



What Information Do Kidney Transplant Candidates Need to Make Informed Treatment Decisions about Participating in a First-in-Human Pig Xenotransplant Clinical Trial?



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INTRODUCTION

- First-in-human pig xenotransplant (XTx) clinical trials may soon begin.
- XTx trials raise ethical concerns about informed consent, given the lack of data on XTx recipient and graft outcomes.¹
- Prior research on transplant candidates report unique information needs for other clinical research contexts² suggesting that they would have particular information needs for XTx.
- Little is known about kidney transplant candidates' information needs to make an informed decision about whether to participate in a XTx clinical trial.
- This study assessed kidney transplant candidates' information needs for decision-making about participating in first-in-human XTx clinical trials.

METHODS

Design: Cross-sectional study

Setting: Northwestern University, Chicago, IL; Lehigh University, Bethlehem, PA; Rutgers, Piscataway, NJ

Participants: English-speaking adult (18+ years) waitlisted kidney transplant candidates

Data Collection: Semi-structured telephone interviews with patients (July 2022–Feb 2023) on information needs about:

- The clinical trial
- The kidney
- The pig

Data Analysis: Thematic analysis (K > 0.80)

RESULTS

- N=28 participants, 36% participation rate
- Participants: mean age: 49 years, male (65%), White (53%) or Black/African American (36%) or Other (11%), and not Hispanic or Latino (79%)

Table 1. Themes about Participants' Information Needs about Pig XTx Clinical Trials

Themes	Illustrative Quotes
Theme 1: Risk of Contracting and Transmitting Infection <ul style="list-style-type: none">Probability, duration, curability of infection	<ul style="list-style-type: none">“What potential viruses that can happen... Is there any potential viruses that I can give to my family members or to the public.” (NU3004)
Theme 2: Risks, Benefits, Impact <ul style="list-style-type: none">Success rate, rejection rate, graft longevityImpact on quality of life	<ul style="list-style-type: none">“You know, the viruses, the longevity, rejection rate, all that.” (LU3002)“...the expected quality of life after it.” (NU3018)
Theme 3: XTx Research, Recipient Experience <ul style="list-style-type: none">Prior XTx research leading to studySuccess stories of XTx recipients# XTx performed, functional outcomes, benefits, patient experience with medication	<ul style="list-style-type: none">“What generation of trial this is? You know, how far along in the trials we are? How many ... pig transplants have been done prior, and how far along are they?” (LU3008)
Theme 4: Clinical Trial Logistics <ul style="list-style-type: none">Obligations of XTx recipient: monitoringXTx failure “back-up plans”	<ul style="list-style-type: none">“What the research entails; how invasive is it? ... What do I have to do?” (NU3012)“If the kidney failed, would I be moved to the top of the list for a transplant?” (NU3015)
Theme 5: The Pig and Its Kidney <ul style="list-style-type: none">Pig's and kidney's health, medical history, genetic modificationHow the pig was treated, diet, killedPig's age, name	<ul style="list-style-type: none">“Has this animal had any life-threatening diseases before?... Did the pig have any previous diseases or viruses?” (NU3021)“I'd just want to make sure it's healthy enough to do the transplant. And like I say – the health of the pig actually. Yeah. Was it dying? Did it get killed? ... How it was raised.” (LU3003)“I'd want to know how old it was.” (NU3004)

CONCLUSION

- Findings suggest that kidney transplant candidates desire extensive information.
- Information needs are unique and pertain to the pig and the XTx research context.
- The informed consent process for XTx clinical trials should address patients' information needs to facilitate informed decision-making.
- Our findings may enhance previously proposed recommendations for a XTx informed consent form to reflect a patient-centered approach.^{3,4}
- Future research should assess patients' actual decision-making and information needs upon trial initiation.
- Limitations: Perceptions reported reflect patients' consideration of hypothetical XTx trial participation rather than an actual trial.

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