

## REGULATIONS ON THE DONATION OF ORGANS IN INDIA AND OUTSIDE

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### ABSTRACT

*This research paper deals with the background, significance, and history of Organ Donation and also explores the regulations and practices governed by the regulatory bodies in India and at the international levels. This study also explores the cultural beliefs and traditional aspects of organ donation. This paper also provides recommendations and directions for the future to ensure the effective regulation of organ donation and also recommends creating awareness through large-scale campaigns and education among youth and in society. Along with this Ethical Considerations are also examined in this study with the collaboration of regulatory bodies, health institutions, and Lawmakers.*

**Keywords:** Organ Donation, Ethical Consideration, Legal Framework, International level, Public Awareness, Cultural Beliefs.

### INTRODUCTION

The act of physically taking an organ (by surgery) or tissue from one person (the donor) and having it transplanted into another person (the recipient), who needs that organ or tissue due to illness, injury, or organ failure, is referred to as organ donation. Although sometimes living people can sometimes give some organs or tissues, organ donation is mainly done after the donor has passed away. It should be done legally and with the consent of the live person or with the assent of their legal heirs in the case of a dead person. Organs like the heart, lungs, bone marrow, kidney, pancreas, skin, cornea, etc. are frequently included in organ transplantation<sup>1</sup>.

Organ Transplantation has revolutionized modern medicine by providing life-saving treatments for patients suffering from end-stage organ failure.

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<sup>1</sup> Tamuli, R. P., Sarmah, S., & Saikia, B. (2019). Organ donation – “attitude and awareness among undergraduates and postgraduates of North-East India”. *Journal of Family Medicine and Primary Care*, 8(1), 130-136. <[https://doi.org/10.4103/jfmpe.jfmpe\\_206\\_18](https://doi.org/10.4103/jfmpe.jfmpe_206_18)> accessed on 12 July 2023

## HISTORY

The concept of organ donation was considered a myth in ancient times. Resistance from the Immune system was one of the major challenges faced by early transplant surgeons. But in 1960, Dr. Peter Medawar came to rescue transplant surgeons from this problem by introducing a way of typing tissue. In the 1980s, the immunosuppressant medication "cyclosporine" was developed, marking a significant advancement. 9000 kidney transplants were carried out in the United States in 1986, with a respectable 85% success rate in the first year<sup>2</sup>.

## SIGNIFICANCE

Organ Donation has the potential to save lives and enhance the lives of recipients who are suffering from organ failure. Organ Transplantation is the only reliable option for the treatment of end-stage organ failure. It increases life expectancy and improves the recipient's way of living.

Organ Transplantation is very helpful in deadening the misery of people who are suffering from organ failure, as it can cause immense physical and emotional suffering for individuals and their families. Organ Donation helps them to regain confidence and independence in the life of the needy with better health. It also prevents long time treatment like dialysis etc.

Understanding the Background, History, and Significance of organ donation this study intends to investigate Indian organ donation laws and practices and evaluate them against international norms.

## ORGAN DONATION: AN OVERVIEW

### Definition

The act of willingly giving one's organs or tissues to another person in need of transplantation due to organ failure or disease is referred to as organ donation. It entails the selfless act of giving an organ, in part or whole, from a live or deceased donor to improve or save the recipient's life. Both deceased donations, in which organs are obtained from people who have died away but have given their agreement to donate their organs, and living donations, in

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<sup>2</sup> History of Organ Donation <[History Of Organ Donation - Organ Donation Information in India | Donate Life | NGO](#)> accessed on 12 July 2023

which organs or tissues are donated by people who are still alive and in good health, are possible in the case of organ donation. The recipient's failing or sick organ is replaced with the given organs by surgical transplantation, potentially enhancing or even saving their quality of life<sup>3</sup>.

## TYPES OF DONORS

**Living Donors:** When a person who is physically healthy and mentally fit donates any one of a paired organ or a part of an organ or a tissue and is alive is known as a live donor. The organs donated are Kidneys (because donors can survive on one kidney), Eyes, Liver (because the liver can grow back to its normal size), etc<sup>4</sup>.

**Deceased Donors:** The act of obtaining organs from a brain-dead person who is on artificial life support and certified by a team of doctors that he is brain-dead or who has passed away in circumstances that permit organ retrieval. Organs such as Heart, Kidney, Liver, intestine, etc. can be used for transplantation. Permission is required from the family member of the deceased person for organ transplantation<sup>5</sup>.

