**Author’s response to reviews**

**Title:** Identifying and selecting implementation theories, models and frameworks: a qualitative study to inform the development of a decision support tool

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Dr. Alison Cuff
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Dear Dr. Cuff,

Re: MIDM-D-19-00529

Thank you for considering our manuscript entitled, “Identifying and selecting implementation theories, models and frameworks: a qualitative study to inform the development of a decision support tool” (MIDM-D-19-00529). We are pleased that the BMC Medical Informatics and Decision Making journal has invited us to submit a revised version of this paper.
We have carefully reviewed the comments made by the peer reviewers and have revised the manuscript accordingly. Enclosed please find our reply to each of the reviewers’ recommendations. The revised manuscript has been uploaded to your website.

We look forward to receiving a final decision from your journal.

Sincerely,

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Reviewers’ Comments and Responses: MIDM-D-19-00529 “Identifying and selecting implementation theories, models and frameworks: a qualitative study to inform the development of a decision support tool”

We thank the reviewers for their helpful feedback to improve our manuscript. Please find below our reply to the reviewers’ recommendations. Our responses describe any changes made to the manuscript; line numbers correspond to the tracked changes version of the manuscript.

Jim Smith (Reviewer 1)

The following comments are suggested to enhance the coherence and clarity of the manuscript.

Thank you for taking the time to review our revised manuscript and provide additional feedback. We have attempted to address your comments below.

1) Did the authors follow any guidelines on developing a decision support tool? If not, why not?
   ‘We will be using established methods and will be guided by theory, a model and a framework to inform tool development. Because tool development is not the focus for this paper, we did not provide details on the methods.
   To clarify this to the reader, we have added the following sentences to the Background section, starting on Line 116: "As tool development is not the focus for this paper, we did not provide details on the methods. These methods will be described in a subsequent development and evaluation paper".’
I note the authors' sentence however, this paper is part of the tool development. In order to inform a decision tool methods/guidelines are beneficial to follow and will show that the author considered the following steps of the tool development. It seems the authors have considered a method as they mention they will be following established guidelines. A short sentence is only required stating that they considered XXX guidelines in developing the tool. The authors need to justify why qualitative methods were used and the benefits qualitative methods can bring to the development of the tool.

Thank you for providing this clarification. We have revised our statement in the Methods section, starting on Line 110:

“To address this problem, we propose to use the findings from a rigorous scoping review of over 300 implementation theories, models and frameworks (2) to develop a decision support tool, with input from implementation researchers and practitioners using qualitative research methods. A decision support tool provides structured guidance to help users make an explicit decision (19). In this case, a decision support tool may facilitate appropriate selection of one or more implementation theories, models or frameworks by engaging the user to answer key questions, resulting in relevant options to consider. The decision support tool will be developed using rigorous methods guided by theory and evidence on user-centered design and implementation science. The overarching approach will be informed using the Knowledge-to-Action Cycle (20) and the United Kingdom Medical Research Council Framework for Development and Evaluation of Complex Interventions (21). These methods have been used for creation of other decision support tools (22). As tool development is not the focus for this paper, details on the methods will be described in a subsequent development and evaluation paper.”

2) The abstract background is not clear on the tool development aim and I would suggest to revise ‘develop’ to ‘inform’ in the following sentence as it still implies you will be developing the tool in the current paper: ‘We propose to develop a decision support tool to facilitate the appropriate selection of an implementation theory, model or framework in practice.’

Thank you for this suggestion. We have revised ‘develop’ to ‘inform’ in the Abstract background, starting on Line 30:

“We propose to inform a decision support tool to facilitate the appropriate selection of an implementation theory, model or framework in practice.”

3) Ethics was obtained in Toronto. How did this cover recruiting in the US?

‘This research study was conducted by a graduate student at the University of Toronto (Ontario, Canada) as part of her PhD thesis. The research was conducted at the Li Ka Shing Knowledge Institute at St. Michael's Hospital, Unity Health Toronto, where the student's thesis supervisor and university-affiliated lead investigator is based. As such, we applied for ethics approval from both Unity Health Toronto and the University of Toronto. Our study protocol outlined the tools we would use to identify potential participants for recruitment, who would identify potential study participants, who would make initial contact with potential participants and how that contact would be made. Specifically, this included in-person recruitment at two large conferences, including one in the USA, by handing out study information sheets to attendees; collecting contact information from those interested in participating in an interview using a hard copy sign-up sheet; and sending a personalized email to interested participants following the
conference to schedule a phone interview, all of which was done by the graduate student. This protocol was approved by both Unity Health Toronto and the University of Toronto.

