

LIFE AND DEATH IN HUMAN ORGAN TRANSPLANTATION

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Abstract:

Human organ transplantation has become one of the most lucrative commercial transactions in the world. The present article attempts to ascertain the effectiveness of the present regulatory frame work in this regard. After giving a Bird's eye view on the statutory provisions relating to transplantation of human organs in the United States, United Kingdom and India, the author concludes that the Indian law has failed to prevent the unethical practices resorted to by the medical practitioners and the misuse in the procurement of organs for transplantation in India.

Key words: Brainstem, Death, Human organ, Penalty, Transplantation, Vegetative state

I. Introduction

The face of death and dying has changed dramatically in recent years; especially due to the unprecedented rise in organ transplantations for saving human lives. To overcome organ shortage, developed countries are re-looking at the ethics of unrelated programs and there seems to be a move towards making organ transplantation an acceptable legal alternative. The supply of deceased donors in these countries has peaked over the last few years. India is currently having a deceased donation rate of 0.05 to 0.08 per million population¹. The procurement of organs for transplantation involves the removal of organs from the bodies of deceased persons. This removal must follow legal requirements, including the confirmation of death and consent. It is an undisputable fact that an organ cannot be removed until a person is dead. Consequently, a crucial question arises as to when death occurs.

The medicalization of death leads to an over-emphasis in law, on the ethics and the expertise of the doctor, and a subsequent under representation of other value systems.² In *Airedale NHS Trust v. Bland*,³ the court accepted "brain stem death" as the definition of death for the purpose of medical law. Lord Mustill further stated that, "the authority of the State, through the medium of the court, is being invoked to permit one group of its citizen (doctors) to terminate the life of another." In *Re A*,⁴ Johnson J. held that a child who was on ventilator and certified as brain stem dead was also legally dead.

The dictionary meaning of death is the total and permanent cessation of all the vital functions of an organism.⁵ For those of religious persuasion, death is "the moment the soul leaves the body and moves on to the afterlife." In India, the Transplantation of Human Organ Act, 1994⁶ defines a "deceased person" as "a person in whom permanent disappearance of all

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/>, visited on 20/2/19

² Sheila McLean, *Old Law, New Medicine: Medical Ethics and Human Rights* (Rivers Pub., London) p. 146

³ [1993] 1 All ER 821

⁴ [1992] 3Medical Law Review303

⁵ <https://www.Dictionary.Com/Browse/Death>, visited on 22/2/19

⁶ Section 2 (e), Transplantation of Human Organ Act 1994

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.” In *Aruna Ramachandra Shanbag v. Union of India*,⁷ the apex court observed, death must be understood as irreversible and total failure of all parts of brain i.e. cerebrum, cerebellum and brainstem. Person in persistent vegetative state cannot be considered to be brain-dead, because brainstem is still functioning and therefore such person can support breathing, digestion etc. without any mechanical aid.

In the United Kingdom, the Department of Health’s Code of Practice for the Diagnosis, 2008⁸ defines death as, “Brain Stem Death which includes: (a) It must be concluded that the coma is not due to reversible causes, such as drug overdose; (b) It must be demonstrated that the several components of brain stem have all been permanently destroyed significantly this includes the respiratory centre; and (c) Patient is unable to breath spontaneously.”⁹

The Constitution Indian protects right to life as a fundamental right under Article 21. It is silent on the aspect of ‘death.’ In *Gian Kaur v. State of Punjab*,¹⁰ the apex court observed that the right to life does not include “right to die” or “right to be killed.” The right to die is inherently inconsistent with the right to life as is death with life. Verma J., further observed, “any aspect of life which makes it dignified may be read into Article 21 of the Constitution but not that which extinguishes it and is, therefore inconsistent with the continued existence of life resulting in effacing the right itself.” In *Maneka Gandhi v. Union of India*,¹¹ the apex court held that right to live is not merely confined to physical existence, but includes within its ambit the right to live with human dignity. In this backdrop, the present article attempts a discussion on the effectiveness of the present regulatory framework over death and transplantation of human organs.

