

Preparing Patients, Care Partners, and Clinicians for Discussions About Xenotransplantation: A Kidney Transplant Research Possibility



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End-stage kidney disease or kidney failure, is a leading cause of illness and death in the United States. In 2020, over 800,000 people in the United States were living with kidney failure, with 69% receiving dialysis and 31% with a kidney transplant.¹

Kidney transplantation is the best available treatment for kidney failure. However, there are not enough human donor kidneys for all the people who need them. About 93,000 people are on the waiting list for a kidney transplant.² Wait times can vary depending on a person's situation with many people waiting up to 5 years, sometimes longer, for a kidney transplant.³ Although total kidney transplants exceeded 25,000 for the first year ever in 2022, continued progress is needed to meet demand.⁴ It is estimated that one out of 20 or 5% of people with kidney failure die each year while waiting for a kidney transplant.² Furthermore, disparities in access to kidney transplantation disproportionately affect historically marginalized and underserved populations.^{5,6}

Read AIR's ["Addressing Health Disparities in Kidney Care"](#) In the Field article to learn more about efforts to improve in kidney care.

Researchers are exploring the possibility of xenotransplantation as a potential future treatment for kidney failure. Xenotransplantation is the transplantation of organs, tissue, or cells from one species to another.⁷

In collaboration with the American Society of Nephrology (ASN) Kidney Health Initiative (KHI), in April and May 2022, American Institutes for Research® (AIR®) experts conducted one-hour-virtual, individual interviews with a diverse, purposive sample of 20 adults with kidney failure who were either receiving a form of dialysis or living with a kidney transplant, 10 care partners, and nine nephrologists.

In this article, we share findings related to participants' awareness of xenotransplantation as a potential future kidney transplant option in light of recent advancements, their perceived benefits and risks of xenotransplantation, and their recommendations for when and how patients, families, and clinicians should have discussions about xenotransplantation, and

what information is most important to share. A description of study methods is provided in Appendix A.

Findings related to participants' overall reactions to xenotransplantation as a potential future transplant possibility, concerns about the concept and process of xenotransplantation, and considerations for clinical trials including consent and likelihood of participating in a clinical trial for xenotransplantation if offered, informed two patient perspective articles published in *Kidney360*.^{8,9}

Read Kidney360's "[Patient Perspective on Xenotransplantation](#)" and "[Xenotransplantation and the Role of the Patient Voice](#)" to learn more.

Advancements in Xenotransplantation Research

Recent breakthroughs in pig-to-human kidney and heart transplant studies offer great promise for addressing the human donor organ shortage, including the following:

- In the first successful transplant study, a genetically engineered pig kidney was attached to blood vessels in the upper leg of a donor who was brain dead at New York University Langone in September 2021.¹⁰ As of August, 2023, New York University Langone has performed three pig kidney xenotransplantation studies.¹¹
- Two pig kidneys were transplanted into the abdomen of a donor who was brain dead at the University of Alabama at Birmingham in September 2021.¹² As of January 2024, the University of Alabama at Birmingham team has conducted three decedent model xenotransplant studies and have established the optimal immunosuppression regimen for pig-to-human kidney transplants.¹³
- The first pig heart was implanted in a living recipient with terminal heart disease at the University of Maryland Medical Center in January 2022.¹⁴ In September 2023, the University of Maryland team performed the second pig heart transplant on a patient who was not eligible for a traditional heart transplant.¹⁵
- On March 16, 2024, the Massachusetts General Hospital Transplant Center conducted the first successful transplant of a genetically-edited pig kidney into an individual living with kidney failure.¹⁶

Researchers are developing plans for the first-in-human studies to advance understanding of xenotransplantation as a kidney transplant option pending regulatory approval.^{17,18,19} With

clinical trials on the horizon, it is important that researchers and sponsors actively engage and help prepare patients, care partners, and clinicians for discussions about xenotransplantation.

Participants' Awareness, and Perceived Benefits and Risks of Xenotransplantation

Reported Awareness

Of the 30 patients and care partners interviewed, 57% were aware of xenotransplantation. They recalled hearing about testing of pig organs for transplantation on the news, social media, or directly from their doctors. Many patients and care partners shared their thoughts on the news about the pig heart transplant surgery that was conducted at the University of Maryland in January 2022, a few months prior to the interviews.¹⁴

"I heard about the animal organ transplant. I guess he had heart failure, and they gave him the pig heart. It was successful then he ended up dying like a couple weeks later, or a couple days later. I'm not sure how long he survived. I was really impressed."

