Author’s response to reviews

Title: Beyond pros and cons – Developing a patient decision aid to cultivate dialog to build relationships: Insights from a qualitative study and decision aid development

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Author’s response to reviews:

(*Please see response to reviewers document in attached files.)

Response to Editor and Reviewer comments:

Editor/Reviewer comment Author response

Reviewer 1:

1. In the ‘Authors’ contribution’ section please include the contribution of each and every of the authors. Each author is expected to have made substantial contributions to the conception OR design of the work; OR the acquisition, analysis, OR interpretation of data; OR the creation of new software used in the work; OR have drafted the work or substantively revised it.

AND to have approved the submitted version (and any substantially modified version that involves the author's contribution to the study);

AND to have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

The section has been modified as follows:
CHY participated in study conception and design, data interpretation, and drafted the manuscript. CK and AJ contributed to the creation of new software used in the work and drafted portions of the manuscript. SH participated in data acquisition and analysis. SES contributed to study design and substantively revised the manuscript. PC, KC, PF, NI, DK, FL, JM, JR, SS, and DT contributed to study design and data acquisition. JS and DS contributed to study design and interpretation of data.

All authors have approved the submitted version and have agreed to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

2. While assessing your manuscript in-house, we found several instances in the Introduction and Methods where the text displayed similarities to text found in another previously published article that you have authored. We ask you to please make sure to keep the overlap to a minimum. In the methods section, please always state that the methods have already been described elsewhere and provide a citation.

We have tried to identify each instance of similarity and have made appropriate modifications to minimize overlap using track changes.

We have also stated that the methods have already been described elsewhere and provided the citation in the first sentence of the Methods section as follows:

“This study was part of a larger study focused on developing and evaluating an SDM toolkit for goal setting in patients with diabetes and other comorbidities; the development and evaluation protocol is described in detail elsewhere (16).”

3. Please cite appropriately the ‘Tables’ in the main text to indicate that they are part of the Supplementary files.

Tables in Additional File 1 have been updated as follows and indicated thus in the main text:

1) Table 1: COREQ checklist
2) IPDAS checklist
3) Feasibility interview guide
Reviewer 1:

This paper attempts to present a broad overview of the process of developing an interprofessional PtDA for PwD. Due to the breadth of the paper, it has both strengths and weaknesses. The strength is that is is able to capture for readers the whole process of development. The limitation is that the article is heavily weighted in Phase 1’s results.

Due to word count limitations, we elected to focus on novel findings regarding goal-setting and decision-making. However, we appreciate the reviewer’s perspective. We will implement the suggestions below to add additional depth and detail to the other phases.

I find that the overall structure of the paper is unclear as it "aims to explore decision making experiences and then develop an intervention to facilitate IP SDM." So, it describes the process / phases of development, but spends a large amount of text on the exploration of decision making. There is not much description on the intervention developed (e.g. what is this MyDiabetes website like?) and how values were incorporated into the intervention from decision making barriers identified in Phase 1. I would suggest to either report just the decision making interview analysis, or to be more balanced in presenting the overall development. For the latter perhaps report how findings from preliminary phases informed subsequent ones, or how the tension between value weightage and user friendliness was resolved in iterative versions.

We have enriched description of the subsequent phases to provide more balance to the paper as follows:

(1) Addition of screenshots in Additional File 2
Details regarding patient values incorporation are have been added to Results under “Intervention Development” as follows:

“While clinical goals consist of cardiometabolic risk factor targets, we found in Phase 1 that patients’ goals were informed by their personal values and life contexts. Thus, we designed the tool to collect a detailed baseline profile containing each patient’s hobbies (specifically categorized as requiring the ability to see or move around), most feared complication (for example, dialysis, blindness, etc.), sexual activity level, barriers to diabetes management (for example, medication non-adherence), and social supports in addition to routine demographic and clinical data.

