

Legal framework of Organ Transplantation in India: Issues and Challenges

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ABSTRACT

One of the major medical innovation of the twentieth century was organ transplantation. The idea of organ transplantation became a life-saving procedure and a symbol of human solidarity thanks to a person's willingness to offer his or her organs. Currently, there is a huge gap between the supply and demand for organ transplants. The Transplantation of Human Organs and Tissues Rules, 2011, explicitly outline the procedures, rules, and steps that must be taken to overcome the aforementioned gap. This article examines the standards for organ transplantation, in the context of living organ donation practises in India, in the light of "The Transplantation of Human Organs Act (THOA) of 1994 as amended in 2011." This paper discusses a number of issues, including the lack of comprehensive data on risk assessment for living donors, gender bias, the function of "Authorization Committees," misuse of technology by dishonest individuals resulting in an overly cautious approach by the health system, disregard for donors' future health issues, and exorbitant costs of transplant as a result of these issues etc. Article also focus upon the roles played by various authorities constituted under Transplantation of Human Organs (THO) Amendment Act-2011 and Transplantation of Human Organs and Tissue (THOT) Rules 2014 and the challenges faced by the donors in the cases of organ transplantation.

Keywords: Organ transplantation, Authorization Committees, Transplantation of human organs Act, National Organ Transplant Programme, NOTP, NOTTO, SOTTO, ROTTO.

Introduction

One of the major medical developments of the twentieth century was organ transplantation. Medical advancements including the use of mechanical ventilators for brain-dead patients and the development of immunosuppressive medications have significantly changed the donation and transplantation of organs. The concept of organ transplantation became a life-saving procedure and a symbol of human solidarity thanks to a person's willingness to offer his or her organs. Currently, it is possible to donate or transplant organs such as the heart, liver, kidneys, lungs, pancreas, cornea, skin, heart valves, bones, ligaments, and more. The key long-term answer to the world's organ scarcity is deceased organ donation.

An organ transplant is a life-saving surgery which involves the transfer of healthy organs or tissues from a donor to a recipient, who has a damaged or failed organ. It is a life-saving procedure that has revolutionized modern medicine. For many life-threatening illnesses, including end-stage organ failure, heart disease, and liver diseases, organ transplantation has emerged as a critical treatment alternative. However, organ transplantation is a complex and highly regulated process that requires careful consideration of ethical, legal, and social issues. India has one of the highest rates of organ failure in the world as a result of a number of variables, including a sizable population, an increase in lifestyle disorders, and a lack of understanding regarding the significance of organ donation. To control organ transplantation and advance moral behaviour, the government of India has built a strong legal framework. A total of 7,761 organ transplants took place in the year 2013–2014, as compared to over 15,000 organ transplants in the year 2022 with an annual rise of around 27% as compared to year 2021[1]. These statistics take organ transplants for the kidney, liver, heart, lungs, pancreas, and small intestine into account. It is noteworthy that India still has very low organ transplantation rate when compared to other nations. There is a severe lack of organ donors, and the demand for organs considerably outweighs the supply. Government of India has taken a number of initiatives to boost the rate of organ donation, including establishment of NOTTO, the support of public awareness campaigns, and the creation of a legal framework to control organ donation and transplantation. However, despite these initiatives, organ transplantation in India still has a number of problems that need to be resolved.

Legal Framework for Organ Transplantation in India

1. Transplantation of Human Organs and Tissues Act, 1994

The legal framework for organ transplantation in India is primarily governed by the Transplantation of Human Organs and Tissues Act, 1994[2] (hereinafter called as ‘The Act’), and its subsequent amendments. The Transplantation of Human Organ and Tissues Rules, 2014 (hereinafter called as ‘The Rules, 2014’), have been formulated for the effective implementation of the Act. The Act regulates the removal, preservation, and transplantation of human organs and tissues for medical purposes and prohibits the sale of human organs for profit. Term ‘human organ’ is defined under the Act, any part of human body consisting of a structured arrangement of tissues which, if wholly, removed cannot be replicated by the body.[3] Organ transplantation, under the Act, is only permitted by hospitals or other registered institutions that have been given a licence by the appropriate authority.[4] The Act further stipulates that the organ donor and the recipient of the organs must be genetically and

emotionally connected, and that the transplantation can be done only with the donor or his/her next-of-kin's written consent.[5]The Act also provides for the formation of the National Organ and Tissue Transplant Organisation (NOTTO), as a nodal agency created for promoting and organising organ transplant activities in India.[6] All hospitals, institutes, organ donors, and recipients are required to be registered with NOTTO. The National Apex Committee for Regulation of Transplantation (NACROT), a regulatory organisation was established in 2011 after the Act was amended, to incorporate measures for the regulation of living donor transplantation. The NACROT is responsible for monitoring and regulating all ethical and legal aspects of organ transplantation in India, including those of living donor transplantation. Act also requires Central Govt.to establish national registry of donors and recipients of human organs and tissues.[7]

