IJRAR.ORG E-ISSN: 2348-1269, P-ISSN: 2349-5138

INTERNATIONAL JOURNAL OF RESEARCH AND ANALYTICAL REVIEWS (IJRAR) | IJRAR.ORG

An International Open Access, Peer-reviewed, Refereed Journal

LEGAL AND ETHICAL APSPECTS OF ORGAN TRANSPLANTATION IN INDIA

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Abstract: World Health Organization[1] defined health as "A state of complete physical, mental and social wellbeing, not merely absence of disease or infirmity".[2] In India the right to health is human right and is as old as Vedas. Our constitution also declares that safeguarding human life is of the utmost importance in Article 21[3] in addition to banning commercial transactions in human trafficking (Article 23).[4] Organ transplantation was first proposed in response to discovery of vascular anastomoses[5]. A lucrative, international criminal organization that allows organs seekers to acquire organs from donors has emerged in response to the urgent need of organ transplantation especially in India, Iran, Pakistan, Bolivia, China, Brazil, Moldova, Israel, Moldova, Peru, Columbia and Turkey[6] and is known as 'organ trafficking 'with annual revenues estimated to range from US$ 840 million to US$ 1.7 billion.[7] In 2022, there were total of 1, 57,494 organ transplants worldwide[8]. India has long been called as a "warehouse for kidneys" as organs from underprivileged people are inexpensive and widely available. India now serves as 'International Center for Kidney Transplantation'. As per the report by National Organ and Tissue Transplant Organization the total number of transplantation was at its highest 16,041 with an increase of 30% in 2022 both in living and cadaver donations. There existed complete transformation of Indian legal framework relating to organ transplantation after passing of the Transplantation of Human Organ Transplantation Act, 1994. Keeping these issues in mind the current research have been carried out with the following objectives such as to discuss the factors adversely affecting well-being and health of people, to find out the endorsement of right to health and how far it is recognized, to analyze the role of judiciary in ensuring health, , to consider the legal control mechanism for preventing illegal organ transplantation, to identify legal loopholes in implementation of the organ transplantation law and to analyze the transformation of Indian legal framework relating to organ transplantation after passing of the Transplantation of Human Organ Transplantation Act, 1994. Methodology adopted for the present research paper is qualitative and doctrinal where date used has been collected from both primary and secondary sources.

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1 World Health Organization hereinafter referred as WHO

2 Ibid.,

3 For detail, see Article 21 of Constitution of India, 1950.

4 For detail see Article 23 of Constitution of India, 1950.

5 It involve surgical connecting of two previously unconnected blood arteries

6 Yosuke Simazano, "The State of the International Organ Trade : a provisional picture based on integration of available information", *Bulletin of the WHO*, Vol. 85(12), 2007, available at https://www.who.int/bulletin/volumes/85/12/06-0399370.pdf, last accessed on 20/04/2024

7 Transnational Crimes, Executive Summary, www.gfintegrity.org, available at https://www.gfintegrity.org/wp-contents/uploads/2017/03/Transnational_Crime-final_exec-summary.pdf, last accessed on 20/04/2024.

8 John Elflein, "Global number of Organ transplants in 2022", available at htttps://www.statista.com/ statistics/398645/global-estimation-of-organ-transplantations/, last accessed on 29/04/2024

Index Terms - **Health, transplantation, human organ, legal framework**

INTRODUCTION

World Health Organization[9] defined health as "A state of complete physical, mental and social wellbeing, not merely absence of disease or infirmity".[10] In India the right to health is human right and is as old as Vedas. Our constitution also declares that safeguarding human life is of the utmost importance in Article 21[11] in addition to banning commercial transactions in human trafficking (Article 23).[12]

Organ transplantation was first proposed in response to discovery of vascular anastomoses[13]. A lucrative, international criminal organization that allows organs seekers to acquire organs from donors has emerged in response to the urgent need of organ transplantation especially in India, Iran, Pakistan, Bolivia, China, Brazil, Moldova, Israel, Moldova, Peru, Columbia and Turkey[14] and is known as 'organ trafficking 'with annual revenues estimated to range from US$ 840 million to US$ 1.7 billion.[15] In 2022, there were total of 1, 57,494 organ transplants worldwide[16].Kidney and renal transplantations are most common type of transplants worldwide followed by the liver and the heart. Most kidney transplants are done in America and Europe where there are large number of donors and better access to such procedures .Spain tops the list with the highest numbers of donors with 35.3 donors per million, having opt-in and opt-out policy. However, in India there exists no such policy.

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Dr. Ramesh Kumar (2019)[17] have given a detailed description about the procedure by which kidney transplants are being conducted in India ,how scams are being done and formation of cartels by the hospitals and doctors description. **E.F Wijdicks (2017)[18]** has elaborated the idea of Brain Death. **Micheal Davis(1998)[19]**has illuminated the ethical as well as moral concerns with the live and cadaver transplantations . **George J Annas(1985)[20]**has discussed issues associated with patient selection and scarcity of organs and difficulties relating to organ transplant.**K. Mathiharan and A.K Patnaik (2008)[21]** have discussed various

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9 World Health Organization hereinafter referred as WHO

10 Ibid.,

11 For detail, see Article 21 of Constitution of India, 1950.

12 For detail see Article 23 of Constitution of India, 1950.

13 It involve surgical connecting of two previously unconnected blood arteries

14 Yosuke Simazano, "The State of the International Organ Trade : a provisional picture based on integration of available information", *Bulletin of the WHO*, Vol. 85(12), 2007, available at https://www.who.int/bulletin/volumes/85/12/06-0399370.pdf, last accessed on 20/04/2024

15 Transnational Crimes, Executive Summary, www.gfintegrity.org, available at https://www.gfintegrity.org/wp-contents/uploads/2017/03/Transnational_Crime-final_exec-summary.pdf, last accessed on 20/04/2024.

16 John Elflein, "Global number of Organ transplants in 2022", available at htttps://www.statista.com/ statistics/398645/global-estimation-of-organ-transplantations/, last accessed on 29/04/2024

17 Ramesh kumar, "Kidney transplants and scams : India's troublesome legacy", sage publications, 2019.

18 E.F Wijdicks, "Brain death", OUP USA, 2017

19 Micheal Davis, "Medical Law", Blackstone press ltd., 1998.

20 George J Annas, "Regulating Heart and Liver Transplantation", Jurimetrics Journal, 1985, www.scholarship.law.bu.edu, available at https://scholarship.law.bu.edu/faculty_scholarship/3518

21 K. Mathiharan and A.K Patnaik, "Modi's Medical Jurisprudence And Toxicology", *LexisNexis Butterworths India*,2008

aspects of medical jurisprudence including brain steam death. **Columbia Law Review (1969)**[22] describes the importance of voluntary donation. **Eliot Corday (1969)**[23] enumerates the question of Law, Ethics and public policy relating to organ transplantation. **Judith Areen(1988)**[24]analyze the role of Law in Human Organ Transplantation and scarcity of organs. The scarcity has been a problem despite increasing rate of potential donors. Various case laws giving the wide interpretation of transplant law implemented in India has been discussed in the book. **Jugal Kishore (2005)**[25] in his has described the national policies and legislations relating to health.

CONCEPT

Who can donate?

