

Evolving Frameworks: A Narrative Review of National and Global Policies on Organ Donation and Transplantation

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ABSTRACT

Organ donation is a life-saving intervention; however, a global shortage of organs persists due to various medical, legal, ethical, and social factors. Policies governing organ donation play a pivotal role in shaping public attitudes, regulating practices, and improving donation rates. A narrative review approach was used to analyse national and international policies, acts, and regulatory frameworks related to organ donation. Sources included government documents, published literature, and reports from transplant organisations. Presumed consent policies, national registries, and centralised allocation systems have led to higher donation rates in several developed countries. In contrast, countries with opt-in systems often face challenges related to public awareness, infrastructure, and legal enforcement. India's Transplantation of Human Organs Act (1994) laid the groundwork for legal organ transplantation; however, ongoing challenges include low deceased donation rates and the persistence of illegal organ trade. Effective organ donation policies require a balance of legal regulation, ethical safeguards, public engagement, and medical infrastructure. Strengthening policy implementation, promoting deceased donation, and ensuring transparency are essential steps toward improving organ donation systems globally and within India. The present review aimed to examine organ donation policies across different countries, with a focus on their structure, effectiveness, and implementation. It also highlights the evolution and impact of policies in the Indian context.

Keywords: Deceased donor, Health policy, National organ and tissue transplant organisation, Presumed consent, Transplantation law

INTRODUCTION

Organ transplantation represents one of the most remarkable achievements of modern medicine and remains the most effective and cost-efficient life-saving treatment for patients with end-stage organ failure [1,2]. It improves patient survival and quality of life and has a significant beneficial impact on public health as well as on the socioeconomic burden of organ failure [3].

In recent years, outcomes of human organ transplantation have improved due to advancements in surgical techniques, organ preservation, immunosuppression, and antimicrobial therapies [4]. However, its practice necessitates a robust legal and ethical framework to ensure the protection and dignity of donors, recipients, and their families [1].

The World Health Assembly (WHA) has adopted two key resolutions and a guidance document regarding the availability, safety, and appropriate use of organs and tissues: the resolutions on Human Organ and Tissue Transplantation (WHA57.18 and WHA63.22), and the accompanying document World Health Organisation (WHO) Guiding Principles on Human Cell, Tissue, and Organ Transplantation [4].

Clinical transplantation has been proven to be a life-saving intervention [5]. According to the Global Observatory on Donation and Transplantation, 140,964 organ transplants were performed worldwide in 2018 [2]. In 2017, kidneys and livers were the most commonly transplanted organs, while small bowel transplants were the least frequent [6].

Organ donation is typically categorised into two main types based on the donor-recipient relationship: specified and unspecified donations. A specified donation involves a known recipient to whom the donor is genetically and/or emotionally connected. For example, a spouse donating a kidney to their partner constitutes a specified direct donation. Donation to a known recipient through an exchange

program is considered a specified indirect donation. In contrast, an unspecified donation refers to a donation made to an anonymous recipient who is selected from a fixed waiting list [2,7].

Globally, there is a significant shortage of donor organs compared to the number of patients awaiting transplantation. In fact, only 1-2% of all deaths meet the medical criteria necessary for organ donation, highlighting the critical gap between potential donors and transplant needs [8]. In India, recent data indicate that the organ donation rate remains among the lowest worldwide, underscoring a substantial disparity in meeting the needs of patients awaiting transplantation [9].

India performs approximately 17,000 to 18,000 solid organ transplants annually, ranking third globally after the United States and China. Notable progress has been made in areas such as deceased donor organ harvesting, with the average number of organs retrieved per donor increasing from 2.43 in 2016 to 3.05 in 2022 [10]. Nevertheless, the majority of these procedures are carried out in the private healthcare sector, rendering them financially inaccessible to a large portion of the population. Although India has made significant strides in organ transplantation- particularly in the field of nephrology over the past five to six decades- challenges related to inclusivity and equitable access remain pressing [10].

Several challenges complicate the process of organ donation, including medical contraindications (such as infections or chronic health conditions), policy-related issues (such as reimbursement procedures), and lengthy waiting periods, including a 3-5 year wait time for kidney transplants [11,12]. Among these challenges, organ shortages remain one of the most critical barriers to successful transplantation. This shortage is evident in global statistics: in 2015, 74.63% of transplant candidates in the United States did not receive a transplant, while in the United Kingdom, 19.89% faced the same outcome in 2018 [2].

Despite significant medical advancements that enable hundreds of thousands of solid organ and tissue transplants each year,

the WHO estimates that less than 10% of the global demand for transplants is met annually [13]. In addition to limiting access to life-saving procedures, the scarcity of organ donation opportunities also deprives grieving families of the potential comfort and sense of purpose that this altruistic act can provide in the aftermath of a loved one's death [14].

