Development of digital decision aid among surrogate decision makers for critically ill patients requiring renal replacement therapy: a formative research study

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Research Article

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Abstract

Introduction: Renal replacement therapy (RRT) is increasingly being adopted for critically ill patients suffering from acute kidney injury, followed by inevitably high rates of morbidity and mortality. Whether or not to choose RRT for critically ill patients is a significant concern of surrogate decision makers, which issues a serious decision dilemma. While few evidence supports for surrogates to make the best decision when their loved ones face the possibility of RRT in ICU. The aim of our study is to develop a decision aid through user-centered design to help surrogate decision making for critical illness requiring RRT.

Methods: We conducted a user-centered design to develop the decision aid, with following four steps: (1) competitive analysis - to gain insights from the decision support tactics and development strategies of existing decision aids through a systematic environmental scan; (2) user needs assessment - to explore targeted user decisional needs by semi-structured interviews with surrogate decision makers; (3) user persona - to develop a typical user persona by users’ context immersion to inform subsequent development strategies; (4) evidence synthesis - synthesize latest clinical evidence on RRT decision making according to above requirements.

Results: The rapid prototyping of the RRT decision aid brought four steps to achieve the best decision making, including identifying the treatment decisions, weighing the benefits and risks, clarifying values and preferences, and making the decision. We identified sixteen available decision aids related to RRT in the areas of end-of-life issues (N=2), end-stage renal disease (N=5), and chronic kidney disease (N=9). Available resources informed us of insights from the evidence-based necessity for development, the effective tool to collect primary sources, content presentation, and interactive features. We conducted semi-structured interviews with fifteen family surrogates to explore their decisional needs for their loved ones in an ICU setting. Four thematic domains of stuck into dilemmas, limited capacity, sense of uncertainty, and delayed confirmation were identified by qualitative descriptive analysis, which was further refined into targeted users’ potential needs of professional support, role guidance, information needs, and value clarification. The typical user persona “Booby”, a family surrogate decision maker for his elderly father diagnosed with septic AKI after ICU admission, was constructed to help understand users’ needs and inform design choices through context immersion. We searched a total of 15, 220 records from databases and websites between Dec 2019 and May 2020, and 27 studies were included to form the main content of the prototype. Evidence from eligible studies was extracted manually and classified as aspects of benefits and risks of RRT, possible outcomes, and reasons to choose, to provide comprehensive evidence-based decision support.

Conclusions: We have rapidly prototyped a digital decision aid using a user-centered design targeted at family surrogate decision makers of critically ill patients requiring RRT in ICU. Future studies are warranted to evaluate the usability, feasibility, and comprehensibility of the decision aid through iterative refinement.

Trial Registration: ChiCTR2000031613

Background

Acute kidney injury (AKI) is one of the most common critical symptoms in the ICU, coinciding with high rates of morbidity and mortality [1]. Renal replacement therapy (RRT) has already become an effective life-sustaining treatment and is increasingly being adopted for critically ill patients with AKI. Recent research shows that 51% of critically ill patients in China developed AKI [2], and when it indicated with RRT the mortality risks increased around 50% [3, 4]. When critically ill patients are incapacitated and unable to make decisions about their medical care, family surrogate decision makers need to interact with healthcare professionals and conscientiously choose life-sustaining treatment for their loved ones [5, 6]. The prevalence of RRT as a form of treatment for critical AKI is high, constituting more than 20% of treatment plans in this context [7, 8]. Given that the most effective time to start RRT is uncertain and the prognostic outcomes are hard to predict, there has been noted conflict between different ethical principles when this treatment is at stake and thus difficulty in determining the best treatment options [1]. It is necessary to make sure the patients’ values and preferences are in line with the selection of RRT as a treatment plan so that the patients’ best interests are protected as much as possible.

When critically ill patients are unable to make decisions for themselves, the choice about whether or not to pursue RRT is made by the patients’ legal surrogates with the help of ICU clinicians. In China, surrogate decision makers are usually the patients’ family members [9, 10]. Despite the relative prevalence of RRT for ICU patients suffering from AKI, it is difficult for family surrogates to find reliable information about RRT and therefore challenging for them to share in the decision-making process with clinicians [11]. Furthermore, family participation in RRT decision making was uniformly reported as a stressful experience [12], and discrepancies between the values and priorities of the medical system and those of the patient were identified [11]. Usually, family surrogates face dilemmas when participating in preference-sensitive decision making for critically ill patients. However, ICU clinicians typically do not receive training regarding the shared decision-making process and have limited knowledge about how to facilitate family surrogates’ participation. Thus, it is a tremendous challenge for clinicians to conduct effective decision-making interactions with family surrogates and to keep this process aligned with their patients’ autonomy and best interests [13]. Authoritative and reliable access to information is therefore needed to support family surrogates who must choose whether or not to proceed with RRT for their loved ones in the ICU.

