



REVIEW ARTICLE

**Bioethical implications of xenotransplantation: analysis of its challenges and ethical considerations in medicine today**

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**ABSTRACT**

**Introduction:** the global shortage of organs for transplantation has driven research into xenotransplantation, an option that offers clinical benefits but also raises complex ethical dilemmas.

**Objective:** to examine the bioethical implications of xenotransplantation through the analysis of its scientific, social, and philosophical challenges in contemporary medicine.

**Methods:** a bibliographic review of the literature published between 2017 and 2024 was conducted, following the PRISMA methodology. Various databases were consulted using an algorithm, which allowed the identification of sources that, once inclusion and exclusion criteria were verified, enabled the selection of articles for critical analysis.

**Development:** animal organs, especially those from pigs, can be genetically modified to increase their compatibility with humans, reducing immune rejection. However, risks of zoonotic transmission remain, along with concerns about animal welfare, genetic manipulation, and environmental sustainability. Ethical debates are highlighted regarding informed consent, patient autonomy, and distributive justice in access to these technologies. Philosophical implications are also discussed, including human identity and transhumanism, considering the psychological and social impact of integrating animal organs into the human body.

**Conclusions:** xenotransplantation represents a promising alternative to the shortage of organs, but its implementation requires solid ethical frameworks. Regulation must ensure health safety, respect for animal welfare, and equity in access, integrating principles of global bioethics that harmonize scientific innovation with social and environmental responsibility.

**Keywords:** Animal Welfare; Bioethics; Organ Transplantation; Transplantation, Heterologous.

## INTRODUCTION

In recent decades, medical advances have grown exponentially in both therapeutic interventions and procedures aimed at improving human quality of life. Today, numerous treatment options exist for various diseases, and increasingly effective alternatives continue to emerge, contributing to a sustained increase in global life expectancy.<sup>(1)</sup> Within this context, organ transplantation—or allotransplantation—has become an established procedure involving the transfer of cells, tissues, or organs from one individual to another.<sup>(2)</sup>

The first successful transplant recorded was a corneal transplant in 1905 in the Czech Republic, while in 1954 Dr. Joseph Murray performed the first successful kidney transplant—initially between identical twins, later between non-identical twins, and eventually using a deceased donor.<sup>(3)</sup> The adoption of these procedures sparked ethical debates regarding donor dignity, though their moral validity was acknowledged as they saved lives without violating the principles of the Hippocratic Oath. Subsequently, solid organ allotransplants—including liver, heart, and kidney—were developed, yet they have failed to meet the growing global demand from patients with end-stage organ failure.<sup>(2)</sup>

However, the limited availability of human organs, combined with legal restrictions on cadaveric organ procurement and reduced donor-recipient compatibility, has maintained a significant gap between supply and actual need. Even with advanced organ donation promotion programs, healthcare systems cannot satisfy this demand, driving the search for alternatives such as xenotransplantation—defined as the transplantation of cells, tissues, or organs between different species—to address urgent health needs.<sup>(3,4)</sup>

Since the 17th century—with Jean-Baptiste Denys's xenotransfusions—attempts have been made to transplant animal organs into humans, such as the cases of James Hardy and Baby Fae. Since the 2000s, genetic research in primates and pigs has sought to improve cross-species compatibility, raising ethical dilemmas concerning safety, identity, and human dignity.<sup>(2,4)</sup> In light of these developments, the present review was conducted with the objective of examining the bioethical implications of xenotransplantation through an analysis of its scientific, social, and philosophical challenges in contemporary medicine.

