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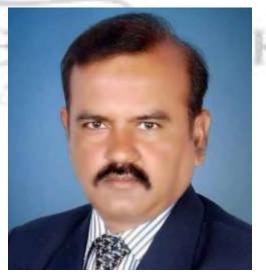


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ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

LEGAL

NAVIGATING THE LEGAL LANDSCAPE OF ORGAN TRANSPLANTS: ETHICAL ISSUES AND GREY AREAS

AUTHORED BY - SHIVANI PAHUJA

Abstract:

The most important yardstick of a developed human society is the recognition of the right to health. The evolution of the right to health on an international level led to the development of a framework of norms that needs to be adhered by the states to accelerate an individual's right to health. Organ transplantation acted as a landmark event that inscribes the advancement of medical care and casts a light on the constant attempts in medical research to improve the quality and longevity of life. The significant discussions in this area are can organs only be removed after the lifetime of the donor, whose consent is required for the donation, and how to prevent the illegalities e.g. organ trafficking in cases of organ transplantation. This paper primarily attempts to shed light on the legal and illegal aspects of organ transplantation on an international level with primary focus on India, including the important aspects like organ trafficking and transplant tourism.

Keywords: right to health, organ transplant, donation, organ trafficking, cadaver And Lord Shiva was enraged and Beheaded Ganesha: and Parvati was pained beyond grief. "Ganesha! Oh My son! Be it that it were me." She wailed, and Lord Shiva was moved and transplanted an elephant's head on Ganesha and Ganesha became a deity of Learning & Wisdom.

- Hindu Mythology

Introduction

EGA

Organ transplantation refers to the utilization of organs of a living or dead person for saving the life of some other person or removing a serious disability from him. It is not a very new concept for the world. The first ever human to human kidney transplant was performed back in the year 1954. Consequently with the betterment of technology and advanced tools the success rates of organ transplantation escalated. But the biggest gap in this area is the limited number of organ donors in contrast to the excessive number of individuals who are in need of the organs. There exists several data that shows that a large number of deaths occur due to shortage of organs & organ donors as several patients die waiting for a suitable organ. As per the available data, in India around 1 person is added to the waiting list for the organs every 10 minutes.¹

Death as per physician's definition basically means the total termination of circulation of the blood and consequently, a cessation of the vital body functions.² In cases where an organ is to be removed after the death of a person, it needs to be an immediate process and hence it becomes really difficult to take his relative's consent. A way to remedy this is that widespread campaigns should be organized for encouraging people to provide in their will that their organs can after death be used for transplantation purposes. An alternative to the will of consent can be some legal regulations that provide that permission can be assumed unless the removal of organs has been explicitly prohibited by him during his lifetime. Such a law has already been passed in many countries including Sweden, Denmark, Austria, Israel & France.³

Under International standard a brain death is said to have occurred in case of "whole brain death" i.e. when the cerebrum, cerebellum and brainstem have all stopped to demonstrate any electrical activity for a significant amount of time i.e. no sustenance of the respiration and circulation is possible. Cadaver transplantation is basically defined as harvesting organs from brain dead persons for transplantation purposes.⁴

Organ Transplantation Mechanism in India

The topic of transplantation and donation in India is covered under **The Transplantation of Human organs & Tissues Act, 1994**. The act defines deceased person as *"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"⁵ and brain-stem death as the <i>"Stage at which all*

¹World Health Organisation (WHO), *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, 63rd World Health Assembly Resolution, May 2010.

²Cited in *Medico-legal Invest Death*, edited by WV Spitz and RS fisher, Charles C Thomas (1973).

³World Medical Association, Statement of Measures for the Prevention and Fight Against Transplant- related crimes (2020): <u>https://www.wma.net/policies-post/wma-statement-on-measures-for-the-prevention-and-fight-against-transplant-related-crimes/</u>, accessed on 10 February, 2024.

⁴ICAT, 20th Anniversary of the Trafficking in Persons Protocol- An Analytical review (2021), p. 14: <u>https://icat.un.org/sites/default/files/publications/icat analytical paper 2020 final 0.pdf</u>, accessed on 10 February, 2024.

