Author's response to reviews

Title: Guideline adaptation and implementation planning: a prospective observational study

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Author's response to reviews: see over
18 January 2013
Dr. Denise O’Connor
Editorial Team
Implementation Science Editorial Team

**MS:1037921551806294:** Guideline adaptation and implementation: a natural experiment.

Dear Dr. O’Connor

We would like to thank our three Reviewers for their substantive feedback. It was thoughtful and constructive and will assist us in improving this manuscript.

In response, we have endeavoured to address each reviewer’s comments separately in the Addendum that follows this letter. In general, major additions and edited sections are highlighted in grey in this version of the manuscript.

We trust that this next version responds to the major and minor revisions requested by the reviewers and we look forward to your feedback.

Sincerely,

[Signature]

Professor, School of Nursing
Director, Queen’s Joanna Briggs Collaboration and
Scientific Director, Practice and Research in Nursing Group
ADDENDUM: RESPONSE TO REVIEWERS

Manuscript ID 1037921551806294
Guideline adaptation and implementation: a natural experiment.
Changes are shaded in the main document.

Reviewer: Alison Hutchinson

Minor Essential Revisions
1. In Table 3, the acronym PIPOH is used – please include the full text.
   PIPOH now defined with full text Table 4.

Discretionary Revisions:
2. The title of the manuscript implies that the guideline implementation process will be described. “Guideline adaptation and implementation planning …” may more accurately reflect the content of the manuscript.
   Agree; title has been changed to better reflect the design and content, revised title: “Guideline adaptation and implementation planning: a prospective observational study”

3. In the Abstract, the phrase “guideline entity mandate and infrastructure” is unclear. The meaning later becomes clear in the body of the manuscript. Suggest this is re-worded in the Abstract to provide clarity.
   The term ‘entity’ has been removed from the abstract.

4. Data management and evaluation protocols are mentioned on page 8 – could examples be provided in Table 3?
   Yes we could certainly do that - we have a detailed protocol manual (70 pages) and have formulated the section on data collection tools and management into a separate document. We are willing to include as an additional file if it might be useful for others who want to replicate such a study. It is an additional PDF file for your perusal.

5. A number of groups and individuals are mentioned throughout the text e.g. partnership, case teams, steering committee, case panels, chair, facilitators. While some of these are described in the Discussion section, a definition/description would provide context for the reader.
   Agree; we have reduced the multiple terms, ‘teams’ ‘groups’ ‘panels’ throughout to address labels/language issues and are more specific and consistent about ‘cases’; have also reverted to lower case convention for ‘cases’. Trust this simplifies and makes things clearer.

6. While the references for the conceptual framework and taxonomy for facilitation are provided (refs 13-15), a brief description of the framework would strengthen this section.
   This section has been revised and expanded as noted in shaded content.

7. Version 3 of CAN-IMPLEMENT is referred to in the text. A brief explanation of the background to development of this framework e.g., development of versions 1 and 2, would provide greater context for the reader.
   Agree; this was confusing and unnecessary detail. We have removed references to ‘versions’ of CAN-IMPLEMENT and simply refer to the final product.
Reviewer: Tari Turner
Are the methods appropriate and well described, and sufficient details provided to replicate the work for an exploratory study? More detail of the methods used to analyse the data would be helpful.

We have created a new section and added content under Methods re: ‘data analysis’ (pp.11-12); references are also made to additional publications re: the ADAPTE evaluation, and associated Facilitation study and Network Analysis work by B. Poole.

Discretionary revisions
1. I don’t think that “a natural experiment” is the most accurate description of this study and I’d remove it from the title.
   Agree (as per AH); title has been changed to better reflect both the design and content: Guideline adaptation and implementation planning: a prospective observational study

2. The occasional use of italic text is distracting; I suggest it be removed throughout except where it is used in quotes.
   Agree; all italics have been removed except for quotations (if a new or unique term is introduced, single quotes are now used).

3. “Unlike most dedicated guideline enterprises, these groups were 100% volunteers working over and above their full-time clinical and/or administrative responsibilities” I suggest this is common for many guideline development (and particularly adaptation) projects.
   Agree; we clarify this comment on pp.13.

4. It is not immediately clear how the section in the Background titled “Conceptualization in Activating Health Care Knowledge” links to the rest of the work. It could be removed.
   A frequent criticism of KT and implementation science is the lack of a theoretical foundation in studies. We purposefully used a planned-action approach to further operationalize it at the mid-range theory level, i.e., actually carrying out the steps in the CIHR KTA meta-framework. The study and this paper are not about this theoretical development but to our surprise the use of a framework was seen as instrumental by the participants. They used it themselves when working in their groups and with decision-makers. Therefore we felt it was important to introduce and describe. This section has been tightened and edited and hopefully links it better with the rest of the work, pp. 7-8.
Reviewer: Cheryl Stetler

