Ethics in Organ Transplantation - Some Facts and Thoughts

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INTRODUCTION

Successful transplantations give patients with otherwise untreatable degenerative diseases a new lease on life, or enable them to lead a more fulfilling or productive existence.¹

HISTORY

Timely Kidney transplantation is the only hope for quality long term survival of a end stage renal failure patient. The first successful kidney transplant was performed in 1954 by Dr Joseph Murray at Peter Bent Brigham Hospital in Boston. In July 1959, Peter Raper (Leeds) performed the first deceased donor renal transplant in UK. In 1960 the successful living renal transplant in the UK was performed by Dr Michael Woodruff between identical twins.

The first successful live donor renal transplant in India was done at CMC Vellore in January 1971. The first ever human kidney transplant performed in India was done at KEM Hospital Mumbai in May 1965 using a cadaver donor in a non-renal failure patient who had hypernephroma. The first kidney transplant performed in Kerala was at Medical College Calicut in 1986 by Prof Roy Chally (Urology), Prof Thomas Mathew (Nephrology) and team.

The first liver transplantation was done by Dr Thomas E Starzl in 1963 and the first successful liver transplantation was done in 1967, both at the University of Colorado, US. The first deceased donor liver transplant was done in India in 1995 and was unsuccessful. The first successful liver transplant recipient was 18 month old child at Indraprastha Apollo Hospitals in New Delhi in November 1998.

The first successful cardiac transplantation was done by Dr Christian Barnard in Cape Town South

Africa in 1967. Dr P Venugopal performed the first cardiac transplant surgery in India on 3rd August 1994 at AIIMS New Delhi. The first Cardiac transplantation was performed in Kerala by Padmasree Dr Jose Chacko Periapuram in 2003 at Kochi.

BACKGROUND

Kidney transplants in India first started in the 1970s and since that time, India has been a leading country in this field on the Asian sub-continent. The evolutionary history of transplants in the last four decades has witnessed a different facet of transplant emerging in each decade. The first 10 years were spent mastering the surgical techniques and immune-suppression. Its success resulted in a phenomenal rise in the numbers of transplants in the next 10 years and unrelated kidney donation from economically weaker sections started taking place with commerce in organ donation becoming an acceptable integral part of the program. After this was accepted, the ethics of transplants in India has always been on a slippery slope and all kinds of nefarious activities were accepted as normal practice. The general dictum was "when you can buy one why donate?"2 The next 10 years saw an outcry from the physicians of the western world at the growing numbers of these exploitative transplants being done in India. There were also protests from many sections in India. The pressure on the Government saw the passing of the Transplantation of Human Organ Act (THO) legislation that made unrelated transplants illegal and deceased donation a legal option with the acceptance of brain death.3 Overcoming organ shortage by tapping into the pool of brain-dead patients was expected to curb the unrelated transplant activity. The last decade has seen the struggle of the deceased donation program evolve in India. Simultaneously, it has witnessed the living donation program being marred with

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constant kidney scandals. In most instances, the donor accused the recipient or the middle man of having not compensated them with the promised sum. It also saw liver, heart, and pancreas transplants from deceased donors. Although the history of cadaver transplants in India is recent, the first attempts to use a cadaver donor's kidney were undertaken in 1965 in Mumbai. The author describes the medical and social problems they faced. The medical problems included technical difficulties in engrafting, immunological problems, and infection. However, it was the hostile reaction from some members of the medical profession and the general public that was a more daunting task to tackle. The whole process was described by some as neo-cannibalism. This was a setback for the cadaver program for not only Mumbai but also rest of the country.4

In India, despite the THO act, neither has the commerce stopped nor have the number of deceased donors increased to take care of organ shortage. 5 The concept of brain death has never been promoted or widely publicized. Most unrelated transplants currently are being done under the cloak of legal authority from an authorization committee. The few deceased donations that are taking place are due to the efforts of a few Non-Government Organizations (NGO) or hospitals that are highly committed to the cause. Recently, the government has come under much criticism by the public and media and has added a few legislations in the form of a Gazette to curb the illegal unrelated donation activities and has tried to plug the loopholes in the THO act.6 To a large extent, the failure of the THO act has been because of the way it has been interpreted and implemented by authorities and hospitals. In Kerala the deceased donor transplantation programme started off well but ran into difficulties and the Government issued fresh guidelines.⁷