Any person above 18 can donate his organs at any stage of his life or even after death with the consent of next to kin for removal of organs for the purpose of transplantation.[26]

Who is an Organ recipient?

Any person into whom any human organ or tissue or both is, or is proposed to be, transplanted.[27] They are severely ill people in the last stages of organ failure.In India National Organ and Tissue Transplant Organization (NOTTO) has been established under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India It has two divisions namely National Biomaterial Center and National Human Organ and Tissue Removal and Storage Network for the removal and storage of human organs and tissues[28]. It serves as Delhi's nodal networking agency and has the following functions…..

- Establish protocols and policy standards for different functions and make connections with like-minded state and regional groups.
- Compilation and publication of all register data from States and Regions
- Raising awareness and promoting transplantation and organ donation initiatives.
- Information sharing with hospitals, individuals, and all relevant entities.
- Keeping a data &eye on transplantation activities in the states and regions.
- Support the administration of data for organ donor and organ transplant surveillance.
- Assistance with regard to legal and extra-legal matters pertaining to transplantation and donation.
- Organize and plan trainings for different worker cadres.[29]
- Organizing the distribution and acquisition of tissues
- Screening of donor tissue extraction and storage
- Monitoring Tissue Sterilization Data security, confidentiality, and record keeping of details on the patient's.
- Helping additional tissue banks with their registration as needed.[30]

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22 "Compulsory removal of Cadaver organs", *Columbia Law Review*, Vol. 69(4), 1969 at pp. 693-705.

23 E. Corday, "Life and Death in Human Transplantation", *American Bar Association Journal*, Vol. 55(7), 1969 at pp. 629-632.

24 J.C Areen, "A Scarcity of Organs", *Georgetown Law Faculty Publications and Other Works*, www.scholarship.law.edu, available at https://scholarship.law.georgetown.edu/facpub/1438, last accessed on 17/10/2024.

25 Jugal Kishore, "National Health Programs: National Policies and Legislation Related to Health*", Century Publications*, 2005.

26 For detail, see Section 9 of Transplantation of Human Organs Act, 1994

27 For detail, see section 2(m) of Transplant of Human Organs Act, 1994.

28 National Organ and Tissue Transplant Organisation, www.notto.mohfw.gov.in, available at https://www.notto.mohfw.gov.in/about-us.htm, last accessed on 16/10/2024.

29 Ibid.,

30 Ibid.,

Table 1.1
Synoptic View of tissue and organs available for donation after brain stem death[31]

• Kidney
• Heart
• Liver
• Cornea
• Skin
• Pancreas
• Bones
• Intestines
• Veins

Source: Article on Organ Donation- Current Indian Scenario by S. Nallusamy and Balaji Shyamalapriya. Available at: https://www.rsearchgate.net/publication/330317160Organ_donation_current_indian_scenario.

Table 1.2
Synoptic view of deadline of cadaver organ transplantation

Organ	Deadline
Heart	4-6 hours
Lungs	4-8 hours
Intestine	6-10 hours
Liver	12-15 hours
Pancreas	12-24 hours
Kidney	24-48 ours

Source: Adopted from National Organ and Tissue Transplant Organization. Available at https://notto.mohfw.gov.in

Important organizations involved in organ donation in India

The MOHAN Foundation an NGO established a free helpline in August 2012.[32]It maintains database with details on eye banks, skin banks, donation centers, and non-governmental organizations supporting this helpline. The number is promoted through print, web, and television advertising and responded by well trained staff members.[33] 95% of callers find the number online and through the MOHAN Foundation.

HISTORICAL BACKGROUND

Buddhism

Life is seen as eternal in Buddhism. Only a shift in perspective. A Buddhist believer therefore sees the act of getting an organ from a donor and spending significant sums of money to have it fitted into the patient's body in order to save their life as an act of self- fantasy that may indicate a lack of awareness of one's own spiritual identity. In the dying phase, mental clarity is crucial since it affects the likelihood of one's next incarnation. Even the majority is of the opinion that serving the donor's body will lessen the possibility of reincarnation. As a result, neither the Buddhist philosophy nor it's teaching's advocate organ transplantation.[34]

Hinduism

Donating one's organs is not against Hinduism. In the presence of close family, the Hindu religion permits the entire burning of a dead person's body. Hindus who practice religion generally avoid organ donation from corpses. The Hindu mythological God of medicine is known as Dhanvantari. Soon after creation, Lord Shiva replaced the head of the Hindu deity Lord Ganesha with the head of an elephant (Rigveda, 1500 B.C). In Hindu Sacred tradition, Sushruta – known as the "father of surgery" – is reverently regarded as the progenitor of who pioneered transplantation.[35]

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31 S. Nallusamy and Balaji Shyamalapriya,"Organ Donation- Current Indian Scenario", Journal of Practice of Cardiovasular Sciences, Vol. 4(3),2018,pp. 177-179

32 H. Knvinde, S Shroff, P Kumar, J Jairam, "Experiences and challenges in an Ngo run Organ Donation Helpline", *Transplantation*, Vol. 102, 2018,at p. 197.

33 Ibid.,

34 M. Slabbert & F.D Mnyongani, "Law, Religion and Organ transplants", Vol. 76(2), 2011, pp. 261-282.

35 Ibid.,

Christianity

Saints, Cosmas and Damian are famous in Christian history for replacing a Christian disciple's unhealthful limb with a black moor's limb, making them the patron saints of doctors and surgeons..[36]Any act of charity, including donating an organ, is encouraged by Christian faith. Christians are still reluctant to donate their organs as they believe that they'll one day rise.[37] As a result, there is conflict between Christian faith and charity, which is further strengthened by Immanuel Kant's ideas. Kant holds that one shouldn't view themselves or other people as means to a purpose.

Islam

In the eyes of Muslims, "breaking a dead person's bone is equivalent to breaking it while that person is still alive".[38] On basis of this belief, many Muslims oppose cutting open a person's body to remove their organs. However, the Shariah law permits an incision to be done on pregnant women for saving the unborn child.[39]In a similar vein, organ removal under specific guidelines may be acceptable if it benefits the society as whole.

INTERNATIONAL PRACTICES RELATED TO ORGAN DONATION AND TRANSPLANTS

Guiding principles on human cell, tissue and organ transplant[40]

The 63rd World Health Assembly adopted the WHO Guiding Principles on May 2010, by Resolution WHA63.22 .These are as follows….

- If the dead person's agreement is obtained as needed by law and there is no cause to suspect that they opposed to the removal, cells, tissues, and organs may be taken from their bodies for transplantation.[41]
- When a doctor determines that a possible donor has passed away, they shouldn't be actively engaged in the removal of the donor's cells, tissues, or organs or in the subsequent transplantation procedures..[42]
- Live donors should be fully and comprehensibly informed of the likely dangers, rewards, and repercussions of their donation and should be doing voluntarily, free from undue pressure or influence.[43]
- With the exception of certain limited conditions no living minor's cells, tissues, or organs should be removed for transplantation. When possible, the juvenile's consent should be sought prior to donation, and specific safeguards should be in place to protect the minor.[44]
- Donating cells, tissues, and organs should only be done freely and without receiving remuneration or any other kind of financial benefit.[45]
- Ads or public appeals may be used to promote the selfless donation of human cells, organ & tissues in compliance with national laws.[46]
- If the cells, tissues, or organs involved were obtained by exploitation, coercion or payment to the person who is the donor or the next of kin of a donor who has died, then doctors and other medical professionals should refrain from performing transplantation procedures, and health insurers and other payers should not cover such procedures.[47]
- It's required to be illegal for any medical facility or professional involved in the procurement and transplant of cells, tissues, or organs to be rewarded more than the reasonable cost of the services provided.[48]

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36 Holy Bible. American Standard Version, Bible Domain Publishing, 2013.