Major Compulsory Revisions:
1. There is considerable lack of clarity in use of terms, especially in the beginning and for the reader who has not been exposed to prior publications. For example, the following:

   a. What does adaptation mean and what are its limits in this context?
   *We have added a definition of ‘adaptation’ (pp. 5).*

   b. What does “local” mean? For example on page 10: “locally, groups engaged a part-time internal facilitator” … presumably this person was a facilitator for one of the Cancer care groups; is that correct? Or does it mean, as it seemed later, that it means the clinical practice context of individual members of the group/s? Or…both?
   *We reduced and clarified use of the term ‘local’ where possible. We clarified and made consistent references to ‘internal’ and ‘external’ facilitators; now use the term facilitator/coordinator for ‘local, case-based’ individuals; Section on Facilitation, pp. 15-16, was revised to clarify roles and activities.*

   c. What is the difference or similarity of adaptation, customization and tailoring?
   Again, a clear definition of terms is needed.
   *We clarified use of customizing and tailoring as equivalent terms (p.5).*

2. A statement is made that guideline adaptation is essential, without a definition, explanation/rationale or evidence regarding this issue for the uninformed reader. These should be provided.
   *We did not state guideline adaptation is essential but have provided some rationale (pp.6.)*

3. The core of this paper relates to the ADAPTE process. This should be included for reference, as an Additional file, if necessary; e.g., the Fervers et al 2010 Table 1: Steps in the adaptation process.
   *The ADAPTE references are cited and on pp. 6 clarification has been made to use of ADAPTE version 1.0 (2007. A table outlining the ADAPTE steps has been added. To be clear though, ADAPTE was a starting point. After an introduction to ADAPTE, the process involved much more than the linear 24-step approach which users could not actually follow in sequence or manage without additional support. The central message is that ADAPTE is necessary but not sufficient. Two of us (MBH, IDG) were involved in developing the ADAPTE. It was not developed in the field or experientially informed.*

4. Methods section: This is clearly called a case study but there is also the natural experiment and its “intervention.” Within the narrative of the Methods section there should be more clarity about the CAN-ADAPTE study vs Case Series study: e.g., please clarify their relationship and related design issues.
   *A section has been added to clarify this. References to intervention removed. The intent was to provide groups with access to ADAPTE, then, as participant-observers, provide facilitation and support as required. ‘CAN-ADAPTE’ was an interim working title. We have removed that reference. Also agree that it is more accurately described as a ‘multiple case study’, so we have also removed the references to ‘series’.*

   a. Are the “pan-Canadian study “objectives on page 9 for the CAN-ADAPTE or the Case Series?
   *As per above, clarification has been provided under the Methods section (pp. 9-10)*
b. Does the Canadian Guideline Adaptation Study cover both the CAN-ADAPTE and Case Series? *Yes, as noted above, clarification provided that this was single, ‘multiple case’ study.*

c. Please place the Guidelines Action Group therein.  
*The ‘Guideline Actions Group’ was essentially the sponsoring arm of the Canadian Partnership Against Cancer. We have removed reference to this “Group” here to avoid confusion and mention them instead only in the Acknowledgements.*

5. Other method issues that need to be addressed:
   a. There should be a Limitations section. *This has been added pp. 25.*

   b. There needs to be more information on data analysis, its rigor and the trustworthiness of related observations/interpretations.  
   *More information has been added, and new subsections ‘Data Collection’ and ‘Data Analysis’, pp. 11-12.*

6. Results section:
   a. Under the Facilitation heading, there is no in-depth description of the experience of having external facilitators. As the objective appeared to reference both, more data should be provided.  
   *A major revision was made to this section. ‘Facilitation’ is now summarized under internal and external activities and observations. The previous subtitled section: “An adaptation methodology necessary but not sufficient: participant perspectives and experience” was removed. The bulk of the content in the previous section actually described the support provided by the Queen’s team to study cases, i.e. the extent of additional ‘external’ facilitation.*

   i. Was there an operational definition of facilitation and its expected components, at either level that could be or was used in evaluation; e.g., was the external role [albeit not discussed in the paper] evaluated based on explicit related expectations?  
   *Facilitation was not evaluated per se but rather tracked and described. At the outset we did not have specific tasks/functions assigned as we did not have a clear idea what type of support they would require or how the internal and external might overlap. It was unmistakably internal with the local facilitator and external when they accessed the Queen’s research team.*

   b. Starting in the middle of page 16 and on the top of page 18, the narrative seemed to get confusing, perhaps because of sentence structure and the focus on detail (including wordy tables) rather than on more general themes.  
   *The revision to the facilitation observations should help with this. Also, in the section “Implementation Action during Guideline Adaptation”, the two case examples were revised – hopefully easier to read.*

   As for the “wordy tables” (Evolution of the ADAPTE material and methodology and Participant ideas for streamlining process), these are intended to summarize and demonstrate the differences with ADAPTE process when carried out in the field. They synthesize important information and we would request keeping them in.