Ethics of Organ Transplantation

- 1. Refers to the ethical concerns on organ transplantation procedures.
- Ethical principles are general descriptive terms identifying characteristics of human actions or practices that tend to make them morally right OPTN/UNOS document June 2016

The Principles of Ethics are generally considered under the following headings:8

- 1. Autonomy-thefreedomtotakedecisionsforoneself
- 2. Beneficence means doing good to others

- 3. Non-malificence means no harm be caused to an individual either unintentionally or deliberately
- 4. Justice requires every individuals to be treated equally
- 5. Fidelity fulfil all commitments
- 6. Confidentiality
- 7. Veracity truthfulness
- 8. Accountability individuals need to be responsible for their own actions

Ethical Issues in Organ Transplantation was considered under the following sub headings:

- 1. Consent
- 2. Organ procurement
- 3. Marketing
- 4. Organ allocation
- 5. Financial incentives
- 6. Religious beliefs

Issues involving Consent:

- 1. Presumed consent works by assuming that, unless people express a wish otherwise, they are willing to donate their organs. Presumed consent systems are in place in a number of countries, including Spain, Belgium, France, Austria and, as of late 2015, Wales. Presumed consent is sometimes described as an 'opt-out' system for organ donation.
- 2. Informed consent in the context of organ donation has four components (i) decision making capacity to reflect on the benefits and burdens expected from the procedure, (ii) voluntary from pressures and coercions, (iii) having adequate information and (iv)having understanding and reflection. Any of these four components could be incomplete leading to poor decisions regarding the organ donation.
- 3. Notarisation of the informed consent The prospective donor should enclose notarized affidavit on Rs.10/- value Non-judicial stamp paper about his willingness to donate his kidney.
- 4. Assent note by a minor-When children or minors (<18 years of age in many states, including Virginia) are involved in transplantation, the regulations require the assent of the child or minor and the permission of the parent(s), in place of the consent of the subjects. While children may be legally incapable of giving informed consent,

they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the donation.

- 5. Coercion/threat / vested interests often take place while donations are sought for the powerful and influential persons
- 6. Prisoners (vulnerable group) are often utilised in China for forceful donation

Issues involving Organ Procurement

- 1. Organ Donor Registry (ODR) is a register maintained including individuals who have consented for organ donation either live or in the event of their death. National Organ & Tissue Transplant Organization (NOTTO) is the national level agency set up by the Government of India to monitor transplantation related activities and maintain the organ donor registry in India. The Australian Organ Donor Register is an Australian government register, recording individuals who have agreed to donate organs and tissues in the event of their death. The register is administered by Medicare Australia. The NHS Organ Donor Register is a confidential list of people who want to donate their organs and/or tissue. Presently, successful donation in the UK often depends on the unequivocal and readily accessible confirmation that the patient had expressed the wish to become an organ donor, both by signing up to the organ donor register (ODR) and by discussing the issue with their relatives. Agreeing to inclusion on the ODR may merely be an authorization for one's organs to be used after death. The current system of voluntary sign up to the ODR is viewed by many donors and relatives as a positive decision which can help them take something positive out of a tragedy.
- 2. Near relative.....? 'Near relative' category in organ donation law is being expanded by a new Government regulation. Initially, spouses, sons, daughters, fathers, mothers, brothers and sisters were defined as 'near relatives' and could legally donate organs (1994). The government amended the Act in 2011 when grandfather, grandmother, grandson or granddaughters were included in the definition of 'near relatives'. The draft amendment observes that the 2011 expansion of the definition of 'near relatives' has not led to any significant increase in the availability of

- living donors "as grandparents are either too old to donate or can't donate due to some adverse medical condition". The government is planning to expand the definition of 'near relatives' category in the Human Organs and Tissues Transplantation Act, by including step-parents, step-siblings and extended family members.
- 3. Donor card An Organ Donor Card is a great way to show you're committed to saving lives. You can carry your card in your purse or wallet as a symbol of your decision to help others.
- 4. Encouraged volunteerism Organ Donations after death should be encouraged. Donation has been always promoted in the society whether it of money or organs for the simple reason that it shows humanitarian concern.
- 5. Swap donation Paired exchange programmes have been proposed to combat compatibility issues and increase the donor pool. But ethical objections that it is a threat to the conventional system and that it gets closer to the barter system and payment for organs exist.²⁶
- 6. Authorization Committee: SOPs?