37 Ibid.,

38 Ebrahim A.F.M & Haffejee A.A, "The Shari'ah and Organ transplants", Durban: Islamic Medical Association, 1989

39 Ibid.,

40 WHO Guiding principles on human cell, tissue and organ transplant, as endorsed by the sixty third World Health Assembly in May 2010, in resolution Wha63.22.

41 For detail, see guiding principle 1 of WHO guiding principle on human cell, tissue and organ transplant

42 For detail, see guiding principle 2 of WHO guiding principle on human cell, tissue and organ transplant

43 For detail, see guiding principle 3 of WHO guiding principle on human cell, tissue and organ transplant

44 For detail, see guiding principle 4 of WHO guiding principle on human cell, tissue and organ transplant

45 For detail, see guiding principle 5 of WHO guiding principle on human cell, tissue and organ transplant

46 For detail, see guiding principle 6 of WHO guiding principle on human cell, tissue and organ transplant

47 For detail, see guiding principle 7 of WHO guiding principle on human cell, tissue and organ transplant

48 For detail, see guiding principle 8 of WHO guiding principle on human cell, tissue and organ transplant

- Clinical standards and ethical principles, not money or other factors, should direct the distribution of organs, cells, and tissues.[49]
- The planning, carrying out, and clinical outcomes of donation and transplantation operations must be open and transparent, while guaranteeing the privacy and anonymity of donors and receiver is always safe.[50]

World Health Organization

The World Health Organization adopted Guiding Principles on Human Organ Transplantation in 1991, with a focus on important topics like free and voluntary informed consent and the non-commercialization of human organs and tissues[51]. The Guiding Principles were updated and republished in 2010, with the addition of "measures to protect the poorest and vulnerable groups from transplant tourism and the sale of organs and tissues."

World Medical Association

The World Medical Association (WMA, 1985)[52], has declared that it "condemns the purchase and sale of human organs for transplantation, and calls on governments to take effective steps to prevent the commercial use of human organs." The World Medical Association General Assembly updated its Statement in October 2006 and restated its proscription against commercialism.[53]

Declaration of Istanbul

The Declaration of Istanbul (DOI,2008)[54]offers guidelines for organ donation and transplantation along with practical recommendations to stop, prevent, and mitigate human organ trafficking[55]. It prohibits organ trafficking, transplant commercialism, and transplant tourism. It defines these as exploitative practices targeting vulnerable populations and urges governments to outlaw the purchasing of organs, ensuring transplantation is equitable and ethical.

Council of Europe Resolution 1978

In 1978 the Committee of Ministers of the Council of Europe adopted Resolution (78)29[56].Under Article 9[57] it forbade the sale of any human material, whether it came from living or dead people .It addressed topics like respecting the anonymity of donors and recipients and obtaining informed consent for donations (both living and dead). It lays out these principles to be incorporated into national laws of European Union member states however not legally binding.

INTERNATIONAL PRACTICES RELATED TO ORGAN DONATION AND TRANSPLANTS

United States Law

Table 1.3
Synoptic view of The Uniform Anatomical Gift Act[58], 1987

SECTIONS	INTERPRETATION
SECTION 1	A person who consents to donate their own body or authorized to donate the body of another people (member of their immediate family).[59]

[49] For detail, see guiding principle 9 of WHO guiding principle on human cell, tissue and organ transplant

[50] For detail, see guiding principle 11 of WHO guiding principle on human cell, tissue and organ transplant

[51] WHO, World Health Assembly. Resolution WHA42.5 On "Preventing the purchase and sale of human organs:" and Resolution WHA 44.5 on "guiding principles on Human Cell, Tissue and Organ Transplantation", 1991.

[52] WMA Statement on Live Organ Trade, 1985

[53] WMA Statement on Human Organ Donation and Transplantation, adopted by the 52nd WMA General Assembly in Edinburgh, Oct 2000.

[54] For detail, see Declaration of Istanbul, available at https://declarationofistanbul.org, hereinafter referred as DOI for further reference.

[55] Steering Committee of the Istanbul Summit, "Organ trafficking and transplant tourism and commercialism: The Declaration of Istanbul", *Lancet 2008*, Vol. 372, pp. 5-6.

[56] Council of Europe, Committee of Ministers, Resolution 29(78) on "Harmonization of legislation of member states relating to removal, grafting and transplantation on human substance", adopted on 11 may 1978.

[57] For detail, see Article 9 of Council of Europe Resolution, 1978.

[58] Herein after Uniform Anatomical Gift Act,1987 will be written as UAGA,1967 for further reference

[59] For detail, see section 1 of Uniform Anatomical Gift Act, 1967, available at https://www.uniformlaws.org/shared/docs/anatomical_gift/uaga%201968_scan.pdf, last accessed on 16/02/2024.

SETION 2	Firstly the decedent if they are an adult and still alive. Secondly the decedent's next of kin, if an adult, has the power to donate the dead body if the decedent has passed away.[60]
SECTION 3 .	It includes people who will receive the gift for transplantation as well as hospitals, medical schools, universities, and storage facilities used for research and education.[61] The correct paperwork must be signed by the donor voluntarily.[62]
SECTION 5	Explains the procedure for delivering the gift documentation. [63]
SECTION 6	Deals with the process of modification / cancellation of a gift.[64]
SECTION 7	Deals with process of donation at death which requires a doctor to confirm the decedent's time of death.[65]

Table 1.4
Synoptic view of The National Organ Transplant Act, 1984

TITLE	INTERPRETATION
TITLE 1 **Task group on Organ Procurement and Transplantation**	It mandates the Health Secretary and Human Services to create a Task group consisting of 25 persons with the following task- Addressing all medical, legal, ethical, economic and social concerns arising from the transplantation of dead people's organs. Evaluating the usage of immunosuppressive medication to stop organ rejection in transplant patients Putting together a report that evaluates both public and private efforts to obtain dead people's organs, discuss difficulties and making recommendations Evaluation of the benefits and creation of national database for dead human organ donors.[66]
Title II **Organ Procurement Activities**	The Act includes arrangements for the creation of the OPTN, a membership association for entities involved in organ transplantation.
Title III **Prohibition of Organ Purchases**	Anyone who willfully obtains receives, or otherwise transfers an organ for usage in transplantation among human is prohibited by the Act .A $50,000 fine, up to five years in jail, or both may be imposed for

60 For details, see section 2, Uniform Anatomical Gift Act, 1967

61 For detail, see section 3,Uniform Anatomical Gift Act,1967

62 For detail, see section 4, Uniform Anatomical Gift Act, 1967

63 For detail, see section 5,Uniform Anatomical Gift Act, 1967

64 For detail, see section 6,Uniform Anatomical Gift Act, 1967

65 For detail, see section 7,Uniform Anatomical Gift Act, 1967

66 For detail, see Section 101(3), National Organ Transplant Act, 1984.

	breaking this law, as per Section 301.

