

Original Research

A Comparative Analysis of Kidney Donation Regulations and Ethics in Spain, the USA, and Iran: Lessons for the Indonesian Transplantation Framework

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ABSTRACT

Background: Inequitable access to kidney donors remains a global challenge, including in Indonesia, where kidney transplantation is received by only approximately 1% of patients with end-stage renal disease (ESRD). **Comparative analyses** of different kidney donation regulatory models and their ethical implications for Indonesia remain limited. **Objective:** To compare kidney donation regulations and ethical frameworks in Spain (opt-out, where individuals are considered donors unless they explicitly refuse), the United States (opt-in, where individuals voluntarily register as donors), and Iran (regulated compensation), and to assess their relevance to the Indonesian context. **Methods:** A narrative literature review employing comparative thematic analysis was conducted using 12 articles published between 2015 and 2025. **Results:** The effectiveness of kidney donation systems depends not only on legal frameworks but also on their implementation, public trust, donor protection, and transparency. Spain achieved high participation rates through a coordinated opt-out system supported by strong public education initiatives. The United States emphasizes individual autonomy through voluntary donor registration but continues to face challenges related to equitable organ distribution. Iran has increased donor availability through a regulated compensation system, although ethical concerns regarding equity and potential exploitation persist. **Conclusion:** No single kidney donation model is universally applicable. Indonesia requires a context-specific transplantation framework that integrates ethical principles, sociocultural values, and institutional capacity while emphasizing public education, transparency, and donor protection.

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INTRODUCTION

Kidney transplantation is considered the definitive treatment for patients with end-stage renal disease (ESRD) because it has been shown to be more effective in reducing mortality and improving quality of life compared with long-term dialysis (Chadban et al., 2020). Globally, the number of kidney transplants exceeds 150,000 procedures annually; however, this increase has not kept pace with the growing number of patients requiring transplantation (Global Observatory on Donation and Transplantation [GODT], 2024). In the United States, 23,401 kidney transplants were performed in 2019 (GODT, 2024). In contrast, kidney transplantation remains relatively uncommon in Indonesia, accounting for only approximately 1% of patients with ESRD nationwide (Indonesian Renal Registry, 2018). Clinical data indicate that only 491 kidney transplants were performed in Jakarta over a seven-year period (Marbun et al., 2017). Meanwhile, a report from Siloam Hospitals Asri noted that more than 500 kidney transplants have been performed, all involving living donors (Alam, 2026). This imbalance between demand and donor availability reflects an ongoing organ donor shortage that remains a global challenge and contributes to high mortality rates among patients on transplant waiting lists (World Health Organization [WHO], 2023).

The limited availability of donors is closely related to the organ donation system implemented in transplantation practice. In general, kidney donors are divided into two main categories: living donors and deceased donors (Van Arendonk et al., 2015). Deceased donors require a clear registration system, family consent procedures, and a transparent and equitable organ allocation mechanism. In contrast, living donors require robust donor protection and strict oversight to prevent organ trafficking and ensure donor safety (Van Arendonk et al., 2015). From a bioethical perspective, organ transplantation must be guided by four fundamental principles: autonomy, justice, beneficence, and nonmaleficence (Martinelli et al., 2024). Therefore, the development of a strong and ethical organ donation system is essential for maintaining the sustainability of transplantation programs and protecting the rights of both donors and recipients (Delmonico et al., 2011).

Various countries have adopted different policy approaches to organ donation, shaped by their legal frameworks, cultural values, and healthcare systems. Spain is recognized as having one of the highest organ donation rates in the world, with approximately 46 donors per million population. This achievement is largely attributed to its opt-out system, in which individuals are presumed to be donors unless they formally register their refusal before

death (Organización Nacional de Trasplantes, 2023). In contrast, the United States employs an opt-in system that requires individuals to voluntarily register as organ donors. To encourage living donation, the U.S. government also provides support in the form of travel assistance and reimbursement for lost wages during the recovery period (United Network for Organ Sharing, 2023).

Meanwhile, Iran has adopted a different approach by allowing regulated financial compensation for living kidney donors. This policy makes Iran the only country that legally permits direct monetary incentives for kidney donation and has reportedly eliminated the kidney transplant waiting list (Ghods & Savaj, 2006). However, this model remains controversial because of concerns regarding the potential exploitation of socially and economically vulnerable populations (Ghods & Savaj, 2006).

