



ORGAN TRANSPLANTATION IN INDIA; LEGAL AND ETHICAL ASPECTS

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ABSTRACT **Background:** The Organ transplantation is one of the greatest medical marvels of the twentieth century. The readiness of a person to donate his/her organs made the concept of transplantation, a life saving treatment as well as a symbol human solidarity. Currently there is a huge gap in the need and supply of organ transplantation. The Transplantation of Human Organs and Tissues Rules which was enacted in the year 2011 by Govt. of India clearly describes the rules, regulations and measures to be adapted for bridging the above said gap. This article reviews the current norms prevailing in India with regard to organ transplantation.

Methods: In this review the different databases such as PubMed, were searched for articles related to organ transplantation. Additionally information also was obtained from the Press Information Bureau, Govt. of India, official websites of NOTTO (National Organ and Tissue Transplant Organisation) and Mohan Foundation.

Summary: Currently in India 2 to 3 lakh patients are waiting for different organ transplantations against which only 25000 organs (approximately) are available. Therefore, considering the need of organ transplantation there is a need to review the policies and regulations pertaining to organ transplantation in the country.

KEYWORDS : organ transplantation, NOTTO guidelines, kidney transplant, legal and ethical aspects.

INTRODUCTION

The Organ transplantation is one of the greatest medical marvels of the twentieth century. Innovations in medical sciences such as use of mechanical ventilators for brain dead persons and introduction of immune suppressive drugs have made a huge impact in the practice of organ donation and transplantation. The readiness of a person to donate his/her organs made the concept of transplantation a life saving treatment as well as a symbol human solidarity. At present, the organs, for example, heart, liver, kidneys, lungs, pancreas, cornea, skin, heart valves, bones, ligaments and so on can be given/transplanted. Organ shortage is a global issue and deceased organ donation is the major sustainable solution.

Here, through this article we try to overview the existing legal and ethical implications of organ transplantation. Suggestions to improvise upon the current practices have also been incorporated.

Need for Organs in India

According to a study conducted by Santosh Varughese and Georgi Abraham in 2018 there are 130,000 patients receiving dialysis in India and the number is rising about 235 per million populations and only 8% are blessed with a transplant.³ Currently there are 668 transplantation centers across India.¹

Type of Transplant	Number of Transplantation Centers
Heart	87
Kidney	358
Liver	12
Lung	45
Pancreas	29
Homograft	5
Hand	3
Small Intestine	3
Cornea	16
Total	668

According to the information published by NOTTO (National Organ and Tissue Transplant Organization) the following statistical figures are available with regard to organ transplantation done in India over the last few years. The actual figures may vary as it shows only the registered cases.⁴

Year of transplantation	Number of Liver transplantation	Number of Kidney transplantation	Number of Heart transplantation
2014	803	1917	02
2015	931	2289	06

2016	845	2025	18
2017	991	3379	29
2018	459	1887	40

According to an article published by NDTV on 04/01/2019 by Priyanka Bhattacharya nearly 1.6 lakh patients are waiting for organ transplantation while only 12000 donors are available. According to Ministry of Health and Family Welfare the annual requirement of kidneys would range from 1 to 2 lakh with around 5000 transplantation happening in a year. There is huge discrepancy of the kidney demand and kidney transplantation. The lack of awareness and resistance of the family members are the main problems in the creation of this gap of supply and demand.⁵

Currently, the need of liver transplantation in India is estimated to be 25000 per year, whereas only 1400 liver transplantations have been done in India during 2014.⁶ Similarly with regard to the heart transplantations there is a need of 50,000 hearts in India with an actual figure of 40 to 50 heart transplantations in 2018. The availability of organs from brain-dead persons is very low.

Religious and Ethical dimensions of organ transplantation.

It is universally accepted that the ground rules of ethics is derived from the rules of religion, culture as well as philosophical concepts which is time specific. It is also understood that an ideal set of moral principles must consider these empirical facts into account while framing the ethics.

In India, the religious principles of Hinduism, Buddhism and Islam contributed positively to the ethical and moral concepts that gave rise to the medical ethics expected of a medical practitioner. According to Indian concepts the human body is perishable and one's conduct is important in order to achieve salvation. In a nutshell, in India, no religion has any explicit objection or opinion with regard to organ transplantation.

According to survey conducted in India during 1995 and 1996 among 5008 participants revealed that 72% of the population was willing to donate eyes and they had a donor card. Among them 74% Hindus, 72% Christians and 58% Muslims were willing to consider organ donation.² Unfortunately, the Medical Council of India (MCI) and Indian Medical Association (IMA) have not come out with any specific guidelines on organ transplantation.

