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ORGAN TRANSPLANTATION IN INDIA & GLOBALLY

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BACKGROUND

An organ transplant is said to be a medical procedure attributed to transplantation of organ from a person who gives the organ (also known as the donor) to a person who's damaged organ needs to be replaced (also known as the recipient). The globe has been evolving with respect to the sphere pertaining to organ donation. The first transplant that was successfully transplanted was the kidney in the 1954. Later, similar procedures were practiced on liver, heart & pancreas by late 1960s, followed by lung & intestinal organs in the 1980s. Fortunately, all these procedures were a success. As these medical practices witnessed tremendous success, the demand for organs shot up high. Organ Transplantation was a huge asset to the medical industry but the core ethics, moral practice & credo of the medical profession was said to be tested as commercial dealings began to rise exponentially. As a result, regulations were formed to regulate the practices of organ transplantation & organ donation to eradicate unfair practices.

LEGAL FRAMEWORK IN INDIA

Transplantation of Human Organs Act (THOA) was enacted in the year 1994 to provide with an appropriate system that deals with organ transplantation & donation for therapeutic purposes. Later, in 1995, the Transplantation of Human Organs Rules were followed which was amended in 2014. The main aim of this act is to deal with certain stages of the transplantation such as removal, storage, transplantation & prevention of commercial dealings with respect to human organs. One of the important trait of this act was legalization of donation of organs by a brain dead person. Some important provisions are said to be discussed below:

1. One of the most important concept that was said to be introduced is 'living donors'. A living donor can donate one kidney, a portion of their liver or a portion of their pancreas. The THO

Act dictates who are eligible to donate organs without any legal formalities and they are mother, father, brothers, sisters, grandmother, grandfather, son, daughter and spouse. In an episode of transplantation, people in this list, do not need any special permission or authorization from the government. They are also called 'first relatives'. Foreign citizens, who are 'near related' to the recipient, are said to be permitted for organ donation.

2. Secondly, formulation of proper authorities in each state or Union Territory to oversee and regulate transplant activities. They were done by the formulation of Authorization Committee (AC), Appropriate Authority (AA) & Advisory Committee.

(A) **Authorization Committee (AC)** - The cardinal principle of this committee is that the donor must not consider donation for consideration. If the total number of transplants performed at the designated transplantation surpasses 25 in a year, an authorization committee with a hospital in a metro area or major city shall be formed. If there are less than 25 transplants in a district in a year, there are State or District level Committees for small communities. The donor and the recipient is said to fill an application. The application is said to be studied & investigated which is followed by a personal interview. The motive of this investigation is to understand if the donor recipient understands the potential risks involved in the surgery & to ensure that there is no plausible commercial transaction. The decision is made by following Sub Clause (3), Clause 9 of Chapter II of THO Act and the approval or rejection is sent to the respective hospitals.

(B) **Appropriate Authority (AA)** - The cardinal principle of this authority is regulation of removal, storage & transplantation of human organs and make sure that these acts are performed only after the approval. They are also entitled to check the standards of the hospitals, examine if the hospital has a proper procedure for the transplantation and if the hospital is making sure that the donors & the recipients get proper follow up medical care.

(C) **Advisory Committee** - The cardinal principle of this committee is to advise the committees. They are constituted with a Chairman and 2 other medical experts who possess a postgraduate degree, with not less than 5 years of work experience in the sector of organ transplantation.

3. Thirdly, Declaration of Brain Death. If a person is said to declared brain - dead when:

(a) His/Her brain- stem functions have stopped working

(b) His/Her heart maybe working due to external measures, like a ventilator.

In such circumstances, there are 2 certifications that are required from 2 doctors , one being a neurologist, who are nominated by the appropriate authority, 6 hours apart.

4. The fourth ingredient dealing with organ donation is deceased or cadaver donors. When a person gives his or her consent during their lifetime and if they are more they have attained majority, then the organs of that person can be donated. With respect to the cost of maintaining the body and other changes, for instance, retrieval of organs or tissue, transportation of the organs & preservation of the organs shall be borne will the recipient or the institution, as declared by the respective state government.

5. Lastly, the act also includes certain punishments. The following sections are:

(a) Section 18 states that a person who is guilty of removal of a human organ or a tissue without the permission of the prescribed authority can be slapped with a fine of Rs. 20,00,000/- and an imprisonment upto 10 years. If the person found guilty is a medical professional, they shall be reported to the State Medical Council and his or her name shall be removed from the register for 3 years if it is a first offense and if it is a repeated offense, then the name shall be removed permanently.

(b) Any person dealing organs for a consideration or commercial purposes shall be held guilty under Section 19 of the the THO Act, for a period of 5 - 10 years and they shall be liable for a fine of 20,00,000 - 1,00,00,000.

(c) If any other provision of the act is said to be violated then they shall be punished under Section 20 with an imprisonment that can extend upto 5 years or with a fine which can be extended upto 20,00,000.

ISSUES & CHALLENGES

There has fashion with respect to organ transplantation has evolved tremendously. There are a lot augmentation in surgical methodology, organ preservation, and pharmaco-immunological therapies. In spite of such upgrades this sphere has some critical issues that are not easy to get a handle on. There are a lot of ethical, legal, cultural issues regarding organ transplantation.

Regarding issues & challenges, there are 3 limbs to it:

(a) **Ethical Issues Regarding the Recipient:** This issue deals with the lifestyle of the candidate for transplantation. The question here is ‘Should people who have refrained to maintain a healthy lifestyle by smoking, drinking, or diet receive new organs? Should organs be given to people whose organs were damaged by illness?’