In Indonesia, the development of a kidney transplantation system continues to face various structural and social challenges. Kidney transplantation is estimated to meet less than 5% of the needs of patients with ESRD who require this therapy (Supit et al., 2019). The low transplantation rate is influenced by several factors, including limited public awareness of organ donation, a suboptimal national donor registration system, and the absence of comprehensive policies supporting living donors. In addition, the potential for illegal organ trafficking remains a concern, highlighting the need for stronger regulation and ethical oversight within the transplantation system (Kusumawati, 2024). Although Indonesia has established a legal framework through Health Law No. 17 of 2023 and Government Regulation No. 53 of 2021 concerning Organ and Tissue Transplantation, the current system remains largely based on explicit donor consent and prohibits any form of commercial organ transaction (Government Regulation of the Republic of Indonesia Number 53 of 2021 Concerning Organ and Tissue Transplantation, 2021; Law of the Republic of Indonesia Number 17 of 2023 Concerning Health, 2023). Consequently, the implementation of alternative models such as presumed consent (opt-out) or compensated donation faces substantial legal, ethical, and sociocultural challenges. These constraints highlight the importance of examining international experiences to identify policy approaches that may be adapted to the Indonesian context. Based on these considerations, this literature review aims to analyze and compare the regulatory systems and ethical approaches to kidney donation in three countries with distinct policy models: Spain, the United States, and Iran. This analysis is expected to provide a more comprehensive understanding of international approaches to kidney donor management and identify best practices that may inform the development of Indonesia's kidney transplantation system. In addition, this study is expected to contribute to the development of more ethical, effective, and sustainable

transplantation policies while taking into account social and cultural values as well as the safety of both donors and recipients.

METHOD

This study employed a narrative literature review with comparative thematic analysis to evaluate regulatory and ethical approaches to kidney donation in Spain, the United States, and Iran. These countries were purposively selected because they represent three contrasting policy models frequently discussed in the transplantation literature: a solidarity-based opt-out system (Spain), a voluntary opt-in system (the United States), and a regulated compensation system (Iran) (Ghods & Savaj, 2006; Matesanz et al., 2017; Shimazono, 2007). Beyond their policy differences, these countries were considered relevant to Indonesia because they address key challenges also faced by the Indonesian transplantation system, including donor shortages, ethical concerns regarding living donation, public acceptance of organ donation, and the need for effective regulatory oversight. Furthermore, these three models offer distinct perspectives on balancing autonomy, justice, donor protection, and societal responsibility, which are central considerations in developing a sustainable and ethically acceptable kidney donation framework in Indonesia. A narrative review approach was chosen because it enables an in-depth exploration of policy contexts, sociocultural influences, and ethical dimensions that shape transplantation practices across different healthcare systems (Greenhalgh et al., 2005).

The literature search was conducted in major electronic databases, including PubMed, Scopus, ScienceDirect, and Google Scholar. The search was supplemented with official policy documents from international organizations and relevant institutions, such as the WHO, GODT, ONT, UNOS, and the Iranian Society of Organ Transplantation (Global Observatory on Donation and Transplantation (GODT), 2024; Organización Nacional de Trasplantes, 2023; United Network for Organ Sharing, 2023; World Health Organization, 2023). The search strategy used the keywords “kidney donation,” “organ transplant policy,” “ethics of organ donation,” “Spain opt-out system,” “Iran kidney market,” “UNOS kidney allocation,” and “transplant regulation in Indonesia,” combined with Boolean operators (AND, OR, NOT) to optimize search results (Booth et al., 2016).

The inclusion criteria comprised scientific articles and policy documents discussing regulatory and/or ethical aspects of kidney transplantation, available in full text, published in English or Indonesian, and published within the last ten years. Eligible publication types included review articles, qualitative studies, quantitative studies, and reports from international organizations. Seminal publications published before the predefined eligibility period were retained when considered essential for explaining the historical development, regulatory evolution, and ethical foundations of national kidney donation policies. Exclusion criteria included gray literature (e.g., theses and dissertations), articles focusing solely on clinical or

technical aspects without addressing ethical or policy dimensions, and duplicate publications.