When it comes to organ donation and transplantation, the main issue in our country is the dearth of awareness and improper infrastructure facilities. Administrative hurdles and conservative mindset also

contribute to organ transplantation scenario in India. Additionally the myths associated with organ transplantation also hinder the process. Many people in India believe that organ transplantation is against the nature and religion, though nothing of that kind is written in any religious books. Few are suspicious on the hospital staff that they may not work hard to save the life of a patient if they want the organs. Similarly, there is a problem of certifying brain deaths; if people are not aware of brain deaths; it becomes difficult to convince the relatives of the patients for organ donation.⁷

Transplantation of Human Organs and Tissues (THOT) Rules, 2014.

The Transplantation of Human Organs Act (THOA) was enacted by Government of India in 1994. This act was amended in 2011 and the same was notified as Transplantation of Human Organs and Tissues (THOT) Rules 2014. It provides guidelines regarding the removal, storage and transplantation of human organs for therapeutic purposes and prevents the commercial dealings of human organs. According to THOT 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 birth. Brain-stem death is a stage at which all the functions of the brain-stem have permanently and irreversibly ceased.

Authority for removal of human organs or tissues

As per the current medical practice of the land a living person can be an organ donor and can permit the removal of any of his/her organ or tissue during his or her life time for therapeutic purpose in accordance with the provisions of Section 3 of the THOT Act 2014. The organ also can be removed from the human body after the declaration of brain stem death subject to the consent and authorization of the near and dear ones and permission of competent authority as per the THOT Act 2014. The brain stem death of a person is declared by a panel of experts. The panel of experts shall be framed in accordance with provisions in the said act and they should be fully operational in all levels of the need. The authorization authority for organ removal and transplantation is available at three tier stages such as State level, District Level and Institutional Level. The Institution refers to the authorized hospitals or health care centers for organ removal, storage and transplantation.

Procedure for Organ Donation & Transplant. (According to NOTTO (National Organ and Tissue Transplant Organisation) in reference to THOT Rules 2014.)

- **Living donors**

It refers to any living person who is ready to donate his/her organ. It can be related donors (parents, siblings etc.), spousal donors, other than related donors. There should be a valid documentary evidence of relationship in case of related donors in accordance with provisions of the THOT Act.⁸

- **Spousal donor**

Here the proposed transplant is between a married couple, documents such as marriage certificate and marriage photograph are kept for records along with the information on the number and age of children and a family photograph depicting the entire family and birth certificate of children containing the particulars of parents.⁸

- **Swap donation**

Swap donation is the transplantation of organ within the family between persons who are related but their blood group is incompatible. Swap transplant should be carried out simultaneously, so there is no donor renegeing. Donor renegeing means that one of the donors backs out from donation. Furthermore, the donor and recipient pair in a family should be near related.⁸

- **Other than near-related donors**

It is controversial category of organ donation as the possibility of illegal, forceful and monetary based transplantations are involved in it. If the donor – recipient pair is non related then the permission is granted by the authorization committee. The THOT Act 2014 has made several provisions to avoid organ trade.⁸

- **Donor or recipient from other state**

When the living donor is unrelated and if donor or recipient belongs to a state, other than the state where the transplantation is to be undertaken, verification of residential status by Tehsildar, or any other authorized officer for the purpose with a copy marked to the

appropriate authority of the state of domicile of donor or recipient is required.⁸

- **Foreign donors**

In case of foreign donors donating to their relatives in India, the transplantation is permitted only in near-related donors. Indian living donors wanting to donate to a foreigner other than near relative shall not be considered. In case of foreigners coming for transplantation in India the transplant is permitted in India with permission from a senior embassy official of the country of origin who certifies the relationship between the donor and the recipient.⁸

- **Deceased (cadaver) donor/transplant**

It is another source of organs. Deceased donation can be either after brain stem death or after cardiac death. People can pledge their organs during their lifetime if they want their organs to be used after death. After certification of brain stem death of the person, it is now mandatory for the medical practitioner to ask the near relative or person in lawful possession of the body of a person admitted in Intensive Care Unit (ICU) regarding the plan of organ donation. Even if the donor has pledged his organs before death, the consent of near relative or person in lawful possession of the body is also required. In case of Medico-Legal Case is involved in the organ donor then the Medical Practitioner after obtaining necessary permissions and consent may intimate the proceeding to nearby Station Officer or Superintendent of Police in the limit for the retrieval of organs or tissue from the donor and a copy of such a request should also be sent to the designated post mortem doctor of area simultaneously.⁸

Commercialization of Organ Transplantation.

