

NOTES AND COMMENTS

ORGAN DONATION AND TRANSPLANTATION IN INDIA: SEARCHING SCOPE FOR LAWFUL FINANCIAL STRATEGIES

Abstract

Current organ procurement and transplantation law and policy in India have failed to alleviate the organ shortfall. The result is that thousands of individuals are left to wait patiently for death to arrive. The failure of our current laws to meet the ever-increasing organ demand calls for aggressive exploration of alternative means of procurement, including financial incentives to living and deceased organ donors. Concerns and worries about illegal selling and buying of organs are some major problems in organ donations. Our lawmakers must realise that organ trafficking and illegal markets will continue as long as the demand exceeds the supply. Financial incentives may be the only option for increasing organ pools. A complete prohibition of the price mechanism in the free market negatively impacts the ability to harvest organs and transfer them to those in need. The development of a regulated market for payment to live organ donors can drastically reduce the waiting lists for organ transplants in India and many other countries. This paper provides a thoughtful and insightful engagement with the subject of health law and ethics. Further, it addresses the relevant law and policy position on organ transplantation, and explores the scope for lawful financial incentives to cure the shortage of transplantable human organs.

I Introduction

THE ADVANCEMENT of medical science has made transplantation easy today, which was not possible earlier. The number of critical patients awaiting organ transplantation of the kidney/liver is more than the number of people ready for organ donations. The variation between this is due to logistic and medical factors, the capacity to decide the issues of brain death, and religious and cultural factors that affect the decisions of the people to donate their organs to needy persons beyond religious and cultural factors. Accordingly, there is a big gap in organ donation and transplantation rates in India, and so the waiting list for organ transplants is mostly serious and complicated. Every year, hundreds of thousands of people are cremated and buried when their living organs can save the lives of many. In India, the human dead body is considered pious by many religious and cultural families. The selling and buying of human organs is broadly regarded to be morally pernicious and legally not permissible. Animal organs, artificial organs, and tissue engineering have practical medical limitations and raise differing extents of legal and moral concerns.

India has been recognised as an organ-exporting country to those countries, where organs are routinely transplanted to foreigners in need by way of sale and purchase.

The Indian legislation commonly called the Transplantation of Human Organs Act (THOA) was enacted in 1994 to strike a balance between demand and supply of human organs. The THOA completely banned the commercialisation of human organs. In spite of the strong legislation, commercial transactions in kidneys and livers are regularly highlighted in the media, making it a serious social issue. In many situations, the enforcement of the Act has been ineffective and very often the provisions of the THOA have been abused. Although the numerical figure of foreign recipients of organs appears to have dropped after the passing of the legislation banning the organ commercialisation, the clandestine sale and purchase of organs is still in practice in India.

Human organs that can be successfully transplanted in medical practice include the kidneys, heart, lungs, liver, intestine, pancreas, tissues and thymus. All over the world, the kidneys are the highest transplanted organs almost in all countries, followed by the liver and after that the heart. The donors of organs may be living persons, brain-dead persons, or those who are declared heart-dead *via* circulatory death. The law regards death as a significant gateway for organ donation. There is, nonetheless, no statutory definition of death. In the main, the Act recognised brain death in the matter of organ donation as sufficient criteria of death and also made the sale and purchase of organs a punishable offence. By the recognition of brain death as a criterion of death for organ donation, it became feasible to not only perform kidney transplantations but also made it feasible for other solid human organ transplantations like heart, liver, pancreas and lungs.

The scarcity of human organs is practically a global issue, but Asia falls behind many developing and developed nations. Even in Asia, India lags far behind in comparison to other Asian countries. The matter is not that there are not enough human organs for transplants, but rather the matter of legal and ethical concerns. Almost everyone who dies a natural death, or dies in an accident, can be a possible donor; however, numerous patients cannot find a donor.¹ The problem of scarcity is very real and complex. There is a large gap between people who require transplantations and the number of human organs that are legally available for transplantations in India. According to an estimated report, nearly 1.8 lakh people suffer from severe renal failure every year, in whatever way the number of renal transplantations performed is around 6,000 only. Around 2 lakh people die because of liver cancer or liver failure every year in India; undoubtedly, the lives of about 10-15% of them can be saved by a timely liver transplantations.² What is more, about 25-30 thousand liver

1 Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, 2023 (about 1.5 lakh deaths happen annually due to road accidents in India—a large number of these cases could be harvested for organs).

2 *Ibid.*

transplantations are needed annually in India, but only about fifteen hundred liver transplants are being done. Likewise, around 50,000 patients suffer terribly from heartbreaks annually, but only around 100 to 300 heart transplantations are done each year in India. In the case of cornea, around 25,000 transplantations are performed each year, corresponding to a demand of 1 lakh annually.³ The discrepancy between supply and demand for human organs leads to death and distress. Transplantation is the only hope for some of those suffering from organ and tissue failure, and is the preferred treatment option for many others.

II Development of underground organ markets in India

Although the success rate for transplantation operations is improving, the demand for organs and other tissues through black market is increasing. As per the Bulletin of the World Health Organisation in 2007, around 2000 Indians sell their kidneys each year.⁴ Trading in organs was made clear by Debra Budiani, the Executive Director and Founder of Coalition for Organ Failure Solutions (COFS), in 2012. COFS-India identified 1500 victims of organ trading in Chennai and Erode. Considering the active and prevalent illegal kidney markets in Chennai, Calcutta and Bangalore, this number represents the tip of the iceberg.⁵ India is considered one of the biggest illegal markets for organ trafficking, despite having specific legislation prohibiting the commercialisation of transplantable human organs and tissues, and imposing criminal liability for such dealings. Some of the factors promoting organ trade in India include wide gaps between demand and supply of organs, lack of awareness about the legislation and illegality of commercial dealings in organs,⁶ participation of medical professionals and hospitals in maintaining the organ trade market, *etc.*⁷

Recently, organ transplantation irregularities were found in Tamil Nadu. Foreign patients had been given priority in transplantations, overlooking a lengthy list of Indian patients waiting for transplants for a long duration.⁸ This is against the national policy, which clearly says that Indians should be given preference over foreigners.

