

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Prospectively investigating the impact of AI on Shared Decision Making in post-kidney transplant care (PRIMA-AI) – protocol for a longitudinal qualitative study among kidney-transplant patients, their support persons and treating physicians
<b>AUTHORS</b>	Sassi, Zeineb; Eickmann, Sascha; Roller, Roland; Osmanodja, Bilgin; Burchardt, Aljoscha; Samhammer, David; Dabrock, Peter; Möller, Sebastian; Budde, Klemens; Herrmann, Anne

### VERSION 1 - REVIEW

<b>REVIEWER NAME</b>	<i>Cheungpasitporn, Wisit</i>
<b>REVIEWER AFFILIATION</b>	Mayo Clinic College of Medicine, Nephrology and Hypertension
<b>REVIEWER CONFLICT OF INTEREST</b>	na
<b>DATE REVIEW RETURNED</b>	16-Jan-2024

<b>GENERAL COMMENTS</b>	<p>The authors outline a protocol for a 2-year longitudinal qualitative study that aims to investigate the impact of artificial intelligence (AI) on shared decision making between patients, their support persons, and physicians in post-kidney transplant care.</p> <p>The study will conduct semi-structured interviews at baseline, 3 months, 6 months, 12 months, and 24 months with 50 patient-support person dyads and their treating physicians. The interviews will explore participants' communication experiences and preferences related to AI-assisted shared decision making, their views on concepts like trust and transparency with AI, and their perceptions of using an AI-based decision support system in routine care. The goals are to understand how AI is impacting doctor-patient communication and decision making over time, identify barriers and facilitators to implementing AI-assisted shared decision making, and ultimately develop communication guidance and patient education materials to facilitate appropriate use of AI in patient-centered care.</p> <p><b>Comments</b></p> <p>There is also a risk of selection bias, as volunteers more actively engaged in research may be more likely to enroll and continue participation over the 2-year study period. Participants lost to follow-up may differ systematically from study completers in ways that skew results. Attempts should thus be made to recruit a maximally diverse and representative participant sample at the outset.</p> <p>Retention strategies could help minimize attrition over time - such as check-in calls, flexibility around scheduling, and reminders.</p> <p>The study's reliance on self-reported qualitative interview data is heavily dependent on the vagaries of participant memory, honesty, insight and articulation. Linking such data to quantitative metrics in medical records could help validate and contextualize findings. Records could provide objective data on clinical status, health services utilization, medications, adherence and health behaviors. Furthermore, qualitative interviews are subject to researcher bias in</p>
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question framing, administration, analysis and interpretation. Using standardized interview protocols and enlisting multiple researchers to independently code transcripts can help reduce bias. Assessment of inter-rater reliability is advisable.

Participants' initial hypothetical views on AI pre-exposure may not fully reflect their actual perceptions and experiences once they have actively used the AI tool on an ongoing basis. Supplementing interviews with direct observation of real clinical encounters could provide vital additional in-the-moment insights. Moreover, the study will not be able to quantitatively evaluate impact of the AI tool itself on health outcomes. Linking to clinical data could help assess outcomes like graft survival, complications, hospitalizations that may be related to use of the AI tool itself. Control groups could enable comparison along these lines.

Importantly, rigorous development and testing of the AI algorithm itself on representative sample datasets is imperative prior to deployment, to assess and refine accuracy, transportability across settings, and guard against unintended consequences. Ongoing monitoring will also remain necessary following implementation. Additionally, the 2-year study period may not fully capture longer term impacts of AI integration. Following some cohorts of patients, clinicians and systems for 5+ years could reveal interesting evolutions in perceptions, workflows and outcomes emerging over more extended time frames.

Finally, the communication guidance developed will not undergo formal feasibility testing or evaluation of any impact on care experiences, decision quality, appropriateness or health outcomes within this study. Follow up implementation research should address this. Additionally, the patient education materials should undergo quality assurance evaluations by end users – patients and families – to ensure they meet cultural appropriateness, health literacy, numeracy and usability requirements before widespread dissemination. Materials may warrant tailoring for vulnerable groups.

