

## Meeting Report

### **ACCESS, JUSTICE AND AUTONOMY IN TRANSPLANTATION IN INDIA**

#### **Voices from the ground**

**A Summary of the DICG and NATCO Roundtable meeting, New Delhi, February 9, 2025**

#### **Abstract**

The DICG-NATCO round table meeting held during the World Congress of Nephrology, 2025 explored hitherto less explored complexities of organ transplantation in India, focusing on access, justice, and donor autonomy. It drew insights from successful advocacy efforts in disability rights, rare diseases, and medical cost reductions to inform policy and activism in transplantation. The discussions examine the medical, ethical, legal, and socio-economic dimensions of transplantation, highlighting both advancements and persistent challenges in India and globally. Equitable access remains a major concern, with economic disparities affecting patient care and post-transplant treatment. While government-funded programs improve access, high medication costs and gaps in post-transplant care persist. Ethical concerns arise from the commercialization of organ transplants, necessitating cost regulation and citizen-driven advocacy. Donor autonomy is critical, especially given the prevalence of living organ donations in India. Ethical issues such as informed consent, coercion, and gender disparities are central. While legal safeguards exist, inconsistent enforcement weakens donor protection. The role of transplant coordinators was examined, emphasizing the need to strengthen donor advocacy through better training and independent decision-making authority. Gender disparities are stark, with women disproportionately serving as living donors, often due to societal pressures. Limited research on the medical and ethical implications underscores the need for reforms. Additionally, post-transplant care for donors remains inadequate compared to recipients. Legal constraints on donor autonomy require urgent review to ensure stronger protections and a more equitable system. The challenges faced by deceased donor families highlight the need for better support and recognition. Policy recommendations include healthcare benefits, insurance, and memorial spaces to honour their sacrifice. The meeting advocated for systemic reforms to enhance donor rights, improve accessibility, and ensure ethical transplantation practices. It underscored the importance of civil society-driven advocacy in shaping a fair and just transplantation framework.

#### **INTRODUCTION**

Organ transplantation is a remarkable advance of modern science with high success rates. It now has a central role in saving & improving the quality of life of those with end stage organ failure. It is also being performed in increasing numbers in South Asia and India. Globally, India ranks very high in total number of transplants, though the number per million population is low which means access is a big challenge. With improved expertise and capacity there is now an opportunity for Indian citizens to benefit from this life saving treatment.

The region's huge population, the increasing incidence of organ failure and recognition of transplant as a viable option for many diseases has resulted in an increase in the demand supply gap. Like the rest of the globe, donation and transplantation in the region is impacted by socio-political and cultural factors and the health system structure. This reflects in many ways some of which are unique to the region.

With barriers to deceased donation, a large majority of transplants are performed with living donors. Given limited public sector capacity, transplants are largely performed (around 80 to 90%) in the private sector where costs are unaffordable for ordinary citizens and push many into financial catastrophe. Though the private sector has helped accelerate the growth of transplantation this is also leading to monetisation of the process. Unrelated paid donation continues to rear up its head serving as a grim reminder of the organ trade in response to which India's Human Organs Transplant Act of 1994<sup>1</sup> was promulgated. India has also become a major destination for foreigners seeking transplants and recent government data shows that ten percent of transplants are performed on foreigners one of the highest in the world<sup>2</sup>. This includes both legal travel for transplant and commercial donation. Whilst this is seen as a part of the growth of medical tourism it has implications for public perception as well as access for locals. Besides, given strong social hierarchies living donors often hail from vulnerable groups and subtle coercion is not uncommon. In related transplantation family & social hierarchies operate and data consistently shows women especially wives donating to men. A free and fair consent is thus a challenge and donor autonomy, and protection continues to be a key concern.

The Government and NGOs are leading national campaigns to promote organ donation after death which is globally how a majority of transplants are performed. In some states citizens have responded with magnanimity with families agreeing to donate organs of a close relative. This has also enabled heart & lung transplants. However, given the high costs access to transplantation of deceased organs is still out of reach for ordinary citizens. We are thus faced with an incongruous situation where appeals are made to all citizens to donate organs in social solidarity, but a majority are unable to receive a transplant. Financial barriers are mainly due to an inbuilt structural bias as most donated organs end up in private hospitals which currently have the capacity to perform transplants.

Transplantation policies in India have attempted to address access, justice and donor autonomy through legal instruments and regulation. Recently national and state insurance and funding schemes are attempting support but are inadequate for most patients. The high costs and private sector profile of transplantation results in it being perceived as an elite activity and such public perception is likely affecting deceased donation rates. Transplantation in the region thus needs conscious reform for its benefits to reach all our citizens in a fair and justiciable manner.

One reason why reform maybe slow is because decision making is dominated by the healthcare industry and transplant clinicians. This leads to conflicts of interest. A recent study of six countries across the globe which included India & Pakistan the two largest countries of South Asia identified lack of representation of voices from the ground and

regulatory domination of policy making as one of the barriers towards the implementation of ethics and equity principles<sup>3</sup>. The inclusion of the voices of citizens, patients, health rights groups, non-governmental organisations, allied healthcare staff including nurses and transplant coordinators will bring in fresh and independent voices. Listening to those with lived experience of transplantation, individuals working at the frontiers as well as movements for health equity and patient's rights is one pathway towards reform. This will also improve public perception & trust which is key to citizens participation and improving donation.

The Declaration of Istanbul Custodian Group (an initiative of the Transplantation Society & the International Society of Nephrology) is a global body which promotes the Declaration of Istanbul<sup>4</sup> which upholds and advocates for ethics, equity & justice in transplantation across globe. A recent meeting involving multiple global organisations including the WHO renewed the call for transparency & oversight in the conduct of global transplantation including in the emerging areas of cell & biologic therapies<sup>5</sup>. This was followed by a new resolution which was passed by the 77<sup>th</sup> World Health assembly in June 2024<sup>6</sup>. The Resolution emphasises the need to expand transplantation, maximise donation from the deceased, guarantee protection of the living donor, combat organ trafficking and address innovation.

Jointly organised with the ISN & NATCO, the round table meeting focussed on issues of access and autonomy in India's transplant ecosystem. The meeting had the following broad aims:

1. To provide a platform to voices from the ground & foster dialogue
2. To learn from the experience of other campaigns in the health sector
3. To document and disseminate the proceedings for a wider audience & advocacy
4. To create the nidus for a long-term alliance for inclusive and justiciable transplantation in India

The meeting successfully brought together a diverse group of stakeholders, including medical professionals, patients, representatives from civil society organizations, legal experts, and government officials, to engage in meaningful dialogue around the critical challenges in organ transplantation in India.

This report summarises the key presentations and discussions from the round table, "*Access, Justice, and Autonomy in Transplantation in India*", organised by the Declaration of Istanbul Custodian Group (DICG) in collaboration with the Network and Alliance of Transplant Coordinators of India (NATCO) on February 9, 2025. The conversations explored the ethical, social, and systemic barriers that continue to hinder equitable access to transplantation services in India. The meeting also underscored the vital role of civil society in driving policy reform and drew meaningful parallels with broader movements for equity in healthcare policy and practice.

# ACCESS AND JUSTICE

## Nothing About Us Without Us: The Journey for Inclusion in Health Policy

### Dr Satendra Singh

Distinguished Advocate for Disability Rights in Medical Education and Healthcare

The pursuit of inclusivity in healthcare policy is imperative to ensure equitable access and representation for individuals with disabilities.