Decision aid (DA) [14] is a decision-making assistant that enables users to make a deliberate decision by providing evidence-based information and knowledge about treatment options and possible outcomes related to patients’ diseases, as well as clarification regarding how treatment options prioritize different values. Evidence [15–17] suggests that a DA is an effective method for improving the quality of decision making in several respects, including increased knowledge for the decision makers, reduced anxiety over the decision-making process, greater alignment between available choices and patients’ preferences and values, and reductions in adverse outcomes such as decisional conflicts, decisional regrets, depression, and so on. Several benefits to patients, clinicians, and the health care system have been identified in DAs designed specifically for RRT decision making [18]. Unfortunately, current relevant DAs only target for chronic kidney disease patients which are not suitable for critically ill patients. It is crucial to develop a specific DA for family surrogates to enable and support their participation in the RRT decision-making process for their loved ones in ICU.
User-centered design (UCD) [19] is the field in which target users and other stakeholders are intricately involved in the design of information products to guarantee that those products meet the users’ needs. UCD is routine in a range of industries, has been used to develop many transformative information and communication technologies, and is increasingly applied in the development of patient decision aids [20–22]. This problem-focused method offers a robust and pragmatic approach to design development that incorporates a deep understanding of users’ needs through interviews, observation, and context immersion. In medical decision support techniques, UCD is increasingly being used to explore patients’ decisional needs, to maximize goal achievement for users, and to improve the effectiveness, efficiency, and satisfaction of the decision-making process [23]. However, case studies regarding the development of DAs [24–27], indicate little empirical experience detailing the methods used to transform users’ needs into design elements that enable the optimal uptake, effectiveness, and usability of the DA in future applications.

Accordingly, the aim of the study is to develop a digital DA for surrogate decision makers of critically ill patients requiring RRT. Under the application of UCD, following approaches were implemented to achieve rapid prototype: (1) To conduct a competitive analysis of available DAs related to RRT decision making in the academic arena and application market; (2) To evaluate the unmet decisional needs of target users, who experienced RRT decision making in the ICU; (3) To develop a typical user persona with designated features that can be integrated into our design choices; (4) To synthesize evidence regarding RRT decision making thereby providing evidence-based decision support. This method enables us to scientifically analyze the circumstances of DA development, determine its requirements based on evidence, and inform our design decisions appropriately.

**Methods**

A systematic methodology conceiving UCD was conducted to develop the digital DA, including competitive analysis, user needs assessment, user persona development, and evidence synthesis (Fig. 1). The study protocol has been published in a peer-reviewed journal [28].

**Project Team**

The project team was multidisciplinary, comprising three experienced researchers in shared decision making and patient decision aids (a principal researcher and two senior researchers), three experts in critical care medicine (two clinicians and a nurse). The principal researcher, under the guidance of senior researchers, was responsible for data collection and analysis in the development process. Three clinical experts contributed to the professional judgement in evidence selection and evaluation. Regular meetings were held to prepare for and reflect upon the rapid prototyping of the DA.

**Phase 1: Competitive Analysis**

With broader reach and inclusive criteria than systematic review, an environmental scan was used to yield a more complete landscape of available DA resources related to RRT decision making, involving resources from both academic researchers and private organizations [29]. This method enabled us to gain insights from existing competitors through their decision support tactics and development strategies. We searched available DAs on the official website of Patient Decision Aids [30], PubMed, Google Scholar, and app stores (HUAWEI App Gallery and Apple App Store), from the earliest available search dates to June 2019. The search strategy was developed with a librarian (see Additional file 1). We included DAs designed to help patients or caregivers make decisions about RRT. Resources were excluded if without detailed content mapping for decision-making support or targeting education/communication skills interventions. A data extraction form including description of development features (location, year, format, and sources), decision-making subjects and options, main content, theory framework or design strategy, development procedure, and quality criteria, was used to analyze eligible resources. All searching results were screened for inclusion by MZ and YC, data extraction and synthesis were conducted by MZ, and the final overview was independently reviewed by all members of the project team. Regular group meetings were held for discussion on DA designing insights and developing issues from available resources, which provided us further development guidance.

**Phase 2: User Needs Assessment**

We conducted a phenomenological qualitative study to investigate family surrogates’ perspectives when tasked with choosing RRT for their loved ones in an ICU setting and explored their decisional needs through in-depth analysis. Participants were recruited from Southwest Hospital, Chongqing, China, between August 2019 and October 2019. Family surrogate decision-makers of critically ill patients requiring RRT were invited and required to: (1) be older than 18 years; (2) have the primary care responsibility for patient requiring emergency treatment; (3) be related by blood or marriage to patient; (4) be the legal surrogate providing written informed consent; (5) have no physical or mental health problems. Potential participants were identified by the intensivists according to electronic clinical records and contacted by MZ via telephone or face-to-face communication in ICU waiting room.

