
LEGAL REGIME ON ORGAN DONATION IN INDIA

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ABSTRACT

Organ donation is defined as giving an organ or part of an organ to be transplanted into another person who is in need of the organ for his or her survival. Organ transplantation can save lives. However, there exist a disparity between the supply and demand for donated organs. In this article, the researcher would throw light upon the concept of organ donation, its kinds, challenges or hindrances in organ donation, legal regulations & rulings and lastly, the guidelines or policy framed by our Government.

Keywords: Organ donation, Kinds, Challenges, Legal Regulation, Rulings and Guidelines.

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Meaning of Organ donation:-

Organ donation is a process of gifting an organ from one person to another person who needs the organ for survival.¹ Organ donation is a noble and charitable act through which someone's life can be saved or enhanced. It is done voluntary and without any compensation in return to the person donating organ. Organ donation can be done during the lifetime of a person as well as after the death of the person. In medical terms, there are three kinds of organ donors: - *live donors, cadaveric donors or brain-dead donors, and natural death donors.*²

Living donors: They are those who are willing to donate his or her organ to someone in need of a transplant and they are above the age of 18 years.

Cadaveric donors: Brain death is an irreversible cessation of cerebral and brain stem function characterized by the absence of electrical activity in the brain, blood flow to the brain, and brain. "*A brain-dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time*³." Hence, the organs from a brain-dead individual can be transplanted into the body of a living recipient.

Natural death donors: A person after his or her natural death can donate his or her organs for example: eyes

In India, the first organ donation happened in the year 1970 and since then, more donations started happening. It has been reported that 25 (twenty-five) different organs or tissues can be donated by humans after checking the psychiatric, and medical fitness of donor. The most transplanted solid organs are kidneys, liver, pancreas, and heart, while cornea and musculoskeletal grafts are the most transplanted tissues. Organ donation is a very complex procedure and hence, requires a robust legal framework to make sure that donation process remains ethical, transparent, and safe.

¹ Kanmani Job and Anooja Antony, "Organ Donation and Transplantation: Life After Death" *IntechOpen* 2 (2018).

² Lalitha Mohan and T Thanga Panneer Selvam, "Perspective on Organ Donation in India: A Comprehensive Review" 7 *The Journal of Community Health Management* 73-76 (2020).

³ Noble Gracious and Veena Roshan Jose, "Certification of Brain Stem Death in India: Medico-Legal Perspectives" 16 *Amrita Journal of Medicine* 71-73 (2020).

Challenges encountered in organ donation: -

1. Lack of awareness among people about organ and tissue donations.
2. Some cultural and religious beliefs discourage people from organ donation
3. Some have fear and mistrust due to the exploitation by the hospitals & on the doctors.
4. The demands for organ are more as compared to donor.⁴

Regulation & Rulings: -

The primary legislation related to organ donation and transplantation is “*Transplantation of Human Organs and Tissues Act, 1994*”, and is aimed at regulating the removal, storage, and transplantation of human organs for therapeutic purposes and prevention of commercial dealings in human organs. As per the Act,

“The concept of transplantation is grafting of human organs from living or dead persons to a living person for therapeutic process. Further, the deceased person is a person who does not have any symptoms of life such cases that is of brain stem death or cardio-pulmonary sense after live birth⁵.”

The regulation of transplant activities is done by forming an “*Authorization Committee*,” “*Appropriate Authority*,” “*Advisory Committee*” and “*Medical Board*.” The purpose of authorization committee is to regulate the process of authorization i.e., to approve or reject the transplants between the recipient and donors. The foremost duty of this committee is to ensure that the donor is not exploited for monetary consideration to donate their organ. By virtue of this Act, joint application made by the recipient and donor is scrutinized and a personal interview is essential to satisfy the authorization committee the genuine motive of donation. Further, to ensure that the donor understands the potential risks of the surgery as well. The information about approval or rejection is sent through mail to the concerned hospitals. A hospital is only permitted to perform such activities only after being licensed by the authority but in case of removal of eyes from a dead body of a donor the same is not governed by such

⁴ Vivek B Kute, Hari Shankar Meshram, *et.al.*, “Current Status, Challenges, and Opportunities of Organ Donation and Transplantation in India” *Transplantation* (2023).