The selection process involved title and abstract screening followed by full-text eligibility assessment. The identification, screening, eligibility, and inclusion stages were documented using a PRISMA-style flow diagram to enhance transparency in the literature selection process (Moher et al., 2009; Page MJ et al., 2020). As this study employed a narrative literature review approach, a formal quality appraisal tool was not applied. Nevertheless, efforts were made to ensure the credibility of the evidence by including peer-reviewed publications, official policy documents, and internationally recognized reports that met the predefined inclusion criteria.

Eligible articles were analyzed using content analysis. Extracted data included donor system models, donor protection mechanisms, equity in organ allocation, and the ethical principles underpinning kidney donation policies in each country (Tong et al., 2012). Quantitative indicators, such as donation rates per million population and annual transplant numbers, were used to support the descriptive comparative analysis (Global Observatory on Donation and Transplantation (GODT), 2024; Organización Nacional de Trasplantes, 2023; United Network for Organ Sharing, 2023).

To enhance validity, source triangulation was conducted by comparing findings from peer-reviewed scientific articles with official policy documents and reports issued by national and international transplantation authorities (Patton, 1999). Information regarding donor regulations, ethical principles, organ allocation systems, and donor protection mechanisms was cross-checked across multiple sources to verify consistency and identify potential discrepancies. In addition, findings were compared across the three countries to ensure that policy interpretations were supported by both empirical evidence and official regulatory frameworks.

RESULT

A total of 12 articles met the inclusion criteria and were included in the final analysis. The study selection process consisted of identification, screening, eligibility assessment, and inclusion stages, as summarized in Figure 1. From an initial 1,248 records identified through database searches and supplementary policy sources, 312 duplicate records were removed, leaving 936 records for title and abstract screening. Following screening, 124 articles underwent full-text eligibility assessment, and 12 studies were ultimately included in the review. These studies represented three countries with distinct approaches to kidney donation regulation and ethics: Spain ($n = 4$), the United States ($n = 4$), and Iran ($n = 4$).

Thematic analysis of the included studies identified four overarching themes: (1) regulatory models of kidney donation, (2) ethical principles underpinning donation policies, (3) donor protection and safeguarding mechanisms, and (4) equity and access in organ allocation. These themes served as the analytical framework for comparing kidney donation systems across the three

countries and for identifying policy implications relevant to Indonesia. The characteristics and key findings of the included studies are summarized in Table 1.

