



ROLE OF CONSENT IN ORGAN DONATION: A HUMAN RIGHTS PERSPECTIVE

AUTHOR NAME – INDU W/O SANDEEP KUMAR

DESIGNATION – ASSISTANT PROFESSOR

Abstract

Consent in medical practice is a complicated process. This is partly because different medical conditions bring up different challenges for doctors and patients. Informed consent and risk assessment are important public health topics that have become even more important during the Covid-19 pandemic. In this article, we look at the key factors that doctors should consider when getting consent for solid organ transplantation. Consent for solid organ transplantation is more complicated than most surgeries or other medical procedures because of the many factors involved, the complexity of the choices, and the need to balance different risks. We start by looking at the context in which a patient gives consent. Then we outline the legal principles of consent in medical practice as they apply in the UK and the implications of recent legal cases. The third section looks at the specific difficulties of consent in organ transplantation and highlights the important factors in making sure consent is properly given. The fourth section provides practical advice. We suggest a new "multi-factor approach" to informed consent in transplantation that includes understanding risk, effective communication, and strong review processes. Although understanding risk and communication are essential, our suggestion is that including review processes into the consent process is very important. By this, we mean identifying and creating space for judgment in decision-making to help ensure that informed consent is actually given in practice. Discretion means that healthcare professionals use their judgment to guide their actions rather than follow legal decisions as strict rules.

Background History

The history of organ transplantation is not just a medical journey, but also a philosophical and ethical one. From early experimental surgeries to modern complex procedures, the discussion around rights, consent, and human dignity has developed alongside scientific progress. The first half of the 20th century saw big advances in surgical techniques and immunology, which laid the foundation for modern organ transplantation. In 1954, Dr. Joseph Murray performed the first successful human kidney transplant between identical twins, solving the problem of immune rejection (Murray, 1992). This important operation led to the development of ethical guidelines, as it involved informed consent and showed the importance of voluntary participation in organ donation. By the 1960s and 1970s, organ transplantation expanded to include other organs like the heart, liver, and lungs. However, these advancements brought new ethical challenges. The concept of brain death was introduced to determine when it was appropriate to harvest organs from deceased donors, which sparked debates about the definition of death and its moral implications. During this time, bioethics as a field began to take shape, especially after the book "Principles of Biomedical Ethics" by Beauchamp and Childress was published in 1979, providing a structured way of looking at issues like consent, autonomy, and dignity in medical practice. As transplant success grew and the demand for organs increased, the ethical challenges became more complex. The

1980s and 1990s saw a rise in awareness of unethical practices such as organ trafficking and transplant tourism, where organs were taken from vulnerable people—often without proper consent or compensation (Scheper-Hughes, 2000). These practices broke basic human rights and showed how the human body was being treated as a commodity, which contradicted the ethical belief that the body should not be treated as a market item. In response, international guidelines were created. The World Health Organization (WHO) released its "Guiding Principles on Human Cell, Tissue and Organ Transplantation" in 1991, which were updated in 2010, reaffirming the need for voluntary, unpaid organ donation and the protection of human dignity. Similarly, the "Declaration of Istanbul" (2008) condemned organ trafficking and transplant tourism, calling on countries to adopt ethical frameworks based on justice and transparency. Medical ethics in transplantation has moved from a model that focused on the doctor's decision-making to one that centers on the patient's autonomy and informed consent. Today, the ethical focus extends beyond individual cases to broader issues like equitable access to transplantation and the need for public trust. The evolution of organ transplantation has shown that technical success must be backed by ethical integrity to protect human rights and dignity in all medical settings.

Contextualising Consent in Solid Organ Transplantation

Like any medical treatment, it is generally agreed that a patient should give informed consent before undergoing solid organ transplantation. However, the challenges of organ transplantation are greater than most other medical or surgical procedures. Transplantation is usually offered to either increase the length or quality of a person's life, or both. In most cases, the patient is likely to be anxious, and their ability to receive, understand, and process information may be affected by their condition (such as encephalopathy in people with advanced kidney or liver disease, or hypoxia caused by heart or lung disease) or by the medications they take, or both. Encephalopathy may not always be obvious and can change in severity over time. This adds to the difficulty of making sure the patient is fully informed and able to make their own decision.

