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THE LEGAL TERRAIN OF ORGAN TRANSPLANTATION POST BRAIN DEATH

~ *Anugraha P*

Medical history of organ transplantation:

Organ transplantation in India has a relatively short history compared to the developed world. In the 20th century, there was an increase in the number of kidney transplants. Other organ transplants are a recent activity. The increase in technologies and educational developments also lead to a boost in the sector. In the last few years, as part of the scientific achievements, organ transplantation has gained pace in our country.

Legal & Procedural Methodologies:

In Indian context, the transplantation mainly is done after the brain death of a person, whose family willingly consents to donate his/her organs for transplantation. Almost 37 organs can be transplanted after death of brain stem in a person. Organs such as. Kidneys, heart, liver, cornea, skin, pancreas intestines, bones, veins etc can be used for transplantation¹. Brain death² can be caused by several reasons, that can be brain tumours, severe head injuries etc. The role of hospitals and medical practitioners are very crucial in organ transplantation. Convincing the family members about brain death, management of the brain-dead person after transplantation, coordination for the procurement of the organ to the recipient and the ultimate target is the surgery of the recipient for the transplantation to achieve the best outcome. Generally, in a brain-dead person, the body is given artificial respiration so as to sustain life in the inner organs that is in other sense, organs like kidney, liver, pancreas and intestines are suitable for transplantation. For a brain-dead person, there

¹ Nallusamy S, Shyamalapriya, Balaji, et al. Organ donation – current Indian scenario. J Pract Cardiovasc Sci 2018;4(3):177–179. DOI: [10.4103/jpcs.jpcs_59_18](https://doi.org/10.4103/jpcs.jpcs_59_18).

² Section 2(d) of the Transplantation of Human Organs and Tissues Act 1994

is no possibility for recovery. After the confirmation of brain death, there are other cross matching techniques used to realize whether the donor is capable of donating the organs to the recipient. Procedure to be followed in case of determining the brain death of a person involves several complicated medical tests³ which are enumerated in the enactment⁴, that includes examining about:

- i. Absence of Pupillary reflex response to light
- ii. Absence of Corneal reflexes
- iii. Absence of Vestibulo-Ocular reflex
- iv. Absence of Cranial nerve response to pain
- v. Absence of Gag and Cough reflexes
- vi. Apnoea Test

According to the law in force, proceeding to the organ transplantation requires declaration by a panel of 4 doctors on which 2 must be government approved who are authorised for the same. The tests in 2 tiers must be done in an interval of 6 hours to declare the death of brain stem of that patient. Before further steps, counselling of the family and request for the organ donation of the patient are mandatory requirements of the Act. Usually, the next of kin of the donor will decide whether to donate the organs or not.

In *Dr S Ganapathy v. State of Kerala*⁵, a public interest litigation was filed in order to throw light on the tests that are mandatorily to be followed to declare that a person is Brain dead. The court reiterated the position that it is the duty of state and central governments to take actions against the malpractices and also ensuring the proper procedure of medical tests to be followed as per the enactment, further the court pointed out that the THO&T Act has necessary provisions to ensure the same and is in par with guidelines laid down by WHO.

In concern with the procedure to be followed in cases of Organ Transplantations, in *Dr Mathew Jacob v. State of Kerala*⁶ the Kerala High Court ordered for an enquiry against the doctors who unauthorisedly approved the brain death of a person and claimed money for two organ transplantations which in reality was only one.

³ Wijdicks EF, Varelas PN, Gronseth GS, et al. American academy of neurology. evidence-based guideline update: determining brain death in adults: report of the quality standards subcommittee of the American Academy of Neurology. *Neurology* 2010;74(23):1911–1918. DOI: [10.1212/WNL.0b013e3181e242a8](https://doi.org/10.1212/WNL.0b013e3181e242a8).

⁴ Section 3(6) of the Transplantation of Human Organs and Tissues Act 1994

⁵ CMP No. 1004 of 2021, Order dated May 29, 2023.

⁶ WP(C) 19123/2019

Legislations in this point:

In 1994, the Transplantation of Human Organs and Tissues Act was introduced by our legislature so as to take essential management in organ transplantation. This Act made brain death as a type of death and made sale of human organs a punishable offense. The legislation was formulated because of the protests led by various people from different strata of our society. The protest was against the illegal selling and marketing of human organs and also, non-availability of such technologies to the poor sections of the society. The Transplantation of Human Organs Rules were followed in 1995. Later, the rules alone were amended in 2011. The law and most of the criteria and methodologies were derived from the British law.

The establishment of the Authorization Committee⁷ is a part of Transplantation of Human Organs Act 1994 which functions to regulate the removal, storage and transplantation of human organs. All transplantations should be done with the approval of the Authorization Committee. They have the authority to approve or reject the transplantation. These have Central, State and District level authorities to take care of transplantations. They take decisions on the basis of documentation and interviews of both donor (Living donor) and recipients. The interaction between the parties and officers in the committee is essential for the right interpretation in this sector. Only licensed hospitals and registered medical practitioners are allowed for conducting organ transplantations and licenses are established to the hospitals by the Authorization Committee. The transplantation of human organs act, 1994 provides many provisions for the authorization or regulation of living donation, regulation of activities of hospitals and human organ retrieval centres, medical practitioners etc. The objective of THO Act 1994, is to streamline the organ transplantation activities.

Indian legal arena seems to have a series of precedents in the point of organ transplantations.

