

Organ and Transplantation: Insight into Transplantation of Human Organs Act (THOA)

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Abstract

Transplantation of Human Organs Act (THOA) was brought in by the Central Government of India in 1994 to promote legal and ethical organ transplantations across the country in a uniform manner. This Act was adopted by all the states, and certain states have brought in changes suitable for their requirement.

As per the act, organ is a any part of the body which performs a specific function. After its transplantation into another human being, it takes the function and starts functioning. Most of the organs from the body can be transplanted. But within a specific time period. These organs cannot be transplanted to anybody. There are certain rules and regulations laid in this act which guide us to proceed with the transplantation.

Keywords: Transplantation; Organs; Legal issues; donor

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Introduction:

Transplantation of Human Organs Act (THOA) was brought in by the Central Government of India in 1994 to promote legal and ethical organ transplantations across the country in a uniform manner. This Act was adopted by all the states, and certain states have brought in changes suitable for their requirement. The Act mentions the registration of hospitals performing transplantations, the renewal of the registrations, and the prerequisites of the same. With the expanding depths and vastness of organ transplantation, certain amendments were made in 2008 and in 2011, wherein the concept of near relative was redefined, and the entity of swap transplantation was introduced legally. In addition, the term and the fine for punishments for the offence were changed.

In 2014, for easy work policy, the Rules were redefined for workup and scrutiny of transplant case scenarios within the framework of Act of Transplantation.¹

During the period 1995–2000, deceased-donor organ transplantation (DDOT) had been attempted from only 35 hospitals in Maharashtra and Tamil Nadu states. In 2005, a National Organ Registry was established. During the first 12 years, the program was sustained by the efforts of the governments, non-governmental organizations (NGOs) and other stakeholders until 2010. In 2011, the act underwent an amendment, resulting in the formation of the National Organ and Tissue Transplant Organization (NOTTO) to function as the Indian National Registry for organ donation and transplantation and to perform the functions of the National Human Organs and Tissues Removal and Storage network. In the then-combined state of Andhra Pradesh, a scheme called 'Jeevandan' was initiated in 2003, following the success in Tamil Nadu. The term 'Jeevandan' fundamentally translates to the *gift of life* where in a person willingly

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donates his/her organs, thus gifting another person, a second chance at life.²

The term, “Donor” means any person, not less than eighteen years of age, who voluntarily authorizes the removal of any of his human organs for therapeutic purposes. “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; therapeutic purposes” means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and “transplantation” means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes.³

Organ donation is defined as “When a person allows an organ of theirs to be removed, legally, either by consent while the donor is alive or after death with the assent of the next of the kin.”⁴

Common transplantations include kidneys, heart, liver, pancreas, intestines, lungs, bones, bone marrow, skin, and corneas. Some organs and tissues can be donated by living donors, such as a kidney or part of the liver, part of the pancreas, part of the lungs, or part of the intestines. Even though possible while living, most donations occur only after the donor’s death.⁴

Organ transplantation is one of the greatest medical marvels of the twentieth century, which has prolonged and improved the lives of hundreds of thousands of patients, worldwide. Countless acts of generosity by organ donors and their families have made transplantation not only a life-saving treatment but also a shining symbol of human solidarity. The disparity between the huge demand for organs and their poor supply is the main issue of concern. Organ shortage is a global issue and deceased organ donation is the major sustainable solution.⁵

Specified and unspecified donation form two significant classification types for the donor-recipient relationship. A specified donation entails an intended/known

recipient to whom the graft donor may be genetically and/or emotionally related (e.g., a spouse giving her kidney to her husband represents a specified direct donation, whilst a donation to a known recipient through an exchange program is a specified indirect donation). An unspecified donation represents an undefined graft recipient (completely anonymous) who is placed in a fixed donation waiting list.⁶

Donation after brain death (DBD) remains one of the primary sources for organ transplants.¹ Irreversible coma from a known cause, brainstem areflexia, and apnoea are the essential criteria for brain death determination. Organ donation also occurs after circulatory death (DCD); defined as the permanent loss of consciousness capacity and brainstem functioning. Compared to DBD, DCD donors are younger. The donors are further differentiated into standard criteria donors (SCD) or extended criteria donors (ECD), depending on whether the age of the donor is 60 years or more, or the age is 50 – 59, with the presence of at least two of the following: hypertension, death from cerebrovascular accident and terminal creatinine >1.5 mg/dL.⁵

