ORGAN DONATION AND TRANSPLANTATION LAWS IN INDIA

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ABSTRACT

The idea of sharing the essence of life is divine. A person who donates an organ has the honor of saving another person's life. It redefines the purpose of life in a much better way and gives life a new meaning. It is a fact that the community does not fully understand the value of organ donation because of a wide range of factors that influence and limit organ donation in India. India has the potential to lead the world in transplantation, but for a variety of reasons, it is still lagging behind. This is a consequence of a variety of problems, including a general lack of awareness among the public and medical professionals, sociocultural and religious considerations, organizational issues, moral and legal issues, and problems with the law and morality. This essay examines the state of organ donation and transplantation in India as well as the gaps that prevent the transplantation of deceased organs there.

Keywords: Organ, Transplant, Donation, Donor, Thoa.

INTRODUCTION

Giving one or more organs to someone else for transplantation without receiving payment is known as organ donation.[1] Organ donation is a personal decision, but it also has legal, ethical, organizational, social, and medical ramifications.[2] Technological advances in the past few decades have enhanced the feasibility of organ transplantation, which has pushed the demand for organs. Consequently, the shortage of organs has become a global concern.[3] The viability of organ transplantation has increased thanks to technological advancements in recent decades, which have increased the demand for organs. As a result, organ shortage has gained international attention. The Transplantation of Human Organs Act (THOA) was passed by the

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[1] Gruessner R. Organ donation. Available at www.britannica.com/EBchecked/topic/ 431886/organ-donation (acessed on 15 Dec 2014).

[2] Edwards TM, Essman C, Thornton JD. Assessing racial and ethnic differences in medical student knowledge, attitudes and behaviors regarding organ donation. J Natl Med Assoc 2007;99:131–7.

[3] Badrolhisam NI, Zukarnain Z. Knowledge, religious beliefs and perception towards organ donation from death row prisoners from the perspective of patients and nonpatients in Malaysia: A preliminary study. Int J Humanit Soc Sci 2012;2 (24 Special Issue):197–206.

Indian government in 1994.[4] In contrast to affluent nations, India has a low rate of organ donation (0.34 per 100 000 people).[5] In India, organ donation after brainstem death is not common as well. In comparison to the industrialized world, India has a very young history of organ transplantation. India has made only a small conceptual and scientific contribution to this field of study while being at the center of one of the major transplantation-related ethical disputes. In India, the first kidney transplants took place in the 1970s. Even though the number of transplants increased in the 1980s and early 1990s, they were mostly limited to live donor kidney transplants in a few major centers. Kidney transplants increased in the 1990s as a result of the opening of more centers and the availability of qualified personnel. Other organ transplantation, like that of the liver, is a relatively new practice.
It is important to recognize right away that a sizable section of India's population who needs transplant benefits still cannot access them. Many end-stage renal disease patients have a very low quality of life since they are dependent on long-term dialysis. Even dialysis facilities are scarce, pricey, and inconvenient. Because they cannot afford therapy, more than 90% of patients in South Asia pass away within months of receiving a diagnosis. According to estimates, just 2.5% of Indian patients with end-stage renal disease really end up receiving a transplant.[6] This percentage would represent an even smaller minority for the liver. Other organ transplantation, such as that for the heart and lungs, has not seen much significant action.

TRANSPLANTATION OF THE HUMAN ORGAN ACT, 1994:

On four separate occasions in 1989 and 1990, two union ministers of the Government of India stated in parliament that they intended to draught comprehensive legislation addressing the recognition of brain stem death and the prohibition of commercial trafficking in human organs. On August 20, 1992, the Transplantation of Human Organs Bill was introduced in the Lok S abha. It was referred to a select committee after being discussed in both Houses of Parliament. The report from the select committee was delivered on December 21, 1993. The select committee's recommendation led to another discussion of the bill in both Houses of Parliament. The "Transplantation of Human Organs Act, 1994[7]" (42 of 1994)" was enacted on July 8, 1994,

[4] Shroff S. Legal and ethical aspects of organ donation and transplantation. Indian J Urol 2009;25:348–55.
[5] Mohan Foundation. Deceased donation statistics. Indian Transplant Newsletter 2014–15;14 (43).
[6] Abraham G, John G T, Shroff S, Fernando EM, Reddy Y. Evolution of renal transplantation in India over the last four decades. Clinical Kidney Journal. 2010;3:203-7.
[7] Transplantation of Human Organs Act, 1994

after being approved by both houses of parliament and the president. India thereby joined the elite group of nations possessing a national human organ donor act.[8]

RESEARCH METHODOLOGY:

The research is carried out using a doctrinal research approach, using data gathered from diverse sources such as case laws, online journal articles, books, research papers as well as online websites.