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

Rules were enacted through an amendment in the Act in 2011 and are further amended to be enforceable as THOT Rules, 2014. The Rules forbid sale of human organs for profit and offer standards for the removal, preservation, and transplantation of human organs for medical treatment. The notion of transplantation, according to the Rules, is the grafting of human organs from alive or deceased individuals to a living individual for medicinal purposes. A deceased person is someone who has no signs of life, such as in cases of brain-stem death or cardio-pulmonary sense following live birth. All of the functions of the brain-stem are completely and irrevocably ceased at the stage of brain-stem death.

Procedure for Organ Donation & Transplantation

Procedure for organ donation and transplantation is governed by the NOTTO (National Organ and Tissue Transplant Organisation) in accordance with The Rules, 2014.

Living donor

Any living person who is willing to give an organ is referred to as living donor. Other than spouse donors, it may also be related donors like parents, siblings, etc. The Act requires a valid documentary proof of the said relation in the cases where related donors are involved[8].

Spouse donor

In the cases of transplant between a married couple, documentary proofs like the marriage certificate, the marriage photograph, the number and ages of the children, a family photo of

the entire family, and the birth certificates of the children, including the parents' information, are required[9].

Swap donor

The transplantation of an organ within a family between members who are related but have different blood types is known as a swap donation. To prevent donor renegeing, a swap transplant should be simultaneously performed. Reneging on a donation refers to one of the givers withdrawing their support. Donor and recipient pair of the family should be closely related [10].

Other than near-related donors

Organ donation is a controversial issue due to the possibility of forced, illegal, and financially motivated transplantations. The authorization committee will give permission if the donor and recipient are unrelated. There are many provisions to prevent organ trade under the Act of 2014[11].

Donor or recipient from other state

When the living donor is unrelated and the donor or recipient is from a different state than the state where the transplant is to be performed, it is necessary for the Tehsildar or another authorised officer to verify their residential status and send a copy to the relevant authority in the respective states of their domicile[12].

Foreign donors

Only close relatives of overseas donors who donate to their relatives in India are eligible for transplantation. Foreigners other than close relatives are not eligible to receive donations from Indian living donors. Foreigners undergoing transplants in India are only permitted to do so with the approval of a senior embassy official from their home country, who can attest the donor and recipient's relationship[13].

Deceased donor

This is an additional source of donation. Donation made by deceased is permissible only in the cases of either cardiac or brain stem death. If a person wants his organs to be utilised after death, he can pledge them while still alive. It is mandatory for the medical professional to inquire about the organ donation plans from the close relative or person, who is legally in possession of the body of a patient admitted to the intensive care unit (ICU) after the individual's brain stem death has been certified. Even if the donor had pledged his organs before death, approval of a close relative or the person, legally in charge of the body, is mandatory. Where an organ donor is involved in a medico-legal case, medical practitioner may notify the local station officer or superintendent of police in the area of the proceeding

for the retrieval of organs or tissue from the donor after obtaining the necessary permissions and consent. A copy of this request should be sent simultaneously to the local post mortem physician[14].

Legal and Ethical Challenges

In spite of the legal structure, India still has difficulties with organ donation and transplantation. The scarcity of organs is one of the main problems, which has given rise to a thriving black market for organs and illegal organ trafficking.