<b>REVIEWER NAME</b>	<i>Porteny, Thalia</i>
<b>REVIEWER AFFILIATION</b>	Tufts University
<b>REVIEWER CONFLICT OF INTEREST</b>	Na
<b>DATE REVIEW RETURNED</b>	29-Mar-2024

<b>GENERAL COMMENTS</b>	<p>Thank you for the opportunity to review your very interesting paper. Researching the triad of patients, SP and physicians around perceptions of AI on SDM is highly relevant to the field of complex medical decision-making and the chronic kidney care population.</p> <p>Major points:</p> <ol style="list-style-type: none"> <li>1. Support persons is understudied section needs major updates in its review. While it is important to reference older papers, there is much work that's been done considering the role of caregivers/caretakers in SDM for patients with CKD. This section needs to be more specific and up to date. While I do not necessarily suggest changing the word SP to caregiver if it makes more sense to you, if you are just searching for SP in your lit review, you may be very limited in your results.</li> <li>2. I disagree with, "Kidney transplantation is one of the most performed solid organ transplantations and although the application of SDM before and after kidney transplantation has been discussed, little is known about how to improve SDM in this setting (Sendak et al. 2020)." There is quite a lot known about how to improve and</li> </ol>
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	<p>integrate SDM into transplant. There's a significant amount of work around decision-aids and other educational tools to facilitate decision-making around transplant and kidney care modality. Consider revising and adding more literature. You can make the sentence more specific to your research question. I do agree that there is very little known on the role of AI in SDM and how it can be optimized.</p> <p>Minor points:          Abstract:          1. What framework will you use? 2. Were the interviews be audio or video recorded?          Introduction:          3. Consider adding that SDM aims to achieve goal concordant care.          4. Separate paragraph that begins with Advancing AI systems, line 32          5. Consider changing the word physician to clinician. It is considered more inclusive.          Methods          6. Is there a specific reason why you are expecting 20% dropout?          7. I am a bit confused about who the physicians are. Are these MD transplant surgeons, nephrologists, nurses? Can you say more about their profile please? How many are you anticipating?          8. Include citation for narrative approach.          9. How will the codes be developed? Inductively? Deductively?</p>
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### VERSION 1 – AUTHOR RESPONSE

**1. Author's responses to the 1st reviewer:**

**Comment:** “There is also a risk of selection bias, as volunteers more actively engaged in research may be more likely to enroll and continue participation over the 2-year study period. Participants lost to follow-up may differ systematically from study completers in ways that skew results. Attempts should thus be made to recruit a maximally diverse and representative participant sample at the outset. Retention strategies could help minimize attrition over time - such as check-in calls, flexibility around scheduling, and reminders.

The study's reliance on self-reported qualitative interview data is heavily dependent on the vagaries of participant memory, honesty, insight and articulation. Linking such data to quantitative metrics in medical records could help validate and contextualize findings. Records could provide objective data on clinical status, health services utilization, medications, adherence, and health behaviors.”

**Response:** Patients are scheduled for routine follow-ups at the participating Kidney Transplant Center (KTC). The risk of selection bias will be reduced as participants are included consecutively in the study and will not be selected individually by the researcher. The recruitment will occur during regular outpatient treatment at the KTC and is carried out by assigned study staff who are not the treating physicians.

Randomization will be performed using a predefined variable block randomization scheme with the help of a web-based randomization service called “simple randomization service” (Sealed Envelope, 2022). A literature review by Kahan et al.

(2015) concluded that selection bias may be eliminated through this type of simple randomization (Kahan, Rehal et Cro 2015). After screening for eligibility and assignment of the individual patient identifier, each patient-support person dyad can only be assigned once to one of the treatment arms. The site will record the time of randomization. Due to the nature of the intervention, blinding of clinicians and patients is not possible (Osmanodja et al. 2024). The age and sex of consenters and non-consenters as well as of those lost to follow-up will be compared. Participants receive reminders two days before each interview and are provided with maximum flexibility when scheduling interview appointments to reduce the research-related burden on participants and decrease the drop-out rate.

As pointed out by the reviewer, the study uses qualitative interview data that is impacted on by participants' memory, honesty, insight, and articulation. However, qualitative research methods are valuable for generating new hypotheses and insights that may not be captured by quantitative methods alone (Pilcher and Cortazzi, 2023). The open-ended nature of qualitative interviews allows for the discovery of unexpected findings, enhancing the description and understanding of the data, which can in turn inform future quantitative research directions (Wasti et al., 2022). As this is an integral part of qualitative research, it is essential to reflect on these important aspects during the analysis of the data, therefore the research team will schedule regular meetings using systematic coding and categorization to organize the data in a structured way. A clear coding system will be developed to categorize the qualitative data into themes and patterns.