Semi-structured interviews were conducted to collect surrogate perceptions by MZ and YC. We constructed an interview syllabus on the basis of Ottawa’s decision-making needs assessment guides [31] and refined by pilot interviews with three surrogates (Textbox 1). During the interviews, communication techniques such as rhetorical questioning and repetition were used to reflect the views of the interviewees as truthfully and comprehensively as possible. Each interview was recorded with participant’s oral consent lasting about 30 to 60 minutes, and with 1 or 2 times to ensure data integrity. Finally, sample saturation was achieved when none new data generated. Audio recordings were transcribed verbatim by MZ and double-checked by YC. Field notes were analyzed alongside the transcripts. The Colaizzi’s seven-step approach was used to qualitative analysis [32] and performed independently by MZ and YC. The third author (LW) was invited to arbitrate any disagreement. The NVivo 12.0 software was applied for the transcription and coding process.

Textbox 1. The interview outlines for assessing users’ decisional needs
1. What were your impressions of the decision-making process that you undertook together with physicians when choosing whether to pursue RRT for your loved one in the ICU?

2. What factors did you consider when you were faced with the decision of whether or not to choose RRT for your loved one?

3. What confused or bothered you during this decision-making process?

4. Which other kinds of relevant information should be provided to others during this process?

Phase 3: User Persona (Dup: Abstract ?)

User persona is a detailed description of a fictional person (usually a composite of real individuals), and takes a role of communicating key motivations, concerns, and interests of a user group, which can be developed through immersion into users’ context [33, 34]. Persona development has been used in a number of studies contributing to digital educational solutions or physical activity advisors [35, 36]. We created a user persona describing the typical user expected to engage with the DA, which informed us subsequent developing works by users’ context immersion. The persona fostered our empathy and better understanding of users’ needs and also enabled us to shape an outline with the awareness of users’ unmet decisional needs. Family surrogates were informed about what a DA is and how it works and then asked to think about the potential impact such a tool would have on them, as well as their expectations about the time they would like to interact with and the ideal presentation of a DA. Then, we discussed the role served by a DA in the RRT decision-making process proposed to family surrogates for their loved ones in the ICU. This discussion allowed us to identify key points of the design problems on DA interface.

Phase 4: Evidence Synthesis (Dup: Abstract ?)

Based on the elements derived from users’ decisional needs and the clinical experience, we summarized latest clinical evidence regarding RRT decision making for critically ill patients. The evidence search strategy was constructed by a combination of MeSH terms and keywords, including “critical illness,” “acute kidney injury,” and “renal replacement therapy” (see Additional file 2). Evidence databases were searched from UpToDate, clinical guideline websites and professional association and institution websites, PubMed, Embase, and the Cochrane Library; note that local evidence was complemented by the search of China National Knowledge Infrastructure, China Science and Technology Journal Database, and the Wanfang Database. With the guidance of 6S model [37], we included evidence from advanced level (decision support) to low level (original research). If available resources could not answer our question, the original studies were included appropriately.

We included evidence that: (1) relating to critically ill AKI patients who requiring RRT; (2) patients aged ≥ 18 years; (3) published in English or Chinese. Articles were excluded for incomplete evidence (study protocols, drafts, discussion papers, and conference abstracts, etc.) or irrelevant content of decision-making support. MZ performed the search and screened evidence through titles and abstracts reviewing, and YC confirmed the relevance of the articles that were submitted for consideration. The selection of evidence was conducted independently by MZ and YC through full-text reviewing based on the eligible criteria. If any objections were recorded, whether or not to include the evidence was decided by CY. We chose the AGREE II tool [38] for quality evaluation of guidelines, and the Joanna Briggs Institute critical appraisal tools for determining the trustworthiness of systematic reviews [39], expert opinions [40], and original studies [41–43]. The quality of evidence was assessed by (MZ), who is qualified in systematic curriculums for evidence-based medicine. CY, YZ and YC were responsible for final reviewing. Project meetings were conducted to discuss the best strategy of evidence integration, according to following rules: (1) with the most complete published data (usually, the latest publication); (2) with the highest-level evidence among studies with consistent results; (3) conflicting evidence would not be synthesized, and the original content would be preserved.