## METHODS

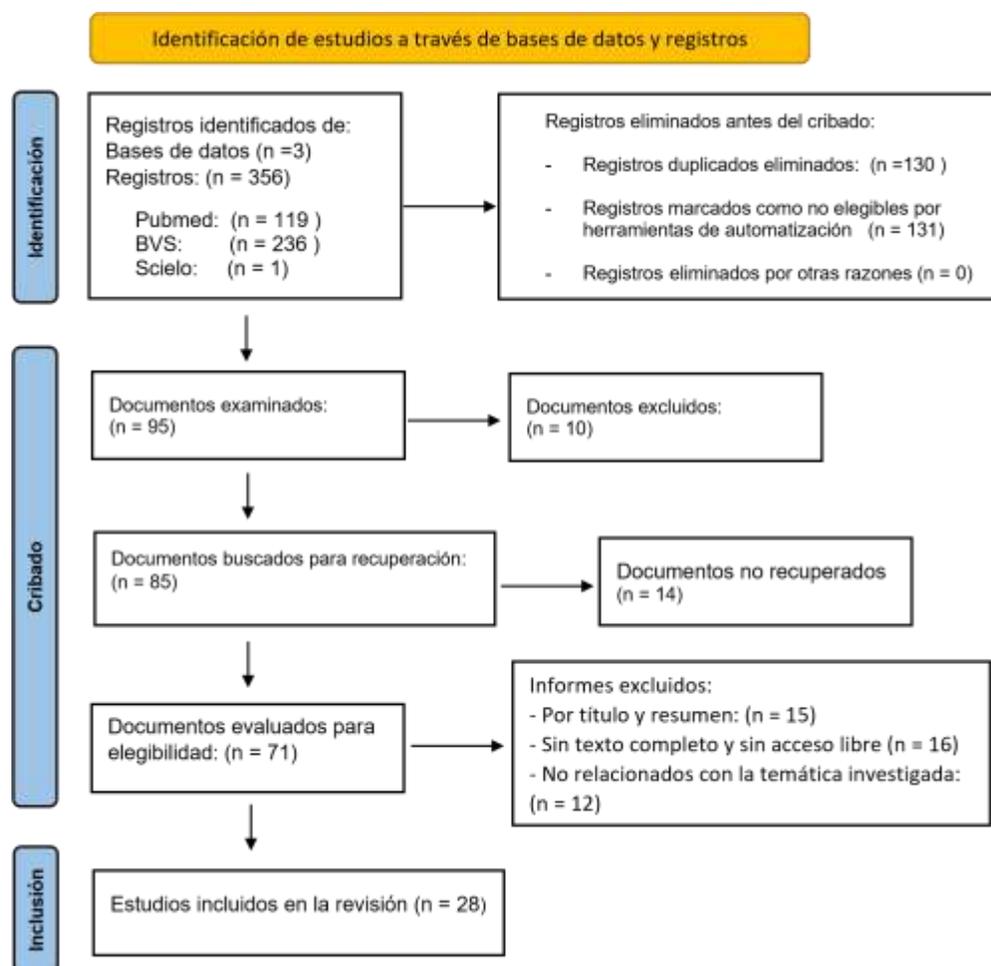
This study was designed as a systematic literature review, conducted in accordance with the PRISMA 2020 guidelines. The search period spanned from 2010 to 2024 to capture the most recent and relevant advances on the topic. The review aimed to identify, select, and synthesize available scientific evidence on the bioethical implications of xenotransplantation, considering clinical, social, and philosophical dimensions.

Information sources included widely recognized biomedical and multidisciplinary databases: PubMed, SciELO, ScienceDirect, Google Scholar, LILACS, and BVSAUD. Additionally, secondary references from key article bibliographies and grey literature—including institutional documents and technical reports—were reviewed, provided they met quality and relevance criteria. This strategy broadened the information scope and reduced publication bias.

The search strategy employed algorithms combining keywords and Boolean operators. Terms included *xenotransplantation*, *bioethics*, *genetic modification*, *immunologic rejection*, and *distributive justice*, along with their Spanish and Portuguese equivalents. Search equations used AND/OR operators—for example: (“xenotransplantation” AND “bioethics”) OR (“xenotrasplante” AND “ética”). Publications in English, Spanish, and Portuguese with full-text access were considered.