United Kingdom Law

Table 1.5
Synoptic view of Human Tissues Act (Scotland), 2006

SECTIONS	INTERPRETATIONS
Section 3 Use of part of body of dead person for transplantation, research etc.[67]	Any part of the body of a dead person may be removed from the body and used, for transplantation, research, education or training and audit provided it shall be in accordance with section 6, 7, 8, 9 10 and 11.[68]
Section 6 Authorization: adult[69]	lult can authorize the removal and use of a part of his after his death either in writing or expressed verbally writing.[70]
Section 7 Authorization by adult's nearest relative[71]	If any adult has not provided any kind of authorization to donate it can be given by the nearest relative of the dead adult in writing .[72].But he cannot give the authorization if he knows that the adult was not willing to donate any part of his body for transplantation. [73]
Section 8 Authorization: child 12 years of age or over[74]	A child over the age of 12 has authority to authorize the removal of his/her organ after his death. in writing and can be withdrawn only in writing.[75]If the child cannot see and write authorization may be signed as signatory but this should be witnessed by a witness.[76]
Section 10 Authorization as respects child who dies under 12 years of age[77]	If a child dies under the age of 12 his/her parents may authorize for the removal of a child's organs for the purpose of transplantation.[78]
Section 11 Removal of part of body of dead person:	Before passing away, a person may declare their desires for

67 For detail see section 3 of Human Tissues (Scotland) Act, 2006.

68 Ibid.,

69 For detail see section 6 of Human Tissues (Scotland) Act, 2006

70 Ibid.,

71 For detail see section 7 of Human Tissues (Scotland) Act, 2006

72 For detail, see section 7(6) of Human Tissue (Scotland) Act, 2006

73 For detail, see section 7(4) of Human Tissue (Scotland) Act, 2006.

74 For detail see section 8 of Human Tissues (Scotland) Act, 2006

75 For detail, see section 8(1) & 8(2) of Human Tissues (Scotland) Act, 2006.

76 For detail, see section 8(3) of Human Tissues (Scotland) Act, 2006.

77 For detail see section 10 of Human Tissues (Scotland) Act, 2006

78 For detail, see section 10(1) of Human Tissue (Scotland) Act, 2006

further requirements[79]	organ donation in writing, verbally, or through a third party, preferably a close relative. A person can become an organ donor in a number of ways, including putting their name to the NHS Organ Donor Register, signing an organ donor card, or personally contacting medical staff or family members.
Section 16 Offences: removal or use of part of body of dead person for transplantation, research etc.[80]	rson commits an offence if he removes a part of the body ead person for any of the purposes ut authorization.[81]and shall be punished with 12 ns imprisonment and fine in case of a summary ction and 3 years imprisonment and fine or on conviction on indictment.[82]
Section 17 Restrictions on transplants involving live donor[83]	A person commits an offence if he removes or uses any organ or tissue or any part of organ from body of a child, living adult or living adult with incapacity with the intention of using it for the purpose of transplantation with a knowledge that the organ is being removed from the body of a child, living adult or living adult with incapacity.[84]and is liable on summary conviction for a term not exceeding 12 months and fine not exceeding level 5 on a standard scale or both.[85]
Section 50 Nearest relative[86]	The nearest relative is the person who immediately before the adult's death was— The spouse or civil partner of the adult; Live –in relationship for not less than 6 months; The child of the adult; The parent of the adult; The brother or sister of the adult;

[79] For detail see section 11 of Human Tissues (Scotland) Act, 2006

[80] For detail see section 16 of Human Tissues (Scotland) Act, 2006

[81] For detail, see section 16(1) of Human Tissue (Scotland) Act, 2006.

[82] For detail, see section 16(3) of Human Tissue (Scotland) Act, 2006.

[83] For detail see section 17 of Human Tissues (Scotland) Act, 2006

[84] For detail, see section 17(1) & 17(3) of Human Tissues (Scotland) Act, 2006.

[85] For detail, see section 17(9) of Human Tissues (Scotland) Act, 2006.

[86] For detail see section 50 of Human Tissues (Scotland) Act, 2006

	The grandparent of the adult; The grandchild of the adult; The uncle or aunt of the adult; The cousin of the adult; The niece or nephew of the adult; Adult's friend of longstanding.

NATIONAL PRACTICES RELATING TO ORGAN DONATION AND TRANSPLANTS

As follows-

- The Transplantation of the Human Organs Act of 1994
- The Transplantation of Human Organs (Amendment) Act, 2011
- The Transplantation of Human Organs and Tissues Rules, 2014

The Transplantation of Human Organs Act, 1994[87]

Based on the recommendations of L.M Singhvi committee report The Transplantation of Human Organs was enforced [88] on July 8, 1994. Its main goals are to outlaw the selling relating directions of human organs for profit and to deal with the the removal, preservation and transplantation of human organs for medical treatment. Brain Stem Death is defined as "the stage at which all functions of the brainstem have permanently and irrevocably ceased and is so certified under sub- section (6) of Section 3[89]" and a deceased person is defined as "a person in whom permanent disappearance of all evidence of life occurs, due to brain stem death or in a cardio- pulmonary sense, at any time after live birth has taken place".

The Act allowed anybody over the age of 18 to freely authorize the extraction of any of his or her organs before passing away for therapeutic cause's i.e systematic management of any illness or actions taken to promote health using a particular technique or modality[90]in the presence of two or more witnesses, out of which one must be a close family and must do so in writing. Parents may permit the taking out of any organ when it comes to a child who experience brain stem death[91]. Anytime a human organ is removed, a licensed medical practitioner is required to take the essential precautions to maintain the organ[92].

The Act also put limitations on organ harvesting and forbids the extraction of any human organ for any reason except medical . An organ may be transplanted to anyone who is in need of it if the donor or another competent person grants permission for its removal after death on accordance with the Act's provisions.[93] and it is mandatory for the enrolled medical professional to informs both the donor and the recipient of all potential side effects, complications and risk before any organ removal or transplantation[94].

This Act has casted duty on all hospitals to register with the Act and to participate, associate, or assist in the human organ extraction, preservation or transplantation by an expert licensed medical professional. Under this Act many Regulatory Bodies are established such as Advisory Committee for two-year period under the presidency of an administrative expert who is not below the level of Secretary to the State Government and two medical professionals with five years of experience in the concerned area[95]with following functions…

- Performs the task of accepting or rejecting the transplants.
- Monitors the donor's behavior to ensure that he is not taken advantage of in return for trivial financial considerations in exchange for his organs.