3 *Ibid.*

4 Yosuke Shimazono, 'The State of the International Organ Trade: Provisional Picture Based on Integration of Available Information', *Bulletin of the World Health Organisation* [WHO] 85(12), (2007).

5 Debra Budiani, *Human Trafficking for an Organ Removal (HTOR): A Call for Prevention, Protection, Investigations and Accountability*, (2012) at 9.

6 Anju Vali, 'Transplantation of Human Organs: The Indian Scenario', 1, *Indian Law Institute Law Review* (Summer, 2017).

7 Kidney racket: Mastermind doctors get 7-yr jail, *The Hindustan Times*, (Mar. 23, 2013); The unravelling of a kidney racket, *The Hindu* (Jul. 27, 2019); Top Indian hospitals, foreign clients, donors from UP caught in 'kidney transplant racket', *The Print* (Jun. 13, 2019).

8 S. Vijay Kumar, Irregularities in Organ Transplants: Tamil Nadu, *The Hindu* (April 3, 2024).

The following guidelines have been recognised as a policy agenda for legal reforms of organ transplants:

- (i) The first and foremost norm is that an available organ should first in priority be provided to an Indian patient needing transplants.
- (ii) In case no Indian patient is available, a Non-Resident Indian (NRI) should then be considered.
- (iii) The offer to an international patient can be considered only when both the Indian and the NRI refuse an organ offer. This refusal must be confirmed by express words, not by implications.
- (iv) Allotment of human organs to receiver is based on tests that comprise the date of registration for transplantation and the illness of the organ recipient.
- (v) The financial condition, religion, class or gender of an organ recipient has no meaning when a recipient is receiving a donated organ.

The gap between demand and supply is the main cause for the development of underground organ markets in India. To bridge this gap, many plan of actions have been suggested and discussed within the medical community.⁹ The proposed actions include income tax relaxations for donor, repay for funeral and other ritual expenses, cash rewards to the donors and/or their families, a philanthropic donation named by the donors or the closest relatives, repayment for costs incurred by the closest relatives supplemental to the donors' death, insured health and/or life insurance scheme and clearance for lost wages for living donors.¹⁰ In any case, a particular financial scheme is ethical or not rests upon the balance of profits and losses that result. All these are presently not known because they all have never been enquired into with an impact factor.

The ever-increasing gap between the haves and have-nots in India, the vast disparity between the requirement and supply of transplantable organs, and the lack of national health insurance schemes make the commercialisation of organs and tissues an easy and lucrative financial proposition for some and the solving of medical problems for others. Poor and vulnerable sections of the society are being coerced or financially persuaded into donating their organs as a near relative of the recipients or someone who has affection or close attachment with regard to the recipient, whereas the real

9 R. Arnold, *et al.*, Financial Incentives for Cadaver Organ Donation: An Ethical Reappraisal, (2002) *Transplantation* 73: 1361-1367.

10 A. J. Matas, Should We Pay Donors to Increase the Supply of Organs for Transplantation? Yes, (2008) *British Medical Journal* 336: 1342.

fact is that the donors and recipients did not know one another until a few days ago.¹¹ Several such examples of removal of organs even without the consent and knowledge of the donor, overlooking pre-transplant and post-transplant requirements, leading to serious health complications, have come to light by various mass media reports and medical bulletins from other countries.¹²

III Legal frameworks governing organ donations in India

The donation and transplantation law in India centres on the Transplantation of Human Organs Act (THOA) of 1994, enacted to combat illegal organ trading, following a surge in kidney scandals in the late 1980s and early 1990s. The Act was later amended in 2011, with some new rules notified in 2014, which changed the law's title to the Transplantation of Human Organs and Tissues Act (THOTA) of 1994, bringing both organs and tissues within the ambit of its regulatory framework. The passing of the Act led to a new legal regime in Indian medical science and medicine. The spirit of this transformative law was mainly threefold:

1. To recognise 'brain death' as also a definition of death in addition to heart death in case of organ donation.¹³
2. To prevent commercial trading in organ donations and transplantations.¹⁴
3. To clarify the near relative (spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter) who could donate organs without any authorisation from the Authorisation Committee (Government).¹⁵

Presently, THOTA is accepted by almost all Indian states to prevent trading in human organs. The Act is designed in such a way as to place the consent and accountability at the heart of the law. It is also noted that the Act is setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human organs and tissues for medicinal and curative purposes and for the prevention of trafficking in human organs in the country. Given the impetus provided by the scandals outlined above, the Act came into being to control organ trafficking in India through strict penal provisions. Section 19 and Section 19A of the Act provide for criminal prosecution and punishment for all commercial and illegal trading in human tissues and organs. The penalty and punishment for commercial

11 Merin Mathew, *Organ Trade in India: A Critical Analysis of the Transplantation of Human Organs and Tissues Act, 1994* (A dissertation submitted to the Advanced Legal Studies, Kochi, for award of LL.M. degree in Public Health Law).

12 K.S. Chugh *et.al.*, 'Problems and Outcomes of Living Unrelated Donor Transplants in Developing Countries', 57 (74) *Kidney International*, 131-135 (2000).

13 Transplantation of Human Organs and Tissues Act, 1994, S. 3 (6).

14 *Id.*, s. 19.