**Advocacy as an Integral Component of Healthcare** Advocacy plays a critical role in medical education and practice. Global movements such as "Black Lives Matter" and "Me Too" serve as examples of how collective activism can drive meaningful policy changes. Integrating advocacy into medical curricula fosters a culture of inclusion and empowers future healthcare professionals to challenge systemic inequities.

Firsthand accounts of discrimination within the medical profession were shared, including instances where disabled individuals were denied opportunities to participate in government medical examinations. Legal interventions contributed to the creation of 1,674 central government positions for disabled doctors, marking a significant milestone in disability rights advocacy.

A critical issue raised was the unethical treatment of disabled individuals within medical education. The practice of using disabled individuals solely as case studies without regard for their dignity and agency was condemned. This medicalization perpetuates stigmatization and hinders the development of inclusive medical training programs.

Structural barriers that hinder accessibility in hospitals and medical colleges were highlighted. The absence of disability-friendly infrastructure and accommodations limits the participation of disabled professionals and patients in medical institutions. Policy-driven initiatives are necessary to ensure inclusivity and dignity in healthcare facilities.

A significant achievement of disability advocacy was the successful incorporation of disability competencies into the National Medical Commission (NMC) curriculum<sup>7</sup>. This reform ensures that medical students are equipped with the knowledge and skills necessary to provide inclusive care, thereby fostering a healthcare system that is responsive to the needs of disabled individuals.

Systemic discrimination faced by disabled individuals in organ transplantation was addressed. The landmark case of Sandra Jensen<sup>8</sup>, who overcame institutional bias to become the first person with Down syndrome to receive a heart-lung transplant, was cited. Research highlights the ethical concerns surrounding discrimination in organ transplantation against individuals with intellectual disabilities, and Legal precedents and empirical studies demonstrate that individuals with disabilities have comparable post-transplant survival rates<sup>9</sup>, reinforcing the need for equitable policies in organ allocation.

Critical inconsistencies within the National Organ and Tissue Transplant Organization (NOTTO) guidelines<sup>10</sup> pertaining to the Indian Law, Transplantation of Human Organ's Act were identified, where psychosocial and intellectual disabilities are often conflated. This misclassification leads to discriminatory medical decisions, restricting access to life-saving procedures. A recent Supreme Court ruling<sup>11</sup> reaffirmed the right of disabled individuals to equal medical treatment, calling for a revision of national transplantation policies to align with human rights frameworks.

A crucial discussion point was the International Society for Heart and Lung Transplantation's stance that "mental retardation or dementia may be regarded as a relative contraindication to heart transplantation"<sup>12</sup>. This perspective has led to ethical concerns regarding the exclusion of individuals with intellectual disabilities from transplant eligibility. Additionally, the American Association for the Study of Liver Diseases has stated that "children with mental retardation pose significant logistical and ethical challenges"<sup>13</sup>. The Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation has also stated that the presence of Mental Retardation represents a contraindication for transplantation<sup>14</sup>, further highlighting the ethical implications of such policies. Addressing these biases is essential to ensuring equitable access to life-saving medical interventions.

## Transplantation: A Public Health Perspective

### **Dr Mala Ramanathan**

Ethicist, Professor - Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, Kerala

**Medicine vs. Public Health in Transplantation** The distinction between medicine and public health is critical in understanding transplantation ethics<sup>15</sup>. While medicine is primarily concerned with individualized patient care, public health seeks to maximize benefits for society as a whole. This divergence in focus presents challenges in balancing individual rights with collective well-being.

**Public Health and Human Rights** Public health interventions are designed to achieve the greatest good for the largest number of people. However, such interventions can sometimes infringe upon the rights of specific individuals or subgroups within the population they aim to serve. Ethical public health practice necessitates identifying and mitigating disadvantages faced by these individuals, ensuring safeguards are in place to protect those adversely affected by large-scale policies.

**Ethical Considerations in Organ Donation and Transplantation** Organ donation and transplantation program primarily focusses on the patient, whose welfare is safeguarded through professional medical oversight and ethical guidelines, as outlined in the National Medical Council Act<sup>16</sup> and the Code of Medical Ethics Regulations<sup>17</sup>. However, the process of organ transplantation inherently involved a third party – the donor – whose interests need to be protected. Physicians primarily advocate for their patients, yet the donor, despite their critical role in the process, often lacks a designated advocate.

While the principle of autonomy underscores voluntary organ donation, the inherent power imbalance in the doctor-donor relationship raises concerns about potential conflicts of interest. Medical professionals, whose primary duty is to their patients, may perceive donors as a means to achieving optimal patient care. This perspective underscores the need for an independent mechanism to safeguard donor interests.

### **The Role of Public Health in Donor Advocacy**

Hospitals are responsible for ensuring that donors make informed decisions by providing comprehensive information about long-term consequences and other relevant information. However, the question remains—who advocates for the donor? If the physician represents the interests of the patient, public health must assume the role of advocating for the donor through regulatory oversight. This necessitates state intervention in several key areas:

- **Long-term Health Care for Donors:** Who will bear the cost of medical needs if a donor requires additional care post-donation?
- **Insurance and Coverage:** If insurance coverage is mandated, will it be sufficient to address long-term health consequences? Will universal healthcare coverage adequately manage these needs?
- **Support for Extra-Familial Donors:** While family members may absorb some costs associated with donation, who will assume responsibility for non-family donors requiring care?

### **A Public Health Approach to Transplantation**

To ensure ethical and equitable transplantation practices, the state must actively provide for living donors while simultaneously promoting deceased organ donation through systematic policies. A comprehensive public health approach would encompass human rights considerations, extending beyond the doctor-patient dyad to examine broader donor demographics, vulnerabilities, and emerging patterns in transplantation. By addressing these concerns, public health can foster a fair and sustainable transplantation framework that upholds the rights and welfare of both donors and recipients.

## **Learnings from Patient-Centered Advocacy**

### **Malini Isola**

Co-Convenor of the All-India Drug Action Network and the Campaign for Dignified and Affordable Healthcare.

Patient-centered advocacy plays a crucial role in shaping healthcare policies and improving accessibility. The efforts of organizations such as the All-India Drug Action Network (AIDAN) have been instrumental in advocating for healthcare reforms, particularly in the regulation of medical product pricing. One of the most notable achievements in this area has been securing price caps for cardiac stents, which significantly reduced costs, dispelled myths about innovation, and encouraged local manufacturing.

**Challenges in Organizing a Unified Patient Movement** Despite the existence of various patient advocacy groups, a singular patient movement remains elusive due to the diverse nature of healthcare concerns. The fragmentation of interests among different patient populations makes it challenging to establish a unified platform for advocacy.

**Impactful Advocacy Efforts** The success of securing price caps for cardiac stents highlights the effectiveness of advocacy in reducing healthcare costs. This achievement underscores the necessity of continued efforts to regulate medical expenses and ensure affordability for all patients.

**The Fight for Affordable and Dignified Healthcare** High-profile cases of medical overcharging and unethical practices in corporate hospitals emphasize the urgent need for stronger regulation and enforcement mechanisms. Strengthening policies that safeguard patient rights is essential to prevent financial exploitation in healthcare settings.

**Strategies for Effective Advocacy** Several key strategies contribute to successful patient-centered advocacy:

- Sustained and voluntary grassroots efforts.
- Comprehensive documentation and technical research.
- Forming alliances with diverse stakeholders.
- Leveraging policy developments to drive systemic changes.
- Campaigning for transparency in medical regulations.
- Taking a firm stance against powerful entities when necessary.
- Grounding advocacy in compassion and lived patient experiences.