Inclusion criteria encompassed original articles, reviews, and academic documents published within the defined timeframe that directly addressed the bioethical aspects of xenotransplantation. Excluded were duplicates, studies without full-text access, non-indexed publications, irrelevant documents, and those outside the search period.

A total of 356 publications were identified (119 in PubMed, 236 in BVS, and 1 in Scielo). The results from these databases were grouped, and the screening process of the articles was carried out using the PRISMA methodology. Duplicate documents (130) were removed, leaving a total of 226. Afterwards, inclusion and exclusion criteria were applied to filter the results, determining the final studies that met the established criteria. In this study, 28 articles with the highest quality of information were included. The procedure was represented through a PRISMA flow diagram (Fig. 1), which details each phase of screening and refinement.<sup>(5)</sup>



**Fig. 1.** PRISMA Flow Diagram.

## DEVELOPMENT

Organ transplantation is a viable treatment option for patients with end-stage organ failure. Although a transplanted organ can significantly improve quality of life, the number of transplants performed remains far below the number of patients on waiting lists. In the United States alone, 116,690 patients await allotransplantation. Despite campaigns to promote organ donation, it is unlikely that donor availability will ever meet recipient demand.<sup>(6,7)</sup> Moreover, transplant recipients may require additional organs over time due to immunological complications.

Historically, immune responses in allotransplantation caused graft dysfunction, limiting transplants to genetically identical donors and recipients. Today, complex immunosuppressive therapies prolong organ survival. While these treatments extend functional lifespan, the shortage of human organs—from living or deceased donors—continues to grow, compounded by resource limitations in transplant services.<sup>(8,9)</sup>

These challenges have spurred the exploration of new biomedical alternatives, particularly xenotransplantation, which gained prominence in the second half of the 20th century. Xenotransplantation could alleviate organ shortages but presents significant hurdles, including immunological rejection and zoonotic disease transmission.<sup>(7)</sup>

Non-human primates—such as baboons, gibbons, and chimpanzees—have been used in xenotransplantation research due to their genetic proximity to humans.<sup>(10)</sup> However, their use raises serious ethical concerns and high zoonotic risks. Fish, meanwhile, have primarily provided transplantable tissues like skin and corneal tissue—tilapia skin, for instance, has been used in burn treatment. Yet their applicability remains limited to specific tissues.<sup>(11)</sup>

Pigs have since emerged as the primary source for xenotransplantation due to the anatomical and physiological similarity of their organs to human counterparts. Additional advantages include ease of breeding, high fertility, rapid sexual maturation, and a 15–20-year lifespan—making their organs clinically suitable. Crucially, pigs enjoy greater ethical acceptance and are highly amenable to genetic engineering. Pig hearts, kidneys, livers, and lungs have all been investigated for human use.<sup>(10,12)</sup>

Currently, pigs are considered the optimal candidates for genetic modification and controlled breeding for xenotransplantation.<sup>(11,13)</sup> Porcine zoonoses occur less frequently than those from non-human primates and can be more effectively managed through biosecurity protocols in controlled environments.<sup>(10,14)</sup> Nevertheless, xenotransplant candidates must provide a list of close contacts who require epidemiological monitoring to mitigate public health risks.<sup>(15,16)</sup>

While animal organs share some similarities with human ones, unmodified animal organs are not clinically viable for human transplantation.<sup>(17)</sup> Evidence shows that transplanting an unmodified porcine organ into a non-human primate triggers hyperacute rejection within minutes to hours.<sup>(16)</sup> Over the past three decades, significant progress has been made in porcine genetic engineering, yielding various genetically modified pig phenotypes. However, the ideal genetic profile for a “perfect donor pig” remains undefined, and in vitro studies must precede in vivo applications.