15 *Id.*, s. 2 (h) (i).

trafficking in human organs range from five years to ten years and a fine of twenty lakhs to one crore, whereas the illegal trafficking in human tissues would attract imprisonment of one year to three years and a fine of five lakhs to twenty-five lakhs. A huge portion of the population, especially poor and vulnerable sections, is still unaware of such legislation and the criminal liability imposed upon the offender.

IV Appropriate consent and qualifying relationships in organ donation law

The organ donation law requires “appropriate consent” for the removal, retention and use of organs and tissues from cadavers for transplantation. Sub-section (1) and (2) of Section 3 of the Act is devoted to this issue. Indeed, none of the transplantations can take place without the existence of the appropriate consent. Sub-section 1 and 2 detail how appropriate consent may be obtained from children, adults and the mentally ill. This means that the organ may only be removed for transplantation if the organ donor has volunteered by giving informed consent for the procedure. However, if the person is not competent to give consent, then the state is competent to deal with that issue.

In an endeavour to know different organ donation strategies prevalent in other nations of the world, an experts team headed by R.K. Srivastava, the Director General of Health Services, visited to all the important nations and pointed out that most of the nations have accepted the assumed consent system, in which the person, who is declared brain dead is believed to have given consent to donate the organs. In all other circumstances, close family members of the donor possess the right to give consent for donation. In India, spouses, parents, children, siblings, grandparents and grandchildren are considered ‘near-relatives’ and can donate without requiring approval from an Authorisation Committee, provided their relationship is proved through legal documents or genetic tests. Here, it may be noted that the list of near-relatives is much more exhaustive in the United Kingdom under the Human Tissues Act, 2004. Stepfather, stepmother, half-brother, half-sister and friend of long standing are also included in the list of near relations in addition to other close relatives.¹⁶

As stated above, all donors other than near relatives need permission from the Authorisation Committee. Authorisation in such cases is granted only on the satisfaction of certain strict conditions. The State Authorisation Committees under the Act are given the power to examine all cases in matters of unrelated transplantations carefully. The same rule applies in case of foreign donors wanting to donate to their relatives in India, the transplants are allowed only in near-related donors in the same way as the donors are Indian. The Indian living donors wanting to donate to a foreigner, aside from a near relative, shall not be considered. Regarding foreigners coming to India for transplantation, if the donor and recipient both are foreigners, the

16 See the Human Tissues Act, 2004, s. 27 (4).

transplantation is allowed in India, subject to leave from a senior official of the embassy of the country of origin who verifies the related relationship between the donor and the recipient. If a foreign country does not have any diplomatic relationship through an embassy in India, the certificate of relationship can be issued by the government of that country.

The legislation adopts a wide opt-in system under which the deceased's objection prevents others from opting in on his or her behalf. In practice, the legislation has never been applied as strictly as it can be. Loved ones and family members are always consulted even if the donor has made a valid request for organ donation. Relatives are therefore granted the *de facto* power to veto the deceased opt-in. The main challenge for law is to balance the need to encourage donation of organs with the need to respect the autonomy of the potential donor. Indeed, what we see is the requirement that the transplantation is free from payment and exploitation. Payment in organ transplantation is a situation where the organ transplantation law introduces layer upon layer of regulation in an attempt to ensure as much as possible that, if the patient might have wished to consent, that consent must be free from a commercial element.

In India, like many other countries, brain stem death has been recognised as a legal death under the Transplantation of Human Organs and Tissues Act, 1994. This has revolutionised the concept of organ donation after brain death. Here, it may be noted that after natural cardiac death, only a limited number of organs/tissues can be donated (like bone, cornea, blood vessels and skin), whereas after brain stem death, about 37 different organs and tissues can be donated including, more vital organs such as heart, kidneys, lungs and liver.

Despite a favourable law, cadaveric donors continue to be very minimal in traditional societies. In India, there is a requirement to facilitate cadaveric donations because donations from living persons cannot satisfy the requirements of the organ recipients in the country. Also, there is medical evidence that the living donors need much more medical care and proper follow-up after donation. Apart from this, there is also an element of trading associated with living organ donations, which may be considered a violation of the law and human rights. In a situation of heavy organ scarcity in the country, the rich can make good use of the poor and exploit them by being involved in organ trading, which is taking place in every region of the country.

V Making people aware of brain death to consent

The classical concept of cardio-respiratory death, that is heart stops beating, and the blood circulation ceases, is not particularly significant in any way while dealing with organ transplantation. Most countries have recognised the concept of brain death (or brain stem death), which permits doctors to declare death for donation of organs while the body is still circulated with blood. Several studies and investigations of the

family members of potential donors of organs in India have constantly revealed that they have an inadequate understanding and knowledge about brain death. This is usual among both educated and non-educated donor and non-donor families. Many people are accustomed only to heart death, which is common among physicians and common people. The common position is that those potential donors with a good knowledge of brain death as a real death are more potential persons to consent to organ donations.¹⁷

It appears that those family members and relatives who correctly realise that their beloved one is really brain dead can more clearly give consent for organ donation. Sque and colleagues remarked that “for some, being unable to ‘witness the observable ending of life’ was a barrier to consent.”¹⁸ Some researches show a higher rate of consent in the donation after circulatory death (DCD), this is not established by the possible donor audits. Ideas and recommendations to make better a family’s perception of brain death include permitting them to observe medical tests or showing them diagrams or images to explain brain death and cardio-respiratory death concepts.¹⁹

The debate around brain death as a sufficient criterion of death for transplantation purposes is moot. The Transplantation of Human Organs and Tissues Act, 1994 legalised brain death as a sufficient criterion of death in India, allowing people for organ donations. The Act specifies that a “Board of Medical Experts must certify brain stem death before organs can be removed for transplantation purposes.

