of America
Vic	Victoria
WA	Western Australia
WHO	World Health Organisation

JOURNALS

Br J Anaesth	British Journal of Anaesthesia
Br. Med. J.	British Medical Journal
CCNQ	Critical Care Nursing Quarterly
CJASN	Clinical Journal of the American Society of Nephrology
Crime Law Soc. Change	Crime, Law and Social change
CULR	Cochin University Law Review
IDHL	International Digest of Health Legislation
ILILR	Indian Law Institute Law Review
Indian J Anaesth	Indian Journal of Anaesthesia
Indian J Transplant	Indian Journal of Transplantation
Indian J Urol	Indian Journal of Urology
JAMA	Journal of American Medical Association
JILI	Journal of Indian Law Institute
JMP	Journal of Medicine and Philosophy
McGill J Med	McGill Journal of Medicine
MAMC J Med sci	MAMC Journal of Medical Science
Natl Med J India	National Medical Journal of India
Nat Rev Nephrol	Nature Reviews Nephrology
NUJHS	Nitte University Journal of Health Science
SSRN	Social Science Research Network
Tranplant Int	Transplant International

TABLE OF CASES

- Balbir Singh v. The Authorisation Committee, 2004 SCC OnLine Del 709.
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CHAPTER I: INTRODUCTION

1.1 INTRODUCTION

India regulates organ transplantations and prohibits any commercial dealings in human organs and tissues through the Transplantation of Human Organs and Tissues Act enacted in 1994.¹ The Act also recognizes brain death as legal death and tries to promote deceased or cadaver organ donations. As per Section 2(d) of the Act, ‘brain-stem death’ means the stage at which all brain-stem functions have permanently and irreversibly ceased and is so certified as per the provisions of the Act. However, the rate of deceased donations has not picked up even after more than two decades of its implementation. The legislation suffers from several flaws, and organ trade and trafficking are still prevalent in India at an alarming rate, proving the legislation to be ineffective in curbing the menace of organ trade in the country. Section 19 and Section 19A of the Act provide for punishment for commercial and illegal dealings in human organs and tissues. The punishment for commercial dealings in human organs ranges from five years to ten years and a fine of twenty lakhs to one crore, whereas the illegal dealings in human tissues would attract imprisonment of one year to three years and a fine of five lakhs to twenty-five lakhs. A huge portion of the population, especially poor and vulnerable sections, are still unaware of such a legislation and the criminal liability imposed upon the offender.

The ever-increasing disparity between the rich and poor in India, the wide gap between the demand and supply of organs, the absence of national health insurance schemes make the commercialisation of organs and tissues a simple and attractive business proposition for some and a solution for others. Poor and vulnerable sections of the society are being coerced into donating their organs as a near relative or someone who has affection or attachment towards the recipient while the fact is that the donor and recipient did not know each other until a few days ago. Several such instances of removal of organs even without the knowledge of the donor without satisfying pre-transplant and post-transplant requirements leading to serious health

¹ The Transplantation of Human Organs and Tissues Act, No. 42 of 1994 [Hereinafter ‘THOTA’].

complications have come to light through various media reports and scientific publications from other countries.²

World Health Organisation has recognized the commercial traffic in human organs, particularly from living donors who are unrelated to recipients, due to the shortage of available organs in many countries in the Preamble of WHO Guiding Principles on human cell, tissue, and organ transplantation. WHO states that cells, tissues and organs should only be donated freely, and all the donations have to be done without any financial reasons, payment or rewards of monetary value, etc. Commercial dealings in human organs and tissues for transplantation are to be banned as per the Guiding Principle 5. The commercialisation of organs will result in the rich taking unfair advantage of the poor and vulnerable groups of the society, undermining altruistic donation, and leads to profiteering and human trafficking.³

The evolution of organ transplantation, the causes or factors promoting organ trade in India, the analysis of the Transplantation of Human Organs and Tissues Act, 1994, and whether it is effective enough to curb the high rate of organ trade and the rackets involved in the same is discussed under the research study. There would also be a comparative analysis of the legislations, mainly in the USA and Australia, and the position of organ trade in countries like Iran where sale of the kidney is legalized and Spain where there exists a system of presumed consent is also considered.

While not necessarily hot locations for transplant tourism, countries like Australia, Canada, Israel, Japan, Oman, Saudi Arabia and the United States have been identified as organ recipients, while India, Pakistan, China, Bolivia, Brazil, Iraq, Israel, Moldova, Peru, Turkey, and Colombia have all been identified as common organ sellers.⁴ India is considered as a major source of organs when it comes to transplant tourism. India is known for its organ exports, and organs from local donors are regularly transplanted to foreigners by way of commercial dealings. The commercial

² KS Chugh et.al., '*Problems and Outcomes of Living Unrelated Donor Transplants in Developing Countries*', 57 (74), KIDNEY INT., 131-135 (2000) [Hereinafter '*Problems and outcomes of living transplants*'].

³ WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION, WORLD HEALTH ORGANISATION [WHO] 5 (2010), https://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf?ua=1?

⁴ Yosuke Shimazono, *The state of the international organ trade: a provisional picture based on integration of available information*, BULLETIN OF THE WORLD HEALTH ORGANISATION [WHO] 85(12), (2007), <https://www.who.int/bulletin/volumes/85/12/06-039370.pdf> [Hereinafter '*The state of International organ trade*'].

dealings are mostly like one-way traffic from the poor to the rich and the poor end up having more debts with deteriorating health after such donations. Acknowledging the fact that commercial dealings are illegal, it is important to mention that the amount promised is not usually paid to the donors and the pre-transplant and post-transplant procedures are not carried out, resulting in the donor's deterioration of health. It is true that there was a fall in the number of such dealings after the enactment and implementation of the Transplantation of Human Organs and Tissues Act, 1994. However, the underground organ market is still widely prevalent and resurging in India.

As per the Bulletin of the World Health Organisation in 2007, around 2000 Indians sell their kidneys each year.⁵ As per the statement of Dr. Debra Budiani, the Executive Director and Founder of Coalition for Organ Failure Solutions in 2012, COFS-India has identified 1500 victims of organ trafficking in Chennai and Erode. Considering the active and prevalent illegal kidney markets in Chennai, Calcutta and Bangalore, this number represents the tip of the iceberg.⁶ India is regarded as one of the biggest markets for organ trafficking despite having specific legislation prohibiting the commercialisation of human organs and tissues and imposing criminal liability for such dealings. Some of the factors promoting organ trade in India include wide gaps between demand and supply of organs, lack of awareness about the legislation and illegality of commercial dealings in organs,⁷ participation of medical professionals and hospitals in maintaining the organ trade market,⁸ etc.

There is a huge gap in the demand and supply of human organs in India. This high demand has automatically led to the commercialisation of organs in the country. The healthcare system in India is corrupted and inefficient to a great extent when it comes to organ transplantations. Though this was tried to rectify through the legislation

⁵ *Id.*

⁶ Debra Budiani, COFS, '*Human Trafficking for an Organ Removal (HTOR): A Call for Prevention, Protection, Investigations and Accountability*', (2012) at 9.

⁷ Anju Vali, '*Transplantation of human organs: the Indian scenario*', 1, ILIR (Summer, 2017) [Hereinafter '*Transplantation of human organs*'].

⁸ *Kidney racket: Mastermind doctors get 7-yr jail*, The Hindustan Times, (Mar. 23, 2013), <https://www.hindustantimes.com/india/kidney-racket-mastermind-doctors-get-7-yr-jail/story-OUEAL33HijQabKVnlhATsK.html>; *The unravelling of a kidney racket*, THE HINDU (Jul. 27, 2019), <https://www.thehindu.com/sci-tech/health/the-unravelling-of-a-kidney-racket/article28725737.ece> [Hereinafter '*Unravelling of a kidney racket*']; *Top Indian hospitals, foreign clients, donors from UP caught in 'kidney transplant racket'*, THE PRINT (Jun. 13, 2019), <https://theprint.in/india/top-indian-hospitals-foreign-clients-donors-from-up-caught-in-kidney-transplant-racket/249221/>.

criminalising commercial dealings in organs, the active involvement and support of medical practitioners and authorities in the field is a major concern and contributes significantly to the illegal organ market. The way the Act is interpreted and implemented by the authorities and hospitals is also a major concern.

The increase in the rate of crime has exposed various flaws and drawbacks of the Act. Even after more than two decades of its implementation, the Act has not been able to achieve either of its two main objectives which are the promotion of cadaver donation and prevention of commercial dealings in human organs. Hence, the Act has not helped in reducing the wide gap between demand and supply of human organs and tissues. This gap is widening globally and the high demand of organs has led to its commodification, especially in countries like India where there is a huge portion of the population below the poverty line. This has contributed to transplant tourism and like mentioned above, India has become a major source of organs in this sector.

There is little awareness about the legislation and the illegality of the commercialisation of organs which results in the general public contributing to a substantial rate of organ trade without knowing that it is illegal. They tend to follow the instructions of hospitals and medical practitioners which might or might not disclose that such commercial dealings are illegal. There are also various ethical, religious, and emotional constraints that discourage individuals from going for organ donation. The concept of brain death and cadaver organ donations are still unknown to a large population and the same has not been actively promoted or publicized widely in the country.

Section 9 of the Act makes it clear that no human organ or tissue removed from the body of a living donor shall be transplanted into a recipient unless the donor is a near relative of the recipient. An authorisation committee has to approve when the donor is not a near relative and he authorises the removal of organ, stating reason of affection or attachment towards recipient or for any other special reasons. But the legislation is not strict enough to stop unrelated living donors pretending that they are a friend or relative of the recipient for giving organs for emotional rather than financial reasons. Most of such organ transplantations are being carried out under the cloak of legal authority from an authorization committee.

How far the Act has achieved certain objectives like promotion of cadaver organ donations and prevention of commercial dealings in human organs is examined under the research study. By recognising 'brain death' as legal death, the Act aims to promote cadaver organ donations. However, the estimates as per National Organ and Tissue Transplant Organisation show that less than 8% of the total transplantations from 1994 to 2019 are cadaver donations leaving all the other transplantations into account of living donations.⁹ A substantial part of such cadaver organ donations has been carried out due to the efforts of some Non-Government Organizations or hospitals that are highly committed to the cause.

The need for the promotion of cadaver organ donations expecting that the same will contribute to a substantial fall in illegal donations, is emphasised under the research study. In India, there is a huge potential for deceased organ donations as the number of fatal road traffic accidents is high and this pool is yet to be tapped. However, only a few hospitals and NGOs in the country working towards this cause might not help to better the situation to a great extent. Concentrating on increasing cadaver organ donations is expected to bring a fall in the illegal organ donations from living persons for financial reasons.

1.2 STATEMENT OF THE PROBLEM

Despite having a specific legislation to curb the menace of organ trade, trafficking in human organs and tissues are widely prevalent in India and is increasing at an alarming rate. The Transplantation of Human Organs and Tissues Act, 1994 punishes commercial dealings in human organs or tissues. However, organ commerce and kidney scandals are being regularly reported in India and the country is considered as one of the biggest markets for organ trafficking despite having a specific legislation on the matter. Though brain death has been recognised as legal death under the legislation, the statistics show that there has been only a minimal number of deceased organ donations as compared to the high rate of living donations.

⁹ ORGAN REPORT, NATIONAL ORGAN AND TISSUE TRANSPLANTATION ORGANISATION [NOTTO] [Hereinafter 'Organ Report'].

1.3 SCOPE OF STUDY

This research study mainly focuses on the Indian legislation regulating organ transplantations and preventing commercialisation of organs which is the Transplantation of Human Organs and Tissues Act, 1994. The various objectives of the Act and how far the objectives have been achieved after more than two decades of its implementation is analysed. The rate of cadaver organ donations is examined and the need for promoting the same is discussed. The various factors contributing to the flourishing organ market in the country is analysed and an attempt is made to propose solutions for the same. Though the study mainly focuses on the Indian scenario, the legal position in other countries like USA and Australia is also analysed in order to provide a comparative perspective on the matter.

1.4 RESEARCH QUESTIONS

- 1) Whether the Transplantation of Human Organs and Tissues Act, 1994 has been effective in curbing organ trade and commercialisation of organs in India?
- 2) Whether the Transplantation of Human Organs and Tissues Act, 1994 have any legal flaws facilitating organ trade in the country?

1.5 RESEARCH OBJECTIVES

- 1) To identify and study the causes for the increasing rate of illegal organ trafficking in India.
- 2) To analyse the Transplantation of Human Organs and Tissues Act, 1994 and identify the drawbacks or flaws in the Act.
- 3) To examine organ trade in a comparative perspective and laws governing the same in different countries.

1.6 HYPOTHESIS

The Transplantation of Human Organs and Tissues Act, 1994 fails to promote cadaver organ donations and prevent commercial dealings in human organs in India.

1.7 RESEARCH METHODOLOGY

The research study is undertaken through the method of doctrinal research by analysing the legislations. The provisions of the Transplantation of Organs and Tissues Act, 1994 is analysed and its efficiency in preventing commercialisation of organs is examined. The researcher relies on various secondary sources of data like WHO reports, articles by investigative journalists, Government websites, newspaper and journal articles, etc. for the purpose.

1.8 CHAPTERISATION

1.8.1 CHAPTER 1: INTRODUCTION

This chapter attempts to give a general overview of the position of organ trade and cadaver organ donations in India, the significance and need for this research study. The factors contributing to the ineffectiveness of the Transplantation of Human Organs and Tissues Act, 1994 have been introduced in the chapter. The problem and scope of the research study have been stated and the aims and objectives of the research study, research questions and hypothesis have been enumerated in this chapter to help the audience understand the purpose, need and scope of this study. The list of chapters and a brief of the content of the chapters are also stated.

1.8.2 CHAPTER 2: EVOLUTION OF ORGAN TRANSPLANTATION AND LEGAL FRAMEWORK IN INDIA

The absence of a legislation regulating organ transplantation in India led to illegal organ trafficking and kidney scandals. The vulnerable sections of the society were highly exploited by the middlemen and unscrupulous medical practitioners. The increase in such instances and various other factors resulted in the enactment of Transplantation of Human Organs and Tissues Act, 1994. The legislation was passed keeping in mind two major objectives viz, regulation of transplantation of human organs and tissues for therapeutic purposes and prevention of commercial dealings in human organs and tissues. The evolution of organ transplantation and the legal framework in the country aiming at curbing the menace of organ trade is discussed under this chapter.

1.8.3 CHAPTER 3: FACTORS CONTRIBUTING TO ORGAN TRADE IN INDIA

Several factors contribute to the flourishing organ trade in the country. Some of the major factors include a huge gap in demand and supply of organs, the involvement and support of doctors and other medical authorities in the process, lack of effective initiatives from the part of the government, low rates of cadaver organ donations, ethical, emotional and religious constraints in organ donation, etc. have contributed significantly to the illegal organ market thriving in India. These are the major reasons why commercialisation of organs and tissues is still prevalent in India. The growing disparity between the rich and the poor also contributes to the illegal organ market. Such factors and the background are discussed in detail under this chapter.

1.8.4 CHAPTER 4: FLAWS IN THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994

The frequent reports of organ trade and kidney scandals in the country have exposed various flaws in the legislation. Section 9 of Transplantation of Human Organs and Tissues Act, 1994 allows an authorisation committee to approve when the donor is not a near relative and when he authorises the removal of organ by reason of affection or attachment towards recipient or for any other special reasons. However, what constitutes affection or attachment has not been made clear under the Act and this has led to the authorities misusing this provision to buy and sell organs from random people who are not related to the recipient. Various other flaws and drawbacks of the Act making the ground fertile for organ mafias are also discussed under this chapter. The researcher tries to answer the second research question, “Whether the Transplantation of Human Organs and Tissues Act, 1994 has any flaws?” mainly through this chapter.

1.8.5 CHAPTER 5: COMPARATIVE STUDY (POSITION IN USA AND AUSTRALIA)

The legal position in the United States of America and Australia regarding the regulations of organ transplantation and commercialisation of organs are discussed in this chapter. There have been around 26 legislations passed in the US aiming at regulating organ transplantations and donations and these regulations range from what constitutes being dead, to what constitutes consent for organ donation, to national

honors for organ donation. Under the research study the main focus is on the National Organ Transplant Act, 1984 banning commercialisation of organs for transplant. In Australia, there are state based Human Tissues Act with substantially similar provisions and these legislations aim at regulating organ transplantations and preventing organ trade. There will also be references to the countries like Iran where the sale of kidney is legalised and Spain where there exists a system of presumed consent.

1.8.6 CHAPTER 6: CONCLUSION

This chapter gives an overview of the current position of organ trade in India and how far the objectives of Transplantation of Human Organs and Tissues Act, 1994 have been achieved as per the analysis derived from the research study. The need for promotion of cadaver organ donations and mass awareness of the legislation and the illegality of organ trade are emphasised under this chapter. The researcher also tries to provide suggestions and recommendations in curbing the menace of organ trade and promoting cadaver organ donations in India under this chapter.

CHAPTER II: EVOLUTION OF ORGAN TRANSPLANTATION AND LEGAL FRAMEWORK IN INDIA

2.1 INTRODUCTION

Organ transplantation is referred to as the transfer or engraftment of human cells, tissues or organs from a donor to a recipient with the aim of restoring functions in the body.¹⁰ It is considered as the medical miracle of the 20th century and it has evolved over the years to be at a significantly developed stage as it can be seen today. For a significant duration, there were no legal frameworks to regulate organ transplantations and prevent any commercial dealings. The need for an effective legislation was felt due to the disparity between demand and supply of human organs, scarcity of organs leading to unethical practices, etc. This chapter examines the history and evolution of organ transplantation with particular focus on Indian historical milestones. The legislative history with respect to organ transplantations, which is mainly the evolution of the Transplantation of Human Organs Act, 1994 and its journey till the 2014 Rules is also analysed. This includes various amendments over the years with respect to the Act and related rules, various committee reports on the need and functioning of the Act and the significant changes in relation to the prevention of commercialisation of organs or tissues in the country.

2.2 HISTORY OF ORGAN TRANSPLANTATION IN INDIA

The term ‘transplant’ was coined by John Hunter in the year 1760. Researchers have been experimenting on the process of organ transplantation on animals and humans since the 18th century, which after the inevitable failures over many years, is now considered as a routine medical treatment. The transplantations are primarily carried out with respect to the organs like kidneys, livers, hearts, pancreas, intestine, lungs and cornea. The first ever transplantation of an organ was a kidney transplantation

¹⁰ World Health Organisation [WHO], *Global Glossary of Terms and Definitions on Donation and Transplantation*, at 14, (Nov. 2006), <https://www.who.int/transplantation/activities/GlobalGlossaryonDonationTransplantation.pdf?ua=1>.

which took place in 1954 at Brigham & Women's Hospital in Boston, carried out by Dr. Joseph E. Murray.¹¹

Organ transplantation in India can be traced back to the 1960s. The first successful corneal transplant in the country was carried out in Indore in 1960 by Dr. Dhanda preceded by the establishment of first eye bank in Madras in 1945. The first successful cadaver kidney transplant in India was carried out at KEM Hospital, Mumbai in 1967. While Indians had to travel abroad for getting a heart transplant till 1994, the position was changed by a team of at least twenty surgeons led by Dr. P Venugopal and the first successful heart transplant was carried out at the All India Institute of Medical Science, New Delhi on 3rd August, 1994. The year 1998 witnessed two milestones as a result of India's first cadaveric liver transplant carried out by a surgeon from Singapore at Apollo Hospital, Chennai and India's first successful lung transplant in Chennai. Later in 2005, the country's first successful ovarian transplant was carried out in Mumbai.¹² Now, organ transplantations are carried out widely in the country.

2.3 EVOLUTION OF LEGAL FRAMEWORK

Technological advancements and development in medical research promoted organ transplantations as well as widened the scope of the same across the country. However, the commercialisation of human organs and tissues was widely prevalent in India, mainly due to the absence of a legislation regulating organ transplantation. This led to the poor and vulnerable sections of the society being exploited by the rich, middlemen and unscrupulous medical authorities in the country. Though some of the states had legislations restricted to specific body parts like the Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 and Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 in Delhi, the Maharashtra Kidney Transplantation Act, 1982 and the Bombay Corneal Grafting Act, 1957, the increase in the kidney scams made it clear that a single comprehensive legislation to curb and punish this practice was the need of the hour. The major issues behind state legislations were that it was restricted to a specific body part and the commercial dealings in organs being a grave issue, state legislations did no good in curbing such

¹¹ Organ Procurement and Transplantation Network, U.S. Department of Health and Human Services, *About Transplantation: History*, <https://optn.transplant.hrsa.gov/learn/about-transplantation/history/>.

¹² Sulania A et al., *Organ donation and transplantation: An updated overview*, 2, MAMC J MED SCI, 18-27 (2016).

practices in the country. Hence, a legislation applicable to all states and covering all body parts which can be potentially traded in a market became a pre-requisite in the country.

Such a legislation would serve different purposes. Significant contribution would be that it would provide legal sanction to organ removal from the deceased by recognising 'brain-stem death' as 'death'. Secondly, the absence of such a legislation was hindering the ability to transplant organs legally despite the availability of technology and know-how. Hence, the legislation would permit the transplantation of human organs and human tissues at a later point of time. Finally, and most importantly, enacting such law would curb the practice of rampant illegal trade in human organs. As seen in various parliamentary debates, concern was expressed about the blatant exploitation of the poor by the rich and the commodification of human organs and thereby the human body. The Act was also expected to protect patients against contracting unnotified diseases from transplanted organs and to eliminate commercial dealings and any criminal activities associated with organ transplantations.¹³

In 1989, Rajiv Gandhi, the then Indian Prime Minister, asked the Ministry of Health and Family Welfare the reason why heart and liver transplants were not being performed in the country. Organ transplantations and their techniques were common and standardised in the West and the introduction of the new immunosuppressant drug, cyclosporin, had dramatically improved the success rate of transplantation. More than 80% of recipients who might otherwise have died from organ failure within six months, were alive after a year and 50% of them were alive after five years. However, such procedures were very expensive which made a liver transplant in the USA unaffordable in India. Illicit organ trade was also prevalent in the country especially in the cities of Bombay and Madras which had destroyed the reputation of the country and its medical profession.¹⁴

It was imperative to study and analyse the problems related to heart and liver transplants so as to devise legislative and other initiatives to overcome these difficulties. Towards achieving this goal, a Committee was set up by the Ministry of

¹³ Dhvani Mehta et al., Vidhi Centre for Legal Policy, *Organ Transplant Law: Assessing Compatibility with the Right to Health*, at 2-3 (Sept. 2017) [Hereinafter 'Organ Transplant Law'].

