Author’s response to reviews

Title: Using Qualitative Evidence Syntheses to Develop Implementation Considerations and Inform Implementation Processes

Authors:
Claire Glenton (claire.glenton@fhi.no)
Simon Lewin (simon.lewin@fhi.no)
Theresa A. Lawrie (tesslawrie@gmail.com)
María Barriex (barriexm@who.int)
Soo Downe (sdowne@uclan.ac.uk)
Kenneth Finlayson (kwfinalyson@uclan.ac.uk)
Tigest Tamrat (tamratt@who.int)
Sarah Rosenbaum (sarah.rosenbaum@fhi.no)
Özge Tunçalp (tuncalpo@who.int)

Version: 1 Date: 27 Mar 2019

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Response to reviewer comments

Reviewer #1

1. A very interesting and important paper with both policy and methodological implications. This would benefit from minor restructuring particularly in separating implications for researchers and decision makers as suggested in detail below.

Response:

Thank you. Please see responses below.

2. Abstract / Background: This section implies that "implementation" is only a minor subordinate feature of the qualitative evidence base. However, the subsequent Methods section of the Abstract makes implementation a major focus. Suggest that the Background section is tweaked to make this expectation clearer from the start: "In
addition to incorporating standard data on effectiveness WHO guidelines are increasingly using evidence that explores acceptability and feasibility, derived from QES, to address important implementation considerations”.

Response:

We have now edited the text as follows:

“In addition to the standard data on effectiveness, WHO guidelines are increasingly using evidence derived from QES to provide information on acceptability and feasibility and to develop important implementation considerations.”

3. Abstract: "to develop implementation considerations" Prefer "identify" as they already exist in the synthesised dataset.

Response:

We have substituted “develop” with “identify”.

4. Abstract / Conclusions: The Conclusions section of the Abstract is rich but confusing. Part of the reason for this is that the Conclusions operate at different levels and target different decision-makers. I suggest that instead they are structured around different target audiences e.g. implications for researchers then implications for policy makers. At the moment this achieves a scatter gun effect which is difficult to follow.

Response:

We have now edited this text by simplifying it slightly and highlighting which target audiences each point pertains to:

“These include: whether researchers should use existing health systems frameworks when developing implementation considerations; whether researchers should take confidence in the underlying evidence into account when developing implementation considerations; whether qualitative evidence that reveals implementation challenges should lead guideline panels to make conditional recommendations or only point to implementation considerations; and whether guideline users find it helpful to have challenges pointed out to them or whether they also need solutions to be suggested. Finally, we need to explore how intervention-specific evidence-to-decision frameworks can be adapted to allow for broader, cross-cutting issues identified through qualitative research.”
5. **Background**

The first two paragraphs of the Background are fairly sparse in terms of supporting referencing. They assume an internal knowledge of the WHO process. It would be helpful to add a few more supporting references to allow the interested reader to derive a clearer picture of the WHO process through follow up reading, if desired.


Response:

We have now added three supporting references to the first two paragraphs. We have, however, not used the reference suggested by the referee. The EtD framework described in the paper is a GRADE Working Group product and we have therefore referred to the appropriate GRADE papers when describing this framework. The paper the referee refers to describes a later WHO adaptation of the GRADE EtD framework and was not used in the guidelines we describe (although is likely to be relevant in future guidelines).

6. **Background:** It would be very helpful to move the description of the three papers from the Methods to the Background (where it describes this third paper). The Methods section will then refer to the three papers generically.

Response:

We have now edited the background text as follows:

“This is the third paper in a series examining the use of QES in developing clinical and health systems guidelines (Fig. 1). The focus of the first paper is on how to adapt QES methods for the guideline context [], and of the second is on how to use findings from QES to populate EtD frameworks []:”

7. **Methods:** "the result of a range of processes". What is described is not really a "range" of processes - they reflect diversity not extremes.

Response:

This has now been edited.
8. Methods: "a number of processes" - How many, exactly?