Cooper and Hara<sup>(17)</sup> describe key genetic techniques developed over time:

- Random integration transgene microinjection (1992)
- Somatic cell nuclear transfer (2002)
- Transcription activator-like effector nucleases – TALENs (2013)
- CRISPR/Cas9 (2014)

These advances have enabled targeted gene insertion or deletion in pigs, with CRISPR/Cas9 proving the most precise method for editing DNA sequences to enhance xenotransplant tolerance.<sup>(16)</sup> However, the exact number of modifications required for an ideal donor pig remains unknown. Factors such as expression of human complement-inhibiting CD59—which appears to promote graft survival in vitro—must also be considered.<sup>(17,18)</sup>

Recently, genetically modified pig organs enabled three human xenotransplants. Two involved renal xenografts in brain-dead patients with severe renal failure. Within 54 hours, kidney function improved significantly with no signs of rejection; the patients were subsequently euthanized per protocol.<sup>(19)</sup>

The third case involved a critically ill patient ineligible for heart allotransplantation. The donor pig carried ten genetic modifications: three porcine genes linked to hyperacute rejection were knocked out, one gene responsible for uncontrolled organ growth was deleted, and six human genes were inserted to enhance immune tolerance.<sup>(16,19)</sup> Despite this, the patient survived only 60 days. Although the exact cause of death remains unclear, it has been attributed to a porcine cytomegalovirus (CMV) infection present in the donor pig prior to transplantation.

### **Bioethical Implications of Animal Genetic Modification and Xenotransplantation**

One of the primary bioethical concerns is the welfare of genetically modified animals. Animals used in these procedures—particularly pigs—are often subjected to invasive interventions and strictly controlled living conditions, raising questions about animal pain and respect for animal life. Genetic modification itself may cause unforeseen health and behavioral problems in animals.<sup>(10)</sup> Furthermore, there is concern that these animals may be viewed merely as biological resources, potentially leading to less respectful and compassionate treatment.<sup>(20)</sup>

Animal harm of this type would go against animal welfare, which is based on three relevant aspects for animal production systems: reducing or avoiding unnecessary suffering, whether severe pain, hunger, or thirst.<sup>(15)</sup> The second aspect limits the natural lifestyle or the expression of normal behavior, and the third mainly refers to not causing unjustified or intentional death to animals.

On the other hand, we must recall the existence of the Farm Animal Welfare Council (1979), which outlined five freedoms that animals should have: first, freedom from hunger and thirst; second, freedom from discomfort; third, freedom from pain, injury, and disease; fourth, freedom to express normal behavior; and fifth, freedom from fear and distress. Each of these can be violated during genetic modifications and invasive processes previously described, or through modifications to the rearing environment required to prevent zoonoses.<sup>(10,13,15)</sup>

Additionally, the genetic modification of animals for xenotransplantation involves altering their genome in ways that do not occur naturally. Such intervention raises questions about naturalness and biological integrity. Some argue that genetically engineering animals to make their organs compatible with humans constitutes excessive manipulation of nature, warranting ethical reflection on how such practices affect other forms of life on the planet.<sup>(21)</sup>

While humans routinely conduct experimental activities on various animal species, we must examine the moral duties involved. Kantian deontology posits that humans have indirect duties toward animals used in research: if a person is capable of inflicting harm or suffering on an irrational being, they may also be capable of extending that violence to fellow humans.<sup>(15,22,23,24)</sup> This reasoning provides a foundation for establishing and regulating animal protection measures—and even rejecting unnecessarily cruel procedures, even if they benefit

humanity.<sup>(25,26)</sup> From a utilitarian perspective, one must weigh whether the global benefit to human populations outweighs the pain and cruelty required to achieve the “perfect” xenotransplant.<sup>(10,11,15,27)</sup>

Patient safety is another critical area of debate. Despite advances in genetic engineering aimed at minimizing zoonotic disease transmission, the possibility of undetected viral or bacterial transfer cannot be entirely eliminated.<sup>(14,20)</sup> From this ethical standpoint, humanism is indispensable in healthcare, as patients are the most vulnerable and in need of care and human values. The attitudes and values of healthcare professionals can profoundly impact patient outcomes, emphasizing the need to maximize benefit without harming others.<sup>(22)</sup>

Key humanistic values include human dignity, human development, and compassion—principles every physician should uphold firmly to avoid violating or harming human beings, even when potential benefits are claimed. In this context, informed consent emerges as another vital ethical requirement in xenotransplantation. Patients receiving genetically modified animal organs must be fully informed about the risks, benefits, and experimental nature of the procedure.<sup>(17,21)</sup> Moreover, physicians and researchers are responsible for clearly communicating the uncertainties and associated risks, ensuring patients understand what participation entails.

