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Organ transplantation in India - Would an opt-out system of organ donation be effective?

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According to World Health Organization recommendations, organ donation and transplant operations in India are overseen by the National Organ and Tissue Transplant Organisation, which was founded in accordance with the Transplantation of Human Organs and Tissues Act of 1994. India like many other countries follows the opt-in system for organ donation. In recent years, the opt-out system of organ donation has gained a lot of attention as it has shown a promising increase in rates of organ donation in countries like Spain. But as with every system, the opt-out system also has its own pros and cons. This article talks about organ transplantation in India and whether an opt-out system for organ donation would be effective.

Keywords: organ transplantation, opt-out system, organ donation, WHO.

INTRODUCTION

A gift organ is a gift of life. In a country with a population of 1.39 Billion¹ (in the year 2021), the need for organ transplantation is high in general. The high rate of communicable and non-communicable diseases in the country just increases the demand even more. India's tropical

¹ 'Population, Total - India' ([Data.worldbank.org](https://data.worldbank.org))

<<https://data.worldbank.org/indicator/SP.POP.TOTL?locations=IN>> accessed 07 August 2022

climate is what causes this high rate of illnesses that are spread by water, insects, and animals.² Social inequality in society is also a major cause of this situation.³ There exists a huge discrepancy between the supply and demand for organs around the globe.⁴ The Indian subcontinent is home to a diverse culture. Indian population consists of people from different religions, namely Hindus, Muslims, Christians, Jains, Sikhs, Buddhists, etc. Apart from the discrepancy between the demand and supply of organs, the different religious beliefs in the country also act as a hindrance to effective organ transplantation. Health professionals are required to be sensitive to the different beliefs of people from various cultures and religions that are prevalent in India.⁵

Currently, the Transplantation of Human Organs Act 1994⁶ which was amended in 2008⁷ and 2011⁸, governs the organ transplantations that take place in India. The act was enacted “to provide for the regulation of removal, storage, and transplantation of [human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues] and for matters connected therewith or incidental thereto”. According to this act, India currently follows an opt-in system for organ donation i.e., the donor and the kin get to decide whether to donate the organs or not. Unlike the opt-in system for organ donation, the opt-out system presumes consent of the donor to donate their organs and they are provided with the option to opt-out.

EVOLUTION OF ORGAN TRANSPLANTATION LAWS IN INDIA

The journey of organ donation begins in India when the first successful kidney transplant took place in the year 1971 in CMC hospital, Vellore. Slowly, the transplantation of kidneys took place all across the country, mostly in urban places. The transplants were restricted to living donors

² *Ibid*

³ Ramesh V & Pal C, ‘Organ Donation and Transplantation in India in 2019’ (2021) 19 *Experimental and Clinical Transplantation* 1313

⁴ Kute V & Ors, ‘Deceased-Donor Organ Transplantation in India: Current Status, Challenges, and Solutions’ (2020) 18 *Experimental and Clinical Transplantation* 31

⁵ *Ibid*

⁶ Transplantation of Human Organs Act 1994

⁷ Transplantation of Human Organs (Amendment) Act 2008

⁸ Transplantation of Human Organs (Amendment) Act 2011

though. Due to 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. Medical organisations, 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 trade⁹. These various multi-million kidney scams were what led to the formulation of the Transplantation of Human Organs Act in 1994 and its amendments in the years 2008 and 2011. Even though the illegal trade of organs is still a huge problem in the country, THOA, 1994 has been effective in curbing the rates of illegal organ trade in the country.¹⁰

THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

The Central government established a committee in 1991 to draught a report that may serve as the foundation for all-India legislation controlling organ transplantation, in part as a response to kidney frauds. The committee's major area of focus was "brain death," but it also made the recommendation that the sale of human organs is considered a crime. India's government enacted the Transplantation of Human Organs Act (THOA) in 1994. In 1995, the Transplantation of Human Organs Rules were adopted. The Rules alone were subsequently changed in 2008. Later, in 2011, the THOA was changed. In 2014, notification of the Rules for the modified Act was only made. Any sort of "commercial trading" of organs was prohibited under the THOA of 1994. Altruistic reasons allowed for the authorization of unrelated donations, but only with the approval of an authorisation committee. A decision was made by the committee based on