Data collected from electronic patient records was used to supplement the qualitative data, including details provided on medication, health service history, and adherence of the patient, as well as his (current) clinical status and (changes in) health behavior. This triangulation with quantitative data (i.e. patient records and quantitative questionnaires) helps to objectify findings. Areas of convergence or divergence between the qualitative and quantitative data will be examined to validate or provide additional context (Ramanadhan, 2021).

This study also obtains additional quantitative data through questionnaires given to participants before the qualitative interview exploring participants' communication experiences and preferences. These quantitative questionnaires may counteract the above-mentioned vagaries and help assess the generalizability of our findings (Pilcher and Cortazzi 2023). By applying a parallel mixed-method design, this study aims to provide a more comprehensive picture than either quantitative or qualitative approaches alone to investigate complex phenomena such as the role and impact of AI on SDM (Huyler et McGill 2019; Wasti et al. 2022).

Additionally, recordings of the physician-patient-support person conversations will be analyzed to further supplement the qualitative interview data. These recordings provide the opportunity to review and analyze participants' statements in more in-depth (Al-Yateem 2012; Berazneva 2014). Multiple researchers will be involved in the coding and analysis process to minimize individual biases and increase reliability. Inter-rater reliability will be calculated to assess the consistency and objectivity of the coding.

Throughout the analysis, the research team will maintain detailed documentation of the data collection and analysis process to ensure dependability. An audit trail will demonstrate how the raw data was transformed into codes, categories, and final interpretations. This structured documentation will help establish the rigor and credibility of the qualitative analysis.

**Comment:** "Furthermore, qualitative interviews are subject to researcher bias in question framing, administration, analysis, and interpretation. Using standardized

interview protocols and enlisting multiple researchers to independently code transcripts can help reduce bias.

Finally, the communication guidance developed will not undergo formal feasibility testing or evaluation of any impact on care experiences, decision quality, appropriateness, or health outcomes within this study. Follow up implementation research should address this.

**Response:** The research team received intensive training from an interdisciplinary panel involving experts in the areas of medicine, communication and behavioral science, health services research, ethics, and medical informatics in conducting these interviews to reduce bias and ensure methodological rigor in data collection and analysis. Standardized interview protocols are being used and three researchers will code the transcripts independently (Yarborough 2021). The protocols were developed based on discussions among the research team and a comprehensive review of the literature. They were also pilot tested with n=5 kidney transplant patients and n=5 support persons. The study team made sure that the communication guide underwent formal feasibility testing carried out by the medical subproject at the kidney transplant center involving 5 patients to increase its usability, readability, and accessibility. It has been elaborated and developed based on a literature review and discussions among the research team which involves experts in medicine, communication and behavioral science, health services research, ethics, and medical informatics.

**Comment:** Additionally, the patient education materials should undergo quality assurance evaluations by end users – patients and families – to ensure they meet cultural appropriateness, health literacy, numeracy and usability requirements before widespread dissemination. Materials may warrant tailoring for vulnerable groups.

**Response:** As these materials may warrant tailoring for vulnerable groups, they will undergo a rigorous quality assurance evaluation. This evaluation will be developed and conducted by a multidisciplinary study team, comprising experts in communication science, clinicians, social science, and computer science, among others. To ensure the materials' feasibility and acceptance within specific subgroups, the team will employ readability tests and adhere to ISO norms.

**Comment:** “Participants' initial hypothetical views on AI pre-exposure may not fully reflect their actual perceptions and experiences once they have actively used the AI tool on an ongoing basis.

Supplementing interviews with direct observation of real clinical encounters could provide vital additional in-the-moment insights.

Importantly, rigorous development and testing of the AI algorithm itself on representative sample datasets is imperative before deployment, to assess and refine accuracy, and transportability across settings, and guard against unintended consequences. Ongoing monitoring will also remain necessary following implementation. Moreover, the study will not be able to quantitatively evaluate the impact of the AI tool itself on health outcomes. Linking to clinical data could help assess outcomes like graft survival, complications, and hospitalizations that may be related to the use of the AI tool itself. Control groups could enable comparison along these lines. “

**Response:** We agree with the reviewer that participants' initial hypothetical views on AI pre-exposure may not fully reflect their actual perceptions and experiences once they have actively used the AI tool on an ongoing basis. As indicated above, we will supplement the interviews with direct observation of real clinical encounters and further quantitative data gathered by patient and support person surveys to provide additional in-the-moment insights, as suggested by the reviewer.