**Specific Areas for Organ Transplantation Advocacy** Advocacy efforts in organ transplantation must focus on the following priority areas:

- Expansion of transplantation services within the public sector.
- Regulation of private sector costs.
- Enhancement of transparency in organ allocation and registry data.
- Addressing the issue of transplant tourism, which limits access for Indian residents.
- Reducing cost disparities in immunosuppressant medications.
- Strengthening regulatory oversight to prevent organ trafficking.

Greater oversight, policy intervention, and transparency are critical to ensuring equitable access to organ transplantation services in India. A patient-centered approach, driven by research, collaboration, and persistent advocacy, is essential to achieving systemic improvements in healthcare access and affordability.

## Commentary: Regulatory Challenges and Patient Rights in Organ Transplantation

**Dr. Anil Kumar**

Director NOTTO (National Organ and Tissue Transplant Organisation, under the aegis of Ministry of Health and Family Welfare, Government of India, Delhi)

**Clinical Establishments Act** This act mandates compliance with patient rights and grants authorities the power to revoke licenses for non-compliance. However, adoption has been inconsistent, with major metropolitan areas like Delhi, Chennai, Mumbai, and Kolkata yet to implement the act due to resistance from organizations like the Indian Medical Association (IMA). This resistance hinders the establishment of standard patient protections across the country.

**Financial Barriers to Transplantation** High out-of-pocket expenses continue to be a major barrier to accessing transplantation services. Many patients exhaust their insurance coverage limits, leaving them without financial support for post-transplant care. Additionally, insurers often refuse to extend coverage once a transplant is deemed necessary, further restricting access to life-saving procedures.

**Cost of Medication and Affordability** The cost of immunosuppressant medications poses an ongoing financial burden for transplant recipients. Some hospitals have begun incorporating drugs from the Pradhan Mantri Jan Aushadhi scheme to provide more affordable alternatives. However, further regulatory interventions are required to control corporate hospital pricing and ensure wider access to cost-effective treatment options.

**Transparency in Transplantation Outcomes** Access to data on transplantation success rates is essential for patients to make informed decisions. Greater transparency in outcome reporting would help manage patient expectations and enhance trust in the transplantation system. A notable case involved a lung transplant recipient who remained in the ICU for over a year, underscoring the need for clearer risk disclosures and informed consent processes.

The enforcement of patient rights, regulation of hospital costs, and promotion of transparency in transplant procedures are crucial to improving the organ transplantation landscape in India. Strengthening policy frameworks and ensuring their effective implementation can help bridge existing gaps and enhance equitable access to transplantation services.

## Strategies to Increase Access to Costly Treatment

### Prasanna Shirol

Co-Founder and Executive Director – ORDI (Organization for Rare Diseases India), Bengaluru

**Challenges in Rare Disease Diagnosis & Treatment** Rare diseases in India present significant challenges due to high treatment costs, limited awareness, and inadequate policy support. Before 2007, awareness among healthcare professionals was minimal, leading to delayed or non-confirmed diagnoses. The absence of government policies, coupled with a lack of awareness among the public, media, policymakers, and even the medical fraternity, posed substantial barriers. Additionally, the high cost of treatment left

many patients without access to necessary care. The lack of national patient advocacy bodies and clinical research further exacerbated the situation, limiting treatment availability for individuals affected by rare diseases.

**Advocacy and Policy Interventions** The establishment of a coalition, Organization for Rare Diseases India (ORDI), played a crucial role in advocating for policy changes. Focused engagement with policymakers in Karnataka led to legal petitions advocating for government intervention. As part of these efforts, alternative treatment access options were explored, including leveraging the public sector and defense establishments to support patients.

Notable milestones include:

- The first government-supported rare disease treatments in Karnataka (2017), benefiting over 300 patients.
- The introduction of the National Rare Disease Policy (NRDP) in 2017, revised in 2021, with treatment implementation beginning in 2023, has benefitted more than 1000 patients.
- Legal actions and judicial interventions that resulted in the Employee State Insurance (ESI) scheme covering rare disease treatments nationwide.

Additionally, the definition of rare diseases was not initially recognized in India, prompting advocacy groups to publish peer-reviewed articles<sup>18</sup> and initiate discussions that ultimately contributed to policy advancements. In 2017, the Indian Council of Medical Research (ICMR) introduced rare disease definition as 'A disease or disorder is defined rare in India when it affects fewer than **1 in 2500 individuals**'. These efforts coincided with the introduction of the Clinical Trial Act and Orphan Drug Act in India. Under the Clinical Trial Rules of 2018, Rule 2(1)(x)<sup>19</sup> defined an orphan drug as one intended to treat conditions affecting fewer than 500,000 individuals in India. These developments further strengthened regulatory frameworks for rare disease treatment.

**Awareness and Public Engagement** Raising public awareness has been instrumental in mobilizing support for rare disease treatment. Strategies include:

- Involvement of public figures and celebrities to amplify messaging.
- The annual "Race for 7" event, conducted across 20 cities, to generate awareness and support for rare disease communities.

### **Policy Challenges and Recommendations**

The National Rare Disease Policy categorizes diseases into three groups:

- **Group 1:** One-time curative treatments such as bone marrow transplants, liver transplants, and renal transplants in rare diseases, with a ₹50 lakh cap, though funding for transplants has yet to be fully implemented.
- **Group 2:** Conditions requiring long-term or lifelong therapy, with annual costs ranging from ₹5-15 lakh.
- **Group 3:** Supportive care for conditions without definitive treatment options, costing ₹50 lakh to ₹1 crore annually.

Currently, 63 conditions are listed under the policy for treatment.

To improve access to costly treatments, the following recommendations should be considered:

1. Strengthening the implementation of government funding for transplants, particularly in private hospitals.
2. Expanding Karnataka's ₹25 crore rare disease budget, which is currently limited to Scheduled Caste/Scheduled Tribe (SC/ST) communities, to include all eligible patients.

### **Recent Developments in Rare Disease Advocacy**

- In 2024, the High Court directed the central government to constitute a National Rare Diseases Fund of ₹974 crore, mandating monthly meetings to monitor the disbursement of funds. Although program rollout has been delayed, continued advocacy efforts are underway to expedite implementation.
- In 2025, ICMR became a co-sponsor for the World Health Organization's (WHO) World Health Assembly (WHA) resolution, thereby elevating India's rare disease advocacy efforts to a global level.

The progress in rare disease advocacy and policy development provides valuable lessons for patient advocacy in organ donation and transplantation programs. Similar to rare disease treatment, organ transplantation faces challenges in accessibility, affordability, and regulatory oversight.

## **Incorporating Justice in Transplantation Policy**

### **Dhvani Mehta**

Co-founder and Lead Health and Medical Law expert - Vidhi Centre for Legal Policy in New Delhi

Organ transplantation policy encompasses a broad range of measures, instruments, and frameworks—both legal and non-legal—implemented by public authorities to regulate and improve organ transplantation. These include legislation, rules, regulations, orders, circulars, programs, and schemes. Organ transplantation policies have been extensively debated, covering specific aspects such as the qualifications of the medical practitioner declaring brain death, and the broader aspects such as -the ethical criteria for constructing waiting lists, eligibility criteria for organ donation and the role of autonomy in determining organ donation preferences. Further considerations include whether the donor pool can be expanded by allowing non-related swap transplants or non-directed donations and whether minors should be permitted to donate organs.

When formulating organ transplantation policy and implementing change, it is crucial to identify the core issues that drive these discussions. A clear understanding of the objectives being advocated for is essential to ensuring transparency and fairness in policy development.

**Justice in Transplantation** Justice, as a philosophical and legal concept, is complex in the context of organ transplantation. Various theoretical frameworks provide different

perspectives on justice, influencing how organ donation and allocation policies are structured.

