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Investigating Legal Gaps and Ethical Challenges of Xenotransplantation in Iran's Legal System and International Instruments

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ABSTRACT

Xenotransplantation, as a potential solution to the global shortage of organs for transplantation, represents one of the significant advances in modern medicine. However, this technology raises complex legal and ethical challenges at both national and international levels. This study aims to comparatively examine the legal gaps and ethical challenges associated with xenotransplantation in Iran's legal system and international instruments. This analytical-descriptive study adopts a comparative approach. Data were collected and analyzed through library-based research, including domestic laws and regulations, authoritative religious rulings, and relevant international instruments, such as reports of the World Health Organization and statements of the International Xenotransplantation Association. The findings reveal that, despite a strong jurisprudential foundation supporting the permissibility of xenotransplantation in Iran, including progressive religious rulings and reliance on the principle of no harm and the principle of self-preservation and treatment, there is a clear legal gap, as no specific legislation or comprehensive regulatory framework governing xenotransplantation currently exists. By contrast, international instruments, including World Health Assembly Resolution WHA57.18 and the Changsha Communiqués, emphasize effective regulatory oversight, infectious-risk assessment, and ethical considerations such as collective consent. Furthermore, shared ethical challenges, including the risk of zoonotic disease transmission, animal welfare and rights, and equitable access to this technology, remain the subject of ongoing debate in the international scientific community. This study highlights the clear discrepancy between the strong jurisprudential and legal support for xenotransplantation and the existing legal gap in Iran. It is therefore imperative that the legislature, drawing upon established international regulatory frameworks while taking into account relevant jurisprudential foundations, undertake the development of comprehensive legislation governing xenotransplantation.

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Introduction

Xenotransplantation, recognized as one of the remarkable advances in modern medicine, refers to the transplantation of living cells, tissues, or organs from animals to humans. This technology has emerged in response to the escalating global shortage of organs available for transplantation and offers a potential means of saving the lives of thousands of patients awaiting life-saving organs (1). However, owing to its interdisciplinary nature and its technical, ethical, and legal complexities, xenotransplantation has become one of the most controversial fields of contemporary medicine and has long attracted the attention of researchers and international regulatory bodies.

Since 1997, the World Health Organization has emphasized the need for effective regulatory frameworks governing xenotransplantation through the establishment of advisory groups and the adoption of relevant resolutions. World Health Assembly Resolution WHA57.18 called upon Member States to develop national policies on xenotransplantation and establish effective regulatory and surveillance systems (2). At the regional level, the Changsha Communiqués of 2005 and 2008, as significant ethical instruments in this field, emphasize principles such as respect for human dignity, informed consent, continuous assessment of infectious risks, and long-term monitoring of recipients. These instruments demonstrate that xenotransplantation is not merely a clinical issue but a multidimensional challenge that raises significant legal and ethical questions for national legal and regulatory systems.

In this context, Iran's legal system, with its distinctive jurisprudential and legal foundations, occupies a particular position. On the one hand, progressive religious rulings issued by prominent Shi'a jurists, including the fatwa of Imam Khomeini affirming the permissibility of transplanting organs from animals considered intrinsically impure under Islamic law, based on the principle of no harm and the principle of self-preservation and treatment, have facilitated the religious acceptance of this technology. On the other hand, an examination of the existing legal framework reveals that Iran lacks specific and codified legislation governing

xenotransplantation. This legal gap poses a significant obstacle to the clinical application of the technology and to the effective management of its associated risks.

This legal gap exists while other countries, drawing upon international regulatory frameworks, are gradually moving toward the development of comprehensive legislation. In addition to the legal gap, xenotransplantation raises numerous ethical challenges, including the risk of zoonotic disease transmission, the ethical concerns surrounding the use of animals as sources of organs, issues relating to informed consent, and equitable access to this costly technology (3). These challenges further increase the complexity of the field and underscore the need for a comparative examination of the relevant legal and regulatory frameworks in Iran and international instruments.

The present research is guided by the following research question: What legal gaps and ethical challenges confront Iran's legal system in the context of xenotransplantation, and how can international instruments inform the development of a comprehensive regulatory framework for this technology in Iran?