TYPES OF ORGAN DONATION:

There is a great misconception that an organ donation can only happen after death. Reality is something different, living donor and deceased donor transplants are the two different types of transplant donation. The former occurs when a person is still alive and voluntarily gives their organs, and still survives, as the term implies. The latter occurs when a brain-dead person's organs are removed and given to a needy living person. Not all organs, however, are eligible for donation after death or even before.

FEATURES OF THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

On February 4, 1995, all of the union territories and the states of Goa, Himachal Pradesh, and Maharashtra adopted the Transplantation of Human Organs Act (THOA), 1994. Following that, all states followed these rules, with the exception of Jammu & Kashmir and Andhra Pradesh, which had already passed their own laws.

The THOA addresses the control, preservation, and transplantation of human organs for medical use as well as the avoidance of commercial use of human organs. It outlines restrictions on who is eligible to donate and receive donations, as well as the locations where they may occur. Certification of brain death must follow certain rules. The guidelines for putting the Act into effect were supplied by the MOHFW of the Indian government. Additionally, the proper authorities for each state and union territory have been established. To perform transplants, institutions (hospitals) must register; these registrations must be renewed every five years. A THOA violation can result in a 5-year prison sentence and a fine of up to Rs 10,000. The Act allows for the donation of organs by family members, including a parent, mother, son, daughter,

[8] Transplantation of Human Organ Act, 1994. Available at: http://india.gov.in/allimpfrms/allacts/2606.pdf. Accessed June 8, 2012.

sister, brother, husband, and wife. Unrelated donors may make donations based on "affection and attachment" with the approval of "authorization committees." Three official members and three unofficial members work under a chairman (the director of the hospital or institution) on authorization committees. The group also includes representatives from the director of health services and the secretary (health). A registered medical practitioner (RMO), a neurologist or neurosurgeon from a notified panel, an RMO in charge of the institution, and an RMO treating the patient make up the four-person committee for certifying brain stem death. The cost of extracting, transporting, or conserving the human organ to be donated, as well as any expenses or lost wages incurred by the donor, are allowable under THOA; however, other payments are prohibited and punitive. Advertisements that promote the purchase or sale of organs are prohibited and illegal.[9]

THE KIDNEY TRADE IN INDIA:

Because of the infamous kidney trafficking in the 1980s, organ transplantation in India has attracted significant public attention. For transplants from paid "donors," foreign patients went to India. Although some large commercial institutions participated covertly in this activity, these transplants were frequently carried out covertly in tiny hospitals in subpar settings. These transplants' outcomes were also subpar.[10] Medical organizations, such as medical councils and other regulating authorities, mostly kept quiet while the media covered these crises. Given the historically poor self-regulation of medical practice in India, this was not unexpected. The rapidly growing private sector also benefited greatly financially from the kidney trade. Nephrologists and kidney transplant surgeons were among the many members of the medical community who participated in the kidney trade.

There have been attempts to provide an intellectual justification for this behavior, arguing that monetary donations are in line with a libertarian and free-market worldview.[11] The same reasoning was used to support arguments for a "controlled" market. On the ground, however, it was evident that middlemen had frequently used coercion and even fraud to defraud donors

[9] Agarwal, Sanjay K.1,5; Srivastava, Rakesh K.2; Gupta, Sudhir3; Tripathi, Samidha4. Evolution of the Transplantation of Human Organ Act and Law in India. Transplantation Journal 94(2):p 110-113, July 27, 2012. | DOI: 10.1097/TP.0b013e31825ace15

[10] Salahudeen AK, Woods HF, Pingle A, Nur-El-Huda Suleyman M, Shakuntala K, Nandakumar M, Yahya TM, Daar AS. High mortality among recipients of bought living-unrelated donor kidneys Lancet. 1990 Sep 22;336(8717):725- 8.

[11] Radcliffe-Richards J, Daar AS, Guttman RD et al. for the International Forum for Transplant Ethics. The case for allowing kidney sales. Lancet. 1998;35:1950-2.

in this market of any financial incentives. Additionally, follow-up research on unrelated donors revealed that they had poor quality of life.[12] States that have tried out a regulated, state-sponsored model, like Iran, have reported some success.[13] Although the specifics of this discussion are outside the scope of this paper, it is crucial to remember this historical context when discussing problems with deceased donations.

PROBLEMATIC INTERPRETATIONS OF THE THOA:

The law appeared to solely define brain death in terms of organ transplantation, which created an odd circumstance. There is no legal penalty for disconnecting life support, including the ventilator, if brain death is determined and the family declines to give authorization for donation, according to a troubling and commonly accepted reading of the law by the medical profession in India. This has created a significant ethical dilemma in real life. The family is told that their loved one is "dead" and requested to give their permission for donation. However, if they decline and ask for the body to be delivered, their request to remove life support is denied.