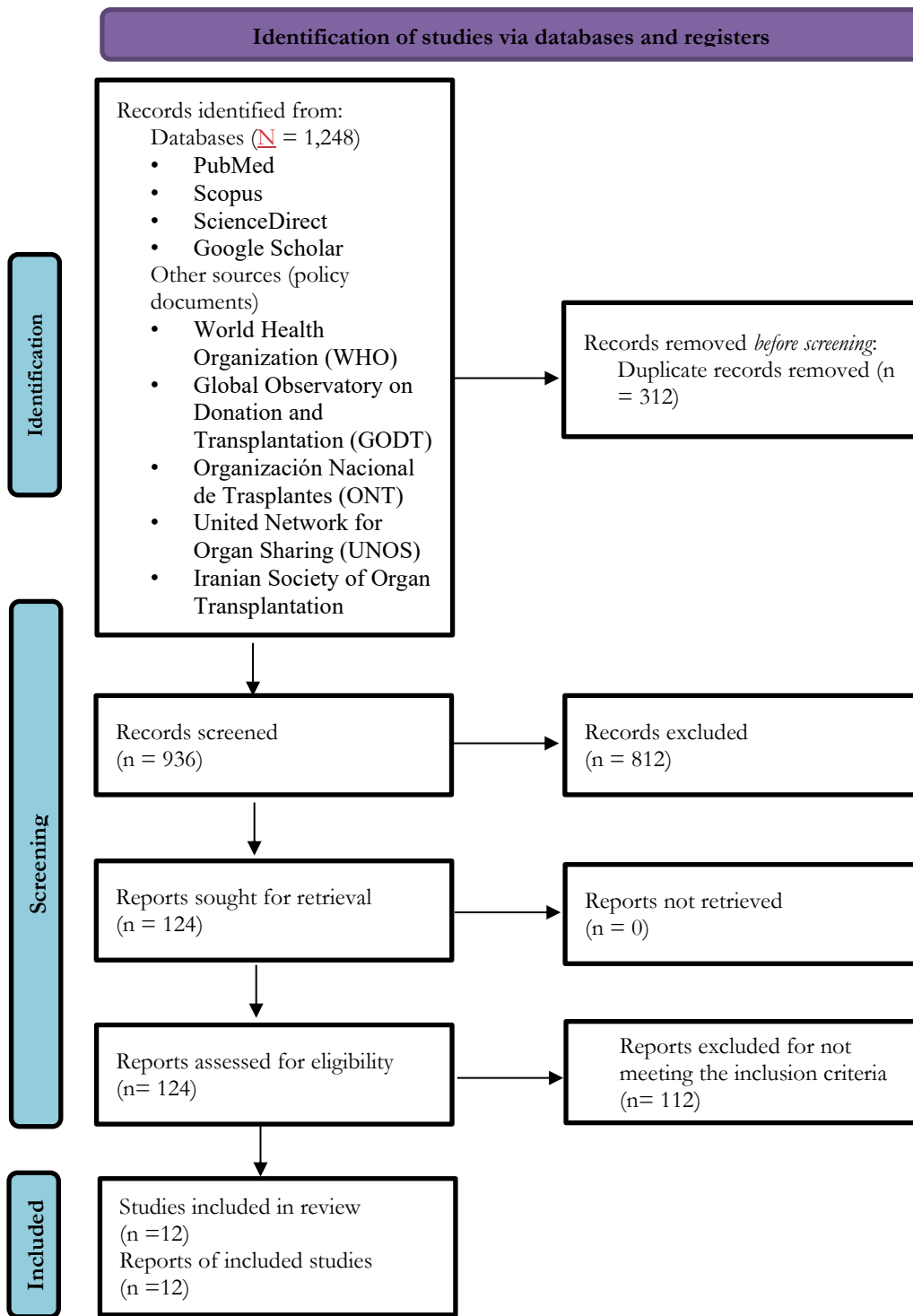


Figure 1. PRISMA Flow Diagram

Table 1. Summary of Articles Comparing Kidney Donation Regulations and Ethics by Country

Author (year)	Country	Article Title	Main Focus	Policy System	Results
Streit et al., (2023)	Spain	Ten Lessons from the Spanish Model of Organ Donation and Transplantation	Opt-out	Solidarity, Justice	National coordination systems and broad public education have been proven to enhance organ donation rates.
Sharif (2017)	Spain	Viva España-Lessons from the Spanish Organ Donation System	Opt-out	Beneficence, Solidarity	Family consent is maintained even when a national presumed consent system is implemented
Díaz-Cobacho et al., (2022)	Spain	Public Perception of Organ Donation and Transplantation Policies in Southern Spain	Opt-out	Autonomy, Collective, Transparency	Research shows widespread public approval for donation; however, a significant gap in understanding persists concerning opt-out policies.
Rudge (2018)	Spain	Organ Donation: Opting In or Out?	Opt-out	Justice, System effectiveness	The opt-out system is considered more effective and ethical in the context of populations with high health literacy.
Klarman & Formica (2020)	USA	Ethical and Legal Imperative	<i>Opt-in</i>	Justice, Utility	The new national allocation policy is considered more equitable in reaching geographically vulnerable patients.
Organ Procurement and Transplantation Network (2015)	USA	Ethical Principles in the Allocation of Human Organs	<i>Opt-in</i>	Respect for person, Justice, Utility	The document establishes national principles to ensure a fair and ethical allocation across the system
Henderson & Gross (2017)	USA	Living Organ Donation and Informed Consent in the United States: Strategies to Improve the Process.	<i>Opt-in</i>	Autonomy, Non-maleficence	The need for institutional support was emphasized to ensure that donors make decisions free from pressure.

Author (year)	Country	Article Title	Main Focus	Policy System	Results
Hays (2015)	USA	Informed consent of living kidney donors: Pitfalls and best practice.	<i>Opt-in</i>	Autonomy, Beneficence, Justice	The informed consent process remains inconsistent across transplant centers; national standardization is needed.
Roth et al., (2022)	Iran	Criminal, Legal, and Ethical Kidney Donation	Compensation (Regulated)	Justice, Non-maleficence	The government compensation scheme has been shown to increase the availability of kidneys without increasing the rate of exploitation.
Siraj (2022)	Iran	How a compensated kidney donation program facilitates the sale of human organs in a regulated market: the implications of Islam on organ donation and sale	Compensation (Regulated)	Autonomy, Justice	An emphasis on the need for regulations grounded in religious values to curb illegal practices.
Kiani et al., (2018)	Iran	Ethical Challenges in Iran	Compensation	Autonomy, Beneficence	Disparities in access and weak legal protections for donors in rural areas have been identified.
Moghaddasi Kelishomi & Sgroi (2024)	Iran	A field study of donor behaviour in the Iranian kidney market	Compensation	Autonomy, Justice	Donations are driven more by economic factors than by altruism; the risk of exploitation remains.