II. The UN Declaration on Organ Trafficking and Transplant Tourism

The UN Declaration of Istanbul on Organ Trafficking and Transplant Tourism¹² laid down certain principles relating to the role of the governments and the areas to be taken care in transplantation of human organ: (i) Governments should develop and implement ethically and clinically sound programs for the prevention and treatment of organ failure, consistent with meeting the overall healthcare needs of their populations; (ii) The optimal care of organ donors and transplant recipients should be a primary goal of transplant policies and programs; (iii) Trafficking in human organs and trafficking in persons for the purpose of organ removal should be prohibited and criminalized; (iv) Organ donation should be a financially neutral act; (v) Each country or jurisdiction should develop and implement legislation and regulations to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards; (vi) Designated authorities in each jurisdiction should oversee and be accountable for organ donation, allocation and transplantation practices to ensure standardization, traceability, transparency, quality, safety, fairness, and public trust; (vii) All residents of a country should have equitable access to donation and transplant services and to organs procured from deceased donors; (viii) Organs for transplantation should be equitably allocated within countries or jurisdictions, in conformity with objective, non-discriminatory, externally justified, and transparent rules, guided by

⁷ AIR 2011 SC 1290

⁸ <http://aomrc.org.uk/>The revised Code of Practice is a working document in UK, aimed primarily at doctors and other healthcare workers who are responsible for the diagnosis and confirmation of death

⁹ Jonathan Herring, *Medical Law and Ethics* (3rd ed., Oxford University Press), p. 464

¹⁰ (1996) 2 SCC 648

¹¹ AIR 1978 SC 594

¹² <https://journals.lww.com/> visited on 28/2/19

clinical criteria, and ethical norms; (ix) Health professionals and healthcare institutions should assist in preventing and addressing organ trafficking, trafficking in persons for the purpose of organ removal, and transplant tourism; (x) Governments and health professionals should implement strategies to discourage and prevent the residents of their country from engaging in transplant tourism; and (xi) Countries should strive to achieve self-sufficiency in organ donation and transplantation.

III. The Human Tissue Act, 2004 (UK)

In UK, the Human Tissue Act, 2004¹³ provides for the lawful storage or use of bodily material with the consent of adults.¹⁴ Stringent punishments are prescribed for:- (i) removing, storing or using human tissue for scheduled purposes without appropriate consent; (ii) Storing or using human tissue donated for a scheduled purpose for another purpose; (iii) Trafficking in human tissue for transplantation purposes; (iv) Carrying out licensable activities without holding a licence from the HTA; and (v) Having human tissue, including hair, nail, and gametes (i.e. cells connected with sexual reproduction) with the intention of its DNA being analysed without the consent of the person from whom the tissue came or of those close to them if they have died. However, medical diagnosis or treatment, criminal investigations, etc., are excluded.

IV. The National Organ Transplant Act, 1984 (US)

In US, The National Organ Transplant Act, 1984 prohibits organ transplantation for commercial purposes. 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. Any person who violates this provision shall be fined not more than \$50,000 or imprisoned not more than five years, or both.¹⁵

The Advisory Committee on Organ Transplantation (ACOT) was established to assist the Health and Human Services (HHS) Secretary in enhancing organ donation; ensuring that the system of organ transplantation is grounded in the best available medical science; assuring the public that the system is as effective and equitable as possible; and increasing public confidence in the integrity and effectiveness of the transplantation system.¹⁶

V. Policy and Law in India

In India, there is no concrete vision and idea among the legislators with respect to the control of multispecialty hospitals and to satisfy the needs of common man in transplantation of human organ. There are only 0.9 hospital beds per 1000 population in India; whereas the figure is 6.5 per 1000 population in developed countries.¹⁷ Lack of government health services results in dependence on private sector. The National Health Policy (NHP), 2017 is also silent on transplantation of human organs.¹⁸ NHP itself admits that, tissue and organ transplantations

¹³ <https://www.hta.gov.uk>, visited on 4/4/19. The Human Tissue Act 2004 covers England, Wales and Northern Ireland. It established the HTA to regulate activities concerning the removal, storage, use and disposal of human tissue. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living.