This study is embedded in a larger randomized controlled trial involving patients who

will be assigned to the intervention (treatment with AI) or control group (treatment without AI) to enable comparisons within and between groups. Within this larger PRIMA AI research project, there is also a sub-study that uses clinical data to assess graft survival and complications such as graft loss and tract infection (see also (Osmanodja et al. 2024). The AI algorithm, its current system, based on a gradient-boosted regression Tree (GBRT), has been tested on retrospective data and has been rigorously developed and pretested within an experimental setup before deployment. The algorithm is constantly being monitored by the study team of the technical subproject.

**Comment:** “Additionally, the 2-year study period may not fully capture the longer-term impacts of AI integration. Following some cohorts of patients, clinicians, and systems for 5+ years could reveal interesting evolutions in perceptions, workflows, and outcomes emerging over more extended time frames.”

**Response:** We agree with the reviewer that a longer follow-up would help provide insights into the long-term effects and sustainability of AI use in routine care. Given the funding period, we can only include a two-year follow-up but added the necessity of exploring long-term effects to the research implications of the manuscript (page 7, line 33).

## **2. Author’s responses to the 2nd reviewer**

### **Major points 2nd reviewer**

**Comment:** “Support persons is an understudied section that needs major updates in its review. While it is important to reference older papers, there is much work that’s been done considering the role of caregivers/caretakers in SDM for patients with CKD. This section needs to be more specific and up-to-date. While I do not necessarily suggest changing the word SP to the caregiver if it makes more sense to you, if you are just searching for SP in your lit review, you may be very limited in your results.”

**Response:** Many thanks for this comment. While we are indeed very limited in our literature review when searching for a Support person (SP) as there’s more literature on caregivers/caretakers, we have included both literature on caregivers/ caretakers and support persons in this study. We included the word “Support person” as a “support person” is a person that - in a patient’s treatment - may improve medication adherence, help communicate concerns to the physician, remember the physician’s advice, and make decisions (Aikens et al. 2015; Schilling et al. 2002). On top of that, patients commonly feel more certain about their decision after consulting their SPs (Girgis and Sanson-Fisher 1995). A person will be eligible as a support person (SP) if they are nominated by the patient as someone helping him cope with the consequences of their kidney transplant through support, encouragement, and communication. There is considerable evidence to suggest that SPs may be the most important sources of information and advice for patients and may be able to facilitate patients’ engagement in Shared Decision Making (National Cancer Institute; Terranova et al. 2017; Shin et al. 2017). The vast majority of patients prefer their SPs to have a say about treatment decisions (Girgis and Sanson-Fisher 1995), with some even preferring their SPs to lead the decision-making process (Salkeld et al. 2004; Shin et al. 2017).

**Comment:** “I disagree with, ‘Kidney transplantation is one of the most performed solid organ transplantations and although the application of SDM before and after kidney transplantation has been discussed, little is known about how to improve SDM in this setting (Sendak et al. 2020).’ There is quite a lot known about how to improve and integrate SDM into transplants. There’s a significant amount of work around decision aids and other educational tools to facilitate decision-making around transplant and

kidney care modality. Consider revising and adding more literature. You can make the sentence more specific to your research question. I do agree that there is very little known on the role of AI in SDM and how it can be optimized.”

Response: Many thanks for this comment. I consequently consider revising and adding more literature to this section. The reviewer agrees with rephrasing the sentence as “there is very little known on the role of AI in SDM and how it can be optimized”. The following sentence was added to the manuscript to highlight better previous research in SDM related to kidney transplant: “Kidney transplantation is one of the most performed solid organ transplantations and although the application of SDM before and after kidney transplantation has been discussed, very little known on the role of AI in SDM and how it can be optimized” (page 3, line 11).

Minor points 2nd reviewer:

Abstract section

Comment: 1. What framework will you use? 2. Were the interviews be audio or video recorded?