Based on this research question, the hypothesis is that, although Iran possesses a strong jurisprudential foundation supporting the religious permissibility of xenotransplantation, a clear gap exists in domestic legislation. Furthermore, it is hypothesized that international instruments, including World Health Organization resolutions and the Changsha Communiqués, can provide valuable models for the development of comprehensive legislation, provided that their principles are critically adapted to Iran's specific legal, cultural, and religious context.

In light of the foregoing, this study aims to examine the existing legal gaps in Iran's legal system concerning xenotransplantation and to comparatively analyze the associated ethical challenges in light of international instruments.

The present study employs an analytical-descriptive method with a comparative approach. Using qualitative content analysis, the study examines and compares laws and regulations, jurisprudential rulings, international instruments,

and authoritative scientific sources relating to xenotransplantation.

The research population comprises Iran's domestic laws and regulations, the fatwas of prominent sources of emulation, resolutions of the World Health Organization, statements of the International Xenotransplantation Association, and published scholarly articles in this field.

Data were collected through library-based research and systematic searches of reputable databases, including PubMed, Scopus, Google Scholar, SID, and Magiran, as well as the official websites of the World Health Organization and the International Xenotransplantation Association.

The analytical process initially involved extracting data relevant to Iran's legal system and subsequently comparing them with international instruments in order to identify and analyze the existing legal gaps and ethical challenges.

The findings of this study are presented in two main sections: legal gaps in Iran's legal system and ethical challenges at both domestic and international levels.

1. Legal Gaps in Iran's Legal System

An examination of Iran's domestic laws and regulations reveals that, despite the increasing demand for organ transplantation and the presence of thousands of patients with end-stage organ failure in the country, there is no specific and codified legislation governing xenotransplantation. What currently exists is merely an incomplete research guideline for researchers, which is insufficient to address the practical needs of patients.

From a jurisprudential perspective, however, a solid foundation exists for accepting this technology. Research indicates that a teleological approach to jurisprudence enables movement beyond traditional approaches and that, by invoking fundamental principles such as the principle of no harm and the principle of self-preservation and treatment, the religious permissibility of xenotransplantation can be established. The absence of definitive jurisprudential evidence prohibiting xenotransplantation further facilitates this approach.

With regard to the use of pigs as animals considered intrinsically impure under Islamic law, the fatwa of Imam Khomeini explicitly provides that once an organ from an intrinsically impure animal is transplanted into the human body and becomes living tissue, it is no longer regarded as an animal organ but becomes part of the human body. However, some perspectives concerning the transplantation of chimeric organs produced using human stem cells within animal bodies adopt a more cautious approach and permit their use only in emergency situations rather than in non-emergency circumstances (4).

With respect to ethical challenges, international instruments identify several key concerns. The risk of zoonotic disease transmission represents a major concern because, unlike conventional medical interventions, xenotransplantation may pose risks not only to the individual recipient but also to broader segments of society and public health. This risk has also been recognized in relation to the use of human skin cells cultured on mouse feeder cells, which have been used for more than a decade in the treatment of burn patients. Although the risk of transmission of murine retroviruses is very low, it cannot be entirely excluded. Accordingly, international instruments emphasize lifelong monitoring of recipients and the preservation of blood and tissue samples from both donors and recipients for subsequent monitoring and follow-up.

Animal rights and welfare, human identity, and informed consent constitute other significant ethical challenges. The use of animals for the production of organs raises serious questions concerning the treatment of living beings as mere means to human ends, while the potential effects of animal organ transplantation on the recipient's human identity remain a matter of ethical concern. Furthermore, educating patients and the public about the potential benefits, risks, and scientific limitations of xenotransplantation is regarded as an important regulatory responsibility (4).

At the regulatory level, the World Health Organization has encouraged Member States to establish effective regulatory systems and to register xenotransplantation activities. The Changsha Communiqués, published in 2005,

2008, and 2018, have formulated guiding principles and recommendations for Member States, researchers, and applicants for clinical trials. The International Xenotransplantation Registry, established in 2006 with the support of the WHO and the International Xenotransplantation Association, has to date registered 54 clinical protocols dating back to 1995. Notably, since 2005, all cases registered in this system have received regulatory approval from an official authority, whereas unregistered cases have largely lacked official approval and have been conducted in jurisdictions without adequate regulatory oversight. This demonstrates that a transparent regulatory system and codified legislation constitute essential prerequisites for the safe and ethical introduction of xenotransplantation into clinical practice (4).