¹⁴ Samiran Nundy, *Origin and genesis of the Transplantation of Human Organs Act, 1994, of India*, 47(1) IDHL, at 1 (1996) [Hereinafter 'Origin and genesis of THOA']

Health and Family Welfare to identify these issues and it identified two major issues. First and foremost, Indian law did not recognise 'brain-stem death' as 'death' and as per Section 46 of the Indian Penal Code¹⁵ defines death as "Death of a human being unless the contrary appears from the context" and Section 29(13) of the Registration of Births and Deaths Act, 1969¹⁶ defines death as "the permanent disappearance of all evidence of life at any time after live birth has taken place". These definitions were ambiguous and not adequate in the context of organ transplantation. There were also concerns about the uncertainty of acceptance of brain stem death as death by the Indian population. These definitions also did not allow heart and liver transplantation that required a heart-beating, brain-stem-dead donor. The second issue identified by the Committee was the rampant organ trade prevalent in the country. There was massive exploitation of the poor by the rich, the human organs were treated as mere commodities and there was huge risk to recipients from unnotified diseases in donors, and there were reports of criminal activities involving middlemen and even physicians.

The Committee was of the opinion that the prospects of formulating a successful cadaver donation programme was very remote owing to the flourishing illicit organ trade in the country. Hence, it was recommended that a law should be enacted introducing the concept of brain death, recognising the same as legal death and criminalising the buying and selling of organs in the country. There were various conferences held in major cities with an intention to familiarize people from all sections of the society with the government's objectives. The conferences took place in Bombay under the auspices of the National Academy of Medical Sciences and the Biomedical Ethics Centre in August 1989, Madras and Calcutta in January 1990 and June 1990 respectively and Delhi in September 1990 which was a national conference sponsored by the Ministry and WHO. These conferences made it clear that public was firmly in favour of such legislative changes with respect to organ transplantations in the country. The Government then established a committee of medical and legal experts under the chairmanship of Dr. L.M Singhvi, an eminent Constitutional Lawyer to clarify and bring about solutions to the issues mentioned above.¹⁷

¹⁵ PEN. CODE [Hereinafter 'IPC'].

¹⁶ Registration of Births and Deaths Act, No. 18 of 1969 [Hereinafter 'Registration of Births and Deaths'].

¹⁷ Origin and genesis of THOA, *supra* note 14.

2.3.1 L.M. SINGHVI COMMITTEE

L.M Singhvi Committee was set up to clarify:

- the concept and definition of brain death;
- the need for a separate legislation to recognise brain death and the legal, medical, and social implications of such legislation;
- the safeguards that have to be adopted for preventing the misuse of the concept of brain death;
- the manner in which the concept of brain death must be utilized to promote the availability of human organs for transplantation.¹⁸

The Committee submitted its report in June 1991 and received the Cabinet approval in October 1991. The report recommended for a legislation similar to that of the United Kingdom's Human Organ Transplants Act, 1989 with appropriate modifications to address and suit the conditions specific to India. This legislation should recognise brain-stem death and provide for authorisation and accreditation of hospitals having the skilled workforce, equipment and associated facilities for the removal and transplantation of human organs. The report also stated that a person before his/her death should be able to execute in writing the presence of witnesses an authorisation for the removal of specified organs from that person's body after death. It also recommended that medical care should be provided to donors in order to promote voluntary donation of organs from living persons. Most importantly, the Committee also recommended that organ trade must be prohibited and made a punishable offence.¹⁹

2.3.2 THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994²⁰

Subsequent to the L.M. Singhvi Committee report, a Bill was prepared and three States viz., Goa, Maharashtra, and Himachal Pradesh passed resolutions in its favour. On 5 May 1993, the Transplantation of Human Organs Bill was submitted to the Rajya Sabha and received the House's unanimous approval. In December 1993,

¹⁸ *Office Memorandum No. S. 12011/1/91-MS, Constitution of a Group to examine the proposal for enactment of legislation for use of human organs and their donation for therapeutic purposes, MINISTRY OF HEALTH AND FAMILY WELFARE [MOHFW] (Feb. 25, 1991).*

¹⁹ *Report of the Group Constituted to Examine the Proposal for Enactment of Legislation for Use of Human Organs and their Donation for Therapeutic Purposes* as cited in Organ Transplant Law, *supra* note 13, at 3.

²⁰ The Transplantation of Human Organs Act, No. 42 of 1994 [Hereinafter 'THOA'].

however, the Lok Sabha decided to refer the Bill to a Select Committee for further examination. The Committee suggested minor amendments with respect to the inclusion of in-laws as near relatives and the payment of living donors. These were not accepted by the Union Cabinet and on 15 June 1994 the Bill was passed by the Lok Sabha. It received Presidential assent on 8th July 1994. Rules under the Act were notified in February 1995.²¹

SALIENT FEATURES OF THE ACT

The primary objective of the Act is to provide for the regulation of the removal, storage, and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs. The Act repealed the Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 and the Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1989. The major features of the Act are discussed below:

- Recognition of ‘brain-stem death’ as ‘death’:

Section 2(d) and 2(e) of the Act defines “brain-stem death” and “deceased person” respectively. Brain-stem death means “the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3”²² and deceased person means “a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place”. Through these provisions, the Act made it clear that brain-stem death can be considered as death and the person can be treated as a deceased person for the purposes of organ transplantations.

- Authorisation for removal of human organs:

The Act permitted any person above the age of 18 years to voluntarily authorise before his death, the removal of any of his organs for therapeutic purposes i.e.,

²¹ The Transplantation of Human Organs Rules, GSR No. 51(E), Feb. 4, 1995.

²² Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following namely, (i) the registered medical practitioner in charge of the hospital in which brain-stem death has occurred; (ii) an independent registered medical practitioner, being a specialist, to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate authority; (iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; and (iv) the registered medical practitioner treating the person whose brain-stem death has occurred.

systematic treatment of any disease or the measures to improve health according to any particular method or modality.²³ He/she has to do so in writing in the presence of two or more witnesses, at least one of them, being a near relative. In such a case, once the person dies, the person who is in lawful possession of the body, can grant to a registered medical practitioner all reasonable facilities for the removal of such human organ from the body of the donor for therapeutic purposes. However, the same must be done only if he has no reason to believe that the donor had subsequently revoked the authority.²⁴ If no such authority has been granted but no objection was also expressed by the deceased, the person who is in lawful possession of the dead body can authorise the removal of any organ of the deceased person for therapeutic purposes. He can do so only when he has no reason to believe that any near relative of the deceased might have an objection.²⁵ The removal of any organ can be done only by a registered medical practitioner and he has to satisfy himself that life is extinct in such body through a personal examination of the said body before the removal of the organ. In cases of brain-stem death, removal of the human organ can be done only after the death has been certified as per the requirements of the Act by a Board of medical experts.²⁶ If the brain-stem death occurs to a minor, his parents can give authority for the removal of any organ.²⁷ The removal cannot be authorised or no facilities can be granted in certain situations where the person empowered to grant authority has reason to believe that an inquest is required to be held in relation to such body as per any existing law. Authority should also not be taken from a person to whom the body has been entrusted solely for interment, cremation or other disposal.²⁸

If a dead body in a hospital or prison is not claimed by any near relative within 48 hours of the death, the authority for removal of human organ or organs can be granted by the person in charge of the management or an authorised employee of the hospital or prison. Authorisation cannot be given if the person empowered to give authority has reason to believe that though the body has not been claimed within the time specified, any near relative is likely to claim the body of the deceased.²⁹

²³ THOA, *supra* note 20, § 2(o).

²⁴ *Id.* § 3(2).

²⁵ *Id.* § 3(3).

²⁶ *Id.* § 3(5), § 3(6).

²⁷ *Id.* § 3(7).

²⁸ *Id.* § 4.

²⁹ *Id.* § 5.

In situations where the body has been sent for post-mortem for the purposes of medico-legal or pathological purposes, the person competent can give authority if he believes that such human organ is not required for the purpose for which such body has been sent for post-mortem examination, provided that he has satisfied himself that the deceased person had not expressed before his death, any objection to such removal or he had already given authority for removal of organs after his death and the same has not been revoked.³⁰ Once any human organ is removed, the registered medical practitioner has to take necessary steps to preserve the organ so removed.³¹

- Restrictions on the removal and transplantation of human organs:

A human organ removed from the body of a living person can only be transplanted to a near-relative of the donor and no one else. When a person gives authority for removal of his organs after his death or when any competent person as per the provisions of the Act gives authority, such organ can be transplanted to any person who is in need of such organ. If a donor authorizes removal of an organ before his death for transplantation into the body of a person who is not a near-relative, stating affection or attachment towards the recipient or any other special reasons, such human organ should not be removed and transplanted without the prior approval of the Authorisation Committee. If the donor and recipient make an application jointly, the Authorisation Committee can grant approval for transplantation after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements under the Act and Rules. However, if the Authorisation Committee is satisfied that the applicants have not complied with the requirements after holding inquiry and hearing them, can reject such application after recording the reasons in writing.³² The Act prohibits removal of any human organ for any purpose other than therapeutic purposes³³ and it is essential that a registered medical practitioner before any organ removal or transplantation, explain all possible effects, complications and hazards related to the removal and transplantation to the donor and the recipient.³⁴

- Regulation of hospitals

³⁰ *Id.* § 6.

³¹ *Id.* § 7.

³² *Id.* § 9.

³³ *Id.* § 11.

³⁴ *Id.* § 12.

Every hospital has to be registered under the Act to conduct, associate, or help in the removal, storage or transplantation of any human organ. No medical practitioner or any other person should conduct or help in conducting any activity relating to the removal, storage or transplantation of a human organ at a place other than a place registered. Removal, storage or transplantation of human organs should not be conducted for any purposes other than therapeutic purposes. However, eyes or ears including ear drums and ear bones can be removed at any place from the dead body of a donor by a registered medical practitioner for therapeutic purposes.

▪ Offences and Penalties:

Provision	Offence	Punishment
S. 18	Renders his services, conducts or helps in the removal of any human organ without authority.	Imprisonment upto 5 years and fine upto Rs. 10,000. (If the person convicted is a registered medical practitioner, the same shall be reported to the respective State Medical Council by the Appropriate Authority and necessary action must be taken including the removal of his name from the Council's register for a period of 2 years in case of first offence and permanently for the subsequent offence.)
S. 19	a) makes/receives any payment for the supply or an offer to supply any human organ; (b) seeks to find person willing to supply any human organ for cash; (c) offers to supply any human organ	Imprisonment of 2 to 7 years and fine of Rs. 10,000 to 20,000. ³⁵

³⁵ The proviso states that the court may, for any adequate and special reason to be mentioned in the judgement, impose a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees.

	<p>for payment;</p> <p>(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;</p> <p>(e) takes part in the management of a body of persons, whose activities consist of or include the initiation or negotiation of any arrangement as mentioned above;</p> <p>(f) publishes/distributes/causes to be published/distributed any advertisement: inviting persons to supply or offering to supply any human organ for cash, or indicating that the advertiser is willing to initiate or negotiate any arrangement.</p>	
S. 20	Acting in contravention to any provision of the Act or Rules, or any condition of the registration granted, for which no punishment is separately provided.	Imprisonment upto 3 years or fine upto Rs. 5000.

2.3.3 THE TRANSPLANTATION OF HUMAN ORGANS RULES, 1995

The Transplantation of Human Organs Rules, 1995 was made in exercise of the powers under Section 24(1) of the Transplantation of Human Organs Act, 1994. The Rules provide Form 1 through which any donor may authorize the removal of any of his organ before his death for therapeutic purposes. The Rules lists out various duties of a medical practitioner under Clause 4:

- a) Before removing an organ from the body of a donor before his death, the medical practitioner should satisfy himself that the donor has authorised the same in Form 1; that donor is healthy and fit to donate the organ and has to sign a certificate in Form 2; that the donor is a near relative of the recipient,

and has to sign a certificate in Form 3 after carrying out the relevant tests on the donor and the recipient,

- b) In cases where the recipient is a spouse of the donor, the medical practitioner has to record the statements of them to the effect that they are so related and shall sign a certificate in Form 4.
- c) Prior to the removal of human organs after the death of a person, he has to satisfy himself that the donor had authorised the same before his death as per the requirements of the Act; that the person lawfully in possession of the dead body has signed a certificate in the prescribed form.
- d) In the event of brain stem death, he has to ensure before removing any organ from the body of the such person that a certificate has been signed by all the members of the Board of medical experts according to the Act.³⁶ If the person is a minor, the medical practitioner has to ensure that an authority signed by the parent of such person has been obtained in addition to the certificate of Board of medical experts.

The Rules also deal with the registration or renewal of registration of hospitals, conditions for grant of certificate of registration, etc.

2.3.4 THE TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT) RULES, 2008³⁷

The amended rules add to the duties of the medical practitioners. If the live donor is not a near relative, the medical practitioner has to satisfy himself that he has signed the appropriate form and submitted a joint application with the recipient and the permission from the Authorisation Committee has been obtained. He should also ensure that, before the removal of any organ from the body of a person after his death, the donor had in the presence of two or more witnesses, out of which at least one is a near relative of the person, unequivocally authorized before his death, the removal of any organ from his body after his death for therapeutic purposes. There should also not be any reason to believe that the donor had revoked such authority subsequently and the person who is lawfully in possession of the dead body has signed a certificate in the appropriate form.

³⁶ THOA, *supra* note 20, §3(6).

³⁷ The Transplantation of Human Organs (Amendment) Rules, GSR No. 571(E), Jul. 31, 2008 [Hereinafter 'Rules, 2008'].

The amendment adds a new rule 4A containing provisions concerning Authorisation Committees. It is stated that a medical practitioner who is a part of organ transplantation shall not be a member of the committee. When the organ transplantation is carried out between a married couple, the registered medical practitioner who is in charge of the transplant centre must evaluate the factum and duration of the said marriage, ensure that all relevant documents, information regarding number and age of children, family photograph illustrating entire immediate family, birth certificate of children, etc. Authorisation Committee should also consider requests in circumstances where the donor or recipient or both are not Indian nationals whether near relatives or not.

Authorisation Committee should make certain evaluations when the proposed donor and recipient are not near relatives as defined under the Act. The committee should ensure that there have been no commercial transactions or payment of money or in kind or promises of such kind to the donor or any other person. The committee has to specifically analyse certain factors like explanation of the link between the donor and recipient and the situations which led to the offer being made, reasons why the donor wishes to donate his organs, documentary evidence of the link between them, (for instance, proof that they lived together if that is the connecting link between them) and old photographs of the donor and recipient together. The committee should also ensure that there is no intermediary or broker involved in this process and that the donor is not a drug addict or is not a known person with criminal history. The financial position of the donor and recipient should also be assessed and any gross disparity between the status of the two should be evaluated in the backdrop of preventing commercial dealings of organs. The next of kin of the proposed donor who is not a near relative should be interviewed with respect to matters concerning awareness about his intention to donate the organ, authenticity of the link between donor and recipient and reasons for such donation. Disagreement, objection or any strong views of such person should be recorded and taken note of.

With respect to the application to grant approval for removal and transplantation of organs, the Committee should take a decision in accordance with the guidelines as provided in Rule 6-A which was inserted through this amendment and deals with composition of Authorisation Committees. It states that there must be one State Level Authorisation Committee and additional authorization committees can be set up at

various levels according to the norms given under the Rules which are: a member of the transplant team of the institution should not be a member of the Authorisation Committee and all Foreign Nationals, related and unrelated are supposed to go to Authorisation Committee as more precautions have to be taken in such case, the committees have to be Hospital based in Metro and big cities if the number of transplants conducted at the respective institutions exceeds 25 per year while in small towns, there are State or District level Committees if transplants are less than 25 in a year in the respective districts. The Rules provide for the composition of hospital-based as well as state or district-level Authorisation Committees.

Rule 6B states that the State level committees have to be formed for providing approval or no objection certificate to the donor and recipient in order to establish the legal and residential status as a domicile state. It makes the approval or no objection certificate from the respective domicile State Government necessary, if donor, recipient and place of transplantation are from different states. The quorum of the Committee must be minimum four, as stated under Rule 6C. However, quorum cannot be regarded as complete without the chairman and Secretary (Health) or Nominee and Director of Health Services or nominee is also mandatory. While the Committee examines the applications, if any document or information is found to be inadequate or doubtful, explanation has to be sought from the applicant. If the Committee considers necessary to verify any fact or information to confirm its veracity or correctness, the same must be ascertained through the concerned officers of the State or Union territory Government.

Rule 6F of the Rules lays down provisions requiring the Authorisation Committee to focus on certain matters. Clause (a) deals with transplantation between genetically related persons like mother, father, brother, sister, son or daughter above the age of 18 years and that the competent authority has to evaluate certain matters like results of tissue typing and other basic tests, documentary evidence of relationship, documentary evidence of identity and residence of the donor and family photograph of the donor and recipient along with another near relative. If the relationship is not conclusively established from such evidence in its opinion, it can direct certain medical tests as provided in the rules³⁸ and if such tests do not prove a genetic relationship between the donor and the recipient, the same tests have to be performed

³⁸ Rules, 2008, *supra* note 37, Rule 6F (a)(iv).

on both or at least one parent. If the parents are not available, the tests have to be performed on the available and willing relatives of donor and recipient, failing which, genetic relationship between will be deemed to have not been established. Clause (c) deals with transplantation between married couples and the competent authority or Authorisation Committee has to ensure factors as mentioned under Rule 4-A. Clause (d) of Rule 6F deals with transplantation between individuals who are not “near relatives”. In such circumstances, the authorization committee should evaluate various aspects as mentioned above. Clause (e) deals with the situation when both donor and recipient are foreigners. In such circumstances, a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient. Authorisation Committee is supposed to exercise greater caution while examining cases of Indian donors consenting to donate organs to a foreign national, who is a near relative, including a foreign national of India origin and such cases should be considered rarely on case-to-case basis.

While determining the eligibility of an applicant to donate, he should be personally interviewed by the Authorisation Committee and minutes of that interview should be recorded and video graphed. Greater precautions have to be taken when the donor is a woman. The identity of such woman and independent consent must be confirmed by a person other than the recipient. The documentary evidence of the residence or domicile and particulars of parentage should be relatable to the photo identity of the applicant so as to ensure that the documents pertain to the same person, who is the proposed donor. In the event of any inadequate or dubious information regarding the same, the committee can seek any other information or evidence which may be expedient and desirable in the peculiar facts of the case. The Committee should state in writing its reason for rejecting or approving the application of the donor. Any approval by the Committee should be subject to certain conditions viz., the approved donor to be subjected to all medical tests that are required at different stages to determine his biological capacity and compatibility to donate the organ, the psychiatrist clearance to certify his mental status, awareness, absence of any overt or latent psychiatric disease, his ability to give free consent, filled up forms by the concerned persons involved and all interviews to be video recorded. Where the patient requires immediate transplantation, the committee should expedite its decision-making process and use its discretion judiciously and pragmatically.

The Rules contain provisions requiring every authorized transplantation centre to have its own website.³⁹ The Committee should take its final decision within 24 hours of holding the meeting for grant of permission or rejection for transplant. The decision must be displayed on the notice board of the hospital or institution immediately and on the website within 24 hours of the decision. In addition to this, the website has to be updated regularly with respect to the total number of transplantations carried out in the hospital along with relevant details and such data must be accessible for compilation, analysis and further use by the respective State Governments and Central Government. The amended rules also contain various forms that have to be filled by the related donor, spousal donor, un-related donor, the concerned medical practitioner, and application for approval of removal and transplantation in case of live donor which has to be filled by both donor and recipient.

2.3.5 THE TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT) ACT, 2011⁴⁰

Despite the implementation of the Act in 1994, there were numerous reports of illegal transplantations and commercial dealings of organs in the market which led to a widespread perception that the Act was not successful in curbing the commercial dealings of organs, may have even hindered genuine transplantations due to the lengthy and complicated procedures for approval and there was no significant increase in the deceased donor transplantations. Some major incidents of commercial dealings were reported in Bangalore in 1995 and 2002, Amritsar in 1995, New Okhla Industrial Development Area, Noida in 1998, Delhi in 2000, New Delhi in 2004, Calcutta in 2006, and Gurgaon in 2008.⁴¹ These issues were addressed by the Delhi High Court in the case of *Balbir Singh v. The Authorisation Committee* and the Court ordered for setting up of a review committee to review the functioning of the Act.⁴² The Review Committee recommended various amendments to the Acts and Rules like setting up of a National Organ Transplant Programme with particular focus on promoting cadaver donations, mandating the hospital staffs to request for brain donation to the relatives of brain dead patients, next of kin to be given preference in

³⁹ *Id.* Rule 6F (j).

⁴⁰ The Transplantation of Human Organs (Amendment) Act, No. 16 of 2011 [Hereinafter 'THOA 2011'].

⁴¹ Agarwal et al., *Evolution of the Transplantation of Human Organ Act and Law in India*, 94(2), *TRANSPLANTATION*, 110-113 (Jul. 27, 2012).

⁴² *Balbir Singh v. The Authorisation Committee*, 2004 SCC OnLine Del 709.

the waiting list, providing benefits through comprehensive health schemes to live donors, etc.⁴³ Some of these recommendations were taken into consideration and the government introduced the Transplantation of Human Organs (Amendment) Bill, 2009 in the parliament with several significant changes in the Act. Later, in 2011 the Human Organs (Amendment) Act, 2011 was passed on 27th September 2011 after the Bill was referred to the Standing Committee on Health and Family Welfare which submitted its 44th Report on the Transplantation of Human Organs (Amendment) Bill, 2009 to the Rajya Sabha and Lok Sabha on 4 August 2010. However, the Act did not come into force till January 2014 and the rules of the amended Act was notified only in March 2014. This Act has been adopted by all states and Union Territories except Andhra Pradesh⁴⁴ and Jammu and Kashmir⁴⁵ which have their own legislations based on the Act.

The significant development which came into force through the 2011 amendment was the inclusion of human tissues under the ambit of the Act and more stringent punishment and penalties for violation of the provisions of the Act. The Act was hence renamed as Transplantation of Human Organs and Tissues Act. The Amendment defines 'Human Organ Retrieval Centre'⁴⁶ to be a hospital having adequate facilities for treating seriously ill patients who can be potential donors of organs in the event of death and which is registered under the provisions of the Act. The definition of 'near relative' under Section 2(i) of the Act was revised to include grandfather, grandmother, grandson and granddaughter. Section 2(oa) defines tissue as a group of cells performing a particular function in the human body, except blood.

Section 3 (1A) was inserted under the provisions of authority for removal of human organs and tissues. It imposes certain duties upon the registered medical practitioner who in consultation with transplant co-ordinator, if available has to ascertain whether the proposed donor had authorised before his death the removal of any human organ or tissue, from the person admitted to the ICU or from his near relative. The hospital must then proceed to document such authorisation in the manner which is prescribed

⁴³ *The Report of Transplant of Human Organs Act Review Committee*, MINISTRY OF HEALTH AND FAMILY WELFARE [MOHFW] (May 25, 2005), <http://www.prsindia.org/uploads/media/Organ%20transplantation/The%20Report%20of%20the%20transplantati%20of%20human%20organs%20act%20review%20committee.pdf>.