We used the baseline profile to help patients select a “goal”, which we conceptualized as a specific diabetes complication that a patient would want to avoid in their life (for example, avoiding blindness). We prepared a list of 8 goals, and instructed each patient using the tool to select one. Our testing indicated that the 8-item list was too complicated, so we narrowed the list down to the 3 most relevant goals by ranking each goal using a scoring algorithm). This scoring algorithm considered all relevant characteristics in the baseline profile, including both patient values and clinical data. For example, a patient with a history of diabetic retinopathy might fear having a stroke, and also enjoy marathon running as a hobby. Their history of retinopathy would add 1 point towards the goal of “avoiding blindness”. Additionally, their fear of stroke and enjoyment of marathon running (which requires preserved motor function) would each add 4 points, with a total of 8 points for the goal of “avoiding stroke”. In this simplified example, avoiding stroke (8 points) would be ranked above avoiding retinopathy (1 point). We weighted the point value of clinical risk factors (e.g. age, smoking, retinopathy, etc.) based on published risk-prediction algorithms from large studies (31-38). We weighted patient-important factors more strongly than clinical risk factors because of the patient-centred focus of this tool. We adjusted the value of all weights according to our findings from extensive iterative testing with patients and interprofessional clinical experts. To contextualize the selected goal, we further asked each patient using the tool to identify their motivation for achieving this goal (within a free form text box) according to his or her personal values, hobbies, and lifestyle. For example, a patient could select a goal as “I want to avoid blindness”, and identify their motivation as “because I want to continue to see my grandchildren”.

To develop goals into action plans, we created an extensive set of “options”, conceptualized as specific and measurable tasks that patients could do to help them achieve their selected goal. For example, one option could be “taking my metformin in the morning and evening at least 6 days a week”. Because there were >100 possible options, we again narrowed the list to the 3 most relevant options for each patient using a scoring algorithm. Similar to the process described
above, patient using the tool were then instructed to select their preferred options from this shortened list. The algorithm accounted for both patient-important and clinical factors, with patient-important factors again being weighted more strongly. We further adjusted the values of these weights based on the iterative development process.”

(3) Details regarding iterations based on previous phases have been including in Results under ”Refinement of MyDiabetesPlan” and in Table 1, as follows:

“Based on findings from our interviews and usability testing, we refined MyDiabetesPlan, as outlined in Table 1. In addition, to overcome implementation barriers identified in the literature and in our interviews, we developed an implementation strategy consisting of a training video, training session, enabler card, engagement of a clinical champion, and integration of MyDiabetesPlan output into the electronic medical record (Table 1).”

Besides the overall structure, some individual terms and components were also not too clear:

- What is the format of the MyDiabetes PDA- not clear that it was a website until quite far into the paper, why was the decision made to develop a website and not a book for e.g.

  We have added earlier indication and rationale of MyDiabetesPlan as a web-based decision aid to Methods: Phase 2 MyDiabetesPlan Development as follows:

  “Although we started with a paper-based prototype, due to the number of required inputs and potential management options, as well as complex weighting algorithms to arrive at the tailored management option based on user input, we elected to use a web-based format for our decision aid.”

- Some terms need to be defined for readers: Interprofessional team approach (pg 5 line 93). What do you mean by that, why is this important in your setting?

  We have added the following explanation regarding interprofessional care:

  “An interprofessional (IP) team approach may overcome these barriers to SDM. Interprofessional care, where professionals from different disciplines collaborate to provide an integrated approach to patient care (8), is particularly appropriate for diabetes care. Participation by more than one profession, expanding roles, and adding new team members in diabetes care has been demonstrated to improve clinical outcomes (9-11).”
- Phase 1 Feasibility refers to a toolkit- what is the difference between a toolkit and a PDA? (pg 7 line 139)

  We have clarified this in the first paragraph of the Methods section:

  “This toolkit consisted of a PtDA (MyDiabetesPlan) and its accompanying implementation tools (such as how-to videos, and enabler cards with step-by-step instructions).”

- What are the multi-component materials developed in this study? You mention patient, doctor and point of care materials, but what really are these?