Response:

In the text, we refer the reader on to figure 2, where these processes are presented:

“For each guideline, a number of processes took place before the technical teams could begin developing the implementation considerations (Fig. 2). “

9. Methods: "The technical team then created EtD frameworks for each of the guideline's questions or recommendations." Potentially confusing because questions and recommendations represent different ends of the process. Perhaps "or areas to be targeted by recommendations" because current wording implies that you know what the recommendations are a priori whereas I presume you mean that you can anticipate what areas you will recommend in even though the exact nature of these will only emerge from the findings?

Response:

We have now removed the word “recommendations” so that the text reads as follows: “The technical team then created EtD frameworks for each of the guideline's questions or recommendations.”

10. Methods: Given their centrality to the subsequent discussion it would be helpful to define formally both "conditional (context-specific) recommendation" and "implementation consideration", perhaps in a Box? Furthermore it might be helpful to distinguish conceptually between what are limitations of evidence and what are limitations of context as this seems central to the confusion between application of these two terms.

Response:

We have now edited the text as follows:

“In many cases, the evidence from the QES pointed to problems with the acceptability or feasibility of the intervention or problems tied to equity. In some cases, this evidence led the panel to give a conditional or context-specific recommendation. This type of recommendation generally includes a description of the conditions under which the end-user should or should not implement the recommendation [1]). In other cases, the panel decided to recommend the intervention without conditions, and to deal with these concerns as implementation considerations only.”
11. Methods: "failed in other ways to meet our needs" - "our" is ambiguous given that the authors represent both decision-makers and technical teams with two distinct but related types of need. Perhaps frame as specific types of needs?

Response:

We have now edited this text as follows:

“or failed in other ways to meet the needs of this guideline.”

12. Methods: "In some cases, the team combined this information with other sources of information, including research-based or non-research-based information from the EtD frameworks, information from external sources, and input from invited stakeholders." Technically this raises two questions: (i) how was the reliability of these types of information assessed? If at all? (ii) how was this information combined with more rigorously derived information and how was its influence circumscribed. Needs further explanation.

Response:

We have now added the following information:

“In most cases, this additional information added little to the main text about implementation considerations and the reliability of this additional information was not formally assessed.”

13. Methods: "The process from QES finding to implementation consideration" Prefer "The process of transformation from QES finding to implementation consideration"

Response:

As the end of this sentence already refers to “transformation”, this would be repetitive and we prefer to keep as is: “The process from QES finding to implementation consideration involved varying degrees of transformation.”

14. Methods: The discussion of the normative values of WHO, while fascinating, is methodologically confusing. Are the authors able to make a suggestion as to the point at which these norms should consistently be introduced into the process. For example, a team that has worked regularly with the WHO will recognise these normative values from the beginning (which may explain the current suggestion in the Lessons Learnt) while a newer team may need to sensitise themselves to these issues. NICE handles this
by introducing these values explicitly at the end of the technical process and perhaps there is some claim for WHO to do the same?

Response:

We agree with this comment and have now tried to make this slightly clearer under “lessons learnt”:

“Therefore, when using this approach, guideline commissioners, technical teams, and panels should consider adopting a more reflexive and transparent approach early on in the guideline process where they explicitly identify the overarching principles, including normative values, driving the guideline.”

15. Methods: "a range of challenges" Not a range! Diverse!

Response:

This has now been edited.

16. Discussion: As mentioned above in connection with the Abstract this Discussion would be a lot clearer if it separated considerations for technical teams from considerations for decision-makers. I suspect that the dual authorship has resulted in these getting lumped together - it would be a much more actionable document if split into implications for review teams and implications for decision makers.

Response:

This has now been edited in the same way as the abstract (see comment #4)

17. Methods: "a range of challenges" Not a range! Diverse!

Response:

This has now been edited.

18. Discussion: I felt ambivalent about the inclusion of material on derivative products. While this is self-evidently a good idea it is not strongly "evidence based" and does not seem very clearly determined by the experience of the teams as recorded in this article. Could the team make a clearer and stronger case between the characteristics of the
derivative products and their experience from this process. Otherwise this section simply seems like a tangentially related news item.

Response:

This has now been edited.

This paragraph has now been replaced by the following edited sentence:

“We are currently exploring different approaches to assist them in doing so, including how logic models based on qualitative evidence and local data can be used to inform derivative products (e.g. manuals, toolkits) for guideline implementation.”