(b) **Ethical Issues Regarding Allocation of Limited Resources:** Since there are a shortage of resources factors such as criteria for selection, usage of animal organs (Xenotransplantation such as bovine heart transplant), usage of artificial substitutes for tissues & organs, high costs, etc.

(c) **Ethical Issues Regarding Procurement of Organs & Tissues** - Malpractices are said to be momentous factor as far as ethical issues in organ donation are concerned. In order to procure organs the concept of buying and selling organs for consideration was a huge problem.

(d) **Cultural Barriers** - Every culture has its own myths, cultural misunderstandings, social values, death taboo etc. & therefore it has also influenced organ donation.

DEMAND & SUPPLY FOR ORGAN DONATION IN INDIA

Across the world there is said to be a disequilibrium in the demand and supply regarding organs. In India, there are a lot of factors that determine a successful outcome in an organ transplant, such as, the consent of the family, the decision making process, and psychological factors. There are about 4,00,000 people who die every year in India while waiting for an organ transplant. Considering India's population being 140.76 crores (as of 2021) there is an enormous gap between the demand & supply. 185,000 kidneys, 33,000 livers, and 50,000 hearts are required in India every year, yet only 6,000 kidneys, 1200 livers, and 15 hearts are transplanted there each year. According to the Organ procurement of Transplant Network, one organ donor can save the lives of almost eight other individuals. Unfortunately, when compared to a nation like Spain, which has a donation rate of 36 PMP, India's rate of dead organ donation is appallingly low at 0.34 per million people (PMP). This led to an organ donation shortage in India, which can be solved even if only 5–10% of those responsible for tragic accidents choose to donate their organs.

There are some big challenges that India faces with reference to organ donation. Firstly, Acceptance of Brain Death As Death. Families often find it hard to believe that the patient is

no more and they often tend to confuse with the state of coma, which gives them hope. According to families, they are still under the impression that the patient is still alive since the organs and vitals are stable. This makes the family antipathetic to provide consent for donation.

Secondly, Need for Transplant Coordinators is censorious. A set of tests must be performed on a brain dead person by four certified transplant coordinator in order to determine and confirm the condition. Also, if a qualified transplant coordinator is not present, this certification could not result in donations because the conversion rate might be lower. The transplant coordinator must address issues and offer advice to a possible donor family in addition to being certified as a donor.

Thirdly, Length between Death of the patient & Final Rites of the Patient. The amount of time taken to harvest organs after a patient has been deemed brain dead is one of the largest obstacles. Families of donors who have lost their relative are frequently apprehensive when the patient's last rites are delayed.

Fourthly, The type of Consent, the final decision is made by the next of kin, but if the family refuses, the organs of the deceased person cannot be donated.

Lastly, Challenges regarding ICUs. The greater issue is the hospitals' incapacity to recognize, certify, and keep track of a patient who has passed away from brain death. With an estimated six out of ten patients willing to donate, hospitals with transplant coordinators see an improvement in conversion rates. Therefore, hospital ICUs must be set up to recognise, certify, and care for individuals who have passed away from brain death. Only then can the process of persuading a family be considered.

SITUATION OF ORGAN TRANSPLANT IN OTHER COUNTRIES

Approximately 100 of the Member States of the World Health Organization (WHO) currently report transplant services. Over 80,000 kidney transplants from both live and deceased donors occurred in the world in 2014.

Spain has always topped the list for highest donor rates in the world for 24 years. As of 2015, with 39.7 donors per million, 4,769 transplants were performed and one of the reasons why

Spain has topped the list is because due to level of organ donation in the country, the rate of refusal is very low as estimated in 2015 which is 15.3%.

In the United States of America, with more than 42,800 organ transplants carried out in the country in 2022, the number of transplants conducted there has been rising steadily. Even with the rising numbers in transplant there is a serious shortage of organs. About 121,678 people are waiting in the UNOS list for a transplant. There were other measures taken in the US, for instance, Facebook users were able to post their "donor status" to their accounts in 2013, which increased registrations. In a more recent software upgrade for iOS 10, Apple allowed American customers to register as donors directly from their iPhones.

In Brazil, the notion of organ donation was attempted through the presumed consent model in 1997 but it was repealed after 8 years as there was a denunciation by the public who had a fear that their organs will be removed before they were clinically dead. Currently, Brazil opted the system back and the rate of donation is 16 per one million people.

In France, one of the main motives of the country is press upon Organ Donation. On March 14, France launched a new €210 million strategy for organ and tissue donation for the years 2022 to 2026. By 2026, the goal is to do 40% more transplants, or a total of 6,760 to 8,530 transplants annually. 527 living donors and 1,392 deceased donors combined for 5,273 organ transplants in France in 2021. This represents a 19.3% increase over 2020, when the pandemic had a significant negative impact on donations.

In the Russian society places a high value on maintaining the integrity of the deceased's body, making organ donation a particularly delicate topic. According to data retrieved from the 2018 National Registry, the number of organ transplants in Russia has been on a long-term upward trend, increasing around 10-15% annually.

Iran is said to be the only country where it is legal to buy a kidney. The government will compensate these unrelated contributors with money in the amount of \$1,200 and the recipient will pay them an extra sum ranging from \$2,300 to \$4,500.

CONCLUSION

Organ Donation is considered as 'Life After Death'. There are a lot of factors that causes a turbulence in this process, but beyond that there is an increase in organ donation many

countries. The law regarding organ donation is evolving but, unexpectedly, medical students and nurses are unaware of the Act as well. They, along with the rest of the community, must thus be better informed about the Act. It has been shown that desire to give organs directly relates to education level, which should be raised. Medical practitioners must establish ethical standards and punish offenders. The committees that will monitor these activities must include members who are representative of the general public.

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