⁴⁴ The Andhra Pradesh Transplantation of Human Organs Act, No. 24 of 1995.

⁴⁵ Jammu and Kashmir Transplantation of Human Organs Act, No. 3 of 1997.

⁴⁶ THOA 2011, *supra* note 40, § 2(ha).

under the Act. If such authorisation has not been made, the medical practitioner has to make aware that person or near relative about the option to authorise or refuse donation of his organs or tissues. The hospital is then required to inform in writing to the Human Organ Retrieval Centre for removal, storage of transplantation of human organs or tissues of the identified donor. These duties of the medical practitioner also apply to those working in an ICU in a hospital that is not registered under the Act.

Under the provisions related to restrictions on removal and transplantation of organs and tissues or both, Section 9(1A) has been inserted. It is stated that where the transplant is between near relatives and the donor or recipient is a foreign national, prior approval of the Authorisation Committee is required before removing or transplanting such organ or tissue. The critical aspect to note here is that the proviso prohibits any such approval by the Committee when the recipient is a foreign national and the donor is an Indian national, and they are not near relatives. Section 9(3A) deals with swap donations and mandates the prior approval of the Authorisation Committee for the same.

A human organ or tissue cannot be removed from a minor's body before his death for transplantation except in the manner prescribed and no such removal can be carried out in the case of a mentally challenged person before his death.⁴⁷ The amendment also provides for the establishment of advisory committees to advise the appropriate authority in discharging its functions.⁴⁸ It also provides for the establishment of National Human Organs and Tissues Removal and Storage Network⁴⁹ and the Central government is required to maintain a national registry of the donors and recipients of human organs and tissues, containing prescribed information to an ongoing evaluation of the scientific and clinical status of human organs and tissues.⁵⁰ There were also significant changes in the punishments of offences and the changes are listed below:

Provision	Offence	Punishment (Before amendment)	After amendment
S. 18(1)	Renders services, conducts or helps	Imprisonment	Imprisonment

⁴⁷ *Id.* § 9(1B), § 9(1C).

⁴⁸ *Id.* § 13(A)(1).

⁴⁹ *Id.* § 13(C).

⁵⁰ *Id.* § 13(D).

and 18(2)	in the removal of any human organ without authority.	upto 5 years and fine upto Rs. 10,000. (In case of a registered medical practitioner, removal of his name from the Council's register for a period of 2 years for the first offence and permanently for the subsequent offence.)	upto 10 years and fine upto Rs. 25,000. (Removal of name of a RMP from the register for a period of 3 years for the first offence and permanently for subsequent offence)
S. 18(3) (New provision)	Renders services, conducts, associates or helps in the removal of human tissues without authority.		Imprisonment upto three years and fine upto Rs. 5 Lakhs
S. 19 (a) to (f)	a) makes/receives any payment for the supply or an offer to supply any human organ; (b) seeks to find person willing to supply any human organ for cash; (c) offers to supply any human organ for payment; (d) initiates or negotiates any arrangement involving the making	Imprisonment of 2 to 7 years and fine of Rs. 10,000 to 20,000.	Imprisonment of 5 to 10 years and fine of Rs. 20 Lakhs to 1 Crore.

S. 19(g) (New provision)	<p>of any payment for the supply of, or for an offer to supply, any human organ;</p> <p>(e) takes part in the management of a body of persons, whose activities consist of or include the initiation or negotiation of any arrangement as mentioned above;</p> <p>(f) publishes/distributes/causes to be published/distributed any advertisement: inviting persons to supply or offering to supply any human organ for cash, or indicating that the advertiser is willing to initiate or negotiate any arrangement.</p> <p>(g) abets in the preparation or submission of false documents to establish that the donation is between near relatives or by reason of affection or attachment.</p>		
S. 19A (New provision)	<p>(a) makes/receives any payment for the supply or for an offer to supply any human tissue</p> <p>(b) seeks to find person willing to supply human tissue for payment</p> <p>(c) offers to supply any human tissue for payment</p> <p>(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human tissue</p>		Imprisonment upto 3 years and fine of 5 Lakhs to 25 Lakhs.

	<p>(e) takes part in the management of a body of persons, whose activities consist of or include the initiation or negotiation of any arrangement as mentioned above</p> <p>(f) publishes/distributes/causes to be published/distributed any advertisement: inviting persons to supply or offering to supply any human tissue for cash, or indicating that the advertiser is willing to initiate or negotiate any arrangement.</p> <p>(g) abets in the preparation or submission of false documents to establish that the donation of human tissues is between near relatives or by reason of affection or attachment.</p>		
S. 20	Acting in contravention to any provision of the Act or Rules, or any condition of the registration granted, for which no punishment is separately provided.	Imprisonment upto 3 years or fine upto Rs. 5000.	Imprisonment upto 5 years and fine upto 25 Lakhs.

2.3.6 THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES RULES, 2014

The Transplantation of Human Organs and Tissues Rules, 2014 operationalize the new entities and institutions which were set up by the 2011 Amendment Act and provide procedural and technical guidance for the procedure of organ transplantation and people carrying out the process under the Act. It introduced 21 forms that have to be filled by the concerned persons during the course of transplantation. Though most of the provisions remain to be the same with minor changes, there have been changes

in the numbering of the clauses and the provisions have been reorganised. Some of the major changes include the introduction of provisions on the priority of organ allocation, provisions on the working and scope of organ registry at the national and regional levels, swap donations to be approved by the Authorisation Committee and to be permissible only from near relatives of the swap recipients, the cost for maintenance of cadaver or retrieval or transportation or preservation of organs or tissues to be borne by the recipient's family and not the donor's, etc.

2.4 CONCLUSION

As discussed herein there have been series of amendments of the Act and its Rules to incorporate the technological advancements and to prevent commercial dealings in the process of organ donations. While acknowledging that there have been significant changes and efforts in preventing the commercialisation of organ donations, the situation seems to be no different than before. Organ trade is an open secret in India, making it a popular destination for organ transplantation where organs can be purchased and sold, treating it to be a commodity, rather than a human organ which is necessary for the survival of a human being. It is important to analyse why there is an organ market out there, where one can easily access organs for cash while exploiting the poor in need who are ready to give up on anything to lead a normal life, despite all these legislative provisions and amendments suiting the technological and social demands. These aspects of organ transplantation and the major reasons of commercialisation of organs will be discussed in the next chapter.

CHAPTER III: FACTORS CONTRIBUTING TO ORGAN TRADE IN INDIA

3.1 INTRODUCTION

Organ transplantations are considered as one of the most outstanding achievements of the medical industry by saving and extending the lives of thousands of patients with organ failures. Numerous instances of generosity by organ donors and their families and several significant scientific and clinical advances achieved by dedicated medical professionals have made transplantation not only a life-saving therapy but a symbol of human solidarity.⁵¹ However, such a process has been tarnished by the several instances of trafficking in human organs and trade in human organs, which involves patients who are ready to spend any amount to save their own lives and the poor and vulnerable who are ready to sell their organs for cash. In 2007, it was estimated that up to 10% of organ transplantations across the world involved such illegal practices.⁵²

India is a commonly known organ exporting country, where organs are regularly transplanted from local donors to foreigners for money. Though the enactment of the Transplantation of Human Organs and Tissues Act, 1994 seems to have contributed to reductions in the number of foreign recipients, the underground organ market is still existent and resurging in India.⁵³ The Voluntary Health Association of India estimates that about 2000 Indians sell a kidney every year, and this figure does not include all donations and transplantations taking place under the proper procedures.⁵⁴ This chapter deals with the reality of organ trade and organ trafficking, especially in India, various instances of illegal organ transplantations in the country, and most importantly, examines the multiple factors facilitating organ trade in India which includes the wide gap between demand and supply of organs, involvement of medical professionals in such practices, low rate of cadaver organ donations and high rate of live donations, cultural/religious and emotional constraints, lack of awareness about organ donations, etc.

⁵¹ The Preamble, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*, 2018 ed. [Hereinafter 'Declaration of Istanbul'].

⁵² The state of International organ trade, *supra* note 4.

⁵³ *Id.*

⁵⁴ Chris Hogg, *Why not allow organ trading?*, BBC NEWS, (Aug. 30, 2002), <http://news.bbc.co.uk/2/hi/health/2224554.stm>.

3.2 ORGAN TRADE AND TRAFFICKING

Organ trade is the commercial dealing in human organs where one person purchases and sells the organs which usually occurs outside legal transplantation systems. It involves diverse actors and consists of various practices, i.e., organ trafficking, transplant tourism, organ sales and organ harvesting.⁵⁵ Organ trade can be traced back to the late 1980s which was conducted by transplant physicians in the Gulf States, who were confronted with high mortality amongst patients who had purchased a kidney in India and returned home for follow-up treatment. It was revealed by the physicians that 130 patients from the United Arab Emirates and Oman travelled to Bombay to buy kidneys from a living unrelated Indian donor between June 1984 and May 1988, however, such practices were not criminalised in India till 1994.⁵⁶ India has been a hub for organ transplantations due to the low costs of treatment and willingness of people ready to sell their organs due to poverty, and the same is carried out even today despite a legislation in force criminalising such practices. As per the Declaration of Istanbul on Organ Trafficking and Transplant Tourism,⁵⁷

“Organ trafficking consists of (a) removing organs from living or deceased donors without valid consent or authorisation or in exchange for financial gain or comparable advantage to the donor and/or a third person; or (b) any transportation, manipulation, transplantation or other use of such organs; or (c) offering any undue advantage to, or requesting the same by, a healthcare professional, public official, or employee of a private sector entity to facilitate or perform such removal or use; or (d) soliciting or recruiting donors or recipients, where carried out for financial gain or comparable advantage; or (e) attempting to commit, or aiding or abetting the commission of, any of these acts.”

This definition was derived from the Council of Europe Convention on Trafficking in Human Organs, 2015⁵⁸ by the drafters of the Declaration. While organ trade includes organ trafficking, it can also be carried out between persons with valid consent with or without knowledge of the illegality of such practices. On the other hand, organ

⁵⁵ Seán Columb, *Beneath the organ trade: a critical analysis of the organ trafficking discourse*, 63, CRIME LAW SOC. CHANGE, 21-47 (2015).

⁵⁶ Jessica De Jong, *Human Trafficking for the purpose of Organ removal* (2017).

⁵⁷ Declaration of Istanbul, *supra* note 51, at 2.

⁵⁸ Council of Europe, *Council of Europe Convention on Action Against Trafficking in Human Beings*, May 16, 2005, CETS 197.

trafficking involves coercion, force, or undue advantage or removing the organs either without obtaining valid consent from the donor or without his knowledge.

There are instances where organs are removed from persons on the pretext of unrelated surgeries or medical treatments without their knowledge. While some do not realise their bodies have been functioning without one kidney or any part of other organs in their lifetime, some realise the same at a later point in time while undergoing random medical check-ups or diagnosis of any related ailments. There are even cases where the demand for dowry eventually led to the removal of a kidney and selling it for cash by the husband and in-laws.⁵⁹

There have been various reports and arrests of rackets involved in organ scandals especially involving kidney, in various parts of the country even after the Transplantation of Human Organs and Tissues Act, 1994 had come into force. The Gurugram Kidney scandal, which was a multi-billion-rupee racket, has been well known for its implications on a national and international scale, led by an untrained non-medical and self-proclaimed surgeon who carried out 600 illegal kidney transplants between 1996 to 2008. This person was arrested a number of times but eventually managed to obtain bail or flee from police custody, relocate to different places, and continue carrying out such illegal practices. In 2013, a Special CBI Court awarded seven years imprisonment with a fine of Rs. 60 Lakhs to him and his brother, who was involved in the scandal.⁶⁰ However, he managed to escape from the police custody and was finally arrested in late 2017 and in February 2020, the convict was again sentenced to 7 years imprisonment and a fine of Rs. 20,000 for threatening the witness in the scam.⁶¹

During the period between September 2010 to May 2012, a Non-Profit International Health and Human Rights Organisation called Coalition for Organ Failure Solutions - India identified approximately 1000 victims of human trafficking for organ removal

⁵⁹ DR. RAMESH KUMAR, *KIDNEY TRANSPLANTS AND SCAMS: INDIA'S TROUBLESOME LEGACY* (Sage Publications Pvt. Ltd) (2020) [Hereinafter 'Kidney transplants and scams']; As stated in 'Kidney transplants and scams', a woman in Kolkata who got married in 2005 was under constant pressure from her husband and his family for dowry. In 2016, while she was admitted to a hospital for appendectomy, the ultrasound revealed that her kidney had been removed illegally. The police arrested her husband and in-laws who confessed that the woman's kidney was sold to a businessman in Chhattisgarh.

⁶⁰ *Id.*

⁶¹ *Kidney scam kingpin gets 7 yrs in jail for threatening witnesses*, THE TRIBUNE, (Feb. 29, 2020), <https://www.tribuneindia.com/news/chandigarh/kidney-scam-kingpin-gets-7-yrs-in-jail-for-threatening-witnesses-49165>.

in India and conducted semi-structured in-depth qualitative interviews with 153 of them from four areas of the country viz., Erode, Chennai, villages of West Bengal and small towns around Karnataka. Out of these victims who were interviewed, one of their kidneys was removed between 1981 and 2012, of which 34 cases, i.e., 22 % of these removals occurred from 2009 to Summer 2012, which makes it amply clear that the illegal transplantations and commercial dealings on human organs are being carried out even after the implementation of the Transplantation of Human Organs and Tissues Act, 1994. Victims described their experiences and stated that their health has been deteriorating in addition to the negative social, economic, and psychological consequences of the removal of their organs. Each of these cases involved the commercial removal of a kidney which was confirmed by the doctors through medical follow-up examinations.⁶²

In the state of Kerala, there have been reports in 2002 stating the tribals were the targets of organ rackets. The tribals were made to donate their organs and were paid money in exchange. The tribal people from the Ulladas, Ooralis, Aaryas communities and the Dalits were not hesitant to admit that they survive by selling their kidneys. This made the unscrupulous racketeers tighten their grip on these tribes as they clearly knew that the tribes were ready to sell their kidneys. The tribals came forward to sell kidneys for Rs 1.5 Lakh each without any persuasion. Hence, a village called Poomala began to be known as the 'Kidney Village' among middlemen. The tribal kidney racket in the state involved money power, muscle power, political power and also components of deceit and duping of potential recipients and swindling lakhs of rupees on the false promise of finding a suitable kidney donor. In 2014, the city police in Kochi arrested the kingpin behind the scam. The relatives of the victims claimed that they met the accused through a newspaper advertisement for kidney donors that they themselves had put out in 2011, when the Transplantation of Human Organs and Tissues Act, 1994 was in force prohibiting any activities involving soliciting kidney donors through print or visual media. There were also other reports of paid organ transplantations and illegal dealings in organs in the state.⁶³ Another kidney racket involving transactions worth Rs. 150 Crores was arrested in the city of Amritsar in

⁶² Coalition for Organ Failure Solutions, *Human Trafficking for organ removal in India: An Evidence-Based, Victim-Centered report* (2014).

⁶³ Kidney transplants and scams, *supra* note 59.

Punjab in 2012. The police arrested one of the top kidney transplant surgeons in the city, other doctors, lawyers and middlemen.⁶⁴

Cyber scams with respect to the sale and purchase of organs are also not new in the country. Cyber scams are really dangerous as they are invisible, uniformly fake and numerous money transfers taking place online to unknown and fraudulent entities without any gain to the donor and often to the recipient. There are fake advertisements through WhatsApp, Facebook, other social media websites, fake hospital websites, fake foundations, etc. which facilitates not only domestic trade but international organ trade too.⁶⁵

3.3 FACTORS FACILITATING ORGAN TRADE IN THE COUNTRY

Organ trade in India is associated with certain constant factors persisting in the country. These are the major causes for a flourishing organ market in the country and these factors facilitate organ trade and such illegal practices associated with it. Some of the major factors have been identified and are discussed below:

3.3.1 WIDE GAP BETWEEN DEMAND AND SUPPLY OF ORGANS

One of the major reasons for the flourishing organ trade in the country is the direct consequence of the wide gap between demand and supply of human organs. It is a general tendency that when there is a shortage of something, people accumulate the same through illegal means, especially in this case, when it is a matter of life and death, the gravity and frequency of such practices increase. The high demand for human organs has led to its commodification. India's deceased organ donation rate is significantly low as compared to other countries across the world. As per the International Registry in Organ donation and transplantation, the organ donation rate of India stands at 0.52 per million, compared to the donation rate of other countries like America's 38, Spain's 37.9, Croatia's 24.5 per million, respectively.⁶⁶

⁶⁴ Ramesh Vinayak, *Cash-for-kidney racket exposed in Amritsar; top doctors, lawyers and middlemen held*, INDIA TODAY, (Jan. 27, 2003), <https://www.indiatoday.in/magazine/crime/story/20030127-cash-for-kidney-racket-exposed-in-amritsar-top-doctors-lawyers-and-middlemen-held-793674-2003-01-27>.

⁶⁵ Kidney transplants and scams, *supra* note 59.

⁶⁶ Donation and Transplantation Institute, *International Registry in Organ Donation and Transplantation*, (Jun. 2021) [Hereinafter 'International Registry'].

In 2016, while answering a question in the Lok Sabha, the Union Health Minister acknowledged the fact there was a wide gap between the demand and supply of human organs for transplant even though the precise numbers of premature deaths due to heart, liver, lung and pancreas failures have not been compiled. It was stated that only 6000 kidneys were available against the requirement of 2 lakh kidneys. Likewise, only 1500 livers were available against the requirement of 30,000 livers and merely 15 hearts were available against the requirement of 50,000 hearts for organ transplantations across the country.⁶⁷ Though around 1.8 lakh persons suffer from renal failure every year, the number of renal transplants carried out in the country is only around 6000. Likewise, around 2 lakh patients lose their lives due to liver failure or liver cancer annually in India, out of which about 10-15% of such patients can be saved with a timely liver transplant. Though the country needs to carry out around 25,000 to 30,000 liver transplants annually, only around 1500 are performed. Similarly, around 50,000 people suffer from Heart failures annually, but the number of transplants performed per year stands at a mere 10 or 15. The case of Cornea is not different where about 25000 transplants are performed annually against the requirement of 1 lakh.⁶⁸

It is evident from these rates that there is a significant shortage of organs in the country. Hence, this wide gap between the demand and supply of human organs is the main contributing factor to illicit organ trade in the country. People tend to procure organs through illegal means on payment of cash. India has to go a long way to bridge the gap between demand and supply. This can be done through increasing awareness of organ donations and increasing the rate of cadaver organ donations. If the gap is narrowed down and the organs are readily available through legal means, there would be a significant reduction in the rate of illegal practices with respect to organ donation and organ transplantation in the country.

3.3.2 COLLUSION OF MEDICAL PROFESSIONALS

The involvement of medical practitioners and hospital authorities plays a significant role in promoting these illegal practices existing in the country. There are reports of

⁶⁷ Lok Sabha Parliamentary Q & A on Organ Donation & Transplantation, Unstarred Question No. 1563, (Mar. 4, 2016), available at <https://www.mohanfoundation.org/loksabha/loksabhaQA.asp>.

⁶⁸ National Organ Transplant Programme, DIRECTORATE GENERAL OF HEALTH SERVICES, MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA, https://dghs.gov.in/content/1353_3_NationalOrganTransplantProgramme.aspx.

the doctors or the hospital authorities getting arrested because of being involved in the rackets practicing organ trade or organ trafficking. While the medical profession is regarded as a sacred and noble profession saving the lives of people, there is a group of medical professionals who assist the middlemen and the recipients in procuring organs for cash. Though they clearly have knowledge about the illegality of such practices, their involvement in the industry still continues. There are instances where doctors have been arrested for being involved in kidney rackets or other organ scams. 15 people involving doctors, hospital administration staff and medical staff, were arrested in 2019 for being a part of a kidney racket based in Delhi. National Capital Region is regarded as the epicentre of well-organized illegal organ trade.⁶⁹

A similar racket was unearthed in Mumbai in 2016 and 14 people were arrested for such illegal practices. Out of these 14 people, five were doctors who were arrested based on the report of a committee of medical experts set up by the Maharashtra Directorate of Health Services, which found various irregularities in the kidney transplants conducted in the hospital.⁷⁰ Such incidents result in the public losing trust and confidence in the medical fraternity. The medical professionals and hospital authorities assisting and involving in such a grave offence that has been criminalised in the country is deplorable. Apart from the illegal transplantations conducted in unregistered clinics by untrained professionals, it would be impossible for the organ market to flourish in the country if there is a strong objection from the part of the medical fraternity. However, the situation is different in India, where at least a group of medical professionals are part of organ rackets and play a significant role in maintaining the organ market in the country.

3.3.3 POVERTY AND UNEMPLOYMENT

Poverty and unemployment are the major reasons behind exploiting the poor and vulnerable by the rich and middlemen for organs. The unemployment rate in India stands at 7.1 % as of 2020⁷¹ and 22% of the country's population was poor as of

⁶⁹ Unravelling of a kidney racket, *supra* note 8.

⁷⁰ *Kidney Racket: All 5 Doctors of Mumbai's Hiranandani Hospital Get Bail*, NDTV, (Aug. 18, 2016), <https://www.ndtv.com/mumbai-news/kidney-racket-all-5-doctors-of-mumbais-hiranandani-hospital-get-bail-1445667>; *Kidney racket: Five Hiranandani doctors charge sheeted for criminal conspiracy*, THE TIMES OF INDIA, (Oct. 11, 2016), <https://timesofindia.indiatimes.com/city/mumbai/kidney-racket-five-hiranandani-doctors-chargesheeted-for-criminal-conspiracy/articleshow/54789249.cms>.

⁷¹ *Poverty Data: India*, ASIAN DEVELOPMENT BANK, <https://www.adb.org/countries/india/poverty>.