  We have clarified this as indicated above.

- The structure and content of MyDiabetesPlan. I would suggest to include some description and screenshots in the Appendix as without a rough idea of the PDA website, it is hard to grasp how processes like compatibility testing and probability testing (pg 20) were incorporated.

  We have included a description of MyDiabetesPlan in the Results section of the manuscript, under “Intervention Development” as indicated above.

In addition, we have included screenshots of MyDiabetesPlan in Additional File 2.

- The title mentions "a decision aid to cultivate dialog to build relationships" but these design features (cultivating dialog; building relationships) are not described in the article.

  We have added the following sentences under “Phase 2; MyDiabetesPlan and Implementation Strategy Development” and “Refinement of MyDiabetesPlan and implementation strategy” of the Results section:

  “As such, by enquiring about and eliciting patient-important values, beliefs, facilitators, and barriers to care, MyDiabetesPlan was designed to enable dialog between patients and their clinicians and thus facilitate cultivation of a therapeutic relationship and shared decision-making.”

  “The training session and training videos emphasized the importance of dialog and therapeutic relationship as facilitators of shared decision-making.”
Reviewer 2

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?

Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?

Yes - the approach is appropriate

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?

Yes - experiments and analyses were performed appropriately

STATISTICS - Is the use of statistics in the manuscript appropriate?

Yes - appropriate statistical analyses have been used in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?

Yes - the author's interpretation is reasonable

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?

Probably - with minor revisions

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: This is a well-planned, 4 phased study that is well described. The investigators took a thorough stepped-approach in developing a diabetes decision aid. Other than some "copy editing" to address some typos, etc., the study is nicely outlined
ADDITIONAL REQUESTS/SUGGESTIONS:

This is a carefully planned study that is clearly presented in the manuscript. The investigators began with a qualitative approach with a mix of patient and provider interviews in gaining their insights into the development of the decision aid. All of the critical elements of shared decision aids, e.g. knowledge, risks and barriers, goal setting were built into the program. Implementation and training users was well-described.

Note: This reviewer report can be downloaded - see attached pdf file.

Thank you for your review. Please see below for revisions that will hopefully improve the manuscript.

- Some clarification is needed around the reason for the role play. What is the rationale for the role play as patient or clinician when testing the PDA? Was any data collected from this or was it just a preparation for the interview?

  We conducted a role play of the prototype use to mimic actual clinical use in order to identify facilitators and barriers that may arise with real use. We were able to collect data regarding barriers and facilitators to use as well as feedback regarding format and content. We have clarified this in the Methods section as follows:

  “We chose to conduct role play with a prototype to mimic actual clinical use in order to identify facilitators and barriers that may arrive with real use, as well as feedback regarding format and content.”

- Is this role play done with the website, and is this the planned protocol for implementation that patient and clinician use it together? Sometimes websites are meant to be used alone by the patient as a preparation for SDM in the consultation.

  This role play was done with an early web-based prototype of MyDiabetesPlan, which was designed for patients and clinicians to use together, as well as the patient by themselves.

  We have added this detail to the Methods Section.

- What is the rationale for excluding pregnant women / considering pregnancy?

  We excluded pregnant women and women considering pregnancy because of the requirement for timely rigorous metabolic control for optimal maternal-fetal outcomes in this population.
Although SDM is still relevant in this population, goals of care of pregnant women and women considering pregnancy differ from the general diabetes population.

Results

- There is no demographic table for Phase 3.

  Phase 3 (heuristic evaluation) is conducted by a human factors engineer, without users. Thus, there is no demographic table.

- Illustrative Quotes in Additional File- Suggest to include an identifier on whether the participant being quoted is a patient or a doctor.

  Table 3a includes quotes from people living with diabetes; Table 3b includes quotes from clinicians. We have included this in the respective titles:

Table 3a: Representative quotes from feasibility interviews with people living with diabetes
Table 3b: Representative quotes from feasibility interviews with clinicians

- In the demographic table: the age for the clinicians is wrong (starts from <5, to >20); CDE does not total 10, why include Other in Profession if the count is 0.

