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 are in italics and describe any changes made to the manuscript; line numbers correspond to the tracked changes version of the manuscript.

Jim Smith (Reviewer 1)

I read this paper with great interest.

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

INTRODUCTION

The introduction seems on the light side. Can you add further evidence that this research is required? The authors only report on one study (10) line 90.

We have revised the Background section to include additional evidence to support the need for this research, starting on Line 87:
“Despite a growing interest in the appropriate selection and use of implementation theories, models and frameworks (7-11), it can be difficult to sift through and make sense of the various options available – especially when most are used in practice only once or with limited justification (2,12). For instance, participants in an implementation practice training course (13) reported that they struggled to identify and select suitable theories, models or frameworks to guide their work. Studies also suggest that implementation theories, models and frameworks may not be used appropriately (8,14).

The following references have been added to this paragraph:
(10) Lynch EA, Mudge A, Knowles S, Kitson AL, Hunter SC, Harvey G. "There is nothing so practical as a good theory": a pragmatic guide for selecting theoretical approaches for implementation projects. BMC Health Serv Res. 2018 Nov 14;18(1):857

Following this revised paragraph, we have added a new paragraph to the Background on existing tools and guides, starting on Line 95 [Note: we moved some of this content from the Discussion section to the Background section]:

“Implementation researchers and practitioners looking to identify a theory, model or framework to inform their work can access existing tools and publicly available resources such as guidance documents (e.g., 15-17). For example, drawing on their personal experience working with novice implementation practitioners, Lynch and colleagues (10) suggested five questions to consider when selecting a theory, model or framework: who are you working with, when in the process are you going to use theory, why are you applying theory, how will you collect data and what resources are available. Birken and colleagues (9) developed a checklist of 16 criteria (organized within four categories: usability, validity, applicability, acceptability) for implementation researchers or practitioners to consult when selecting a theory, model or framework. A major limitation identified by the tool developers is the prerequisite of a candidate list of suitable theories, models or frameworks to draw from and compare (9). Researchers at the University of Colorado developed a database of models and frameworks, www.dissemination-implementation.org, however the content is based on the findings of a narrative review of theories, models and frameworks (18) and is not comprehensive.

To address this problem, we propose to use the findings from our 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.”
The following references have been added to this paragraph:
(10) Lynch EA, Mudge A, Knowles S, Kitson AL, Hunter SC, Harvey G. “There is nothing so practical as a good theory”: a pragmatic guide for selecting theoretical approaches for implementation projects. BMC Health Serv Res 2018;18

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”.

The authors use a very old reference from 1980 (11) line 96 on decision support and there is a wealth of information on this area.

We chose this reference to provide a comprehensive definition of a decision support system. However, we agree that more recent information on decision support is available and can be cited. We have replaced the old reference with the following more recent citation on Line 113, to provide readers with an example of a comparable online decision support tool to guide implementation practice:

Ethics
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.

METHOD

Further explanation is required as to why interviews were chosen instead of other methods for example, focus groups.

We have elaborated on our rationale for conducting individual interviews, starting on Line 137 in the Methods:

“We chose to conduct individual, semi-structured interviews to understand individual perspectives, including challenges and successes related to identifying and selecting implementation theories, models and frameworks in research and practice. While focus groups would have allowed for group interactions and may have helped participants generate and share their ideas (21), we were most interested in individual opinions and decision processes (20). Therefore, we felt that interviews would be more informative for tool development. Feasibility was also a factor, as our participants were from a wide geographic area.”

The following references have been added to this paragraph in the manuscript:

Participant Selection

Line 140 mentions non-responders. How many participants were actually invited? Did any decline and if so, why? If many did, it would be interesting to know reasons why.

Due to space constraints in the manuscript, details on non-responders were initially included only in the Supplemental File, Appendix 1 Consolidated criteria for reporting qualitative studies (COREQ) checklist. We have now added the following paragraph to the manuscript, starting on Line 227 of the Results section:
“One eligible participant declined consent due to a confidentiality agreement with their current employer. Of the eligible workshop participants contacted, 2 were not reached due to undeliverable email addresses and 33 did not respond to our email invitation. Participants were recruited until no new themes were identified; therefore, not all workshop participants were sent a study invitation.”

Line 146 states between 20-30 participants is sufficient. Why was recruitment stopped at 24 interviews?

See response directly above, clarifying that participants were recruited until no new themes were identified.

DATA COLLECTION

Were interview transcripts anonymised before being imported to NVIVO?

Once audio-recorded interviews were transcribed and verified for accuracy, they were de-identified using a master linking log, prior to being imported into NVivo. Data will remain de-identified (i.e., a hard copy of the master linking log with identifiers being kept and stored separately from data) for a period of 7 years following the completion of the study, at which point the hard copy of the master linking log will be destroyed, rendering study data anonymized.

