

Study title

Perceptions of Kidney Transplant Recipients Regarding the Role of Artificial Intelligence in Medicine

Date


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Principal investigator	
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(Physician or pharmacist, whether board-certified or not, who will also have access to the data.
This may be a resident.)

Associated partners	
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Signature of the principal investigator	
Date of request	13/05/2026
Signature	

Approval of the head of department/team of the principal investigator (if applicable)	
Name and surname	Loupy Alexandre
Department	Paris Institute for Transplantation and Organ Regeneration
Signature (mandatory)	
Study summary	
Study background (with bibliographic references)	<p>Kidney transplantation is currently the reference treatment for end-stage kidney disease, with more than 170,000 transplants performed worldwide each year (Global Observatory on Donation and Transplantation, 2024). Despite major progress in short-term survival, long-term graft survival remains limited: approximately 40% of patients return to dialysis within 10 to 15 years after transplantation (Hart et al, AJT 2019, PMID 30838768).</p> <p>In recent years, artificial intelligence (AI) has emerged as a promising tool to predict graft outcomes and support clinical decision-making (Raynaud et al, Lancet Digital Health 2021 PMID 34756569; Loupy et al, Nature Medicine 2025 PMID 40659768). The iBox system, developed by the Paris Institute for Transplantation and Organ Regeneration, makes it possible to calculate a personalized probability of graft loss up to ten years after the evaluation of a kidney transplant recipient.</p> <p>This algorithm has been internationally validated in several cohorts and clinical trials (Lombardi et al, AJT 2025, PMID 39674514; Truchot et al, JASN 2025, PMID 40168162), performs better than clinicians in predicting risk (Divard et al, Communications Medicine 2022, PMID 36418380), and was qualified by the European Medicines Agency as an endpoint for clinical trials in 2022.</p> <p>However, although the clinical value of iBox and similar predictive tools is well documented, how patients perceive them remains largely unexplored.</p> <p>Understanding how kidney transplant recipients perceive the prediction of their individual risk of graft loss (in terms of usefulness, acceptability, fears, or impact on daily life), as well as their broader views on the role of artificial intelligence in medicine, including their hopes, expectations, and concerns regarding its deployment, is essential to ensure implementation that is ethical, transparent, and truly patient-centered (Young et al, Lancet Digital Health 2021, PMID 34446266).</p>

Primary objective and corresponding endpoints (Please specify the longer-term application of the study if necessary)	This study therefore aims to explore the perceptions, expectations, and concerns of kidney transplant recipients regarding the use of artificial intelligence, and to assess their specific perceptions of the use of a graft loss risk prediction system, through an open-ended questionnaire distributed on a large scale in France and the United States.
Secondary objectives and corresponding endpoints	--
Study period (Please specify what justifies it)	May 2026: Distribution of the questionnaire to the collaborating transplant centers and patient associations. June 2026: Data collection and management. July 2026: Analysis of the results. September 2026: Presentation and discussion of the results with the participating centers/associations. October 2026: Publication
Number of participants (Please specify what justifies it)	The investigators plan to distribute the questionnaire to a sample of between 10,000 and 20,000 kidney transplant recipients. Based on response rates observed in comparable studies using patient questionnaires, an estimated response rate of between 10% and 15% is expected, which would provide a sufficient volume of responses to ensure statistical robustness and diversity of represented profiles.
Inclusion criteria	age \geq 18 years proficiency in French or English electronic consent provided
Exclusion criteria	severe cognitive impairment preventing understanding technical inability to access the questionnaire