⁵Section 2(e) of The Transplantation of human Organs and Tissues Act 1994.

functions of the brain- Stem have permanently and irreversibly ceased and is so certified under subsection (6) of Section 3 of the Act".⁶ The act allows for the storage, transplant and donation of organs only for therapeutic proposes, it prevents any kind of commercial dealing of the organs.

The National Organ Transplant Program has been implemented by the Indian government for the increase in deceased organ and tissue donation.⁷

Due to the advent of technology the use of mechanical ventilators & other equipments have made it possible to continue the circulation and respiration in a person even in cases of irreversible brain damage. These people are classified as brain- stem dead or "beating cadavers" and there organs can be used for medicinal purposes. Brain Stem is connected to the spinal cord in the lower part of the brain and performs the automatic functions of the body considered essential for life including breathing, heartbeat, blood pressure or swallowing. If it stops working the rest of the body abates and as a consequence the brain's core functions like consciousness, awareness & movement is also lost, indeed constituting death.

In the case of **Aruna Ramachandra Shanbaug v. Union of India⁸**, the Supreme Coast was of the contention that the brain is the most important organ of a person's body. Any other organ can be transplanted or an artificial limb may be used but a brain cannot be transplanted. When a person's brain is dead then he/she is dead.

In India if any person providing his services to or at any hospital involves himself in whatever way for the removal of organ for transplantation purposes without any authority is liable for punishment.⁹ This involves the removal of organ only for transplantation proposes, and not any other. Any kind of commercial dealings in human organs is prohibited by the law.

⁶Section 2(d) of The Transplantation of human Organs and Tissues Act 1994.

⁷https://www.pib.gov.in/PressReleasePage.aspx?PRID=1739456 Ministry of Health and Family Welfare, National Organ Transplant Programme (NOTP)

⁸AIR 2011 SCC 1290

⁹Section 18(1) of the Transplantation of Human Organs Act, 1994

Illegal aspects - Trade in Human Organs

As the success rate for organ transplant has increased, the demand for it has consequently increased as well.

Almost every place in the world records a high number of scandals which involve people including the medical practitioners, in spite of the law curtailing the commercial dealing in human organs. The current regulatory system proves to be incapable of preventing it. As per different studies conducted in this area¹⁰ it is quite common to find end- stage renal disease men marrying other women for their kidney and then divorcing them after the work/transplant is done; using proxy donors to get the approval of the Authorization Committee (or with whatever name it is known under different laws of different countries); getting into unrelated transplants without any authorization; and providing false details of the donors so that they cannot be traced. Another major problem with the regime is that in cases where the Authorization committee rejects a donor or donation of any organ it is required to give reasons for the same, but no such recorded reason is required in cases where the donation is approved. These have also been instances where middlemen are allowed to operate in the hospital premises by the medical practitioners, leading to the commercialisation of the organ transplant. The financial considerations involved in these transactions lead to the dilution of medical norms and often those are cases where the donation should not have been allowed, and poverty and debts come up as the most common reason behind these.¹¹

But the studies in this area noted that in most of the cases of organ donation of such kinds the health status of the donors further deteriorated leading to an increased number of people below the poverty line.¹² It can be identified that most of the areas of medicine are governed by general principles of common law but specific legislations are required in cases involving complexities like the Organ Transplantation law.

Transplant Tourism:

The hopeless need for organ transplant surgeries have led to a profit -making, transnational criminal

¹⁰Krishnakumar Asha," Organ Trade - A curse worse than a disease" in *Frontline*, vol 21(3).

¹¹Ambagtsheer, F., Bugter, R. The organization of the human organ trade: a comparative crime script analysis. *Crime Law Soc Change* **80**, 1–32 (2023). <u>https://doi.org/10.1007/s10611-022-10068-5</u>, accessed on 10 February, 2024. ¹²ibid

enterprise enabling organ seekers to purchase organs from donors. Even after being illegal in most countries the estimates show that the trafficked organs account for almost 10% of the organ transplants that is done in the world. As the cost of the trafficked organs is very high, it is generally afforded by the wealthier population from the developed nations. It is usually conducted by the involvement of a vast network including a broker acting as an intermediary between the organ buyer & seller, some local recruiters and the medical professionals & hospitals performing the illegal organ transplantation. These sellers are mostly the vulnerable population who are misled, coerced or forced for selling their organs in return of money. The illegitimate profit is much higher than other forms of trafficking and thus it serves as an attractive business opportunity for some actors. It is an internationally recognised problem, several attempts have been made to curb this pervasive problem around the world but it has experienced little success because many parts of the world including Canada does not prohibit travelling for organ transplantation purposes.