87 For detail, see Transplantation of Human Organs Act, NO. 42 OF 1994.

88 For detail, see Transplantation of Human Organs Act, NO. 42 OF 1994.

89 For detail, see section 3(6) of Transplantation of Human Organs Act, 1994

90 For detail, see section 2(o) of Transplantation of Human Organs Act, 1994

91 For detail see section 3(7) of Transplantation of Human Organs Act, 1994

92 For detail, see section 7 of Transplantation of Human Organs Act, 1994

93 For detail, see section 11 of Transplantation of Human Organs Act, 1994

94 For detail, see section 12 of Transplantation of Human Organs Act, 1994

95 For detail, see section 30 of Transplantation of Human Organs Rules 2014.

- Informs the donor of any hazards he might encounter following surgery.
- Following the filing of the transplant application on behalf of the patient, a meeting between the donor, recipient, and authorization committee occurs. [96]

Appropriate Authority (Section 13)

The government established an authorization committee and an Appropriate Authority[97] in very State and Union territory to oversee activities relating to transplant across the entire country under the Transplantation of Human Organs Act, 1994.[98]

- Only hospitals with a legitimate license from the authorities may conduct it. The license is good for five years and can be renewed after that time with primary responsibility to inspect, oversee, and register hospitals for organ transplant surgery. It also keeps an eye on hospitals to make sure that the normal requirements are upheld and that organ quality is not compromised.[99]

Competent Authority[100]

- It refers to the chairman or committee appointed by the transplantation institute.
- Any transplant team member is eligible to join.
- It only permits transplants that are closely similar.

Table 3
Synoptic view of types of donors under The Transplantation of Human Organs Act

Type	Definition
Living Donors	Legally, a live person above 18 with free consent may donate: One Kidney Half of the pancreas. Portion of the liver.
Living Near Related Donors	Only immediate blood relatives, such as parents, children, and siblings, grandparents and grandchildren and spouses[101] are permitted[102] to donate.[103]
Living Non-near Donors	Here the donor is not in any way tied up to the receiver but nonetheless feels a strong bond and attachment to him or her. In this situation, authorization is necessary, and it is provided by the authorization committee by participating in an interview.[104]
SWAP Donors	Here the donor and recipient are not related, this is appropriate. When the donor of the first pair matches the

96 For detail, see section 6A, Transplantation of Human Organ (Amendment) Rules, 2008

97 Appropriate Authority, hereinafter referred as AA.

98 Ibid.,

99 For detail see section 13(1) of Transplantation of Human Organs Act, 1994.

100 For detail, see Transplantation of Human Organ Rules, 2014.

101 They must, however, provide appropriate legal documentation or genetic testing to demonstrate their link to the recipient

102 As per Transplantation of Human Organs Rules of 2014.

103 For detail see section 6F(a), Transplantation of Human Organ and Tissues Rules, 2008

104 For detail see section 6F(d), Transplantation of Human Organs Rules, 2008

	second receiver and the donor of the second pair matches the first recipient, such a provision includes switching the donors. However, it is only acceptable when donors are close relatives.
Foreign Donors	Only foreign donors who are "nearly related" to the recipient are allowed in this situation. According to the laws, Indian live donors who wish to donate to a foreigner except close family are not permitted to do so. The embassy of the place of origin must give authorization for the transplant and clarifies the acquaintance between the donor and the recipient in the process that a foreigner travels to India for the procedure.[105]
Deceased/Cadaver Donors	In order to obtain organs, a donation must occur either after brain death (brain death) or cardiac death (when the patient's heart stops beating). If a person is more than 18 years in age and agrees to donate their organs after death, they may provide their consent while still alive. The medical professional is now required to inquire about any plans for organ donation from the patient's close relative or the person in legal possession of the body after certifying the patient's brain death, even if the patient had previously given his consent during his lifetime.

Authority for removal of human organs [106](Sections 3-8) - Only registered medical practitioner is allowed to carry out transplantations of human organs inside hospitals that have been registered with the Act as per section 3(4). The registered medical practitioner must be certain that the donor has been confirmed including brain-stem dead in the manner specified above in order to donate a cadaverThe section establishes unauthorized removal is considered a serious offense, punishable by fines, imprisonment, or other legal sanctions. Section 5 provides that if there is any unclaimed body in the prison or hospital and is not being claimed by any near relatives of the person who have died within forty eight hours of death then the authorization may be given by any employee of that prison or hospital.[107]No authority can be given if the person empowered has reason to believe that the body may be claimed within time specified.[108] As per section 6 were a dead body has been sent for postmortem for medico legal purposes or for pathological purposes the

[105] For detail see section 6F(e), Transplantation of Human Organ Rules, 2008

[106] For detail, see Section 3 of Transplantation of Human Organs Act, 1994. A "registered medical practitioner" is someone who is listed on a State Medical Register, as mentioned in Section 2(n) of the Act, clause (k), and who has any recognized medical qualification, as specified in Section 2 of the Indian Medical Council Act, 1956 (5), clause (h).

[107] For detail, see section 5(1) of Transplantation of Human Organs Act, 1994.

[108] For detail, see section 5(2) of Transplantation of Human Organs Act,1994

person competent to give authority may have reason to believe that such human organ will not be required for purpose for which such body has been sent for post- mortem.[109]The person giving authority has to be pleased that the dead person before dying had not provided any objection for using his organs for therapeutic purposes after his death and such authority had not been revoked by him before his death.[110] According to section 7 after removing human organ from body the registered medical practitioner is required to take necessary steps for its preservation.[111]

Regulation of Cadaver Donation (Sections 9-12)

Living contribution is governed by Section 9[112] of the Act. There exist distinct procedure for living donations from unrelated donors and donations from close relatives.[113]

- Close relatives who wish to donate their bodies while still alive must submit Forms 1 or 2[114] of the Transplantation of Human Organs and Tissues Rules, 2014, along with Form 11[115], to the appropriate authority[116] The transplant is approved if the committee is satisfied following interviews with the donor, recipient, and their families. A video recording of the full interview was made.[117]
- In certain places, if a patient, donor, or both are not residents of the state where transplant is to be performed, approval/NOC of the applicable State authorization committee is required[118].
- Where a living donation from an un-related donor, the Hospital Authorization Committee must receive an application in Forms 3 and 11[119] of the Transplantation of Human Organs and Tissues Rules, 2014, just like it does for related transplants.
- As per section 11an organ can only be transplanted to a close family of the donor and none else after being removed from a living individual. An organ can be transplanted to anyone needing it if the donor or another competent person grants permission for its removal after death according to the Act's provisions. In the absence of the earlier approval of the Authorization committee, a human organ cannot be taken out and transplanted if donor authorizes its removal prior to his/her passing for the transplantation inside the body of a individual who is not a close relative, citing affection or attachment towards the recipient or any other special reason. If the donor and receiver submit a joint application, the authorization committee may approve the transplantation after conducting an investigation and determining that applicants have met with all Act and Rule's requirements[120].
- The Act forbids the taking out of any human organ for any of the reason other than medical ones[121] and it is crucial that a registered medical professional informs the donor and the recipient of all potential side effects, complications and risk before any organ removal or transplantation.[122]Section 19[123] declares that selling human organs for profit is a felony that is subject to a minimum five-year sentence but not a maximum of ten years in jail including minimum fine of twenty lakh rupees but not a maximum punishment of one crore

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[109] Ibid.,

[110] Ibid.,

[111] Ibid.,

[112] For detail, see section 9, Transplantation of Human Organs Act 1994.

[113] Ibid.,

[114] For detail, see form 1 or 2 of Transplantation of Human Organs and Tissues Rules, 2014. Section 2(i) defines a "near relative" as a spouse, kid, parent, sibling, grandpa, grandmother, grandson, or granddaughter

[115] For detail, see form 11 of Transplantation of Human Organs and Tissues Rules, 2014

[116] The chairman of the medical facility where the transplant will take place or the committee made up by the hospital, known as the Hospital Authorization Committee).