<p>Type of study (Monocentric or multicentric, qualitative, quantitative, mixed, practice study, reuse of data collected during care, use of biological samples, etc.)</p>	<p>International multicenter cross-sectional survey conducted using an anonymous online questionnaire.</p> <p>The study adopts a mixed-methods approach, combining qualitative and quantitative analysis of responses. No medical or biological data will be used, and there will be no reuse of data collected during care.</p>
<p>Does this study fall within the scope of a care team?</p>	<p>No</p>
<p>Summary methodology (What statistical analysis strategy, what type of interview, what mode of observation, etc.)</p>	<p>Collaboration with transplant centers and patient associations: The investigators' team is highly collaborative and has a broad international network of clinical and patient-association partners in the field of kidney transplantation. This network, built over the course of the investigators' research and previous collaborations, will be mobilized for the present study.</p> <p>The investigators have already obtained preliminary agreement from three French kidney transplant centers, as well as five patient associations (including France Rein and Le Flambeau de la Vie in France, and The Voice of the Patient and the American Association of Kidney Patients in the United States). These partners will play a key role in disseminating the questionnaire to kidney transplant recipients and in representing the patient perspective.</p> <p>Questionnaire development: The questionnaire was developed based on a literature review on patients' perceptions of artificial intelligence and predictive medicine (Erul et al, Cancer Control 2025, PMID 40407404; Fritsch et al, Digital Health 2022, PMID 35983102).</p> <p>The questionnaire was co-designed and tested with six kidney transplant recipients (French and American), allowing us to refine the wording of the questions and validate the bilingual French-English translation. The questionnaire is implemented via the secure REDCap interface (GDPR-compliant). Each participant receives a personal code allowing them to return and modify their responses before final validation (questionnaire presented in the appendix to this document).</p> <p>Questionnaire distribution: Dissemination will take place through partner patient associations and collaborating transplant centers in France and the United States. The questionnaire will be distributed via a secure and anonymous REDCap platform hosted on institutional servers that comply with data protection standards (GDPR). Participants will receive a unique link providing direct access to the online questionnaire. They will be able to respond independently, at their own pace, and may interrupt their participation at any time without justification or consequence.</p>

	<p>Data analysis: The responses collected will be analyzed using a quantitative approach. Qualitative analyses will rely on thematic analysis assisted by Large Language Models (LLMs). These models will make it possible to automatically extract recurring themes, associated emotions, and nuances of perception in free-text responses, according to a standardized methodology developed by the investigators' team. The investigators have already successfully conducted this type of LLM-based thematic analysis (Raynaud et al, PsyArxiv 2025 https://osf.io/preprints/psyarxiv/pnx9e_v1).</p> <p>Analyses will be conducted via commercial language-model APIs (Anthropic Claude, OpenAI ChatGPT, xAI Grok), justified by their superior performance for multilingual qualitative analysis. Only pseudonymized text responses will be transmitted, with no identifiers or sociodemographic data. Providers contractually guarantee zero data retention. Participants will be asked not to mention identifying information in their free-text responses (see the information notice in the appendix to this document).</p> <p>To ensure reliability and scientific rigor, systematic manual verification will be performed on a representative subsample of responses. This independent review will make it possible to compare human and automated coding and refine the thematic categories.</p> <p>Originality of the study: Unlike the vast majority of surveys conducted with patients, the questionnaire will contain only open-ended questions, giving each patient the opportunity to express themselves freely and in a nuanced way about their perceptions and feelings.</p> <p>Such an approach, previously difficult to implement on a large scale, is now made possible by language models (LLMs), which are able to finely analyze large sets of textual responses.</p> <p>This innovative methodology will provide a more faithful, precise, and human understanding of patients' perspectives, paving the way for a new generation of studies centered on patients' lived experience and voice.</p>
<p>Data collected (Justify the collection of sensitive/identifying data, if applicable)</p>	<ul style="list-style-type: none"> • Age • Sex • Year of the last transplant • Country of the last transplant • Transplant follow-up center • Transplant rank • Current occupation or last occupation held • Perceptions of the role of AI in medicine • Perceptions regarding a graft loss risk prediction system

