

REVIEW

The importance of public engagement in clinical xenotransplantation

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Abstract

Over the past several decades, significant scientific progress in xenotransplantation has brought the field to the threshold of clinical trials. In the past 3 years in the United States, experimental pig kidney and heart xenotransplantation have been performed on human subjects recently declared dead by neurological criteria (decedents). In addition, two pig heart transplants have been carried out in living patients under the United States Food and Drug Administration's expanded access guidelines. However, though there has been a flurry of activity there remain unanswered questions regarding how the public views xenotransplantation, what concerns may exist, and how to address these concerns in a meaningful way. This paper aims to underscore the importance of public engagement in xenotransplantation, emphasizing the ongoing need for studies to assess public opinions. The current evidence on public engagement studies is reviewed and gaps in our understanding are identified. We propose practical steps to advance this field. Additional studies to determine the extent of racial/ethnic differences in attitudes to xenotransplantation should be conducted. Empirical and descriptive analysis of certain religious viewpoints—especially minority faiths—would be valuable. As public engagement is an important aspect of public acceptance of novel research that is accompanied by risk, we suggest that xenotransplantation biotechnology companies might consider leading the way in funding this research.

KEYWORDS

clinical trials, ethics, public engagement, viewpoints, xenotransplantation

Abbreviations: IXA, International Xenotransplantation Association; UAB, The University of Alabama at Birmingham; USA, United States of America; WHO, World Health Organization.

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1 | INTRODUCTION

There is a critical need for alternatives to solid organ transplantation from deceased human donors (allotransplantation) to address the persistent shortage of transplantable human organs. Xenotransplantation (or cross-species transplantation), specifically of genetically-modified (gene-edited) pig organs or tissues into humans, is one potential solution to this need. Since 2021, both cardiac and renal xenotransplantation have been studied in human subjects recently declared deceased by neurological criteria, known as “decedents.” At least 5 gene-edited pig kidneys have been experimentally transplanted into decedents in the United States of America (USA) [1–3]. Clinical trials of pig kidney xenotransplantation in adults may begin soon.

Pig heart xenotransplantation has also been studied in human decedents [4]. Of greater importance, in January 2022 and September 2023, gene-edited pig cardiac xenotransplantation was performed in two living patients at the University of Maryland Medical Center in Baltimore, living for approximately 8 and 6 weeks, respectively. These xenotransplants had been approved by the United States Food and Drug Administration on “expanded access guidelines”, i.e., on a “compassionate” basis as no other realistic form of therapy was available to the patients.

Despite the surge in xenotransplantation activities over the past 3 years and the growing likelihood of formal clinical trials, we question whether the perspectives of the public have been sufficiently taken into account in this emerging medical field. In the USA, the context from which we write and where solid organ xenotransplantation clinical trials are being planned, no large-scale studies of the public attitude toward xenotransplantation have been published. Furthermore, it is uncertain whether and how centers that are considering a clinical trial of xenotransplantation are planning to engage the public.

In this brief paper, we explore the significance of public engagement in emerging medical technologies, with a specific focus on xenotransplantation. We then provide a review of existing studies, summarizing what is currently understood regarding the public’s perspectives and identifying present omissions. Last, we discuss potential steps to address and bridge the knowledge gaps in this area.

2 | THE IMPORTANCE OF PUBLIC ENGAGEMENT

Engaging the public in discussion about novel medical technology promotes (i) ethical, (ii) transparent, and (iii) inclusive practices. The result is that this may increase trust and rapport, improve social acceptance, and lead to

the successful integration of advances into the treatment of patients. First, public engagement helps address ethical concerns regarding emerging technologies. Unlike many novel therapies, xenotransplantation presents the small but potentially consequential risk of zoonosis—the transmission of a pathogenic microorganism from the porcine graft to the xenograft recipient and possibly from the recipient to the public. This could potentially put at risk those who have no special or close relationship with the patient, a group termed “bystanders” [5]. These potential risks must therefore be made known during the informed consent process to individuals who potentially may participate in xenotransplantation clinical trials and also to the communities in which clinical trials are being planned so that dialogue can take place.

The importance of community engagement is recognized in international research ethics guidelines, such as the United Nations Educational, Scientific, and Cultural Organization’s “Universal Declaration on Bioethics and Human Rights” [6] and the “International Ethical Guidelines for Health-related Research Involving Humans,” a joint venture from the Council for International Organizations of Medical Sciences and the World Health Organization (WHO), which states:

Guideline 7: Researchers, sponsors, health authorities and relevant institutions should engage potential participants and communities in a meaningful participatory process that involves them in an early and sustained manner in the design, development, implementation, design of the informed consent process and monitoring of research, and in the dissemination of its results [7].