— Care Partner of Patient Receiving in-center Hemodialysis

All nephrologists reported being aware of xenotransplantation, having learned about it during medical training or hearing of the recent pig heart and pig kidney transplant studies at nephrology conferences, in medical literature, or from news outlets and social media.

Perceived Benefits and Risks

Across participant groups, interviewees discussed the following perceived benefits and risks of xenotransplantation.

Perceived Benefits

- Expanding the supply of organs available for transplantation and reducing long waiting times
- Reducing or eliminating the need for dialysis and resulting complications and hospitalizations
- Improving the quality of life for people with kidney failure and their care partners

- Providing a bridge therapy for people with kidney failure who do not want to start dialysis, experienced a rejection event from a donor kidney, or who are unlikely for human donor kidney transplants because of age or health constraints

Perceived Risks

- Major risks similar to human kidney transplants, such as organ rejection, infection, bleeding, or other complications requiring hospitalization
- Zoonotic infections or transmission of other infectious organisms
- Possible religious, moral, or ethical concerns about organs coming from nonhuman species

Nephrologists stated that many of their patients may be willing to try xenotransplantation because they have been suffering for a long time and are willing to accept the risks.

Nephrologists also identified the unknowns associated with xenotransplantation as posing risks because there is little data available related to short-and long-term outcomes that would better indicate the safety of this form of transplant. The potential long-term health consequences are not well understood, and many providers had questions about risks for cancer or immunological side effects.

"No clinical trials have been done with organs. I know we have been using pig valve, the insulin from the pig, but that's different from the pig organ that we transplanted. Eventually we'll need a few years to see if there are any complications."

— Nephrologist

Participants' Perspectives on What Patients and Families Need and Want to Know About Xenotransplantation

Patients, care partners, and nephrologists expressed a need for transparent and understandable information about xenotransplantation that is accessible and understandable for diverse audiences. Patients, care partners, and nephrologists identified information that would be important for patients and families to know about:

- **Donor Pigs.** Participants expressed that it is important to share information about the health and age of donor pigs, the environment in which they are raised and how they are treated, and how genetic modification is accomplished and compatibility is maintained.

- **The Xenotransplantation Process.** People with kidney failure and their care partners need information about immunosuppressant medicines and any risks associated with their use, the recovery and aftercare process, risks of rejection and potential for infections or infection spread, the longevity of a xenotransplant, and treatment options if the xenotransplant fails.
- **Clinical Trials.** To support discussions about potential participation in a clinical trial for xenotransplantation, people with kidney failure and their care partners must receive detailed information about trial eligibility and expectations for participation. This information includes trial timeline and compensation, as well as potential benefits and risks, results from previous testing, success and failure rates, and any available data on short- and longer-term outcomes. Participants also noted that there are many unknowns about whether xenotransplantation could be a viable option for people with kidney failure but were optimistic that forthcoming clinical trials would help answer such questions.

Participants' Recommendations for Discussing Xenotransplantation: Considerations for Practice

When to Have Discussions about Clinical Trials for Xenotransplantation

Patient and care partner participants shared varying perspectives about when either they, or the person they care for, should be approached about participating in a clinical trial for xenotransplantation. Several stated that patients and families should be approached about the potential option of a

clinical trial as soon as possible or as soon as it is determined that this is a viable way to treat kidney failure. Others suggested that patients should be approached as soon as they start dialysis or when they are being initially evaluated for a transplant so that participants have time to research and evaluate their options. One patient felt that anyone who has been receiving dialysis for a long time and is running out of time, or anyone who is anxious to try anything, should be approached right away. Patients and care partners also suggested including xenotransplantation as a potential option that is presented when they first learn that they or their loved ones have kidney failure. However, some patients and care partners thought that clinicians should wait to share xenotransplantation as a treatment option once more research has been conducted to show that it is safe.

"The sooner the better, like immediately. Let's get the ball rolling on it...because time is of the essence for people with the kidney failure to see if anything will help."