The legal systems governing organ and tissue procurement vary significantly across countries, reflecting differences in cultural values, ethical perspectives, and public health strategies. A central component of these frameworks is the consent system used to authorise organ donation. There are two primary models of consent: opt-in and opt-out [1].

In an opt-out system, all individuals are presumed to consent to organ donation after death unless they have explicitly stated otherwise. Those who do not wish to donate must record their decision in a national opt-out registry while alive; if they fail to do so, consent is assumed. Conversely, in an opt-in system, individuals must explicitly express their willingness to donate organs after death. No one is considered a donor unless they have provided formal consent, usually by registering in an official donor database [15].

Both systems present ethical, cultural, and practical implications that influence donation rates and public trust in the organ procurement process. Understanding how these systems are implemented and perceived is essential for evaluating their effectiveness and ensuring ethical integrity in transplantation practices [1].

For many years, the international transplant community has actively debated the advantages of shifting from default opt-in systems to opt-out policies, with the goal of increasing organ donor numbers and more effectively addressing the growing demand for life-saving transplants [15].

The present review aimed to investigate global disparities in organ transplantation ethics, laws, and policies, and to assess their implications for practice and policymaking.

DISCUSSION

Historical Evolution of Organ Donation/Milestones in Transplantation History

Solid organ transplantation represents one of the most remarkable and transformative therapeutic advances in medicine over the past 60 years [16-18]. Human beings have long demonstrated an interest in the transplantation of tissues from one anatomical site to another-either within the same individual or between different individuals-for cosmetic, reconstructive, or therapeutic purposes. Although not directly linked to the premodern or modern eras of organ transplantation, intriguing descriptions in mythological, religious, and historical literature, as well as archaeological records, allude to the concept of tissue transplantation dating back several millennia [19].

The history of solid organ transplantation is characterised by alternating phases of progress and setbacks over the past century [Table/Fig-1] [20].

Year	Event
1901	First dog to dog kidney transplantation
1906	First two renal transplantations in humans
1910	First xenotransplantation in humans
1939	First transplantation from a deceased human donor
1954	First long-term successful living donor kidney transplantation
1962	First unrelated living donor kidney transplantation
1979	First living donor segmental pancreas transplantation
1988	First living donor liver transplantation
1992	First living donor lobar lung transplantation
1993	First successful adult-to-adult living donor liver transplant using the left hemiliver
1995	First laparoscopic liver donor nephrectomy

1996	First successful adult-to-adult living donor liver transplant using a right lobe graft, and the first living donor intestinal transplantation
1999	First minimally invasive donor distal pancreatectomy
2001	First simultaneous minimally invasive living donor nephrectomy and distal pancreatectomy First living donor uterus transplantation
2002	First robot-assisted living donor nephrectomy First total laparoscopic left hepatectomy
2006	First robot-assisted living donor distal pancreatectomy and nephrectomy
2012	First minimally invasive whole pancreas transplantation

[Table/Fig-1]: A timeline with all the milestones that mark the history of living donor transplantation [20].

Ethical and Legal Considerations in Organ Donation and Transplantation

Complex ethical and legal considerations increasingly shape the field of organ transplantation. The persistent global shortage of donor organs-combined with rapid advancements in medical technology, evolving geopolitical contexts, and changing socio-economic conditions has led to a wide range of ethical dilemmas and legal challenges [21-23]. These developments demand continuous vigilance and adaptability from professionals involved in transplantation to ensure that practices remain both morally sound and legally compliant [22,23].

This issue remains one of the most pressing health policy challenges faced by governments worldwide. In response, some researchers have proposed shifting organ donation laws from an informed consent (opt-in) model to a presumed consent (opt-out) system as a potential strategy to address the persistent shortage of donor organs [24].

In addition to limited global access, organ donation and transplantation activity vary significantly between countries, even among those with comparable socioeconomic conditions and healthcare infrastructures. Notably, some countries with well-funded universal healthcare systems and decades of transplantation experience still report among the lowest donation rates [25]. This variability has prompted numerous reform efforts; however, commonly proposed solutions-such as expanding donor registries or altering consent models-often lack robust empirical evidence supporting their effectiveness [25,26].

Organ Donation Policies: Opt-Out vs. Opt-In

Opt-in (Express consent): The opt-in system, also known as explicit consent, requires individuals to actively express their willingness to donate organs-either by registering with an official donor registry, informing family members, designating a representative, or including their wishes in a testamentary document. This system relies heavily on public awareness and individual initiative. Countries such as Brazil and the United States follow the opt-in approach, emphasising the importance of personal autonomy and informed consent [1].