Similarly, the Changsha Communiqué, a summary document produced following the First WHO Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials specifies that any xenotransplantation regulatory system “should be transparent, must include scientific and ethical assessment and should involve the public” [8]. This principle was reaffirmed by the WHO in 2011 and 2018 in collaboration with the International Xenotransplantation Association (IXA), an official section of The (international) Transplantation Society [9, 10].

Second, open and transparent communication has the ability to foster trust between the public and researchers. Intentional dialogue creates a platform for addressing hesitations, concerns, and any misconceptions that may exist. Engaging the public early in the process of introducing a novel technology, such as xenotransplantation, helps identify potential barriers to social acceptance and allows for

researchers to make adjustments to enhance acceptance. Open and transparent communication must include allowing the public to have a voice.

A cautionary tale relates to the experience in Australia. Public consultations were held in Australia between 2002 and 2004 to decide whether xenotransplantation should proceed. The process has been criticized on the basis that the public consultations were flawed in their design by preemptively suggesting that xenotransplantation clinical trials are inevitable and should be allowed to proceed [11]. The consultations led to a moratorium on xenotransplantation in Australia. Hence, the content of what constitutes adequate, open, and transparent communication and dialogue with the public must be thoughtfully considered.

Third, involving a diverse range of perspectives ensures that considerations such as cultural, religious, socioeconomic, and demographic factors are taken into account. This inclusivity acknowledges the voice that the public should have in democratic societies, which is especially important when novel technology has the potential to greatly impact society which is the case with xenotransplantation as when a porcine infectious agent could possibly spread into the community [12]. The goal of such inclusivity is that more comprehensive and equitable healthcare solutions may result.

3 | REVIEW OF CURRENT PUBLIC ENGAGEMENT

The recent studies that have been conducted to engage the public on their viewpoints toward xenotransplantation will be briefly reviewed. A 2020 meta-analysis of public perceptions towards xenotransplantation examined published studies from 1985 to 2019 and concluded that the majority of what is known about public perceptions comes from students, hospital staff, and other non-patient stakeholders [13]. While surveys of the opinions of patients were published during that time-period, the number of patient respondents (those who had received an organ transplant or were on a waitlist for a deceased human donor organ) was too low for meta-analysis. This is worrisome. Clinical trials of pig kidney or heart xenotransplantation seem likely to take place within a very few years, yet it is still somewhat unknown—on a large scale—what potential patients think about this new form of therapy.

In a 2023 systematic review of the attitudes to xenotransplantation of patients with kidney disease, 14 studies were included, only 4 of which had been published since 2011. Of the 4 studies carried out in the USA [14], 2 were published as long ago as 1998 [15, 16], while the 2

additional studies were published in 2020 and 2021, respectively. Additional studies have been published elsewhere globally, yet the focus in many of these studies is on stakeholders other than patients, such as healthcare workers or healthcare students [17–20]. Much has transpired in xenotransplantation over the last decade and so the vast majority of available patient viewpoint data are therefore outdated. Further, some of the completed quantitative studies are open to criticism for not using a validated survey; one such validated survey in Spanish was published in 2018 [21].

Although the data are well over a decade old, the majority of kidney patients (63%, $n = 1354$) included in these studies were favorable toward xenotransplantation as long as the function of the xenograft was comparable to that of an allograft, i.e., a transplant of a human donor organ (Obviously, this is hitherto unknown). Acceptance fell considerably (to 15%) if function was anticipated to be inferior to that of an allograft. Acceptance also fell (to 35%) even if the xenograft was considered to be a “bridge” to allotransplantation, i.e., a temporary therapy to help a patient survive for a relatively short period of time (weeks or months) until a deceased *human* organ becomes available.

This concept of “bridging” is particularly relevant to babies born with complex congenital heart disease (i.e., born with an abnormal heart structure) for whom no truly successful therapy may be available [22]. In these babies, the transplantation of a human heart (allotransplantation) is followed by very successful outcomes, but it may be several months before a heart from a suitable-sized deceased human donor becomes available (during which period the patient may not survive). If the baby's life could be sustained by a pig heart for a few months until a human heart became available, this could be life-saving and result in long-term survival.