Issues involving Marketing

The presence of a growing middle class, the lack of a national health insurance scheme, the growing disparity between the rich and poor, and to some extent the presence of technology in the country makes the process of commodification of organs a simple, quick, and attractive business proposition for some and a solution for others. In many affordable middle class or upper class families, even when there are relatives in good health who can donate, the general argument that is often presented is "why donate and take any risks when you can buy a kidney?" Organ trade in India like other problems such as child labour and prostitution has a societal issue to it. 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.

In an interesting field study on Economic and Health Consequences of Selling a Kidney in India, it was found that 96% of participants (over 300) sold their kidneys to pay off debts. The average amount received was \$1070. Most of the money received

was spent on debts, food, and clothing. The average family income declined by one-third after removal of the kidney (p < .001) and the number of participants living below the poverty line increased. A total of three-fourths of the participants were still in debt at the time of the survey. About 86% of participants reported deterioration in their health status after nephrectomy. A total of 79% would not recommend that others sell a kidney. The article concludes that among the paid donors in India, selling a kidney does not lead to a long-term economic benefit and may be associated with a decline in health. Goval, et al. conclude that: "In developing countries like India, potential donors need to be protected from being exploited. At least, we need to educate them about the likely outcomes of selling a kidney".9

Advertising

1. Recently advertising for organs has been seen. Is it ethical/non-ethical? Several organ transplant candidates have launched campaigns in the print, visual and/or social media to procure organs from living or deceased donors. These campaigns for "directed donations" have raised concerns from the medical community, lawmakers, and the public. While there are several important reasons to consider organ advertisements, a careful analysis reveals that the practice raises serious ethical problems. Medical societies should continue to discourage these appeals, 10,11 and legislation must outlaw the practice. Those who argue in support of media appeals cite the autonomy rights of potential donors and recipients. They champion the prerogative of the intended organ recipient to procure an organ in any legal manner possible and "the right" of the donor to give the "gift of life" to the recipient of his or her choosing. As a society, we encourage potential transplant recipients to persuade their families and friends to become organ donors, and we applaud those individuals who choose to donate to a loved one, never questioning their right to designate a recipient. How, then, can we condemn media appeals and their respondents who make the same choices? Justice issues oppose these strong autonomy claims when we consider the effect of media appeals on the larger community. We offer family members and close friends the choice of donating to a loved one because of the special bond that these intimate relationships create; some ethicists even argue that there is a prima facie obligation for family

members to donate.9 The same obligations and privileges do not extend to strangers because intimate bonds do not exist between them. Proponents of media appeals offer several reasons besides respect for autonomy to support this practice. Some argue that allowing donors to choose recipients may overcome some current barriers to donation. 12 It is important not to fault the patients or their families for the problems associated with media appeals. These families are using legal means to do what any one of us would try to do in a similar situation—save the life of someone we love. The responsibility to see that transplant candidates are treated justly lies with the transplant community, not with the candidates. We must remain committed to all the waiting transplant candidates, not just those with the ability to campaign for their lives. We should refuse to participate in such campaigns and urge lawmakers to close the legal loopholes that allow them. At the same time, we need to develop strategies that will increase overall organ donation and address existing disparities in the allocation system. Media campaigns are an unfair practice that undermines the values of distributive justice that the OPTN and other national networks were created to champion.¹³ In Kerala in November 2017 the Kerala High Court permitted some individuals to campaign but the State Government expressed concern.¹⁴

- 2. Directed Donations are organ donations either live unrelated or cadaver directed for a certain recipient. The directed-donation exception in the Final Rule has been used in several situations where a friend or close family member of a person waiting for transplant dies unexpectedly. More recently, however, transplant candidates have attempted to use this rule to ask strangers to donate a loved one's organ, not to the general waiting list, but to them in particular. It is the perception that these media campaigns unfairly circumvent the traditional system that creates the controversy.
- 3. Support groups
- 4. Organ sale and dignity NOTA prohibits the purchasing of organs, either from living or deceased donors.¹⁵

Issues involving Allocation

Several issues regarding allocation of the donated organs through the deceased donor program exist.