⁹ Nagral S & Amalorpavanathan J, 'Deceased Organ Donation in India: Where Do We Go from Here?' (*Indian Journal of Medical Ethics*, 2014) <<http://ijme.in/articles/deceased-organ-donation-in-india-where-do-we-go-from-here/?galley=html>> accessed 07 August 2022

¹⁰ *Ibid*

documentation and discussions with potential donors and recipients.¹¹ The Transplantation of Human Organs Act, which has transformed the idea of organ donation after death in many other nations, recognises brain stem death as a legal death in India. Only a small number of organs and tissues (such as cornea, bone, skin, and blood vessels) can be donated following natural cardiac death, compared to over 37 different organs and tissues that can be donated after brain stem death, including crucial organs like the kidneys, heart, liver, and lungs.¹²

The cost of extracting, transporting, or conserving the human organ to be donated, as well as any expenses or lost wages to the donor, are acceptable expenses under THOA; however, other payments are prohibited and punitive. Advertisements that promote the purchase or sale of organs are prohibited and illegal.¹³ The THOA, 1994's foundational premise of "consent" is shown in the authorization to remove an organ from a deceased person. According to Section 3(1) of the Act, any donor may give or authorise the removal of any of his organs or bodily tissues prior to death, but only for medically necessary reasons. As long as the deceased did not oppose the donation while he was alive, the deceased's kin may also consent to the donation of organs under section 3(3) of the Act.¹⁴ Therefore, India follows an opt-in system for organ donation.

OPT-OUT SYSTEM FOR ORGAN DONATION AND ITS EFFECTIVENESS

A private member's bill that would permit all adult residents to be listed as organ donors in a national register was announced by MP Varun Gandhi during Organ Donation Week. On August 13th, he announced this on his social media account. The proposed bill might be a step toward reducing organ failure-related fatalities in the nation and closing the gap between organ demand and availability. Under this law, it shall be presumed that all citizens are organ donors and they shall be provided with the option to opt-out by choice. Few nations around the world have already adopted this opt-out system for organ donation.

¹¹ *Ibid*

¹² DGHS, 'National Organ Transplant Programme' (*Directorate General of Health Services*) <https://dghs.gov.in/content/1353_3_NationalOrganTransplantProgramme.aspx> accessed 07 August 2022

¹³ *Ibid*

¹⁴ Tikoo Dav, 'Transplantation of Human Organs: The Indian Scenario' (2017) 1 ILI Law Review

Countries that use the opt-out approach, like Croatia and Spain, have rates of 46.9 and 38.6 per million people, respectively. The implied consent mechanism is now in place in England as of May 2020. This was done in response to Wales's success, which switched to opt-out in 2015 and saw a surge in consent rates from 58% to 75%. In opt-in countries, the United States has been thinking about changing its policy.¹⁵ The high rates of organ transplantation in countries like Spain are usually attributed to the opt-out system the country has adopted. But the high rates can also be attributed to the lack of autonomy of the organ donors. Many argue that this system also takes away the altruistic nature of organ donation.

According to McEwen¹⁶, presumed consent is a concept that has historically been used in healthcare settings when the patient is deemed incompetent or unable to make an educated decision, allowing healthcare workers to make decisions that are in the patient's best interest. He contends that using a presumed consent model when deciding whether to donate organs to the deceased violates the fundamental right to autonomy and fails to take into account the fact that people who are still alive are unable to make an informed choice about their own fate. In addition, he contends that social intolerance of this kind of paternalistic rule-making might take the form of resentment, mistrust of the medical establishment, and possibly even a refusal to donate blood.¹⁷

The major problem with presuming consent is that it is not always informed consent. Especially in a developing country like India where the literacy rate is 74.04 percent (according to the 2011 census)¹⁸, spreading awareness about organ donation is hard.¹⁹ Most people are not even aware of the initiative by the government to enable citizens to pledge their organs for donation by including an option in their driver's licenses to opt-in for organ donation. While it is hard to

¹⁵ Ishwarya Thyagarajan, 'Presumed Consent: Will It Work in India?' (*Medindia*, 17 August 2020) <<https://www.medindia.net/news/healthinfocus/presumed-consent-will-it-work-in-india-196894-1.htm#:~:text=Under%20the%20presumed%20consent%20scheme,and%2038.6%20per%20million%20respectively>> accessed 07 August 2022

¹⁶ P M McEwen, 'Valid informed consent: the key to increasing supply of organs for transplantation?' (2005) 7(3) *Critical care and resuscitation*

¹⁷ *Ibid*

¹⁸ 'Profile – Literacy' (*Know India: National Portal of India*) <<https://knowindia.india.gov.in/profile/literacy.php>> accessed 07 August 2022

¹⁹ *Ibid*

spread awareness about an opt-in system, it is even more difficult with an opt-out system. Without informed consent, taking a person's organs for donation on basis of presumed consent would be unethical and would violate the basic rights of such individuals.