**Minor Essential Revisions**

1. Cancer care groups; please indicate the number of groups overall, number of volunteer groups including the 5 cases, and membership size.  
   *Additional case profile information has been added to description under Results, p. 13.*
2. Page 9: “context-specific approach as they operationalized their approach”: Does this relate to jurisdictional level?
   *This sentence was rephrased for clarification, p. 9.*

3. Please clarify: When the term local is used, does it mean that the members of the cancer groups were formally linked, i.e., therein representing, their point-of-care organizations? My concern is whether there is evidence that national or regional “adapted” guidelines [vs. de novo national or regional guidelines] are sufficiently “localized” for real-time point-of-care end-users. Ergo, is there any difference when the adaptation guideline comes from a different level in terms of the “specific needs, priorities … scope of practice” at the lowest local level? This is especially problematic for me as this case study does not have any evidence of actual use of the adapted guidelines at the point-of-care.
   *To address this point in the Limitations, pp. 25 “It should also be recognized that the ‘pan-Canadian’ adapted guidelines would likely need further adaptation at a local (provincial or institutional) level which was not possible to follow in the timeframe of this study.”*

4. The meaning of the differently shaded lowest “B” circle is unclear in Figure 2…how is it iterative? What does “reached” mean? ...completed it?
   *Figure 2 has been edited to clarify A, B, and C patterns. The note below the Figure indicates the activity required before starting the ADAPTE steps. Pattern B (iterative activity) occurred at the ‘Customization’ level in ADAPTE involving multiple drafts of the guideline document (often written by committee and often with a need to revisit assumptions and decisions made by the panel along the way, revealing, for some, weaknesses in their documentation processes.)*

5. Middle of page 19: Observations have been made that do not seem to be adequately substantiated and are rather only suggestive.
   *These observations have been more accurately described as ‘Participant Perspectives’ in the revised narrative, pp.20-22.*

6. Not sure the “Moving beyond CAN-ADAPTE” should be included in the Results, as not part of objectives and would need more description to be useful. Seems better to just keep in the Discussion.
   *Agree; the continued observation of two study cases beyond the initial evaluation of ADAPTE - and the further development of the implementation planning elements of CAN-IMPLEMENT based on this extended period of observation - is explained in a revised section of the Discussion. Also, as noted above, references to CAN-ADAPTE have been removed.*

7. In the Discussion section: are these findings a surprise? Are there not other sources that reference/suggest/support or enhance the findings in terms of the need for education, knowledge, support, project management, group leadership, etc. in such a program?
   *This section has been revised to better reflect actual “Participant Perspectives” (for whom many of the outcomes, though they may be evident in the literature, were not necessarily anticipated by the cases). The title ‘Unexpected Impact’ has been removed. The final paragraph reports an ‘unexpected’ finding (for the Queen’s team) related to the value perceived by participants of the KT conceptual framework as a means to focus implementation planning discussions within their respective organizations.*

8. How is the “catch-up phase” different from the “set-up phase” reported previously? Is it not theoretically integrated therein?
We are not entirely clear on this mention of “catch-up-phase” as it is not a term we used. However, if the question is about how the new “call-to-action” element in CAN-IMPLEMENT is different from ADAPTE Phase 1 “set-up”, the greater complexity and longer time needed for newly forming groups (particularly for national initiatives) has been clarified, pp. 14-15.

Discretionary Revisions

1. And is it the evidence-based “guideline” or local processes/policies that need identification/adaptation in order to implement a guideline --- or both, per the lowest level local point-of-care gaps and context?
   It is both and is relevant to the level of implementation i.e. context.

2. Sub-headings might be of use, e.g. under Facilitation and, within Methods, the addition of “Analysis.”
   Agree; these have been addressed.

3. Do you have any reflections, in the context of related literature, regarding use of the term Facilitation or the Facilitator role at the internal level?
   There are a number of general reflections included in this paper but as we noted it was such a substantial element it became a separate focused study (now published and referenced). Given the length of this paper and worries with self-plagiarism we felt it best to send readers to the original sources (Dogherty et al) where there is a good deal more comment.

4. In terms of the reference to confusion on page 16: Consider what details [versus general themes] are essential in the narrative and perhaps make the details, including some tables, available in an additional file for those interested in such details of ADAPTE or for later reference.
   Some clarification provided as per item 6 regarding ADAPTE (Compulsory revisions above)

5. Figure 2: I found the layout of Figure 2 confusing; i.e., the “call-to-action” phrase (an individual phase) seems to head the column relating to other phases.
   The schematic has been revised to more clearly distinguish CAN-IMPLEMENT “Call-to-Action step as pre-ADAPTE work which extended case timelines 4-6 months.

6. Were there data re: the “external review” in terms of whether the adapted guidelines met assumed “expectations”/principles of the original ADAPTE: e.g., were adaptations sufficiently consistent with an original, sound evidence base? Would certainly strengthen perception/process-based data.
   Unfortunately we do not have much more we can add here. That information was not shared with the central team consistently as the reviews occurred in some case beyond the tenure of the study.

7. Was there any difference related to the national vs provincial jurisdiction level?
   The process in this study was more complex with as there were more jurisdictions involved with a national endeavor accessing international guideline – costly meetings, challenges in getting many stakeholders together and getting them on the ‘same page’ (already noted). However given the small number to compare I don’t believe we can say much more based on this data.