2012.⁷² Hence, India has a significant population living below poverty line and is unemployed. These factors push such sections of the society to engage in activities, legal or illegal, which can provide them with money to meet their fundamental needs. Poor and vulnerable sections of the society are being coerced into donating their organs as a near relative or someone who has affection or attachment towards the recipient. However, the truth is that the donor and recipient did not know each other until a few days ago. Several such instances of removing organs even without the knowledge of the donor without satisfying pre-transplant and post-transplant requirements leading to serious health complications have come to light through various media reports and scientific publications from other countries.⁷³

While some people are coerced into organ donations in such groups, some are ready to sell their organs to pay off their debts, spend on food, clothing, housing, etc., the basic needs of a human being which they cannot afford otherwise.⁷⁴ It is an irony that despite a legislation criminalising the commodification of organs in the country, a village in Chennai is popularly known as 'Kidneyvakkam' or 'Kidneyville' as most of the residents there have sold their kidney in order to lead a normal life. This village was seriously affected by the Tsunami in 2004 which resulted in many losing their lives, houses, and earning members of the family, making them potential organ sellers. Their financial burdens forced them to sell their kidneys to meet their very basic needs. Many of them later claimed that the promised amount was not paid to them.⁷⁵

Journalist Scott Carney refers to the marketplace of bones, organs and blood as the 'red market' in his book and, had visited and interviewed the victims of organ trade in Kidneyvakkam. It was stated in the book that a woman in the village had sold her kidney as she could not afford to pay for the medical expenses of her daughter, who

⁷²Joyita, *Poverty Estimation in India*, PRS LEGISLATIVE RESEARCH, (Aug.5, 2013), <https://www.prsindia.org/theprsblog/poverty-estimation-india>.

⁷³ Problems and outcomes of living transplants, *supra* note 2.

⁷⁴ M Goyal et al, *Economic and Health Consequences of Selling a Kidney in India*, 288, JAMA, 1589-1593, (2002); A survey conducted by the authors of the article in 2001, among 305 individuals who had sold a kidney in Chennai revealed that 96 % of the participants sold their kidneys to pay off debts. The average amount received was \$1070, and most of the payment received was spent on debts, food, and clothing.

⁷⁵ *In TN's Kidneyvakkam, an organ can be bought for Rs 40,000*, THE TIMES OF INDIA, (Jan. 29, 2008), <https://timesofindia.indiatimes.com/india/in-tns-kidneyvakkam-an-organ-can-be-bought-for-rs-40000/articleshow/2739927.cms> [Hereinafter 'TN's Kidneyvakkam']; Scott Carney, *Inside 'Kidneyville': Rani's Story*, WIRED, (Aug. 5, 2007), <https://www.wired.com/2007/05/india-transplants-rani/> [Hereinafter 'Inside 'Kidneyville': Rani's Story'].

tried to commit suicide because of being in a difficult marriage. The brokers approaching such people in need of cash to sell their kidney was common there. The said woman was not able to resume her job at construction sites as she still suffers from pain due to the removal of her kidney.⁷⁶ There has to be proper medical follow-up not only for the recipient of the organ, but also the donor in case of removal and transplantation of organs. In cases of commercial dealings of organs, especially from the poor, such medical follow-up and post-transplant requirements are not carried out and they are left with a deteriorated health which makes it difficult for them to even continue working and earn their livelihood. Acknowledging the illegality of such dealings, it is a sad reality that the poor are not benefitted and their health and financial position worsen even after selling their organs.

Hence, it is clear that it is easy to exploit people who are desperate enough to sell their organs for cash. While the middlemen, doctors or hospital authorities gain considerable profits in the name of a single commercial dealing, the donors are left with one kidney or part of any other organ, a weak body and no solution to their financial issues. As stated by a senior police official from the Uttar Pradesh Police, a kidney is sold for a rate between Rs 70 Lakhs and Rs 1 crore, depending on the urgency of the need. However, the donor or seller of the organ never receives an amount above Rs. 3 Lakhs and the remaining amount is shared and distributed among those who run this illegal business.⁷⁷

The people who run such kinds of kidney rackets or organ scams take advantage of the poor who desperately need money to pay off their debts and meet other basic needs. Hence, poverty and unemployment play a significant role in contributing to such illegal practices. People believe that selling their organs for cash is the last resort to maintain their lives and hence, they willingly sell their organs or are coerced into such illegal practices. Studies have shown that the organ sellers mostly come from the poor and vulnerable populations across the world.⁷⁸ A considerable reduction in

⁷⁶ SCOTT CARNEY, *THE RED MARKET: ON THE TRAIL OF THE WORLD'S ORGAN BROKERS, BONE THIEVES, BLOOD FARMERS, AND CHILD TRAFFICKERS*, (Harper Collins Publishers) (2011); *Blood, Bones and Organs: The Gruesome 'Red Market'*, NPR, (Jun. 10, 2011), <https://www.npr.org/2011/06/10/136931615/blood-bones-and-organs-the-gruesome-red-market>; Inside 'Kidneyville': Rani's Story, *supra* note 75.

⁷⁷ Unravelling of a kidney racket, *supra* note 8.

⁷⁸ MESHELEMAH, J.C.A., LYNCH, R.E., *THE CAUSE AND CONSEQUENCE OF HUMAN TRAFFICKING: HUMAN RIGHTS VIOLATIONS*, ch. 9, (Ohio State University Pressbook) (2019).

poverty and unemployment in India can prevent the exploitation of the poor and vulnerable by the rich and middlemen for organs.

3.3.4 LOW RATES OF CADAVER ORGAN DONATIONS AND OVER-RELIANCE ON LIVE DONATIONS

The estimates as per National Organ and Tissue Transplant Organisation show that less than 8% of the total transplantations from 1994 to 2019 are cadaver donations leaving all the other transplantations into the account of living donations.⁷⁹ A substantial part of such cadaver organ donations has been carried out due to the efforts of some Non-Government Organizations or hospitals that are highly committed to the cause. There is a general trend that the patients in need of organ transplantations and their families prefer living donors, which can be regarded as one of the major reasons for the commodification and illegal dealings with respect to organs. It is evident from the numbers mentioned above that there is a significant number of transplantations performed from live organ donors as compared to cadaver organ transplantations across the country. As mentioned earlier, India's deceased organ donation rate is significantly low as compared to other countries across the world, which stands at 0.52 per million as per the International Registry in Organ donation and transplantation.⁸⁰

For instance, in the state of Kerala, between 2017 to 2020, only 205 cadaver organ transplantations have been performed against 2,895 live donations. Experts opine that this over-dependence on live organ donations is a major reason for the illegal organ trade thrive.⁸¹ Another instance suggesting the same as reason is the number of patients who were declared brain-dead and those who became potential organ donors at All India Institute of Medical Science in Delhi during a period of five years between 2007 to 2012. A study stated that out of the 205 patients who were declared brain-dead at the hospital, only 10 of them turned out to be potential organ donors. Some of the reasons for such non-organ donation in the remaining cases include lack of consent, procedural issues, patients not counselled, too unstable for donation, age

⁷⁹ Organ Report, *supra* note 9.

⁸⁰ International Registry, *supra* note 66.

⁸¹ Dileep V Kumar, *Demand for organs from living donors behind thriving illegal trade in Kerala: Experts*, THE NEW INDIAN EXPRESS, (Oct. 28, 2020), <https://www.newindianexpress.com/states/kerala/2020/oct/28/demand-for-organs-from-living-donors-behind-thriving-illegal-trade-in-kerala-experts-2215854.html>.

and co-morbidities, etc.⁸² Increase in live donations while cadaver organ donation remains meagre contributes to commercial dealings in organs in the country. The low rate of deceased organ donations leads to the adoption of live organ donations by people even through illegal means.

In India, there is a huge potential for deceased organ donations as the number of fatal road traffic accidents is high and this pool is yet to be tapped. As of 2006, India had 6% of the world's road accidents and the total number of road accidents is approximately 90,000 per annum. In 2005, one of the states, Tamil Nadu alone reported 13,000 fatal deaths due to road accidents. The cause of death in around 40 to 50% of all fatal road accidents across the world is head injury leaving potential cadaver organ donors in the country from road accidents alone. Other causes of brain death such as sub-arachnoids' haemorrhage and brain tumours would potentially add more numbers. Even if 5 to 10% of these deceased persons became organ donors, there would be no requirement for any live organ donations.⁸³ Hence, educating and convincing the relatives about the potential of saving lives from a brain-dead person as a result of road accidents can make a huge difference. Concentrating on increasing cadaver organ donations is expected to bring a fall in the illegal organ donations from living persons for financial reasons.

3.3.5 EMOTIONAL, CULTURAL/RELIGIOUS CONSTRAINTS IN ORGAN DONATION

A dead body is considered as sacred by many religions, cultures and thereby people at large. India is a country with people of many religions and cultural differences. In India, some religions generally discourage practices such as stockpiling and collecting organs from cadavers.⁸⁴ Though none of the religions stand specifically against organ donations, there are some popular misconceptions surrounding organ donations. People who believe in re-birth have a general tendency to believe that if a person donates his organs, such a person will be born without the organs so donated in the

⁸² Chhavi Sawhney et al., *Organ retrieval and banking in brain dead trauma patients: Our experience at level-1 trauma centre and current views*, 57(3), INDIAN J ANAESTH., 241-247 (2013).

⁸³ Sunil Shroff, *Legal and ethical aspects of organ donation and transplantation*, 25(3), INDIAN J UROL., 348-355 (Jul-Sep. 2009) [Hereinafter 'Legal and ethical aspects'].

⁸⁴ Molly Moore, John Anderson, *Kidney Racket Riles Indians*, THE WASHINGTON POST, (Apr. 30, 1995), <https://www.washingtonpost.com/archive/politics/1995/04/30/kidney-racket-riles-indians/4c51d8b0-429a-4294-afd6-5a991cd29ea0/>.

next life.⁸⁵ Some other barriers for organ donation are related to cultural barriers, bodily integrity, emotional aspects of donation, family's refusal to donate organs in case of cadaver organ donations, etc. Research on this matter found that the constraints are likely to be related to bodily integrity and family refusal rather than issues of religious permissibility, which suggested that the concerns surrounding organ donation are more cultural rather than religious in nature.⁸⁶

In the case of cadaver organ donations, the relatives or the person in lawful possession of the body might not be prepared to understand the importance of organ donation at this stage and may not be in a mental state to give authorisation of the organs of the deceased. The grieving relatives are reluctant to think or understand about the concept of cadaver organ donations due to a variety of reasons like they do not want their loved one's body to be dismembered, they might still be hoping for recovery as brain death is still not widely accepted by the people, they have the fear that the body will not be treated with integrity and respect, considering removal of organs as disrespect to the dead body, etc.⁸⁷

The ideas of charity and organ donation vary from one community to another and the concept of organ donation largely is cultural. As opined by a nephrologist, there is a general suspicion towards the doctors and hospital authorities when a person is declared brain dead in India. The relatives tend to believe that the brain death was declared in order to acquire the organs of the deceased and make money. Hence, it is difficult to communicate and discuss the issue of organ donation to the relatives of the deceased and they need not necessarily react well to such communication. There is a lack of trust in the fairness of the medical system for deceased organ donation in the country which might be the result of various reports of collusion of medical professionals in the organ trade.⁸⁸ These are some emotional aspects acting as barriers to cadaver organ donations. Obtaining consent from the relatives is one of the difficult tasks for increasing the rate of cadaver organ donations, failing which, there will be illegal dealings due to the non-availability of human organs.

⁸⁵ Transplantation of human organs, *supra* note 7.

⁸⁶ Joanne Blake, *Religious beliefs and attitudes to organ donation*, Welsh Government Social Research No. 44/2015, <https://orca.cardiff.ac.uk/115471/1/150730-religious-beliefs-attitudes-organ-donation-en.pdf>.

⁸⁷ Transplantation of human organs, *supra* note 7.

⁸⁸ 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> [Hereinafter 'Organ India'].

People are still not fully aware about the concept of brain death and tend to believe that there might be a recovery as the heart still beats. It is necessary to educate the people about the concept of brain death to the extent that they do not have any misconceptions about cadaver organ donations. Eliminating such misconceptions can itself help people understand the concept of organ donation clearly, resulting in more cadaver organ donations. Hospital authorities are also a bit reluctant to obtain consent from the relatives due to the emotional aspects involved. Doctors and medical staff should take necessary measures to educate the relatives or person in lawful possession of the body about the aspects of cadaver organ donations. Though no specific religion stands against organ donations and some even recognise it as a form of charity, there are some popular misconceptions as mentioned above. This can be resolved to a great extent through increasing awareness about organ donation and its importance, religious leaders or public figures promoting the cause, etc.

3.3.6 LACK OF AWARENESS ABOUT ORGAN DONATION

Lack of awareness about organ donation is a crucial factor contributing to organ trade in the country. There exist groups of people who are unaware of the concept of organ donation and the illegality of commercial dealings in human organs. There are also myths and misconceptions about organ donation prevalent in the society preventing the general public from donating organs and, involving in commercial dealings in human organs. A study conducted in an urban area in India revealed that 78% of the participants of a survey were aware of the concept of organ donation, while 22% had not even heard about it. 39% of the people who participated did not have any idea on who can be an organ donor, 31.7% believed that organ donation is carried out after cardiac death, 24.4% were aware of live organ donation and only 14.6% were aware of organ donation from brain-dead persons. Only 7.3% of the participants were aware that a brain-dead person is legally dead, while 39% stated that they were not aware of brain death.⁸⁹ Considering the level of awareness in the urban population, it is assumed that the level of awareness will be much lesser in the rural populations of the country.

Though it is not argued that awareness is the only factor guiding organ donations, it plays a significant role in increasing the number of organ donations in the country. If

⁸⁹ Vaishaly K. Bharambe et al., *Awareness regarding body and organ donation amongst the population of an urban city in India*, 5(4), NUJHS, 51-57 (2015).

people are not aware or have misconceptions about the basic concepts of organ donation, it would adversely affect the organ donation rate as stated earlier under the emotional and cultural barriers to organ donation. Increase in the level of awareness about organ donation among the public has resulted in a significant increase in the organ donation rate in the country.⁹⁰ Hence, increasing the level of awareness among the public about organ donations, especially cadaver organ donations, can contribute to a significant increase in organ donations in India and thereby bridge the gap between demand and supply of organs. Once the gap is reduced, there would be a substantial reduction in the commercial dealings of organs. Most of the factors mentioned above can be resolved to a great extent through increasing awareness among the public through mass awareness campaigns, seminars, development of medical infrastructure in government hospitals, etc. Since the general public is not fully aware of the concepts of organ donation or brain death, they should be explained to the concerned people in simple language, assure that these organs will not be a commodity in the organ market, will be utilised for good and be treated with utmost respect to the deceased. Though there has been a change in the level of awareness over the years, the level has still not made it to a level to curb the illegal dealings in organs. Increasing the level of awareness and eliminating the misconceptions in the minds of the people can help in reducing the rate of organ trade in the country to a great extent.

3.4 CONCLUSION

If illegal organ trade is not controlled in the country, it will lead to other offences like kidnapping and trafficking of people for organ removal and theft of organs. India being a highly populous country with a significant group of poor and vulnerable population, it is important to ensure that such people are not exploited through such illegal practices. It is necessary to put an end to the commercial dealings in human organs and to look down seriously on commodification of the same. The factors explained above contribute to the flourishing organ trade and aid the kidney rackets

⁹⁰ Ann Alex et al., *Did an increase in knowledge and awareness about organ donation improve organ donation rate in India over the past two decades*, 13(3), INDIAN J TRANSPLANT., 173-178 (2019); A study conducted by the authors of the article to examine the difference in knowledge and attitude among the public about organ donation over two decades from 1998 to 2017 by dividing the participants into two groups on the basis of the time period, showed results stating that there was a significant increase in the level of awareness which resulted in an increase in the rate of organ donations [Hereinafter 'Increase in awareness improve organ donation'].

and criminals involved in such practices to function effortlessly in the country. This has to be changed by making a difference or eliminating the factors responsible for the flourishing organ trade in the country.

All these factors discussed above play a significant role in maintaining the illicit organ market in the country and increases commodification of human organs. Organ trade can be reduced to a great extent by eliminating the factors mentioned above. Though some factors can be cured to a great extent through various measures like mass awareness campaigns on organ donations, increasing the rate of cadaver organ donations, doctors and hospital authorities refraining themselves from involving in commercial dealings, etc., effective government interference is necessary to bridge the wide gap between demand and supply of organs, reduce poverty and unemployment rate in the country, etc. In addition to the factors mentioned above, the inefficiency of the Transplantation of Human Organs and Tissues Act, 1994 is also a crucial factor resulting in the persistent organ trade in the country. Though the Act criminalises commercial dealings in human organs and tissues, such practices are still being carried out in India. The reasons for the failure to curb such illegal practices and the flaws in the legislation will be analysed in the next chapter.

CHAPTER IV: FLAWS IN THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994

4.1 INTRODUCTION

The illicit organ trade is flourishing in India despite a legislation criminalising the commercialisation of human organs and tissues. As discussed in the previous chapter, there have been numerous instances of commercial dealings in human organs across the country even after the implementation of the Transplantation of Human Organs and Tissues Act, 1994. In addition to the factors explained in the previous chapter, the inefficiency of the Act seems to be a crucial factor contributing to the illegal organ trade in India. This chapter tries to evaluate the efficacy of the Act in achieving its objectives and curbing the illegal practices associated with human organs. The primary objectives behind the Act are to provide for the regulation of the removal, storage, and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs. As discussed in the previous chapter, the various reports of organ trade show that the Act has not been effective enough to curb the illegal organ trade in the country. The ineffectiveness can be traced to certain flaws in the provisions and improper implementation of the Act. This chapter tries to examine such flaws and the possible reasons for the failure in preventing organ trade in the country, which is one of the main objectives of the Transplantation of the Human Organs and Tissues Act, 1994.

4.2 DRAWBACKS OF THE TRANSPLANTATION OF THE HUMAN ORGANS AND TISSUES ACT

As stated above, the Act has not been successful in achieving one of the primary objectives behind its enactment, i.e., to prevent commercial dealings in human organs, which is evident from the previous chapter substantiated by news reports of numerous organ scams in the country. While hearing a writ petition in 2010, the High Court of Orissa found that even though the Act has been in existence for more than 16 years, the aims and objectives of the said Act remain largely unfulfilled.⁹¹ The numerous instances of illegal organ trade across the country even after the implementation of Act demand an analysis of the flaws or loopholes in the provisions facilitating the

⁹¹ Arup Kumar Das v. State of Orissa, 111 (2011) CLT 2 [Hereinafter 'Arup Kumar'].

same. An attempt is made to analyse certain provisions that seem to pave the way for commercial dealings in human organs rather than preventing them. The provisions are discussed below:

4.2.1 SECTION 9: AMBIGUITY IN WHAT CONSTITUTES AFFECTION AND ATTACHMENT

Section 9 of the Act deals with various restrictions on the removal and transplantation of organs and tissues. As per Section 9(1), a human organ cannot be removed from the body of a donor before his death and transplanted onto a recipient unless they are near relatives. An exception to this provision is provided in Section 9(3), where a person can donate his organ to a person who is not a near relative for the reason of affection or attachment towards the recipient or for any other special reasons with the prior approval of the Authorisation Committee. This provision is widely abused by the middlemen and organ racketeers to carry on with commercial dealings in human organs.⁹² Section 9(3) does not provide any clarity on what constitutes ‘affection’ or ‘attachment’. Poor and vulnerable people are lured into selling their organs for cash and are given the label of donating the organs due to reasons of affection or attachment.⁹³

The phrase ‘for any other special reasons’ is also extremely wide and vague. Whether there is a special reason or not is left to be decided by the Authorisation Committee without any established guidelines on what can or cannot be included under the ‘special reasons’. Section 9 being a major provision of the Act that tries to prevent the commodification of human organs and tissues, there needs to be more clarity on the provision. Though it is difficult to provide a clear definition for ‘affection’ or ‘attachment’, there needs to be clarity on what constitutes enough affection and attachment to donate one’s organ to the other. It is important to address the concerns of people who do not have a near relative or do not have a matching donor even if they have one, by allowing organ donations from friends or distant family. However, this provision is wide enough to accommodate even a donor who was not known to the recipient until a few days ago or for a minimum time period needed to build affection or attachment to donate an organ. This provision is abused to carry out commercial dealings in human organs and bring it under the label of ‘affection’ or

⁹² Legal and ethical aspects, *supra* note 83.

⁹³ Kidney transplants and scams, *supra* note 59.

‘attachment’ towards the recipient where the donor and recipient are nothing more than strangers.

In the case of B.L. Nagaraj and Ors. v. Dr. Kantha and Ors.,⁹⁴ while allowing a writ petition filed before the High Court of Karnataka challenging the order of the Authorisation Committee that rejected an application for organ removal and transplantation, held that:

“The donor’s relationship with the recipient, period of acquaintance and the degree of association, reciprocity of feelings, gratitude and other human bonds are perhaps some of the factors which 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.”

Most of the transplantations from unrelated donors would be for money, where the rich and middlemen exploit the poor. The major difference between a rich and a poor donating organ would mainly be related to their health status. It would be one thing for a healthy, middle-class, sedentary worker to donate a kidney, and quite another for a malnourished, poverty-stricken manual labourer to do the same.⁹⁵ Another major concern is the post-transplantation requirements and follow-up which might not always be affordable to the poor. Hence, the Authorisation Committees have to be extra cautious while granting approval for organ donations from unrelated donors. The words ‘affection’ or ‘attachment’ should not be kept wide open to accommodate even strangers who buy and sell organs for cash.

For instance, in the state of Karnataka, 1012 patients were officially granted approval by the Authorisation Committees to receive kidneys from unrelated live donors between January 1996 and March 2002. Though there is no sufficient data to prove that such transplantations were commercial arrangements violating the Act, experts opine that it should be apparent to any sensible person that it is highly improbable that so many people should be imbued with this selfless spirit, strong enough to inspire them to undergo major surgery and sacrifice a vital organ for no material benefit.⁹⁶ The data strongly suggests that far from being a demonstration of altruism, virtually

⁹⁴ B.L Nagaraj and Ors. v. Dr. Kantha and Ors, AIR 1996 Kant 82.

⁹⁵ M.K Mani, *Letter from Chennai*, 15(5), NATL MED J INDIA, 295-296 (2005).

⁹⁶ *Id.*

all these cases of kidney donation on the grounds of emotional ‘affection or attachment’ or ‘compassion’ is an exploitative and illegal financial transaction between a poor donor and a relatively well-to-do patient. The kidney trade is exploitative of the poor and the needy as highlighted by the large number of cases where donors are shown, in the second set of official records, to be employees or unrelated dependants of the recipients.⁹⁷

The Supreme Court of India in the case of *Kuldeep Singh and Anr. v. State of Tamil Nadu and Ors.*,⁹⁸ where a person wanted to donate one kidney to another out of love and affection, stated that, since the object of the Act is crystal clear that it intends to prevent commercial dealings in human organs, the Authorisation Committee is required to satisfy that the actual purpose of the donor authorizing the organ removal is because of affection or attachment towards the recipient or for any other special reason. Such special reasons should in no way encompass commercial elements. The burden is on the applicants to establish that the donation is carried out of affection or attachment by placing relevant materials for consideration of the Authorisation Committee. The existence of any affection or attachment or special reason is within the special knowledge of the applicants, and hence, a heavy burden lies on them to establish it. Several relevant factors like relationship if any, period of acquaintance, degree of association, reciprocity of feelings, gratitude and similar human factors and bonds can throw light on the issue.