Response: The interviews will be audio-recorded, transcribed, checked for accuracy by one researcher, and analyzed using framework analysis according to Gale et al. (page 1, line 3)

Introduction section

Comment: 3. Consider adding that SDM aims to achieve goal concordant care

Response: As suggested by the reviewer, we added that “SDM is advocated when discussing treatment with patients diagnosed with cancer, as difficult trade-offs must be made that require patients’ consideration to reach goal concordant care (Bos-van den Hoek et al. 2023). “(page 2, line 70-72)

Comment: 4. Separate paragraph that begins with Advancing AI systems, line 32

Response: We separated the paragraph that begins with Advancing AI systems in line 32 as requested.

Comment: 5. Consider changing the word physician to clinician. It is considered more inclusive.

Response: The reviewer suggested changing the word physician to clinician, as it is considered more inclusive. We deliberately chose the term “physician” as it describes the study physicians, namely non-surgical nephrologists working in the participating clinic responsible for the patients’ after-care routine. While the more inclusive definition of a clinician is not restricted to a physician or doctor, but to any person involved in providing principal care for patients, meaning an individual who uses a recognized scientific knowledge base and has the authority to direct the delivery of personal health services to patients (Donaldson, Yordy et Vanselow 1994) . We considered the term “physician” more precise and suitable for describing the healthcare staff included in the study.

Methods section

Comment: 6. Is there a specific reason why you are expecting 20% dropout?

Response: Drawn from a literature review and conclusions from experiences from previous studies in similar disciplines, we expect a dropout rate of 20% (Bell et al. 2013; Fielding et al. 2008). For example, a review conducted by Wood et al., analyzing a total of 71 randomized controlled trials in four top medical journals showed dropout

rates of 20% or more in 18% of the trials (Wood, White et Thompson 2004).

**Comment: 7.** I am a bit confused about who the physicians are. Are these MD transplant surgeons, nephrologists, nurses? Can you say more about their profile please? How many are you anticipating?

**Response:** The reviewer asked to give more information about the profile of the physicians and how much we are anticipating. We added that the physicians in the study are nephrologists working in the participating kidney transplant center and are responsible for the patients' after-care routine. We anticipate to include 20 treating physicians (page 4, lines 166-167).

**Comment: 8.** Include citation for narrative approach

**Response:** As suggested by the reviewer, we included a citation for the narrative approach in the methods section (Przyborski et Wohlrab-Sahr 2014) (page 6, line 204).

**Comment: 9.** How will the codes be developed? Inductively? Deductively?

**Response:** The reviewer brought up to mention how the codes will be developed. We appended that coding will be conducted inductively and then deductively by two researchers and discussed during regular meetings of the interdisciplinary research team (page 6, line 208).

## References

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Salkeld, Glenn; Solomon, Michael; Short, Leonie; Butow, Phyllis N. (2004): A matter of trust--patient's views on decision-making in colorectal cancer. In: *Health expectations :*

an international journal of public participation in health care and health policy 7 (2), S. 104–114. DOI: 10.1111/j.1369-7625.2004.00257.x.

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#### VERSION 2 – REVIEW

REVIEWER NAME	<i>Cheungpasitporn, Wisit</i>
REVIEWER AFFILIATION	Mayo Clinic College of Medicine, Nephrology and Hypertension
REVIEWER CONFLICT OF INTEREST	na
DATE REVIEW RETURNED	23-Jul-2024

GENERAL COMMENTS	Overall, this appears to be a well-developed protocol manuscript. The core elements expected in a high-quality study protocol are present.
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	<p>Comments that could potentially be improved further</p> <ol style="list-style-type: none"><li>1. More details could be provided on the specific AI decision support system being studied.</li><li>2. The patient and public involvement section is very brief and could be expanded.</li><li>3. The interview guide in the appendix could potentially be streamlined.</li></ol>
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## VERSION 2 – AUTHOR RESPONSE

### Author's responses to the reviewer:

**Comment:** Overall, this appears to be a well-developed protocol manuscript. The core elements expected in a high-quality study protocol are present.

**Comments that could potentially be improved further:**

**1. More details could be provided on the specific AI decision support system being studied**

**Response:** Thank you very much for this comment. We provided more details on the AI-based decision support system being studied and used in this study (see page 5, line 172 – 179)

**Comment: 2. The patient and public involvement section is very brief and could be expanded.**

**Response:** We expanded the patient and public involvement section (see page 7, line 268 – 274)

**Comment: 3. The interview guide in the appendix could potentially be streamlined.**

**Response:** Many thanks for this comment. The interview guide will be adapted within the course of the study including streamlined.