Studies conducted at the University of Alabama at Birmingham (UAB) in the USA represent the most current empirical data on viewpoints of the public toward xenotransplantation. In 2019, researchers at UAB conducted qualitative and quantitative studies with various populations. Quantitative surveys were conducted with medical professionals, pre- and post-transplant kidney patients, and parents of children with congenital heart disease who were likely to need a heart transplant. In a survey of medical nephrologists, transplant surgeons, nurses, and pre- and post-kidney transplant patients, 80% of the medical professionals and 69% of patients viewed xenotransplantation positively, but again this was dependent on the risks and outcomes being similar to those of allotransplantation [23]. Notably, acceptance declined by 30% for medical professionals and by 42% for patients if the

results were anticipated to be inferior to those of allotransplantation [24].

In a survey of surgeons specializing in the correction of congenital heart disease, pediatric transplant cardiologists, pediatric cardiac nurses, and parents of children with congenital heart disease, acceptance toward xenotransplantation was generally high (75%), but once again only if outcomes were likely to be similar to those of allotransplantation [25]. Physicians had a more positive view of xenotransplantation than nurses and parents (86%, 71%, 64%, respectively). Notably, parents did raise psychosocial concerns based around how xenotransplantation may affect other peoples' interactions with their child. There was an inverse relationship between greater parental psychosocial concern and lower acceptance. In addition, persons reporting religion as an influencing factor in their medical decision-making process were less likely to approve of xenotransplantation.

A survey of members of the Congenital Heart Surgeons Society and Pediatric Heart Transplant Society, which consisted of pediatric heart surgeons and cardiologists, found high levels of acceptance toward xenotransplantation if risks and outcomes were predicted to be similar to allotransplantation [26]. However, surprisingly only 41% of surgeons and 17% of cardiologists would recommend parents to consider a pig cardiac xenograft as a bridge to allotransplantation. Nonetheless, and perhaps equally surprising, if the outcome of a pig cardiac xenotransplant was good, both groups agreed they would not recommend replacement of the xenograft if a human heart subsequently became available.

Based upon the results of surveys conducted at UAB, further analysis was conducted to ascertain if acceptance of xenotransplantation differed according to race/ethnicity [27]. Sufficient data were available only from persons identifying as Black or (non-Hispanic) White to analyze their viewpoints. White kidney patients' acceptance of xenotransplantation was higher (91%) than Black kidney patients (70%). In addition, White kidney patients were more likely to accept xenotransplantation if the results were expected to be similar to those of allotransplantation and were also less likely to be concerned about potential psychosocial changes.

Focus groups with various stakeholders from the community surrounding UAB were also held [28, 29]. Five focus groups were conducted, comprised of the following participants—(i) local religious leaders, (ii) organ procurement staff/administrators, (iii) parents of children with congenital heart disease who may need an organ transplant, (iv) pre- and post-transplant kidney patients, and (v) local businesspersons. There was general agreement among the participants in their respective groups that xenotransplantation is an exciting

medical advance, and most were accepting of it as an alternative to allotransplantation.

Religious leaders (1 Catholic, 8 Protestant, 1 Muslim, and 1 Jewish representative who was not present in person but sent in a written statement of his viewpoints) expressed concerns about animal welfare, potential long-term risks of xenotransplantation, and “playing God,” which one participant defined as “overstepping what the Creator [God] has provided.” However, no religious leader stated that placing a genetically-modified pig organ into a person was necessarily forbidden in their tradition. Both the Islamic and Jewish representatives—two faith traditions whose adherents do not consume pork—stated that the life of the individual would take precedence over any religious law forbidding interaction with pigs. Social concerns around stigma were expressed by participants in several of the focus groups, including parents of children with congenital heart disease who worried their children could be bullied or teased for having a pig organ.

Some additional empirical and descriptive literature on religious viewpoints toward xenotransplantation has been published. The empirical data that does exist have mainly been collected via demographic records in viewpoint studies that were not specifically concerned with religious perspectives. Hence, detailed empirical data based upon religious viewpoints are lacking. Nevertheless, descriptive analysis on how Catholic [30–32], Protestant [33], Jewish [34, 35], Sunni [36, 37] and Shia Islam [38], and Hindu [39] faith groups may approach xenotransplantation, much of which expresses an openness toward xenotransplantation, has been published. Much less is known about how adherents to certain other religious/philosophical traditions—such as Buddhism, Jainism, Shinto, Sikhism—view xenotransplantation. Little is also known about the viewpoints of Orthodox Christianity, Coptic Christianity, The Church of Jesus Christ of Latter-Day Saints, and if nuance may exist among the myriad Protestant denominations.