Finally, given the increasing demand for transplantation in Iran and the limited public awareness of xenotransplantation, the Iranian government has an important role to play in raising public awareness and addressing the ethical and legal gaps in this field. Research indicates that, although no comprehensive study has yet addressed the various dimensions of this issue, the challenges ahead can be identified and appropriately addressed (4).

2. Inconsistency between Jurisprudential Support and the Legal Gap in Iran's Legal System

The findings of this study reveal a profound structural inconsistency within Iran's legal system regarding xenotransplantation. On the one hand, there is a robust jurisprudential foundation capable of establishing the religious permissibility of this technology; on the other hand, a conspicuous legal gap exists in the statutory and regulatory framework. This situation places Iran in a unique yet precarious position: while jurisprudential principles facilitate the acceptance of this technology, the absence of a comprehensive legal framework renders any movement toward clinical application fraught with ambiguity and risk (5).

An examination of jurisprudential sources indicates that a teleological approach to Imami jurisprudence, grounded in principles such as the

principle of no harm and the principle of selfpreservation and treatment, reinforces the religious permissibility of xenotransplantation. Furthermore, the progressive fatwa of Imam Khomeini, according to which an organ from an intrinsically impure animal, once it becomes living tissue within the human body, ceases to be regarded as an animal organ and becomes part of the human body, constitutes a significant jurisprudential basis for overcoming the obstacle of ritual impurity. However, some perspectives concerning the transplantation of chimeric human-animal organs produced using human stem cells within animal bodies adopt a more cautious approach and permit their use only in emergency situations rather than in non-emergency circumstances (6).

In contrast to this strong jurisprudential support, a critical examination of Iran's domestic laws and regulations reveals that there is no specific and codified legislation governing xenotransplantation. What currently exists is merely an incomplete research guideline for researchers, which is insufficient to address the practical needs of patients. This legal gap may create serious difficulties for patients in need of life-saving transplantation, limiting their access to this technology while also increasing the risk of unauthorized and unregulated activities (5).

Beyond the absence of specific legislation, it is essential to consider whether existing general legal provisions can be applied to xenotransplantation. The Organ Transplantation Act of 2000, which regulates human-to-human organ transplantation, does not expressly address xenotransplantation. The Act focuses on cadaveric and living unrelated organ donation among humans and establishes specific conditions for such procedures. Because its provisions are framed in terms of human donors, its direct application to xenotransplantation appears problematic. The Act's silence regarding animal donors suggests that its scope cannot readily be extended to xenotransplantation without legislative amendment or an expansive interpretation.

Even under a broad interpretation, fundamental differences between human and animal organ

transplantation, including issues of ritual impurity under Islamic law, immune rejection, and zoonotic disease transmission, render the Act's provisions inadequate for regulating this emerging technology.

Furthermore, the Islamic Penal Code, particularly its provisions concerning medical liability, presents additional challenges. The general principles governing the criminal liability of healthcare professionals, as set out in the Code, could potentially apply to cases of harm arising from xenotransplantation. However, the Code contains no specific provision addressing the distinctive risks associated with xenotransplantation, including the possibility of transmitting zoonotic infections to the recipient or to the wider community.

Similarly, the Civil Liability Act of 1960 provides a general framework for compensation for harm caused by the acts of individuals or entities. Although this Act could theoretically be invoked to seek compensation for damage resulting from xenotransplantation, several obstacles arise. The Act requires proof of fault, causation, and damage. In the context of xenotransplantation, establishing fault may be particularly difficult given the experimental nature of the technology and the inherent uncertainties involved. Moreover, the Act does not address specific forms of harm that may arise from xenotransplantation, such as latent infections that may manifest years after the procedure.

The scope of these general laws is therefore limited, and their application to xenotransplantation would require either extensive judicial interpretation or legislative clarification. A narrow interpretation would render them largely inapplicable, whereas a broad interpretation could generate legal uncertainty for both patients and healthcare providers. In either case, the absence of specific legislation creates a regulatory gap that cannot adequately be addressed through existing general legal provisions.

