PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Development and Evaluation of a Decision Aid for Family Surrogate Decision Makers for Patients with Acute Kidney Injury Requiring Renal Replacement Therapy (RRT) in ICUs: A Study Protocol
AUTHORS	Zheng, Miao; Yin, Changlin; Cao, Ying; Zhang, Yonghui; Zhang, Kuoliang; Zhang, Xiaoqin; Bian, Wei; Wang, Lihua

VERSION 1 – REVIEW

REVIEWER	Lee Yew Kong University of Malaya, Malaysia
REVIEW RETURNED	22-Oct-2020

GENERAL COMMENTS	Introduction - It is stated that RRT is preference-sensitive, but it is unclear what the risks of RRT are to qualify this statement; only pros are given. - Are there differences in how PDAs for patients vs surrogates are designed? Any examples of surrogate-type PDAs? - The literature states that patients often overestimate RRT prognosis; this is for patients, what about for surrogates? I think a key consideration is whether the PDA explores what the surrogates want, what they think the patient wants, or both. This issue needs to be discussed more in a surrogate PDA, and subsequently how different value sets will be explored, and integrated in the PDA design in the Methods. Methods: - If possible, briefly describe the search strategy used for evidence synthesis (search terms, databases) - pg 12 ln 12: More details should be given on what the Opportunity statement exercise is and how it is conducted. - pg 15 line 15: This line is not complete, missing a word which should be before and after: " including a knowledge survey like before and an acceptability survey.." - It is not clear if the paper based prototype is converted into a web-based pdf format? Or is it converted into an interactive website/ app on the phone? - What is the rationale for using a phone-based PDA? - Pg 17 Ln 15: It is not clear what steps are involved in this line: "We are proposing to recruit more participants as soon as possible, to generate sufficient feedback for further refinement."

REVIEWER	Ann O'Hare University of Washington, Seattle, USA
REVIEW RETURNED	28-Oct-2020

GENERAL COMMENTS	The proposed work has a high degree of significance and the

	proposed methods seem appropriate for decision aid development. I would like to see more progress on the literature review proposed as part of the study, would provide a stronger rationale for what is proposed. I would recommend involving patients as well as surrogate decision-makers in the development and testing of the intervention. I might also broaden the scope of the decision-aid to be flexible in terms of whether or not patients are involved in the decision-making, as decisions about RRT for AKI in ICU do not always fall to surrogate decision-makers, patients may be able to participate to different degrees in the decision-making process, a decision aid that can be flexible to a variety of different situations would probably be more valuable than one specifically tailored to surrogate decision-makers.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. Comment: It is stated that RRT is preference-sensitive, but it is unclear what the risks of RRT are to qualify this statement; only pros are given.

Response: We thank the reviewer's comments. We have added the descriptions of the risks of RRT and made a further explanation as follows:

"However, compared to those non-RRT patients, critically ill patients suffered from AKI initiated RRT results in two-fold 28-day mortality, which accounted for 46.3%, and ICU overall costs would be three times.1 The individual critically ill patient indicated with RRT requirements by their attending physicians needs to make a choice coincided with their preferences and values, to continue with whether or not to initiate RRT. There is no doubt that the decision to opt for RRT should be described as preference-sensitive as the preferred treatment option is dependent on patient preferences due to non-ideal clinical outcomes between the life-sustaining choices.2, 3"

2. Comment: Are there differences in how PDAs for patient vs surrogate are designed? Any examples of surrogate-type PDAs?

Response: Indeed, PDAs designed for surrogates compared to PDAs for patients with the same purpose of improving the quality of patient treatment and boosting shared decision making in ICU. Due to critical illness, patients are unable to take roles in the decision-making process or can express treatment preferences to their attending physicians or bed nurses at most.4 Anyway, each treatment referred to informed consent requires critically ill patients' legal representative (surrogate decision-maker) to written consent before initiating in ICU workflow. Therefore, it's more suitable to develop a decision aid tailored for surrogates. In terms of different potential recipient between decision aid and treatment, a decision aid designed for surrogates of incapacitated patients would be more attentive in patient values clarification excises on surrogate view.5 Of course, our decision aid would integrate with the family meeting which is a formal discussion for patient treatment decision between families and clinicians. We tend to apply our decision aid to family surrogates before the family-clinician discussion occurs, and we hope it can elicit surrogates' struggle roles in decision-making and facilitate decisional communication with healthcare professionals. Accordingly, our decision support to family surrogates of incapacitated patients, their critically ill loved ones, would endeavor to achieve patient and family-centered care that RRT decision-making matches with patient preferences and values.