  Thank you for picking up on this! We have changed it to “Years in Practice”.

We have amended the CDE “No” category to 7.

We have deleted “Other” in Profession.

- How was interprofessional SDM incorporated into the PDA?

  We have included the following in the Methods section to address this:

  “Use of MyDiabetesPlan within the care team was dependent on the usual roles, responsibilities and processes of care, and the needs of the patient. For example, if the usual process of care was that the patient first saw the clinic nurse followed by the family physician, then this was adapted for the study.”
The primary discussion points center around Phase 1 only, i.e. the negotiation between goals and preferences for patients and healthcare professionals. The topics of goal negotiation and decisional preference are quite well established as you have pointed out a number of systematic reviews on this. You found that there is a process of autonomy vs shared-ness, and discordant goals being negotiated in the treatment decision making process...how did your PDA attempt to address these issues? It would have been good to see some discussion of the rationale, pros and cons of your approach taken in the Methods and Results was for users (i.e. the nine-point goal weighting process).

We have elaborated on this under “Development of MyDiabetesPlan” in the Results section as follows:

“While clinical goals consist of cardiometabolic risk factor targets, we found in Phase 1 that patients’ goals were informed by their personal values and life contexts. Thus, we designed the tool to collect a detailed baseline profile containing each patient’s hobbies (specifically categorized as requiring the ability to see or move around), most feared complication (for example, dialysis, blindness, etc.), sexual activity level, barriers to diabetes management (for example, medication non-adherence), and social supports in addition to routine demographic and clinical data.

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As such, by enquiring about and eliciting patient-important values, beliefs, facilitators, and barriers to care, MyDiabetesPlan was designed to enable dialog between patients and their clinicians and thus facilitate cultivation of a therapeutic relationship and shared decision-making.”

- In the Discussion, some of the Results are mentioned here e.g. how some decision making facilitator designs were incorporated into the website; try not to mention new results in the discussion section.

These facilitators have now been included in the Results section and in Table 1.

- Phase 2-4 seem to be missing from the Discussion (and are given only minor paragraphs in the Results). This makes the manuscript a bit top heavy as the methods detail 4 phases in detail, which are then cut down to only Phase 1 in the results and the discussion. Please see comment on overall structure.

This was also raised by Reviewer 1. We have enriched description of the subsequent phases to provide more balance to the paper as detailed in the response above.

- What is the value of the heuristic evaluation, it would be good to discuss your view on the value of this step, given that many do not have access to a human factors engineer, how feasible is the process for other people and how valuable was the contribution of this step to refining the PDA.

We have added the following justification for heuristic evaluation:
“This and the next phase of the study involved usability evaluation of the tool. United States Food and Drug Administration recommends incorporating “usability engineering processes during the development of medical devices, focusing specifically on the user interface […]”. The goal is to ensure that the device user interface has been designed such that the user errors that could cause harm or degrade medical treatment are either eliminated or reduced to the extent possible. (40).

Heuristic evaluation was the first of the usability evaluations undertaken during this study as its objective is to identify weaknesses in the design, especially when use error could lead to harm (40). This review can be completed by usability experts, thus providing an opportunity to address major usability issues before the end users interact with the user interface.

Usability issues were identified, listed, and then categorized by severity as minor, moderate, major, or catastrophic or “show-stoppers” by a human factors engineer; severity estimates were based on frequency, impact, and persistence of errors(41). In addition extensive quality assurance was also conducted by a member of the human factors engineering team using various clinical scenarios to confirm that the program produced the expected result.

The user interface was refined in response to the usability issues that were identified prior to proceeding to the Phase 4.”

- Under limitations, it is stated that the participants were representative of a primary care population. This is hard to claim given that there were only 7 patients.

We have deleted this statement.

“However, our study participants represented a diverse range of socio-demographic and clinical characteristics representative of a primary care population (56).”