Besides the enactment of the THOT-2014 to restrict and control the commercialization of organ transplantations a number of scandals have come up in the near past across the country involving number of Medical Practitioner and Middle Man revealing the failure of the present regulatory system to prevent the organ trade. According to Dr VR Muraleedharan and S Ram Prasad' the commercialization of kidneys is as common now as it was before the implementation of the Act and the present regulatory system is incapable of preventing it. The study notes that it is not uncommon to find end-stage renal disease patients marrying women for their kidney and then divorcing them; getting the approval of the Authorization Committee using a proxy donor; doing unrelated transplants without the approval of the Authorization Committee; and providing false addresses for the donors. It also states that several medical professionals and hospitals have unabashedly allowed middlemen to operate in their own premises and thus have allowed the commercialization of kidneys to boom. In spite of the measures by various state governments to curb the sale in human organs, reporting of such nefarious activities from every state continues.⁹ It is understood that the much of the trade in human organ take place under the misuse of section 9 (3) of THOA Act. According to this section the donor with the approval of the authorization committee or the competent authority can allow the removal of organs before his/her death by reason of attachment or affection towards the recipient or any other special reason. The intentional wrong interpretation of this section leads to monetary based or illegal organ trade.

Improving the transparency and efficiency of Organ Transplantations.

Factually, there is a clear gap in the supply and demand of organs. The above mentioned dimensions and aspects of organ donation and transplantation support this fact. As long as this gap remains there will be unlawful efforts to follow the illegal methods of organ donation and transplantation. The legal system and the THOT Act 2014 may not be sufficient to control this phenomenon. The possible suggestions to improve this system may seem controversial, impracticable or inadequate. Let's discuss few.

Primarily the availability and use of cadaver organs should be increased. Currently, India has "opt-in" approach to organ donation. It may be modified into "opt-out" approach. The 'opt-in' approach: is a method wherein the potential donor expresses readiness for removing the organs for transplantation after their death or a declared brain stem death. Whereas, the 'opt-out' approach is a concept, where the person expresses the unwillingness to donate his/her organ. The 'opt-out' approach considers the concept of presumed consent to donate the organs by anyone who is potential to donate. The person will be given a chance to opt-out rather than opt-in for organ donation. Currently the concept of presumed consent and opt-out approach is legally accepted in Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland,

France, Greece, Hungary, Italy, Luxembourg, Latvia, Norway, Poland, Portugal, Slovak Republic, Slovenia, Singapore, Spain, Sweden and Switzerland.¹⁰

Even though the concept of presumed consent may curtail the organ shortages to a certain extent it cannot completely meet the needs of the people. Moreover, the possibility and practicability of alternatives for organ transplantations such as xeno-transplantation, tissue engineering and artificial organs should be explored. As on date the most successful in this cadre is the artificial kidney that is widely used in dialysis though it is not a permanent solution for renal failure.

Additionally, it is also recommended that the policy makers may reconsider the financial incentives for transplantation. As a matter of fact there is no legal restriction regarding the financial involvement of blood donating and receiving in health care sector of India. Paid blood donation is a common phenomenon in government as well as private health care sectors across the country. As we all know that blood is also a human tissue but in India it is considered as a therapeutic agent.

On the contrary, the universal declaration of human rights by WHO states that "The human body and its parts cannot be the subject of commercial transactions". Hence, the financial incentives for organ donation and transplantation is not promoted by WHO and the physicians are advised to not to perform organ transplantations if the credibility of the organ donation is doubtful. Ideally, it recommends the banning of all unrelated live donations. It is suggested that if it is not possible, policy-makers, civil society and physicians should re-examine the value of using regulated incentive-based organ donation to increase the supply of organs.

Similarly, another serious concern with regard to organ transplantation and THOT-2014 is that of the organ harvesting in case of medico legal cases. Most of the time, the Road Traffic Accident Cases require autopsy and legal clearance and it prevents the organ harvesting. Currently the organs are harvested after the certification of brain stem death and obtaining consent from the concerned and the legal officer in case of RTA. The main concern is that all the concerned members such as investigating officer, forensic medicine expert, etc. may not be available in all health care organizations and it causes unnecessary delay. To avoid the controversies in cadaver transplantation the inquest in case of an RTA may be conducted in front of an executive magistrate with the help of forensic medicine expert who is a member of cadaver transplantation team.

Similarly the spousal donation shall be valid only if the marriage is more than 7 years old. This will prevent exploitation of marriage related kidney transplantations.

Every year thousands of human bodies are buried or cremated when their organs could save lives. Similarly, every year thousands suffer or die on waiting lists when there are potential living organ providers willing to sell their organs. The trade in organs should be regulated rather than banned. A committee comprising of representatives of the judiciary, government, medical professionals and prominent persons of civil society with sufficient statutory powers to implement the regulation with penal powers can be established.

CONCLUSION

There should be a reappraisal of the policies concerning organ donation and harvesting of organs from live donors and cadavers for transplantation. The exact guidelines for organ transplantation must be worked out on a national and not on an international level.

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