VI International guiding principles on human organ transplantation

The recent past few years have recorded growing interest from international organisations, led by the World Health Organisation (WHO), and professional associations, directed by The Transplantation Society, in the matter of organ transplantation. Their core efforts have focused on the advancement of an array of legal and ethical frameworks, planned to promote legal guidelines to eliminate impermissible practices, while initiating policies and schemes that endeavour to attain self-sufficiency at national, regional and international levels in meeting the requirement for organ transplantations. These schemes should pursue to decrease both the demand for transplants and also promote cadaveric donations to their highest possibilities.

The commercial trade in organs came on the agenda of the World Health Organisation (WHO) in the late 1980s, contributing to the setting up of the Guiding Principles on

17 L. A. Siminoff, *et. al.*, Factors Influencing Families’ Consent for Donation of Solid Organs for Transplantation, *Journal of the American Medical Association*, (2001) 286: 71–77.

18 M. Sque, *et. al.*, Why Relatives Do Not Donate Organs for Transplants: ‘Sacrifice’ or ‘Gift of Life’? *Journal of Advanced Nursing*, (2008) 61: 134–44.

19 I.Y. Pearson, *et. al.*, Survey of Families of Brain Dead Patients: Their Experiences, Attitudes to Organ Donation and Transplantation, *Anaesthesia and Intensive Care*, (1995) 23: 88–95.

Human Organ Transplantation in 1991.²⁰ As per the International Guiding Principles, the human bodies and their parts cannot be commercialised in any way.²¹ Therefore, giving or taking any payment (including any other financial benefits, reward or compensation) for human organs and tissues should be strictly prohibited.²² This Guiding Principle is planned to forbid trading in human tissues and organs for any kind of payment or financial incentives. The method of banning, including criminal sanctions, will be decided by each jurisdiction independently. However, the guiding principle does not forbid payment of reasonable expenses incurred in donation, medical recovery, preservation and delivery of organs for transplants. The guiding principles also prohibit advertisements in any form that have a commercial (profit-making) element. Encouragement and promotion of selfless (altruistic) donation of transplantable human organs and tissues by way of public appeal or advertisement are not affected in any way by this principle.²³ It is forbidden for physicians and other health professionals to engage in dealing with organ transplantation procedures if they have a reasonable ground to believe that the organs concerned in transplantations have been the subject of commercial transactions.²⁴ It is also forbidden for any person or facility provider to be involved in organ transplantation procedures to receive any payment that exceeds a legitimate fee for the services provided in transplants.

Recognising the fact that illegal organ trafficking is increasing rapidly throughout the world, the World Health Assembly resolution of 2004 encourages Member States to “take measures to protect the poorest and vulnerable groups from ‘transplant tourism’ and the sale of tissues and organs.”²⁵ Despite increasing consciousness of the problem, the fact of the international organ trading is not well identified due to a paucity of accurate data and also an absence of efforts to share the possible accessible information.

The Istanbul Summit submits a report that emphasised the necessity to maximise the utilisation of cadaveric donor organs, the requirement for countries with established cadaveric donor programs (or even living donor organs, for that purpose) to integrate their knowledge and experiences with countries without such programs, the requirement to safeguard the interests of poor and vulnerable populations from abusive and exploitative acts, the need-based allocation of donor organs based on ideal moral

20 Guiding Principles on Human Organ Transplantation, Forty-fourth World Health Assembly Geneva (1991).

21 *Ibid.*

22 *Id.*, Guiding Principle 5.

23 *Id.*, Guiding Principle 6.

24 *Id.*, Guiding Principle 7.

25 WHO, Resolution on Human Organ and Tissue Transplantation (WHO Resolution 57.18, 2004).

prescriptions and the prohibition of organ trafficking and brokerage.²⁶ The WHO guidelines and the Declaration of Istanbul demonstrated that organ trading is not only a local and regional matter, but an issue of concern for the whole international community.²⁷ These reports further stipulated the presence of a worldwide concurrence against this immoral practice.

The American Society of Transplantation and the American Society of Transplant Surgeons proposed a set of guidelines²⁸ which may be accepted by the world communities as a model for national legal framework. The guidelines recommended that:

- (i) Every country applying a policy of financial incentives for organ donations and transplants should have an effective legal and regulatory structure for the process.
- (ii) The whole process of procurement and transplants must be clear and open and subject to governmental and international overview.
- (iii) The financial incentives should be made available by the State or State-recognised body. Under simple, explicit, open and strictly controlled situations, prospective recipients of an organ may help fund a charity that supports the transplant program. There should be no direct payment in money or kind from the recipients to the donors, and funding the charity should not result in progress on the waiting list.
- (iv) Allocation of the transplantable organ(s) should be done in accordance with the single recognised window system of the concerned country, similar to that of the United Network for Organ Sharing (UNOS) in the United States, applying a pre-defined and open algorithm so that everyone on the waiting list has a good and equal chance to be transplanted. Kidneys should be allotted to the number one person on the list (as fixed by well-defined and open criteria).
- (v) There should be a clear policy and programmes for management and for strict supervision to ensure that parameters for acceptance, allocation, evaluation and provisions of the financial incentive to the donor (or donor's family) are being rigorously observed.
- (vi) All donations should be nameless and pointless. No other solid organ donation incentive programme would be legal.

26 The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, *Transplantation* (2008) 86: 1013-1018.

27 Steering Committee of the Istanbul Summit, Organ Trafficking and Transplant Tourism and Commercialism: The Declaration of Istanbul, (2008) *Lancet* 372: 5-6.

28 American Society of Transplantation and the American Society of Transplant Surgeons, Incentives for Organ Donation: Proposed Standards for an Internationally Acceptable System (2011).

- (vii) There should be a national law to control wrongful acts and how hospitals and health centres administering organ transplants would be condemned, including criminal actions, fines and punishment, if a wrongful act is identified.