The Aristotelian concept of justice is traditional and rooted in morality and rightness. This perspective emphasizes the obligations individuals have toward one another within a society. However, applying this to organ transplantation raises fundamental questions: Do individuals have a fundamental right to an organ? Can the need for an organ override another person's right to bodily autonomy? The principle of justice as morality suggests that while society has a responsibility to facilitate access to life-saving treatment, it cannot forcibly require individuals to donate organs, even posthumously. Nevertheless, differing legal systems worldwide have implemented opt-out frameworks for organ donation, reflecting alternative interpretations of societal obligations.

A utilitarian approach to justice seeks to maximize overall well-being. From this perspective, any measure that increases the organ pool could be deemed just, as it promotes the greatest good for the greatest number of people. However, this approach also encounters ethical conflicts. For instance, while a market for organs might theoretically increase both donor and recipient satisfaction, it conflicts with fundamental moral and legal norms that reject the commodification of the human body. Similarly, the inclusion of minors in organ donation may be seen as beneficial under a utilitarian lens, but counterarguments rooted in child welfare and vulnerability prevent such policies from being widely adopted.

Another significant conception of justice is the one proposed by John Rawls, which emphasizes fairness and equity<sup>20</sup>. Rawl's theory suggests that social and economic inequalities should be arranged to benefit the most disadvantaged. His "veil of ignorance" thought experiment, which asks individuals to design policies without knowledge of their own social status, offers a compelling framework for organ allocation. A just system, under this framework, would prioritize need-based allocation. However, practical barriers such as infrastructure limitations, transparency concerns, and sociopolitical biases complicate its implementation.

Justice in organ transplantation is also influenced by regulatory, cultural, and political factors. In some systems, even when an individual expresses a desire to donate, a veto from a family member can override that decision. This raises concerns about the justice of such policies, particularly when they prevent willing donors from contributing to the organ pool. Regulatory limitations, including the absence of clear policies on non-related swap donations, further restrict access to transplantation despite potential utilitarian benefits.

**Addressing the Barriers to Justice** To develop a substantive conception of justice in organ transplantation, several key factors must be addressed. First, comprehensive data collection is necessary to evaluate the effectiveness and fairness of organ distribution. Without clear insights into how organs are allocated, and which populations face systemic disadvantages, discussions on justice remain theoretical rather than actionable.

Second, public discourse on the ethics of organ transplantation must be expanded. Many individuals remain unaware of how organ allocation decisions are made, limiting societal engagement in policy debates. Establishing forums for ethical discussions and increasing transparency in policymaking can foster greater trust and acceptance of reforms aimed at achieving justice.

Furthermore, legislative frameworks should explicitly incorporate principles of justice. The preamble to organ transplantation laws often emphasizes regulation and the prevention of commercial exploitation but lacks a clear articulation of justice as a guiding principle. A more explicit commitment to social, economic, and political justice in transplantation policy can help shape ethical and equitable regulatory reforms.

## Discussions: Access and Justice

**Moderator: Dr Sanjay Nagral**

**Balancing Human Rights and Ethics in Transplantation** An analysis of transplantation reveals its intersection with public health, medicine, human rights, and ethics. A comparative study across six countries underscores the inherent tensions between legal, cultural, and ethical considerations. The central debate revolves around whether transplantation policies should adhere to universal principles or be tailored to specific cultural contexts.

**Perspectives from an Organ Recipient** The lived experience of the recipient provided valuable insights into the ethical and emotional complexities of organ allocation. The recipient emphasized the importance of addressing systemic inequities in organ transplantation beyond the immediate concerns of individual patient care.

**Linking Transplantation to Public Health and Climate Change** The increasing prevalence of chronic kidney disease (CKD) has been linked to broader environmental and public health challenges, including climate change, deforestation, and shifting lifestyle patterns. There is an urgent need to implement preventive measures aimed at mitigating CKD cases, thereby reducing the escalating demand for organ transplantation.

**Cultural and Religious Barriers to Organ Donation** Cultural and religious beliefs play a significant role in shaping organ donation practices. Engaging religious leaders in public discourse is crucial to dispelling misconceptions and fostering greater acceptance of organ donation, particularly in communities where opposition remains prevalent.

**Honoring Organ Donors** A proposal to plant trees in honor of organ donors garnered broad support as a meaningful means of recognizing both donors and their families. This initiative reflects the growing recognition of the ethical responsibility to acknowledge organ donors' contributions.

**Prioritization of Healthcare Resources** Debate surrounding the allocation of limited healthcare resources underscore the ethical dilemmas inherent in balancing priorities. Some argued for directing resources toward childhood malnutrition over high-cost

treatments for rare diseases. However, counterarguments stress that healthcare decisions should not be based solely on cost considerations but rather on the intrinsic value of human life.

**Organ Transplantation for HIV-Positive Individuals** Advancements in medical science have enabled the successful transplantation of organs in HIV-positive individuals, a practice now recognized and implemented in India. This development challenges outdated restrictions and underscores the importance of evidence-based policymaking.

**Economic Barriers and Access** Economic disparities continue to shape access to organ transplantation, often excluding financially disadvantaged patients. Expanding government-funded transplantation programs and increasing public hospital capacity are critical measures to bridge this gap. Pediatric transplants receive significant charitable support, yet post-transplant care remains a persistent challenge due to the prohibitive cost of lifelong medication.

**Public vs. Private Sector Roles in Transplantation** The predominance of private-sector transplants exacerbates accessibility concerns due to prohibitively high costs. The general public perceives transplantation as financially out of reach, except in states like Tamil Nadu, where systemic reforms have improved access. India's transplantation landscape remains an anomaly, operating largely outside a universal healthcare framework, highlighting the need for government intervention and regulation.

**Cost Regulations & Conflicts of Interest** Efforts to regulate transplantation costs remain contentious due to conflicts of interest within the medical community. Past attempts at government cost caps, such as those on essential medicines during the COVID-19 pandemic, faced legal and lobbying resistance from the Indian Medical Association. This underscores the need for citizen and patient driven advocacy to lead efforts to counteract the systemic barriers, rather than the medical fraternity.

**Health Insurance and Financial Support** Despite limited participation from private hospitals in government-subsidized transplants, patients frequently encounter delays in public hospitals, compelling them to seek unaffordable private care. Lack of literacy about health insurance among the middle class, who do not qualify for Government schemes, further exacerbates financial distress. Tamil Nadu and Gujarat have demonstrated improved access through policy interventions, while crowdfunding remains an emergent yet insufficient financial solution.

**Challenges in Government Support** Existing government schemes provide immunosuppressive medications for only two years post-transplant, placing a substantial financial burden on low-income patients. Additionally, a high 30% taxation on imported medical technology further inflates costs, necessitating policy reforms to improve affordability.

**Universal Values in Healthcare** The discussion explored whether "access" and "justice" held the same meaning across cultures. The influence of profit-driven industries in shaping healthcare priorities diverts attention from transplantation toward more

commercially lucrative treatments, such as dialysis. While emerging technologies like xenotransplantation attract significant investment, ensuring equitable resource distribution remains a critical challenge.

**Potential Policy Solutions** Key policy recommendations include-

- The introduction of government-funded long-term immunosuppressive medication support for both public and private sector transplant recipients.
- Centralized state procurement of immunosuppressants to reduce costs.
- Establishing a dedicated national budget for post-transplant care.

**Government's Role in Private Healthcare** Private hospitals depend heavily on government schemes such as CGHS and ECHS for financial stability. The withdrawal of these schemes would challenge private hospitals' sustainability. The Supreme Court's attempt to cap CGHS beneficiary treatment costs was not enforced, highlighting gaps in regulatory oversight.

