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Key Points:

Abstract:

Disclosures: M. Baliker reports the following: Employer: Baliker Healthcare Consulting; Ownership Interest: Exact Science, CareDx; and Honoraria: CareDx, Department of Defense, Talaris Therapeutics, American Kidney Fund. G. Roberts reports the following: Employer: University of Washington (UW), Kidney Research Institute; University of Washington, Center for Dialysis Innovation; UW Justice, Equity, Diversity, and Inclusion Center for Transformative Research; Consultancy: Vortex (spouse); Ownership Interest: I own 50% of Options Unlimited International; Advisory or Leadership Role: Center for Innovations in Cancer & Transplants, chair of Community Engagement (Eng.) Committee (Comm.), Steering Comm.; KRI Patient Advisory Comm.; CDI Patient Advisory Board; Kidney Precision Medicine Project Community Engagement Committee; C-Path Patient Eng. Comm. & DIKI Project; Expert Patient Panel, CRIC study; University of Minnesota's Office of Discovery and Translation: Reduce Medication-Related Disparities in African American Patients with Chronic Kidney Disease; Speakers Bureau: American Association of Kidney Patients Speakers Bureaus; and Other Interests or Relationships: KHI PFPC; ASN COVID-19 Response Team & Transplant Subcommittee; HDU Advisory Comm; APOLLO CAB.; ASN NTSD Quality, Assessment, Improvement and Education WG; APOLLO; International Nephrology Society (ISN), Patient Group; Can-SOLVE CIRAC; KHI APOL1 Steering Comm.; American Association of Kidney Patients; KDIGO CKD & Complications in Dialysis WGs; NKF Ambassador, KAC Diversity WG & Patient Education Series; NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney.

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Patient Perspective on Xenotransplantation

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We would like to thank The American Society of Nephrology’s Kidney360 for inviting us, the patients, to present our view on xenotransplant. There are currently two types of kidney transplants, living donor and deceased donor. As kidney transplant recipients, we are encouraged that xenotransplant could potentially be a third.

As the kidney organ donor shortage continues to be an ongoing problem, we must look at potential solutions. Might xenotransplant be one of the solutions for kidney failure patients?

A person is added to the national organ transplant waiting list every 9 minutes. On average, 17 people die each day waiting for a lifesaving transplant.(1) Kidneys account for more than half of the transplants each year. We need to look at innovation.

**Clinical trials**

We need rigorous clinical research to look at xenotransplant and determine its safety and effectiveness. There will need to be a tremendous amount of education in lay language, and complete transparency. It would be preferred to centralize all research, data, and education for not only patients, but for healthcare professionals. This will also need to be updated in real time. Communication is key to success.

We think patients who might consider enrolling in a xenotransplant clinical trial would be: older (e.g. 80+) who cannot get a human donor kidney, but otherwise in good health; someone doing poorly on dialysis and having health complications; a patient unable to continue waiting for an organ because the list is so long; or someone who wants to help advance science and help with the organ donor shortage.

With xenotransplant being in its infancy, the patients will need a very thorough informed consent discussion with the xenotransplant team about previous research in xenotransplant and related outcomes, potential risks and benefits of the trial, as well as all the details of participating in a clinical trial. It will also be critical for the consent form and discussion to address anticipated questions that potential trial subjects will have such as:

- How compatible are humans and pig kidneys?
- Would pigs be bred for organ donation?
- What does genetically modified mean?
- Would I get one pig kidney or two?
- If I only get one pig kidney, will someone else get the other one and will they need immune suppression drugs?
- Is the transplant temporary as a bridge therapy instead of dialysis?
- Can I still get a human donor kidney transplant if the xenotransplant fails?
- Can I get a xenotransplant if my previous transplant(s) failed?
- Would I remain on the waiting list while receiving a xenotransplant?
- What are the implications of receiving a human kidney transplant or another xenotransplant?
- Will there be more immunosuppression needed and what is the immunosuppression protocol for induction and maintenance?
- What, if any, are the complications and side effects of any required immunosuppression and is other medication prophylaxis needed?
- What possible animal-borne disease or infections might I be exposed to?
- What is the lifespan of a pig and how long is the xenotransplant expected to last?
- What are the survival rates at 1, 3, 5, and 10 years and beyond and what are the rates of rejection and infection?
- Do I need to be concerned about animal rights and religious issues and what my family and the community will think?

**Xenotransplantation and Patient Mistrust**

Beyond addressing all of the questions above and patient concerns about animal rights and religious issues associated with xenotransplantation, mistrust of research and the healthcare system is another area that must be addressed.

The most straightforward definition of trust is to be reliable. That is, as a study participant or patient, can I trust the researchers and healthcare team to do what they say they will do?

The nation’s response to the COVID-19 pandemic demonstrates the effect that the mistrust of research and science has had on health and outcomes. Patients, particularly those who face the greatest risk or who have already used vaccines and other treatments, are increasingly polarized around vaccine acceptance and the use of new treatments and therapies to fight the virus. The national discussion around patients’ trust continues in the context of issues like health, health care, health equity, health policy, physician-patient dynamics, health information and science. Mistrust, particularly of science, is impeding our ability to explore the potential for opportunities like xenotransplantation.

So, what can be done to improve trust in xenotransplantation research and clinical trials? Patient advocate, Celeste Castillo Lee was the founder of the Kidney Health Initiatives Patient and Family Partnership Council. She believed in the transformative power of collaboration between patients, families, staff, faculty and community stakeholders to drive research and patient care forward. To overcome trust issues and achieve Lee’s vision in the context of xenotransplantation, we must have patients involved with researchers as equal partners. Patients should be involved in all aspects of the research from the very beginning to the end. It’s important that we listen and act constructively to address patients concerns.

Organizations involved with xenotransplantation should establish patient advisory boards (PAB) whose representatives mirror the community of people affected by kidney disease. This will enable your efforts to (a) foster a “patient-centered” research culture; (b) help to understand participant priorities, which should help foster retention; and (c) enable your organization to cultivate trust through transparency.
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Reference: