

INTERNATIONAL JOURNAL OF LAW
MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 4 | Issue 4

2021

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Medico Legal Issues Related to Tissues and Organ Transplantation in India

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ABSTRACT

The medicinal field has taken a new turn with advancement of sciences and technologies. With development in the field of science, many new practices and equipment have also been introduced in the medicinal field. One such field, that modern science has touched is the field of transplantation of human organs and tissues. It means removal of an organ from a body of person whether alive or dead and transplantation of such organ into the body of another person. The person who donates such organ is known as donor, while the person who receives such organ is known as the recipient.

Donor of such organ can be a cadaver, a dead person or a brain-dead person which can also be a donor of such organs. In India, The Transplantation of Human organs and Tissues Act, 1994 regulates such organ donation. As per the Act, we follow the concept of 'opt-in' consent which means such organ donor has explicitly opted for organ donation after his death, but ultimately it is the decision of the family of such cadaver and of brain-dead patient. The Act, also deals with regulation, registration of hospitals as well as with Appropriate authority and prescribes offences and penalties under the Act. Though, there are some drawbacks too.

'Right to health' is the fundamental right of every citizen. Though, such right is not expressly mentioned in the Constitution but has been enshrined under Article 21 of the Constitution, which talks about 'Right to life'. The scope of Article 21 is wide enough, to take under its ambit various other aspects of human life, namely 'Right to live with dignity' or 'Right to have a clean environment' etc., that deals with humanly conditions. To have organ transplantation also comes within the ambit of 'Right to health'.

There are many malpractices prevalent in India. One such malpractice, that is followed by the medical practitioner is of medical negligence or professional misconduct. Which can be curbed by following up of professional code of conduct and adherence to various other legislations. As duty of medical practitioner is the right of an individual and violation of such right may result in liability of the medical practitioner.

Keywords: *Transplant of human organs and Tissues Act, 1994, Brain-stem death, Right to health, Medical negligence and Professional misconduct.*

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I. INTRODUCTION

Donation of organs is one of the noblest deed in the world. It is a chance to save life of another person as well as a chance to live beyond one's life. By donating organs, a person can save up to 9 lives. India being the second most populous nation in the world, stands far behind than other countries in global organ donation index. In India there is a huge gap between the demand of organs and supply of organs. According to the report of World Health Organization only around 0.01 percent of people donate their organs after death in India. There are various reasons for such low rate of organ donation in India, namely lack of awareness among people, social and religious dilemmas, fear of mutilation of bodies, emotional impact of death of such person and so on..

Such gap of demand and supply of organs can be bridged by propagation of awareness among people about the benefits from such organ donation, busting the myths related to such organ donation and proper functioning of the authorities, established under the Act for keeping a check on such organ donation and transplantation.

Government has set-up organisations like National organ and tissue transplant organisation (NOTTO), which functions as an apex body for procurement, allotment and distribution of organs in the country. The government has also set-up other organisations like Regional organ and tissue transplant organisations (ROTO) at the regional level and State organ and tissue transplant organisation (SOTTO) for states, for regulation of such organ transplantations. Government has also launched programme like National programme of organ and tissue transplantation (NOTP) for organizing a system for procurement, allocation and distribution of organs. With such initiatives, a gap can be overcome between the demand and supply of such organs or tissues for transplantation.

II. LEGAL FRAMEWORK FOR ORGAN AND TISSUE TRANSPLANTATION IN INDIA

In India, organ and tissues transplantation is regulated, by the Transplantation of Human Organs and Tissues Act (THOTA) 1994. The Act, was enacted after the recommendation of the *L.M Singhvi* committee after, there was a rampant rise in organ trafficking and illegal organ harvesting. The Act, deals with removal, storage and transplantation of human organs and tissues for therapeutic purposes and to prevent illegal trafficking of organs and tissues as well as prevention of commercial dealings of such.

Under the Act, a person above 18 years of age can give such consent for removal and transplantation of his organs, after his demise, in presence of two witnesses. Such consent can be revoked by such person, anytime before his demise. The last decision of such donation is of

the family of the cadaver or the person, in whose lawful possession such body is.