Three prerequisites should be met with while certifying brain death, such as (i) coma or unresponsiveness, (ii) absence of brainstem reflexes, and (iii) apnoea. As there is no global consensus on the criteria for establishing brain death, different tests are used in different parts of the world. In India, apnoea testing is used for documenting brain death, which checks the integrity of the brain stem respiratory centre at high levels of carbon dioxide. Candidates should be normothermic (core temperature $\geq 36^{\circ}\text{C}$), stable hemodynamically (systolic pressure ≥ 90 mm Hg), free from sedative and paralytic drugs with normal oxygenation and near normal PaCO₂. If respiratory movements are not present and the PaCO₂ is >60 mm Hg or elevated >20 mm Hg from baseline value, the test is considered positive. A second apnea testing is required

for certifying brain death in many countries. The time interval between the first and second testing is also country specific. The second test is done at an interval of 6 hours in India. Cold ischemia time refers to the amount of time that an organ is not receiving blood supply and is maintained on a cold preservation fluid. Cold ischemia time varies widely from organ to organ, but in general, the sooner an organ can be transplanted, the better it is for ensuring its viability. The commonly accepted cold ischemia times for various organs are as listed below: Heart: 4 hours Lungs: 4 to 6 hours Liver: 6 to 10 hours Pancreas: 12 to 18 hours Intestines: 6 to 12 hours. Kidneys: 24 hours (may be extended up to 72 hours if placed on mechanical perfusion)⁵ With new evidence that organs can tolerate short periods of warm ischemia with successful outcomes, the concept of DCD is gaining much interest. DCD is further categorized based on the modified *Maastricht classification*.⁵

In India, the potential organ donor pool is majorly comprised road traffic accident (RTA) victims who have sustained traumatic head injuries and have been declared brain dead.⁷

Barriers to organ donation includes consent, ethics, lack of understanding and race whereas the barriers can be tackled with early identification and expanded donor eligibility, compensation and incentives, education and communication, efficiency of organ allocation and awareness and prevention of diseases.⁶

Ongoing Efforts for Circumventing the Problems:⁵

- Public-private partnerships with the help of transplant coordinators have immensely contributed to improving organ-procuring rates in India over the recent years. This holds true in the case of southern states of India (Tamil Nadu, Kerala, Andhra Pradesh and Pondicherry), where deceased organ donation and transplantation is much better established than in other parts of

the country. MOHAN(Multi-Organ Harvesting and Networking) foundation is a philanthropic non- governmental organisation based in south India, which works to improve organ donation and transplantation rate. It is the first organisation to promote deceased organ donation and has been in existence since 1997.

- Appointment of a transplant coordinator has been made mandatory for all transplant centres. They help in counselling of families for taking consent for organ donation and coordinate the process of donation and transplantation.
- NOTTO–National Organ and Tissue Transplant Organization is a national level organization set up under the Directorate General of Health Services, Ministry of Health and Family Welfare. The National Human Organ and Tissue Removal and Storage Network is a subdivision of this organization, which was formed as mandated by the Transplantation of Human Organ Act (THOA) amendment in 2011.
- Green corridor refers to a special road route that facilitates the transportation of harvested organs meant for transplantation to the desired hospitals. The street signals are manually operated to avoid stoppage at red lights and to divert the traffic to ensure a rapid transportation of the desired organ.
- Tissue banking is the process in which biomedical tissue is stored under cryogenic conditions to be used later when the need arises. A number of tissue banks have been established in India in the recent times, which help in storing tissues such as the cornea, skin, heart valves, bones and tendons for later use.
- A relation between positive reciprocity and organ donation behaviour seems intuitive if people regard others' willingness to donate organs as kind. For equal beliefs about other people's organ donation attitudes and behaviour, people

with higher positive reciprocity should then be more willing to donate organs. Anecdotal evidence for this comes, for example, from the so-called “Nicholas Green effect”, named after an American boy who was killed by robbers while vacationing in Italy. His parents consented to donating his organs to patients awaiting transplantation. This choice received intense media coverage and contributed to a threefold increase in organ donations nationally.⁸

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