[117] For detail, see section 2(i) of Transplantation of Human Organs Act, 1994.

[118] According to the Supreme Court of India's New Delhi judgment in W. P. No. 156/05, dated March 31, 2005. The Transplantation of Human Organs (Amendment) Rules, 2008[1] changed Rule 6B to make it applicable to organ transplants from related donors even though the Supreme Court's decision only applied to transplants from unrelated donors. The Ministry of Health and Family Welfare provided clarification on the issue on November 1, 2011, stating that "article 6B of the Transplantation of Human Organs Rules, 2008 only applies to unrelated occurrences (and to all foreigners); it does not apply to cases involving "close relative" "donor/recipient."

[119] For detail, see Form 3 and 11 Transplantation of Human Organs and Tissues Rules, 2014

[120] For detail, see section 9 Transplantation of Human Organs Act, 1994.

[121] For detail, see section 11, Transplantation of Human Organs Act 1994.

[122] For detail, see section 12, Transplantation of Human Organs Act 1994

[123] For detail, see section 19 of Transplantation of Human Organs and Tissues (Amendment Act), 2011

rupees.[124] Offenders can be imprisoned for a period which is not less than one year but up to three years and fine not less than five lakh rupees but up to twenty-five lakh rupees even for other illegal uses like offering to supply human tissue in exchange for money or looking for someone who will supply for payment. Therefore, it is necessitated to persuade the authorization committee that the consent for the removal of organ or tissue is not being given for financial advantage. Section 12 The Act states that a donor may provide his or her consent in writing when two or more witnesses are present for any human organ, tissue, or both to be removed from his body before death to get transplanted into the bodies of the donor's close relatives. A minimum of one of those witnesses should be an immediate /close family members of the donor. The individual overseeing the body after the death of that willful donor shall provide all reasonable facilities for the removal of that particular organ or tissue from the non-alive body of the donor through a licensed medical professional[125]. The removal may be approved by the donor for any of his organs or tissues or both prior to his death for the purpose of transplanting into the body of a recipient who is not a close family member out of affection or attachment to the recipient or for any additional unique cause as stated in Section 9(3)[126] which outlines the exception to the near relative rules. However, the Authorization Committee must first give its prior consent for this to be done. The Authorization Committee may make any orders after giving the donor, beneficiary and any other relevant parties a chance to be heard.[127] Any licensed medical professional, who removes or transplants any human organ, tissue, or both necessitated to notify the donor and recipient in the way as may be mandated of any potential dangers, side effects, or difficulties.[128]Additionally, it is the licensed medical practitioner's responsibility to verify through a personal examination that the event in question has indeed occurred in cases of brain death. When a dead body is reclining in a prison or hospital and is not asserted by close family members of the dead person within 48 hours of the moment of the said person's death the individual overseeing the management or control of the prison or hospital, or by a staff member of such prison or hospital authorized in this regard, may grant the authority to remove human organs or tissue. These requirements are put in place to safeguard both the recipient's right to the best healthcare and the donor's right to their body.[129]The person in command or a designated employee of the medical center or detention center may provide permission for the removing human organ(s) from a non-alive body if no close relative claims it within 48 hours of death. Authorization cannot be granted if the individual with the authority feels that even if the dead body hasn't been claimed within the allotted time, a close relative most likely will do so. [130]If the qualified being feels that a particular human organ is not necessary for the cause whereby the post mortem of the body has been requested for medical, pathological or legal reasons, he or she may provide authorization as long as the coroner is certain that the dead individual had not previously indicated any disagreement with removal of organs or that his prior consent to organ removal after has not been rescinded. Anytime a human organ is removed, a licensed medical practitioner is necessitated to undergo the essential precautions to preserve the organ.[131]

National Organ and Tissue Transplant Organization (NOTTO)[132]

It is acknowledged as the top hub in India for planning all operations involving the collection, maintenance and distribution of tissues and organs including their donation and transplantation.

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[124] For detail, see section 19 of Transplantation of Human Organs and Tissues (Amendment Act), 2011; see also M.C Gupta, "What are the Legal Aspects of Over-the-Counter Sale of Allopathic Medicine?", *Indian Journal of Clinical Practice*, Vol. 23, 2013, pp. 864-868 at p. 865.

[125] The only person authorized to remove the organ for therapeutic purposes is a trained medical expert or technician

[126] For detail, see section 9(3) of Transplantation of Human Organs Act, 1994.

[127] Ibid.,

[128] For detail, see section 12 of Transplantation of Human Organs Act, 1994.

[129] Ibid.,

[130] Ibid.,

[131] Ibid.,

[132] National Organ and Tissue Transplant Organization, hereinafter referred as NOTTO.

Registration of Hospital (Section 14-17)

SECTION 14 Registration of Hospitals engaged in removal, storage or transplantation of human organs[133]

A hospital cannot be registered under the present act that is being discussed until the satisfaction of AA that hospital that is being registered have specialized services and facilities to maintain the standard as prescribed.[134]under section 15[135]

SECTION 16 Suspension or cancellation of registration[136]

If AA is satisfied that the hospital is involved in the breach of any provision of this act, after providing the reasonable opportunity of being heard it can take any criminal measure against such hospital and suspend its registration the reasons should be recorded in writing.[137]

SECTION 17 Appeals [138]

A person unsatisfied by the order of authorization committee rejecting the application of approval or suspending or cancelling the registration may file an appeal to the central government or the state government within 30 days from the date of receipt of order.[139]

Penal Provisions under Transplantation of Human Organs Act, 1994

The maximum punishment prescribed under the act was 7 years imprisonment and maximum fine was rupees 20000.[140]

Offences and Penalties (Section 18-22)

Table 3.1

Synoptic view of Offences and punishment under Transplantation of Human Organs Act, 1994

Section	Offences	Punishment
S.18	Renders services, conduct or help in the human organ removal without authority.	5 years of imprisonment with up to rupees 10000
S.19	Makes, seeks, offers, initiates, any transaction relating to supply of organs for cash.	Imprisonment ranging from 2 to 7 years and fine ranging from 10000-20000
S.20	Acting in contravention to any provisions of the act or Rules, or any condition of the registration granted, for which no punishment is separately provided	Imprisonments of 3 years and fine up to 5000 rupees
S.21	Offences by companies	Where a company is involved in the commission of the offence shall be prosecuted and punished accordingly the person is not liable for the punishment if he proves that he has committed the offence without his knowledge or that he had taken all necessary steps to prevent the commission of such offence.[141]

(SOURCE: Adopted from Transplantation of Human Organs Act, 1994)

[133] For detail, see Section 14, Transplantation of Human Organs Act, 1994

[134] Ibid.,

[135] For detail, see Section 15 of Transplantation of Human Organs Act, 1994

[136] For detail, see Section 16 of Transplantation of Human Organs Act, 1994

[137] Ibid.,

[138] For detail, see Section 17 of Transplantation of Human Organs Act, 1994

[139] Ibid.,

[140] For detail, see section 19 Transplantation of Human Organs Act, 1994.

