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ORGAN TRANSPLANTATION LAWS

~*Harshitha Aila*

INTRODUCTION

Kidney transplantation was the foremost form of organ transplantation that was first performed on December 1st, 1971, at the Christian Medical College in Vellore.¹ Following the success of the procedure, transplantation activities witnessed a phenomenal increase during the 1980s and 1990s, with an increase in medical facilities and skilled personnel. However, it was restricted to live donors from selected urban areas. The organ shortage led to the exploitation of the economically weaker class, who were forced to sell their organs, especially kidneys, to wealthy, desperate organ failure patients for transplantation. To address this notorious kidney scam in India that garnered extensive media coverage, the Indian government formulated the ‘Transplantation of Human Organs (THO) Act’² in 1994 to provide a legal framework for the removal, storage, and transplantation of human organs for medical purposes and the prevention of commercial dealings in organs. The last amendment to the act was adopted in 2014, which made the commercial trade of organs a punishable offence and legalized the concept of donations from brain-stem dead people.

¹ *Organ transplantation acts: Health Department haryana: India* (no date) *Health Department Haryana/ India*. Available at: <https://haryanahealth.gov.in/organ-transplantation-acts/> (Accessed: 07 June 2024).

² *DGHS* (no date) *Directorate General Of Health Services*. Available at: https://dghs.gov.in/content/1353_3_NationalOrganTransplantProgramme.aspx#:~:text=Transplantation%20of%20Human%20Organs%20Act,have%20their%20own%20similar%20laws. (Accessed: 07 June 2024).

Organ transplantation is a therapeutic procedure wherein the damaged or missing organ of an individual (the recipient) is replaced with a healthy organ from another individual (the donor). The donor or recipient can be in the same place, or the organs can be transplanted from one place to another, where the organs are washed free of blood and placed in sterile containers packaged in wet ice to ensure their viability for transplantation.

To date, organs that have been successfully transplanted include the heart, liver, lungs, kidneys, intestines, pancreas, uterus, and thymus, and tissues include bones, tendons, skin, nerves, cornea, veins, and heart valves.

TYPES OF DONORS

A legal donation from a living person can be done only when the living donor is not less than 18 years of age and intentionally volunteers to donate his organs or tissues for therapeutic purposes during their lifetime, in accordance with the standard medical procedures. A living person during his lifetime can donate one of his kidneys (as a donor's body is incapable of functioning without both kidneys), a portion of his pancreas (as half of the pancreas is sufficient for sustaining pancreatic functions), and a part of the liver (the liver segments in both the donor and recipient will eventually regenerate). The THO Act 1994 classifies the types of donors into two categories: *living donors* and *Deceased/Cadaver donors*.

1. LIVING DONORS

(i) Living near related Donors:

Section 9 of the Transplantation of Human Organs states the living donation. The act further classifies living donations into donations by near relatives and donations by an unrelated donor. Section 2(i) defines 'near relative' as someone who is a spouse, daughter, son, father, mother, brother, sister, grandfather, grandmother, grandson, or granddaughter.³ The extent of donations from a near related living donor was restricted to immediate blood relations. The 2014 amendment of the Act included grandparents and grandchildren, expanding the fabric of immediate blood relations for

³ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

organ donations. However, it was mandatory for all the potential near-related donors to establish an evidence of their relationship with the recipient through genetic tests or by providing legal documents. The living near-related donors must submit an application in Form 1 (near-relative consent), Form 2 in case the donor is the spouse of the recipient, along with Form 11 (joint transplant application by donor/recipient) of the Transplantation of Human Organs and Tissues Rules, 2014, to the appropriate authority, which is the head of the hospital where the transplantation is performed, or to the Hospital Authorization Committee.⁴

(ii) Living non-near donors:

In this instance, the donor donates his organs/tissues out of affection or attachment towards the recipient, although they do not have a near relation with them. The living non-near donor must receive the approval of the authorization committee by appearing for an interview.