The Act, also deals with brain-stem death of the patient. In such death the other vital signs of the body are strong except the brain. Such person generally depends upon a ventilator for all its life, with no chance of getting better again. The brain-stem dead person can donate almost 37 organs of his body and tissues, which includes donation of some vital organs also like, kidneys, liver, lungs, heart and skin as well while, natural cardiac dead person can only donate few organs like, cornea, bones or the blood vessels etc.

The Act, also deals with regulation and registration of hospitals, which are capable to store, remove or conduct such transplantation procedure. The Act, also expresses appointment of an Appropriate authority by the central government, to enforce such standard as prescribed by the Government. An advisory committee shall also be formed, for advising such Appropriate authority. The Act, also deals with offences and the penalties happened under the Act, for removal of such human organ, without the permission of authority may result in 10 years of imprisonment and fine of 20 lakh Rupees. On commercial dealings of such organs, punishment may extend from 5 years to 10 years and fine may extend from 20 lakh rupees to 1 crore rupees.

Right to health and organ transplantation

Every human being is entitled to good health and appropriate health care system, which includes important facilities like, well-equipped hospitals, affordable drugs and other facilities on an equitable basis. They all comes under, the Article 21 of the Constitution which expresses 'Right to life and personal liberty'. Article 21 expresses few words but the scope of such words is wide enough. Right to life does not only include right to live, but it implies right to live with dignity and not mere existence or animal like existence. Every human is entitled to basic amenities of life like food, shelter and home, but now with changing time, a proper health care has also been included in right to life.

Right to life is wide enough to include within its ambit 'Right to health'. Although, 'Right to health' has not been expressly mentioned in the Constitution, but with the help of judicial prudence, 'Right to health' has been interpreted within 'Right to life'.

In the famous case of *Pt. Parmanand Katara vs. Union of India And Others*², the court held that the recipient has a right to receive, medical treatment and medical aid. Which includes transplantation of human organs as well, for therapeutic purposes. Such organ may be removed

² (1989) 4 SCC 286

from a living person or a deceased person for treatment of any disease or to improve the health of such recipient.

Thus, right to have organ or tissues transplanted also comes under 'Right to health'. Every citizen has a right to live a healthy life and transplantation of organs and tissues paves a way to live an extended, healthy life.

III. ORGAN AND TISSUE TRANSPLANTATION: CURRENT SCENARIO

It is estimated that, around 5000 kidneys, 1000 livers, and 50 hearts are transplanted every year in India and the poor donation rate, stuck at around 0.26 per million. This rate of donation of organs is seen as poorest in the world, where other countries like Croatia, Spain and United State of America stands at the donation rate of more than 25 per millions.³

India being the second most populous country in the world, really lacks behind in this field of organ donation and transplantation. Where everyday many people die of accidents or any other mishap, such people and their families, if convinced or made aware about the benefits of organ donation, can pledge, their organs for donation and they may save many lives via such donation.

Organ wastage

Due to many prevalent myths in the society and lack of awareness, everyday many life-saving organs and tissues are burnt to ashes or are dug beneath the soil, which if donated and used would have saved the life of many.

Nearly around 1.5 lakh people becomes brain-dead due to accidents in India, annually⁴. Death due to brain tumours or any other reasons may automatically raise the count of such death in India. Heart is among the most wasted organ from a human body, which could give life to many cardiac patients, who otherwise has to suffice on medications and drugs for their entirely life.

Organs are wasted due to many reasons, which might be lack of awareness about such organ donation, religious and social issues, fear of mutilation of the body of such loved one, unavailability of such transplantations specialist and issue of affordability of such transplantation and many other reasons. There is need of approximately 2 lakh kidneys, Fifty Thousand Hearts and Fifty Thousand livers to fulfil the demand of such organs for transplantation annually. Thus, to bridge the gap between such demand and supply of organs for transplantations, there is a need to devise policy for organ harvesting and prevention of such

³ Nallusamy S, Shyamalapriya, Balaji, Ranjan, Yogendran. Organ donation – Current Indian scenario. *J Pract Cardiovasc Sci* 2018; 4:177-9.