The authors need to briefly cover that the recruiting process covered the conferences which covered participants in USA and Australia.

Thank you. We have added a second sentence to our ethics statement in the Methods section, starting on Line 148:

“We obtained research ethics board approval from Unity Health Toronto (REB #16-335) and the University of Toronto (REB #33907). Ethics approval covered recruitment at the conferences and workshops, which covered the study participants in the United States (USA) and Australia.”

4) More information is required to explain why you selected the TDF over other popular Frameworks. In addition, why did you select these specific TDF domains for consideration over other TDF domains? What was your rationale for this?

‘We have revised the manuscript to more clearly justify our use of the Theoretical Domains Framework to inform our interview guide. First, we have moved, and revised, the following paragraph from the Discussion section to the Methods section, starting on Line 192 of the Methods: “The Theoretical Domains Framework is a validated determinant framework (25) that has been applied in numerous implementation studies to uncover the underlying barriers to and facilitators of behaviour change. Further, the framework includes a comprehensive set of barriers at the individual or person level, along with the organizational-level (e.g., groups of individuals), which we felt were most important to understand when developing a decision support tool to meet the needs of our targeted end-user.” (25) Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci 2012;7(1):37. Second, the following paragraph was added to the Discussion section, starting on Line 468: "There are numerous determinant frameworks that we could have chosen to inform our interview guide. For example, our team recently mapped over 300 implementation theories, models and frameworks to Nilsen's taxonomy (3) and identified over 50 determinant frameworks targeting at least individual-level change. However, many did not include a comprehensive set of barriers and facilitators (unpublished data)." (3) Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci 2015;10(1):53.’

The authors comments are noted, can they please explain why specific TDF domains were chosen. For example, TDF includes more domains than 'knowledge', 'skills' 'beliefs about capabilities' 'intentions', 'social/professional role and identity' on pg 8. Why did the authors select these specific domains for consideration over the other domains within the TDF? The authors need to justify this.

Thank you for providing this clarification. We would like to clarify that we used the Theoretical Domains Framework loosely to inform our interview guide as a starting point, to allow for inductive analysis. We have revised the Methods section, starting on Line 191:

“The interview guide questions were informed loosely by the Theoretical Domains Framework (27) as a starting point, to allow for inductive analysis. Direct questions inquiring about perceived barriers and facilitators were also included to allow for free-flowing discussion.”

Andrea Smith (Reviewer 2)
Thank you the opportunity to review this manuscript again, and for your response to my comments. I have no further comments.

Thank you for taking the time to review our revised manuscript.

FORMATTING CHANGES

1. Please move the Abbreviations and Declarations after Conclusions section.

We have moved the Abbreviations and Declarations sections after the Conclusions, starting on Line 532.

2. Ethics approval and consent to participate
   -- If verbal, please state the reason and whether the ethics committee approved this procedure. If the need for consent was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation.

   Verbal consent was approved by the research ethics boards and obtained by phone at the start of the interview. We have revised our ethics statement in the Methods section, starting on Line 148: “We obtained research ethics board approval from Unity Health Toronto (REB #16-335) and the University of Toronto (REB #33907). Ethics approval covered recruitment at the conferences and workshops, which covered the study participants in the United States (USA) and Australia. Verbal informed consent was approved by the ethics boards and obtained (and audio-recorded) from all participants using a predetermined script prior to the phone interview.”

   Similarly, we have revised our ethics statement in the ‘Ethics Approval and Consent to Participate’ section of the Declarations, starting on Line 537: “Research ethics board approval was obtained from Unity Health Toronto (REB #16-335) and the University of Toronto (REB #33907). Ethics approval covered recruitment at the conferences and workshops, which covered the study participants in the USA and Australia. Verbal informed consent was approved by the ethics boards and obtained and recorded at the start of the phone interview using a predetermined script.”

3. Funding
   -- Please state clearly the role the funder(s) had in your study in the "funding" section of the declarations.

   We have added a sentence clarifying the role of the funder in the study in the ‘Funding’ section of the Declarations, starting on Line 551: “The funders had no role in the design of the study, the collection, analysis or interpretation of data, or the writing of the manuscript.”