Informed consent fundamentally respects the principle of patient autonomy—a concept introduced by Kant in the 18th century, who viewed humans as moral agents capable of rational, free decision-making, responsible for their actions, and deserving of respect. Only such autonomous individuals can choose whether or not to participate in experimental procedures.<sup>(23)</sup>

Justice and utilitarian ethics also play a significant role. Technologies involving genetic modification and xenotransplantation must be organized to ensure equitable access and benefit those most in need, preventing them from becoming available only to those who can afford high costs. Equitable distribution of these medical advances is crucial to avoid exacerbating existing disparities in healthcare access. Global bioethics must also consider how these technologies affect diverse communities worldwide, emphasizing responsibility, care, social justice, and distributive equity. For example, in some low-resource countries, inadequate infrastructure may limit access to these technologies, worsening health inequities. Therefore, efforts should aim to maximize global well-being and ensure equal access to scientific advancements.<sup>(20,21)</sup>

In this sense, environmental ethics, the ethics of responsibility, and the precautionary principle argue that the use of genetically modified animals should be carried out with caution and preventive measures should be taken to avoid possible risks and global harm, questioning animal welfare and their instrumental use.<sup>(15)</sup> It also raises perspectives on long-term sustainability that must be evaluated in terms of efficiency and environmental impact.<sup>(20)</sup> Furthermore, the accidental or intentional release of these animals into the environment could have unpredictable ecological consequences, affecting biodiversity and natural ecosystems.<sup>(14)</sup>

Xenotransplantation represents not only a medical challenge but also ethical implications related to identity and self-perception. Personalism recognizes humans as free, rational, social, and communal beings—distinct from objects. This view intersects with biopower and posits that human rationality and freedom place us above animals, excluding them from the social contract.<sup>(15)</sup> This explains why animals are not held accountable for their actions, nor are they granted rights or bodily sovereignty. However, while technological advances allow us to benefit from genetically modified animal organs, it is essential to uphold respect for human dignity and individual uniqueness, as organ integration may lead patients to question their identity—triggering stress, anxiety, feelings of alienation, and organ rejection.<sup>(21)</sup>

Given humanity's technological and scientific progress—including xenotransplantation—transhumanist ethics offers a framework to evaluate which boundaries should or should not be crossed in human enhancement, without compromising our self-conception, self-esteem, identity, or humanity.<sup>(24,28)</sup> Each patient's mind-body unity must be respected, as integrating a non-human organ may challenge their understanding of what it means to be human, potentially causing internal conflict and social stigma. Thus, psychological support and companionship during the acceptance process are essential. Ethically, society must promote understanding and education to provide holistic support and respect for the internal and external changes patients undergo.<sup>(21)</sup>

Xenotransplantation holds significant promise for addressing the critical shortage of human organs for transplantation, yet it raises ethical concerns affecting patients, researchers, animal caregivers, and society at large.<sup>(25)</sup> As Fischer and Schnieke,<sup>(6)</sup> emphasize, the scarcity of cadaveric organs for transplant makes xenotransplantation a favorable alternative.