¹⁴ Section 1, Human Tissue Act, 2004

¹⁵ Section 301 (a), the National Organ Transplant Act, 1984

¹⁶ <https://www.organdonor.gov/about-dot/acot.html>, visited on 28/2/19

¹⁷ "Ayushman Bharat-Long Live Private Health Care" 63 (46) EPW 8 (2018)

¹⁸ https://www.nhp.gov.in/NHPfiles/national_health_policy_2017.pdf, visited on 6/4/19. Objectives of the National Health Policy 2017 are to improve health status through concerted policy action in all sectors and expand

and voluntary donations are at present, areas of private sector services. The private sector and public sector could play a vital role in awareness programmes. What is left unexplained in the policy document is now our policymakers shall reconcile the two diametrically opposite aims, that of the imperative to maximise profits of the corporate hospitals and that of the government to provide health care to people irrespective of their ability to pay, and that too when the energies of these hospitals shall be focused on generating revenue through hospitality arrangements and through certain procedures (unnecessary) and services.¹⁹

A joint report published by World Health Organisation and World Bank in December 2017²⁰ revealed that 49 million Indians are pushed into poverty every year due to out of pocket expenditure on health care. The *economic survey 2017-18* shows that the government spends only 1.4% of its gross domestic product on Health. When a government fails to ensure a life with dignity for the sick and the elderly, it loses all moral authority to deny people the right to a dignified death. Lack of government policy on transplantation of human organ in India is the major reason for the weakness of the legislative and executive action.

In 1994, the parliament enacted the Transplantation of Human Organ (THO) Act.²¹ It provides for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs. The word “human organ” means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body.²² The person who donates the organ is called the ‘donor.’ It means any person, not less than eighteen years of age, who voluntarily authorizes the removal of any of his human organs for therapeutic purposes under the Act.²³ No human organ can be removed from the body of a donor before his death and shall be transplanted into a recipient unless the donor is a near relative²⁴ of the recipient.²⁵ A donor can authorize the removal of his organ after his death and transplanted to a recipient who is in need of human organ.²⁶

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 from the panel of names approved by the appropriate authority; (iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner 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.²⁷

preventive, promotive, curative, palliative and rehabilitative services provided through the public health sector with focus on quality.

¹⁹ Vikas Bajpai, “National Health Policy, 2017; Revealing Public Health Chicanery” 63 (28) *EPW* 31 (2018)

²⁰ “The Right to a Dignified Death” 63 (6) *EPW* 7 (2018)

²¹ The Act was amended in 2011

²² Section 2 (h), Transplantation of Human Organ Act, 1994

²³ Section 2 (f), Transplantation of Human Organ Act, 1994

²⁴ *Ibid.*, Section 2 (i) (Near-relative means spouse, son, daughter, father, mother, brother or sister)

²⁵ *Ibid.*, Section 9 (1)

²⁶ *Ibid.*, Section 9 (2)

²⁷ *Ibid.*, Section 3 (6)

The Government shall constitute one or more Authorisation Committees consisting of members nominated by the Government for the purposes of the THO Act.²⁸ If the donor authorises the removal of any of his human organs before his death and recipient not being a near relative, then the human organ shall not be removed and transplanted without the prior approval of the Authorisation Committee.²⁹ In *Sonia Ajit Vayklip v. Hospital Committee*,³⁰ the Court held that ‘Authorization Committee would theoretically be required to consider whether the donor and the recipient are near relatives. The applicants would, therefore, have to place some material before the Committee to enable it to hold that the applicants are near relatives.’

On an application jointly made by the donor and the recipient, the Authorisation Committee shall after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements of the Act and the rules made there under, grant to the applicant approval for the removal and transplantation of the human organ.³¹ The Committee shall have power to reject the application.³² The Authorisation Committee should be hospital based in metro and big cities if the number of transplants exceeds 25 in a year at the respective transplantation centre. In small towns there are District or State level committees if the transplantations are less than 25 in a year in the respective District.³³ In *Mohan Patnaik v. Government of A.P.*,³⁴ it was observed, Authorisation Committee shall take necessary precautions which a quasi-judicial authority is required to take. Authorisation Committee is one which is also required to consider whether removal of the organ is arranged on the basis of some sort of commercial transaction or for reasons which do not satisfy the conditions of authorisation as contemplated under the Act.