Comparative studies demonstrate that many leading countries in the field of xenotransplantation, drawing upon the frameworks developed by the World Health

Organization and the International Xenotransplantation Association, are gradually moving toward comprehensive regulatory frameworks (7). For example, World Health Assembly Resolution WHA57.18 has encouraged Member States to establish effective regulatory systems and to register xenotransplantation activities. Moreover, the Changsha Communiqués of 2005, 2008, and 2018, as significant ethical instruments in this field, emphasize principles such as lifelong recipient monitoring, genuine informed consent, continuous assessment of infectious risks, and transparency in reporting. However, Iran, despite its jurisprudential support, remains without codified legislation in this area. This gap not only limits patients' access to the technology but also increases the risk of unauthorized and unregulated activities. The International Xenotransplantation Registry, established in 2006 with the support of the WHO and the IXA, has to date registered 54 clinical protocols, with all cases registered since 2005 having received regulatory approval from an official authority. In contrast, unregistered cases have largely been conducted in jurisdictions without adequate oversight.

These statistics demonstrate that effective legal and regulatory oversight is an essential prerequisite for the safe and ethical introduction of this technology into clinical practice and that the absence of such oversight may facilitate unethical and unlawful activities. Ultimately, the inconsistency between jurisprudential support and the legal gap not only deprives patients in need of a potentially life-saving treatment but also exposes the country's healthcare system to significant legal and ethical risks, underscoring the urgent need for legislative action (8).

3. Ethical Challenges of Xenotransplantation at the Intersection with the Legal Gap

The ethical challenges of xenotransplantation in Iran are rendered more complex by the existing legal gap. These challenges arise in circumstances where the absence of a comprehensive legal framework has effectively limited the mechanisms available for addressing and managing them. This section examines the most significant ethical challenges identified in this field.

The risk of zoonotic disease transmission represents one of the most significant and serious ethical challenges associated with xenotransplantation. Unlike many medical interventions that primarily affect the individual patient, this risk has a collective dimension and threatens not only organ recipients but also public health and, potentially, populations beyond national borders (9).

The experience of using human skin cells cultured on mouse feeder cells, which have been used for more than a decade in the treatment of burn patients, demonstrates that although the risk of murine retrovirus transmission is very low, it cannot be entirely excluded. For this reason, international instruments emphasize lifelong monitoring of recipients and the preservation of blood and tissue samples from both donors and recipients for subsequent follow-up.

Within Iran's legal system, given the absence of a transparent regulatory framework, the legal obligations of hospitals, treating physicians, and the healthcare system toward patients and society in the event of complications arising from xenotransplantation remain largely undefined (10).

Informed consent constitutes another fundamental ethical challenge in this field. Because of its experimental nature and the uncertainties surrounding its risks, xenotransplantation requires a particularly robust process of patient information and education. Educating patients and the public about the benefits, risks, and scientific limitations of xenotransplantation is an important responsibility of regulatory authorities and governments.

In Iran, given the existing legal gap and limited public awareness of xenotransplantation, this situation may create serious challenges in the future for the treatment of patients requiring transplantation and for addressing the associated ethical and legal questions. The Iranian government therefore has an important role to play in increasing public awareness and addressing the ethical and legal gaps in this field.

Animal rights and welfare, as another significant ethical challenge, raise fundamental questions concerning the use of animals to improve human

survival and health (11). Human dignity requires that human beings themselves not be treated merely as instruments. This issue is further complicated in Iran by the absence of specific legislation governing animal rights and by the legal gap concerning xenotransplantation. Although jurisprudential principles based on the principle of no harm and the principle of self-preservation and treatment support the permissibility of using animals in emergency circumstances, the ethical governance of this issue in the absence of a comprehensive legal framework remains ambiguous.

Equitable access to treatment represents another significant ethical concern in the field of xenotransplantation. This technology is highly costly, and if introduced in Iran without adequate regulation, there is a serious risk of creating a dual healthcare system serving the wealthy and the poor differently (7). This concern becomes even more significant when considering that human organ transplantation in Iran already faces challenges relating to access and equity. Accordingly, any legislation concerning xenotransplantation should be designed to ensure equitable access to the technology for all patients in need, regardless of their economic circumstances.