Form 3 (other than near relative consent) and Form 11 (joint transplant application by donor/recipient) must be submitted to the appropriate authority, as in the case of near relative donors.⁵ There is a two-level evaluation in the case of unrelated donors, where the applications are thoroughly reviewed by the Hospital Authorization Committee through an interview with the donor, the recipient, and their relatives to ensure that there is no commercial dealings of organs between the recipient and the donor and the donor is not under any coercion to donate their organ. The application is then forwarded to the State Authorization Committee for a second round of evaluation through interviews with the donor, the recipient, and their families. These interviews are recorded. If the committee sees through their interview that the parties have not complied with the rules of the Act, then the Committee shall reject their application for approval, and the reasons are recorded in writing.

(iii) Swap Donors:

⁴ *Organ transplantation in India: Organ transplant governing laws (2019) ORGAN (organ receiving & giving awareness network) India.* Available at: <https://www.organindia.org/organ-transplant-laws-made-easy/> (Accessed: 08 June 2024).

⁵ *Organ transplantation in India: Organ transplant governing laws (2019) ORGAN (organ receiving & giving awareness network) India.* Available at: <https://www.organindia.org/organ-transplant-laws-made-easy/> (Accessed: 08 June 2024).

In the instance of a pair of donors and recipients who are near relatives, where the donor of the first recipient has a biological issue and is deemed to be incompatible for the transplant, and the other pair is suffering from the same issue, but, the first donor's organs are compatible for transplantation with the second recipient and the second donor's organs are compatible for transplantation with the first recipient, the Transplantation of Human Organs and Tissues Act, 2014, legalizes the swap transplant between the pair, wherein the first recipient's organ donor donates his organ to the second pair recipient and the second recipient's actual organ donor donates his organ to the first recipient. The evaluation procedure for approval for the swap transplant is the same as the evaluation procedure for approval for the unrelated transplant. However, the procedure becomes inconvenient when one of the donors/recipients is from another state, and approval for the swap transplant requires approval from that State's Authorization Committee. Such inconvenience results in a delay in the approval of the transplantation, which can cost a life.

The Author of an article about the legalities of organ transplantation in India has witnessed one such case where the recipient and the donor (spouses) belonged to Gujarat, and another pair of a daughter and mother, wherein the daughter belonged to Rajasthan and the mother was from Haryana, were all set for a swap transplant. The review process for the swap transplant required approval from three different states, and relevant copies must be submitted to the Maharashtra Authorization Committee. The whole procedure took approximately seven months, and the transplant was set to take place in a hospital in Mumbai.⁶

2. DECEASED/CADAVER DONORS

Section 3-8 of the Transplantation of Human Organs and Tissues Act, 2014, regulates Cadaver donation. Subsection (2) of Section 3 states that any donor, in their writing and in the presence of two witnesses, at least one of whom is a near relative, at any time of their life before their death, can authorize the removal of organs/tissues after his death for therapeutic purposes. In the instance where the person has not written before his death to donate their organs/tissues, the person in lawful possession of the dead body can authorize the removal of organs for therapeutic purposes unless they

⁶ Shah, Sunny B.; Shah, Bharat Vallabhdas. Legal Aspects of Transplantation in India. Indian Journal of Transplantation 12(3):p 169-173, Jul-Sep 2018. | DOI: 10.4103/ijot.ijot_43_18

have a reason to believe that any near relative has an objection to the same.⁷ Form 7 of the Transplantation of Human Organs and Tissues Act, 2014, regulates the procedure for self-consent for deceased donation.⁸

Sub-section (6) of Section 3 states that to proceed with the donation of organs/tissues from a deceased/cadaver donor, a certificate from an authorized Board of medical experts declaring that the person is indeed a brain stem dead person is required, along with:⁹

- (i) the registered medical practitioner in charge of the hospital in which brain-stem death has occurred;
- (ii) An independent registered medical practitioner from the panel of names approved by the appropriate authority;
- (iii) A neurologist/neurosurgeon approved by the panel of names approved by the appropriate authority;
- (iv) A registered medical practitioner treating the deceased person.

REGULATORY BODIES FOR MONITORING ORGAN TRANSPLANTATION IN INDIA

APPROPRIATE AUTHORITY:

The various functions of the Appropriate Authority body include regulating the removal, storage, and transplantation of organs, inspecting them, and granting registration to hospitals for transplantation surgeries. The body also conducts regular inspections to evaluate the quality of the transplantations performed.