Amar Singh Bhatia & Anr. vs Sir Ganga Ram Hospital & Ors. the court pointed out the delay caused in the procedural requirements of organ transplantation which led to death of a person. It mainly focussed on the delays on decision making by Authorisation committee which led to sufferings by the patient and their families.

⁷ Yadla M. Legal policies of organ transplantation in India: basics and beyond. Saudi J Kidney Dis Transpl 2019;30(4):943–952. DOI: [10.4103/1319-2442.265472](https://doi.org/10.4103/1319-2442.265472).

Relying on the judgement delivered in the case of *Neha Devi v. Govt. NCT Delhi*⁸, the Delhi High Court stated about spousal consent is not a statutory mandate under the Act thus in cases where the donor can give consent voluntarily then a spousal consent is not required.

Pointing Finger against the Ground of Marketing in human organs:

The aim of establishment of the THOTA 1994, is to analyse the methodologies, allegations and punishments for those who infringe the provisions of the Act. Even though many legislations raised this issue, there are no proper implementations into the roots of our society. Every year in India 100,000 people is in need of organ transplants, but only about 25,000 transplants are taking place⁹. The crisis is suffered mainly by poor sections of the country because of the increase in gap between the availability and donation of human organs.

The challenge starts from the very beginning, that is to convince the families of the donor further paving way for the approval by the State Authorization Committee that may take more time. In *Parveen Begum v. Appellate Authority*¹⁰ the Delhi High Court relied upon the fact that organ transplants cannot be rejected only on the mere existence of disparity between the income of the recipient and donor. Thus directed the Authorisation committee to grant approval for the kidney transplant.

The existence of very smaller number of licensed hospitals¹¹, and registered medical practitioners to carry out the process is a going concern, and ones having licenses are mostly owned by private individuals. Public sector has not flourished in the organ transplantation sector; this can be the reason for the illegal trade in human organs. The huge mafia involved in the black marketing of human organs are usually not in notice of the law or any other authorities which paves way for the non-availability of human organs to the poor sections or the one who wants. The World Health Organization [WHO] has called upon all countries to go with self-sufficiency in the area by decreasing the burden and increasing the availability of organs.¹²

⁸ W.P (C) 8671/2022

⁹ Sachdeva S. Organ donation in India: scarcity in abundance. *Indian J Public Health* 2017;61(4):299–301. DOI: [10.4103/ijph.IJPH_230_16](https://doi.org/10.4103/ijph.IJPH_230_16).

¹⁰ 2012 SCC OnLine Del 2839.

¹¹ Section 14 of the Transplantation of Human Organs and Tissues Act 1994.

¹² WHO task force on donation and transplantation of human organs and tissues. Available from: <https://www.who.int/transplantation/donation/taskforce-transplantation/en/> [Accessed May 26, 2024].

In India the transportation of organs mainly takes place through road, this increases the risks of wastage of healthy organs and even loss of the organs due to delay in delivery to long distances green corridors¹³ are a significant step to tackle the issue. The infrastructural developments in this sector are not in a developing stage, especially in our country. The facilities for preserving and ventilating organs are not yet emphasized.

The law relating to organ transplantation does little to protect the organ donors, who are mostly from poor social backgrounds. The law prescribes punishment for commission of illegal and brutal crime of commercialising the organs, which states an imprisonment ranging between two to seven years and a fine ranging between Rs. 10,000 and Rs. 20,000¹⁴. Section 18¹⁵, 19¹⁶, 20¹⁷ and 21¹⁸ of the Transplantation of Human Organs and Tissues Act 1994 deals with the offences relating to unauthorised rendering of services in organ transplants by persons, medical practitioners and companies involving in such dealings.

Despite these efforts, still there are many large rackets headed by prominent personalities in the black marketing or illegal trade of human organs. The consent for organ transplantation from the close relatives of the donor can be obtained by coercion etc. Towards monitoring these issues, the officers should be more alert and make investigations about the consent to the relatives or the donor. In some cases, they don't know the consequences of the surgery. In most cases, the donations are made by women and poor people, these can be because of financial crises or consents made by coercion. Organs gained by these means are used for illegal marketing. These are commercially very valuable so that their marketing is done by various rackets. Lack of connection between the officers of the committee and the parties is a reason for the crisis. Protection on the basis of law to the people who are exploited in commercial trade of organs is vital. The government and the concerned officers should be more concerned and seemed towards the law and other aspects in this organ transplantation.

Every section of the country should avail their benefits in the surgery of transplantation of organs.

¹³ Patel A, Balwani M, Patel H, et al. Deceased organ donation in India – current challenges and scenario. *Indian J Transplant* 2018;12(3):174–176. DOI: [10.4103/ijot.ijot_26_18](https://doi.org/10.4103/ijot.ijot_26_18).

¹⁴ Section 19 of the Transplantation of Human Organs and Tissues Act 1994.

¹⁵ Punishment for removal of human organ without authority.

¹⁶ Punishment for commercial dealings in human organs.

¹⁷ Punishment for contravention of any other provision of this Act.

¹⁸ Offences by companies.

Transplantation of any form, let alone brain death, is a vital service to the society and monitoring and observation is equally important for its development and maintenance. For this, a well-connected, more transparent and unambiguous authorization community is required. Awareness and implementation of schemes and policies among the society with equal regards to all communities and sections of the society will aid us in building up an altruistic society. This will result in a better state of health socially and physically in the near future.