Only transplant hospitals were recognized by the law as authorized institutions where brain death might be certified. Thus, it was impossible to declare brain death in the enormous number of facilities where transplantation was not being done. As a result, odd circumstances developed where the cadaver donor had to be transferred to another reputable hospital just for the purpose of organ retrieval. Organs can now be removed with consent and transported to a facility where the recipient procedure will be carried out thanks to recent amendments to the Act (2011)[14] and the Rules (2014)[15]. These institutions are referred to as "non-transplant organ retrieval centers." Prospective donors are frequently transferred to transplant-recognized hospitals because a significant proportion of institutions are still not recognized. The hospital can then use the organs since it receives precedence as an "in-house" donor, which is a clear instance of a conflict of interest. Therefore, it is possible to persuade people who may be brain-dead to transfer by offering even "soft" incentives like fee exemptions.
It's still unclear if brain death can be formally recognized without regard to organ donation. Brain-dead people are actually still hooked up to rigorous organ support techniques.[16] This

[12] Goyal M, Mehta RL, Schneiderman LJ, Sehgal AR. Economic and health consequences of selling a kidney in India. J Am Med Assoc. 2002; 288: 1589- 93.
[13] Ghods AJ, Savai S. Iranian model of paid and regulated living-unrelated kidney donation. Clin J Am Soc Nephrol. 2006 Nov;1(6):1136-45. Epub 2006 Oct 11.
[14] Transplantation of Human Organs (Amendment) Act, 2011
[15] Transplantation of Human Organs and Tissues Rules, 2014
[16] Pandya SK: 'Brain death' and our transplant law. Issues Med Ethics. 2001;9:51-2.

frequently entails denying care to another patient who is suffering from a serious illness in a nation where intensive care unit beds and ventilators are few.

After the Act was passed in 1994, there was little significant activity in terms of declaring brain death and organ donation after brain death for a considerable amount of time. Approximately 2,500 cadaver transplants had been carried out in India as of 2014, the majority of which took place in the previous five years in the states of Tamil Nadu, Andhra Pradesh, Maharashtra, Kerala, and Gujarat. Around 1,400 cadaver organ transplants have taken place in Tamil Nadu, mostly in Chennai, demonstrating the state's notable success with corpse donation.[17] The relative success of Tamil Nadu has been attributed to a number of factors, including frequent communication between the government and stakeholders and the supply of the required legal and administrative support through routine government directives. Since the beginning, the Tamil Nadu program has made an effort to maintain complete transparency. Mumbai has seen an increase in cadaver donations in recent years,[18] and in the first half of 2014, there have already been 15 contributions.

A detailed examination of the country's donation trends reveals that hospitals with active transplant programs are primarily responsible for the deceased donation trend. These organizations directly gain from recognizing brain death and encouraging donations, whether financially or otherwise. These institutions are mostly located in big cities and frequently serve the corporate sector.

GROUND REALITIES IN INDIA:

Transplants using deceased donors have encountered issues unique to the Indian context. Only intensive care units (ICUs) have the resources to keep a brain-dead patient's organs functioning through mechanical ventilation, cardiac support, and intensive monitoring, making the diagnosis of brain death and eventual donation possible. These ICUs are scarce and primarily found at large hospitals in major cities. They frequently lack central command structures, are overworked, and are understaffed. Brain-dead patients are frequently treated with "benign neglect" in this circumstance, with the detection of brain death and obtaining consent frequently receiving low priority. However, if these individuals decide to donate their organs, they must

[17] Department of Health and Family Welfare, Government of Tamil Nadu. Cadaver Transplant Program, Government of Tamil Nadu. Chennai: DHoFW;2008 Sep 15. Available from: http://www.dmrhs.org/tnos/
[18] Government of Maharashtra. Zonal Transplant Co-ordination Centre website. Mumbai: GoM; date unknown [cited 2014 Jun 10]. Available from: http:// www.ztccmumbai.org/

get the same care as other patients in order to preserve the organs' viability until removal. An already overworked team finds this to be demanding and demands a significant attitude adjustment.