To address the shortage of organs for transplantation and provide life-saving treatments for those with end-stage organ failure, both deceased and living organ donations are essential.

## GLOBAL ORGAN SHORTAGE

When there is a significant disparity between the demand for organs for transplantation and less availability of organs known as organ shortage. It is a problem that affects people globally in the world. World Health Organization estimated that there are over 1.5 million people on waiting lists for organ transplantation, and every 10 minutes, a new name is added to this list. Many patients who are suffering from organ failure acquires death bed while waiting for suitable donors. Organ Shortage is a huge and increasing problem in the world even for developed countries like the USA. The annual data report by the U.S. Department of

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<sup>3</sup> Organ Donation and Transplantation <[Organ Donation and Transplantation: How it works \(clevelandclinic.org\)](https://www.clevelandclinic.org)> accessed on 13 July 2023

<sup>4</sup> What is organ Donation <[Organ Donation - Information, Process, Types, FAQs \(organindia.org\)](https://www.organindia.org)> accessed on 13 July 2023

<sup>5</sup> Kanmani Job and Anooja Antony; Organ Donation and Transplantation: Life after Death <[Organ Donation and Transplantation: "Life after Death" | IntechOpen](https://www.intechopen.com)> accessed on 13 July 2023

Health and human services shows that about 20 people die each day waiting for a suitable donor and transplantation<sup>6</sup>.

Major reasons and factors that contributed to the Global Organ Shortage are listed below.

Limited supply and demand for organs are the common and major factors for shortage and it is because small pool of potential donors. As not every deceased person has any prior will for donation or their family gives any consent for organ donation. People who wish to donate their organs are unable to donate due to medical conditions or age criteria.

As Organs Transplantation required compatible donors with matching organs and this criterion is approved by Human Leukocyte Antigen (HLA) System. Getting a suitable donor match is difficult hence, it led to a shortage of organs for donation. Generally speaking, when the number of HLA mismatching is smaller the chances of compatibility are higher<sup>7</sup>.

Lack of awareness and education about this topic led to a shortage of organs for donation and donors. As living people fear that if they will donate the organ this act will harm their health and life. We need to educate people by telling them the importance of organ donation for people who are suffering from organ failure and give a second life to those patients. The sale of Organs violates the Universal Declaration of Human Rights as well as the constitution of that country, clearly said by WHO. If any professional or physician has reason to believe that the organs concerned are subject to commercialization, the WHO advised not to perform that transplantation<sup>8</sup>. Although, many steps are taken by the government to overcome this problem at the global level by making some laws and legislations, by awareness campaigns and international collaboration, etc.

## **ETHICAL CONSIDERATIONS**

This advancement of this technology of transplantation also brings a wide range of ethical dilemmas that society has to deal with along with the professionals and donors. A person has to become a patient to give strength and a new life to another patient and the rights and consent of a deceased person become a major question upon ethicality for the donation of the organs of that dead person. There are laws and legislation for transplantation on national and

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<sup>6</sup> OPTN/SRTR 2021 Annual Data Report <[2021 ADR \(hrsa.gov\)](https://www.hrsa.gov/2021-adr)> accessed on 14 July 2021

<sup>7</sup> HLA System <[HLA System | The Organ Donation and Transplantation Alliance \(organdonationalliance.org\)](https://www.organdonationalliance.org/)> accessed on 14 July 2023

<sup>8</sup> Legal and Ethical Aspects of organ donation and Transplantation <[Legal and ethical aspects of organ donation and transplantation - PMC \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/35484848/)> accessed on 14 July 2023

international levels with consideration of ethical issues. There are some ethical considerations listed below.

**Beneficent manner:** Professionals should do the best for their patients<sup>9</sup>.

**Autonomy and informed consent:** Donating an organ is a big decision for a donor whether living or deceased so it is crucial to inform the risks, benefits, and alternatives of donation. This consideration allows individuals to make free and voluntary consent with all the information.