Human identity constitutes another ethical challenge in this field. The potential subjective and objective effects of animal organ transplantation on the identity of human recipients represent an additional concern. In Iran, given the profound religious and cultural beliefs surrounding the human body and human identity, this issue assumes particular sensitivity and requires interdisciplinary dialogue among bioethicists, psychologists, legal experts, physicians, and jurists (12).

In sum, these ethical challenges, combined with the existing legal gap in Iran, have created a critical situation that not only obstructs the safe and ethical introduction of this technology but also exposes the country's healthcare system to significant risks. Research indicates that, although no comprehensive study has yet examined the various dimensions of this issue in Iran, the challenges ahead can be identified and addressed

in light of the country's legal and religious context.

4. Comparative Study of International Systems and Lessons to Be Learned

A comparative examination of Iran's situation and leading legal and regulatory systems worldwide demonstrates that various countries have adopted different approaches to managing the risks associated with xenotransplantation. These experiences offer valuable lessons for Iran, which can draw upon them while adapting their principles to its own jurisprudential and cultural foundations in developing an appropriate regulatory framework.

Since 1997, the World Health Organization has emphasized the need for effective regulatory frameworks for xenotransplantation through the establishment of advisory groups and the adoption of relevant resolutions (13). One of the most significant instruments in this field is World Health Assembly Resolution WHA57.18, adopted in 2004, which called upon Member States to establish effective regulatory systems, register xenotransplantation activities, and promote international cooperation in this area. Furthermore, in 2008, the World Health Organization published a comprehensive report emphasizing the need for continuous assessment of infectious risks and long-term monitoring of recipients. These instruments demonstrate that xenotransplantation is not merely a clinical issue but a multidimensional challenge requiring international cooperation and global governance (14).

The Changsha Communiqués, published in 2005, 2008, and 2018 by the International Xenotransplantation Association, represent important ethical instruments in this field and provide guidance for national regulatory systems. These communiqués emphasize principles such as lifelong recipient monitoring, genuine informed consent, continuous assessment of infectious risks, transparency in reporting, and international cooperation. The 2018 Communiqué, as the most recent version, specifically addresses ethical challenges arising from advances in genetic technologies and the development of chimeric human-animal organs.

Although these international instruments provide valuable guidance, their direct incorporation into Iran's legal system raises significant challenges. First, the principles of informed consent and patient autonomy, which occupy a central position in international ethical frameworks, are not comprehensively developed in Iran's legal system in relation to emerging medical technologies. There is no specific legislation governing informed consent in experimental treatments, and the general principles of consent in medical law may be insufficient to address the distinctive risks associated with xenotransplantation.

Second, the regulatory infrastructure required to implement international standards, including oversight bodies, patient registries, and monitoring systems, is largely absent in Iran. Establishing such infrastructure would require significant institutional and legislative efforts.

Third, the international framework's emphasis on public health surveillance and community-level risk assessment may present challenges for Iran's current legal and administrative capacity, which is primarily oriented toward individual patient care rather than population-level monitoring. The practical feasibility of adapting international standards to Iran's legal system therefore requires careful consideration of these institutional and legal gaps.

The International Xenotransplantation Registry, established in 2006 with the support of the World Health Organization and the International Xenotransplantation Association, provides a practical example of international cooperation in this field. The Registry has to date recorded 54 clinical protocols dating back to 1995, with all cases registered since 2005 having received regulatory approval from an official authority. In contrast, unregistered cases have largely lacked official approval and have been conducted in jurisdictions without adequate regulatory oversight (15).

These statistics demonstrate that a transparent regulatory system and codified legislation constitute essential prerequisites for the safe and ethical introduction of xenotransplantation into clinical practice.

At the national level, leading countries have adopted different approaches. The United States, through the establishment of the Xenotransplantation Advisory Committee in 1999 and the development of regulatory guidance by the Food and Drug Administration, has established one of the more comprehensive regulatory systems in this field. These guidelines emphasize rigorous assessment of infectious risks, long-term monitoring, and informed consent requirements (16).