Consent to Medical Treatment

This section outlines some of the key ideas and principles of consent to medical treatment in law, with the aim of highlighting important issues related to consent before moving on to the specific topic of solid organ transplantation in the next section. According to Beauchamp and Childress, the four fundamental principles of medical ethics include: beneficence, nonmaleficence, autonomy, and justice. Within this framework, consent is a central part of medical ethics and continues to be important in situations where individual autonomy is highly valued. Respect for patient autonomy has become one of the key indicators of good medical care. The process of giving and obtaining consent is based on ethical practice, supported by local, national, and international guidelines, and underpinned by a legal framework.

Identifying relevant risk factors in giving and determining consent for transplantation

There are many complex risks involved in organ transplantation that are not typically seen in most surgical procedures. When assessing risks, both standard and personalized factors must be considered. There are several main groups of risks [1, 2, 34, 35]:

- Risks of staying with non-transplant support
- Risks related to the surgery (both short and long-term) and anaesthesia
- Risks of the graft failing (both short and long-term)
- Risks connected to the donor (like passing on infection or cancer, which could be known or unintentional)
- Risks linked to the organ (such as organs from donors who died before circulation stopped or from obese donors that are more likely to fail)
- Risks from immunosuppression (which includes both specific drug risks and general risks, such as higher chances of certain cancers, infections, heart and kidney damage)

- Changes in lifestyle (like needing long-term care, avoiding unnecessary risks, not smoking, possible problems during pregnancy, and needing lifelong immunosuppression)
- Risks of the disease coming back and rejection happening early or later

Rights and Autonomy

The ethical idea of respecting autonomy means everyone has the right to make decisions about their own body. This is a central part of modern medical ethics, especially in organ transplantation. Autonomy includes the right to donate organs either after death or while still alive (like with kidney or part of the liver donation). However, autonomy isn't just about making a choice—it matters only when the decision is well-informed, given freely, and not forced or influenced by others. Challenges to real autonomy often happen, especially among people who are economically poor or socially excluded. In many parts of the world, individuals have been tricked, forced, or pressured financially into donating or selling their organs. These people often do not understand the medical dangers and might agree to the procedure out of desperation rather than true choice. This is a serious breach of ethical standards and human rights, as it treats the donor as a means to an end, harming both their dignity and their bodily rights. As anthropologist Nancy Scheper-Hughes (2000) has pointed out, these practices show a troubling global trade in human organs that mainly affects the poor, turning their bodies into “spare parts” for the rich. In the context of organ transplantation, protecting rights and autonomy means having strong systems to ensure informed consent and to protect vulnerable people from exploitation. Doctors, government officials, and ethics groups must work together to uphold these principles and ensure fairness and respect in organ donation systems.

Global Guidelines and Ethical Safeguards

To address the growing ethical and legal issues around organ transplantation and trafficking, many global and national organizations have created detailed ethical guidelines and legal tools.

These aim to protect human dignity, ensure donor rights, and create fair and open transplant systems. One of the most significant initiatives is the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2008), which brings together international agreement on ethical practices in transplantation. This declaration strongly opposes organ trafficking, commercial organ sales, and transplant tourism, promoting fairness, transparency, and the protection of vulnerable people. It also highlights the importance of national self-sufficiency in organ donation, suggesting that countries should create their own ethical donation programs to meet local transplant needs.

The World Health Organization's Guiding Principles on Human Cell, Tissue and Organ Transplantation (2010) also outline key ethical standards.