The Court held that it would be desirable to require the donor and recipient to give details of their financial positions and vocations as the major objective of the Act is to rule out commercial dealings in human organs. The Court also suggested that it would be appropriate for the Legislature to amend the Rules and Form I, so that requirement for disclosing incomes and vocations for some previous financial years (say three years) gets statutorily incorporated which would help the Authorisation Committees to assess if any commercial arrangement is involved or not. The Court held that the Authorisation Committees as per this judgment, require the applicants to furnish their income particulars for the previous three financial years and the vocations till

⁹⁷Vidya Ram, *Karnataka's unabating kidney trade*, FRONTLINE, (Mar. 30, 2002), <https://frontline.thehindu.com/other/article30244486.ece>.

⁹⁸ *Kuldeep Singh and Anr. v. State of Tamil Nadu and Ors.*, AIR 2005 SC 2106.

legislative steps are taken.⁹⁹ Such a requirement was included later under the Transplantation of Human Organs and Tissues Rules, 2014 as per the judgment.¹⁰⁰

Despite such measures to curb commercial dealings, Section 9(3) still enables the organ racketeers to buy and sell organs by labelling it as organ ‘donation’ due to reasons of ‘affection’ or ‘attachment’. There seems to be an issue in the judicial approach too in such matters. The High Courts have been liberal in granting sanctions even when the Authorisation Committees have found the grounds insufficient.¹⁰¹ It is hard to find a consistent rationale for the various approaches by the High Courts where the decisions by the authorities are modified in writ jurisdictions. The major issue here is that the Courts have limited reach to gathering facts by evidence, however, decide the matters only on the basis of incontrovertible facts brought through admitted documents and affidavits. There is a general tendency to be carried away by sympathetic considerations for the patient and ignore the possibility of financial allurements to non-relative poor donors.¹⁰²

Section 9(3) has to be tightened in order to prevent any commercial dealings in the pretext of ‘affection’ or ‘attachment’. This provision has been often referred to as a loophole facilitating commercial arrangements in organ donations.¹⁰³ There needs to be clarity on what constitutes ‘affection’ or ‘attachment’ and what can be the ‘special reasons’ sufficient enough to permit an unrelated donor to donate his organ to a patient and ensure that the same does not involve any commercial arrangements. While the Act intends to prohibit commercial dealings in human organs, it now provides protection for those very commercial dealings. The live donations and transplantations continue to be on the same level before and after enactment of the Act, the main difference being, such transplantations are carried out with the seal of approval from the Authorization Committee now¹⁰⁴ or the Committee accepts even

⁹⁹ *Id.* at 128.

¹⁰⁰ The Transplantation of Human Organs and Tissues Rules, 2014, G.S.R. No. 218 (E), Mar. 27, 2014, Rule 7(3)(vii), Form 3, Form 11 [Hereinafter ‘Rules, 2014’].

¹⁰¹ *Rajinder Kumar v. State of Punjab and Ors.*, AIR 2005 P&H 172; *R. Shailaja and Anr., v. State of Karnataka*, ILR (2005) Kar 953; *S Malligamma @ Malligavva and Anr v. State of Karnataka*, ILR (2005) Kar 557; Arup Kumar, *supra* note 91.

¹⁰² K. KANNAN, *MEDICINE AND LAW*, (Oxford University Press) (2014), at 467.

¹⁰³ Legal and ethical aspects, *supra* note 83; Ganapati Mudur, *Kidney trade arrest exposes loopholes in the India’s Transplant Laws*, 328(7434), BR. MED. J., 246 (2004) [Hereinafter ‘Loopholes in Indian Transplant Law’]; Transplantation of human organs, *supra* note 7.

¹⁰⁴ Mani MK, *Making an Ass of the Law*, 10, NATL MED J INDIA, 242-243 (1997) as cited in Legal and ethical aspects, *supra* note 83.

strangers donating organs to other out of affection or attachment due to the ambiguity in the provision.

4.2.2 SECTION 19(f): PROHIBITION OF ADVERTISING

Section 19 of Transplantation of Human Organs and Tissues Act, 1994 deals with punishments for commercial dealings in human organs. Section 19(f) prohibits any advertisement for offerings or inviting people to supply organs for cash. The section reads as follows:

“Whoever publishes or distributes or causes to be published or distributed any advertisement,— (a) inviting persons to supply for payment of any human organ; (b) offering to supply any human organ for payment; or (c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d)¹⁰⁵, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to ten years and shall be liable to fine which shall not be less than twenty lakh rupees but may extend to one crore rupees.”

However, the issue here is that this provision does not expressly prohibit advertisements seeking or offering organs if the same is not a commercial arrangement. The provision has to be made clear on this aspect and any advertisements for human organs have to be prohibited in order to avoid any commercial dealings. There is no way to regulate such advertisements and ensure that no commercial arrangement is involved once the advertisement is made. The Act makes it amply clear that an organ can be donated either by a near relative or by a person due to the reason of affection or attachment or any other special reasons¹⁰⁶ with the prior approval of Authorisation Committee.¹⁰⁷ However, there have been instances where the high courts have allowed such advertisements as it does not establish any commercial arrangement and brought it under the ambit of ‘special reasons’. The High Court of Kerala has been permitting such publications by orders looking into the provisions of the Transplantation of Human Organs and Tissues Act, 1994, finding that such publication is not prohibited by law so long as it does not

¹⁰⁵ Initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ.

¹⁰⁶ Though it is not expressly stated in the provision, altruistic organ donations are brought under the ambit of ‘special reasons’ by the Courts; E M Moideen v. State of Kerala, 2017 SCC OnLine Ker 21219 [Hereinafter E M Moideen; T G Suresh v. State of Kerala, 2017 SCC OnLine Ker 33151 [Hereinafter ‘T G Suresh].

¹⁰⁷ THOTA, *supra* note 1, § 9(1), § 9(3).

invite ‘supply for payment’ or ‘offers such supply’ or ‘indicate willingness to initiate or negotiate any arrangement’, looking at Section 19(f).¹⁰⁸ Here, some questions would arise on the genuineness of such advertisements, for instance, what is the need for an advertisement when someone cannot receive an organ from a stranger and altruistic organ donations are not expressly brought under ‘special reasons’ by the Act, and if so, is there any way to regulate such organ donations and ensure that there is no commercial arrangement involved.

Though the legislative intent of Section (19)(f) is to prohibit and criminalise any advertisements which can contribute to potential co possibly for commercial arrangements, the same is misinterpreted in a way that the advertisements which do not establish a commercial arrangement are permitted. In the case of *E.M Moideen v. State of Kerala*,¹⁰⁹ the High Court of Kerala heard 16 writ petitions together seeking permission to make publications in print media, seeking a kidney from willing altruistic donors from the public. Since there are no safeguards to prohibit commercial dealings in human organs and tissues once the publication has been permitted, the Court prohibited publications seeking kidney donations even if they do not establish any commercial arrangement.

The way the provision is interpreted is problematic where the Courts have been allowing advertisements stating that it does not establish any commercial motives and are purely altruistic organ donations. There needs to be clarity on this aspect and the provision must be modified in such a way that no advertisements inviting or offering organs are permitted as the same cannot be regulated in an efficient manner and the possibility of a commercial arrangement cannot be ruled out. Alternatively, state or national organ donation systems or regulatory authorities like National Organ and Tissue Transplantation Organisation can be used in order to address the demand and supply of organs purely on altruistic motives without any direct contact between the donor and recipient.

4.2.3 COMPOSITION OF AUTHORISATION COMMITTEES

As per Section 9(4)(a), the composition of the Authorisation Committee shall be prescribed by the Central Government from time to time and Rule 11 of the

¹⁰⁸ E M Moideen; T G Suresh, *supra* note 106.

¹⁰⁹ E M Moideen, *supra* note 106.

Transplantation of Human Organs and Tissues Rule, 2014 deals with the Composition of Authorisation Committees. There will be one State level Authorisation Committee and additional Authorisation Committees in the districts or Institutions or hospitals.¹¹⁰

As stated under Rule 12, hospital-based Authorisation Committees shall consist of:

“(a) the Medical Director or Medical Superintendent or Head of the institution or hospital or a senior medical person officiating as Head - Chairperson;

(b) two senior medical practitioners from the same hospital who are not part of the transplant team – Member

(c) two persons (preferably one woman) of high integrity, social standing and credibility, who have served in high-ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member;

(d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration – Member.”

Composition of State or District Level Authorisation Committees is also similar as provided under Rule 13.¹¹¹ The quorum of the Authorisation Committee has to be minimum four and the quorum shall not be complete without the participation of the Chairman, the presence of Secretary (Health) or nominee and Director of Health Services or nominee.¹¹² The Authorisation Committee comprises mainly of medical professionals or authorities without any necessary investigative powers and skills to

¹¹⁰ Authorisation Committee should be hospital based if the number of transplants is twenty five or more in a year at the respective transplantation centres, and if the number of organ transplants in an institution or hospital are less than twenty-five in a year, then the State or District level Authorisation Committee would grant approval(s) as stated under Rule 11(4).

¹¹¹ A Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main or major Government hospital of the District – Chairperson; two senior registered medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team– Member; two persons (preferably one woman) of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member; Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration–Member.

¹¹² Rules, 2014, *supra* note 100, Rule 15.

verify the affidavits and enquire into the genuineness of the organ donation.¹¹³ Though the composition includes two persons of high integrity, social standing and credibility, who have served in high-ranking Government positions, such as in higher judiciary or senior cadre of police service, etc., they need not be necessarily from these areas of expertise, and can be from other categories listed under the provision. The quorum requirement also suggests that the attendance of persons of high integrity, social standing and credibility is not mandatory. Persons who served in higher judiciary or senior cadre of police service or persons possessing investigative skills must be made members of the Authorisation Committee mandatorily and the quorum must not be complete without their presence. Like the medical aspects, it is equally important to be cautious about the possibility of commercial dealings between the donor and the recipient and hence, it is crucial that persons having adequate investigative powers and skills be made a part of the Authorisation Committee.

Since the major objective of the Act is to prevent any commercial dealings in human organs and tissues in the country, it is crucial that necessary measures are taken to curb such practices and no loophole is left unattended. The appropriate composition of Authorisation Committees plays a vital role in curbing illegal organ trade in the country. While the medical practitioners look into the medical aspects of the organ removal and transplantation, it is inevitable to ensure that the donation does not involve any commercial arrangements. Hence, it is important to have persons with the necessary skills and expertise in the area especially while dealing with donations made out of affection or attachment or any other special reasons. Since the Authorisation Committees mainly comprise of medical authorities or professionals, it would be difficult to analyse whether there are any financial motives involved. Hence, professionals capable of the same must be made part of the Authorisation Committees to prevent any possible commercial dealings in human organs.

4.2.4 SECTION 5: WAITING PERIOD FOR REMOVAL OF ORGANS FROM UNCLAIMED DEAD BODY IN HOSPITAL OR PRISON

Section 5 of the Transplantation of Human Organs and Tissues Act, 2014 deals with the authority for removal of human organs or tissues in case of unclaimed bodies in

¹¹³ Sangeetha Sriraam, *Transplantation of Human Organs Act: A Critical Analysis*, SSRN, (Jan. 22, 2016), at 3 [Hereinafter 'TOHOA'].

hospital or prison.¹¹⁴ The provision permits removal of any human organ from the unclaimed dead body, if the authorities are unable to locate near relatives of the deceased within 48 hours of the death on a reasonable enquiry. Though organs can be preserved for few hours by cooling and other procedures, organs from a deceased have to be procured very soon after the death. The time factor in this Act diffuses the purpose of organ transplantation as most of the vital organs need to be transplanted from the deceased soon after death has occurred. In order to get more organs for transplantations, it is essential that organs should be retrieved before the degenerative process begins.¹¹⁵ Hence, it is important to ensure that potential organs for transplantation do not go waste due to the statutory requirement of waiting time of 48 hours before removal of organ from an unclaimed dead body. This duration needs to be reduced to such an extent where there is reasonable time to locate the near relatives of the deceased but the organs remain in a healthy state capable of removal and transplantation.

The statutory requirement of 48 hours makes the provisions meaningless for organ donation unless such body that is left unclaimed in a hospital or prison is on a ventilator, however the provision is applicable to a dead body. A dead body would be decomposed in 48 hours under normal circumstances and the organs from the body cannot be utilised even if the body is not claimed after 48 hours.¹¹⁶ Since the organs can be removed in a healthy state soon after death, the waiting time needs to be reduced to 24 hours so as to ensure that potential organs do not go waste. In order to bridge the wide gap between demand and supply of human organs in the country, it is essential to take measures to tackle the shortage of organs and thereby decrease the possibility of illegal dealings in human organs.

¹¹⁴ (1) In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any [human organ or tissue or both] from the dead body which so remains unclaimed may be given, in the prescribed form, by the person in charge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof. (2) No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even though such near relative has not come forward to claim the body of the deceased person within the time specified in sub-section (1).

¹¹⁵ C. Manickam, *Organ transplantation and the Law*, CULR, 176-212 (1995).

¹¹⁶ Sunil Shroff et al., *Recommendations for Transplantation of Human Organs Act (Amendments) Bill 2009*, 9(28), INDIAN TRANSPLANT NEWSLETTER, (Oct. 2009 - Feb. 2010) [Hereinafter 'Recommendations'].

4.2.5 INCONSISTENCY IN DEFINITION OF DEATH

In addition to the definition of death under the Transplantation of Human Organs and Tissues Act, 1994, Indian Penal Code, 1860¹¹⁷ and Registration of Births and Deaths Act, 1969¹¹⁸ also define 'death'. Section 46 of the Indian Penal Code defines death as "Death of a human being unless the contrary appears from the context" and Section 29(13) of the Registration of Births and Deaths Act defines death as "the permanent disappearance of all evidence of life at any time after live birth has taken place". The ambiguity and inadequacy of these definitions in the context of organ transplantations have led to the definition of 'brain-stem death' under the Transplantation of Human Organs and Tissues Act, 1994. As per Section 2(d) of the Act, 'brain-stem death' means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified as per the provisions of the Act. However, there is still ambiguity as the Act does not state that the definition of death under the Act would apply irrespective of the other two definitions in Indian Penal Code and Registration of Births and Deaths Act respectively. This inconsistency is also an issue with respect to the declaration of time of death.

The definitions when read together, would mean that a person might be brain dead though there has not yet been a 'permanent disappearance of all evidence of life' as needed under Registration of Births and Deaths Act, for instance, the patients who may be brain dead but is still on some life support system. Though brain death has occurred in such patients, they would still be showing signs of life, like a heartbeat, a pulse, and in some cases even involuntary movement. Due to the inconsistency in these definitions, a person may be certified 'brain dead' for the purposes of the Act, but are not yet 'dead' for the purposes of the Registration of Births and Deaths Act, 1969 and Indian Penal Code. Hence, it means that though the Act allows the removal of organs from a brain-dead person, it may constitute an offence under the IPC since the person is still alive for the purpose of the IPC. Though there have not been cases reported on this basis, this inconsistency in the definitions has led to uncertainty about when organs can legitimately be retrieved from a cadaver.¹¹⁹ Hence, in order to ensure that there are no confusions regarding the declaration of brain death or the time of

¹¹⁷ IPC, *supra* note 15.

¹¹⁸ Registration of Births and Deaths, *supra* note 16.

¹¹⁹ Organ Transplant Law, *supra* note 13.

declaration of death, it is important that the definition is made applicable for the purposes of the Act irrespective of the different definitions under the other two statutes and the same be stated expressly under the Act.

4.2.6 CUMBERSOME PROCEDURE BEFORE THE COURT CAN TAKE COGNIZANCE

Section 22 of the Transplantation of Human Organs and Tissues Act, 1994 states that the Court cannot take cognizance of an offence under the Act except on a complaint made by the Appropriate Authority or a person who has given notice of not less than sixty days to the concerned authority, of the alleged offence and of his intention to make a complaint to the court. The cumbersome procedure to be followed before a court can take cognizance of an offence under the Act needs to be simplified so that people can easily access the justice system when there is a violation of their rights in the context of commercial dealings in human organs and exploitation. The general trend when persons are charged for offences under the Act is that the charges are brought not only under the provisions of the Act, but also under the provisions of the Indian Penal Code, 1860.¹²⁰ Due to the lengthy procedure to approach the court, it may be easier to bring charges under the IPC and eschew the provisions of the Act altogether.¹²¹

Hence, the provision needs to be modified in such a way that the public can access the court directly and avoid any unnecessary delay. There is a need to simplify the procedure to file a complaint under the Act and hence the requirement for filing a complaint through an Appropriate Authority has to be removed in order to permit people to approach the courts directly. In order to curb the illegal organ trade in the country, the public should be able to approach the court easily for any grievances when they are affected by any such illegal practices related to commercialisation of human organs. The inaccessibility can result in an increased rate of commercial dealings in human organs across the country as the remedies available are too onerous to pursue.

¹²⁰ IPC, *supra* note 15, § 120-B, § 420, § 467, § 468, § 471.

¹²¹ Organ Transplant Law, *supra* note 13.

4.2.7 ABSENCE OF EMERGENCY PROVISIONS

The Transplantation of Human Organs and Tissues Act, 1994 does not lay down any specific time limit for deciding the matters before the various authorities constituted under the Act. However, Rule 23 Clause 2 of the Transplantation of Human Organs and Tissues Rules, 2014 requires the Authorisation Committee to take decisions expeditiously where a patient requires the transplantation on an urgent basis, but still does not provide any specific time limit for making decision on matters related to organ donations when the donor and recipient are near relatives, unrelated, foreigners, etc. The very nature of the organ transplantation demands an expeditious decision-making process by the authorities and there can be a number of instances when the transplantation needs to be conducted on an urgent basis. There are no provisions addressing such concerns apart from the requirement to take decisions expeditiously. Such matters are left to the Authorisation Committees, ignoring the possibility of discrepancies in practices and delays leading to the patients losing lives.

There needs to be a specific time period provided under the Act for granting or refusing approval to transplantations to ensure that the patients who are critically ill do not lose their lives waiting for the decision of the Authorisation Committees. When the legal procedures lead to delay especially in an emergency situation involving life and death, the general tendency would be to engage in illegal practices violating the provisions of the Act. Hence, there must be provisions specifically for such emergency situations and a specific time limit within which the Authorisation Committee should grant or refuse the approval for removal and transplantation of organs.

4.2.8 IGNORING PEOPLE WITH NO NEAR RELATIVES OR ALTRUISTIC DONOR

The Transplantation of Human Organs and Tissues Act fails to address the rights of people who neither have a near relative nor an altruistic donor. Every person need not necessarily have a near relative or a person who is willing to donate his/her organs purely on altruistic motives. Section 9 of the Act only deals with the organ donations from a near relative, someone out of affection or attachment or due to any other special reasons. As mentioned above, altruistic donors have been brought under 'special reasons' by the Courts. A patient waiting for organ transplantation without

any near relatives is left at the mercy of an altruistic donor and if such a donor does not turn up, the person has no other option but to succumb to the illness. Even when a person has near relatives, it is not necessary that such potential donors are fit candidates to donate their organs to the patient and it is always possible that none of his near relatives are matching donors.¹²²

There are also instances where a person loses his/her near relatives in an accident or to a natural calamity and such a person will have to depend entirely on cadaver organ donations. Hence, a person without a near relative or an altruistic donor loses his life waiting for cadaver organ donations in a country where the rate of cadaver organ donations is abysmal. It is also possible that such persons get involved in commercial dealings of human organs in order to save their lives. Therefore, it is necessary to address the right to health of such critical patients under the Act and special provisions need to be incorporated to protect their rights and ensure that they have equal access to organ transplantations. Increasing the rate of cadaver organ donations is the best possible solution to address not only this particular concern, but most of the issues related to organ trade in the country.

4.3 ISSUES WITH THE IMPLEMENTATION OF THE ACT

Apart from the loopholes and ambiguities in the provisions of the Act contributing to organ trade in the country, there are also various issues surrounding the implementation of the Transplantation of Human Organs and Tissues Act. Effective implementation of the Act is indispensable to curb the commercial dealings in human organs and the various organ scams reported across the country make it evident that the Act has failed in preventing such illegal practices. The various issues with the implementation of the Act aiding commercialisation of organs are discussed below:

4.3.1 WILL OF THE RELATIVES OVER WILL OF THE DECEASED

Section 3(2) of the Act states that if a donor had authorised the removal of any of his organs after death, in writing and in the presence of witnesses, the person who is in lawful possession of the body must provide the registered medical practitioner with all reasonable facilities for the removal of such organ unless the person has any reason to

¹²² Sapna Khajuria and Saugata Mukherjee, *Organ Transplantation: Legal Framework Examined*, 39(2-4), JILI, 299-311 (1997).

believe that the deceased had revoked his earlier consent. Section 3(4) also states that such an authority given shall be sufficient warrant for the removal of the organ of the deceased for therapeutic purposes. However, this provision is not implemented effectively and the respect for personal autonomy and free will of the deceased is totally neglected when the family of the deceased objects to the donation of his organs. The will of the relatives of the deceased supersedes over the will of the deceased in cadaver organ donation. Despite having pledged his organ or making his relatives aware of such wish to donate, the wishes of the deceased are entirely ignored and priority is given to the wishes of his family.¹²³

The Act fails miserably when the wish of a person to donate his organs after death is set aside and the will of his family is considered more important. Since the Act tries to promote cadaver organ donations, it is a paradox that even the decision of a person who is willing to donate his organs after death is not considered and is ignored when his relatives wish otherwise. However, if the person has informed his family or friends about the objection to donate his organs after death or had revoked his earlier consent to donate, then the authorisation of near relatives is not important. The issue here is that as per the law, the autonomy of the deceased is respected only when he had objected to organ donation and not when he had agreed to the same.¹²⁴ This practice acts against the objective of the Act and contributes to the commercial dealings in human organs when the organs are not legally available. A relative must not have the right to nullify a person's decision after his death. The autonomy of the deceased must be respected and organ donation be carried out irrespective of the wishes of the family if a person had already consented to such donation after his death.

¹²³ National Organ and Tissue Transplantation Organisation, *Frequently asked questions: Deceased donor related transplant*, 20: What, if a person had pledged to donate Organs, but his family refuses? In most situations, families agree of donation if they knew that was their loved ones wish. If the family, or those closest to the person who has died, object to the donation when the person who has died has given their explicit permission, either by telling relatives, close friends or clinic\al staff, or by carrying a donor card or registering their wishes on the NOTTO website, healthcare professionals will discuss the matter sensitively with them. They will be encouraged to accept the dead persons wishes. However, if families still object, then donation process will not go further and donation will not materialize. [Hereinafter 'Deceased donor related transplant'].

¹²⁴ Transplantation of human organs, *supra* note 7.