**Unfair Pricing Disparity** Government-insured patients receive treatment at regulated rates, while uninsured individuals often face significantly higher costs, necessitating a push for uniform pricing structures to prevent exploitation.

**Living Donor Protection** Organ recipients should be required to fund at least five years of health insurance for their donors to ensure financial security, particularly in unrelated transplants. Authorization committees must play a proactive role in safeguarding donor welfare.

**Long-Term Support for Patients Below poverty Line** National Organ Transplant Program presently provides lifelong immunosuppressant support for economically backward patients, albeit with financial caps. Further expansion of these benefits is needed to ensure sustainability.

**Corporate Hospitals and Profit-Driven Models** The shift of private hospitals toward a profit-driven model has diminished charitable care. Despite the promotion of organ donation as a moral imperative, transplantation remains a highly commercialized domain, raising ethical concerns about the commodification of altruistic donations. Regulating transplant costs is essential to mitigating these contradictions and ensuring a more equitable transplantation system.

**Conclusion** The discussions on 'Access and Justice' in organ transplantation highlights a fundamental ethical paradox—the coexistence of altruistic organ donation within a highly commercialized system. This contradiction raises critical questions about fairness, equity, and the influence of market forces on life-saving medical procedures. Addressing this challenge requires systemic reforms that prioritize patient welfare, enhance regulatory oversight, and ensure that financial barriers do not undermine the principles of justice in transplantation. Bridging this gap is essential to establishing a more ethical, transparent, and equitable transplantation framework.

# DONOR AUTONOMY

## Introduction

Donor autonomy is a key ethical principle in organ transplantation, yet many individuals face familial and societal pressure when making donation decisions. Some donors hesitate to express unwillingness until the final evaluation stage, highlighting the challenge of asserting personal choice. Gender disparity further complicates autonomy, with women constituting 80% of kidney donors in India. Cultural norms often discourage female recipients from accepting male donations, reinforcing systemic inequalities. Addressing these issues requires stronger ethical safeguards, counseling, and policy reforms to protect donor autonomy and promote equitable practices.

## A Donor's Dilemma

### Vasundhara Raghavan

Kidney Donor & Founder of Kidney Warriors Foundation

The donor's dilemma extends beyond surgery, encompassing societal expectations, psychological challenges, and the necessity for long-term post-donation care.

Live donor organ donation hinges on three important aspects<sup>21</sup>:

1. **Social Desirability** – Donors, especially women, often feel societal pressure to donate to family members. The expectation that a mother or wife should donate to a child or husband can create an unspoken obligation.
2. **Psychological Evaluation** – Donors should undergo mental health assessments.
3. **Gift Exchange Without Reciprocity** – While one expects the donor to be happy about the donation and that they have saved a life, post-donation realities can be far more complex, with donors receiving little ongoing support.

**Pre- and Post-Transplant Considerations** In India, the decision to donate is often influenced by guilt rather than pure altruism. This raises ethical concerns: Are donors making fully informed choices? Was there a genuine will to donate? or are they subtly coerced by societal and familial expectations?

Post-transplant, the attention shifts entirely to the recipient's recovery, often leaving the donor's long-term medical and psychological well-being largely unaddressed. Many living donors later develop chronic kidney disease (CKD) within a few years, raising critical questions about post-donation care:

- Are donors educated on the importance of hydration and avoiding NSAIDs?
- Do they receive regular medical follow-ups?
- Are they provided with the same level of support as recipients?

Initially, donors are celebrated as heroes for their selflessness. However, soon after the procedure, the focus shifts entirely to the recipient. The donor, too, becomes focused on the recipient's recovery, anxiously watching for signs that the kidney is functioning properly—whether urine production has begun and whether the patient is stabilizing. Given the lengthy recovery process, concern for the recipient naturally takes precedence. Meanwhile, the donor's medical and psychological well-being receives far less attention.

In India, there is limited data on long-term donor health outcomes, necessitating reliance on international studies to understand potential risks and challenges.

Deceased donors often receive more recognition, while living donors are largely overlooked. Organizing dedicated events to honour living donors could highlight their contribution and provide them with the support and appreciation they deserve.

**Physician Bias and Decision-Making** In India, the same physician often oversees both the donor and recipient, potentially leading to bias and undue pressure on donors. A second physician—perhaps a general practitioner—dedicated to donor advocacy could help mitigate this bias.

Studies by Simmons et al.<sup>22</sup> on donor behaviour revealed varying decision-making patterns in organ donation:

- 62% of donors make an automatic decision.
- 23% carefully deliberate.
- 17% remain uncertain.

A personal account highlights the unpredictability of donation: After being approved as a donor for her son, she herself was diagnosed with breast cancer. Following a two-year delay for treatment, she ultimately proceeded with the donation. However, not all donors can or should be expected to make such sacrifices.

International studies show that 15.4% of donors withdraw their consent before surgery<sup>23</sup>. In India, there is no clear protocol on whether a donor's withdrawal is kept confidential. Studies suggest that withdrawal should be framed as a medical reason rather than reluctance, to prevent family pressure or emotional distress<sup>17</sup>.

Just as willing donors receive counseling, those who withdraw should also be supported to ease any feelings of guilt and reinforce their autonomy. With proper guidance, some may even reconsider and choose to proceed with donation.

**Psychological Impact of Organ Donation** Post-donation psychological research highlights several challenges faced by living donors. Studies indicate that 28% of donors report a decline in health-related quality of life<sup>24</sup>, and in rare cases, some have even committed suicide. Additionally, individual cases have revealed severe post-donation consequences, such as unemployment due to health complications and deteriorating relationships between the donor and recipient.

One of the key psychological impact stems from the shifting focus post-transplant. While the recipient receives continuous medical attention and emotional support, the donor often feels isolated and overlooked. Family and doctors primarily monitor the recipient's recovery, while the donor's health and emotional state are frequently neglected. This lack of attention can lead to psychological distress, depression, and, in some cases, poor long-term health management.

India lacks comprehensive data on post-donation complications, making it difficult to assess how many donors develop CKD. As more transplant centers open across smaller cities and towns, the enthusiasm surrounding organ transplantation must be balanced with structured donor care. Establishing proper post-donation health protocols, insurance support, and regular medical check-ups can help ensure donors receive the long-term care they deserve.

## The Gender Question: Beyond Numbers

### Dr Nishtha Mishra

Ex-transplant coordinator, PhD scholar at the Tata Institute of Social Sciences, Mumbai

**Transplant Trends in India** Organ transplantation in India is largely dependent on living donors due to a shortage of deceased donors. Data from the National Organ and Tissue Transplant Organization (NOTTO) in 2022 indicates that 83.15% of transplants were from living donors, while only 16.85% originated from deceased donors<sup>2</sup>. Further statistics highlight a significant gender disparity: 63% of living donors were women, compared to 37% men. This discrepancy underscores the disproportionate burden placed on women within the organ donation framework.

**Sociocultural Influences on Women Donors** The decision-making process surrounding organ donation is heavily influenced by sociocultural factors, particularly in regions where patriarchal norms are deeply entrenched. Research conducted in Rajasthan reveals the extent to which family dynamics, societal expectations, and ingrained gender roles shape organ donation decisions<sup>25</sup>.

**Familial and Social Pressure** Women, particularly daughters-in-law, often lack autonomy when deciding to donate an organ. Family elders, especially mothers-in-law, frequently exert significant influence over these choices. Accounts from donors indicate instances of coercion and emotional manipulation. One participant recounted being explicitly ordered by her mother-in-law to donate an organ to her husband, leaving her with no choice but to comply. Similarly, mothers donating to their children frequently feel a sense of obligation, fearing social judgment if they prioritize their own health over their child's survival.