- 1. Equal access policy Equal access supporters believe that organ transplantation is a valuable medical procedure and worth offering to those who need it. They also argue that because the procedure is worthy, everyone should be able to access it equally. To encourage equality in organ transplantation, the equal access theory encourages a distribution process for transplantable organs that is free of biases based on race, sex, income level and geographic distance from the organ. Some who believe in equal access distribution would also like to have an organ distribution process free of medical or social worthiness biases. Medical "worthiness" biases could exclude patients from reaching the top of the transplant waiting list if lifestyle choices like smoking and alcohol use damaged their organs. Social "worthiness" biases would factor in a patient's place in society or potential societal contribution before giving them an organ.
- 2. Medical worthiness Recent research shows that when given scenarios of two people who both needs an organ transplant, the general public's organ distribution preferences are influenced by whether or not a person made behavioural lifestyle choices that caused their illness. 16
- 3. The directed-donation exception in the Final Rule has been used in several situations where a friend or close family member of a person waiting for transplant dies unexpectedly. More recently, however, transplant candidates have attempted to use this rule to ask strangers to donate a loved one's organ, not to the general waiting list, but to them in particular. It is the perception that these media campaigns unfairly circumvent the traditional system that creates the controversy.
- 4. Maximum benefit distribution criteria The goal for maximum benefit criteria is to maximize the number of successful transplants. Transplantation procedures are very advanced procedures and we need to avoid wastage of scarce resources. To avoid wastage we need to take into account how sick the patient is and how much benefit the patient derives from the procedure. Three arguments against the maximum benefit criteria are that it is difficult to predict the degree of success, the possibility of bias when distribution is done in this way and lastly using age and maximising years gained as criteria would discriminate against the older people waiting for transplantation.¹⁷

Issues involving Financial Incentives

A panel of ethicists, organ procurement organization executives, physicians, and surgeons was convened by the sponsorship of the American Society of Transplant Surgeons to determine whether an ethically acceptable pilot trial could be proposed to provide a financial incentive for a family to consent to the donation of organs from a deceased relative. An ethical methodology was developed that could be applied to any proposal for monetary compensation to elucidate its ethical acceptability. An inverse relationship between financial incentives for increasing the families' consent for cadaver donation that clearly would be ethically acceptable (e.g., a contribution to a charity chosen by the family or a reimbursement for funeral expenses) and those approaches that would more likely increase the rate of donation (e.g., direct payment or tax incentive) was evident. The panel was unanimously opposed to the exchange of money for cadaver donor organs because either a direct payment or tax incentive would violate the ideal standard of altruism in organ donation and unacceptably commercialize the value of human life by commodifying donated organs. However, a majority of the panel members supported reimbursement for funeral expenses or a charitable contribution as an ethically permissible approach. The panel concluded that the concept of the organ as a gift could be sustained by a funeral reimbursement or charitable contribution that conveyed the appreciation of society to the family for their donation. Depending on the amount of reimbursement provided for funeral expenses, this approach could be ethically distinguished from a direct payment, by their intrusion into the realm of altruism and voluntariness.18

The widening gap between the number of donated kidneys and the need for kidney transplants has driven interest in incentivizing living kidney donation. Proposals to increase living kidney donation rates using financial incentives have generated vigorous ethical critiques, which can be placed into four categories: undue inducement, unjust inducement, crowding out of intrinsic motivation to donate, and commodification of the body. ¹⁹ The "undue inducement" critique is that payment for living kidney donation will undermine informed consent by coercing individuals into accepting risks that they would otherwise deem unacceptable. For example, a potential donor with a relative medical contraindication, such as abnormal

glucose tolerance or obesity, might ignore the risk of future ESRD because that person will be able to focus only on the immediate financial reward. The concern for "unjust inducement" is that people of lower socioeconomic status will be particularly vulnerable to coercion of this kind. The "crowding out" critique is that thousands of people donate kidneys now without payment, and (at least part of) the motivation is intrinsic generosity. If payments are introduced, everyone will want money to donate. In short, dollars will destroy altruism. The commodification critique holds that the human body has inestimable intrinsic value and allowing someone to sell the body, or part of it, degrades that person's dignity.