4.3.2 LACK OF TRANSPLANT COORDINATORS

Section 2(5) of the Act defines a ‘transplant coordinator’¹²⁵ and appointment of transplant coordinators is a pre-requisite for the registration of hospitals under the Act.¹²⁶ Registered medical practitioners in consultation with transplant coordinators are duty-bound to educate the relatives of the brain-dead person about the concept of organ donation and consequently ask for their option to authorise or decline for donation of organs of the deceased.¹²⁷ Despite such mandatory requirement to appoint a transplant coordinator, factual analysis reveals that more number of transplant coordinators are required for efficacious cadaver donations.¹²⁸ For instance, in Delhi only one or two transplant coordinators are there in each leading hospital registered for transplants. It is crucial that the potential donors are converted into real donors, however, the overburdened Intensive Care Units, drained nursing staff, technicians coupled with a smaller number of transplant coordinators are some of the hurdles to do the same. The websites of various leading hospitals show that there are not enough transplant coordinators to fulfil the objective of the Act to promote cadaver organ, failing which organ trade will be flourishing donations in the country.¹²⁹ The need for transplant coordinators was acknowledged through the 2011 Amendment Act for coordinating and assisting in the matters related to removal or transplantation of organs. If there are enough transplant coordinators to assist and coordinate the removal and transplantation of organs, it will make a substantial difference in the rate of organ donations in the country.

4.3.3 PROSECUTION OF VIOLATORS

Organ trade in India is an open secret and large-scale organ sale rackets have been often reported despite the criminalisation of commercial dealings, however, only a handful of them have been reported to be prosecuted for violating the provisions under the Transplantation of Human Organs and Tissues Act, 1994.¹³⁰ Though the Act was enacted in 1994, the National Crime Records Bureau did not record data on cases

¹²⁵ A person appointed by the hospital for co-ordinating all matters relating to removal or transplantation of human organs or tissues or both and for assisting the authority for removal of human organs in accordance with the provisions of Section 3 of the Act.

¹²⁶ THOTA, *supra* note 1, § 14(4).

¹²⁷ *Id.* § 3(1A).

¹²⁸ Transplantation of human organs, *supra* note 7.

¹²⁹ *Id.*

¹³⁰ *Id.*

under the Act till 2014. In the subsequent years, very few cases were filed under the Act and taken to trial as per the data available.¹³¹ While the cumbersome procedure to be followed before the court can take cognizance of the matter contributes to the smaller number of cases under the Act, the effective implementation of penal provisions is vital to prevent commercial dealings in human organs.

Despite various organ scams being reported across the country, if only a few are being prosecuted and punished under the Act, it would be a green signal for the organ racketeers to continue such illegal practices in India. If strict action is not taken against the offenders, the very purpose of the criminalisation of commercial dealings in organs would be in vain. Hence, there should be major emphasis on implementing the provisions under Section 19 of the Act providing for punishment for commercial dealings in human organs and thereby preventing such practices. The proper implementation of the Act specifically focusing on penal provisions is essential in order to produce a deterrent effect amongst the public.

4.3.4 LACK OF EFFECTIVE CADAVER DONATION PROGRAMMES

The Transplantation of Human Organs Act, 1994 through recognising ‘brain death’ as legal death, tries to promote cadaver organ donations and thereby decrease the need for live organ donations and commercial dealings in human organs. However, despite being an important aspect under the Act, there are no effective provisions incorporated to increase the donor pool from brain dead persons. Even after more than two decades of implementation of the Act, the cadaver organ donations remain low. The estimates as per National Organ and Tissue Transplant Organisation show that less than 8% of the total transplantations from 1994 to 2019 are cadaver donations leaving all the other transplantations into the account of living donations.¹³² Despite the establishment of National Organ Transplant Programme and constitution of National Organ and Tissue Transplant Organisation to promote deceased organ donation and coordination and networking for procurement and distribution of organs and registry of organs donation and transplantation in the country, create awareness and promote organ donation in the country, the cadaver organ donation rate in India stands at a mere 0.52 per million.¹³³ There need to be specific programmes for

¹³¹ Organ Transplant Law, *supra* note 13.

¹³² Organ Report, *supra* note 9.

¹³³ International Registry, *supra* note 66.

increasing the cadaver organ donations and increasing awareness amongst the public, thereby decreasing the live organ donations and, hence, potential commercial dealings in organs.

4.3.5 FAKE DOCUMENTS ESTABLISHING RELATIONSHIP BETWEEN DONOR AND RECIPIENT

Forging documents to establish relationship between the donor and recipient to carry out organ transplantation is a common practice in the country.¹³⁴ Fake documents act as a major hurdle in the effective implementation of the Transplantation of Human Organs and Tissues Act. One of the main reasons making organ trade in India possible is through forging of documents to establish relationship between donor and recipient when they clearly are not. Organ transplantations using organ procured through illegal means happen even in leading hospitals through forging documents and faking that either the donation is from a near relative or is made out of affection or attachment. While involved in commercial dealings in human organs, people forge documents so as to prove that they are near relatives while the donor might be from an economically weak section and the recipient in a financial position well enough to afford to buy an organ. Here, the necessary documents required by law would be forged and the relationship would be established in order to carry out an illegal transplantation. As mentioned above, it may not be possible for the Authorisation Committees to examine the documents and analyse the discrepancies without necessary investigative skills. Hence, that is also a factor resulting in the commercial dealings in human organs going overlooked and unpunished.

4.3.6 LACK OF INFRASTRUCTURE AND INADEQUATE INVESTMENT

Health infrastructure and adequate public health funding are indispensable in the effective implementation of the statutes dealing with public health. Organ transplantations being a complex procedure, need proper health infrastructure and adequate investment to carry out the same efficiently. The low rate of organ transplantations from cadavers in the country can be attributed to the facilities in the

¹³⁴ Ganapati Mudur, *Indian doctors debate incentives for organ donors*, 329(7472), BR. MED. J., 938, (2004); Kiran Sharma, *India's organ shortages spur illegal transplants*, NIKKEI ASIA (Jun. 8, 2016), <https://asia.nikkei.com/Business/India-s-organ-shortages-spur-illegal-transplants>; S Bhattacharya, *India Police Probe Trade in Human Organs*, THE WALL STREET JOURNAL (Jun. 14, 2016), <https://www.wsj.com/articles/india-police-probe-trade-in-human-organs-1465946033>.

Indian health system like lack of facility for the resuscitation of the victim at the accident spot, lack of well-equipped medical institutions, shortage of trained personnel in the Intensive Care Units, lack of quick communication and proper transport facilities, etc. Hence, in practice, the cadaveric donation technology is almost missing considering the large number of brain-stem death patients in India.¹³⁵

The public health infrastructure needs to be improved substantially in order to make the cadaver organ transplantations possible in the country, thereby decreasing the possibility of commercial dealings in human organs. Public health investment is also vital for such complex, diverse and expensive infrastructure needed to carry out organ transplantations. However, India is one of the countries that invest the lowest in health sector as compared to other countries. India's public expenditure on healthcare stands at a mere 1.26% of GDP as of 2021 which is substantially low considering the large population and other socio-economic factors of the country.¹³⁶ The objectives of the Transplantation of Human Organs and Tissues Act, 1994 cannot be fulfilled with inadequate investment in health sector and poor infrastructure and necessary measures need to be taken to improve the status.

4.4 CONCLUSION

As discussed above, the Transplantation of Human Organs and Tissues Act, 1994 is largely flawed and has loopholes aiding the organ racketeers to carry out organ trade in the country by misusing and misinterpreting the law. There are also serious issues with the effective implementation of the Act as explained above. The Act has not been successful in curbing commercialisation of human organs and bridging the gap between the demand and supply of human organs by increasing the deceased organ donations in the country. The various provisions of the Act have created ambiguity in the legality of certain practices and such vague and broad provisions are misused and misinterpreted to accommodate commercial dealings in human organs but under the label of legal donations. There needs to be clarity in such provisions and any possibility of abuse of the law through such loopholes must be prevented in order to achieve the objective of the Act.

¹³⁵ Transplantation of Human Organs, *supra* note 7.

¹³⁶ Indian Brand Equity Foundation, *Indian Healthcare Industry Analysis*, <https://www.ibef.org/industry/healthcare-presentation> [Hereinafter 'Indian Healthcare Industry'].

It is also essential to increase the rate of cadaver organ donations in the country which would be a significant step towards preventing commercial dealings in human organs. This would in turn result in reducing the gap between demand and supply and eliminate the need of buying and selling of organs when the same is available through legal means. Creating awareness amongst the general public about the concept of brain death and organ donation is also important and people must be encouraged to donate their organs after death so that the demand for organs can be met, thereby saving thousands of lives. There are countries with similar legal provisions related to transplantations as in India as well as countries with extremely different take on organ trade and transplantations. The legal position regarding the regulations of organ transplantation and commercialisation of organs in other countries namely, the United States of America and Australia is discussed in the next chapter. The position of countries like Iran where the sale of organs is legalised and Spain where there exists a system of presumed consent in the context of organ donation is also discussed.

CHAPTER V: COMPARATIVE STUDY

5.1 INTRODUCTION

As discussed in the previous chapter, the Transplantation of Human Organs and Tissues Act, 1994 is largely flawed and has loopholes aiding the organ racketeers to carry out organ trade in the country by misusing and misinterpreting the law. There are also serious issues with the effective implementation of the Act. Organ trade is not limited to India and it is an international process exploiting the poor from economically weak countries and where it is easier to evade the law. There are countries with similar legal provisions related to transplantations as in India as well as countries with an extremely different take on organ trade and transplantations. This chapter tries to analyse the international scenario with respect to organ transplantations and commercial dealings in human organs in other countries. International instruments with regard to organ donation, transplantation and trafficking like Council of Europe Convention against trafficking in human organs, World Health Organisation's Guiding Principles on Human cell, tissue and organ transplantation and Declaration of Istanbul are discussed. The legal position in the United States of America and Australia regarding the regulations of organ transplantation and commercialisation of organs are also analysed in this chapter.

There have been around 26 legislations passed in the US aimed at regulating organ transplantations and donations and these regulations range from what constitutes being dead, to what constitutes consent for organ donation, to national honours for organ donation. However, the main focus would be upon the National Organ Transplant Act, 1984 banning commercialisation of organs for transplant and the Uniform Anatomical Gift Act, 1968. Likewise, in Australia, there are state legislations with substantially similar provisions and these legislations aim at regulating organ transplantations and preventing organ trade. The position of countries like Iran where the sale of organs is legalised and Spain where there exists a system of presumed consent in the context of organ donation is also discussed.

It is estimated that 10% of the organs that are transplanted at a global level annually are obtained through organ trafficking, and that in some countries, nearly all kidneys

donated by the local population are for paying foreign recipients.¹³⁷ Trafficking in persons for the purpose of organ removal is a common phenomenon now. As per Article 3(a)¹³⁸ of the Protocol to Prevent, Suppress and Punish Trafficking in Persons, especially Women and Children, supplementing the United Nations Convention against Transnational Organized Crime,¹³⁹ exploitation under the definition of trafficking also includes removal of organs. In 2004, WHO called on its member states to take adequate measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs.¹⁴⁰

5.2 INTERNATIONAL INSTRUMENTS

5.2.1 COUNCIL OF EUROPE CONVENTION AGAINST TRAFFICKING IN HUMAN ORGANS¹⁴¹

The Convention which was adopted in 2005 by the Council of Europe seeks to prevent and fight the trafficking in human organs by providing for the criminalisation of certain acts, to protect the rights of victims of the offences as per the Convention and to facilitate cooperation at domestic and international levels on action against the trafficking in human organs. The Convention calls upon each party to take necessary measures, legislative and others to establish the intentional removal of organs from living or deceased donors as a criminal offence under its domestic law, where the removal of the organ is carried out without the free and informed consent of living or deceased donor or unauthorised removal as under its domestic law in case of the deceased donor; where the living donor or a third party has been offered or has

¹³⁷ *Legal and illegal organ donation*, 369(9577), THE LANCET, 1901 (2007).

¹³⁸ ‘Trafficking in persons’ shall mean the recruitment, transportation, transfer, harbouring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs.

¹³⁹ UN General Assembly, *Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention against Transnational Organized Crime*, Nov. 15, 2000, <https://www.ohchr.org/en/professionalinterest/pages/protocoltraffickinginpersons.aspx>.

¹⁴⁰ World Health Assembly Resolution 57.18, *Human organ and tissue transplantation*, http://www.who.int/gb/ebwha/pdf_files/WHA57/A57_R18-en.pdf.

¹⁴¹ Council of Europe, *Council of Europe Convention against Trafficking in Human Organs*, Mar. 25, 2015, CETS 216, <https://rm.coe.int/16806dca3a>.

received any monetary benefit or comparable advantage in exchange for the removal of organs including removal of organs from a deceased donor.¹⁴²

The purpose of organ removal is not important for constituting an offence under the Convention. Some other offences as provided under the Convention for the parties to establish as criminal offences address all the parties involved in the human organ trafficking including those who solicit or recruit donors,¹⁴³ those who move or transport organs,¹⁴⁴ those who use illicitly removed organs and medical professionals or others who perform illicit transplant surgeries.¹⁴⁵ The Convention hence tries to criminalise the use of illegally removed organs, illegal solicitation and recruitment of organ donors and recipients for any financial gain, acts committed following the illicit removal of organs and aiding, abetting and abetting all the offences as mentioned above.

5.2.2 DECLARATION OF ISTANBUL¹⁴⁶

Shortage of organs has been a significant issue globally too. It was the need of the hour to address the urgent and growing issues in relation to sale of human organs, transplant tourism and trafficking in organ donors with respect to the global shortage of organs. Hence, in 2008, a Summit Meeting of more than 150 representatives of scientific and medical bodies from across the world, government officials, social scientists, and ethicists, was held in Istanbul. Preparatory work for the meeting was carried out by a Steering Committee convened by The Transplantation Society and the International Society of Nephrology in Dubai in December 2007. Draft Declaration by the said Committee was circulated widely and then revised considering the comments received and later at the Summit, the revised draft was reviewed by working groups and finalized in plenary deliberations. It was subsequently endorsed by more than 135 national and international medical societies and governmental bodies involved in organ transplantation.¹⁴⁷ The Declaration of Istanbul was the first concerted effort to mobilize the professional transplant community so as to develop practical and

¹⁴² *Id.* art 4.

¹⁴³ *Id.* art 7.

¹⁴⁴ *Id.* art 8.

¹⁴⁵ *Id.* art 5, art 6.

¹⁴⁶ Declaration of Istanbul, *supra* note 51.

¹⁴⁷ *Id.* Preamble.

ethically acceptable solutions to the problem of international trafficking of human organs.¹⁴⁸

The Declaration seeks to prohibit transplant commercialism, transplant tourism and organ trafficking. It also tries to provide safe, effective, and accountable practices addressing the issues and needs of the organ recipients as well as protects the rights of living organ donors. One of the major objectives of the Declaration is to maximise the benefits of organ transplantations and share them equitably with the people in need and at the same time, no reliance to be placed on unethical and exploitative practices especially against the poor and weak people across the world. As per the principles of the Declaration, trafficking in human organs and trafficking in persons for organ removal should be prohibited and criminalized. It also states that organ donation should be a financially neutral act. It also put forward various proposals to increase the donor pool, prevent organ trafficking, commercialisation of transplants, transplant tourism and to encourage legitimate, lifesaving transplantation programs. They include proposals to respond to the need to increase deceased donation so as to make sure that the protection and safety of living donors and appropriate recognition for the same.

5.2.3 WORLD HEALTH ORGANISATION GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION¹⁴⁹

WHO Guiding Principles was endorsed in May 2010 by the 63rd World Health Assembly Resolution and updated considering the changes in practices and perspectives with respect to organ and tissue transplantation. It intends to provide an orderly, ethical and acceptable framework for the procurement and transplantation of human cells, tissues and organs for therapeutic purposes. The member countries can determine the means through which these guiding principles are implemented. The essential points of the 1991 version have been preserved while new provisions were incorporated as a response to the current trends in organ and tissue transplantation, especially provisions for protecting the living donors and the increasing use of human

¹⁴⁸ Gabriel M. Danovitch & Mustafa Al-Mousawi, *The Declaration of Istanbul-early impact and future potential*, 8, NAT. REV. NEPHROL, 358-361 (2012).

¹⁴⁹ World Health Assembly Resolution 63.22, *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, May 2010, https://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf.

cells and tissues. These principles emphasise on the significance and necessity of ensuring proper documentation and enhancing transparency, both for quality management purposes as well as to justify the confidence of patients, clinicians and the community at large in donation and transplantation services. Cells, tissues and organs may be removed from deceased and living persons for transplantation only as per the Guiding Principles.

Any cells, tissues or organs may be removed from the body of a deceased if any consent is obtained as per the law and there is no reason to believe that the deceased had any objection to such removal. It is also important that the physician who determines the death of a potential donor should not be directly involved in the removal of organ or subsequent procedures so as to avoid any conflict of interest, and they will also not be responsible for the care of the intended recipient of the organ so removed. Cadaver donations have to be improved to their maximum therapeutic potential, however, living donations may be permitted as per domestic regulations and generally, living donors should be related to the recipients genetically, legally or emotionally. Such donations are acceptable when there is informed and voluntary consent, when necessary follow-up and professional care is ensured and the selection criteria should be scrupulously applied and monitored. There should not be removal of any cells, tissues or organs from the body of a living minor or a legally incompetent person except as per the narrow exceptions under national law.

The most important provision in the context of commercial dealings in human organs is Guiding Principle 5 which states that:

“Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.”

The provision makes it clear that it prohibits any commercial dealings in human organs, cells or tissues and the expenses incurred by the donor for the process should however be reimbursed. The commentary to the principle states that this provision

intends to avoid payments for organs as it is likely to take unfair advantage of the poorest and vulnerable sections of the society, undermines altruistic donation, and leads to profiteering and human trafficking. Also, such commercial dealings can convey the idea that such persons lack dignity and are used as mere objects by others. The principles provide the freedom to the countries to decide the details and method of the prohibitions it will use, including punishments that may encompass joint action with other countries in the region. Such a prohibition on commercial dealings of organs, cells and tissues should apply to all individuals including the transplant recipients who try to evade law or domestic regulations by travelling to areas where prohibitions on commercialization are not enforced.

There are also provisions including prohibiting advertisements for inviting donors with an aim to involve commercial dealings, restraining physicians and other parties from involving in transplantations and other procedures where there is exploitation or payments made to the donor or next of kin in case of cadaver donations and prohibiting healthcare facilities and professionals from receiving any payment exceeding the justifiable fee for the services provided. It is also stated that the allocation of organs must be as per clinical criteria and ethical norms and not financial or other considerations.

5.3 POSITION IN THE UNITED STATES OF AMERICA

There have been around 26 legislations passed in the US aiming at regulating organ transplantations and donations and these regulations range from what constitutes being dead, to what constitutes consent for organ donation, to national honours for organ donation. However, the main legislation associated with commercial dealings in human organs is the National Organ Transplant Act (NOTA) passed by the US Congress in 1984 and the Uniform Anatomical Gifts Act, 1968.

5.3.1 THE NATIONAL TRANSPLANT ACT, 1984

The National Transplant Act was enacted to provide for the establishment of Task Force on Organ Transplantation and the Organ Procurement and Transplantation Network with the main aim to authorize financial assistance for organ procurement organizations, and for other related purposes. It is the cornerstone of federal system for organ donation and transplantation. Section 101(b) deals with the duties of task

force which includes conducting comprehensive examinations of the medical, ethical, economic, legal, and social issues presented by human organ procurement and transplantation, making assessment of immunosuppressive medications used to prevent organ rejection in transplant patients, prepare reports on various matters like recommendations to ensure the equitable allocation of donated organs among transplant centres and among patients medically qualified for an organ transplant, etc. Title III of the Act deals with prohibition of organ purchases wherein it is stated under Section 301 that:

(a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.

(b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.

The Act clearly prohibits any commercial dealings in human organs and any violations will result in imprisonment extending to five years and/or fine. The valuable consideration as mentioned above does not include the reasonable payments with respect to the organ removal, transportation, implantation, processing, preservation, quality control, and storage or the expenses of travel, housing, and lost wages incurred by the donor with respect to the donation. NOTA called for an Organ Procurement and Transplantation Network (OPTN) to be created and run by a private non-profit organisation under federal contract. In 1986, OPTN was created with an aim to increase and ensure the effectiveness, efficiency and equity of organ sharing in the national system, and increase the supply of donated organs available for transplantation. The federal contract was given to the United Network for Organ Sharing, a non-profit organization that coordinated more than 4,60,000 transplants from deceased organ donors within the next three decades.¹⁵⁰

5.3.2 THE UNIFORM ANATOMICAL GIFTS ACT, 1968

Prior to NOTA, the legislative activity with respect to organ transplantation has been primarily driven by the Uniform Anatomical Gifts Act, which was passed by the National Conference of Commissioners on Uniform State Laws in 1968 and adopted by the District of Columbia and all fifty states, with slight variations by 1973. It is

¹⁵⁰ Organ India, *supra* note 88.

another significant law in the context of organ transplantation and has been revised in 1987 and in 2006. The Uniform Commissioners is a body of law and policy experts who are appointed by the governors of each state for identifying areas that would benefit from uniformity nationwide but which cannot be federally regulated as they fall under the reserved powers of the state. Organ donation being one of those areas and since there existed a need for a uniform law on the policy of deceased organ donation, UAGA has been enacted in every state in the US, thereby providing national consistency through the state law.¹⁵¹

The Act establishes a regulatory framework for the donation of tissues, organs, and various other human body parts in the country. It tried to increase the number of available organs by streamlining the process for individuals to pledge as organ donors. The Organ Donor Card which was mandated to be recognised as a legal document empowered any person who has attained the age of 18 years to legally pledge to donate his organs upon death.¹⁵² The Act regards donation of an organ as an anatomical gift and lack of any monetary consideration is vital in this context as the federal law prohibits any buying and selling of organs. Under the Act, an adult can make a gift before his death, which is done usually through a donor registry. Donor registries have been very successful with annual growth for 10 years since 2018 and over 142 million registered donors as of January 2018, representing over 54% of the adult population.¹⁵³ Next of kin of the deceased can also authorise a gift at the time of the donor's death. The law also bars anyone including the family from revoking the consent of the deceased, if he has made an anatomical gift before his death. The recipients of a gift are restricted to hospitals, doctors, medical and dental schools, universities, tissue banks, and a specified individual in need of treatment. The purposes of such gift are transplantation, therapy, research, education, and the advancement of medical or dental science. Section 10 of the Act deals with the prohibition on the sale or purchase of parts. It reads as follows:

¹⁵¹ Alexandra K. Glazier, *Organ Donation and the Principles of Gift Law*, 13(8), CJASN, 1283-1284 (2018).