**Emotional Manipulation and Coercion** Indirect coercion is another factor affecting women's autonomy in organ donation. Emotional abuse, silent treatment, and other psychological pressures often compel women to donate against their genuine desires. One donor described how her in-laws and husband distanced themselves from her after she initially refused to donate, ultimately resulting in her emotional submission.

**Healthcare System Bias** The healthcare system also plays a role in reinforcing these traditional power structures. Medical professionals often engage primarily with male family members, limiting women's ability to make independent, informed decisions. This systemic bias further marginalizes female donors, reducing their agency in critical medical choices.

**Addressing gender disparities in Organ donation** The findings underscore the need for structural changes to ensure equitable and ethical organ donation practices.

Key measures to address these disparities include:

- **Increasing awareness** of gender biases in organ donation.
- **Strengthening institutional safeguards** to guarantee voluntary and informed donor consent.
- **Implementing healthcare policies** that prioritize direct engagement with female donors rather than male family members.

Ensuring ethical organ donation practices necessitates a fundamental shift towards empowering women to make autonomous healthcare decisions free from coercion and societal expectations. Addressing these systemic challenges is essential to fostering a more equitable framework for organ transplantation in India.

## Recipients Speak Part I

### **Jaya Jairam**

Kidney recipient since 2010, Project Director – MOHAN Foundation

**Emotional and Psychological Burden on Recipients** Organ donation presents significant emotional and ethical challenges for both donors and recipients. For recipients, particularly those considering an organ from a family member, the decision can be complex and distressing. In addition to coping with the physical and emotional toll of their ailment, recipients often struggle with concerns about their loved family member's well-being, long-term health, and quality of life. These apprehensions are further compounded by a lack of accessible discussions on transplant success rates, surgical risks, and potential complications.

Access to transparent, data-driven conversations about success rates, quantifiable risks involved, and the experiences of past donors and recipients can help alleviate fear and uncertainty. Structured counselling and peer support networks play a crucial role in easing this burden, empowering donors and recipients to make informed decisions that respect both their health needs and the autonomy of the donor.

**Lack of Support for Donors in the Transplant Process** While the recipients, the doctors and the hospitals benefit from the organ donation and transplantation program, the donor is only stakeholder who does not receive a direct advantage. Donors often experience feelings of isolation—not just post-donation but also during the decision-making process. In the absence of data and support, donor decisions are largely driven by emotions. Family dynamics can create additional pressure, with some members expecting the donor to proceed while others urge caution. This results in donors feeling torn, unsupported, and alone as they navigate the pre-surgery evaluation process. The current system places primary focus on the patient's well-being, which is essential, but it must not come at the cost of reducing the donor to merely a means of saving the recipient.

**Strengthening Donor Evaluation Systems** The appointment of Independent Living Donor Advocates (ILDAs) in every hospital must be mandated to ensure donor rights and protection. These advocates should be free from bias and transplant volume pressures, providing continuous support throughout the donor care continuum—pre-donation, peri-donation, and post-donation. They play a critical role in identifying vulnerable donors, including those facing financial, emotional, social, and cultural pressures. Additionally, donor evaluation should be introduced at the beginning of the process rather than at the final stages when donors may feel too invested to withdraw.

### **Addressing Financial Disincentives for Donors**

The contributions of living donors must be acknowledged and supported through legal and financial protections. Several key financial disincentives must be addressed, including:

1. **Priority Listing on Deceased Donor Waiting Lists:** Ensuring living donors receive priority if they require an organ transplant in the future.
2. **Lifelong Health and Life Insurance Coverage:** Establishing government-backed schemes to prevent increased insurance premiums and outright denials of coverage by private insurers.
3. **Workplace Protections:** Guaranteeing paid leave and job security during and after donation to mitigate economic hardship.
4. **Tax Deductions:** Offsetting donation-related expenses through government-supported tax benefits.

**The Need for Legislative Protections for Donors** As one of the highest transplanting countries globally, India must enact legislation to ensure donor care and protection. The establishment of legal safeguards is essential for enforceability, as the rapid expansion of transplant centers, often driven by commercial interests, necessitates robust checks and balances to protect donors from exploitation.

**The Rationale for Systemic Reforms** Dialysis is a costly alternative to transplantation, imposing financial burdens on both patients and government healthcare programs. Encouraging organ donation is a viable solution, as transplantation offers recipients a significantly improved quality of life compared to dialysis. However, with 83% of transplants in India relying on living donors—63% of whom are women—it is imperative to institutionalize donor support rather than leaving it to individual hospitals.

**Institutionalizing Donor Safeguards** Legal frameworks must be established to protect donor rights, ensuring uniform standards across all healthcare institutions. It is the collective responsibility of society to honour those who make significant sacrifices in the interest of saving lives.

The future of organ donation and transplantation programs depends on a fair, ethical, and supportive system. Without donors, the system cannot function, making their protection an urgent priority.

## **Recipients Speak Part II**

**Viney Kirpal**

Heart Recipient since 2018, Former Professor at IIT Bombay

**The Reality of Organ Transplantation** Every ten minutes, a new patient joins the transplant waiting list, while twenty people die due to a shortage of donor organs. Despite these well-documented statistics, the extraordinary journeys of transplant recipients remain largely untold. Misconceptions about recipient survival and limited awareness of medical advancements discourage potential donors. To demystify transplant life, various narratives have been compiled, featuring inspiring stories of transplant recipients and donors. These narratives explore the struggles of organ failure, the financial and emotional burdens of transplantation, and the lifelong commitment to post-transplant care.

**Stories of Resilience** Several remarkable transplant cases highlight the resilience of both donors and recipients:

- A 57-year-old living donor who gave his kidney to his brother at age 58. A decade later, both are thriving and have won medals at the Transplant Games in Perth.
- A heart transplant recipient from Pakistan pays tribute to the donor by writing letters on each milestone of post-transplant life.
- A recipient who underwent organ transplantation at 26 and has survived 24 years post-transplant despite enduring multiple rejection episodes, CMV infections, and Bell's palsy. She remains a committed professional and a gold medalist at the Transplant Games.

**The Need for Long-Term Healthcare Support** The survival of long-term transplant recipients is largely dependent on sustained medical support. Many recipients have access to ongoing healthcare from specialized medical institutions, underscoring the urgent need for long-term healthcare coverage for all donors and transplant recipients. To truly honor the promise made to donors—ensuring life beyond death—governments must guarantee sustained medical care for both donors and recipients.

**Challenges in Insurance Access** Many transplant recipients face significant barriers in accessing insurance coverage. Policies are often granted on a case-by-case basis with stringent conditions, such as permanent exclusions for transplant-related ailments.

Several solutions have been proposed to address these challenges:

1. **Government-mandated insurance** for transplant recipients to ensure continued medical support.
2. **A public-private partnership (PPP) insurance model** that covers essential post-transplant needs, including medications and diagnostics. Insurance experts have expressed willingness to support such a model if backed by government regulations.

**Humanizing Donors and Recipients** Transplant recipients and donors are often reduced to statistics rather than being recognized as individuals with lifelong medical and emotional needs. In the pursuit of becoming a global leader in transplantation, India must prioritize the dignity and well-being of these individuals. The medical community

and policymakers must recognize that donors and recipients require comprehensive, lifelong care and support beyond the surgical procedure itself.