The Appropriate Authority issues a license to the hospitals for 5 years, which needs to be renewed after the term. It may also inquire into accusations of Act violations and

⁷ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

⁸ *Organ transplantation in India: Organ transplant governing laws (2019) ORGAN (organ receiving & giving awareness network) India*. Available at: <https://www.organindia.org/organ-transplant-laws-made-easy/> (Accessed: 08 June 2024).

⁹ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

has the authority to summon people, demand documents, and issue search warrants comparable to a civil court.

AUTHORIZATION COMMITTEE:

This Committee plays a significant role in reviewing the applications for transplantations by living donors and ensuring that no person is being exploited monetarily and to prevent commercial dealings of organs. All the interviews and evaluations for transplantation by living donors are regulated by this body, and the recordings of the interviews are also followed.

ADVISORY COMMITTEE:

The main purpose of this body is to advise the Appropriate Authority.

MEDICAL BOARD:

Consists of a medical panel in charge of certifying brain death certificates. In the instance where a neurologist/neurosurgeon is unavailable, any practiced surgeon, anaesthetist, or physician whose name is nominated by the medical administrator in charge may grant a certificate of brain death to a deceased person.

HOSPITALS AND HUMAN ORGAN DONATION CENTRES UNDER THE ACT

(i) The Transplantation of Human Organs and Tissues Act, 2014, sections 10 and 14, states that no hospital unless registered under the act can conduct the procedure of transplantation.¹⁰

(ii) Any hospital to be registered under the act as a transplant centre must comply with the requirements to be in a position to provide the medical services, have skilled personnel and equipment, and maintain such standards as prescribed.¹¹

¹⁰ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

¹¹ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

(iii) Any organ donation centre to be registered under the act must possess the required equipment and manpower, along with the intensive care facility units to diagnose and maintain brain stem dead person.¹²

(iv) Section 13 of the Transplantation of Human Organs and Tissues Act, 2014, provides the Appropriate Authority with powers to grant certification to the registered hospitals under the act and also cancel the license of any if the hospital breaches the rules of the act.¹³

PUNISHMENT UNDER THE ACT

(i) Section 18 of the Transplantation of Human Organs and Tissues Act, 2014, states that any person who is involved in the removal of any organ without authority shall be sentenced to a punishment of imprisonment of 10 years and a fine that may extend to 20 lakhs.¹⁴

(ii) If a medical practitioner is involved in such, his name will be reported by the Appropriate Authority to the Medical committee, where his name will be suspended for a period of 3 years in the instance of the first crime. If the person commits the crime again, his name will be permanently removed.¹⁵

(iii) If a person is involved in the commercial dealings of organs, under Section 19 of the Transplantation of Human Organs and Tissues Act, 2014, they shall be sentenced to a punishment of imprisonment of 5 years, which may extend up to 10 years, and also be liable to a fine of 20 lakhs, which may extend up to one crore.¹⁶

(iv) If a person breaches any regulations under the act, then he will be sentenced with a punishment of imprisonment up to 5 years and will be liable to a fine of 20 lakhs under Section 20 of the act.¹⁷

CONCLUSION

¹² The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

¹³ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

¹⁴ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

¹⁵ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

¹⁶ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

¹⁷ The Transplantation of Human Organs Act, 1994, § 9, No. 42, Act of Parliament, 1994 (India).

There have been remarkable legal advancements in the field of organ transplantation in India, which has been able to set foundations to deal with the issues of organ donation and the proper means of practicing it ethically. The Transplantation of Human Organs Act 1994 and further regulation enactments set up a legal framework that seeks to safeguard both donors and recipients, avoid traffic in human organs, and provide an equitable distribution of organs.

However, there are some barriers that are still existent, such as organ scarcity, misconceptions about the practice in the community, and other practical concerns. Solving these demands requires policies, awareness, and technology shifts that tend to alter current business models. Other legal highlights have also determined the dramatic interventions, which base the legal structure on justice and equity.

These reasons mean that further attempts need to be made to increase the rate of organ donation and have clear and informed permission to carry out transplantation as well as equal distribution of organs. More voices should be brought into the process of lawmaking, and continued policy improvements should be energised with qualitative medical research. In concert with all the stakeholders, India should be able to enhance the current formulation in order to have a more efficient system of organ transplantation, create more opportunities to save lives, and improve health conditions for many.