In *Siddhant Vikram Pal v. The Authorization Committee*,³⁵ the court observed that the Authorization Committee is expected to take its decision expeditiously and use its discretion judiciously and pragmatically in all such cases where the patient requires immediate transplantation of the human organ. If along with the application, a certificate of a medical practitioner having super specialization in requisite branch is produced recording that the recipient requires immediate transplantation of human organ, if the Authorization Committee is satisfied about the genuineness of the certificate, an endeavour shall be made by the Authorization Committee to decide the Application as expeditiously as possible and preferably within a period of four weeks from the date of receipt of the application. For making departure, in exceptional cases, the Authorization Committee must record brief reasons. However, all applications shall be decided expeditiously.

In *Vijaykumar Hariram Sahu v. State of Maharashtra*,³⁶ the court observed to what extent an organ donation would impinge on the life of the donor or on the extent, nature and quality of life of the donor has to be assessed. That must be balanced with the need expressed in the proposal for a transplantation to save the life of the donee. The need to save the life of the donee is a significant consideration not only from the perspective of the individual recipient and his family but also because there is a public health perspective in saving human lives. In

²⁸ Section 8 (4), Transplantation of Human Organ Act, 1994

²⁹ *Ibid*, Section 8 (3)

³⁰ <https://indiankanoon.org/doc/113917983/>

³¹ *Ibid*, Section 8 (5)

³² *Ibid*, Section 8 (6)

³³ Rule 6 A, Transplantation of Human Organs Rules, 1995

³⁴ 1997 (1) ALT 504 (FB)

³⁵ <https://indiankanoon.org/doc/36717777/>, visited on 12/2/19

³⁶ <https://indiankanoon.org/doc/13673523/>, visited 21/2/19

Parmanand Katara v. Union of India,³⁷ it was pointed out that, “this cannot, however, by any stretch of imagination be extended to taking someone else’s life to save one's own life.”

Any person, who renders his services to or at any hospital and who, for purposes of transplantation, conducts, associates with, or helps in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to ten years and with fine which may extend to twenty lakh rupees.³⁸

VI. Conclusion and Suggestions

The legal and ethical principles that we follow universally with organ donation and transplantation are also important for the future as these may be used to resolve our conflicts related to emerging sciences such as cloning, tissue engineering, and stem cells. Kidney transplants in India started in the 1970s and since then, India has been a leading country in this field in the Asian sub-continent. Despite the enactment of the Transplantation of Human Organ Act, trafficking of human organs especially of the kidney, retina, liver and heart is rampant in India.

Physicians are well placed to play a role in the mitigation of the illegal organ trade, including trafficking in human beings for the purpose of organ removal. They have unique access to patient information and are in a position to provide patients with critical information about the nature of the illegal trade. However, the following unethical practices are being reported frequently against the medical practitioners in India:

- The physicians are charging very high fees for transplantation of human organs or tissues.
- Physicians involving in organ removal from the donor and subsequent transplant often declare brain death at an early stage even though the person is not in brain death.
- Valid information/consent required under the law is not obtained in many cases of organ transplant.
- There is a commercial dealing in the transplantation or removal in donation of the kidney or retina organs or tissues.
- Donated organs are not made available to patient on their medical need; but on the basis of their financial or other consideration.
- The professionals doing organ transplantation surgery are engaged in illegal and unethical methods of transplantation.
- The donors are not told about the risk and side effects of the organ donation.

To conclude, though the Act of 1994 is divine; and helps in the resurrection of life, there are many drawbacks that frustrate the very purpose of the Act. The demerits outweigh the merits. Well defined policy on transplantation of human organs is the need of the hour. Stringent measures for the supervision of private hospitals are necessary. Details of the major surgeries, transplantation of human organs, fees, details of doctors and parties involved; subject to right to privacy should be updated in the government web sites.

³⁷ AIR1989 SC 2039

³⁸ Section 19 A, the Transplantation of Human Organ Act, 1994 (Amended in 2011)