DISCUSSION

The global crisis in kidney donor availability has prompted various countries to develop diverse donation systems, both in terms of regulation and ethical approaches (Streit et al., 2023b). Despite continuous advances in transplantation medicine, the demand for donor kidneys substantially exceeds organ availability worldwide. According to the Global Observatory on Donation and Transplantation (GODT), more than 150,000 organ transplant procedures are performed annually; however, this number satisfies only a fraction of the global need, leaving many patients on waiting lists and contributing to avoidable morbidity and mortality (GODT, 2024). This persistent gap has encouraged countries to implement different regulatory and ethical strategies to increase donor participation while safeguarding donor rights and maintaining public confidence in transplantation systems. Although kidney transplantation has been performed in Indonesia, the existing donor system has not yet been able to meet national needs in a fair and sustainable manner. Therefore, this study compares three contrasting kidney donation models in Spain, the United States, and Iran to identify policy approaches that may inform the development of a more effective, ethical, and contextually appropriate transplantation framework in Indonesia.

The findings indicate that the success of a kidney donation system is influenced not only by legal frameworks but also by public trust, institutional capacity, and effective implementation. Spain serves as a successful example of an opt-out system; however, evidence suggests that its achievements are attributable not only to presumed consent legislation but also to strong national coordination, specialized transplant coordinators, and sustained public education initiatives (Díaz-Cobacho et al., 2022; Streit et al., 2023). From a bioethical perspective, the Spanish model reflects the principle of solidarity, which emphasizes collective responsibility for promoting public welfare through

organ donation. This approach aligns closely with communitarian ethics, whereby individual decisions are understood within a broader social context and a shared commitment to the common good. Importantly, despite the implementation of presumed consent, family involvement remains an integral component of the final decision-making process, thereby preserving relational autonomy and maintaining public trust in the transplantation system (Rudge, 2018). From a health policy perspective, Spain's success also reflects strong institutional governance and policy legitimacy, which foster public confidence and encourage participation in organ donation. These findings suggest that the effectiveness of an opt-out system depends not only on legislative mechanisms but also on the development of social trust and institutional credibility.

In contrast, the United States maintains an opt-in system that prioritizes individual autonomy as its central ethical principle. This approach provides strong protection of individual rights through informed consent mechanisms; however, it continues to face challenges related to equitable access and consistency in policy implementation. Recent reforms to the organ allocation system have sought to improve distributive justice by reducing geographic disparities and expanding access to transplantation for underserved populations (Klarman & Formica, 2020b). Nevertheless, important structural inequities remain. Access to transplantation may be influenced by socioeconomic status, insurance coverage, geographic location, and healthcare resources, potentially creating disparities among patient populations. Furthermore, studies have highlighted persistent racial and ethnic inequities in transplant access and outcomes, raising concerns regarding fairness and equal opportunity within the healthcare system. From an ethical perspective, these disparities challenge the realization of justice and equity despite the system's strong emphasis on autonomy. Variations in informed consent practices across transplant centers further suggest the need for more integrated national standards to ensure consistent donor protection and equitable access to

transplantation services (Henderson & Gross, 2017; Organ Procurement and Transplantation Network, 2015). Thus, while the opt-in system excels in safeguarding individual choice, ongoing efforts are required to address systemic inequities that may limit fair access to transplantation.