4 | DISCUSSION

As this review has indicated, the majority of data on public viewpoints toward xenotransplantation is outdated and does not adequately take into account the critical viewpoints of patients who may benefit from xenotransplantation. In the USA, the studies performed by researchers at UAB are, to date, the only published reports of relatively large-scale studies of public perceptions. In these studies, researchers found an overall positive attitude toward xenotransplantation when risks and outcomes were deemed to be equivalent to allotransplantation. However,

favorable attitudes fell significantly when risks and outcomes of xenotransplantation were anticipated to be worse than allotransplantation. This may have implications for willingness of individuals to participate in early clinical trials when safety and efficacy is uncertain. It is perhaps more surprising that many of those surveyed were not enthusiastic of the use of xenotransplantation as a bridge therapy to allotransplantation.

Due to our work in the USA, we are particularly concerned that xenotransplantation—should it prove to be a safe and effective alternative to allotransplantation—may not benefit certain populations. This is a problem of equity and should be an immediate priority for discussion by stakeholders within xenotransplantation [40]. Aside from one single-center study [27], no empirical data have been published detailing how persons of different racial and/or ethnic backgrounds view xenotransplantation.

In the USA, disparities exist in kidney allotransplantation for Black patients compared to White patients. Black persons are two- to fourfold more likely than White persons to develop kidney failure, but they have lower rates of allotransplantation [41]. Our concern is that in the absence of additional public engagement, xenotransplantation may not actually relieve disparities and thus improve outcomes for Black patients and other racial minorities. While Black patients may be less accepting of a xenograft than White patients, there is, crucially, no specific data on why this is so.

Medical mistrust is relatively high among some Black communities in the USA [42], which may be tied to historic mistreatment such as the Tuskegee Syphilis Study (an infamous study by the US Public Health Service from 1932 to 1972 that sought to examine how syphilis affected Black men, yet the infected men were never told they had syphilis nor were provided treatment for it) [43]. In addition, personal experience of the health care system in parts of the USA and possibly racial bias may have contributed to their mistrust [44]. Additional public engagement is needed to confirm the UAB findings, determine the reasoning of why hesitations exist, and meet the aspirations of the “International Ethical Guidelines for Health-related Research Involving Humans” and the Changsha Communiqué.

In particular, we suggest that public engagement before clinical trials of xenotransplantation should proceed with both qualitative and quantitative studies. These research methodologies can complement each other by using qualitative research as a preliminary to quantitative studies. Qualitative public engagement studies should focus on the specific communities around the institution in which xenotransplantation clinical trials are likely to take place. These qualitative studies could take on various forms, including one-on-one interviews and focus groups with key stakeholders. Patient groups, including persons in need of a

transplant and those who have already received a transplant, as well as influential community members, such as policymakers and religious leaders, should be involved. Ensuring diversity within these groups is crucial, encompassing a broad spectrum of demographics, gender representation, and age ranges, with a deliberate inclusion of both youth and seniors. Based upon these qualitative studies, larger-scale quantitative studies could be conducted to establish widespread viewpoints.

Improving public engagement will require adequate funding and resources. As has been demonstrated, additional studies are needed to further ascertain the public’s viewpoints on xenotransplantation. Hesitation has been noted in quantitative and qualitative work; additional data are needed to understand further these hesitations and to explore ways to ameliorate the concerns. We suggest that biotechnology companies engaged in this scientific research might consider accepting a commensurate responsibility for financing studies on public perceptions. These studies should strive to ensure that advances in clinical xenotransplantation are pursued in a manner that is respectful of communities and benefits and aligns with expectations of patients, rather than introducing the potential for creating additional health inequities or cultivating mistrust.

To accomplish this goal, biotechnology companies could establish collaborations with social science researchers specializing in xenotransplantation who have already conducted studies on patient and public attitudes. Through these collaborations, biotechnology companies would demonstrate their commitment to listening and learning and would be responding to the appeals for genuine public involvement in xenotransplantation advocated by international organizations such as the WHO and IXA.

5 | CONCLUSIONS

The strides made in xenotransplantation research represent a remarkable journey from scientific exploration to the verge of clinical application. Yet, as we navigate this field and approach clinical trials, it is evident that the public’s perspective on xenotransplantation is a crucial factor that merits further consideration. By bridging the gap between scientific progress and public perception, we can pave the way for a more informed, inclusive, and ethically sound future in xenotransplantation.

AUTHOR CONTRIBUTIONS

Daniel J. Hurst wrote the initial manuscript draft and David K. C. Cooper contributed to specific areas and critically revised the overall text.

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The authors have nothing to report.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

ETHICS STATEMENT

Not applicable.

INFORMED CONSENT

Not applicable.

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