—Patient Receiving Home Hemodialysis

Who Should Lead Discussions

Most people with kidney failure and care partners felt that the nephrologist should share this information with patients and families. Other patient- and care partner–reported trusted sources of information about clinical trials for xenotransplantation included nurses, dialysis care team members, spouse or family, social workers, transplant surgical team, researchers or the clinical trial team, representatives from organizations that are studying kidney failure, people with kidney failure, and patients who have received this type of treatment previously (peer-to-peer knowledge sharing).

“This is not for everybody, obviously. The patient has to have not only trust in their provider, as well as trust in the research proposal, but overall trust in the whole medical community in order to want to participate in this.”

— Nephrologist

Nephrologists stated that they would first want more education for themselves about xenotransplantation and clinical trials before sharing information with patients and families. They also discussed the importance of having lengthy, transparent discussions with patients about the trial, presenting all available

information, including the “hard facts” about survival and the need to initiate or return to dialysis, and including family and care partners in those discussions. Although most nephrologists envisioned having these discussions with patients and families directly, a couple mentioned deferring to the transplant team, the trial coordinator, or someone more knowledgeable about xenotransplantation than they are to educate patients and families about it. They also noted that patients who typically have more trust in the health care system and their care providers would be more willing to consider participating in a clinical trial and that it will be easier to present the data and the opportunity to patients and their families once there are more trials. To increase access to information about xenotransplantation, patients and care partners recommended that trusted sources share findings as they become available through multiple channels.

Patients, care partners, and nephrologists recommended strategies to help prepare clinicians to have conversations with patients and families about future clinical trials for xenotransplantation:

- Going out into communities; listening to the concerns of patients and families, whether cultural, religious, or ethical; and sharing information directly with community members

- Ensuring widespread, early education of kidney care teams (e.g., nephrologist, health educator, social worker), as well as the medical community at large, because many specialties will likely explore xenotransplantation
- Developing and disseminating educational materials and literature in language that is widely understandable and tailored to meet the needs of diverse communities (e.g., handouts, videos, pamphlets, websites)
- Sharing information about xenotransplantation via various channels, such as directly with patient advocacy groups via virtual information sessions, directly at the dialysis center, patient health portals, social media, and patient advocacy organization mailing lists, as well as creating a centralized source of education with contact information that patients and families can use to ask questions or get support
- Sharing testimonials or providing opportunities for people with kidney failure and their families interested in xenotransplantation to talk to people who have participated in previous xenotransplantation trials

Regardless of the information dissemination strategy, participants highlighted the importance of ensuring that everyone has access to accurate, reliable, and all available information about xenotransplantation, building trust between the people providing the information and those receiving it, and consistently following up with patients and families who may be interested in participating in clinical trials or have additional questions.

"Taking notes from some of the approaches that were made with introducing the pandemic. You see such a variation of where information is coming from, how it's presented. We've seen it in several languages in our area so that everybody can understand it. We've seen it very diverse where you can see yourself in the situation, see yourself getting the vaccine. Targeted advertising is important."

— Care Partner of Patient with Functioning Kidney Transplant

Strengths and Limitations

This exploratory qualitative study gathered patient, care partner, and nephrologist perspectives about xenotransplantation as a potential future kidney transplant possibility in the wake of several breakthroughs in xenotransplantation research. However, it is important to acknowledge that this article reports on interviewees' expressed viewpoints about the topic and are not based on scientific knowledge as no clinical trials had been conducted. Given the study's exploratory aims, we intentionally recruited a purposive, rather than random sample, to

gather rich information from a smaller, diverse group of participants. Thus, these perspectives may not reflect those of the larger population. Future research could engage a broader swath of perspectives within the nephrology community. Despite these study limitations, this research expands understanding about how patients, care partners, and nephrologists conceptualize xenotransplantation as a potential future therapy, including potential benefits, risks and considerations for discussions about forthcoming clinical trials.

Conclusion

Breakthroughs in xenotransplantation offer great promise for addressing the critical organ donor shortage, particularly for those living with kidney failure. Our discussions with patients, care partners, and nephrologists underscore the need to prepare both clinicians and families for discussions about potential participation in a clinical trial for xenotransplantation. As with other kidney failure treatments, participants emphasized the utmost importance of equitable access to information and opportunity.