We have added the following sentence to the Methods section, starting on Line 210:
“Once the audio-recorded interviews were transcribed and verified for accuracy, they were de-identified using a master linking log, prior to being imported into NVivo.”

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.”


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).”


DATA ANALYSIS

It needs to be clearer what the authors are referring to as the interpretative descriptive approach (and Thematic Analysis). In the abstract it seems to incorporate the design and here it mentions coding. Further detail is required.

Thorne’s interpretive descriptive approach guided all aspects of this research, including the design and analysis. We have revised the start of the Methods section to provide more details, on Line 126:

“Thorne’s interpretive descriptive approach (20) guided all aspects of this research, including the design and analysis. Interpretive description is grounded in traditional qualitative methodologies (e.g., phenomenology) that are derived from the social sciences; yet, it is oriented toward applied health disciplines such as implementation practice and designed to address real-world knowledge gaps (20).


In addition, we have made minor edits to the paragraph on data analysis in the Methods section, starting on Line 206:

“Following an interpretive descriptive approach, we conducted a thematic analysis of the data to synthesize meanings across codes and generate a narrative of the key themes to inform subsequent tool development (20,26). Data analysis occurred concurrently with data collection. We used NVivo 12 qualitative data analysis software (QSR International, Cambridge, MA) to organize and code the transcripts. Once the audio-recorded interviews were transcribed and verified for accuracy, they were de-identified using a master linking log, prior to being imported into NVivo. After reading through the first few transcripts to become familiar with the data, we used open coding to create codes from the text and drafted a coding framework. This coding framework was revised iteratively throughout data collection and analysis. All data were coded inductively by a single investigator (LS), with a subset of 20% (i.e., 5 transcripts in total) coded by a second investigator (JB) with high concordance achieved. This duplicate coding process was done at the start and end of data collection to ensure consistency of themes. Representative quotes from participants were selected to support the themes and study findings. The final manuscript was shared with participants for feedback on the research findings.”

As stated in the Methods section, we shared the final manuscript with study participants for their feedback. This exercise was not intended as a “member checking” step, as we did not intend to assess whether each participant agreed with our interpretations of the data. Instead, we wanted to give study participants an opportunity to review the manuscript. Participants who did not respond to the first email, received a second email 2 weeks later. Of the 21 participants reached by email (3 could not be reached due to undeliverable email addresses), 13 responded. A majority of those who responded had no edits or asked for a few minor clarifications, for example, regarding an aspect of the study characteristics. One participant generously reviewed the manuscript in detail and provided feedback that was largely focused on trying to clarify ideas.

RESULTS

Line 183-194 should be under a participant title and not in the results section.

We feel that this description of the study participants best fits in the results section as it is describing the characteristics of the individuals who participated in an interview. We have added the subheading “Participant characteristics” within the Results section on Line 225.

Tables 2 and 3 were hard to match with the text. I presume the authors have included the quotes in the tables for word limit. The tables need to also show the factor numbers to easily link to the text.

We chose to put the participant quotes in tables due to the word limit. We have clarified the factor numbers in both Table 2 and Table 3 so that the reader can more easily link the quotes with the text in the manuscript. For example, “Interview excerpts reflective of factor 1 ‘attitudes’” … “Interview excerpts reflective of factor 2 ‘knowledge’” … etc.

Line 219 'Some of their' typo on their.

Thank you for catching this typo. We have changed “their” to “there” on Line 267.

A table would be useful to show the overview of the categories and related factors. Coming to the section ‘other categories and factors became confusing in comparison to the other detailed categories.

Thank you. We have added the factor and category numbers to the Figure. If it would be helpful to change this figure to a table, we would be happy to do that. Further, we have changed the “Other categories and factors” heading to “Categories 3 and 4” on Line 377 of the manuscript, to be consistent with the way the earlier results are presented.

DISCUSSION
Its not clear how this research will be used. Further information on future directions is required.

As stated in the conclusion starting on Line 540, “These barriers, together with the findings of our scoping review on existing theories, models and frameworks, will inform and tailor the features and functions of a proposed decision support tool for use by implementation practitioners. Our findings from this interview-based study suggest the tool should be easy to use, accessible and feature questions about the implementation project’s purpose, scope and intended target for change, in addition to presenting a comprehensive list of relevant theories, models and frameworks and the contexts in which they were applied.”

We have also added the following sentence to the Discussion section, starting on Line 502: “We hope that users of our decision support tool will feel better informed, and more confident in identifying and selecting implementation theories, models and frameworks in practice.”

Other comments

It would be useful to include a description next to the names of the Theories, Models, and Frameworks in Table 4.