Another dilemma that is unavoidable in this scenario of limited resources is whether to focus scarce resources on the care of the potential donor who is brain dead or on the sick patients who need the care to save their lives. The price of their upkeep has also been a problem because the majority of benefactors are from the business sector. How is a family who received donated organs billed? And logically speaking, from what point in the disease should it be done if the bill should be waived? And would a complete bill waiver in the private sector be considered an inducement? Early on, it was believed that cultural, religious, and social prejudices as well as a lack of public understanding prohibited families from giving their approval to deceased donation in India. Lack of public knowledge was frequently cited as the reason why cadaver donation hadn't advanced. However, it soon became clear that there were other barriers to donation and that, if institutions made systematic attempts to find and contact family members of brain-dead donors, the consent rate would rise dramatically. Cadaveric transplants were not being carried out not because families were unaware of the procedure or refused to contribute, but rather because there were no institutional processes in place to contact the relatives of brain-dead patients. The same thing has happened with blood and eye donation, which has a much longer tradition in India. The way in which consent is obtained for the removal of organs from brain-dead people has changed over time throughout the world. The most typical scenario is "informed consent," where members of the donor's immediate family consent to organ donation after brain death has been determined. India has traditionally used this type of consent. However, "family consent" is a nebulous concept, and unlike in some other nations, the rules don't specify a hierarchy of kin. Divergent opinions have occasionally existed within the donor family. The moral dilemma here is whether it is appropriate to seek unanimity in agreement and, if not, whether one family member's opinion can take precedence over others.

NECESSITY OF ORGAN DONATION IN INDIA:

Since there is a severe mismatch between the organs donated and the waiting list for transplants, there is an urgent need to encourage organ donation on a global and national level. Many people pass away each day while awaiting an organ transplant. According to current estimates, just

2.5% of patients in India with end-stage renal illness ultimately receive a transplant.[19] While 2.1 million People require kidney transplants each year, the actual number of instances varies between 3000 and 4000.[20] While 12 lakh Indians need corneal transplants each year, only 45,000–50,000 eyes are actually gathered by all eye banks working in the nation.[21] Also, it should be mentioned that transplant results in a longer and higher-quality life compared to renal dialysis.[22] Renal dialysis is more expensive than transplantation.[23]

CONCLUSION AND OPINIONS

It is unfortunate that government initiatives have not yet reached their full potential. There is injustice present in the nation's organ donation system. With the exception of a few groups, NGOs working on this topic in India have not yet adequately addressed this issue. To promote equity, the government should give this issue a top priority.

Only through awareness initiatives can the stigmas and misconceptions surrounding this subject be dispelled. There should be a determined attempt to enlist organizations that have a say in such matters to address the issue because it has religious implications. The fact that practically all organs from a cadaver can be transplanted into a living organism under specific conditions and time constraints is a basic fact. Thus, using creative ways and procedures, the process needs to be further rationalized. Another area that needs to be extensively explored by the nation is research in this regard. Government funding for innovative medical research in organ transplantation is therefore necessary.

Public awareness of organ donation is important, and a number of stakeholders are essential to this process. For this project, the government, NGOs, medical community, media, and youth organizations should work together. On the part of the government, it is necessary to close legal loopholes and lessen administrative red tape.

[19] Abraham G, Jayaseelan T, Matthew M, Padma P, Saravanan AK, Lesley N, Reddy YN, Saravanan S, Reddy YN. Resource settings have a major influence on the outcome of maintenance hemodialysis patients in South India. Hemodial Int. 2010 Apr;14(2):211-7. doi: 10.1111/j.1542-4758.2010.00441.x. PMID: 20529037.
[20] Keshavamurthy HR Organ Donation and Transplantation Provides Second Life. 2015 Press Information Bureau, Government of India Available from: http://www.pib.nic.in/newsite/mbErel.aspx?relid=118012.
[21] National Programme for Control of Blindness (NPCB). Directorate General of Health Services. 2012 Ministry of Health and Family Welfare Available from: http://www.npcb.nic.in/writereaddata/mainlinkfile/File271.pdf
[22] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S. and Gill, J., 2011. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *American journal of transplantation*, *11*(10), pp.2093-2109.
[23] Abraham, G., John, G.T., Sunil, S., Fernando, E.M. and Reddy, Y.N., 2010. Evolution of renal transplantation in India over the last four decades. *NDT plus*, *3*(2), pp.203-207.

The infrastructure for performing transplants in public and private hospitals needs to be improved. There should be several awareness campaigns, including continuing medical education programs for medical and paramedical staff, transplant coordinators, and counselors. Both public and private hospitals should follow the same "standard operating procedures" developed to recognize and certify brain death, maintain and transport organs, and handle medicolegal issues. Because irregularities could lead to mistakes.

We need to prioritize getting cooperation from many stakeholders if we want to spread organ transplantation widely. Physicians can help with this by playing a role in it. Yet, the additional duty of carrying out the purposeful dissemination of this admirable objective falls to the medical students. The expertise and dedication of the doctors to this idea should be systematically assessed. To encourage organ donation, we should incorporate these concepts of life-giving and life-extending measures into both the medical and academic curricula.[24]

[24] Adithyan, G. S.*,; Mariappan, M1. Factors that Determine Deceased Organ Transplantation in India. Indian Journal of Transplantation 11(2):p 26-30, Apr–Jun 2017. | DOI: 10.4103/ijot.ijot_13_17