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Appendix A. Study Methods

Recruitment. The project team partnered with a recruitment firm, L&E Research, to recruit 20 adult patients and 10 adult care partners (30 total recruits) for interviews from its large, engaged, and diverse panel of over 2,500 patients with kidney disease. We intentionally applied a purposive sampling approach aimed to maximize efficiency and heterogeneity in terms of race, ethnicity, gender, education, geographic location, income range, time on treatment and other factors and include participants who reflected varying experiences with kidney failure treatments (i.e., time on dialysis, transplant history, experience with acute and chronic complications, etc.) and other factors that might influence patients' and families' decision to participate in a future clinical trial for xenotransplantation. We did not require patient-caregiver dyads as a criterion for recruitment. The project team recruited nephrologists for interviews via a market research database inclusive of providers who had previously agreed to be contacted about opportunities to participate in ASN-sponsored market research. Similar to patients and care partners, we aimed to recruit a mix of providers with respect to clinical role, geographic location, clinical settings in which they provide care, practice experience and demographic characteristics.

Interview Guide. We developed tailored, comprehensive semi-structured interview guides for each participant group. The structure of the discussion was similar across guides and included the four primary topics: personal experience with kidney failure treatments, awareness of xenotransplantation, perceptions about xenotransplantation, and perceptions about future first-in-human trials for xenotransplantation.

Data Collection. The project team developed and shared two informational handouts with all confirmed and scheduled participants to ensure that they came to the meetings prepared to actively participate in the discussion. One described the project, purpose of interviews, and informed consent. The other handout included general information about xenotransplantation including a definition and facts about the process of a human donor kidney transplant compared to a xenotransplant. Both handouts were written in plain language for broad understandability (Flesch-Kincaid reading level: information sheet=9.6; xenotransplantation handout=8.9). Hour-long interviews were conducted in two rounds between April 1, 2022 and May 14, 2022 (Round 1: 4/1/22-4/12/22; Round 2: 4/18/22-5/14/22) using virtual meeting software, Zoom. Participants joined by phone or video based on preference. Round 1 consisted of five patients and five care partners to test the interview guide and ensure that interviewees were interpreting questions as intended. Upon determining that no changes to the interview approach were needed, we

conducted Round 2, which included all remaining patient and care partner interviews, and all nephrologist interviews. All participants received a \$75 incentive for participation. One care partner interviewed provided care for a patient interviewed as part of this project.

Analysis. All interviews were audio-recorded with participants' permission and professionally transcribed. Qualitative data collected through transcripts from the interviews were imported into NVivo 12 for management and thematic analysis.²⁰ AIR developed a list of codes based on the primary research question and interview topics. The team systematically organized and coded the data to identify core themes and patterns related to information needs across participant groups.

Participant Characteristics.

Patients. We recruited a diverse pool of 20 adult patients who were demographically reflective of the larger patient population. In terms of their current kidney failure treatment, most patients (35%) were undergoing in-center hemodialysis while 25% received home hemodialysis, 20% received peritoneal dialysis, and 20% had a functioning kidney transplant. Patients reported various educational backgrounds including less than high school (5%), high school diploma or GED (15%), Bachelor's degree (30%), and Master's degree (10%). Half (50%) of patient participants were aged 40-64 years. Four patients (20%) identified as Hispanic/Latino ethnicity.

Care Partners. The ten care partners interviewed also represented various educational backgrounds from some college (30%) to Bachelor's degree (30%) and Master's degree (20%). More than half of the care partners (60%) were African American and 40% were White. One care partner (10%) was of Hispanic/Latino ethnicity. Nearly all care partners (90%) were female. Sixty percent of care partners interviewed were aged 40-65 years. Most (70%) care partners were the spouse or partner to the patient, while 20% were adult children of the patient and 10% were the parent of the patient.

Patients of Care Partners. Half (50%) of the ten care partners' patients they cared for were aged 40-64, and 80% were male. In terms of current kidney failure treatment, most patients (40%) cared for received in-center hemodialysis while 30% received home hemodialysis, 10% received peritoneal dialysis, and 20% had a functioning kidney transplant. More than half (60%) of patients cared for identified as African American and 40% were White. One (10%) patient was of Hispanic/Latino ethnicity.

Nephrologists. Eight of the nine (89%) nephrologists interviewed had over 10 years of practice experience. The interview sample included one transplant nephrologist while the remaining

interviewees were general community nephrologists. Four interviewees also serve as dialysis center medical directors. Nephrologists were primarily male (66%), either Asian (56%) or White (44%), and of varying ages (average age=58; range=43-74). Nephrologists practiced in suburban (44%), urban (33%) and rural areas (22%).

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