Within these guiding principles and procedures, what reforms can we envisage? Taking the issue of organ scarcity, it will become evident that the alternative means of organ procurement are at the core of the debate. Crucial to any reforms at the national level is the adoption and integration of the international guiding principles. The World Health Organisation (WHO), the Declaration of Istanbul and many other professional organisations expressly make statements and encourage attempts to eliminate distinctness to living donation²⁹ and international study in this area has displayed public support for interventions that would response the costs possibly connected with living organ donations³⁰ to increase supply of organs for transplantations and diminish exploitation and inequities in access to living organ donations.

VII Payment and financial incentives for organ donation

The arguments for legal systems that financially compensate living donors or their family/guardians in case of deceased and incompetent persons are well documented and debated in the scarcity market; however, Iran is the only country with a legal and centralised system for financial payment to living donors. The discourse mainly engages with the matter of financial payment (or equal to that incentives such as lifelong health support and medical insurance) to a living unrelated potential organ donors, yet great deal of work has also gone into investigating the effect of a financial incentive on the family members/relatives of deceased possible donors. The Ethics Committee of the American Society of Transplant Surgeons came to the conclusion that direct payment in cash or kind to families violated the moral standard of nobility upon which donation is based; however, payment of some expenses, like funeral expenses or to a selected charity, has been recognised as acceptable and compatible with the concept of donation as a gift.³¹ In a study of 155 closest relatives (102 donors, 53 non-donors), 12% of non-donor family members/relatives expressed the view that certainly they would have consented if any financial incentive had been offered to them, although excitingly 6% of donor families expressed that they would have refused financial donation if offered to them, suggesting that financial incentive may offend some, if not all.³²

29 World Health Organisation, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010).

30 K. Hoeyer, *et. al.*, Public Attitudes to Financial Incentive Models for Organs: A Literature Review Suggests that it is Time to Shift the Focus from 'Financial Incentives' to 'Reciprocity,' (2013) *Transplant International* 26(4): 350-7.

31 R. Arnold, Financial Incentives for Cadaver Organ Donation, *supra* note 9.

32 J. R. Rodrigue, *et. al.*, Attitudes Toward Financial Incentives, Donor Authorisation and Presumed Consent Among Next of Kin Who Consented vs. Refused Organ Donation, *Transplantation*, (2006) 81: 1249–56.

The Nuffield Council on Bioethics has focused on financial incentives in certain situations to living donor and their families from altruistically focused recompense, which includes compensation for discomfort, inconvenience, and time and job loss, and reimbursement of direct expenses, such as medical expenses.³³ Israel has recently adopted legislation³⁴ that offers a non-financial incentive to consent, namely preferential access to transplantation for individuals who join the Organ Donor Registry (ODR), the first-degree relatives of individuals who are on the ODR, living donors, and the family members of deceased donors.

Several issues may be taken into consideration while addressing the policies for organ donation and transplantation:

- (i) Today, the whole world is confronting a serious problem of a shortage of transplantable human organs. In spite of many local, national, regional and international drives and media campaigns, the cadaveric and living donations have not been increased. Financial incentives may be the only alternative option for growing organ pools. Likely, at least some of the individuals who are reluctant to consent to the donation of human tissues/organs could be persuaded by the offer of an incentive. It is the right time to address the scarcity of organs by exploiting the power of the organ markets to guide new donors by creating win-win situations for both donors and recipients.³⁵
- (ii) Allowing payment³⁶ and financial inducements to organ donors or their family members (in case of cadaveric donors) will certainly increase the number of transplantations conducted, thereby lessening the number of patients who die because of scarcity and waiting list of patients, and this would also reduce the overall cost to society.³⁷ Even if we assess the policy change based on costs, it will be relatively less costly than life-sustaining methods used for sustaining the life of patients, such as dialysis, used on patients while they wait, even for a long time, for an organ to become available for transplantations.³⁸ The

33 Human Bodies in Medicine and Research, Available from <http://nuffieldbioethics.org/human-bodies> (accessed June 12, 2024).

34 J. Lavee, *et. al.*, A New Law for Allocation of Donor Organs in Israel, *Lancet*, (2009) 375: 1131–3.

35 Jennifer Monti, *The Case for Compensating Live Organ Donors* (Competitive Enterprise Institute, 2009), p. 3.

36 “Payment” as defined in section 2 (k) of the Transplantation of Human Organs and Tissues Act, 1994, means “payment in money or money’s worth but does not include any payment for defraying or reimbursing—(i) the cost of removing, transporting or preserving the human organ to be supplied; or (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body.”

37 David L. Kaserman, Fifty Years of Organ Transplants: The Successes and the Failures, (2007) *23 Issues in Law and Medicine* 45, 54.

38 *Id.* at 54-55.

shortcoming of our present legal system to meet the ever-growing organ demand calls for very aggressive consideration of alternative options of procurement of organs, including payment and financial incentives.³⁹

- (iii) It is clear from the fact that worldwide, the pressure for transplantable organs is increasing, as the delivery of human organs/tissues for transplants has not kept pace with demand. In the U.K., only 1510 cadaveric and 938 living individuals donated their organs in 2023-2024, while more than 8056 persons were found to be in the waiting list for suitable organs for transplantable purposes.⁴⁰ The same situation exists even in the United States. As of September 2024, some 48,000 Americans receive a life-saving heart, liver, lung, or kidney transplant from a deceased organ donor, while demand for transplants exceeds supply, with approximately 103, 223 people on the waiting list.⁴¹
- (iv) The World Health Organisation (WHO) states that organs, tissues and cells should only be donated freely, and all the donations have to be done without any financial reasons, payment or rewards of monetary value, *etc.* Commercialisation of human tissues, organs and cells for transplantation is to be banned as per Guiding Principle 5. The commercialisation of organs will result in the rich taking unjust and unfair benefits of the poor and weaker sections of the society, eroding selfless donation, and leads to human trafficking and profiteering.⁴²