Europe has adopted a different approach, requiring Member States to develop national legislation and align it with relevant European frameworks. The Council of Europe also published a comprehensive recommendation in 2010 addressing this field and emphasizing patient rights, informed consent, and safety oversight.

Australia and Canada have likewise taken steps toward regulating xenotransplantation through specialized ethics committees and national regulatory frameworks.

Among Islamic countries, Malaysia provides a notable case study, having examined the challenges of xenotransplantation from the perspectives of jurisprudence and bioethics. Malaysian research indicates that the use of human-pig chimeric organs, despite their potential benefits, presents significant jurisprudential challenges in non-emergency circumstances and that their use may be permitted only in situations of necessity. This approach is similar to certain perspectives articulated in Imami jurisprudence and demonstrates that Islamic countries face comparable challenges and may benefit from one another's experiences (5).

Notably, Northern Ireland, as the first country to enact comprehensive legislation on organ transplantation, demonstrated that, despite initial opposition, the development of transparent legislation and effective regulatory systems can contribute to creating the conditions for social acceptance of new transplantation technologies. This experience demonstrates that political will and intersectoral cooperation are key factors in successful legislation in emerging and challenging areas of medicine.

In sum, the comparative analysis reveals that Iran, despite possessing strong jurisprudential support, lags significantly behind leading countries in the development of legislation and regulatory systems. This delay not only deprives patients in need of a potentially life-saving treatment but also exposes the country's healthcare system to significant legal and ethical risks.

Accordingly, it is imperative that the legislature, drawing upon the frameworks of the World Health Organization and the International Xenotransplantation Association and considering the experiences of leading countries, promptly undertake the development of comprehensive legislation on xenotransplantation (18). Iran must also address the institutional and legal gaps that currently impede the implementation of international standards, including the development of specific legislation governing informed consent in experimental treatments, the establishment of regulatory oversight bodies, and the creation of patient registries for long-term monitoring.

Conclusion

The present study employed a comparative approach to examine the legal gaps and ethical challenges associated with xenotransplantation within Iran's legal system and in international instruments. The findings reveal that Iran's legal system faces a profound structural inconsistency in this field. On the one hand, there is a robust jurisprudential foundation capable of establishing the religious permissibility of xenotransplantation; on the other hand, a conspicuous legal gap exists in the statutory and regulatory framework.

This inconsistency has serious consequences for the country's healthcare system. In the absence of codified legislation, not only is the safe introduction of this technology into clinical practice hindered, but the oversight of research and therapeutic activities also remains ambiguous.

From a jurisprudential perspective, this study demonstrates that a teleological approach to Imami jurisprudence, grounded in principles such as the principle of no harm and the principle of selfpreservation and treatment, reinforces the religious permissibility of xenotransplantation.

Furthermore, the fatwa of Imam Khomeini, according to which an organ from an intrinsically impure animal becomes part of the human body once transplanted and incorporated as living tissue, constitutes a significant jurisprudential basis for overcoming the obstacle of ritual impurity. However, with regard to the transplantation of chimeric human-animal organs produced using human stem cells within animal bodies, more cautious perspectives exist, permitting their use only in emergency circumstances.

In contrast to this strong jurisprudential support, an examination of Iran's domestic laws and regulations reveals that there is no specific and codified legislation governing xenotransplantation. What currently exists is merely an incomplete research guideline for researchers, which is insufficient to address the practical needs of patients. This legal gap not only limits patients' access to a potentially life-saving treatment but also exposes the country's healthcare system to significant legal and ethical risks.

The ethical challenges associated with xenotransplantation in Iran are further complicated by the existing legal gap. The risk of zoonotic disease transmission, which has a collective dimension and threatens public health; informed consent, which in the absence of sufficient information and an adequate legal framework constitutes a serious challenge; animal rights and welfare, which raise fundamental questions concerning the use of animals to improve human health; equitable access to treatment, which, if the technology is introduced without adequate regulation, may create a dual healthcare system; and human identity, which assumes particular sensitivity in light of Iran's profound religious and cultural beliefs, constitute the most significant of these challenges.