Any debate about incentives for organ donation should begin with specifics. These incentives could be structured in a variety of ways, each with distinct ethical implications (and differing potential for compromise between proponents and critics). Incentives could take the form of direct payments, indirect payment (e.g., tax benefits), reimbursement for all expenses and/or lost wages, and "in-kind rewards," such as health or life insurance. Incentives could also apply to all living donors or only a subset, such as nondirected donors (i.e., those who donate to a stranger on the waiting list).19 Paying all living donors would presumably run less risk of "crowding out" altruistic donation than a policy that provided payments only to nondirected donors. From an operational perspective, this approach also requires that the government (e.g., Medicare) accept the cost of paying existing donors (approximately 5500 per year in the United States with a cost exceeding \$50 million) before reaping any benefit from the appearance of additional donors motivated by this payment. Venkataramani et al. studied the impact of tax deductions for donor-related expenses in certain states and found no evidence that tax incentives disproportionately affected the willingness of lower-income groups to donate. Unfortunately, this study also suggested that implementation of these tax deductions failed to augment rates of living kidney donation.²⁰

Current trends regarding the use of financial incentives in medicine suggest that the time is ripe for new consideration of payments for living kidney donation.

- 1. Rewarded gifting
- 2. Reimbursement Different incentive strategies

- exist to compensate potential donors, such as reimbursement for lost wages and expenses or provision of insurance. Expense reimbursement is a promising alternative to fixed payment. Moreover, in contrast with fixed payment for donation, expense reimbursement is legal in the United States.²¹
- 3. Incentives extended to the family of cadaver donors. This has generated debate about ways to increase deceased donation rates and suggestions of providing some form of incentives or support to family members of those whose organs are donated. Why giving incentives is a bad idea? At first glance, such gestures may seem charitable or even fair, as a reward for a family in recognition of the benefits that donation gives to transplant recipients and the healthcare system and community more generally. But in our view, such proposals raise serious ethical and legal concerns, and are unlikely to achieve their intended goal of helping more people to obtain organ transplants. Those of us who have worked in the field of organ transplantation have every reason to believe that deceased organ donation by ordinary Indians is a selfless act motivated by the desire to help other people in need. Year after year, when family members of donors are felicitated on public platforms, they have spoken about how they decided to donate their loved ones' organs without any expectation or a financial reward. For donor families, the opportunity to consent to donation is a source of comfort at a time of grief and loss. For some, the rewards of donation include being able to fulfil social or religious duties to help one another. Also, the majority of transplants in India are currently performed in the private sector. Consequently, it is largely the well-off who access them, benefiting from the gifts of those who donate. If the idea of compensation for donor families becomes normalised, it will be tempting for individual patients dying from end-stage organ failure or institutions participating in transplantation to offer financially beneficial rewards as incentives to donor families while obtaining their consent for transplant.

In any case, free education for children and free healthcare for families with limited resources are the essential responsibilities of a welfare state. Placing these state duties in the context of rewards for donating organs, however well intentioned, is incongruous.²²

4. Approval of payment...? - The amount of payment, the source of it, and how it would be transferred are ethically relevant process considerations. For instance, in terms of process measures, it is conceivable that the government should take a role if any form of payment were allowed to ensure adherence to procedural safeguards, whether that be direct payments, income tax credits, payment for funeral expenses, or charitable contributions.23 If left to private companies, organ brokerage companies could easily become exploitative. If financial compensation were to be provided, one process measure might include that at the time the organ is procured, the donor will receive a contribution through a central agency.²³

WHO has developed "Guiding Principles on Human Cell, Tissue and Organ Transplantation". To help achieve these goals a series of meetings was organized in Istanbul starting 2008. It endorsed the altruistic nature of organ donation.

"Organs should only be donated freely, without any monetary payment or other reward of monetary value." The Declaration of Istanbul Custodian Group (DICG), which works to promote the Declaration of Istanbul, in its position statement on the issue of payments to donor families argues that "Providing money to people to encourage them to consent to organ removal or reward them for doing so weakens donation programs... exploits the economic vulnerability of... deceased donor families, and undermines equality and justice by reinforcing rather than reducing socioeconomic inequities."