Results

Phase 1: competitive analysis

We identified 16 available DAs related to RRT decision making through a systematic environmental scan. A proposed summary of the resources’ features and content elements is presented in Additional file 3. Most resources were from USA (N = 7), and the rest were developed in UK, Canada, Singapore, Australia, Denmark, Spain, and Sweden. Currently, the DAs designed for RRT decision making mainly cater to chronically ill patients: ‘End of Life Issues (N = 2)’ the advance care planning of kidney failure; ‘End Stage Renal Disease (N = 5)’ the choices of transplantation, dialysis or conservative management; ‘Chronic Kidney Disease (N = 9)’ dialysis modality options. The included studies showed that there is no DA on the topic of RRT decision making has been established for critical illness. Therefore, the evidence-based necessity to develop a target one for surrogates of critically ill patients requiring RRT was confirmed.

The two on end-of-life issues [44, 45], which highly overlapped with our target goals, only provided users with general information (e.g., you may feel better physically, you may be able to return to normal activities, you will no longer have side effects or problems from dialysis, your quality of life may be better, etc.), while details about how these outcomes would otherwise impact patients or about which factors trigger which outcomes were not available. Given the expectation of prognosis between ICU physicians and surrogate decision-makers was discordant [65], our potential DA should better illuminate the effects of clinical outcomes and, further, explain what outcome could be best achieved by prudently and deliberately decision making during life-saving moments. Pros and cons of each choice carried out on a contrast table were recommended to solve this problem. It is important to present relevant potential outcomes as much as possible before decision makers made the final life-saving decision, which can mostly prevent decisional conflicts or regrets.

There is not one single type of sources to develop a DA. Qualitative interview (i.e., individual interview or focus group) combined with systematic literature review was the most selective source of developmental data [46–49]. Other developmental sources including the construction of risk prediction model by national surveillance data [50], national and international patient needs through online survey [51, 52], educational material [53, 54], previous decision-making...
experience [53], and patient flow mapping [54]. The source of DA development depends on the characteristics of population coverage, for example, whether the scope of the population is specific or general, or whether the type of decision making is user preference-sensitive or not. For our targeted users, surrogate decision makers of critically ill patients under Chinese medical decision-making background, it is very important to collect their decisional needs and experience based on this special context. Qualitative interview could be the effective tool to provide us with preliminary sources.

For the display formats, two-thirds were web-based, while others combined with mobile applications, videos, PDF format or paper leaflets. There is no doubt that digital DAs are by far dominating the development market. Interactive features might be the possible reason for the boom. As if digital DAs were available for content control, timely feedback, social support, and other interactive features, users’ decision-making experiences could be optimized further. Given major modifications could be easily made to the prototype by digital technologies, it might also be the best way to provide iterative refinement for DA development. Obviously, it is necessary to apply digital technology to develop a DA with user-centered design.

Regarding the methodology of development, seven (7/10) employed empirical and theoretical frameworks [47–49, 51, 55–57], whereas six (6/16) did not report their development protocols [53, 54, 58–61]. The methodologies applied in their development process including the IPDAS criteria [62], the principles of shared decision-making process [63], Option Grid [64], the systematic development process for patient decision aids [24], and other clinical or service guidelines. In addition, some were also inspired by earlier feasible DAs [49]. However, only one study reported a systematic protocol conceived before development [50]. Note that we have previously published a study protocol for the development [28], and we would followed with the guidance of the IPDAS criteria [62].

**Phase 2: User Needs Assessment**

We invited 15 family surrogate decision-makers to participate in decisional needs assessment. The median (interquartile range [IQR]) age of surrogates was 48 (39.5–56.0) years. The mean APACHE II score for patients was 26 ± 7.9 scores. The mean length of stay in the ICU was ten days (ranging from 3d-28d). The demographic characteristics of family surrogates and their loved ones are presented in Table 1, and the qualitative scripts of family surrogates’ perceptions during RRT decision making is presented in Additional file 4.

We identified four themes with descriptive analyses of surrogates’ decision-making experience (Fig. 2). First, from an overall perspective, family surrogates stuck into decisional dilemmas after experiencing perplexity during RRT decision making. Most participants, even well-educated, could not make reasonable judgements with the information available to them due to the lack of specific guidance. Although participating in shared decision making with clinicians, some surrogates still deemed RRT selections as complex requirements. In addition, there were no criteria or guidelines suggesting the best suitable option for them before the decision making was required by clinicians, which further intensified these dilemmas. Second, family surrogates usually experienced uncertainty during the decision-making process. They reflected that they would be much more decisive if they could be informed about the ratio of risks and benefits for choosing RRT, while in reality they were only provided with rough guesses by clinicians. The unpredictable outcomes of each option likewise induced a sense of uncertainty and anxiety.