Opt-out (Presumed consent): Conversely, the opt-out system, or presumed consent model, operates under the assumption that all individuals are willing organ donors unless they have explicitly stated otherwise during their lifetime. Those who wish to decline participation must formally register their objection to be excluded from the donor pool. This model is based on a public health perspective that prioritises maximising donor availability while still respecting individual autonomy and personal choice [1].

Opt-out systems are widely regarded as a promising strategy to address the global organ shortage by presuming individuals to be willing donors unless they have actively opted out. However, the practical effectiveness of these policies is often limited. A recent study found that in 21 of 25 countries with opt-out systems, families could still refuse donation even if the deceased was presumed to have consented. This highlights a critical gap between policy design and real-world implementation, where familial consent continues to play a decisive role [27].

The “soft” opt-out policy implemented in Wales, UK, in 2015, and the system used in Spain, serve as prominent examples of presumed consent models designed to increase organ donation rates [8]. While such policies have shown positive outcomes in some regions, they have also faced criticism. For instance, Brazil and Singapore initially reported a decline in donation rates following the adoption of opt-out systems. However, retrospective analyses later revealed a positive trend in donation rates over time [8].

In contrast, Japan’s adoption of a similar model in 2010 did not lead to the expected increase in deceased donor transplants, likely because Japan relies heavily on living donor transplantation. As of December 31, 2014, a total of 7,937 liver transplants had been performed across 67 Institutions in Japan, including 7,673 living donor transplants and 264 Deceased Donor Liver Transplantations (DDLTs)-261 from heart-beating donors and three from non heart-beating donors [28]. By comparison, in the United States in 2013, 15,000 patients were on the waiting list, with 252 living donor and 6,203 deceased donor liver transplants performed [Table/Fig-2] [29].

Opt-out consent system	Opt-in consent system
Argentina, Austria, Belarus, Belgium, Bulgaria, Colombia, Costa Rica, Croatia, Czech Republic, Ecuador, Finland, France, Greece, Hungary, Republic of Ireland, Italy, Latvia, Panama, Poland, Portugal, Russia, Singapore, Slovakia, Republic, Spain, Sweden, Tunisia	Australia, Brazil, Canada, Cuba, Denmark, Germany, Guatemala, Hong Kong, India, Republic of Ireland, Israel, Japan, Lebanon, Lithuania, Malaysia, Mexico, The Netherlands, New Zealand, Puerto Rico, Romania, Taiwan, UK, USA, Venezuela

[Table/Fig-2]: Countries with opt-out and opt-in consent system [29].

Global Policies and Programs on Organ Donation

The National Organ Transplant Act (NOTA), enacted in the United States in 1984, is a key piece of legislation governing organ donation and transplantation. It establishes ethical principles and regulatory requirements designed to ensure fairness, prevent commercialisation, and promote public trust in the transplantation system [30].

The Eurotransplant International Foundation is a non-profit organisation that facilitates and coordinates the allocation and distribution of donor organs for transplantation across several European countries [31]. As of 2007, Eurotransplant comprised seven member countries-Austria, Belgium, Croatia (which joined in 2007), Germany, Luxembourg, the Netherlands, and Slovenia. These countries agreed to share organs and transplant-related information through a centralised system managed by Eurotransplant [31].

Countries with a high yield of cadaveric (deceased) organ donors tend to rely less on living donors. For example, nations such as Spain, Austria, Belgium, and Finland have well-established deceased donation systems and therefore make relatively limited use of living donors. In contrast, countries where cadaveric donation rates have remained stagnant-such as Germany, the Netherlands, Sweden, and the United Kingdom-often compensate for the shortfall with living donor transplants [22]. Furthermore, some countries, including Turkey, Greece, Bulgaria, and Romania, rely almost exclusively on living donors due to underdeveloped organisational infrastructure and limited capacity to manage cadaveric donation programmes [22].

Barriers and Outcome policies: Europe currently employs a combination of opt-in (explicit consent) and opt-out (presumed consent) systems for organ donation. To address disparities and promote equitable access, several countries have introduced targeted initiatives to increase organ donation among minority communities, who often exhibit lower donation rates despite a higher prevalence of organ failure. For example, the United Kingdom and the Netherlands have implemented education and awareness programmes specifically designed for Hindu and Islamic communities, aiming to address cultural, religious, and informational barriers to donation [22].

From a human rights perspective, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) affirms

the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. General Comment No. 14 of the ICESCR further asserts that states have a “minimum core obligation” to protect individuals from third-party violations of this right, including those arising from organ trafficking and unethical transplantation practices. Therefore, a state’s failure to prevent such exploitation could be construed as a violation of its international obligations under the ICESCR [32].