Critics of payment for live organ donation go so far as to compare such transactions to prostitution. Francis Delmonico states that:

The fundamental truths of our society, of life and liberty, are values that should not have a monetary price. These values are degraded when a poor person feels compelled to risk death for the sole purpose of obtaining monetary payment for a body part. Physicians, whose primary responsibility is to provide care, should not support this practice. Furthermore, our society places limit on individual autonomy when it comes to protection from harm. We do not endorse as public policy the sale of the human body through prostitution of any sort, despite the purported benefits of such a sale for both the buyer and the seller.⁴³

39 Julia D. Mahoney, Altruism, Markets, and Organ Procurement, (2009) 72 *Law and Contemporary Problems* 17, 18.

40 Organ and Tissue Donation and Transplantation Activity Report 2023-2024.

41 Organ Procurement Transplantation Network, U.S. Department of Health and Human Services (2024).

42 WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, World Health Organisation (WHO) 5 (2010).

43 F.L. Delmonico, "Ethical Incentives—Not Payment—For Organ Donation" (2002) *The New England Journal of Medicine* 346:25.

VIII Ownership and property rights in human organs and tissues

Whether organs and tissues are property is a matter of controversy precisely because there is profound disagreement about what legitimate claims, powers and interests individuals have over the organs and tissues that they were born with. Much of this controversy stems from concern that self-ownership of one's body and body parts (organs and tissues) will have implications for whether consent is required for uses of body parts once they have been removed (or whether the source is entitled for compensation), whether body parts can be sold or traded like any other property, and whether subsequent possessors of body parts can obtain property rights in them.⁴⁴

In the 17th Century John Locke declared that "every man has a property in his own person." Yet, the idea that we have a proprietary relationship with our body or parts of our body remains controversial in both ethics and law. Immanuel Kant, the influential 18th century German philosopher, is representative of a moral perspective that firmly places the human body in a category of its own, removing it from the realm of the mere movable object that can be treated as any other movable object. He raises a number of objections to this, one be a conceptual one:

Man cannot dispose over himself because he is not a thing; he is not his own property; to say that he is would be self-contradictory; for insofar as he is a person he is a Subject in whom the ownership of things can be vested, and if he were his own property he would be a thing over which he could have ownership. But a person cannot be a property and so cannot be a thing which can be owned, for it is impossible to be a person and a thing, the proprietor and the property.⁴⁵

Kant makes no distinction between the individual and her body. Disposing of one's body and its parts (for example, by giving a kidney to a relative) would therefore be a paradoxical transaction, as the 'gift' and the 'giver' are identical. The reasons in the property debate vary from fundamentally religious notions to pragmatic ones. Thomas Hobbes, for example, needs the notion of the sanctity of the individual's life to justify his almost dystopic premise of individuals being locked in a no-holds-barred fight for survival and the consequent absence of super-positive ethical norms.⁴⁶ John Locke, while strongly advocating the presence of super-positive ethical norms, put the same view of the body on a solid religious footing, almost going so far as saying that to destroy or interfere with one's own body amounts to an interference with God's property rights.⁴⁷

44 Shaun D. Pattinson, *Medical Law and Ethics* 517 (London: Sweet & Maxwell, 2013).

45 Immanuel Kant, *Lectures on Ethics*, Translated by Peter Heath (Cambridge: Cambridge University Press, 2001) p. 157.

46 See generally, Thomas Hobbes, *Leviathan* (London: Penguin, 1982).

47 John Locke, *Second Treatise on Government* (Indianapolis, IN: Hackett Publishing, 1980).

As Beyleveld and Brownsword point out, the broader the definition of property used, the easier it will be to justify the claim that something is property.⁴⁸ They present a narrow conception of property that they suggest captures the essence of what capitalist societies traditionally view as private property.⁴⁹ According to this conception, property grants “rule preclusionary” control to individuals, consisting of prima facie rights to use and exclude others from access or use of what one owns, which preclude the owner from having to provide a specific justification for everything he does with what he owns.⁵⁰

It should be clear that ownership of body parts under the rule-preclusionary conception has implications with regard to the owner’s consent and the power to sell or transfer. Rule-preclusionary control implies a presumption requiring the owner’s consent for use by others and places the justificatory burden on those who wish to restrict the owner from selling or transferring his property.⁵¹ Beyleveld and Brownsword argue that property (rule-preclusionary) rights in body parts are implied by Article 22 of the Biomedicine Convention.⁵² This provision holds that:

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

In a 1993 report, United Network for Organ Sharing (UNOS) argued that purely economic approaches to organ donation may start “the ultimate slide down the slippery slope.”⁵³ However, as evidenced by the legality of “men to sell their sperm, for women to ‘rent’ their wombs as surrogate mothers or sell their limited number of reproductive eggs, and for people to sell their blood and hair,” the human body is already a commodity that allows for the donor to reap payment.⁵⁴ It is baffling as to why our government and the zealous opponents to financial incentives view payments for organ donations differently than payments for other parts of the body.⁵⁵

48 Deryck Beyleveld and Roger Brownsword, *Human Dignity in Bioethics and Bio-law* (Oxford: Oxford University Press, 2001) at 174.

49 Deryck Beyleveld and Roger Brownsword, “My Body, My Body Parts, My Property?” (2000) 8(2) *Health Care Analysis* 94-96.

50 *Ibid.*

51 Shaun D. Pattinson, *Medical Law and Ethics*, *supra* note 44 at 517.

52 Deryck Beyleveld and Roger Brownsword, “My Body, My Body Parts,” *supra* note 49 at 89-93.

53 Organ Procurement & Transplantation Network, Financial Incentives for Organ Donation: A Report of the Payment Subcommittee OPTN/UNOS Ethics Committee, U.S. Department of Health & Human Services (Jun. 30, 1993).