[141] Ibid.,

SECTION 22 Cognizance of offence[142]

The court have power to take cognizance of an offence only on complaint made by the AA or a person who has given notice of 60 days to appropriate authority. The offence under this act can only be tried by metropolitan magistrate or judicial magistrate of first class.[143]

Table 3.2
The Transplantation of Human Organs (Amendment) Act, 2011[144]

Section 2(ha) Human Organ Retrieval Center-[145]	The biggest change brought about by the 2011 amendment was the addition of human tissues to the Act's purview and the imposition of harsher penalties for violations of its rules. Transplantation of Human Organs and Tissues Act was thus given as the new name for the Act. The amendment defines "Human Organ Retrieval Center"[146] as a hospital that is registered under the Act's requirements and has suitable facilities for treating extremely ill patients who could potentially be organ donors regarding the instance of death.[147]
Section 3(1a) authority for removal of human organs [148]	Inserted Section 3 (1A). imposed certain obligations on the authorized physician who, in collaboration with the transplant coordinator, if one is available, must determine whether the intended donor had consented, before to his passing, to the removal of any human organs or tissues from the Intensive Care Unit patients or a close relative. The hospital must then go ahead and record this authorization in the way that the law specifies. If such consent has not been given, the doctor must inform the patient or the close relative of the decision to consent to or decline organ or tissue donation. The hospital must subsequently notify the Human Organ Retrieval Center in writing of any plans to remove, store or transplant the identified donor's human organs and tissues. Those who work in an Intensive Care Unit at a hospital
Section 9(3A) [149]	Swap donations must need the Authorization Committee's prior approval.[150]
Section 13(A) Advisory committee to advise	Composition of advisory committee: The administrative expert not below the rank of Secretary to the State Government should be the Chairperson of the Advisory Committee[152]; two medical experts having necessary qualifications[153];

142 For detail, see Section 22 of Transplantation of Human Organs Act, 1994

143 Ibid.,

144 For detail, see the Transplantation of Human Organs (Amendment) Act, 2011.

145 for detail, see section 2(ha), transplantation of human organs and tissues (amendment) act, 2011

146 Ibid.,

147 Ibid.,

148 For detail, see section 3(1A) of Transplantation of Human Organs Act, 2011

149 For detail, see section 9(3A), Transplantation of Human Organs Act, 2011

150 Ibid.,

152 For detail, see section 13(A)(2b) of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

153 For detail, see section 13(A)(2c) of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

Appropriate Authority[151]	one officer of rank of a Joint Director as Member-Secretary[154]; two eminent social workers of high social standing and integrity, one out of which shall be from women organization[155]; one legal-expert who has been remained on the position of additional district judge or equivalent[156]; One should be specialist in the area of human organ transplantation, and he shall not a member of the transplantation team[157].
Section 13(b) Powers of appropriate authority[158]	The Appropriate Authority shall have all the powers of a civil court trying a suit under the BNS, 2023.[159]
Section 13(d) National registry[160]	The Central Government is required to maintain a national registry of the donors and recipients of human organs and tissues.[161].
Section 14(a) Registration of tissue bank[162]	This section calls for the creation of the National Human Organs and Tissues Removal Storage Network[163] and mandates that the Central Government keeps an up-to-date national registry of donors and receivers of organs and tissues[164] maintain necessary data to enable regular evaluations of the scientific and medicinal status of organs and tissues.

Table 3.3
Synoptic view of offences and punishments under Transplantation of Human Organs (Amendment Act), 2011

SECTION	OFFENCES	PUNISHMENT (Post Amendment)
S.18(1)	Rendering services, conducting or helping	10 years imprisonment and fine extendable upto 20 lakh rupees
S.18(2)	In the process of removal of any human organ without prior authorization	3 years imprisonment
S.18(3)(new provision)	Renders services, conducts, associates or helps in the process of taking out of	3 years imprisonment and fine of rupees five lakh.

151 For detail, see section 13(A) of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

154 For detail, see section 13(A)(2d) of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

155 For detail, see section 13(A)(2e) of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

156 For detail, see section 13(A)(2f)of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

157 For detail, see section 13(A)(3) of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

158 For detail, see section 13(B) of Transplantation of Human Organs and Tissues (Amendment) Act, 2011

159 For detail, see Transplantation of Human Organs and Tissues (Amendment) Act, 2011

160 For detail, see section 13(D), Transplantation of Human Organs and Tissues (Amendment) Act, 2011

161 Ibid.,

162 For detail, see section 14(A), Transplantation of Human Organs and Tissues (Amendment) Act, 2011

163 For detail, see section 13(C), Transplantation of Human Organs and Tissues (Amendment) Act, 2011

164 For detail, see section 13(D), Transplantation of Human Organs and Tissues (Amendment) Act, 2011

	human tissues without authority	
S.19(a to f)	Makes offers initiates publishes or distribute material relating to organ in exchange of money.	5years imprisonment extendable upto 10 years and fine not less than 20 lakh extendable upto 1 carore
S.19(g)	Assistance in the preparation of submitting o fraudulent documents proves that the donation is made between close relatives out of love and attachment.	5 years extendable upto 10 years and fine not less than 20 lakh extendable upto 1 crore
S.19A(new provision)	Pays, looks, offers and participate in any illegal activity relating to organs.	3 years imprisonment and fine of rupees 5 lakh extendable upto 25 lakh.
S.20	Acting in violation to any provision, regulation or registration requirement that is not specifically punished.	5 years imprisonment and fine extendable upto 20 lakh rupees.

(SOURCE: Adopted from Transplantation of Human Organs and Tissues (Amendment) Act, 2011

Rules for the Transplantation of Human Organs and Tissues, 2014

The Transplantation of Human Organ and Tissues Rules, 2014 operationalize the new entities and institutions established by the 2011 Amendment Act and offer procedural and technical guidelines for those performing organ transplantation under the Act Some of the crucial changes include the establishment of provision on the priority of organ allocation[165], provisions on the operation and extent of organ registries at the national and regional levels, the requirement that swap donations be authorized by the Authorization Committee[166] and limited to close relatives of the swap recipients, the requirement that the recipient's family bear the cost of maintaining the cadaver, retrieving, transporting or preserving organs and tissues and more.