Third, surrogates’ capacity for decision making was constrained. Most comments from respondents reflected a clinician-oriented model in the decision-making process. Their described feeling as though they were being informed of the patients’ disease and treatment plan, but that the dominant deciding role was occupied by the doctor. Deficiencies of time and opportunity was another restriction. Surrogates reflected that, when the RRT decision making happened suddenly in the ICU, there was no time to think anything other than that their loved one might die without treatment. Furthermore, the self-efficacy of surrogate decision makers was expressed as insufficient. Most of them were unable to clarify the preferences and values of the patients when the decision making happened, while others were incapable of determining the trade-off between the benefits and the risks of treatment. Finally, surrogates responded to RRT decision making with delayed confirmation. When the decision about whether to initiate RRT for critically ill patients was confirmed by clinicians after acquiring the informed consent from surrogates, surrogates would reconstruct their decision later, through information searching or by seeking peer support to obtain familiar and trusted resources in hope of resolve their confusion – often to no avail.

Given the guidance of Ottawa Decision Support Framework [31], surrogates’ decisional needs were identified further, and the specific decision support was constructed (Fig. 2), based on the above four domains of surrogates’ perspectives regarding RRT decision-making experiences in ICU settings. In terms of surrogates’ decisional dilemmas and the sense of uncertainty, decisional conflict was the main barrier for them to further shared decision making with professionals, as available resources were unable to support surrogate decision making in ICU. Therefore, the information needs were identified, and the potential DA need to provide sufficient information for RRT choices clarification, facts and probabilities. For the limited decisional capacity, surrogate decision type (clinician-oriented model), timing (deficiency), stage (low self-efficacy), leaning (unable to clarify preferences) were presented. It is significant to provide additional professional support and values clarification besides DA intervention during surrogate decision making process, through clarifying their needs and preferences in specific decision-making context in reality. Regarding surrogates’ delayed confirmation in RRT decision making by self-searching information and seeking for peer support after the decision making was made, their expectations on knowledge, resources and other support were identified. Hence, corrective role guidance of surrogate decision maker should be better integrated into the DA to guide deliberation and communication. These measures indicated the main targets we needed to account for in DA development.
Table 1
The demographic characteristics of family surrogates and their loved ones (N = 15, respectively)

<table>
<thead>
<tr>
<th>Participant characteristic</th>
<th>Patients, n (%)</th>
<th>Surrogates, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, y</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean, SD</td>
<td>52 (20.3)</td>
<td>49 (12.1)</td>
</tr>
<tr>
<td>Median (interquartile range)</td>
<td>57 (35.5–66.5)</td>
<td>48 (39.5–56.0)</td>
</tr>
<tr>
<td>&lt; 40</td>
<td>4 (27)</td>
<td>4 (27)</td>
</tr>
<tr>
<td>40–59</td>
<td>5 (33)</td>
<td>8 (53)</td>
</tr>
<tr>
<td>≥60</td>
<td>6 (40)</td>
<td>3 (20)</td>
</tr>
<tr>
<td><strong>Gender (man)</strong></td>
<td>11 (73)</td>
<td>12 (80)</td>
</tr>
<tr>
<td><strong>Reasons for ICU admission</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nephrogenic</td>
<td>8 (53)</td>
<td>-</td>
</tr>
<tr>
<td>Pulmonary infection</td>
<td>7 (47)</td>
<td>-</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>6 (40)</td>
<td>-</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>6 (40)</td>
<td>-</td>
</tr>
<tr>
<td>Sepsis</td>
<td>3 (20)</td>
<td>-</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3 (20)</td>
<td>-</td>
</tr>
<tr>
<td>Neurologic</td>
<td>2 (13)</td>
<td>-</td>
</tr>
<tr>
<td>Metabolic</td>
<td>1 (7)</td>
<td>-</td>
</tr>
<tr>
<td>Trauma</td>
<td>1 (7)</td>
<td>-</td>
</tr>
<tr>
<td><strong>APACHE II score (Mean, SD)</strong></td>
<td>26 (7.9)</td>
<td>-</td>
</tr>
<tr>
<td><strong>ICU-LOS (Mean, min-max)</strong></td>
<td>10 (3–28)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Reasons for ICU discharge</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial burden/ forgo therapy</td>
<td>8 (53)</td>
<td>-</td>
</tr>
<tr>
<td>Transfer to the general ward</td>
<td>6 (40)</td>
<td>-</td>
</tr>
<tr>
<td>Death</td>
<td>1 (7)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Relationship to patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>-</td>
<td>5 (33)</td>
</tr>
<tr>
<td>Parents</td>
<td>-</td>
<td>4 (27)</td>
</tr>
<tr>
<td>Spouse</td>
<td>-</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Other</td>
<td>-</td>
<td>3 (20)</td>
</tr>
<tr>
<td><strong>Educational level</strong></td>
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</tr>
<tr>
<td>College/university</td>
<td>-</td>
<td>9 (60)</td>
</tr>
<tr>
<td>High school</td>
<td>-</td>
<td>4 (27)</td>
</tr>
<tr>
<td>Junior middle school and below</td>
<td>-</td>
<td>2 (13)</td>
</tr>
</tbody>
</table>

* More than one choice possible. APACHE: Acute Physiology and Chronic Health Evaluation. ICU-LOS: length of stay in ICU.