- i. Shortage of Organs:**One of the main issues facing organ transplantation in India is the shortage of organs. The demand for organs far exceeds the supply, and this has resulted in long waiting lists for patients requiring transplants. According to the National Health Profile 2018, the demand for organs in India is estimated to be around 500,000 per year, while the supply is less than 10% of this number [15].The lack of organ donor awareness, cultural and religious prejudices, and the low incidence of dead organ donation are a few of the causes that contribute to the organ shortage in India. In addition, there is a dearth of infrastructure and resources to support deceased organ donation, including a lack of a clear certification process for brain death and a lack of adequate hospital infrastructure to support organ donation.India has 41 million people with diabetes[16]. One-third of urban adult and close to one fourth of rural adult Indians are hypertensive[17].Organ failures are likely to rise in India due to these two diseases. It is consequently imperative that emphasis be placed on both deceased and living organ donation. Living organ donation and transplantation are both taking place concurrently in nations with high rates of deceased donation. In 2014, there were 8.6 living organ donors for every million people in Spain, a nation with the highest rates of deceased organ donors (35.1 pmp). Similarly,in USA, there were 18.8 pmp of living organ donors in the same year in which there were 25.9 pmp of deceased donors[18].
- ii. Commercialization of Organ Transplantation:**Organ transplantation in India is also severely hampered by the commercialization of the procedure. Despite the THOTA's prohibition on the commercialization of organ transplantation, there have been allegations of unlawful organ trade and trafficking throughout the nation. The illegal trade in organs frequently targets vulnerable populations, including migrants and the destitute, who are persuaded to sell their organs for money.

- iii. **Lack of Transparency and Accountability:** The lack of transparency in India's organ donation and transplantation system has raised serious concerns about fairness of the process. It is a general assumption that rather than medical need, organs are distributed on the basis of richness and high level connections. Though, a transparent procedure is expected to be followed by the authorities, yet the Act fails to impose accountability on the defaulting authorities.
- iv. **Lack of awareness:** Despite the fact that there are rules governing organ transplantation, a layman is still unaware of the significance of organ donation and transplantation. This causes an organ scarcity and makes it challenging for patients who require transplants to get done.
- v. **Organ trafficking:** Organ trafficking is yet another significant problem, and implementation of existing regulations is a serious issue in India. In order to obtain organs, many people adopt unlawful practices, which have resulted in the exploitation of vulnerable groups.
- vi. **Limited infrastructure:** Patients in India struggle to get timely care due to the country's inadequate organ transplant infrastructure. Many patients are required to wait for a very long time before getting transplants, due to insufficient facilities, equipment, and skilled specialists.
- vii. **Religious and cultural barriers:** The practise of organ transplantation in India gets affected by the cultural and religious concerns. As organ donation goes against the religious or cultural values in some communities, it becomes challenging to convince the donors and motivate them to donate the organs.

Legal challenges: There are many potential legal issues with India's complicated legal system, governing organ transplantation. For instance, it could be difficult to get donors' informed consent or to ensure that organs would not be used for commercial purposes.

- i. **Interpretation of term 'Near Relative':** The Act authorises organ donation between 'near relatives' without prior approval from the government. There is a difference of opinion over the term 'near relatives', whether it should be extended to include friends or non- blood related spouses or not.
- ii. **Restrictions on commercialisation of organs:** Trading of organs for transplantation is forbidden by the Act. Challenges in implementation of the restrictions on commercialization, however, are apparent by several instances of organ trafficking and commercialization.

- iii. **Procedural Challenges:** The Act requires several procedures to be followed during the process of transplantation. This procedure is intended to ensure the safety of both donor and recipient. However, this has been occasionally challenged on the grounds that they are onerous or stringent.
- iv. **Cases of Medical Negligence:** The Act requires hospitals and transplant centres to take reasonable steps to ensure the ethical conduct and safety in the transplantation procedure. The Act stipulates sanctions and penalties to be imposed in the event of any case of medical negligence or malpractice. Although, there have been instances where hospitals and transplant centres have been charged with medical negligence, resulting in conviction of the authorities of such hospitals and centres but the number is very less.
- v. **Consent for Organ Donation:** In order to donate organs, the Act requires informed consent of donor or his family. Nevertheless, there have been instances where the validity of the consent has been challenged, particularly when the donor is deceased and the family members have difference of opinions on organ donation.
- vi. **Punishment for violations:** Though, the Act provides for severe punishments like imprisonment and fines for the violation of its provisions, yet it is submitted that these sanctions are not sufficient to create deterrence on the illegal organs trade.

Conclusion

Most parts of the country are affected by organ trafficking, and the main causes for unrelated living donors to sell their organs are poverty and debt. A donor's health frequently deteriorates as a result of selling their organs, and their family often falls back into debt and poverty. Due to a shortage of funding for the procedure, sometimes even willing family members are unable to donate organs. Despite government initiatives to control organ transplantation and penalise clinics and doctors participating in the organ trade, the issue still persists. Transplanting organs from donors can help addressing the issue of organ shortage, particularly in the increased demand for organs, as a result of high daily accident and fatality rate. Increasing public knowledge about organ donation is essential, even though stricter enforcement of the law is required. It is possible to prevent the commercialization and sale of organs by raising public awareness regarding importance of organ donation. In addition, it is important to deal with the underlying issues that lead to poverty and debt, which are most significant factors in the growth of organ-selling trade.