**Non- Maleficence manner:** Professionals should not do any harm to the patient and donor for any kind of benefit.

**Financial rewards:** There is a high ongoing debate on this topic with a great dilemma. If there will be financial incentives for donation people will not do it in an altruistic manner rather, they will do it for money. This also could lead to the black marketing of organs and exploitation. However, some experts also argue that giving rewards will increase the number of donations<sup>10</sup>.

**Long-term care:** This ethical consideration will follow up on the long-term care and health responsibility of both donor and recipient. If there is no follow-up care, this could lead donor and recipient's health to bad condition, infection, and long-term illness<sup>11</sup>.

Organ transplantation may continue to save lives while upholding the dignity, rights, and autonomy of every person involved by abiding by these moral guidelines. These ethical considerations are obliging in making laws and regulations on organ donation.

## **ORGAN DONATION REGULATIONS IN INDIA**

In India, the donation of organs and "brain death" as a concept is legalized, and it is regulated by the Transplantation of Human Organs Act (THOA) which was enacted in 1994<sup>12</sup>.

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<sup>9</sup> Ethical socio-cultural and religious issues in organ donation <[Ethical, Socio-Cultural and Religious Issues in Organ Donation - PMC \(nih.gov\)](#)> accessed on 14 July 2023

<sup>10</sup> Ethical Considerations in organ donation: The challenges and controversies <<https://medium.com/@muhammadbrennan>> accessed on 14 July 2023

<sup>11</sup> Lawrence Cohen; Where it Hurts: Indian Material for an Ethics of Organ Transplantation, Daedalus, Vol. 128, No. 4, (1999) <[Where It Hurts: Indian Material for an Ethics of Organ Transplantation on JSTOR](#)> accessed on 14 July 2023

The concept of brain death means when an individual is seriously ill and none of his or her brain functions are working and is on a life support system (specifically ventilators)<sup>13</sup>. For declaring an individual brain dead, a board of four specialist doctors is made and they only have the authority to declare a person brain dead after which their organs can be transplanted. In India, donation of organs is discretionary for an individual and any individual can donate his or her organs on his or her death. If any individual willingly wants to donate his or her organs then they need to fill a consent form from the National Organ and Tissue Transplant Organisation (NOTTO) which is accessible on the NOTTO website online. For the donation of your organs, there is no specific age limit and organ donation starts at the age of six weeks. For the donation of organs, there is only one condition which is the health of the organs. Here the donation of organs includes all organs such as lungs, heart, corneas, liver, etc. Here organs also include tissues.

#### **CHALLENGES OF ORGAN DONATION<sup>14</sup>:**

- High demand and low supply (demand-supply gap)
- Unaffordable and overpriced organs (especially for below-par patients)
- Lack of awareness and attitude against organ donation
- Absence of an organized system
- Prohibition and control of organ trading.

#### **INTERNATIONAL ORGAN DONATION REGULATIONS**

**USA:** Concerning organ donation, the United States runs using an “opt-in” method, emphasizing that either the donor while they are still alive or their heirs after their death must decide on their own to give their organs. In the U.S.A. organ donation started to become popular and a practicable procedure in the 1960s. In the late 1960s, the National Conference of Commissioners propagated and publicized the Uniform Anatomical Gift Act (UAGA). The main objective of the UAGA was to encourage the concept of evenness of laws in all the states of the U.S.A. and to make similar the procedure of organ donation from the donor. But to clarify that UAGA is not a law but a model or example on which each state of the U.S.A.

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<sup>12</sup> Team Dr. Lal Pathlabs; Everything You Need to Know about Organ Donation in India <<https://www.lalpathlabs.com/blog/>> accessed on 14 July 2023

<sup>13</sup> Overview <<https://www.nhs.uk/conditions/brain-death/>> accessed on 14 July 2023

<sup>14</sup> Directorate General of Health Services <<https://dghs.gov.in/content/>> accessed on 14 July 2023

can develop its law about organ donation. Because of its wide acceptability, UAGA is deemed to be a federal law of the United States<sup>15</sup>.

The UAGA allows any individual or potential donor of sound mind to donate any body part at the donor's death, followed by the donor's intention in writing with the signature of the donor and two eyewitnesses. The UAGA was amended two times, first in 1987 and then in 2006. There were many motives behind the first UAGA amendment which was done in 1987. The foremost motive was to expand the supply needed for the organs. Secondly, to make UAGA in compliance with the federal legislation National Organ Transplant Act (NOTA) which came into force in 1984. After the 1987 amendment in UAGA, the signature of two eyewitnesses was also eliminated. Till June 2017, 46 states have acquired the UAGA in the United States.