Thank you for this suggestion. While we agree this could be useful to readers, we did not include descriptions in the table due to space constraints. We have added a new appendix, Appendix 3, to the Supplemental File. The new appendix contains citations for the 28 theories, models and frameworks used by participants and listed in Table 4. For example:

“Name: Active Implementation Framework
Citation: Fixsen DL, Naoom SF, Blase KA, Friedman RM, Wallace F. Implementation research: a synthesis of the literature. Tampa FL: University of South Florida, Louis de la Parte Florida Mental Health Institute, The National Implementation Research Network, 2005 (FMHI Publ. #231).
Website: https://nirn.fpg.unc.edu/ai-hub”

We also added a footnote to Table 4: “See supplemental file for citations for the theories, models and frameworks.”

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Andrea Smith (Reviewer 2)

Thank you for asking me to review this paper. It is an interesting, well-written paper exploring an important aspect of implementation science with the potential to make a practical contribution to implementation researchers. I have provided a number of comments and suggestions that I hope might strengthen the paper and increase its utility to readers.

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

General Comment
Several readily accessible online tools and guides exist to help researchers choose and apply appropriate theories (e.g. VA's QUERI Implementation Guide; Birken et al.’s TCaST; the online www.dissemination-implementation.org, based on Tabak et al.’s review of frameworks, and Colorado University's online guide, http://crispebooks.org/). It would be helpful if you could contextualise the current project (and the tool this qualitative work will inform) with the current situation in regard to support for those wishing to use a theory, model or framework to guide their work. So perhaps mention the existing tools/guides in the Introduction (to set the scene and explain the gap), and then in the Discussion relate how the results of this interview-based study can be used to design a tool that meets the needs of implementation researchers/practitioners.

Thank you for your suggestion to improve our manuscript, and for sharing these helpful references. Please see our earlier responses to Reviewer 1, on page 3 and page 9 of this letter. Our subsequent paper on tool development and evaluation will include a more comprehensive summary of existing tools and resources.

Data analysis

Interview schedule: A gap in the interview schedule / data collected is potentially participant awareness / use of existing tools to aid selection of TMFs. Were any questions asked of participants, or did anyone spontaneously volunteer this information? [If not, this is interesting in itself (to researchers about to develop a new online tool) and might warrant a comment in the Discussion.]

This is a great point, thank you. Yes, some participants spontaneously commented on their awareness of and use of existing tools and publicly available resources when asked to describe (a) the process they use (or have used in the past) to identify and select a theory, model or framework, and/or (b) facilitators to identifying and selecting a theory, model or framework in practice. These included Nilsen’s taxonomy, and the website www.dissemination-implementation.org, as well as websites for specific theories, models and frameworks such as RE-AIM, CFIR and Normalization Process Theory. To clarify this, we have added the following sentence to the Results section under ‘Factor 6: ease of use of the implementation theory, model or framework’, starting on Line 356:

“Facilitators to selection and use included existing online tools and publicly available resources, such as websites dedicated to specific theories, models or frameworks (e.g., the Consolidated Framework for Implementation Research).”

Did any of the data collected provide information about whether availability of resources to support use of a theory, model or framework impact on a participant’s decision to use that particular theory, model, framework? E.g. CIFR, RE-AIM, EPIS have website / resources to guide use.

See response directly above. While this was not asked as a direct question, participants described online resources and tools as facilitators to selection.
Did your data analysis provide any insights into differences in perspectives / experiences of implementation science researchers vs implementation practitioners? You make one comment (see below) about implementation researchers being under more pressure to use a theory, model or framework – were there any other differences between these two groups?

No differences were identified, but this could be explored in future studies.

Line 172: You state ‘we used open coding to identify codes’. I would suggest codes are created (not identified).

We agree, and have edited the wording of this sentence, starting on Line 213:
“We used open coding to create the codes from the data.”

Line 177: You state ‘we conducted thematic analysis’. Can you provide a reference for the type of TA you are using (Braun and Clarke’s reflexive TA?). How does TA and Thorne’s interpretive descriptive approach relate – which aspects of each did you use?

Yes, we followed Braun & Clarke’s guide to thematic analysis, which applies to many qualitative approaches including interpretive description. Braun & Clarke’s phases include: familiarizing oneself with the data; generating initial codes; searching for themes; reviewing themes: defining and naming themes; and producing a report. These fit well with the broad ‘steps’ of interpretive description which are identifying and describing what is there (step 1 - description) and interpreting step 1 in terms of what it means and represents (step 2 – interpretation).

We have referenced Braun & Clarke’s approach, on Line 208 in the data analysis section:
“Following an interpretive descriptive approach, we conducted a thematic analysis of the data to synthesize meanings across codes and generate a narrative of the key themes to inform subsequent tool development (20,26).”


Line 188: You state ‘Of the 24 participants, 11 (46%) had completed a ‘Practising knowledge translation course’ (that was run at your institution, with the involvement of one of the authors?). Do you think this could have caused issues with the breadth of data collected, or your interpretation of the data? I acknowledge that you mention this as a limitation, but you might want to expand on this, and perhaps include a footnote to Table 4 to acknowledge that the range of theories, models and frameworks identified may have been limited by the cohort / that half had attended the same training course?