Recommendations:

1. Improvement in government's infrastructure for surgeries is difficult as a result of strain on public health services. NOTTO is given a responsibility of compiling information from SOTTOs and ROTTOs to create a complete database on living donors. All states must work together to accomplish this task.
2. Delays in approvals can be avoided by making it mandatory for the 'Authorization Committees' to thoroughly review these applications within two weeks. Further, procedural requirements with police, lawyer, medical practitioner, pathological tests etc. must be initiated simultaneously so as to avoid inordinate delay.
3. Live donors' health must be insured, to show concern towards them, particularly in the cases of post-donation medical issues. Recipient family must be compelled to contribute to the donor's risk coverage, on the lines of, medical practitioners receiving risk coverage allowance.
4. Implementation of the Amendment Act-2011 and the Rules, 2014, is difficult as they are not ratified by all states. NOTP and NOTTO are persistently urging all states to enact them through conferences, workshops and letters, which will help ROTTO and SOTTO to get more registrations for exchange transplants. Therefore, all states must come to a consensus for its effective implementation.
5. It should be made mandatory for all transplant hospitals to release the list of patients who have undergone transplant surgery as well as the total amount of payments made to the institution, so as to avoid the exploitation of patients and their families.
6. Survival statistics of transplant operations should also be made public on hospital websites to provide families an opportunity to select the facility that best suits their needs.
7. Though, the Act expects a transparency in the transplant process, yet the scenario is otherwise. It is recommended that all the delinquent authorities must be held accountable for the lapses on their part.

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Introduction

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Legal and Ethical Challenges

In spite of the legal structure, India still has difficulties with organ donation and transplantation. The scarcity of organs is one of the main problems, which has given rise to a thriving black market for organs and illegal organ trafficking.

viii. Shortage of Organs: One of the main issues facing organ transplantation in India is the shortage of organs. The demand for organs far exceeds the supply, and this has resulted in long waiting lists for patients requiring transplants. According to the National Health Profile 2018, the demand for organs in India is estimated to be around 500,000 per year, while the supply is less than 10% of this number [15]. The lack of organ donor awareness, cultural and religious prejudices, and the low incidence of dead organ donation are a few of the causes that contribute to the organ shortage in India. In addition, there is a dearth of infrastructure and resources to support deceased organ donation, including a lack of a clear certification process for brain death and a lack of adequate hospital infrastructure to support organ

donation. India has 41 million people with diabetes[16]. One-third of urban adult and close to one fourth of rural adult Indians are hypertensive[17]. Organ failures are likely to rise in India due to these two diseases. It is consequently imperative that emphasis be placed on both deceased and living organ donation. Living organ donation and transplantation are both taking place concurrently in nations with high rates of deceased donation. In 2014, there were 8.6 living organ donors for every million people in Spain, a nation with the highest rates of deceased organ donors (35.1 pmp). Similarly, in USA, there were 18.8 pmp of living organ donors in the same year in which there were 25.9 pmp of deceased donors[18].

- ix. Commercialization of Organ Transplantation:** Organ transplantation in India is also severely hampered by the commercialization of the procedure. Despite the THOTA's prohibition on the commercialization of organ transplantation, there have been allegations of unlawful organ trade and trafficking throughout the nation. The illegal trade in organs frequently targets vulnerable populations, including migrants and the destitute, who are persuaded to sell their organs for money.
- x. Lack of Transparency and Accountability:** The lack of transparency in India's organ donation and transplantation system has raised serious concerns about fairness of the process. It is a general assumption that rather than medical need, organs are distributed on the basis of richness and high level connections. Though, a transparent procedure is expected to be followed by the authorities, yet the Act fails to impose accountability on the defaulting authorities.
- xi. Lack of awareness:** Despite the fact that there are rules governing organ transplantation, a layman is still unaware of the significance of organ donation and transplantation. This causes an organ scarcity and makes it challenging for patients who require transplants to get done.
- xii. Organ trafficking:** Organ trafficking is yet another significant problem, and implementation of existing regulations is a serious issue in India. In order to obtain organs, many people adopt unlawful practices, which have resulted in the exploitation of vulnerable groups.
- xiii. Limited infrastructure:** Patients in India struggle to get timely care due to the country's inadequate organ transplant infrastructure. Many patients are required to wait for a very long time before getting transplants, due to insufficient facilities, equipment, and skilled specialists.

xiv. Religious and cultural barriers: The practise of organ transplantation in India gets affected by the cultural and religious concerns. As organ donation goes against the religious or cultural values in some communities, it becomes challenging to convince the donors and motivate them to donate the organs.