Following Wales, which introduced a “soft” opt-out organ donation system in 2015, England passed similar legislation in 2019, which came into effect in May 2020 [33]. According to the International Registry in Organ Donation and Transplantation (IRODaT), eight out of the top 10 countries with the highest number of deceased organ donations in 2022 operated under an opt-out system [33]. In Europe, 19 of the 27 European Union member states currently follow an opt-out model, including those with the highest donation rates [34]. For instance, Iceland adopted an opt-out system in 2018 and, by 2022, had progressed from a mid-to-low position in global rankings to being among the countries with the highest organ donation rates [34].

National policies and programs on organ donation: With the rising incidence of illegal organ transplants, there was increasing pressure on the Indian government to implement regulatory measures. In response, the Government of India enacted the Transplantation of Human Organs Act (THOA) in 1994 [35]. This legislation made unrelated transplants illegal and legally recognised deceased organ donation, including the acceptance of brain death as a valid criterion for organ retrieval [36].

Despite the enactment of the Transplantation of Human Organs (THO) Act in 1994 to regulate organ transplantation and promote ethical practices, its effectiveness remained limited. This was primarily due to the misinterpretation of its provisions and poor implementation by many hospitals, which hindered its potential to curb illegal transplants and promote deceased organ donation [36].

In response to global concerns, the WHA issued the Guiding Principles on Human Cell, Tissue, and Organ Transplantation in 2010, aimed at promoting ethical governance and safeguarding the right to health through a regulated transplantation framework [32]. In India, this led to the enactment of the Transplantation of Human Organs and Tissues Act (THOTA), 1994, which provides a comprehensive legal framework for regulating both living and deceased organ donation. The Act explicitly prohibits the commercial trade of human organs and tissues, thereby aiming to curb exploitation and promote equitable access to transplantation [32].

Further reinforcing global standards, the Declaration of Istanbul (2008) formally defined organ trafficking as involving the recruitment, transport, transfer, harbouring, or receipt of living or deceased persons or their organs through coercion, fraud, or financial inducement-constituting a grave violation of ethical and legal norms. These frameworks collectively underscore the necessity for legally sound, ethically guided, and socially just systems of organ donation and transplantation [32].

Public Awareness and Educational Policies

As we progress further into the 21st century, the mortality rate among patients on transplant waiting lists continues to rise each year. A key contributor to this ongoing crisis is the persistent shortage of organ donations [37]. In examining the causes of public reluctance to donate, it becomes crucial to assess the effectiveness of social education programs. Despite growing recognition of the need for a revised and more nuanced approach, these programs have remained largely unchanged for decades. Public campaigns still predominantly revolve around the traditional slogan that organ donation is a “gift of life,” a message that, while powerful, may no longer be sufficient to address the complex emotional, cultural, and informational barriers influencing donation decisions [38].

In Brazil, the Unified Health System (SUS) supports one of the world's largest public transplantation programs, yet national demand remains unmet- primarily due to high family refusal rates, as consent is legally required for organ donation. These refusals are often linked to a lack of knowledge or unawareness of the donor's wishes. Addressing this challenge requires open dialogue about brain death, transparency in the donation process, and emotional support for families.

Schools play a crucial role in this effort, as adolescents and young people can become influential advocates, sharing accurate information within their communities. Educational strategies that promote critical and reflective discussions, while acknowledging the emotional complexities of the topic, can foster greater acceptance and potentially increase organ and tissue donation rates [39].

Advertisements and promotional materials related to organ and tissue donation were most frequently encountered through television (43.4%), followed by materials and posts in hospitals or public health centres (39.4%), and internet media such as blogs, cafés, social networking services, and YouTube (31.3%). Strategies considered most effective for improving public awareness of deceased organ and tissue donation included enhancing courtesy and support for organ donors and their families (29.3%), educational activities for students at various levels (27.8%), television programs (23.2%), and online activities (13.1%) [40].

Public education on organ donation and transplantation remains a highly effective strategy to increase awareness of this life-saving practice. Research indicates that children are particularly receptive to learning about these topics. Collaborative international efforts have led to the creation of "Connecting DOTS" (Donation and Organ Transplantation for Schools)- a free online platform developed by The Transplantation Society, offering tailored modules for students, teachers, and parents [41].

CONCLUSION(S)

Organ donation policies worldwide are shaped by a combination of legal, ethical, cultural, and infrastructural factors. While presumed consent models, national registries, and regulatory bodies have contributed to increased donation rates, long-term success depends on maintaining public trust and ensuring equitable access. In India, the Transplantation of Human Organs Act (1994) provided a legal foundation for ethical organ transplantation. However, stronger deceased donor programs, improved infrastructure through National Organ and Tissue Transplant Organisation (NOTTO)/State Organ and Tissue Transplant Organisation (SOTTO), and enhanced public engagement are still required. A coordinated, ethical, and culturally sensitive approach is essential to bridge the demand-supply gap and safeguard the rights of both donors and recipients.

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