54 Robert Berman, “Selling Organs Should Be Legal”, (2005) *Jerusalem Post* (Aug. 10) at 15.

55 *Ibid* (arguing that donations of a kidney and part of a liver are not high risk for the donor and should be treated the same as other body parts that are currently being traded in the marketplace).

IX Lessons from foreign models of organ procurement

Nowadays, most developed and developing countries directly or indirectly prohibit any type of monetary compensation or financial incentives for organ donation. In most countries, donation is limited to “altruistic” donors, and by the legal system, organ donors are not allowed to receive monetary payment or anything of material value in exchange for donating an organ. In some countries, including India, only biological relatives are permitted to be living donors. However, Iran is the only country in the world to have adopted a direct lawful payment system for organs from live donors. Iran used a mixed system of government control and the free market. There, sellers sell their transplantable organs first to the government, which plays the role of intermediary in organ dealings. The government, in turn, pays sellers and gives them free health insurance for at least one year. However, the donor and recipients both must be Iranian, and they are under a legal duty to work to pay for the cost of their organs. The system has, in effect, eradicated the waiting lists for donors. But there are opponents, some of whom even oppose Iran’s mixed model. One opposing group says that any market-based system will necessarily be exploitative of the vulnerable and poor, since they are the ones who will be most enticed to take the chance of risks in order to get the monetary benefits.

In 1984, the United States Congress enacted the National Organ Transplant Act (NOTA), which forbade commercial trading in human organs and tissues. Although the legal controls against making financial consideration for organ donations have been in place since NOTA’s enactment in 1984, public consensus is in favour that financial incentives will benefit the greater good of society in terms of procurement of organs.⁵⁶ As supported by a United Network for Organ Sharing (UNOS) survey, 52% of U.S. citizens were in favour of allowing compensation to those individuals who donate their organs.⁵⁷ As one points out, “[i]f public opinion is in favour of some form of financial incentives, then it seems odd that we are so timid in examining this idea realistically.”⁵⁸ Giving financial incentives in addition to our present unselfish (altruistic) system certainly will assure individuals who might otherwise not be willing in any way to donate their organs without any financial consideration.⁵⁹

In 2004, the Organ Donation and Recovery Improvement Act authorised the federal government in the United States to compensate live-organ donors for expenses incurred in the donation of an organ. Here, it may be noted, these programs do not pay

56 42 U.S.C.A. § 274e.

57 M. Christy, *et. al.*, Deadly Dilemma: The Failure of Nations’ Organ Procurement Systems and Potential Reform Alternatives, (2005) 5 *Chicago-Kent Journal of International and Comparative Law* 1, 24.

58 Peter A. Clark, Financial Incentives for Cadaveric Organ Donation: An Ethical Analysis, (2006) *Internet Journal of Law, Healthcare and Ethics* Vol. 4 (No. 1) (estimating that 22,000 die each year of cardiac arrest that could be potential donors).

59 Gregory S. Crespi, Overcoming the Legal Obstacles to the Creation of a Futures Market in Bodily Organs, (1994) *Ohio State Law Journal* 8 (27) at 21.

donors directly for donating an organ, but, rather, “keep them from losing money” (which is akin to companies offering benefits instead of pay raises). In 2007, Wisconsin passed a law that provides live-organ donors a tax benefit of up to 10,000 dollars for travel, medical costs, and wage loss.⁶⁰ Whilst indirect financial benefits for organ donation are an optimistic step, a better plan to enhance the number of tissue/organ donors would be for the U.S. federal government to abolish Section 301 of the National Organ Transplant Act (NOTA). Section 301, titled “Prohibition of Organ Purchases,” inflicts criminal penalties of up to 50,000 U.S. dollars and five years’ imprisonment on any person who “knowingly acquire(s), receive(s), or otherwise transfer(s) any human organ for beneficial consideration.”

The American Society of Transplantation has organised a national campaign to encourage hospitals and health centres with transplantation services to make available paid medical leave for those employees who become organ donors. New federal legislation, while stressing that monetary benefits should not be the result of or reason for organ donation, however, non-financial incentive can be used to make paid medical leave available to a larger number of would-be organ donors, in the same way as the Health Insurance Portability and Accountability Act, 1996 required medical insurance provision and for the majority of employees workers in the United States.⁶¹

In many countries, including India, the United States, Australia and Germany, cadaveric organ acquisition is carried out under the “informed consent” principle. Under this consent law, cadaveric organ procurement mandates the express consent of the donor before death, which can normally be reflected on a donor’s registration card. Contrary to this, in most European countries, cadaveric organ donation is based on the principle of “presumed consent.” Under this presumed consent law, the deceased individuals are treated as potential donors of organs in the absence of express opposition to organ donation before death. In real practice, irrespective of the nature and type of legislation and of whether a deceased individual has been registered as a donor (or as a non-donor), in most European countries, families and near relatives are allowed to make a decision about organ donation. It is contended, however, that legislative loopholes affect the decisions of potential donors and families. The presumed consent policy is neither illegal nor unethical in any way, and this may be accepted as an alternative approach to solve the issue of scarcity of organs.

Singapore was considered to be the first Commonwealth country to legislate in 1987 a presumed consent policy for organ donations.⁶² Singapore also introduced paired

60 G. Mayes, Organ Donation and Recovery Improvement Act of 2004 Emphasises Increasing Donation Rather than Systemic Change, (2004) *Medscape Transplantation* 5(1).

61 Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. Standards for Privacy of Individually Identifiable Health Information: Final Rule, Federal Register 2000: 65(250): 82475, 82803-5, 82810, 82812-3.