Legal challenges: There are many potential legal issues with India's complicated legal system, governing organ transplantation. For instance, it could be difficult to get donors' informed consent or to ensure that organs would not be used for commercial purposes.

vii. Interpretation of term 'Near Relative': The Act authorises organ donation between 'near relatives' without prior approval from the government. There is a difference of opinion over the term 'near relatives', whether it should be extended to include friends or non- blood related spouses or not.

viii. Restrictions on commercialisation of organs: Trading of organs for transplantation is forbidden by the Act. Challenges in implementation of the restrictions on commercialization, however, are apparent by several instances of organ trafficking and commercialization.

ix. Procedural Challenges: The Act requires several procedures to be followed during the process of transplantation. This procedure is intended to ensure the safety of both donor and recipient. However, this has been occasionally challenged on the grounds that they are onerous or stringent.

x. Cases of Medical Negligence: The Act requires hospitals and transplant centres to take reasonable steps to ensure the ethical conduct and safety in the transplantation procedure. The Act stipulates sanctions and penalties to be imposed in the event of any case of medical negligence or malpractice. Although, there have been instances where hospitals and transplant centres have been charged with medical negligence, resulting in conviction of the authorities of such hospitals and centres but the number is very less.

xi. Consent for Organ Donation: In order to donate organs, the Act requires informed consent of donor or his family. Nevertheless, there have been instances where the validity of the consent has been challenged, particularly when the donor is deceased and the family members have difference of opinions on organ donation.

xii. Punishment for violations: Though, the Act provides for severe punishments like imprisonment and fines for the violation of its provisions, yet it is submitted that these sanctions are not sufficient to create deterrence on the illegal organs trade.

Conclusion

Most parts of the country are affected by organ trafficking, and the main causes for unrelated living donors to sell their organs are poverty and debt. A donor's health frequently deteriorates as a result of selling their organs, and their family often falls back into debt and poverty. Due to a shortage of funding for the procedure, sometimes even willing family members are unable to donate organs. Despite government initiatives to control organ transplantation and penalise clinics and doctors participating in the organ trade, the issue still persists. Transplanting organs from donors can help addressing the issue of organ shortage, particularly in the increased demand for organs, as a result of high daily accident and fatality rate. Increasing public knowledge about organ donation is essential, even though stricter enforcement of the law is required. It is possible to prevent the commercialization and sale of organs by raising public awareness regarding importance of organ donation. In addition, it is important to deal with the underlying issues that lead to poverty and debt, which are most significant factors in the growth of organ-selling trade.

Recommendations:

8. Improvement in government's infrastructure for surgeries is difficult as a result of strain on public health services. NOTTO is given a responsibility of compiling information from SOTTOs and ROTTOs to create a complete database on living donors. All states must work together to accomplish this task.
9. Delays in approvals can be avoided by making it mandatory for the 'Authorization Committees' to thoroughly review these applications within two weeks. Further, procedural requirements with police, lawyer, medical practitioner, pathological tests etc. must be initiated simultaneously so as to avoid inordinate delay.
10. Live donors' health must be insured, to show concern towards them, particularly in the cases of post-donation medical issues. Recipient family must be compelled to contribute to the donor's risk coverage, on the lines of, medical practitioners receiving risk coverage allowance.
11. Implementation of the Amendment Act-2011 and the Rules, 2014, is difficult as they are not ratified by all states. NOTP and NOTTO are persistently urging all states to enact them through conferences, workshops and letters, which will help ROTTO and SOTTO to get more registrations for exchange transplants. Therefore, all states must come to a consensus for its effective implementation.

12. It should be made mandatory for all transplant hospitals to release the list of patients who have undergone transplant surgery as well as the total amount of payments made to the institution, so as to avoid the exploitation of patients and their families.
13. Survival statistics of transplant operations should also be made public on hospital websites to provide families an opportunity to select the facility that best suits their needs.
14. Though, the Act expects a transparency in the transplant process, yet the scenario is otherwise. It is recommended that all the delinquent authorities must be held accountable for the lapses on their part.

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