Regarding animal welfare, Silverman and Odonkor,<sup>(20)</sup> note that xenotransplantation implies animal sacrifice, instrumentalization, species barriers, zoonotic risks, and religious and cultural concerns. One of the greatest challenges remains immunological rejection. On the other hand, the potential to save lives through xenogeneic organs offers tangible hope for many patients who might otherwise die on prolonged waiting lists. This underscores a moral obligation to explore and develop medical technologies that improve human health and well-being.<sup>(8,19)</sup>

An ethical dilemma arises when maximizing benefits for an individual patient may pose risks to public health, and vice versa. Allowing an experimental treatment may benefit a patient but, if insufficiently evaluated for safety, could endanger others. Striking the right balance requires careful consideration of ethical principles, scientific evidence, and public health policies.<sup>(9)</sup>

In the tension between animal and human welfare, a positive aspect is that xenotransplantation advances may lead to protocols that minimize animal suffering, balancing animal welfare with human health benefits. Conversely, efforts to protect animal welfare may limit organ availability, negatively impacting human patients.<sup>(18,22)</sup>

Creating transgenic animals specifically bred for human organ donation raises profound questions about animal welfare and the ethical justification for genetically altering living beings for human benefit. This ethical dilemma intensifies when considering animal autonomy, respect for sentient life, and the creation of beings for purely utilitarian purposes. Comparing genetic manipulation with human benefit and animal welfare reveals both advantages and disadvantages. On one hand, genetic engineering may produce animals with more transplant-compatible organs, potentially reducing the number of animals needed. On the other, as George AJT,<sup>(7)</sup> notes, these procedures may cause suffering and health problems in animals, raising serious ethical concerns.

Social and cultural acceptance of xenotransplantation is a complex issue extending beyond medical and biological considerations. Differences in cultural perceptions and beliefs about using animal tissues in medicine reflect the diversity of traditions and values across communities. These variations pose ethical challenges in establishing universally acceptable policies and practices. It is crucial to address these differences to ensure xenotransplantation is conducted ethically, socially responsibly, and with cultural sensitivity—respecting the beliefs and values of all involved groups.<sup>(19,20)</sup>

Regarding ethical principles, *non-maleficence*—the duty to avoid harm—applies to both animals and humans due to their capacity to feel pain. In xenotransplantation, animals are isolated, subjected to painful tests, and often endure significant physical and psychological harm—constituting a direct violation of this principle.<sup>(4)</sup> Although some effects may be mitigated, isolation and lack of social interaction still cause harm, further violating non-maleficence. The suffering and death of animals in these procedures raise serious moral questions about justifying such practices.<sup>(19)</sup>

The principle of *beneficence* plays a crucial role in the ethical evaluation of xenotransplantation. While these procedures may offer significant benefits to human patients, they also present major ethical challenges regarding animal welfare and resource allocation. Ethical assessment must carefully balance these factors to ensure medical practices are as beneficial and equitable as possible.<sup>(6)</sup> Moreover, the uncertain and high costs of xenotransplantation research may divert financial resources from other research areas that could be more ethical and have greater public health impact.<sup>(3)</sup>

The principle of *autonomy* is difficult to apply to animals and individuals with functional disabilities. Autonomy implies intentional, informed choices free from external influence—criteria that do not readily apply to animals.<sup>(22)</sup> Nevertheless, autonomy should be respected by allowing species-typical behaviors. As the bioethical analysis shows, the balance leans heavily toward disadvantages, making it impossible to perform xenotransplantation without violating core ethical principles. Under these circumstances, xenotransplantation is ethically impermissible. An alternative proposal would be to redirect resources or address these challenges through a transparent, regulated approach that respects both human and animal life, as well as diverse cultural, social, ethical, and political perspectives.<sup>(19)</sup>

## CONCLUSIONS

The growing demand for organ transplants, contrasted with limited supply, has driven the search for alternatives such as xenotransplantation. Despite advances in genetic modification—particularly CRISPR/Cas9, which has improved graft compatibility and survival—xenotransplantation continues to face significant immunological and bioethical challenges. Key concerns include animal welfare, safety regarding potential zoonotic diseases, distributive justice in access, informed consent, environmental sustainability, and philosophical debates on human identity, transhumanism, and dignity. Although xenotransplantation offers a promising solution to organ shortages and severe diseases, its implementation demands an integrated ethical framework that harmonizes scientific innovation with social responsibility and respect for fundamental moral principles.

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