**Phase 3: User Persona**

We recruited 15 family surrogates with RRT decision-making experience in the ICU to produce a user persona, which described the typical user expected to engage with the DA and informed subsequent design decisions. The demographic characteristics of participants is presented in Table 1. Since most of the surrogate decision makers in ICU are men, we created ‘Bobby’, our user persona. He is a family surrogate decision maker for his elderly father, who has been diagnosed with septic AKI after ICU admission.

Bobby’s primary goal is to decide whether or not to choose RRT based on information about his father’s disease’s progression and available treatment options while his father is in a coma and incapable of decision making. To achieve this goal, he expects to be provided with sufficient information about the available
choices and guided by a professional who will ask him how to proceed at each step. He is confused when communicating with ICU clinicians, because there is indeed a knowledge gap between himself and the doctors which renders him unable to engage in a successful discussion with the medical professionals. He is particularly perplexed by ambiguous information about the treatment outcomes and finds it impossible to weigh the potential risks and benefits of RRT without numeric estimations. When participating in the decision making, Bobby is frustrated by uncontrolled factors related to his father's disease and treatment progress, especially if negative information about the procedure is not mentioned before the decision is made.

Bobby expects a DA can facilitate his interaction with clinicians, especially when he suffers psychological distress because of his father's ICU admission. He wants plain explanations to clarify this complex choice so that he can prepare to participate in decision making. The brief and concise content in the DA will be better suited to his needs so that he can understand the situation as quickly as possible, while additional detailed information should be available as a supplement. A digital format will be the best mode of presentation for the potential DA, because he thinks this is most convenient readily available, while paper pamphlets can be prepared if they are needed in different settings.

He sees himself as passive and feels a total mess in his mind when anticipates writing an informed consent for RRT for his father. He thinks it is necessary to take a role in choosing treatment for his father, but he worries about his ability to make the best choice. He is concerned that he may have future regrets if he makes an incorrect decision.

Bobby plans to increase his knowledge about his father's disease and the option of RRT by self-searching on the internet (usually acquiring free results and sample phrase segments through online search engine) or by seeking peer support from others with similar experiences, if possible, but admits he feels stuck within a decision dilemma to some extent.

Phase 4: Evidence Synthesis

Given the preference-sensitive nature and ethical conflicts the choice of RRT presents to the surrogates of critically ill patients, we conducted a separate process to check the relevance of and to update, where needed, 1) the introduction of critical illness with AKI and the RRT, 2) the benefits and risks of RRT selection, 3) the ICU and post-ICU outcomes of critically ill patients receiving RRT as it currently exists.

Evidence searching occurred between Dec 2019 and May 2020. A total of 15,220 records were identified from database and website searches. In total, 27 studies were identified as suitable for inclusion, where Fig. 3 presents the screening process and results. The characteristics of the included literatures are summarized in Additional file 5. Of the 27 included articles, five were published before 2015 and the remaining selection were published in 2015 (n = 1), 2017 (n = 3), 2018 (n = 2), 2019 (n = 6), and 2020 (n = 7). All the articles were published in English except for four published in Chinese. Regarding the types of publication, four were the highest quality of evidence available from UpToDate, while the remaining were published as clinical guideline (n = 6), expert consensus (n = 3), systematic reviews or meta-analyses (n = 10), and original studies (n = 4).

The quality evaluation of guidelines appraised by AGREE II, shows that two were recommend at Level A and four at Level B. All systematic reviews and meta-analyses were evaluated as high quality except for two, which were evaluated as middle quality due to incomplete consideration of the evidence-based method. Two expert opinions were evaluated as high quality and one as middle quality because of the unclear consistency when compared with other studies. Concerning the original studies, two non-randomized controlled trials were evaluated as middle quality since no measure taken when the clinical follow-up lost; the cross-sectional study was evaluated as high quality; the prospective cohort research was deemed as middle quality because three items were evaluated with unknown/unclear, including measures to solve confounding factors, initial observational outcomes, and measures to solve incomplete follow-up.

A total of 21 evidence items were extracted from the above articles through in-depth reading, analysis, and summarization. Based on the framework from the results of needs assessment and the design guidance offered by the user persona, all decision supports available from UpToDate, and relevant guidelines were integrated into background information detailing a general introduction of the disease and the treatment. An additional 21 items of evidence (see Additional file 6) were cataloged detailing the benefits and risks of RRT, possible outcomes, and the reasons to choose this treatment.