These include voluntary and unpaid donation, informed consent, no commercialization, and fair access to transplant services. The WHO also stresses the need for transparent allocation systems and public trust in the fairness of transplantation programs. At the national level, countries have created their own laws to control organ transplantation. For example, India passed the Transplantation of Human Organs and Tissues Act (THOTA) in 1994, which was updated in 2011. This law was designed to stop the illegal organ trade and set up a regulatory system for ethical donation and transplantation. THOTA requires authorization committees to review living donor cases, bans commercial dealings in organs, and sets out penalties for breaking the law. It also encourages deceased organ donation through systems like the National Organ and Tissue Transplant Organization (NOTTO).

Legal Challenges in Organ Donation: Regulatory Limitations

While the Transplantation of Human Organs and Tissues Act (THOTA) was introduced to stop the selling of organs and manage transplant procedures, its strict rules have not kept up with new medical and ethical issues. The law does not clearly cover altruistic donations, where people give organs to non-relatives without any money involved. Also, organ donation across borders is not well handled by India's laws, as they don't offer clear solutions when foreign patients come to India for transplants. Without legal rules that cover these situations, more potential donors may not step forward. Illegal Organ Trade Even though

there are strict laws against selling organs, illegal organ trafficking continues to be a serious problem in India.

People from poor backgrounds are sometimes tricked or forced into selling their organs by middlemen who take advantage of legal gaps. Organ trafficking networks are strong because the enforcement of THOTA is weak, there are not enough monitoring systems, and corruption exists. The ongoing shortage of organs makes this illegal trade even more difficult to stop. Weak Implementation and Monitoring Even with the legal protections in THOTA, the law isn't properly enforced on the ground. Poor monitoring allows unethical practices like illegal trafficking, forced donations, and fake consent forms to go on. Many hospitals and authorities don't have enough resources or willingness to investigate thoroughly, so illegal activities often go unnoticed. There's also no central, open system for tracking living organ donations, which makes oversight weak and allows for more loopholes. Issues with Authorization Committees

Authorization Committees are important for approving organ donations, especially when the donor and recipient are not related. However, these committees often move slowly, causing delays in checking applications. This delay affects patients who need transplants urgently. Health institutions are also too cautious, wanting to avoid illegal trades, which makes them overly strict and sometimes discourages real donors. There's a lack of uniform and clear procedures, making the committees even less efficient. Brain Death Determination Deciding if someone has brain death is complicated due to the complex and personal nature of assessing whether brain function is permanently lost. Differences in medical practices, legal definitions, and the risk of wrong diagnoses can make the process difficult, causing legal and ethical questions about when and how accurately brain death is determined. Consent

Consent is a major legal challenge in organ donation because of cultural stigma, unequal economic conditions, and not enough rules in the legal system.

Judicial Approach

The courts have handled both ethical and legal issues in some ways, proposing ways to ensure the process is transparent, efficient, and fair.

Many court decisions have helped shape the legal setup for organ donation in India, supporting the ideas of personal freedom, informed consent, and proper regulation. In *Neha Devi v. Govt. NCT Delhi* (2022), the Delhi High Court said that a spouse can't control a donor's decision on organ donation, and only free and informed consent is needed. It also relied on the *Common Cause v. Union of India* (2018) case and clarifies that spousal consent isn't required. In *Kuldeep Singh & Another v. State Of Tamil Nadu & Ors* (2005), the Supreme Court said both donors and recipients must get approval through the Authorization Committee in their home state. The court said the people applying must prove the donation was based on love, not just because of emotions. In *Deepa P.M. & Anr. v. State of Kerala & Ors*, the Kerala High Court said the intention is considered bad legally. In *Jillet K.T. & Another v. State of Kerala & Others* (2024), the court asked the government to set up hospital-based Authorization Committees to speed up approvals and said the absence of photos shouldn't stop a donation. In *Amar Singh Bhatia & Anr. v. Sir Ganga Ram Hospital & Ors* (2024), the Delhi High Court set specific time limits for steps in the transplant process, saying delays are against the purpose of the laws involved. These decisions show the importance of honesty, following medical ethics, and protecting people who are vulnerable in the organ donation process. The intentions behind organ donation shouldn't be doubted just because the donor is from a poor background. This affects personal dignity. In *Sanjay Yogi Goel v. Union of India & Ors*, the Delhi High Court said love and affection can't be ignored, and an exchange is only illegal if it's for money or commercial gain.