**Key recommendations** To address these systemic challenges, several key reforms must be implemented:

- **Decentralized Post-Transplant Care:** Physicians across specialties should be trained in transplant recipient management to reduce the burden on major transplant centers.
- **Recipient Identification Cards:** Issuing official ID cards with recipient details to facilitate seamless medical access in emergencies.
- **A Dedicated Government Department:** Establishing a division within NOTTO, NITI Aayog, or the Ministry of Health to address recipient-specific issues, including insurance and post-transplant care.
- **Investment in Research:** Promoting advanced research into immunosuppressants and personalised medications tailored to each individual, so as to minimize organ rejection risks and improve transplant outcomes.

Ensuring lifelong free healthcare, insurance access, localized medical care, recipient ID cards, and a dedicated government body for transplant-related concerns should be considered fundamental rights rather than privileges for transplant recipients and donors. Policymakers must act on these urgent reforms to ensure that those who give and receive the gift of life receive the support they need and deserve.

**“These are not requests; these are our rights.”** – Viney Kirpal

## Transplant Coordinator as a Donor Advocate

**Trilly Mathew**

Director Operations – Alliance for Paired Kidney Donation

The concept of donor advocacy dates back to 1954 when Surgeon Joseph Murray performed the first successful transplant, ensuring the establishment of a separate donor team. However, the significance of donor advocacy gained prominence following the tragic death of a living liver donor in New York in 2002. This event prompted the introduction of donor-specific recommendations aimed at enhancing donor safety and ethical considerations. By 2007, the United States had institutionalized donor advocacy as a mandatory requirement under the policies of the Organ Procurement and Transplantation Network (OPTN). In contrast, India has not yet fully implemented a structured and independent donor advocacy framework, leading to inconsistencies in practice.

### **Donor Advocacy in India**

Donor advocacy in India was introduced as part of the Joint Commission International (JCI) accreditation process<sup>26</sup>, which emphasizes improving patient safety and healthcare quality. Despite JCI's role in promoting donor advocacy, its implementation remains confined to a few large hospitals that hold accreditation. The 8<sup>th</sup> edition of JCI protocols

mandates donor advocacy in accredited institutions; however, it lacks clear directives on who should assume the role of donor advocate. Current practices allow anyone outside the recipient team to act as a donor advocate, resulting in a lack of standardized qualifications and responsibilities.

### **Responsibilities of a Donor Advocate**

A donor advocate plays a crucial role in ensuring ethical, informed and voluntary organ donation<sup>27</sup>. Their responsibilities include:

- **Educating Donors:** Providing comprehensive information on medical evaluation, surgical procedures, risks, complications and long-term implications.
- **Supporting Informed Consent:** Ensuring donors fully understand and voluntarily agree to donation.
- **Psychosocial Evaluation:** Assessing emotional and psychological readiness and addressing concerns.
- **Advocating for Donor's Needs:** Acting independently from the transplant team to provide unbiased support and protect donor interests.

### **Essential Skill set for Donor Advocates**

To perform their duties effectively, donor advocates must possess the following skills<sup>28</sup>:

- Assessment skill – evaluate donor's medical, psychological and social circumstances
- Communication skill – clear and empathetic communication to convey information and address donor's concerns
- Advocacy skills – capability to represent and protect the donor's interests independently
- Cultural competency – sensitivity to cultural and social factors
- Grounding medical ethics – having a strong ethical foundation

### **Can Transplant Coordinators Serve as Donor Advocates?**

Currently, in India, transplant coordinators are often closely attached to or influenced by transplant teams or hospital management. Their roles are primarily administrative, encompassing legal documentation and donor-recipient coordination, rather than independent donor advocacy. They are given limited decision-making power and have limited independence. Transplant coordinators are typically involved after a donor has been deemed medically fit, focusing on legal workup and authorization processes rather than holistic donor support. Additionally, the broad qualifications laid out for transplant coordinators contribute to ambiguity regarding their suitability as donor advocates. While in some parts of the country, hospitals have experienced coordinators engaged in patient counseling and assessment, others employ coordinators for narrowly defined administrative roles.

To function effectively as donor advocates, following reforms are necessary:

- **Independence:** Coordinators must operate without direct influence from hospital management or transplant team.
- **Specialised Training:** Transplant coordinators should receive formal training in donor advocacy, including medical ethics, informed consent, and psychosocial evaluation.

- **Decision-making authority:** They must be empowered to make unbiased recommendations regarding donor suitability and well-being.

### **The Importance of Independence in Donor Advocacy**

An independent donor advocate should possess:

- Comprehensive knowledge of the organ donation process
- Ability to explain potential surgical and long-term complications
- An understanding of family support systems and financial implications
- Expertise in evaluating the donor's medical condition and future health risks

### **Ethical Considerations in Donor Advocacy**

Ethical donor advocacy prioritizes donor welfare, respects their autonomy, and maintains confidentiality. While coercion is often associated with female donors (mothers, wives), male donors in joint family systems may also face pressure due to financial dependencies.

### **Is Donor Advocacy Feasible in India?**

Despite challenges, establishing a structured donor advocacy system in India is feasible. Key reforms necessary for its implementation include:

- Empower transplant coordinators with greater autonomy
- Ensure donor advocates operate free from coercion or conflicts of interest
- Assessing the skill sets of transplant coordinators to determine their suitability for donor advocacy roles
- Defining clear qualifications and standardizing training for donor advocates
- Establish regulatory policies with routine compliance checks

Donor advocacy is a critical aspect of ethical organ transplantation. A well-trained, independent, and empowered transplant coordinator can ensure donor safety and well-being of a living donor. However, systemic changes, policy development, and government intervention are necessary to institutionalize donor advocacy in India.

## **A Nephrologist's Perspective**

### **Dr Noble Gracious**

Nephrologist and Nodal Officer – KSOTTO (Kerala State Organ and Tissue Transplant Organisation), Thiruvananthapuram

Key concerns related to organ donation trends, donor autonomy, and legal challenges in Kerala require careful examination. Despite being one of India's most developed states with high literacy and human development indices, significant gender disparities and ethical concerns persist within the organ donation landscape.

### **Trends in Organ Donation and Transplantation in Kerala**

**Rising Non-related Altruistic Donations** Over the past four years, non-near-relative kidney donations have increased significantly, now accounting for nearly 50% of the

state’s total transplants. This shift poses ethical and regulatory challenges that necessitate closer examination.

Table1: Living Kidney Donor Statistics – Kerala<sup>29</sup>

Nature of donation	2020	2021	2022	2023	2024
Related	280	479	544	554	596
Other than Near Related	241	325	491	457	500

**Gender Disparity in Organ Donation** Despite Kerala’s reputation for gender equality data reveals a stark gender imbalance in organ donation<sup>23</sup>

Table2: Gender Disparity in Living Kidney Donation – Kerala<sup>29</sup>

	2020	2021	2022	2023	2024
Male donor	192	241	353	302	380
Female donors	363	592	718	669	<b>735</b>
Male Recipients	421	639	765	791	845
Female Recipients	134	195	240	252	<b>270</b>

In 2024, the number of female donors (735), were significantly higher than the number of female recipients (270), highlighting a pronounced gender disparity in India’s most developed state.

**Legal Challenges in Organ Transplantation:**

- The Indian organ transplant law, established in 1994, is broadly based on a paternalistic approach towards living kidney donors, often at the expense of donor autonomy.
- Decision-making authority resides with transplant physicians, authorization committees, and government authorities, rather than with the donor themselves.
- While initially relevant in 1994, the law’s primary focus on preventing commercialization has resulted in neglect of ensuring donor autonomy, making a comprehensive review and modernization necessary.
- In cases where authorization committees in Kerala have rejected altruistic donations, donors have frequently approached the courts. Court rulings have often challenged such rejections, emphasizing the ethical principle of respecting individual autonomy and consequentialist moral reasoning.