¹⁵² Arthur Chern, *Regulation of Organ Transplants: A Comparison Between the Systems in the United States and Singapore*, (2008), <http://nrs.harvard.edu/urn-3:HUL.InstRepos:8963882>.

¹⁵³ U.S. Health Resources & Services Administration, Organ Donation Statistics, <https://www.organdonor.gov/statistics-stories/statistics.html>;; Donate Life America, <https://www.donatelife.net/statistics/>.

“(a) A person may not knowingly, for valuable consideration, purchase or sell a part for transplantation or therapy, if removal of the part is intended to occur after the death of the decedent.”

The Act requires every hospital to ask every patient on or before admission to a hospital whether the person has pledged a donation of organ or tissue. Once this law came into force in USA, there was a significant increase in the level of awareness about organ donation and the number of organ donors.¹⁵⁴

Organ Donation Breakthrough Collaborative was an initiative started in the country in 2003 to save thousands of lives a year by spreading awareness and known best practices to the nation's largest hospitals to achieve organ donation rates of 75 percent or higher in these hospitals.¹⁵⁵ As of 2008, the Organ Donation Breakthrough Collaborative has achieved a 30 percent increase in the rate of deceased organ donation in the past five years, compared to a 1-2 percent increase over the past decade.¹⁵⁶

5.4 POSITION IN AUSTRALIA

The supply of organs in Australia largely depends upon the voluntary altruistic donation of deceased organs or an opt-in system. There is a ban on commercialisation of human organs and no financial inducements can be offered to the donors except to cover the expenses incurred as a result of the organ donation. Cadaver organ donations are encouraged through community education campaigns in the country.¹⁵⁷ Number of organ transplants has increased considerably due to major changes in the procurement of deceased organs which occurred after the introduction of the National Organ and Tissue Authority in 2009, with a record 1480 organs donated in 2015.¹⁵⁸ There have been various efforts by the country to improve donation rates to both living and deceased donor organ pools and the same has resulted in significant

¹⁵⁴ TOHOA, *supra* note 113.

¹⁵⁵ Institute for Healthcare Improvement, *Improvement Stories-Organ Donation Breakthrough Collaborative*, <http://www.ihl.org/resources/Pages/ImprovementStories/OrganDonationBreakthroughCollaborative.aspx>.

¹⁵⁶ Shafer et al., *US Organ Donation Breakthrough Collaborative Increases Organ Donation*, 31(3), CCNQ, 190-210 (2008).

¹⁵⁷ Halstead B & Wilson P, *Body crime: human organ procurement and alternatives to the international black market*, Trends & issues in crime and criminal justice no. 30, Canberra: Australian Institute of Criminology, (1991).

¹⁵⁸ Alexander et al., *Organ Transplantation in Australia*, 101(5), TRANSPLANTATION, 891-892 (2017).

improvement in the access to organ transplantation for the citizens, as it was indicated by a 55% increase in the number of organ transplantation carried out from 843 in 2009 to 1303 in 2015.¹⁵⁹

Organ trafficking is an offence under Division 271 of Criminal Code¹⁶⁰ which deals with offences of trafficking in human beings including trafficking for the purpose of removal of organs. It covers trafficking into and out of Australia, as well as between states and territories in Australia, i.e., domestic organ trafficking. It would constitute an offence to involve in the entry or intended entry into the country, reception, exit or intended exit or movement around Australia of a victim by a person who is reckless as to whether it will result in the removal of a victim's organ. It is considered as an aggravated offence if the case involves a child, or if it involves cruel, inhuman or degrading treatment, or conduct that might lead to death or serious harm to the victim or another person. The punishment for such offences is imprisonment extending to 12 years and 20 years for the aggravated offences. There has been only one case of organ trafficking in Australia under the provisions of Criminal Code and prosecution did not proceed with the case due to the death of one of the alleged offenders.¹⁶¹

Apart from the Criminal Code which punishes the trafficking in human beings including trafficking for the purpose of organ removal, each state and territory in Australia has specific legislations dealing with organ transplantations and regulating the removal of human organs and tissues. They are Human Tissue Act 1983 (NSW); Human Tissue Act 1982 (Vic); Transplantation and Anatomy Act 1979 (Qld); Human Tissue and Transplant Act 1982 (WA); Transplantation and Anatomy Act 1983 (SA); Human Tissue Act 1985 (Tas); Transplantation and Anatomy Act 1978 (ACT); and the Transplantation and Anatomy Act (NT).

The legislations have substantially similar provisions and definition of tissue makes it clear that it includes an organ. Each of these legislations makes provisions with respect to offences related to transplant tourism and organ removal. For example, Part

¹⁵⁹ ORGAN AND TISSUE AUTHORITY, AUSTRALIAN GOVERNMENT, AUSTRALIAN DONATION AND TRANSPLANTATION ACTIVITY REPORT, (2015), <https://www.donatelife.gov.au/sites/default/files/Australian%20Donation%20and%20Transplantation%20Activity%20Report%202015.pdf>.

¹⁶⁰ *The Criminal Code Act 1995* (Cth) div 271 (Austl).

¹⁶¹ Natalie O'Brien, *Organ trafficker's death closes case*, The Sydney Morning Herald, (Mar. 25, 2012), <https://www.smh.com.au/national/organ-traffickers-death-closes-case-20120324-1vqvn.html>; Anti-slavery Australia, *Parliamentary Inquiry into Human Organ Trafficking and Organ Transplant Tourism*, Submission to the Joint Standing Committee on Foreign Affairs, Defence and Trade.

VIII of the Human Tissue Act 1982¹⁶² in the state of Victoria deals with prohibition of trading in tissues including organs. While Section 38 of the Act states that a person shall not sell, or agree to sell, tissue (including his own tissue) or the right to take tissue from his body, Section 39 deals with prohibition on buying of the tissue and states that a person must not buy, agree to buy, offer to buy, hold himself out as being willing to buy, or inquire whether a person is willing to sell to the person or another person, tissue or the right to take tissue from the body of another person. If the Minister where he considers it desirable by reason of special circumstances, can grant permit subject to any conditions to buy tissue (other than spermatozoa or ova) or the right to take tissue (other than spermatozoa or ova) from the body of another person.¹⁶³ Covering reasonable expenses incurred as a result of organ removal will not constitute buying and selling of tissues.

The punishment for unauthorised selling of an organ will be 50 penalty units¹⁶⁴ and unauthorised buying of an organ will lead to 100 penalty units or six months imprisonment or both. Section 40 deals with restrictions on advertisements and prohibits advertisements for buying and selling of organs unless the proposed advertisement has been approved by the Minister and contains a statement to that effect. Any violation would attract 50 penalty units or imprisonment for three months, or both.

5.5 PRESUMED CONSENT SYSTEM IN SPAIN

Presumed consent means that someone is believed to have given permission for the removal of the organ and transplant it to a potential recipient. Spain follows the system of presumed consent and a person has to specifically opt-out if he does not intend to donate his organs. Presumed consent plays a vital role in the organ transplantation system and has considerably contributed to the cadaver donation rate in Spain. As per the International Registry in Organ donation and transplantation, the organ donation rate of Spain stands at 37.9 per million.¹⁶⁵ Spanish system permits more government involvement in individual healthcare, and also enables the

¹⁶² *Human Tissue Act 1982* (Vic.) (Austl).

¹⁶³ *Id.* s 39(2).

¹⁶⁴ Penalty units determine the amount a person is fined when they commit an infringement offence. From 1 July 2021 to 30 June 2022, the value of the penalty unit is \$181.74 in the State of Victoria as stated in: Victoria State Government, *Penalties and values*, <https://www.justice.vic.gov.au/justice-system/fines-and-penalties/penalties-and-values>.

¹⁶⁵ International Registry, *supra* note 66.

government to easily collect data and build a donor registry which is managed by the Organizacion Nacional De Transplantes (ONT).

All Spanish citizens are assumed to have consented to organ donation on their death and the organs can be transplanted to a recipient unless the families explicitly refuse the same.¹⁶⁶ Spain is considered best in terms of its rate of deceased organ donation as the organ transplantation system in the country capitalises on brain deaths due to road accidents. The establishment of National Transplant Organization to coordinate cadaver donations at the national level and trained Transplant Donor Coordinators have also increased the rate of organ donations significantly.¹⁶⁷ Presumed consent is a great way to tackle organ shortage and the countries with presumed consent system has shown positive results in the organ donation rates. Apart from Spain, some other countries that follow presumed consent policies for organ donation are Austria, France, Columbia, Norway, Italy, and Singapore.¹⁶⁸

5.6 LEGAL SALE OF ORGANS IN IRAN

Iran is the only country in the world that offers a legal way to its citizens to sell their organs.¹⁶⁹ Buyers and sellers are registered through a government foundation that matches them up and sets a fixed price of \$4,600 per organ. More than 30,000 kidney transplants have been performed in Iran this way since 1993.¹⁷⁰ However, there are various ethical issues surrounding the same like people not operating through the government foundation, exploitation of the poor, people traveling from other countries with forged IDs to buy organs from Iran citizens.¹⁷¹ In the Iranian model, a patient in need of a kidney who does not have a living related donor is referred to the

¹⁶⁶ Organ India, *supra* note 88; C Rudge, *International Practices of Organ Donation*, 108 Suppl (1), BR J ANAESTH, 148, 151 (2012).

¹⁶⁷ TOHOA, *supra* note 113, at 8.

¹⁶⁸ Sheldon Zink et al., *Presumed vs Expressed Consent in the US and Internationally*, 7(9), VIRTUAL MENTOR, 610-614 (2005).

¹⁶⁹ Francesco & Luca, *Kidneys for sale: Iran's trade in organs*, THE GUARDIAN, (May 10, 2015), <https://www.theguardian.com/society/2015/may/10/kidneys-for-sale-organ-donation-iran>; Shashank Bengali & Ramin Bostaghim, *'Kidney for sale': Iran has a legal market for the organs, but the system doesn't always work*, LOS ANGELES TIMES, (Oct. 15, 2017), <https://www.latimes.com/world/middleeast/la-fg-iran-kidney-20171015-story.html> [Hereinafter 'Kidney for sale'].

¹⁷⁰ Kidney for sale, *supra* note 169.

¹⁷¹ Rupert WL Major, *Paying kidney donors: time to follow Iran?*, 11(1), MCGILL J MED, 67-69 (2008).

Dialysis and Transplant Patients Association to locate a suitable living-unrelated donor.¹⁷²

Though the major intention behind legalising sale of organs was to bridge the gap between demand and supply of human organs and thereby tackle organ shortage, the legal sale of organs has not cleared its waiting list and that trading between socioeconomic classes is a substantial problem.¹⁷³ Legalisation of sale and purchase of organs focuses more on donations from living donors which discourages cadaver organ donations which is a much effective way of dealing with organ shortage.

5.7 COMPARATIVE ANALYSIS

The United States of America and Australia follows an opt-in system like India and one has to expressly consent to organ donation before his death or authorisation can be given by next of kin in case of cadaver organ donation. Australia unlike India, does not have a federal law governing organ transplantations and organ donations in the country. The organ donations and transplantations are governed and regulated by the state and territorial legislations which are substantially similar with minor variations. The US also mainly regulates organ donations using UAGA which is adopted by all the states in the country though there is a federal law prohibiting commercialisation of organs. All the legislations related to organ donation as mentioned above in the US and Australia expressly prohibits any commercial dealings in human organs and tissues.

Unlike India, in the US, if an individual has registered to donate his organs in his lifetime, the permission for donation is legally binding and has to be carried out at the time of the donor's death under the UAGA, and his family does not have any right to override his decision. Personal autonomy is given great importance in this context and it is not only on paper, but the current practice in US is that most donations proceed even over objections from the family of the deceased.¹⁷⁴ Through this policy, the United States have experienced over 27% growth in deceased organ donors and

¹⁷² Ahad J. Ghods & Shekoufeh Savaj, *Iranian Model of Paid and Regulated Living-Unrelated Kidney Donation*, 1(6), CJASN, 1136-1145 (2006).

¹⁷³ Griffin A, *Kidneys on demand*, 334(7592), BMJ, 502-505 (2007).

¹⁷⁴ Glazier AK, *The principles of gift law and the regulation of organ donation*, 24, TRANSPL INT, 368-372 (2011).

transplants¹⁷⁵ and some areas of the country exceeds the donation rate of even Spain, which is considered as the country with the best donation rates across the world.¹⁷⁶

While NOTA is the federal law prohibiting commercialisation of organs, UAGA adopted by all the states with minor variations has played a vital role in increasing the number of donors and tackling organ shortage in the country. It provides a good regulatory framework prohibiting the commercialisation of organs as well as giving prime importance to the wishes of the deceased with respect to organ donation. In India, in practice, the respect for personal autonomy and free will of the deceased is totally neglected when the family of the deceased objects to the donation of his organs. The will of the relatives of the deceased supersedes over the will of the deceased in cadaver organ donation. Despite having pledged his organ or making his relatives aware of such wish to donate, the wishes of the deceased are entirely ignored and priority is given to the wishes of his family.¹⁷⁷

The State legislations in Australia prohibits advertising related to organ donation, however, it is permitted when it has been approved by the Minister for special reasons and any other advertisement seeking or offering organs constitutes an offence and is punishable under law. However, in India, the provision relating to the prohibition of advertisements does not expressly prohibit advertisements seeking or offering organs if the same is not a commercial arrangement. The ambiguity in this aspect helps people evade the law stating the same is an altruistic donation and there is no way to regulate such advertisements and ensure that no commercial arrangement is involved once the advertisement is made. As compared to the provision in Australia which makes it clear that the Minister can allow certain advertisements under special circumstances and it is otherwise strictly prohibited, India does not have a strong provision prohibiting advertisements seeking and offering human organs.

¹⁷⁵ United Network for Organ Sharing, *Deceased organ donors in United States exceeded 10000 for first time in 2017*, Jan. 09, 2018, <https://unos.org/deceased-organ-donors-in-united-states-exceeded-10000-for-first-time-in-2017/>.

¹⁷⁶ Gift of Life Donor Program, *Gift of Life Donor Program Records Busiest Organ Donation & Transplantation Month in U.S. History*, <http://www.donors1.org/about-us/media/press1/2017twonationalrecords/>; La Moncloa, *Spain is world leader in organ donation and transplantation for 25 straight years, smashing its own record and reaching 43.4 donors per million population*, (Jan. 11, 2017), <http://www.lamoncloa.gob.es/lang/en/gobierno/news/Paginas/2017/20170113-transplant2016.aspx>.

¹⁷⁷ Deceased donor related transplant, *supra* note 123.

Spain with a presumed consent policy has been successful in increasing the rate of cadaver organ donations and is regarded as the world leader of organ donations.¹⁷⁸ Iran unlike all the other countries across the world follows a different organ transplantation policy and organs can be bought and sold for cash in the country which raises serious ethical questions. Organ trade and trafficking is an international process that is not limited to the boundaries of a particular country and has its influence globally. Hence, each country should ensure that the prohibition on commercial dealings in human organs is implemented effectively and that citizens do not travel abroad to evade domestic law criminalising the same.

Each country has varied deceased donation rates depending upon the legislation in force, its implementation, the consent policy adopted and various other socio-economic factors. The donation rates in the United States, Australia, Spain, Iran and India are as follows:¹⁷⁹

Country	Legal position	Donation rate (per million population)	Donation policy
USA	Commercial dealings in organs prohibited	38.03	Opt-in
Australia	Commercial dealings in organs prohibited	18.0	Opt-in
Spain	Commercial dealings in organs prohibited	37.4	Opt-out
Iran	Sale and purchase of organs are legal.	7.80	NA
India	Commercial dealings in organs prohibited	0.52	Opt-in

¹⁷⁸ Jennifer, *Spanish 'are world leaders in donating transplant organs'*, THE TIMES, (Aug. 19, 2021), <https://www.thetimes.co.uk/article/spanish-world-leaders-donating-transplant-organs-hdkqptw8t#:~:text=Spaniards%20donate%20more%20organs%20after%20death%2C%20proportionally%20than%20any%20other,on%20Organ%20Donation%20and%20Transplantation.>

¹⁷⁹ International Registry, *supra* note 66.

The status of cadaver organ donations in various countries as analysed above makes it clear that India stands at a mere 0.52 as compared to substantially higher rates in other countries. Iran despite having legalised organ donations, a major part of organ donations constitutes living donations and does not make use of cadaver organs and hence, such a low rate of donation rate is estimated in the country. Spain with the best donation policy in place has one of the highest donation rates across the world. Presumed consent is an effective way to increase the cadaver organ donations thereby placing less demand on organs from living donors and the donation rate in Spain proves the same. Australia has a lesser donation rate as compared to the United States though the donation policies and legal position in the countries are similar to a great extent. The data suggests that the legalisation of sale of organs is not an effective way to deal with organ shortage due to various ethical aspects and does not increase the cadaver organ donations in the country.

5.8 CONCLUSION

Each country has a different take on organ donations and organ transplantations and is governed using federal or state laws as most suitable for administrative purposes. Iran is the one and only country in the world legalising sale and purchase of human organs. Most of the countries across the world stand against organ trade and trafficking and have their own legislations criminalising commercial dealings in human organs. Though there is no data available as to the effectiveness of these legislations in various jurisdictions in curbing the illegal practices associated to organ donations and transplantations, it can be seen that the consent policy and the implementation of legislations have played a significant role in improving the cadaver organ donations in various countries as stated in the table above. While Spain's high donation rates can be attributed to the presumed consent policy adopted in the country, the US even with an opt-in system has one of the highest donation rates across the world.

Implementation of the legislations are equally important and it has to be ensured by the authorities that it does not just remain on paper and is put into effect in an efficient manner thereby preventing any illegal practices with respect to organ donation and transplantation and exploitation of the poor by the rich. Taking into consideration the international instruments on organ trafficking while drafting or implementing legislations on the matter would also aid in reducing organ trafficking globally.

Council of Europe Convention against trafficking in human organs, World Health Organisation's Guiding Principles on Human cell, tissue and organ transplantation and Declaration of Istanbul are some of the major international instruments prohibiting commercial dealings and organ trafficking. Hence, it can be stated that the domestic laws of the country are dependent upon various factors including its administrative structure and socio-economic factors. However, each country should try to tackle the global issues of organ shortage and illegal practices in relation to the same with the available resources. Presumed consent is an effective way which can be adopted by the countries where there is adequate infrastructure, man-power and an effective system to implement the same. Suggestions to improve the situation in India on organ donations, reduce organ trade and trafficking in the country, measures that can be adopted for the effective implementation of the Transplantation of Human Organs and Tissues Act and for improving the rate of cadaver organ donations in the country are discussed in the next chapter.

CHAPTER VI: CONCLUSION

6.1 INTRODUCTION

Organ trade and Organ trafficking are some of the major issues in India and addressing the same effectively is the need of the hour. The Transplantation of Human Organs and Tissues Act, 1994 and the Rules have been critically analysed along with the factors contributing to organ trade in the country, flaws in the Act and the drawbacks with respect to its implementation. A comparative study analysing the legal position of organ donations and transplantations in the United States, Australia along with references to Spain and Iran where there is an extremely different take on organ donations have also been discussed. This chapter put forwards various recommendations to tackle the menace of organ trade in the country including adopting a different consent approach for organ donation and measures for effective implementation of the Transplantation of Human Organs and Tissues Act, 1994. It also includes various suggestions that can be incorporated in the Act to provide more clear and stringent provisions.

6.2 FORMS OF CONSENT FOR ORGAN DONATION

There exist various types of consent that are adopted in different countries across the world with respect to cadaver organ donations. The various forms of consent that exist across the world as exhaustively enumerated in the Report of the Organ Donation Task Force on “The potential impact of an opt out system for organ donation in the UK”¹⁸⁰ are as follows:

- **HARD OPT OUT SYSTEM:** Under this consent system, the medical professionals can remove organs from a person after his death, unless the potential donor had registered to opt out before his death.

Example: Austria.

- **HARD OPT OUT SYSTEM WHICH DOES NOT COVER SOME GROUPS:** This model is substantially similar to hard opt out system but does not cover some groups of people. Organs from an adult can be removed after his death, unless the person had registered to opt out or the person belongs to a

¹⁸⁰ Organ Donation Taskforce, *The Potential Impact of an Opt Out system for organ donation in the UK*, 10, (Nov. 2008).

particular group, which has been declared in Law to be against the system of opt-out consent system.

Example: Singapore, where the Muslims have been excluded from the opt-out consent mechanism for organ donation.

- **SOFT OPT-OUT SYSTEM:** Under this system, organs from an adult can be removed on his death, unless the prospective donor had registered to opt-out or his relatives have objection to the removal of organs.

Examples: Belgium; Spain also has this system to an extent as it is advisable for the authorities to ask the family of the potential donor for their consent at the time of his death.

- **SOFT OPT-IN SYSTEM:** Under the soft opt-in system, the medical professionals can remove organs from people who have expressly declared their consent for organ donation after their death. But in this system, it is advisable that the relatives of such person be consulted and if there is any objection on the part of the relatives, the organs may not be removed.

Example: The United Kingdom.

- **HARD OPT-IN SYSTEM:** Under this system, the organs of an adult can be removed from the body on his death, if such person had specifically declared his consent to donate his organs after death and the opinion of the relatives of the deceased is not given primacy and the consent of the deceased prevails.

- **CHOICE TO OPT-IN OR OPT-OUT:** Here there can be two options. One, where people can register their choice to opt-in or opt-out and two, where people must mandatorily register their choice to opt-in or opt-out for organ donation.

6.3 TIME TO ADOPT A DIFFERENT CONSENT SYSTEM IN INDIA

India follows an opt-in system of consent in relation to organ donations and it is the soft opt-in system where the will of the relatives are given primacy over the will of the deceased, rather than the hard opt-in system. This needs to be changed in order to ensure personal autonomy and to facilitate organ removal as per the will of the deceased and not the family. As discussed in previous chapters, it is clear that even if a person consents to donate his organs after his death and the family objects to it after his death, the authorities will not proceed with the removal of organ respecting the

wishes of the family and at the same time undermining the personal autonomy of the deceased.¹⁸¹ However, it is high time that we adopt a hard opt-in system of consent where the will of the deceased is always respected irrespective of the objections from the family, and gradually an opt-out system of consent which would be the best possible way to increase the donation rate in the country which stands at a mere 0.52 pmp.¹⁸²

Presumed consent or opt-out system was first enacted in Maryland¹⁸³ and a presumed consent legislation with respect to organ donation authorizes medical examiners, coroners and other concerned authorities to extract corneas, heart valves and other tissues from cadavers without first obtaining consent from the person previously alive, or from the person authorized to make donation decisions if the person is deceased. As discussed in the previous chapter, Spain follows such a system and the high rates of cadaver organ donations in the country can be attributed to the consent system followed. This form of consent system can be really effective in dealing with the issue of shortage of organs. Countries such as Spain, France, Belgium and Austria, which have presumed consent systems, have higher procurement rates than countries such as New Zealand and Australia,¹⁸⁴ which have systems of encouraged voluntarism. In a presumed consent or opt-out system, the distraught family members do not need to make a positive decision to authorise the organ removal as the deceased has been able to declare their objection to organ removal, if any, before his death and this rule out the need for permission of the family to approve the removal of organs and hence, doctors are spared the difficult task of asking for consent.¹⁸⁵

It is acknowledged that it is not easy to adopt an opt-out system in India being a country that follows various cultural, moral and ethical values. However, it is necessary to adopt such a consent system in order to tackle the issue of organ shortage and prevent people from losing their lives from end-stage organ failures. This can be done gradually by first adopting a strict hard opt-in system where the family of the deceased does not get to override the wishes of the deceased to donate his organs. Once such a system is in place, it would be easier to switch to the opt-out system

¹⁸¹ Deceased donor related transplant, *supra* note 123.