Fairness in organ allocation: The Declaration of Istanbul was created in 2008 as an international statement to deal with the urgent and growing issues of organ trafficking. It builds on WHO Guiding Principle 9 by calling for organs to be 'equitably allocated.' Health equity means that people should have the same health outcomes regardless of their personal characteristics like ethnicity, where they live, or their economic situation. John Rawls introduced his 'difference principle' to create a fair society. He believed that societies should 'try to maximize the interests of the worst off.' This should be the main goal

of any organ allocation policy. People who make decisions about organ allocation at a larger level should figure out who is the worst off in the donation and transplant system, and then take steps to improve their situation and chances. An example is the UK Kidney Offering Scheme, which was changed so that people who are harder to match—often because they are from an ethnic minority—can get a higher transplant priority. This is helping to reduce the waiting time for transplants between different ethnic groups in the UK. Fairness in transplantation is also improved when organ allocation is based on clear and open clinical criteria.

Protection from exploitation:

As a vulnerable group, potential transplant patients need extra protection from being exploited by healthcare professionals.

Exploitation could include obvious wrong actions, like seeking financial gain, but it can also be more subtle, such as when one patient benefits at the expense of another. Seven of the eleven WHO Guiding Principles focus on fairness by preventing exploitation, and four of these are related to money! Three are about payments to donors, and the fourth concerns payments to healthcare professionals. For healthcare professionals and those who regulate and oversee the healthcare system, this is a clear warning against dishonest behavior. As WHO Guiding Principle 8 says, 'All health-care facilities and professionals involved in cell, tissue or organ [recovery] and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.'

Conclusion and Suggestions

Organ donation is an important part of healthcare that can save lives, but in India, it faces several challenges. The Transplantation of Human Organs and Tissues Act, 1994 (THOTA) sets the legal guidelines, but implementing these rules has been tough. Issues like poor enforcement, lack of public knowledge, and illegal trade of organs make it hard to reach the goals of the law. There are also ethical concerns, like making sure people give informed consent and fairly distributing organs, which add to the difficulty. However, over time, there has been a noticeable change in people's attitudes, awareness, and outlook toward organ donation. Still, the law's implementation remains a challenge that continues today. Organ donation should always be done voluntarily. To make the process more effective and fair, these problems need to be tackled in a comprehensive way. This includes enforcing the law more strictly, running awareness campaigns, and setting clear rules for how organs are distributed. Working together between the government, hospitals, and non-governmental organizations is key to building trust and getting more people to take part in organ donation. Solving these issues could help India create a fair and efficient system that saves more lives and benefits everyone.

- Strengthening the legal system by updating the law, fixing its weaknesses, and introducing harsher punishments for breaking the rules, which would discourage illegal organ trade.
- Creating a strong enforcement system with independent bodies to check that organ donation and transplantation rules are followed properly.
- Starting large-scale public awareness campaigns to teach people about the importance of organ donation, common beliefs that are not true, and to help form a culture of voluntary donation.
- Making sure healthcare workers get proper training on ethics, including how to get informed consent and how to handle family concerns with care.
- Improving the infrastructure and making organ retrieval and transplantation services more accessible, especially in rural areas, to reduce unfairness in access.
- Setting up a digital system that connects organ donors and recipients to ensure a transparent and fair way to allocate organs.
- Studying and adapting successful systems from other countries, such as Spain's presumed consent model, to fit India's culture and encourage a shift toward an opt-out system.

By making these changes, India can overcome the legal and ethical problems in its organ donation system. These steps will help build public confidence, increase the number of people willing to donate organs, and ensure a fair and effective system that saves more lives.