PROBLEMS WITH THE OPT-OUT SYSTEM

Ethical aspects:

Critics of opt-out systems argue that these systems increase the number of deceased donors since they assume everyone in a nation is eager to donate organs unless they actively choose not to do so. Additionally, it is asserted that opt-out systems look over a number of conventional barriers to deceased organ donation, including perceived religious or sociocultural exclusions, a lack of education or transplant awareness, and difficulties in reaching out to bereaved relatives. Opt-out is said to accomplish this by shifting the national "default" from non-giving to donation, which has effects on a nation's mentality as a whole.²⁰ The opt-out system, where a person is required to formally object to the donation of his organs, is crucial since it still protects the donors' freedom of choice. However, this approach purposefully shifts the balance in favour of the donee's interests rather than the donor's.²¹

As a result, both supporters and detractors of a position cite autonomy and social good as justifications for their positions, but the relative merits of each position can be determined by weighing benefits and drawbacks.²² The model with the fewest negative effects and the most positive effects would arguably be the ethically preferable one if one were to triumph.²³

²⁰ HR Etheredge, 'Assessing Global Organ Donation Policies: Opt-in vs Opt-Out' (*PubMed Central*, 13 May 2021) <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8128443/>> accessed 07 August 2022

²¹ Heather Merle Rens, 'Ethical issues concerning the implementation of an opt out approach for human organ donation in South Africa' (*Wired Space*, 2008) <<https://wiredspace.wits.ac.za/bitstream/handle/10539/6945/PRESUMED%20CONSENT%20IN%20SOUTH%20AFRICA%20THESIS.pdf>> accessed 07 August 2022

²² *Ibid*

²³ Bruce CR & Koch P, 'Flawed Assumptions: Ethical Problems with Proposed Presumed Consent Legislation' (2017) 17 *American Journal of Transplantation* 3262

Intuitively, it would seem that the harm caused by a mistaken refusal to donate under an actual consent or opt-in model may be of higher concern than an error in presumed consent.²⁴

VIOLATIVE OF ARTICLE 21 OF THE CONSTITUTION OF INDIA

Living with dignity entails maintaining a person's dignity both while they are living and after they pass away. In accordance with Article 21 of the Indian Constitution, a person's mortal remains after death also have the right to dignity and fair treatment. In the case of *Mujeeb Bhai v State of U.P. & Ors.*,²⁵ the court held that the expression person under Article 21 of the constitution includes a deceased person in a restricted sense, and the right to life with dignity should be expanded such that his dead corpse is treated with the respect that, according to his tradition, culture, and religion, he would have received had he been alive.²⁶ Society shouldn't be allowed to treat the departed in a dishonourable manner. Harvesting organs from a deceased person without informed consent would violate their fundamental right provided under Article 21²⁷.

CONCLUSION

As we can see, there is a high probability of opting out system violating the basic rights of individuals if implemented in a developing country like India. Independently switching to opt-out does not appear to have any benefits, and doing so could hurt efforts to increase the number of donors. Along with a system change, it's crucial to address organ donation barriers on various levels. Consequently, a collection of complementary actions is needed to support a new system. These procedures are put into place concurrently with the new system or progressively afterward in the nations with the highest contribution rates.²⁸ The amount to which changes in donor numbers may be attributed to the new system, or the other interventions, and the influence size associated with each, are thus all but difficult to ascertain. Opting out doesn't seem to make enough of a difference, especially in developing nations like India, to justify the

²⁴ *Ibid*

²⁵ *Mujeeb Bhai v State of UP & Ors* (2009) 310 SCC Online All

²⁶ *Ibid*

²⁷ Constitution of India, art 21

²⁸ HR Etheredge (n 21)

time and money needed to enable its successful implementation. There are easy things that countries like India can do today to attract more donors while the workings of bloated legal systems play out, possibly over a period of years.²⁹

²⁹ *Ibid*