⁴ : Nallusamy S, Shyamalapriya, Balaji, Ranjan, Yogendran. Organ donation – Current Indian scenario. *J Pract Cardiovasc Sci* 2018; 4:177-9

wastage of organs.

Malpractice and Medical Negligence

An organ transplantation is one of the most complex surgeries in the world. Only an expert and skilled medical practitioner can do it, but with no 100% guarantee of its being successful and chances of survival of such individual.

Medical negligence is the misconduct on the part of the medical practitioner, while treating a patient resulting in breach of duty of care by such medical practitioner and injury to such patient. Any act, performed carelessly and without caution is a negligent act, which might involve using non-sanitised equipment on the patient while performing a surgery, transplanting incompatible organ to the recipient, resulting in death of such patient or leaving of any surgical equipment or other objects inside the body of such patient or stitching of such wound is carelessly done, which might result in infection and eventually death of such person. The scope of medical negligence is very wide, and so are the liabilities. A medical practitioner can be held liable under civil and criminal laws and might have to pay damages or might go through imprisonment of 2 years as well as with fine.

Disciplinary actions may also be taken against such medical practitioner, which might result in removal of name from such register of registered medical practitioners as maintained by the government.

There are few medical practitioners, who are involved in illegal organ harvesting and selling of such organs at a higher price to the recipients for their monetary benefits. Sometimes organs are even transported to other countries at a higher price. To curb such illegal trade of organs, Transplantation of human organs and Tissues Act was introduced in the year 1994. Under section 18 of the Act, if any such person or medical practitioner removes or assists in removing any organ from body of any person, without the permission of such authority, as established under the Act, shall be held liable for the term which may extend to 10 years with fine, which may extend to 20 lakh Rupees. Anybody who commercially deals in such human organs under section 19 of the Act, shall be punished with the imprisonment, which shall not be less than 5 years but may extend to 10 years along with fine of Rupees 20 Lakhs which might extend to 1 Crore Rupees. According to section 19A of the Act, anybody who illegally deals in such human tissues shall be punished with imprisonment, which shall not be less than 1 year but may be extended to 3 years and shall also be liable to fine of not less than 5 Lakh Rupee but may extend to 25 Lakh Rupees.

Thus, with the introduction of strict laws against such illegal organ and tissues trafficking,

government has managed to reduce such crime in the country. But, with introduction of more initiatives in this filed, such illegal trading of organs could be end fully.

IV. NATIONAL ORGAN TRANSPLANT PROGRAMME (NOTP)

The Directorate General of Health Services, Government of India initiated National Organ Transplant Programme with budget of Rs. 149.5 Crore for 12th Five-year Plan. Which, aims to improve access to the organ and tissues transplantation for needy citizens of the country by promoting organ donation of the deceased and brain-stem dead patients.

The main objectives of the programme were:

1. Organization of system of organ and Tissue procurement as well as distribution to the needy people.
2. Promotion of such organ and tissue donation from the deceased person.
3. Training of manpower, who would perform such complex surgery of transplantation.
4. Protection of poor and vulnerable people from organ trafficking as well as to protect such people from any such pressure or compulsion for organ and tissue donation even in lieu of money.
5. Monitoring of organ and tissue transplantation taking place and to bring new policies and devise new plans according to the need of the society and the needy patients.

V. CONCLUSION

There is nothing more fortuitous in life than to save a life. Donation of organ and tissues provides you with that opportunity to save not only just one life but to save up to 9 lives. by such organ donation, one can live an extended life after death. Such organ and tissue donation plays a crucial role in saving many lives and providing such ed stage organ failure with a new chance of life.