As much as we have known, there is no available decision aid on RRT decision-making for critical illness, while some other aids were verified effective in family support or shared decision making with clinicians in ICU context. Here, we example surrogate-type PDAs as follows:

Cox et al.6 developed a web-based decision aid for surrogate decision-makers of patients with prolonged mechanical ventilation, which defined patient disease and treatment condition, framed 3

treatment options for goals of care, described what to expect from each choice, described the function of surrogate decision-maker and elicited family support needs in the decision-making process. The most crucial element of this web-based decision aid is a graphic, which would indicate the goal of treatment that surrogate seemed to lean toward based on an algorithm informed by their responses to patient values clarification excise. The application of this decision aid was assigned before family meetings, and a document summarized surrogate responses would be given to physicians for discussion. The results of this study reported that this decision aid was effective in reducing surrogate decisional conflicts during the ICU decision-making process (mean difference between intervention group and control group in change from baseline, 0.4 points [CI, 0.0 to 0.7 points]; P = 0.041). Besides, Muehlschlegel et al.7 developed decision aid for surrogates of critically ill patients with traumatic brain injury, in four stages: (1) qualitative study to determine surrogate decision and communication needs and physicians' communication practices; (2) creation of a pilot decision aid; (3) field-testing measuring acceptability and usability among family members; (4) randomized controlled feasibility trial of this decision aid among family surrogates. The resultant decision aid for family surrogates achieved excellent usability, acceptability and feasibility. Furthermore, Suen et al.5 developed a family support tool to help families navigate the complexity of surrogate decision making in ICU, which was designed to help individuals understand surrogate's role and consider treatment decisions through patient preferences and values.
We thank the reviewer's comments. As suggested, we added more progress into our manuscript to give a stronger rationale on decision aid tailored for surrogates in the ICU context.

3. Comment: The literature states that patients often overestimate RRT prognosis; this is for patients, what about for surrogates? I think a key consideration is whether the PDA explores what the surrogates want, what they think the patient wants, or both. This issue needs to be discussed more in a surrogate PDA, and subsequently how different value sets will be explored, and integrated with the PDA design in the Methods.
Response: Thanks to the reviewer for these comments. We think it's our inappropriate expressions that raised your concern. According to the literature review,8 it is surrogates that make an overestimation on RRT prognosis. In this study, Allegretti et al.8 designed each survey triad to assess the understanding of RRT outcomes in the ICU, which included a patient on RRT (or their surrogate), an ICU physician from the critical care team and an ICU nurse employing RRT for the patient. Clearly, the critically ill patient and their surrogate were regarded as patient-side/patient party. Finally, the patient side enrolled 32 participants and exactly included 4 patients and 28 surrogates. We considered the overestimation about prognosis from critically ill patients (4/32) and their surrogates (28/32), and almost reflects surrogate's attitudes. Additionally, misconceptions about prognosis by surrogates in ICU which influence the quality of treatment decision making is also explored among other critically ill.9-11 For example, Chiarchiaro et al.10 reported that inaccurate expectations about the prognosis of patients with acute respiratory distress syndrome at high risk of death are common among surrogates, although most surrogates rate the quality of prognostic communication highly. Regarding currently RRT decision-making process in ICU in China, when patient indicated with RRT requirements, the attending physician will invite family surrogate to participate in treatment decision making to decide whether or not to initiate RRT for their loved one, and informed consent would be written by family surrogate before carrying out following treatment.
To match with the current decision-making process on RRT, we will carry out needs assessment between professionals and target users, which means we will explore what the surrogates want based on their actual RRT decision-making experiences to get their unmet needs, and we will also explore physician perspectives of what surrogates need to know before joining in the RRT decision making, so as to determine surrogate needs at the professional view. The results of the needs assessment will be a foundation of following the development of our decision aid.
To present a clearer framework for development of our decision aid, we have changed the subheading "Target users' interviews" into "Surrogate decision makers' interviews", which is under "Design: needs assessment" in Phase 1.

4. Comment: If possible, briefly describe the search strategy used for evidence synthesis (search terms, databases)
Response: We thank the reviewer's comments. We have supplemented the search strategy for PubMed and added as Supplementary file S1.

5. Comment: pg 12 ln 12: More details should be given on what the Opportunity statement exercise is and how it is conducted.
Response: We thank the reviewer's comments and give more details on Opportunity statement exercise. Therefore, the description was corrected as follows:
"Opportunity statement exercise 12 will be embedded in individual semi-structured interviews to get a whole understanding of surrogate perspectives about RRT decisional needs. Opportunity statement exercise 12 is a type of design thinking activities designed to gather and explore information needs for digital tool development to identify an area in which the proposed digital tool may provide value or have an impact on. Family surrogates will be asked to complete this statement on prepared description (summary outlines of literature review and healthcare professionals' interviews, which describe what a future DA would be), 'How might we improve this DA so that you are more successful to make the best treatment decision combined with your loved ones' preferences?' Overall, interview syllabus will be constructed to explore surrogate decisional needs on RRT and collect delineating facets of the current decision-making process to identify in what way a DA can make a measurable impact."