International Regime and ethical issues related to organ transplant

Some of the major international initiatives to combat forced organ removal & trafficking of organs includes Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children (Trafficking in persons protocol), Supplementing the United Nations Convention Against Transnational Organized Crime (Palermo Protocol)¹³, Declaration of Istanbul on Organ Trafficking and Transplant Tourism which is the first international declaration to distinguish between transplant tourism and travel for transplantation¹⁴, World Health Organization's Guiding Principles on Human Cell, Tissue and Organ Transplantation, Council of Europe Convention Against Trafficking in Human Organs¹⁵ and United Nations General Assembly Resolution 71/322.¹⁶ Article 3 of the Trafficking in Persons protocol States that organ

¹³Ratification of the Palermo Protocol, UN Treaty Collections, "12. a Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the United Nations Convention against Transnational Organized Crime," Chapter XVIII: Penal Matters.

¹⁴Declaration of Istanbul – 2018 Edition. It is a non- legally binding instrument which was first adopted in 2008 and later updated in 2018. The Declaration was endorsed by a significant number of professional Societies Associated with transplantation Medicine across the world and has therefore acquired prominence as an instrument for guidance in the field of transplantation. The 2008 edition, developed at an international summit convened by the Transplantation Society, contained a definition of 'transplant commercialism' which has later been updated to be included in the definition of "organ trafficking ". In addition, the earlier edition did not feature a definition of trafficking in persons for the purpose of organ removal. https:// www. kidney-international.org/ article /50085-2538 (19) 30033-x/fulltext.

¹⁵Council of Europe, Treaty Office, Details of Treaty No. 216: Council of Europe Convention against Trafficking in Human Organs.

¹⁶Adopted on 8th Sep, 2017

removal is one of the explicit form of exploitation that should be eradicated through the national laws. Due to the failure to detect this crime because of various reasons including its wide geographical spread majorly the cases go unreported which becomes a growing cause of concern for the international community.

As per United Nations Office on Drugs and Crime majorly the donors & recipients for organ trafficking includes males but the females get involved as well when the man is the breadwinner of the family and/ or he gets ill.¹⁷ The donors in these cases include the vulnerable particularly the refugees, detainees or people with acute poverty. Illiteracy or low level of education may also be said to be a growing concern for this crime.

Organ trafficking includes a wide range of illicit activities within itself such as :

- 1. organ removal without express, voluntary, and informed consent.
- 2. organ harvesting for commercial or equivalent purposes.
- 3. implanting or using illegally removed organs in any other way.
- 4. the process of preparing, preserving, transferring, receiving, importing, and exporting such illegally removed organs.
- 5. the unauthorized listing or hiring of organ recipients or donors,
- 6. giving or asking unfair benefits from medical personnel or government representatives in order to carry out or facilitate such removal or implantation and other Use
- 7. making an effort to carry out, encouraging, or supporting the commission of such crimes.
- 8. illegal organ harvesting from deceased individuals.

Organ donation & transplantation encompasses a huge gamut of issues within itself including social, legal, ethical, medical & religious ones. There are 3 common rules that are morally acceptable in the domain of organ donation & transplant.

The first being the Dead Donor rule which basically means that when a single, important organ is to be transplanted, at least one doctor other than the recipient's physician must have certified the donor's

¹⁷Council of Europe (CoE), United Nations, Trafficking in Organs, Tissues and cells and Trafficking in Human beings for the purpose of the removal of organs Joint council of Europe / United Nations Study, p. 60: https://rm.coe.int//16805ad1bb.

death. The ethical doctor will employ all accessible, currently acceptable scientific tests to make this conclusion.¹⁸ the transplant physicians are not involved in determining the death of the donor to avoid any real or perceived conflict of interest.