Judicial Response

In **Dr. Ajay Tejraj Oswal v. Joint Director of Health Services, Maharashtra State Government Dental College Building and others**[167]it was held that terms like "appropriate authority," "brain-stem death," "donor," "near relative," and "registered medical practitioner" are defined in the Transplantation of Human Organs Act, 1994 to help make sense of the legislation governing organ transplants. In **Balbir Singh v. The Authorization Committee** court held that donors, regardless of whether they are the donees "near relatives" or complete "outsiders," should be protected and given priority when receiving medical care. In **B.L. Nagaraj and others v. Kantha and others**[168]High Court stated that close relatives are not forbidden to donate by any provision of the act because the near relatives are not the family donors. The committee is required to ask the donor why the donation is being carried out. If it's out of love and affection then the permission may be granted. This is done in order to prevent the organ from becoming a commodity. The act primarily intended to forbid the sale of human organ for profit. In **Fortis Hospitals Ltd. v. State of Karnataka** the court decided "The appellant is fully authorized to execute organ transplants as long as they have a valid Certificate of Registration to perform transplants of the kidney, lever, and homograft (permitted only usage) and it has not been revoked. In **Santosh Hospital Pvt. Ltd., Chennai v. State Human Rights Commission, Tamil Nadu**[169]the issue of whether a "hospital" could be considered a public servant for the purposes of Section 21 of the Indian Penal Code, 1860 as the authorization committee and the petitioner (hospital) cannot consider "public servent" under definition of "public servent" given in Indian Penal Code, 1860[170]. The court decided, "it may be mentioned that the state government has to constitute by notification an authorization committee consisting of such members as the state government nominates under section 9(4)(b) of the transplantation act. It is necessary to do so because they are not included in any category provided under IPC, 1860. The

[165] For detail, see Transplantation of Human Organs and Tissues Rules,2014

[166] Ibid.,

[167] Dr. Ajay Tejraj Oswal v. Joint Director of Health Services, Maharashtra State Government Dental College Building and others 2012 (1) Mh.L.J 835.Also see Rajesh Kumar Srivastava v. A.P. Verma and others

[168] B.L. Nagaraj and others v. Kantha and others AIR 1996 Kant 82.

[169] Santosh Hospital Pvt. Ltd., Chennai v. State Human Rights Commission, Tamil Nadu, AIR 2005 Mad 348.

[170] Indian Penal Code, 1860, hereinafter referred as IPC, 1860.

authorization committee and its members can not consider public servant in the sense as provided under IPC, 1860.

Challenges of Organ Transplantation

- **Lack of knowledge**: The public at large are not aware about the process and importance of the donations and transplant of organs thereby leading to shortage of organs.
- **Organ Shortage**: There exists shortage of donors because religious mindset and lack of trust on medical system lacks in turn due to lack of transparency among people.[171]
- **Legal and Ethical aspect of organ donation**: There exist legal and ethical issues associated with organ donation such as providing consent, allocating organs and equitable distribution of organs.
- **Transportation and preservation**: Organs need to be transported and preserved under specific conditions to ensure their viability for transplantation which has logistical challenges, especially for organs that have short shelf life.[172]
- **Medical suitability:** All donated organs are not preferred for transplantation due to medical insufficiency or standards which limits the quantity of organs that are available for transplant.[173]
- **Cost:** The costs for the process of organ transplantation can be high, which leads to limited accessibility to treatment for poor patients.
- **Flaws in the Existing law:** Even after 20 years of implementation, the Act is incapable of achieving its two major goals i.e promotion of cadaver donation and prevention of salable transactions in human organs. Although Act has recognized "brain death" as legal for cadaver donations. But the estimates of National Organ and Tissue Transplant Organization[174] shows that cadaver donations from 1994-2022 are only 12% of the total transplants[175] contributed by Non- Governmental Organizations. **Non-implementation of the laws** - Finding a match is difficult since the data is not effectively tackled and there exists a lack of understanding among the large number of people.
- **Lacks of establishment of authorization committees and advisory committees** -Almost all states are permitted to establish authorization committees and advisory committee for appropriate monitoring as required by law. Such institutions are rare in most states and in Tamil Nadu and Kerala, where inadequate data is being collected, the condition is considerably worse.
- **Lack of initiative by doctors for promoting transplant**- The doctors hardly ever attempted to contact the patient's family members after his death in order to get their permission for the transplant and that they never keep any record regarding the applications of disinclination for the transplant filed by any relative of the dead.

SUGGESTION

Promoting Donations to Cadaver Organs - It might be very beneficial to inform and persuade the family members of the possibility of preserving lives from brain dead victims of traffic accidents.

Benefits for Organ Donors -Free recurrent medical evaluations related to organ donation and insurance for death or complications resulting from donation may legitimately be provided to the living donors followed by offering incentives for organ donations can serve as inspiration for more people to volunteer to give their organs after passing away.

I**ncreasing Awareness about Organ Donors-** The availability of donor registration forms in hospital, school, universities, public officials and leaflets explaining the process to register oneself for cadaveric donation that can be posted on notice boards at such institutions in a prominent location can increase people's awareness of the issue.[176]

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171 Sachdeva S, "Organ Donation in India: Scarcity in abundance", *Indian Journal of Public Health*, Vol. 61(4), 2017, at pp. 299-301.

172 Ibid.,

173 Ibid.,

174 National Organ and Tissue Transplant Organization, hereinafter referred as NOTTO

175 Organ Report, National Organ and Tissue Transplantation Organization [NOTTO], available at https://notto.mohfw.gov.in/organreport.htm, last accessed on 20/04/2024.

176 B Sandeepa Bhat, Reflections On Medical Law And Ethics In India, Eastern Law House, 2016.

Authorization Committee's Effective Work-The Indian organ trade can be substantially reduced if Authorization Committee's do their essential function of banning commercial deal in human organs. Therefore, having someone with the requisite knowledge and experience in the field is crucial, particularly when handling donation given out of love or attachment or for any other unique reason. This can ensure that the approval committees function effectively by assisting in the prevention of organ trade in the nation.

Clarity on "Affection" Or "Attachment"- Section 9(3)[177] has frequently been cited as a loophole permitting commercial deals In human organs because it is unclear what "Affection" or "attachment" actually is[178] to avoid any business operation under the guise of "affection" or "attachment", the clause has to be tightened. Clarity is required regarding what defines "affection" or "attachment" and what qualifies as "special reasons" that would allow an unrelated donor to donate his organ to a patient without any commercial arrangements.

Prohibited Advertisements- Advertisements soliciting or offering organ are not specifically prohibited under section 19(f) if they are not part of business transaction. Due to dubious interpretations, advertising claiming that they are solely motivated by altruistic organ donations and don't establish any commercial motives have been permitted by the courts. The requirement must be made clear on this point and all marketing for human organs must be forbidden

Reducing Waiting Time for Unclaimed Corpses under The waiting period need to be shortened to 24 hours so that organs can be removed soon after death and potential organs are not wasted.[179]

Clear Definition of Death-Clarity regarding the definition of 'death' is required because the term has different meaning under various laws including BNS ,2023[180] and the Registration of Births and Deaths Act[181].

Need for Emergency Provisions- In order to prevent critically ill patients from dying the Act should establish a specific time period for approving or rejecting transplantations.

Role of medical colleges

Fourth-year medical students' attitudes toward organ donation and their perceived understanding of it can both be greatly improved. If policies are put in place at every medical college/institution that is open to all the students, this initiative may boost the estimate of organ donation as well as transplantation**.**[182]

Role of private institutions and Ngo's in organ transplant must be encouraged.

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

[178] Sunil Shroff, "Legal and ethical aspects of organ donation and transplantation", Vol. 25(3), Indian Journal of Urology,2009, pp. 348-355.

[179] Sunil Shroff, "Recommendations for Transplantation of Human Organs Act (Amendments) Bill", *Indian Transplant Newsletter*, Vol. 9(28), pp. 9-10. Available from: https://www.itnnews.co.in/indian-transplant-newsletter/issue28/Recommendations-THO-Act-294.htm,last accessed on 21/05/2023.

[180] Bhartiya Nagrik Sanhita,2023

[181] Registration of Births and Deaths Act, No. 18 of 1969.

[182] Ibid.,