6. Comment: pg 15 line 15: This line is not complete, missing a word which should be before and after: " including a knowledge survey like before and an acceptability survey…"
Response: Thanks to the reviewer's comments. We have corrected the description as follows:
"Once the task was completed, participants will be required to finish the after-questionnaire, including a knowledge survey like in before-questionnaire, and an acceptability survey."

7. Comment: It is not clear if the paper-based prototype is converted into a web-based pdf format? Or is it converted into an interactive website/ app on the phone?
Response: We thank the reviewer's comments. Actually, we will convert the paper-based prototype into an interactive web-based working prototype on the phone. Accordingly, we have corrected the description into:
"The paper-format prototype will be redrafted and redesigned into a working prototype, which will be an interactive web-based version on phone and can be accessed by scanning Quick Response Code (QR code) through WeChat app."

8. Comment: What is the rationale for using a phone-based PDA?
Response: Thanks to the reviewer's comments. For making a stronger rationale for using a phone-based PDA, we added more descriptions about rationales on phone-based PDA into "Draft: working prototype" in Phase 1 within the Methods section, as follows:
"To provide the right information (rapidly updated), to the right person (tailored), at the right time (the appropriate point in the decision-making process),13 we will use an Internet-based PDA which enables modifying the content suitable with individual users.14 WeChat 15 is the most popular social media mobile application in China, that embraces instant messaging with text, image, voice and video chat and embeds payment, scan functions, to connect with an integral part of people's daily life. More than 95% of Chinese adults have a mobile phone, and over one billion access WeChat at least once a day.16 These features make WeChat highly and commonly usage by hospital services to make appointments with physicians and provide health education.15 Therefore, we deem an Internet-based PDA accessible on mobile phone via WeChat scanning is valuable in supporting decision making in ICU."

9. Comment: pg 17 Ln 15: It is not clear what steps are involved in this line: "We are proposing to recruit more participants as soon as possible, to generate sufficient feedback for further refinement."
Response: Thanks to the reviewer's comments. We think it's our inappropriate English expressions raised your concern. Compared with previous study recommendation17 that a sample of 15-20 participants would be statistically suitable for usability testing, in this line we meant to recruit more participants as much as possible (not as soon as possible) for sufficient feedback for future refinement. And we have corrected this statement into:
"We are proposing to recruit more participants as much as possible, to generate sufficient feedback for further refinement."

Reviewer: 2

1. Comment: I would like to see more progress on the literature review proposed as part of the study, would provide a stronger rationale for what is proposed.
Response: We thank the reviewer's comments. As suggested, we have added more progress in the "Introduction" to give a stronger rationale for what is proposed.

2. Comment: I would recommend involving patients as well as surrogate decision-makers in the development and testing of the intervention. I might also broaden the scope of the decision-aid to be flexible in terms of whether or not patients are involved in the decision-making, as decisions about RRT for AKI in ICU do not always fall to surrogate decision-makers, patients may be able to participate to different degrees in the decision-making process, a decision aid that can be flexible to a variety of different situations would probably be more valuable than one specifically tailored to surrogate decision-makers.
Response: We appreciate the reviewer's comments very much. As suggested, a broad scope of decision aid tailored for both patients and surrogate decision-makers would be more suitable for the clinical decision needs of RRT for AKI in ICU, but it's difficult to accurately identify patient decisional needs as most critically ill patients are unable to engage in the decision-making process, in addition, current ICU decision-making procedure in China limited on written informed consent by family surrogates makes it less focus on patient perspectives on RRT.
The potential challenges associated with involving patients in our development and evaluation phases need to be handled with clinical practice and policy. Therefore, we discussed more about patient involvement in RRT decision making for future researches and added into the end of our manuscript as follows:
"Due to most critically ill patients are incapacitated, decision-making in the ICU is complex. Decision support interventions tailored to the unique needs of the family surrogate decision makers involved was recommended.18-21 Therefore, regarding the RRT decision making in ICU, how to improve the decisional communication and support of surrogates, and to discuss or clarify critically ill patients' preferences and values with surrogates, might be the most important points.22-24 Although our study will not be able to develop the DA tailored for both surrogates and their loved ones, we expect our endeavors will be a reference to explore future opportunities to involve those incapacitated patients in the future appropriately. Of course, these expectations need governments and policymakers to pay more attention to strategies for SDM in ICU."

VERSION 2 – REVIEW

REVIEWER	Ann O'Hare University of Washington
REVIEW RETURNED	03-Jan-2021

GENERAL COMMENTS	No further suggestions.