But as I earlier mentioned that UAGA is not a federal law but only an example or model on which all the other states of the United States can enact their law. No legislation was enacted on a national level for organ donation. To counter this situation the U.S. Congress enacted a law known as the National Organ Transplant Act (NOTA) of 1984. According to NOTA, selling and purchasing of human organs is prohibited in the united states and if done so will be punishable under law with 5 years imprisonment and a fine of any amount which may extend to \$50,000.

Apart from UAGA and NOTA, there is an existence of a "common rule" which was brought out in the year 1991. The "common rule" is a set of rules of the U.S. federal state that protects human subjects in all the projects done by the United States.

**Australia:** In Australia, any individual can be a donor who is of the age 16 years or above. An individual to be a donor has to register in the Australian Organ Donor register which only takes a few minutes. The Australian government has approved the Organ and Tissue Authority to gather all the details of the potential donors to feed it on the Australian Organ Donor Register<sup>16</sup>.

Human Tissue Act forms the basis for the donation of organs in all the states of Australia and all the states have different legislations for the donation of organs in Australia but the basis

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<sup>15</sup>Legal, Regulatory, and Policy Frameworks for Organ Donation and Research Participation <<https://www.ncbi.nlm.nih.gov/books/NBK470922/>> accessed on 15 July 2023

<sup>16</sup> Join the Register <<https://www.donatelife.gov.au/>> accessed on 15 July 2023

remains the same for all the states. For Queensland, the Transplantation and Anatomy Act of 1979 regulates organ donation; the Human Tissue Act of 1983 is the legislation in New South Wales; the act which regulates organ donation in Western Australia and in South Australia are the Human Tissue and Transplant Act of 1982 and Transplantation and Anatomy Act of 1983 respectively; In Australian Capital Territory, Transplantation and Anatomy Act of 1978 regulates organ donation and lastly in Northern Territory, Transplantation and Anatomy Act of 1979 controls donation of organs and tissues<sup>17</sup>.

### **CULTURAL AND SOCIETAL FACTORS AFFECTING ORGAN DONATIONS**

There are many factors affecting organ donation including cultural and religious beliefs. Traditions and culture always affect us even if we do not participate in them. These factors always affect one's perspective on the donation of the organ<sup>18</sup>. Understanding these cultural, religious, and societal factors is very crucial to increase the number of donations.

If we talk about religions almost every religion promotes organ donation as a sign of charity and selflessness. Christianity encourages organ donation as an act of charity and love for others while in Hinduism, priests and sages promote organ donation with the belief of karma and the concept of selfless service to others<sup>19</sup>.

### **FUTURE DIRECTIONS AND RECOMMENDATIONS**

As there are many challenges to date in this area of saving lives through organ donation. But we can overcome these problems and organ shortages by taking action on the following recommendations.

By strengthening the legal framework, making several changes according to the requirement of the time, updating laws, enhancing coordination and collaboration between regulatory bodies and health institutions, etc. for effortless regulation or organ donation.

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<sup>17</sup> What we're doing about organ and Tissue Donation <<https://www.health.gov.au/>> accessed on 15 July 2023

<sup>18</sup> Cultural Considerations in Donation <<http://www.cpd.utoronto.ca/>> accessed on 15 July 2023

<sup>19</sup> Katja Doerry; Religious and cultural aspects of organ donation: Narrowing the gap through understanding different religious beliefs <<https://onlinelibrary.wiley.com/>> accessed on 15 July 2023



Encouraging deceased donors could only be possible through large-scale campaigns and awareness in society. Education on this topic will always be a big recommendation for donor participation<sup>20</sup>.

## CONCLUSION

Organ Donation or Transplantation is a complex and lengthy process. This process requires education, public awareness, cultural understanding, and regulation to make this chain of donating an organ and receiving it successful which will eventually reduce the number of people dying because of not finding suitable donors. By following the recommendations and strategies India can improve this system and can save more lives, enhance transplantation outcomes and bring hope to individuals and needy persons.



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<sup>20</sup> Recommendation- Future Strategy and Action plan <<https://www.organindia.org/>> accessed on 16 Jul. 23