The second is the rule of consent which includes the consent of a deceased or the living donor as the case maybe and the consent of the recipient as well. The consenting deceased donor rule includes the view that the Organs, tissues, and cells from deceased people's bodies may be extracted for transplantation if:

- a) any permission mandated by law is acquired (opt-in system), and
- b) There is no evidence to suggest that the deceased individual objected to the removal in question (opt-out system).¹⁹

Germany is one among the countries which uses the opt-in system and is reported to have a consent rate of 12% for organ donation among its populations. On the other hand, Austria which uses the opt-out system has a consent rate of 99.98% amongst its population. ²⁰ Family members may deny a potential recovery even if the donor has given consent, or they may be compelled to give consent or refuse it in certain systems, such as Australia, when it comes to effective organ donations. While some nations, like Greece, continue to have low donor rates while having an opt-out mechanism, other nations, like Spain, Croatia, or Belgium, have high donation rates.

Nearly thirty-two states of the US and the District of Columbia offers 30 days paid leave for organ donation to the federal executive agency employees in addition to the sick and annual leaves provided by them. Five states of the US (<u>California, Hawaii, Louisiana, Minnesota</u>, and <u>Oregon</u>) require certain private employers to provide paid leave for employees for organ or bone marrow donation, and seven others (<u>Arkansas</u>, Connecticut, Maine, Nebraska, <u>New York</u>, <u>South Carolina</u>, and <u>West Virginia</u>) either require employers to provide unpaid leave, or encourage employers to provide leave,

¹⁸Judicial Council of the American Medical Association, 1968.¹⁹WHO guiding

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 <u>https://www.edqm.eu/documents/52006/286852/WHO+guiding+principles+on+human+cell%2C+tissue+and+organ+tra</u>

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⁵¹a144c6a791#:~:text=Cells%2C%20tissues%20and%20organs%20should,deceased%20persons%2C%20should%20bee%20banned.

²⁰<u>Thaler, Richard H.</u> (September 26, 2009). <u>"Opting in vs. Opting Out"</u>. <u>*The New York Times*</u>. <u>Archived</u> from the original on March 8, 2014. Retrieved February 10, 2024

for organ or bone marrow donation. Nineteen US states and the <u>District of Columbia</u> also provide tax incentives for organ donation.²¹

The consenting live donor rule include that such donations are acceptable only when an informed & voluntary consent has been obtained from individuals.²² The decision shall be made by someone who understands all the consequences of it i.e. should be legally competent to donate his/her organs.

The consenting recipient rule requires that the recipient or their responsible relatives or representatives have a full discussion of the proposed procedure.²³

The third rule is the fair transparent rule which implies that the Clinical standards and ethical guidelines should govern the distribution of organs, cells, and tissues—not money or other factors.²⁴²⁵

Conclusion

An organ transplant is a safe surgery that offers thousands of individuals a second chance at life. It is important to remember that this is a discussion about life and death, where decisions are made about who survives, who dies, and why. Making decisions based on moral principles and a thorough comprehension of social and religious aspects would help to ease the suffering of actual individuals affected by this issue. Organ trafficking on the other hand is an issue that has spread its branches worldwide, and mostly going unreported in spite of its high yielding profits for the organized crime groups. No country is unaffected by it, with the donors being largely from the developing countries while the recipients belonging to the developed and wealthier nations. The only possible remediation of this problem is its widespread awareness and a stringent international and domestic regime.

²¹<u>"Donor Leave Laws and Tax Deductions/Credits for Living Donors"</u> (PDF). *Donor Leave Laws and Tax Deductions/Credits for Living Donors*. National Kidney Foundation. Archived from <u>the original</u> (PDF) on October 11, 2016. Retrieved February 8, 2024.

²²WHO guiding Principle 3

²³Judicial Council of the American Medical Association

²⁴WHO Guiding principle 9

²⁵ Jennifer Lewis, Dale Gardiner, Ethical and legal issues associated with organ donation and transplantation, Surgery (Oxford), Volume 41, Issue 9,2023, Pages 552-558.