⁵ Johny Kutty Joseph and Babitha K Devu, “Organ Transplantation in India; Legal and Ethical aspects” 9 *Indian Journal of Applied Research* 37 (2019).

an authority and can be done at other premises and does not require any licensing procedure. Apart from this, the Act confers powers to the appropriate authority which includes inspecting and granting registration to the hospitals for transplant surgery, enforcing the required standards for hospitals, conducting regular inspections of the hospitals to examine the quality of transplantation and follow-up medical care of donors and recipients, suspending or cancelling the registrations or erring hospitals, and conducting investigations into complaints for breach of any provisions of the Act. The appropriate authority issues a license to a hospital for a period of 5 (five) years at a time and can even renew the license after that period gets over. Each organ requires a separate license. The Act further states that before removing the organ from the body, a medical practitioner should satisfy himself that the donor has given authorization by filling out the *form* and the donor is in a proper state of health and is fit to donate the organ. The complete medical examination is conducted in which the medical and social history are taken into consideration and if the person is eligible for an organ donor, the computer begins to search on the national scale. The best-matched patients are contacted by the transplanting team to the patient and this is the call for which every person on the waiting list is being hoped for. Then the transplant takes place. The first relative such as father, mother, brother, sister, son, daughter, and wife could donate organs without permission from the government. However, the unrelated donor is required to file an affidavit in the court of a magistrate stating that the organ is being donated out of affection, after which the donor must undergo number of tests before the actual transplant takes place. According to the Act, *“any person who is responsible for the removal of a human organ or tissue with the authority of doing so can be punished with imprisonment which can extend to “10 years” and with fine which can extend to Rs. 20 lakhs. In case that person is a medical professional, his name will be reported by the ‘Appropriate Authority’ to the State Medical Council to take appropriate action including removing his name from the register of the council for 3 years for the first offense and if he/she commits an offense subsequently, then remove it permanently. If any person involves himself/herself in the commercial dealing of human organs then such person can be punished with imprisonment for a term not less than 5 years but can extend to 10 years and will also be liable for a fine which will not be less than Rs. 20 lakhs but can extend to Rs. 1 crore⁶.”*

After the amendment made in the Act of 2014, *“the permission to operate transplantation was*

⁶ Transplantation of Human Organs and Tissues Act, 1994 (Act No. 42 of 1994)

given to each hospital which could provide proper care facility to donors as well as ventilators to retrieve the organs. Relaxation was granted in the earlier mandatory provision in confirmation with the appropriate government regarding the mandatory presence of neurosurgeon at the time of declaring a person dead. It was made mandatory on the part of physicians and doctors to approach the deceased's family and make them aware about the whole transplant system and go ahead with the process as it would be beneficial for the society. The transportation cost, medical expenses, donor's maintenance, retrieval of organs, or tissues would be borne by the receipt or his family or the government, and non-government organization."

Some medical practitioner argued that India should have a mandatory deceased organ programme. The question which is still in debate is whether minor can donate organ or not? Recently a case came before the Hon'ble Supreme Court when a 17-year-old boy moved a plea seeking permission to donate his liver to his 43 years old father who suffered from acute liver disease⁷. According to the Act, it is not possible for minors to donate organs or tissue before death. In the similar case, Delhi High Court ruled that: -

"There is no complete prohibition on organ or tissue donation, but clarified that donation is permissible but in exceptional circumstances and in accordance with the rules."

Donation by minor is permissible but only in exceptional circumstances. The Delhi High Court directed to set up a medical board to determine the risk to the life of minor.

Recent developments: -

Recently, Union Ministry of Health and Family Welfare have introduced certain changes in organ donation and transplantation guidelines which is to be followed by each States. Apart from this, Union Health Ministry brought "***one nation one organ allocation policy***" for uniform registration, selection & transplantation criteria, and guidelines. There is no age bar to register for cadaver organ transplant as well as even there will be no imposition of registration fees for donating organs. Gujarat government policy says that giving preference to any patient based on domicile is not allowed and giving such preference is unconstitutional. If anyone

⁷ "Make Organ Donation Mandatory After Death: Doctors Amid Debate on on Living Minor's Organ Donation", *ThePrint*, Sept. 22, 2022, available at: <https://theprint.in/india/make-organ-donation-mandatory-after-death-doctors-amid-debate-on-on-living-minors-organ-donation/1126709/> (last visited on Nov. 26, 2023).

needs transplantation, that patient can directly go to the website of NOTTO and can do the registration without any fees. Our Ministry of Road Transport and Highways have announced that applicants can opt for to become organ donors while applying for driving license. It has introduced an option in the driving license application form to pledge to donate organs in case of death by road accident.

Conclusion: -

India still needs to push more for organ donation though steadily increasing since last decades as well as many more issues persist which needs to be considered and addressed.