- Statement of the Declaration of Istanbul Custodian Group regarding payments to families of deceased donors.²⁷

Religious and Cultural Issues

One of the challenges between medical team about organ transplantation is religious and cultural differences. Various factors influence organ donation such as, this being a humanitarian act, perceived quality of care, family experience, lack of knowledge, fear of donation, and religious view. Beliefs in religious countries play a vital role in tissue and organ transplantation. However, the little attention has been given about religious and cultural issues in different ethnicities, particularly in Iran.

Religious beliefs have a positive attitude about tissue and organ transplantation. Despite positive attitude from different religious, organ donation rate remains low. Maybe, this problem is due to insufficient awareness of people about religious leaders' views on this issue. For example, view of Christianity about organ transplant is positive and support any act of altruism. The Quran accepts removal organs only as a way of treating the ailment; the success of the transplantation must be highly probable; the donor or the family must have consented to it; and if possible transplantation must be between Muslims only.

Cultural view about transplantation is varied. Some cultures give great importance to ancestral traditions and beliefs. They believe there is a transfer of the spirit from the donor to receipt and do special rituals for this process. Asian people have a relatively higher negative attitude about organ donation than other US residents. For example, Caucasian Americans are more willing compared with Asian Americans for organ donation as a social responsibility. Cultural and religious variations are playing an important role in the formation of beliefs about organ donation. Understanding and knowledge about transplantation require teamwork. In addition, providing an opportunity for consultation with a religious leader about organ donation and establishing an educational reform system can improve the current low rates of organ transplantation.²⁴

- 1. Community leaders the role of community leaders in the growth of organ donation needs no reiteration. Religious leaders, social leaders, writers and academicians all have a great role to play in creating a social milieu for the organ donation programme to flourish.
- 2. Media the role of the media can never be taken lightly. Positive news about the noble acts, unbiased reports of the difficulties faced by potential recipients and achievements by individuals and institutions need to reach the public. The print, visual and social media play prominent roles in this effort.
- 3. NGOs bring in mass participation through their activities. Several NGOs have played stellar roles like MOHAN Foundation.
- 4. Inclusion in Medical curriculum the awareness of the medical fraternity and medical students is so poor regarding organ transplantation and the efforts needed for organ donation. Correction

of this possible through the activities of Indian Medical Association (IMA) and through revision of the medical curriculum. IMA under the leadership of National President Dr Ravi Wankhedkar and Chairman of Schemes Dr A Marthanda Pillai has formed a Committee for Organ Donation at the national level for the purpose.

Ethical issues regarding Xenotransplantation

Basically there are two main topics to be distinguished within the overall issue of xenotransplantation.

- Ethical implications of xenotransplantation concerning human beings – raises questions since it benefits only a small number of patients and is still experimental in nature
- 2. Ethical implications of xenotransplantation for animals objections include 4 important theories: anthropocentrism, according to which only human beings possess an inherent moral value, pathocentrism, which defines sentient beings as morally relevant, biocentrism, which assigns moral value to all living beings, and finally holism, a theory that claims that moral significance is not something an individual has but rather the whole system of nature.²⁵

End-of-life decisions

Decisions about end of life have to be unbiased and independent of any external influence. No commercialism should be identified in these decisions.

Suggestions

- 1. NGOs, civil society, leaders and other stakeholders have a major role in creating the right awareness regarding organ donation.
- 2. Cadaveric Donation Programs should be encouraged.
- Standard Operating Policies and Procedures for Authorization Committee will bring in uniformity and curb malpractices.
- 4. Appropriate restructuring of medical curriculum will go a long way in improving the current situation.
- 5. Re-examine the value of using regulated incentive-based organ donation to increase the supply of organs.
- 6. Restructuring the governance related to transplantation procedures is the need of the hour.

- 7. Appropriate amendments in the THOA are warranted.
- 8. Newer technologies cannot ignore the sociocultural and socioeconomic aspects of a country.

END NOTE

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Editor's Remarks: The travails of an organ recipient to obtain a transplantable organ in time and with matching immune structure never end. The ethical aspects often take the back seat in less regulated countries like India. The regulatory aspects of the organ transplantation science and its pitfalls are discussed.

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