¹⁸² International Registry, *supra* note 66.

¹⁸³ Md. Code Ann., Est. & Trusts s 4-509.1 (West 2005).

¹⁸⁴ International Registry, *supra* note 66.

¹⁸⁵ C.M. Thomas, *Commercialisation of the Supply of Organs for Transplantation*, Discussion Paper Series, Massey University, School of Accountancy, (2001).

where the consent is not needed for organ removal after the death of a person, if he has not specifically objected to the same during his lifetime.

6.4 ISSUES WITH RESPECT TO ORGAN TRADE

Many people including medical professionals regard buying and selling of human organs as a win-win situation where both the donor and the recipient are benefitted due to the transaction.¹⁸⁶ However, the reality is not the same and there is a huge issue of exploitation of the poor by rich and middlemen. In addition to such exploitation, there are serious issues revolving around organ trade and it cannot be a win-win situation as it is widely propagated. Some of the major arguments against the commercial dealings in human organs are as follows:

6.4.1 CONSEQUENCES OF COMMERCIAL LIVING DONORS

There are various consequences with respect to commercial living donors after organ removal. Studies have shown that the impacts include negative health, economic, social and psychological consequences. It has been reported that there is a general deterioration in their health status, which is 86% in India. It has also been revealed that selling organs for getting rid of debts and poverty has also not solved such issues. Despite payments received from the recipients of organs, the economic status of commercial living donors tends to decline as a majority of them lose their ability to return to labour-intensive work, compromising their good health and capacity to generate income through such jobs. In India, such commercial living donors' average family income declined by one-third after the nephrectomy and 75% of them remained in debt even after selling their organs. A financially motivated organ donation also causes social and emotional harm to the living donors.¹⁸⁷ The data makes it clear that despite resorting to organ trade to resolve their economic crisis, the same does not help but in fact it adversely affects their health status leading to the inability to work in the future. Hence, commercial dealings in human organs, though it may appear that it would help the poor to solve their economic issues, it just adds to their misery.

¹⁸⁶ Mathew Abraham, *Human Trafficking: Issues Beyond Criminalization*, The Pontifical Academy of Social Sciences, Casina Pio IV, (2015); Tim Ficheroux, 'Organ trade can also be a win-win situation', ERASMUS MAGAZINE, (Jul. 25, 2017), <https://www.erasmusmagazine.nl/en/2017/07/25/organ-trade-can-also-win-win-situation/>.

¹⁸⁷ Budiani Saberi & Mostafa, *Care for commercial living donors: the experience of an NGO's outreach in Egypt*, TRANSPL. INT., (2010).

6.4.2 BENEFITS TO THE RICH AND EXPLOITATION OF THE POOR

It has been proved in the previous chapters that the poor have been widely exploited through the practice of buying and selling organs and the people who are desperate enough to sell their organs to lead a normal life are exploited by the rich and the middlemen. Their financial burdens force them to sell their kidneys to meet their very basic needs. Many of them later claim that the promised amount is not paid to them.¹⁸⁸ Proper follow-up of their health status is not carried out leaving them unattended once the organs have been procured, leading to serious health issues affecting their physical and mental health.

There is also a concern that once a market in human organs is permitted, it would be the wealthy who will be able to purchase the organs and the poor will not be able to afford the same. Organ distribution will be on the basis of wealth and not need.¹⁸⁹ This can seriously affect the very idea of accessibility of organs and resolving organ shortage through an organ market. Hence, it can be stated that there cannot be a market of organs where the poor are not exploited and the rich will always be in a better position to afford and access the organs.

6.4.3 HARM TO ALTRUISM

Organ trade would undermine the voluntary organ donations and if there is a market in organs, fewer people will donate and people will instead sell their organs. Since the current system of organ donation encourages and celebrates altruism and it is a virtue that needs to be upheld, commercial market in human organs could lead to lesser or no altruistic donations, leaving no way for people who cannot afford to buy an organ to survive. Such a market in human organs would eventually deprecate and destroy the present willingness of members of the people to donate their organs out of altruism.¹⁹⁰ Although sometimes promoted as a means of providing a solution to the shortage of organs, repeated experience has shown that commercial donation comes at the expense of altruistic donation and not in addition to it.¹⁹¹ Hence,

¹⁸⁸ TN's Kidneyvakkam, *supra* note 75; Inside 'Kidneyville': Rani's Story', *supra* note 75.

¹⁸⁹ JONATHAN HERRING, *MEDICAL LAW AND ETHICS*, (Oxford University Press) (5th ed. 2014) [Hereinafter 'Medical law and ethics'].

¹⁹⁰ Robyn S. Shapiro, *Legal Issues in Payment of Living Donors for Solid Organs*, 7, *CURRENT OPINION ON ORGAN TRANSPLANTATION*, 375-379 (2002).

¹⁹¹ Gabriel, *The high cost of organ transplant commercialism*, 85(2), *KIDNEY INTERNATIONAL*, 248-250 (2014).

commercialisation of human organs could stand in the way of altruistic donations and can in turn affect people who cannot afford to buy an organ.

6.4.4 COMMERCIALISATION OF THE HUMAN BODY AND ISSUE OF FREE CONSENT

The commercial dealings in human organs treat the organs to be mere commodities that can be bought and sold for payment just like any other commodity. This raises several ethical issues and the dignity of the human body will be compromised if they are treated as objects. This leads to a devaluation of the human body and it would be seen as simply a collection of parts, which can be disposed of at will.¹⁹² Ethically and morally, it will not be a good solution to commercialise and make the human organs mere commodities in order to address the organ shortage.

Another concern is that a person's consent for organ donation would not be genuinely autonomous because of the coercive, manipulative impact of the prospect of receiving money for the organ. Those who sell their organs are often driven by poverty or threats from debt collectors. Any person wanting to sell his organs must be driven by such desperation that such person's consent must be regarded as invalid.¹⁹³ There can be no genuine and free consent to the sale of organs and the three major arguments supporting the same are that the consent is not genuine as there is incompetence through ignorance, coercion by poverty and coercion by unrefusable offers.¹⁹⁴ Hence, the consent cannot be regarded as free will and can be coerced due to the various socio-economic conditions of the donor.

6.4.5 INCREASE IN TRANSPLANTATION COSTS

Organ transplantation being a complex procedure, the complexity has always been reflected in its cost too. Commercial market in human organs can result in a huge increase in the cost of organ transplantations. Payments for human organs could mean that additional costs would be transferred to the recipients making the already expensive procedure much more costly. This would mean that many people will not be in a position to afford the procedure and can result in millions losing their lives. As a country where there is a large disparity in the distribution of healthcare facilities

¹⁹² Medical law and ethics, *supra* note 189.

¹⁹³ *Id.*

¹⁹⁴ Janet Radcliffe, *Nephrologists goings on: Kidney sales and moral arguments*, 21, JMP, 375-416 (1996).

where the rural poor are unable to afford and access the healthcare system, this would have a devastating effect on them who might have to succumb to death due to the reason of high costs of organ transplantations.

6.5 SUGGESTIONS TO TACKLE ORGAN TRADE IN INDIA

Looking at the legal regime and the practice that is prevalent in other countries, one can safely conclude that the Indian law, howsoever well-intentioned it might be, lacks an implementation that would reconcile the apparently conflicting ends of meeting the ever-burgeoning organ deficiency and curbing the evil menaces of illegal organ trading.¹⁹⁵ Some recommendations to tackle organ trade in the country and to ensure effective implementation of the Transplantation of Human Organs and Tissues Act, 1994 are as follows:

6.5.1 PROMOTING CADAVER ORGAN DONATIONS

Though the Transplantation of Human Organs and Tissues Act, 1994 tries to promote cadaver organ donations in the country, the same has not picked up even after more than two decades of implementation of the Act. The issue of shortage in human organs and the wide gap between demand and supply of human organs can be alleviated through increasing the deceased organ donations in India. In India, there is a huge potential for deceased organ donations as the number of fatal road traffic accidents is high and this pool is yet to be tapped. As of 2006, India had 6% of the world's road accidents and the total number of road accidents is approximately 90,000 per annum. In 2005, one of the states, Tamil Nadu alone reported 13,000 fatal deaths due to road accidents. Tamil Nadu is the leading state in brain stem death organ donation in the country and has witnessed 136 donations in 2015.¹⁹⁶

The cause of death in around 40 to 50% of all fatal road accidents across the world is head injury leaving potential cadaver organ donors in the country from road accidents alone. Other causes of brain death such as sub-arachnoids' haemorrhage and brain tumours would potentially add more numbers. Even if 5 to 10% of these deceased persons became organ donors, there would be no requirement for any live organ

¹⁹⁵ B SANDEEPA BHAT, REFLECTIONS ON MEDICAL LAW AND ETHICS IN INDIA, (Eastern law house) (2016) [Hereinafter 'Reflections on Medical law and ethics'].

¹⁹⁶ *Tamil Nadu leads in brain dead organ donation*, NDTV, (Feb. 15, 2015), <https://www.ndtv.com/tamil-nadu-news/tamil-nadu-leads-in-brain-dead-organ-donation-739673>.

donations.¹⁹⁷ Hence, educating and convincing the relatives about the potential of saving lives from a brain-dead person as a result of road accidents can make a huge difference. Concentrating on increasing cadaver organ donations is expected to bring a fall in the illegal organ donations from living persons for financial reasons.

6.5.2 INCREASING THE LEVEL OF AWARENESS ON ORGAN DONATIONS

There exist groups of people who are unaware of the concept of organ donation and the illegality of commercial dealings in human organs. There are also myths and misconceptions about organ donation prevalent in the society preventing the general public from donating organs and, involving in commercial dealings in human organs. People need to be aware about the concept of organ donation on their death and that such an initiative can save many lives. While some people are aware of this, they do not know about the procedure or how it can be done. Availability of donor registration forms in hospitals, schools, universities, public officers, leaflets describing the procedure to register oneself for cadaveric donation which can be put up on notice boards at such institutions at a conspicuous place can improve the level of awareness in people.¹⁹⁸

Though it is not argued that awareness is the only factor guiding organ donations, it plays a significant role in increasing the number of organ donations in the country. If people are not aware or have misconceptions about the basic concepts of organ donation, it would adversely affect the organ donation rate. Increase in the level of awareness about organ donation among the public has resulted in a significant increase in the organ donation rate in the country.¹⁹⁹ Hence, increasing the level of awareness among the public about organ donations, especially cadaver organ donations, can contribute to a significant increase in organ donations in India and thereby lead to a substantial reduction in the commercial dealings of organs. Though there has been a change in the level of awareness over the years, the level has still not made it to a level to curb the illegal dealings in organs. Increasing the level of awareness and eliminating the misconceptions in the minds of the people can help in reducing the rate of organ trade in the country to a great extent.

¹⁹⁷ Legal and ethical aspects, *supra* note 83.

¹⁹⁸ Reflections on Medical law and ethics', *supra* note 195.

¹⁹⁹ Increase in awareness improve organ donation, *supra* note 90.

6.5.3 INCENTIVES TO ORGAN DONORS

Commentary to the WHO Guiding Principle 5²⁰⁰ states that the principle aims to affirm the special merit of donating human materials to save and enhance life. However, it permits situations where it is customary to provide organ donors with tokens of gratitude which cannot be measured in the form of money. The Principle allows compensation for the costs of making donations, including medical expenses and lost earnings for living donors, lest they operate as a disincentive to donation. The need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human organs for transplantation is also accepted as long as the human body and its parts as such are not a source of financial gain.

Though access to healthcare is a basic right that needs to be provided to everyone and not just something that has to be provided in exchange for human organs, free periodic medical assessments related to organ donation and insurance for death or complications that arise from the donation may legitimately be provided to living donors. Providing people with incentives in forms other than monetary benefits for organ donation can be an appreciation as well as an encouragement for more people to come forward to donate their organs after death. Measures can be adopted where the individuals who donate their organs are given facilities of free medical check-up and health insurance till their death, thereby acknowledging their generosity to the society. Such recognition and felicitation have the potential to attract more people into the generous act of donating the organs on their death.

6.5.4 PERSONAL AUTONOMY OVER WILL OF RELATIVES

One of the major issues with the implementation of the Transplantation of Human Organs and Tissues Act, 1994 is that the wishes of the relative override the will of the deceased and the organ removal is not carried out if the relatives object to the same after the death of the person who had consented to organ donation during lifetime.

²⁰⁰ “Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.”

Section 3(2)²⁰¹ and 3(4)²⁰² of the Act are not implemented effectively and the respect for personal autonomy and free will of the deceased is totally neglected when the family of the deceased objects to the donation of his organs. The will of the relatives of the deceased supersedes over the will of the deceased in cadaver organ donation. Despite having pledged his organ or making his relatives aware of such wish to donate, the wishes of the deceased are entirely ignored and priority is given to the wishes of his family.²⁰³

Since the Act tries to promote cadaver organ donations, it is a paradox that even the decision of a person who is willing to donate his organs after death is neglected when his relatives wish otherwise. The issue here is that as per the law, the autonomy of the deceased is respected only when he had objected to organ donation and not when he had agreed to the same.²⁰⁴ This is a serious breach of the personal autonomy of the deceased and disrespects his wishes to donate his organs. There should be effective measures adopted to ensure that when the person had already consented to donate his organs on his death, the procedure has to be carried out irrespective of the wishes of his family. If such practice is put into effect without any relaxations, it would mean that there is lesser time between death of such person and determination of the consent which would guarantee that the organ is as fresh as possible, thereby increasing the success rate of such transplantation.²⁰⁵ As mentioned above, a hard opt-in system should be strictly adopted and gradually, the country should strive for an opt-out system.

6.5.5 EFFECTIVE WORKING OF AUTHORISATION COMMITTEES

Authorisation Committees play a vital role in preventing commercial dealings in human organs and if they work efficiently, organ trade in India can be resolved to a great extent. As discussed in the previous chapters, as Authorisation Committees

²⁰¹ If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall, unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ or tissue or both from the dead body of the donor.

²⁰² The authority given by the donor shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ or tissue or both.

²⁰³ Deceased donor related transplant, *supra* note 123.

²⁰⁴ Transplantation of human organs, *supra* note 7.

²⁰⁵ Reflections on Medical law and ethics', *supra* note 195.

mainly comprise of medical authorities or medical professionals, it would be difficult to analyse whether there are any financial motives and commercial dealings involved in the organ donations. While the medical practitioners look into the medical aspects of the organ removal and transplantation, it is inevitable to ensure that the donation does not involve any commercial arrangements. Hence, it is essential to have persons with the necessary skills and expertise in the area especially while dealing with donations made out of affection or attachment or any other special reasons. This can help in preventing organ trade in the country and thereby ensure effective working of authorisation committees. Proper training of authorisation committee members to examine whether the cases coming before them for approval have any financial motives involved can also help in improving the efficiency of the Committees.

6.5.6 INCREASING THE PUBLIC HEALTH EXPENDITURE AND IMPROVING THE MEDICAL INFRASTRUCTURE

Organ transplantations being a complex procedure, need proper health infrastructure and adequate investment to carry out the same efficiently. Medical infrastructure is necessary to ensure that the objectives of the Transplantation of Human Organs and Tissues Act are achieved in the best possible manner. Increasing the donor pool without adequate facilities does not serve its purpose. This issue has to be addressed with special focus on the remote areas where even the basic amenities of healthcare are not always available. The low rate of organ transplantations from cadavers in the country can be attributed to the facilities in the Indian health system like lack of facility for the resuscitation of the victim at the accident spot, lack of well-equipped medical institutions, shortage of trained personnel in the Intensive Care Units, lack of quick communication and proper transport facilities, etc. Hence, in practice, the cadaveric donation technology is almost missing considering the large number of brain-stem death patients in India.²⁰⁶

India is one of the countries that invest the lowest in health sector as compared to other countries. India's public expenditure on healthcare stands at a mere 1.26% of GDP as of 2021 which is substantially low considering the large population and other socio-economic factors of the country.²⁰⁷ The public health infrastructure and public

²⁰⁶ Transplantation of Human Organs, *supra* note 7.

²⁰⁷ Indian Healthcare Industry, *supra* note 136.

health investment need to be improved substantially to improve the rate of organ transplantations in the country. Improving public health investment is not just needed to improve the status of organ transplantations in the country, but also as a solution to many serious issues faced by the health sector in the country.

6.6 RECOMMENDATIONS FOR UNAMBIGUOUS AND STRINGENT PROVISIONS IN THE ACT

- **CLARITY ON ‘AFFECTION’ OR ‘ATTACHMENT’:** Section 9(3)²⁰⁸ has been often referred to as a loophole supporting commercial dealings in human organs since there is no clarity on what constitutes ‘affection’ or ‘attachment’.²⁰⁹ The provision has to be tightened in order to prevent any commercial dealings in the pretext of ‘affection’ or ‘attachment’. There needs to be clarity on what constitutes ‘affection’ or ‘attachment’ and what can be the ‘special reasons’ sufficient enough to permit an unrelated donor to donate his organ to a patient and ensure that the same does not involve any commercial arrangements.
- **PROHIBITION ON ADVERTISING:** Section 19(f) does not expressly prohibit advertisements seeking or offering organs if the same is not a commercial arrangement. This has led to problematic interpretations where the Courts have been allowing advertisements stating that it does not establish any commercial motives and are purely altruistic organ donations. Since there is no way to regulate such advertisements and ensure that there is no financial motive involved once such advertisement is made, the provision has to be made clear on this aspect and any advertisements for human organs have to be prohibited. Alternatively, state or national organ donation systems or regulatory authorities like National Organ and Tissue Transplantation Organisation can be used to address the demand and supply of organs purely on altruistic motives without any direct contact between the donor and recipient.
- **REDUCING THE WAITING PERIOD FOR UNCLAIMED DEAD BODIES:** Section 5 of the Act allows removal of any human organ from the unclaimed dead body in hospital or prison, if the authorities are unable to locate

²⁰⁸ A person can donate his organ to someone who is not a near relative for the reason of affection or attachment towards the recipient or for any other special reasons with the prior approval of the Authorisation Committee.

²⁰⁹ Legal and ethical aspects, *supra* note 83; Loopholes in Indian Transplant Law, *supra* note 103; Transplantation of Human Organs, *supra* note 7.

near relatives of the deceased within 48 hours of the death on a reasonable enquiry. Since a dead body would be decomposed in 48 hours under normal circumstances and the organs from the body cannot be utilised even if the body is not claimed after 48 hours,²¹⁰ the waiting time needs to be reduced to 24 hours as the organs can be removed in a healthy state soon after death and ensure that potential organs do not go waste.

- **CLARITY ON DEFINITION OF ‘DEATH’:** Since there are multiple definitions of death under other statutes like Indian Penal Code, 1860²¹¹ and Registration of Births and Deaths Act, 1969²¹², there is a need to ensure that there are no ambiguities regarding the declaration of brain death or the time of declaration of death. Hence, it is important that the definition under the Transplantation of Human Organs and Tissues Act, 1994 is made applicable for the purposes of the Act irrespective of the different definitions under the other two statutes and the same be stated expressly under the Act.
- **SIMPLIFY PROCEDURE TO FILE A COMPLAINT:** Section 22²¹³ of the Act provides for a cumbersome procedure to file a complaint and the provision needs to be modified in such a way that the public can access the court directly and avoid any unnecessary delay. The procedure to file a complaint under the Act needs to be simplified and hence the requirement for filing a complaint through an Appropriate Authority has to be removed in order to permit people to approach the courts directly.
- **NEED FOR EMERGENCY PROVISIONS:** Though the very nature of organ transplantations demands expeditious decision making with respect to approval of organ removal and transplantation, the Act fails to lay down any specific time limit for deciding the matters before the various authorities constituted under the Act. Rule 23(2) under the Act states that the Authorisation Committee has to take decisions expeditiously where a patient requires the transplantation on an urgent basis, but still does not provide any specific time limit for making decision on matters related to organ donations. Hence, the Act should provide for a specific

²¹⁰ Recommendations, *supra* note 116.

²¹¹ IPC, *supra* note 15.

²¹² Registration of Births and Deaths, *supra* note 16.

²¹³ Section 22 states that the Court cannot take cognizance of an offence under the Act except on a complaint made by the Appropriate Authority or a person who has given notice of not less than sixty days to the concerned authority, of the alleged offence and of his intention to make a complaint to the court.

time period for granting or refusing approval to transplantations to ensure that the patients who are critically ill do not lose their lives waiting for the decision of the Authorisation Committees and are not forced to rely on illegal practices due to the delay.

6.7 CONCLUSION & SUGGESTIONS

The Transplantation of Human Organs and Tissues Act, 1994 has failed miserably to prevent commercial dealings in human organs or promote cadaver organ donations in the country. The Act has several ambiguous provisions making it easier to evade the law and carry out illegal practices in human organs. This needs to be changed through appropriate amendments incorporating clear and more stringent provisions. This can be done through bringing clarity on what constitutes ‘affection or attachment, or what the ‘special reasons’ are, eliminating ambiguity on the definition of death, simplifying the procedure to file a complaint under the Act, incorporating new provisions laying down specific time limit for deciding matters before the authorities, reducing the waiting period for removal of organs from unclaimed dead bodies, etc.

There can also be various measures adopted to ensure the effective implementation of the Act as explained above. Promotion of cadaver organ donations, ensuring effective working of Authorisation Committees, increasing the level of awareness on organ donations, giving primacy to personal autonomy of the deceased over the will of the family, etc are some measures that can be adopted to tackle the rampant organ trade in the country. India has to gradually adopt the presumed consent system by first adopting a hard opt-in system which could make the shift easier. Since poverty and unemployment are some of the major contributing factors to organ trade in the country, fighting poverty and ameliorating the health conditions of every citizen can eventually help in tackling the menace of organ trade in the country. It is the need of the hour that India takes efficient measures to improve the healthcare system in the country through improving the medical infrastructure, increasing public health expenditure significantly and ensuring effective implementation of the health-related legislations in the country.

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