Draft Prototype

We drafted the prototype according to the elements from competitive analysis (design tactics and strategies), user needs assessment (targeted users’ unmet decisional needs and potential decision support), user persona (context immersion for development), and evidence synthesis (latest clinical evidence of the treatment decision making for critically ill patients requiring RRT). A crucial step for prototype drafting was to reach a consensus within our project team, especially, with respect to expert recommendations on evidence transformation and presentation. The DA was developed with two main parts, a “user guide” which refers to a user instruction to state decision-making problems on patient right and interests, and a “decision guide” to lead the shared decision-making process through a systematized guidance. Specifically, the DA was rapidly prototyped with simplified navigation interface, and with interactive features such as content control, tailored decision-making logic, and timely feedback. A conjunction of contrast table, smiley matrix, pie chart, curve chart, bar graph, etc., was comprehensively applied to transform the numerical data into user views. Finally, the digital DA was developed through FAISCO [66], a self-service website construction system in China. The content framework and key features of the prototype are presented in Fig. 4, and final DA prototype is provided in Additional file 7.

Discussion
To the best of our knowledge, this is the first study to develop a digital DA for surrogate decision makers of critically ill patients, so that surrogates can make specific and deliberate decisions when their loved ones require RRT, thereby safeguarding the best interests of stakeholders in the ICU. We have rapidly prototyped the DA by user-centered design, through competitive analysis, user needs assessment, user persona development, and evidence synthesis. The UCD design thinking was executed with current decisional needs, evidence-based necessities, and the prospect of further development, application, and promotion. Firstly, we have conducted a systematic environment scan to include existing 16 topic-related DAs for competitive analysis and identified potential opportunities to a specific DA for our target users. Secondly, we have invited fifteen family surrogate decision makers who had past decision-making experience in ICU to join in face-to-face interviews, that enabled us to explore their unmet decisional needs of RRT decision making and develop a typical user persona based on user expectations on future decision support when given sufficient descriptions of a decision aid. Then, we have performed the method of evidence-based medicine, through evidence searches, evidence selection, evidence evaluation, and evidence synthesis to collect latest clinical evidence of RRT decision making, and a total of 27 studies were eligible for inclusion. Finally, a user-centered digital DA was developed to provide evidence-based decision support for surrogate decision makers of critically ill patients requiring RRT in ICU, which gives us an opportunity to narrow the knowledge gap between surrogates and clinicians and to achieve the best trade-off in complex life-sustaining decision making.

Although shared decision-making is essential to support patient-centered care [67], evidence suggested that medical necessity and clinicians’ sense of patients’ best interests still drive the direction of treatment decision making when the stakes are high [13]. Unfortunately, patients’ values and preferences of life-sustaining treatment were usually absent in the context. Many studies have highlighted the importance of providing decision support (i.e., DA) and the necessity of paying more attention on patients’ values and preferences in life-saving moments. However, available DAs were unable to match with user decisional needs in the ICU practice. "Advance Care Planning: Should I Stop Kidney Dialysis?" and "Kidney Failure: Should I Start Dialysis?" both developed by Healthwise (a nonprofit organization) [58, 59], which were used to help decide to continue or start kidney dialysis for end of life issues. Above two aids play an important role of value clarification through patient stories and clarifying personal feelings, but are not capable to support precise and prudent decision making by general description of benefits and risks for users to compare options. Given surrogate decision-making experience was identified with stuck into dilemmas, limited capacity, sense of uncertainty, and delayed confirmation by user needs assessment, our DA has provided with specific decision support catering to surrogates’ decisional needs and a practical pathway to achieve shared decision making in the ICU. It also provides the opportunity of the use of extra decision support to meet current needs of clinicians and healthcare systems [5, 11, 13, 68, 69].

Unlike previous studies, our DA incorporates the consideration of family-centered care to improve surrogates’ participation in and preparation for decision making. The role of surrogate decision makers in critical illness has been indicated with associations of surrogates’ decisional dilemmas [10], decisional conflicts [12], decisional regrets [70], personal distress [71], high incidence of PTSD-like symptoms [72], and post-ICU syndrome [73]. Cox et al. [74] conducted a randomized clinical trial to examine the effects of a web-based DA for surrogate decision makers of patients with prolonged mechanical ventilation in ICU, which showed greater reduction in decisional conflict among surrogates, but with no impact on the improvement of surrogates’ psychological distress, prognostic concordance between surrogates and clinicians, or patients’ clinical outcomes. Decision support in ICU is required with more individualized attention for both the cognitive and affective challenges of decision making. Our digital DA developed among family surrogates of critically ill patients was totally combined with family-centered care in the ICU context, by provision of clear information through designated decision-making steps, assistance with eliciting and considering their loved ones’ values and preferences, and focusing on collaboration with clinicians to achieve shared decision making. Moreover, we would further examine the impact of DA on surrogates decision-making outcomes in future studies.