62 K.S. Prabhakar, Cadaveric and Living Organ Donation: Natural Limitations, Possible Solutions—Singapore Experience, (2004) *Annals of Transplantation* 9 (1):31-3.

exchange and reimbursement policy in 2009 by making an amendment in the Human Organ Transplant Act of 1987. Compensating donors for fair and reasonable costs is allowed under the law. The costs that may be compensated include expenses suffered for child care, medical procedures, loss of wage earnings, long-or short-term health care as a result of the organ donation process.⁶³

The “Spanish model” of organ acquisition may be studied extensively for law and policy reform in the area of organ procurement. The Spanish model is based on: (i) an organisation of self-supportive transplant and effective coordination teams, which take initiative in requesting for consent from families of potential donors so the obligation of organ acquisition is taken away directly from treating physicians and transplant surgeons; (ii) a hospital or health care centre compensatory policy, which reimburses hospitals and health care centres for organ acquisition expenses; and (iii) a multi-faceted web at the hospital, national, and regional, level, which manages and correlates organ supply activities.⁶⁴ Sale and purchase of human organs are permitted in the Philippines as long as the donor and recipients are both natives of the Philippines.

The American Society of Transplant Surgeons has encouraged a proposed program in Pennsylvania that gives partial repayment for funeral expenses for a deceased donor.⁶⁵ Gary S. Becker states that “if the laws in the United States are unable to provide the organs needed and our own citizens are being forced to take extreme measures to stay alive, it is the right time to reconsider our existing policies and think about an open market.”⁶⁶ The policy framers must understand that organ trading and unethical and unlawful payments will continue because the demand for organs exceeds the supply.⁶⁷ To encounter this demand, the United States must, with adequate governmental regulations, permit organ donors to be financially reimbursed so that organ recipients can get transplants and receive proper post-operative health care and medication.⁶⁸

Trafficking in human body parts, tissues and cells is ethically and legally unacceptable in Australia. Although paired donation was first practised in Western Australia in late 2005, through legislative reforms permitting donors from non-related families to exchange organs, tissues and cells. However, by the time a limited number of paired donations have taken place in Western Australia, despite legislative changes. Paired

63 Human Organ Transplant (Amendment) Act, 1987, Section 14 (3)(c) (as amended in 2009).

64 Rafael Matesanz, A Decade of Continuous Improvement in Cadaveric Organ Donation: The Spanish Model, (2001) *Nephrology* 21, 59-67.

65 R. Arnold, “Financial Incentives for Cadaver Organ Donation, *supra* note 9.

66 Gary S. Becker, *Should the Purchase and Sale of Organs for Transplant Surgery Be Permitted?* Becker-Posner Blog (Jan. 1, 2006) (arguing that an open market would diminish black markets).

67 Sally Satel, The Case for Paying Organ Donors, (2009) *Wall Street Journal* (Oct. 18).

68 Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commoditisation*, (2004) 56 *Rutgers Law Review* 305, 404.

donations remain illegal in other States and Territories in Australia. Payments to reimburse living donors for certain expenses are illegal in Australia. Such payments may act as an allurements and may, in effect, constitute trafficking in human body parts and tissues, which is illegal and unethical in Australia.

In some countries, the policies of paired donation have been legalised and promoted to facilitate transplants between recipients who are incompatible with their intended living donors. With the paired donation model, potential donor-recipient parties who are unsuited with each other can be matched with other suitable donor-recipient pairs to exchange organs. Paired donation is currently practised in the United States and Netherlands, but it remains unusual presently.

What can be experienced from a study of these practices and its potential role in the modern Indian medical perspective? The careful choice to rely on altruistic donation has been unsuccessful and fails to reflect the advances that have been possible in the donation and transplant techniques. Medical technology and success rates have improved without compromising the ethical values; why has Indian legal policy remained largely unchanged and lagging behind the latest technology? The trend, however, is beginning to change. Some countries are testing with indirect financial incentive systems to enhance the number of live donors. Compensatory model seems to be ethically sound and an internationally acceptable one that can be followed with a proper regulatory system.

X Conclusion

Organ trade in India, like other social problems, is a societal issue. It relates to the exploitation of the poverty-stricken people by alluring them with financial gains that, at times, can be large and can meet their immediate short-term financial needs. Unlike other similar exploitative social situations, organ donation requires an invasive surgical procedure that has both physical and psychological implications. For many, making organs a commodity is fraught with dangers and erodes social, moral and ethical values and is not an alternative that can be acceptable to overcome the problem of organ shortage in a civilized society.

The scarcity of human organs is causing preventable death and suffering. Every year, many suffer or die on the waiting list. The development of a state-regulated market for payment and financial consideration to live organ donors will certainly minimise the number of patients waiting for organ transplantations in India. The problem of scarcity is very real. Despite regulatory changes, the shortage of human organs continues to cause otherwise preventable death. Recently, many countries in the world, suffering from severe scarcity in organ donations, have implemented a policy of financial considerations that uses cash payments. Although cash payments cannot be provided to the organ providers directly, other benefits such as health

insurance, burial costs, tax credits, life insurance, and many other concessions are all possible ways and means in the form of financial benefits.

Legalising financial incentives for donation will eliminate intermediaries and black markets, create a peaceful and safer organ supply, and help ease the scarcity of viable organs. Amending laws is not an easy task in India, but we can move forward in efficient ways to proceed further for policy reform in organ procurement and transplantation. We recognise that the option of monetary considerations should be just one of a range of policy strategies to elevate the supply of transplantable organs. India needs to have laws and policies that can accommodate innovative and ethically acceptable approaches to rising the supply of transplantable organs. The blanket prohibition on any form of payment seems extreme, unjust and unfair. Consequently, there is a good case for reforming organ donation law to permit financial incentives with suitably regulated markets. The law should not reject any idea just because it is revolutionary or contentious. Medical science is ready and waiting to save people's lives, but legal policy remains a roadblock in the name of ethics and morality.

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