Iran presents a distinct model through its legally regulated financial compensation system for living kidney donors. This approach has been effective in increasing organ availability and substantially reducing transplant waiting lists (Ghods & Savaj, 2006). Nevertheless, the model remains the subject of considerable ethical debate. From the perspective of commodification theory, the introduction of financial incentives raises concerns that human organs may be treated as market commodities rather than as elements of human dignity and personhood. Ethical concerns are further reinforced by vulnerability frameworks, which argue that individuals experiencing economic hardship may be disproportionately influenced by financial incentives, potentially compromising the voluntariness of their decisions. Consequently, although participation may appear autonomous, critics contend that socioeconomic pressures can blur the distinction between free and constrained choice. Furthermore, exploitation frameworks highlight the possibility that financially disadvantaged populations may bear a disproportionate share of donation-related risks while wealthier recipients derive the primary benefits. Consistent with these concerns, studies from Iran have reported that economic motivations frequently play a dominant role in donor decision-making and that disparities in legal protection remain evident, particularly in resource-limited settings (Kiani et al., 2018; Roth et al., 2022). These findings indicate that evaluations of transplantation systems should consider not only donor availability but also broader ethical dimensions, including donor autonomy, social justice, and protection against exploitation. Comparatively, these findings suggest that no single donor system model is entirely ideal. A system's success is more determined by the alignment of policies with the social and cultural context, as well as the level of public

trust in healthcare institutions. Spain emphasizes solidarity and public trust, the United States highlights the protection of individual autonomy, while Iran emphasizes efficiency through incentive mechanisms. These three models represent a spectrum of approaches ranging from collective ethics, individual ethics, to a needs-based utilitarian approach.

In the Indonesian context, the development of a kidney donation system requires a holistic and adaptive approach that integrates legal, ethical, institutional, and sociocultural considerations. The establishment of a national donor registry and the expansion of public education initiatives may draw valuable lessons from the Spanish experience in fostering donor participation and public trust. Likewise, principles of transparency, informed consent, and protection of living donors, as emphasized in the United States, should form the foundation of donor governance in Indonesia. However, the implementation of these strategies may face several challenges, including limited transplantation infrastructure, uneven distribution of specialized healthcare services, fragmented data systems, and varying levels of public awareness regarding organ donation.

From a sociocultural perspective, Indonesia shares important characteristics with Spain and Iran, particularly the strong influence of solidarity, communal values, and religious beliefs on health-related decision-making. Similar to Spain, traditions of mutual assistance and collective responsibility may provide a favorable foundation for promoting organ donation as an act of social solidarity. At the same time, as in Iran, religious and moral values play an important role in shaping public perceptions toward organ donation. These factors may facilitate public acceptance when supported by appropriate religious engagement and ethical education. Nevertheless, discussions regarding financial incentives for donors remain ethically sensitive. Although compensation may be viewed as a mechanism to increase organ availability, concerns regarding commodification, unequal bargaining power, and the potential exploitation of economically vulnerable populations warrant careful consideration.

Therefore, any discussion of donor incentives in Indonesia should be accompanied by robust ethical safeguards and regulatory oversight. Ultimately, the development of a sustainable kidney donation system in Indonesia will require not only regulatory reform but also strong institutional capacity, intersectoral coordination, and sustained public engagement to ensure fairness, transparency, and ethical integrity.

Although this study provides a comprehensive comparative analysis, several limitations should be acknowledged. The findings were derived exclusively from secondary data and focused on three countries representing distinct kidney donation models, which may limit their generalizability to other settings. In addition, as a narrative literature review, this study did not include a formal quality appraisal of the included studies. Future research should incorporate empirical data from Indonesian stakeholders to generate more context-specific recommendations for kidney transplantation policy development. As an initial step, qualitative studies exploring public trust, cultural acceptance, and stakeholder perspectives regarding a national donor registry may provide valuable evidence to support the development of an effective and socially acceptable organ donation framework in Indonesia.

CONCLUSION

This review compared the regulatory and ethical approaches to kidney donation in Spain, the United States, and Iran, representing the opt-out, opt-in, and regulated compensation models, respectively. The findings demonstrate that the effectiveness of a kidney donation system is shaped not only by its legal framework but also by broader sociocultural, ethical, and institutional factors. Spain illustrates the importance of solidarity, public trust, and coordinated governance; the United States emphasizes autonomy, informed consent, and donor protection; whereas Iran highlights both the potential benefits and ethical challenges associated with financial incentives.

The findings suggest that no single model can be universally applied across countries. For Indonesia, the development of a sustainable kidney donation system should integrate strong regulatory oversight, public education, donor protection, and culturally sensitive approaches that reflect local social and religious values. Establishing a national donor registry, strengthening public trust, and ensuring safeguards against exploitation may represent important priorities for future policy development. By combining ethical principles with context-specific governance strategies, Indonesia may advance a more equitable, transparent, and sustainable transplantation system.

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