Another valuable aspect of the DA that can be used as a focal point for the development of future DAs for life-sustaining treatment in ICU settings is its combination of decision support with evidence-based practice to best meet users’ needs. With UCD, the more remarkable effects of evidence-based practice in complex clinical contexts are emphasized, and it is easier to custom-tailor the process of designing, refining, and updating the DA. Thus, the comprehensive and effective decision support with high-level feasibility can be provided for and implemented in ICU settings. The DA in our study, developed through a systematic user-centered approach, has the potential to improve family-clinician communication on RRT selection and the quality of RRT decision making for critically ill patients.

**Strengths And Limitations**

A strength of the present study is that the DA was developed based on the needs of target users by a systematically user-centered approach which was then integrated with the evidence-based data, so the effectiveness of evidence-based practice can be trusted. Furthermore, as far as we know, this was the first DA to be designed for RRT decision making in an ICU context and the first developed locally to support surrogate decision making in China. It is meaningful to identify the decision-making needs of Chinese surrogates and to give insight for family participation in life-sustaining treatment decision making for their loved ones.

The study also have several limitations. One of the major limitations is the difficulty in predicting prognostic outcomes for RRT procedures in ICU patients. The clinical evidence included in the DA, or of other information in addressing surrogates’ decisional conflicts, was derived from ICU patient groups diagnosed with AKI as the means to improve family surrogates’ preparation in the participation of decision making. Recently, studies in RRT on critically ill patients with AKI [75–77] reported that the uncertainty surrounding the best time to start treatment poses challenges to the consistency of clinical ethics and decision making in a medical environment. On account of the underlying pathogenic factors and mortality of critically ill patients, it is difficult to accurately predict potential outcomes after choosing RRT. As such, the best way to predict the best interests and rights of ICU patients is to make shared decision making as detailed and sufficient a process as possible.

Another major limitation of the study is that our needs assessment was based only on users of one tertiary hospital, so the user archetypes might be limited and under-represented of all surrogate decision makers in China. Future studies are planned to verify the model’s usability across broader user groups, to assess its use in “near-live” and “real-live” contexts, and to obtain more opinions regarding users’ application experiences for further refinement of the DA.
addition, further research is warranted to investigate the long-term outcomes of decision making at follow-up intervals after survivor discharge from ICU, as well as to construct a patient- and surrogate-reported outcomes database for the purpose of aggregating high-quality evidence regarding shared decision making between patients, family surrogate decision makers, and clinicians.

Conclusions

In conclusion, a digital DA was rapidly prototyped to support surrogate decision makers for critically ill patients requiring RRT in ICU. The systematic process using UCD provided a robust structure to guide cooperation among target users, healthcare professionals, academic researchers, and developers. The mixed method for designing and developing the prototype helped our project team manage the workload effectively and shortened the distance between theory and practice. Based on our results, we concluded that this systematic process to develop a user-centered DA can indeed assist developers in making more appropriate design choices. Future studies to test the usability, feasibility, and comprehensibility of the DA and to evaluate its effectiveness in clinical decision-making settings are warranted.

Abbreviations

AKI: acute kidney injury; RRT: renal replacement therapy; DA: decision aid; ICU: Intensive Care Units; UCD: user-centered design; IT: Information Technology; IPDAS: International Patient Decision Aid Standards; COREQ: Consolidated Criteria for Reporting Qualitative Research.

Declarations

Ethics approval and consent to participate

All methods in this study were performed following the relevant guidelines and regulations. The research protocol was reviewed and approved by the Ethics Committee of the First Affiliated Hospital of Army Medical University, PLA (KY2020236). All participants involved in this study were above 18 years of age and all provided written informed consent after it was read to them.

Consent for publication

Not applicable.

Availability of data and materials

The data analyzed during this study are not publicly available as all data are confidential but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Authors' contributions

MZ and YC contributed equally to this work. LW, CY, and YZ supervise the research progress and provide intellectual input into the development work. CY, YC and YZ has provided special guidance for the study implementation and professional contribution for RRT decision making in the ICU. MZ conceived of the study and drafted the manuscript. MZ contributed to the website construction and prototype written. MZ and LW provided intellectual input into the conceptual framework of the study and revised critically for intellectual content. All the authors have read and approved the final manuscript.

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References


Figure 1

The procedure of RRT DA development
Figure 2

Users' decisional needs assessment
Figure 3
Evidence search & selection process

Figure 4
The framework of decision aid
Supplementary Files

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