<p>Data flow (What happens to the data from extraction until deletion? Collection software, storage, security of storage media, access, partner recipients or subcontractors, retention period, etc.)</p>	<p>Data will be collected through the REDCap platform (HDS-certified hosting on Google Cloud, GDPR-compliant). The questionnaire is anonymous: no nominative data or identifiable medical data will be collected. Each participant will receive a unique link generating a non-traceable alphanumeric identifier.</p> <p>The data flow is as follows:</p> <p>Dissemination: Partner transplant centers and patient associations disseminate the REDCap link to eligible patients.</p> <p>Collection: Participants complete the questionnaire anonymously via REDCap.</p> <p>Export: Pseudonymized data are extracted (CSV format) by authorized members (Marc Raynaud, Alexandre Loupy, Thibaut Thalamas).</p> <p>Storage: Files are stored in encrypted form on the secure PARCC INSERM U970 server, with access controlled by secure authentication.</p> <p>Qualitative analysis by LLM: Only textual responses (without identifiers, sociodemographic data, or transplant-related information) are transmitted via secure API (HTTPS/TLS) to language-model providers (zero data retention). Results are returned to the PARCC INSERM server. Quantitative analyses are performed locally using R.</p> <p>Archiving: 3 years in the active database, then 20 years in archives, under the responsibility of Professor Alexandre Loupy.</p> <p>Fully anonymized datasets may be archived for secondary research purposes or scientific replicability.</p>
<p>Participant information (For example: recruitment during a consultation, or patients recontacted by mail, or call on social networks, etc. Attach the information notices planned for the different types of participants: adults, adolescents, children, legal guardians, etc. Justify the absence of an information</p>	<p>Participants will be contacted by email via their follow-up center, using the existing contact databases available in these centers.</p> <p>The invitation message will briefly present the study and its sponsor, the Paris Institute for Transplantation and Organ Regeneration, as well as the responsible researchers.</p> <p>It will also include an information notice specifying the objectives of the study, confidentiality arrangements, and a direct link to the online questionnaire hosted on REDCap.</p> <p>Participation will be entirely voluntary, with no impact on medical follow-up or on the relationship with the transplant team.</p>

notice, applicable.)	if	
Legal entity responsible for the project		INSERM
Natural person responsible for the project		Marc Raynaud

Questionnaire: Perceptions of kidney transplant recipients about the role of Artificial Intelligence (AI) in healthcare and about a graft failure prediction system

1. Purpose of the study

You are invited to participate in a study aimed at better understanding how kidney transplant recipients perceive the use of a prediction system based on artificial intelligence (AI) that can predict the probability of graft loss (return to dialysis or retransplantation) over time. We also wish to gather patients' opinions on the future role of AI in medicine. The purpose of this study is to better understand how transplant recipients experience the arrival of new technologies such as artificial intelligence in their medical follow-up.

2. Consent Form

Your participation involves completing an anonymous questionnaire of approximately 15 to 20 minutes. No identifiable personal data will be collected. You may stop at any time, without justification.

By ticking the box below, you consent to participate in this study.

☐ Yes, I agree to participate in this study

☐ No, I do not wish to participate

3. Explanation of the prediction system

The prediction system was developed to help physicians and patients assess the health of the kidney graft. It combines several clinical data points (kidney function, histological results, and immunological results) and predicts the percentage of risk that a patient will lose their graft over the next 10 years. The goal of this prediction system is to improve clinical decision-making, as well as the discussion between the physician and the patient.

A. Have you ever heard of this type of prediction system?

B. If yes, does your physician use such a prediction system in your post-transplant follow-up? Do you have access to the predictions?

4. Questions specific to the prediction system

- A. What do you think of the idea that an artificial intelligence such as this prediction system could predict your personal risk of graft loss?
- B. Do you find it useful for your physician to have access to this information? Why?
- C. Would you personally want to know your graft loss prediction?
- D. What fears or concerns do you have about AI being used to predict the outcome of your transplant?
- E. How could this information influence your daily life, for example your personal, family, professional choices, or your leisure activities?

5. General questions about artificial intelligence in healthcare

- A. In general, what do you think about the use of artificial intelligence in today's healthcare?
- B. What hopes or expectations do you have regarding AI in healthcare?
- C. What fears or reservations do you have regarding AI in healthcare?
- D. In your opinion, in what situations should or should not AI be used?
- E. Would you like to add any comments about your feelings regarding this prediction system or AI in medicine?

6. General information (demographics)

Age: _____ (years)

Sex: ☐ Female ☐ Male

Year of last transplant: _____

Country of transplant: _____

Transplant follow-up center: _____

Transplant rank: ☐ First ☐ Second ☐ Third or more

Current occupation or last occupation held: _____

7. Our thanks

Thank you for taking the time to share your perspective. Your responses will help us better understand the role that patients wish to give to artificial intelligence in the medicine of tomorrow. Your transplant center (or your patient association) will share the results of the study with you once the analyses are completed.