**Assessment of Donor Autonomy:**

- Many donors lack basic medical knowledge about kidney function, surgical procedures, and long-term risks.
- Informed consent often falls short of being truly informed, as donors may not fully understand the implications of donation.
- The establishment of an independent body to assess donor autonomy and ensure truly informed decision-making is essential.

**Lack of Donor Support and Follow-up:**

- Unlike recipients, organ donors receive minimal post-operative follow-up care.
- Many hospitals lack proper donor-tracking mechanisms.

- Due to high prevalence of non-near-related donations, recipients often lose contact with their donor's post-transplant, underscoring the absence of a structured donor support system.
- Hospitals, physicians, and even recipients fail to take adequate responsibility for donor welfare. This may explain why the current legal framework prioritizes near-relative live donations, as ensuring donor follow-up in other cases remains challenging.

### **Ethical Considerations in Transplantation**

Organ transplantation is unique in that it does not merely restore health to a patient but transforms a healthy individual into a patient.

As one scholar noted:

**“It is the only medical intervention that does not turn a patient into a healthy person but rather turns a healthy person into a patient.”<sup>29</sup>**

Transplant physicians bear a collective ethical responsibility to prevent such adverse outcomes.

Organ transplantation in Kerala faces complex ethical and legal challenges. Ensuring donor autonomy, its assessment mechanisms, whose responsibility is it and ensuring robust systems that ensure the consent is a well informed in the truest sense, are essential to addressing these issues.

## **Discussions: Donor Autonomy**

### **Moderators**

#### **Dr Sumana Navin**

Member DICG, Worked in NGO sector in Organ donation, Member- Forum for Medical Ethics

#### **Sujata Ashtekar**

Senior Transplant Coordinator and Consultant – ROTTO SOTTO Mumbai

### **Gender and Vulnerability in Organ Donation:**

- The Declaration of Istanbul Custodian Group (DICG) emphasizes the need to protect all living donors, recognizing vulnerabilities across genders.
- Women disproportionately serve as donors due to societal norms, while men may experience pressure due to their roles as breadwinners and protectors.
- Some financially dependent men have been coerced into donation, while others have seen the process as an opportunity to negotiate for financial security or property rights.
- With 63% of living organ donors being women, gender disparity remains a significant concern.
- Women may sometimes be preferred as donors due to a lower incidence of conditions like cirrhosis, but there is insufficient research to support this rationale.

- Ethical and public health frameworks must not only prioritize recipient welfare but also recognize and address the social, economic, and gendered vulnerabilities of donors.

### **The Role of Transplant Coordinators in Safeguarding Donor Autonomy**

- Transplant coordinators play a pivotal role in ensuring that all organ donations are voluntary and free from coercion.
- Case studies highlight instances where hospital teams discreetly intervened to protect potential donors facing familial pressure.
- In deceased donation cases, there have been situations where a wife consented to donation, but a relative, such as an uncle, intervened and opposed the decision. Recognizing the potential social repercussions on the wife in a small community setting, the hospital team chose to decline the donation in her best interest.
- Greater investment in education and support programs for deceased donation is necessary to reduce the reliance on living donors.
- It was reiterated that organ donation is a sacred act—one that must be entirely voluntary, free from direct, indirect, or societal coercion.

### **Sharings by Deceased Donor Families**

#### **Need for Recognition & Support:**

- Donor families emphasized the need for institutional support, including improved healthcare access and symbolic recognition for their contributions.
- Suggestions included government-established memorial parks, where trees could be planted in honor of organ donors, providing families with a meaningful space for remembrance and emotional connection.

#### **Emotional & Logistical Challenges in Organ Donation:**

- Transplant coordinators often face significant challenges when approaching grieving families for organ donation, as they must navigate complex emotional and ethical considerations.
- In one case, a family attempting to transfer their brain-dead son from a private hospital to a government facility encountered severe obstacles. They were denied access to a ventilator-equipped ambulance, and hospital staff even reclaimed the deceased's clothing. Such bureaucratic and logistical barriers only exacerbated the distress of an already traumatic experience, highlighting the urgent need for clearer protocols and more compassionate support systems.

#### **Advocacy for Policy Changes:**

- There were strong calls for government policies that provide donor families with healthcare benefits, insurance provisions, and formal social recognition.
- Systemic reforms must be implemented to ensure donor families are treated with dignity and supported through comprehensive healthcare and policy interventions.

The discussions reiterated the urgent need for ethical and systemic changes to better support both deceased and living donors. While organ donation is an extraordinary act of generosity, the current framework must evolve to ensure that donor families receive the recognition, respect, and assistance they deserve.

## Reflections and Conclusions

Transplantation requires heightened ethical scrutiny, as it hinges on the altruism of donors. The act of asking individuals to donate organs is inherently challenging, and it demands the establishment of higher standards to ensure that this altruism is respected and protected. The ethical framework surrounding organ donation must evolve to keep pace with these complexities.

### **Dr Thomas Mueller; co chair; DICG**

Reflecting on the progress made, gratitude was expressed for the opportunity to engage in such an enriching discussion. The value of diverse perspectives in shaping the future of transplantation and organ donation was emphasized.

While acknowledging the ongoing challenges within the field, it was highlighted that significant strides have been made. Even small acts, such as ensuring the dignity of donors throughout the donation process, can have a profound and lasting impact. Central to this effort is the need to keep donors at the heart of the transplant system. Long-term follow-ups to ensure the well-being of living donors were advocated, with examples drawn from global experiences where living donation, when done correctly, is both safe and meaningful.

The importance of prioritizing deceased donation was also underscored, recognizing the emotional burden it places on families. However, it was emphasized that organ donation, despite these challenges, offers a powerful and lasting legacy for both donors and recipients.

The discussion on access, justice, and autonomy was particularly insightful, with gender disparities and coercion identified as critical issues that must be addressed globally. A concerted effort is needed to create a more equitable and transparent system that addresses these issues, ensuring that all individuals—regardless of gender, socio-economic status, or geographic location—are treated with dignity and fairness.

In closing, tribute was paid to the co-chair of the Declaration of Istanbul Custodian Group (DICG), acknowledging his invaluable contributions and lasting impact on the field.

### **Concluding remarks; Dr Samiran Nundy**

Back in the nineties, the lawmakers envisioned liver transplantation as a procedure that would predominantly rely on whole livers being taken from deceased donors. The present reality is that vast number of liver transplants are being done from living donors, with India

being at the top in living donor liver transplants in the world, and third largest overall. Also, it was originally envisaged that all transplants will take place in public hospitals and the present reality is that 97% of liver transplants are done in private hospitals.

Concerns were highlighted regarding potential corruption within the transplant sector, with some hospitals performing up to 60% of living donor liver transplants for foreign patients. This trend warrants closer scrutiny to ensure that ethical standards are maintained across the system.

Despite these challenges, significant advancements in surgery, anesthesia, blood transfusion, and hepatology have been acknowledged, particularly following the enactment of the Transplantation of Human Organs Act. However, these advancements have not come without their costs, especially in a healthcare system where 60-70% of transplant-related expenses are borne out-of-pocket, leaving many families in financial distress.

It was emphasized that transplantation needs to be evaluated within the context of the broader healthcare system, with ongoing dialogue and meaningful progress needed to ensure that it remains ethical, equitable, and sustainable. The hope is that future conversations will continue to address these challenges, paving the way for reforms that benefit both patients and the healthcare system as a whole.

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