Thank you. We have added the following footnote to Table 4 to acknowledge that the range of theories, models and frameworks identified may have been limited:
“Note: nearly half of the 24 participants attended the same training course, which may have limited the range of theories, models and frameworks identified.”

Results
Much of your analysis focuses on the ‘barriers and facilitators’ to theory, model of framework selection; it might have been interesting to report more on the data collected in Q7 and Q8 about the process of TMF selection, how an individual (or team) get to the point of deciding which TMF they will use.

To inform tool development, we chose to focus our analysis on the barriers and facilitators to identifying and selecting a theory, model or framework. In terms of processes, many participants reported using the same theory, model and/or framework repeatedly, as we describe on Line 288 of the results: “Most participants favoured one or more implementation theories, models or frameworks and used them repeatedly, stating that it was easy to use what was familiar.”

Line 198: You state ‘Participants identified four broad categories and 10 factors’. I would suggest it is the researchers who generate the categories (not the participants; and the categories are not already there in the data waiting to be identified, they are created).

We agree and have revised this sentence, starting on Line 245 to read: “Four broad categories and 10 factors, generated from the data, influenced identification and selection of implementation theories, models and frameworks and were relevant to tool development”

Similarly, we have revised the first sentence of the Abstract - Results, starting on Line 40: “Twenty-four individuals participated in the study. Categories of barriers/facilitators, to inform tool development, included characteristics of the individual or team conducting implementation and characteristics of the implementation theory, model or framework.”

Lines 226-227: You state ‘Participants commented on the importance of engaging in practices that are informed by TMFs and evidence.’ Do you have any data to expand on this? This might be important/relevant.

Additional details are not available for elaboration.

Line 231: You state ‘they preferred to avoid selecting a formal theoretical approach’. This is potentially interesting/important. Can you expand / elaborate on this?

Two participants shared this view, additional details are not available for elaboration.

Lines 233-234: You state ‘A few believed that implementation practitioners may not feel the same ‘pressure’ to use a theory, model of framework in their role compared to an implementation researcher’. Do you have any data to support this/explain why practitioners not feel same pressure to use TMF compared to researchers?

Additional details are not available for elaboration. This could be explored in a future study on this topic.

Line 242: You state ‘Access to a comprehensive repository or database of existing implementation theories, models and frameworks was perceived as helpful’. There are a number
of resources already available (see my earlier comment about what you might like to add to your Introduction). Did any of the participants refer to them? If not, this is in itself an important finding (especially as it indicates an dissemination / implementation failure, which in itself is somewhat ironic) and of relevance to you as you go forward in the design of your decision-making tool (and in the development of your own dissemination plans for the tool).

Thank you, these are great points to consider as we develop and evaluate our tool. Yes, a few participants referenced www.dissemination-implementation.org (see our earlier response). Some also mentioned published systematic reviews, scoping reviews and reviews in the grey literature as helpful.

Line 327: I think Category 3 should be 4.  
Line 329: I think Category 4 should be 3.

Thank you for catching this typo. To match the Figure, we have made the above changes in the Results section, starting on Line 379:

“Other important barriers and facilitators mentioned by participants were related to characteristics of the healthcare environment (Category 4) and, to a lesser extent, characteristics of the implementation intervention or project (Category 3).”

Line 331: I think Category 8 should be 10, and Category 3 should be 4.

To match the Figure, we have made these changes on Line 382:

“Availability of resources (Factor 10) within complex healthcare environments (Category 4)…”

Line 344: I think Category 9 should be 8.  
Line 347: I think Category 10 should be 9.

To match the Figure, we have made these changes to the following paragraph in the Results, starting on Line 394:

“Finally, a few participants mentioned factors related to the implementation project (Category 3), such as consideration of the purpose, problem or goal and intended outcome (Factor 8). For instance, it may be inappropriate to select a theory when part of the research question or outcome of an implementation project was to further develop theory. Another relevant factor that presented a challenge to selection was the level of intervention complexity (Factor 9), including the type of intended behaviour change (e.g., individual, program, practice, policy), and the implementation stage (e.g., planning, evaluation, sustainability) for the project.”

Lines 357 and 358: You state ‘matched with characteristics of the end-users’ implementation project’. Can you be more specific about ‘characteristics’.

To clarify this, we have added ‘aim, scope and level of change’ as examples of what we mean by ‘characteristics’ of the end-user’s project, on Line 411:

“Most importantly, the tool should include a comprehensive list of existing implementation theories, models and frameworks to choose from. Suggested content items included
characteristics of the theories, models and frameworks matched with characteristics of the end-user’s implementation project (e.g., aim, scope and level of change).”