A comparative examination of international systems reveals that leading countries, drawing upon the frameworks of the World Health Organization and the International Xenotransplantation Association, have taken significant steps toward developing comprehensive legislation and establishing

effective regulatory systems. World Health Assembly Resolution WHA57.18 and the Changsha Communiqués of 2005, 2008, and 2018, as significant international instruments, emphasize principles such as lifelong recipient monitoring, genuine informed consent, continuous assessment of infectious risks, and transparency in reporting. Furthermore, the International Xenotransplantation Registry, which began its activities in 2006, demonstrates the importance of transparent regulatory systems and codified legislation as prerequisites for the safe and ethical introduction of xenotransplantation into clinical practice.

Ultimately, this study demonstrates that Iran finds itself in a situation in which strong jurisprudential support and a clear legal gap coexist. This situation underscores the urgent need for legislative action and intersectoral cooperation among scientific, jurisprudential, and executive institutions to develop comprehensive legislation on xenotransplantation and establish effective regulatory systems.

Furthermore, given the research gap in Iran in this field, further studies addressing the various legal, ethical, cultural, and jurisprudential dimensions of xenotransplantation constitute a scientific necessity.

Based on the findings of this study and drawing upon international instruments and the experiences of leading countries, the following practical recommendations are proposed to address existing gaps and manage ethical challenges.

The first and most important recommendation is the development of comprehensive legislation on xenotransplantation. The legislature, in cooperation with the Ministry of Health and Medical Education, the Forensic Medicine Organization, and relevant scientific and jurisprudential institutions, should undertake the drafting of comprehensive legislation. Such legislation should address the conditions and criteria for performing xenotransplantation, including the qualification of authorized centers and physicians; establish a transparent regulatory framework governing licensing procedures, continuous monitoring, and periodic evaluation;

determine the obligations of patients, donors, and relevant authorities concerning potential risks, particularly the risk of zoonotic disease transmission; provide for a patient registration and long-term monitoring system; and establish appropriate legal sanctions and enforcement mechanisms for unauthorized activities.

The second recommendation is the establishment of a specialized national ethics committee for xenotransplantation, comprising jurists, legal experts, physicians, and bioethics specialists, to examine specific cases and provide advice to legislative and executive authorities. Inspired by the Xenotransplantation Advisory Committee of the US Food and Drug Administration, such a committee could perform regulatory and advisory functions in the areas of ethical risk assessment, review of research protocols, and formulation of policy recommendations.

The third recommendation concerns public awareness and education. The government should, through structured educational programs, create the conditions for informed social acceptance of this technology. Such awareness-raising efforts should target the medical community, patients and their families, and the general public and should address the benefits, risks, and ethical dimensions of xenotransplantation.

The fourth recommendation is cooperation with international bodies, including active participation in the International Xenotransplantation Registry and collaboration with the WHO and the IXA. Such cooperation could assist Iran in developing appropriate regulatory standards and benefiting from international experience.

The fifth recommendation is support for basic and clinical research conducted in accordance with ethical and regulatory principles. Such support can contribute to the development of knowledge and technology in this field and help create the conditions for the safe and ethical introduction of xenotransplantation into clinical practice.

The sixth and final recommendation is the development of executive regulations and clinical guidelines. Following the enactment of comprehensive legislation, the Ministry of Health should be responsible for developing such regulations and guidelines. These should include

patient evaluation procedures, informed consent processes, monitoring and surveillance protocols, and adverse-event reporting mechanisms, thereby ensuring that the enacted legislation can be effectively implemented in practice.

The successful implementation of these recommendations requires strong political commitment, intersectoral cooperation, and the participation of all relevant stakeholders, including jurists, legal experts, physicians, researchers, and the public. Such cooperation can constitute an effective step toward managing the risks associated with xenotransplantation and realizing the potential benefits of this life-saving technology within the framework of Iran's legal and ethical system.

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Reza Abedi conducted all stages of the research under the guidance and supervision of Dr. Mahmoud Abbasi and, having approved the final version of the manuscript, accepted responsibility for responding to inquiries concerning the research.

Conflict of Interest Statement

The authors declare that they have no potential conflicts of interest concerning the research, authorship, or publication of this article.

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