The person who pledges his organs motivates other people to do the same. The world celebrates 13th August as ‘World Organ Donation Day’ which is dedicated to motivate and convince people to pledge their organs for donation. In India, we celebrate ‘National Organ Donation Day’ on 27th November every year, to promote awareness and recognition of contributions of deceased organ donors for welfare of mankind and re-kindling of faith in the humanity.

The government has always tried to promote such noble cause of organ and tissue donation, by introducing the Act of 1994, as well as amending such laws in 2011. Such amended laws, known as **Transplantation of Human Organs (Amendment)** of 2011 brought many changes

in the field of organ transplantation like:

- ‘Tissues’ from the body of an individual was included side by side of word organ.
- Swap donation was introduced as well as definition of ‘near relative’ was also expanded to include grand-children and grand-parents within it.
- Provision of mandatory inquiry was introduced, by the attendants of such donors and to inform of such consent to retrieval centre.
- Mandatory appointment of ‘Transplant co-ordinator’ in all the registered hospitals in the Act.
- Protection of poor and vulnerable from higher penalties in such cases of trading organs.
- Constitution of Brain-stem death certification board was simplified. As of now wherever Neuro-physician or Neurosurgeon was not present in such case an anaesthetist or intensivist can be a member of board in his place, subject to the condition that he is not a member of the transplant team and may grant his consent for such brain-stem death certification.
- Provision of an Advisory Committee was introduced to aid and advice the Appropriate authority.
- Provisions has been introduced for greater caution in case of minors and foreign nationals as well as prohibition of such organ donations from mentally challenged persons was mentioned in such amended laws.

Transplantation of Human Organs and Tissues Rules 2014 was also introduced in pursuance of the Amendment Act. The objective of such rules is to pave a way for such amendment act and to facilitate such organ and tissue donation in the country.

By working on the following few suggestions, a government can handle such organ donation and transplantation in a much better way, they are as follows:

1. By spreading awareness among people, via social media or campaigns or any advertisement, where the most popular celebrity can spread awareness among people regarding such organ and tissue transplantation.
2. By making a strong centralized system of organ donation, registered hospitals under the Act, can share such organ related data and may transfer such organ in the time of need of any patient to such hospital. Such will prevent organ from being wasted.

3. Government as well as non-government organisations can take this significant step to raise awareness about such organ donation among the stakeholders.
4. The certification of such brain-stem dead person should be issued properly, after such certification board has gone through the process thoroughly as well as consent of the family of such person has been taken.
5. Proper standard has to be maintained of the transplantation facility as well as tissue banking.
6. Every possible way has to be taken for prevention of illegal organ trading. In many cases, it is seen that poor and vulnerable people are lured into donation of organs for money. So, there is a dire need to protect such vulnerable people from life threatening exploitations.
7. The procedure of organ and tissue transplantation is an expensive one, not everybody can afford it. So, it is the duty of the Government, as well as fundamental right of the citizen under 'Right to health' to have such transplantation done at an affordable price. Government should devise a plan, for such needy patient to make organ and tissue transplantation an affordable affair.
8. The government hospital lags far behind than the Private hospitals, in performing such transplantation surgeries, so to eliminate the risk of any corruption or illegal practices regarding such organ and tissue transplantation in such private hospitals, government has to provide them with set of guidelines or advisory for not indulging in any malpractices.
9. In the time of need, every government or non-government department shall come together for providing help of the needy, 'Green corridors' has to be set-up for easy transportation of organs and for the convenient of such patients.

Thus, it becomes very important for us all to realise the gravity of the situation as well as its impact and many more people should step up for the cause of organ donation. The government should acknowledge those who selflessly pledged their organs, and it will motivate others to follow the suit of such organ donation, which eventually will bridge the gap of such organ shortage and organ requirement in the country. Even if, 5-10% brain dead patient's organ is harvested and stored properly than there would be no requirement of donating organs by the living person.

Donation of organs and tissues is a life saving action, which can provide a person, who has no such hope of life before, a chance to live again. So, the greater number of donors, the more lives could be saved. Thus, everybody in life, should think about pledging their organs for the betterment of society at large and save as many lives as possible.