19. Discussion: Similarly, the Logic Model (Fig 3), although very interesting and useful in a wider context, feels tacked onto this article. I feel that the Logic Model requires further explanation e.g. it is neither a Structural nor Process based Logic Model and, in fact, does not follow a theory of change model (instead it is based on a mid-range theory) which makes it strictly speaking more a conceptual model rather than a logic model. Probably best to sidestep all this need for explanation and source of potential confusion?

Response:

We have now removed this figure as we agree that it does not play a central part in this particular paper.

20. Conclusions: As with Discussion this needs clearer structuring perhaps as two paragraphs for review teams and decision makers respectively (cp the Box 1 which I found very helpful and useful).

Response:

We have edited the conclusion as follows:

As members of the guideline technical teams, we experienced QES as a useful source of information when developing implementation considerations. However, questions still remain about how researchers should prepare and present implementation considerations, how guideline panels should respond to implementation challenges when reaching recommendations, and how we can prepare information about implementation that guideline users find useful. The use of derivative products to further assist these end users also needs further exploration.”
Reviewer #2

21. Thank you for the opportunity to review this reflective paper. The paper is timely and well written with an appropriate group of authors. The reflections are very useful to methodologists, guideline developers and decision-makers.

Response:

Thank you.

22. The paper could however be further strengthened by filling in some of the gaps in the QES production process by cross referencing to another contemporaneous WHO series on producing QES reviews in a guideline context. Specifically, the current manuscript refers to the QES reviews using 'standardized procedures' to produce the QES reviews. This is the only reference to how the QES reviews were produced. These 'standardized procedures' were in reality specifically tailored for this context. Readers may be mislead unless there is some qualification of this statement. In addition, only a small subset of QES methods have been recommended as suitable for this context. The authors may therefore want to consider cross referencing to another contemporaneous WHO series published in Jan 2019 in BMJ Global Health. Two papers in particular (Flemming et al and Noyes et al) draw on two guidelines that were also used in the current manuscript to show how the QES methods were used in this context. Flemming's paper also puts forward 3 QES methods (from a wider pool of over 30) that were considered appropriate for a WHO guideline context. These three QES methods were represented in all the QES reviews that contributed to the WHO guidelines used in the current manuscript. Noyes et al also indicates that the Evidence to Decision frameworks were used as the integration mechanism for quan and qual evidence for two WHO guidelines that are described in the current manuscript. I should also declare a conflict of interest as I co-authored these papers. Nonetheless, their potential use and value as linked cross citations here seems reasonable and appropriate given that they use the same source material and help fill a gap in explanation in the current manuscript. https://gh.bmj.com/content/4/Suppl_1


Response:

I think the referee is referring to the text where we say that “Most of these commissioned QES were registered as Cochrane reviews and therefore met minimum quality standards set by Cochrane for these types of reviews”. We have now added a reference to the Cochrane Qualitative and Implementation Methods Group series.
We have deliberately avoided spending too much time on choice of different QES methods in this paper as we wished to focus on the use of QES in implementation considerations. However, we will consider using these references in the first paper in this series, where we spend more time on this topic.

23. One issue that the authors may want to reflect on is that in the current guideline process, there is no quan/qual synthesis stage before populating the EtD framework. In reality the EtD framework acts as the mechanism for integration - but with very little evidence synthesis. There are however qual/quant data integration methods that are gaining traction as they provide a more nuanced understanding of acceptability, feasibility and implementation issues when the products of the quan and qual reviews are brought together in a third synthesis.

Response:
We agree that this is a topic worth considering. However, we think this is slightly outside of the scope of this paper and would prefer to leave this unchanged.

24. "We then circulated the draft papers to key stakeholders to obtain their feedback on the ideas and processes described. These stakeholders included members of WHO guideline panels (sometimes called Guideline Development Groups), methodologists, guideline commissioners, and implementation experts." It would be helpful to know a bit more detail as to how many people this involved and what sort of input they provided beyond the thoughts of the author team.

Response:
We have referred to these stakeholders in our acknowledgements section, and have now added “See Acknowledgements” to this section.

25. I've only been asked to review one manuscript in this series. It would have been useful to review all three to have a better idea as to how the papers fit together.

Response:
No response necessary.

26. Overall a very well written and useful manuscript.
Response:

Thank you.