Author’s response to reviews

Title: Common issues raised during the quality assurance process of WHO guidelines: a cross sectional study

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Version: 2 Date: 18 Jan 2018

Author’s response to reviews:

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Response to reviewers

Reviewer #1

This is a well written and presented analysis of WHO's quality assurance/auditing of its guideline development process. End-users of WHO guidelines and donors of the work will be interested in the findings of the paper. I have a few suggestions to provide more clarity to readers who may not be so familiar with WHO's guideline development process. Hoping this will strengthen the paper and its readability.

1. It would be helpful to include more brief details about how the GRC functions. For example, it meets nearly every month and is a closed meeting. People need to know that proposals are only presented in writing. Developers are not able to clarify points. Also, how does the committee arrive at its decision(s)? Voting, by consensus, etc.

Thank you for this comment. We have added additional information to the background page 4).

2. A link to the WHO website where the GRC is described could be helpful.

We have added a link in the second paragraph of the background section.
3. Weren't some changes in reporting made over the period of proposal submissions? Earlier on, reporting on equity and human rights did not feature as much as they do now. This may play a role in the extent of approvals (or rather lack of).

The reviewer is correct: many factors have changed over the period of the study, including the introduction of new considerations (e.g. incorporating gender, equity and human rights (GER) as the reviewer notes). These factors could, indeed, impact the rate of approval, along with changes in the GRC Chair, member rotation, staff training, and many others. We have noted these as limitations (page 11) and have elaborated upon this issue. Note, however, that the GRC reviewer checklist did not change with the new handbook in 2014, so incorporation of GER was not a requirement. We are currently revising the checklist, which will make considerations of GER a requirement in proposals and final guidelines in future.

4. What was the distribution of proposals related to 'emergency', 'standard' and comprehensively scoped guidelines? It would be helpful to understand the heterogeneity or homogeneity of scope of the guidelines. This may be a factor in the approval rate and time needed to achieve approval.

All the included guidelines were standard or consolidated (standard) guidelines; none were issued in the context of an emergency with abbreviated processes and methods. We have clarified this on page 5

Reviewer #2

Thank you for the opportunity to review "Common issues raised during the quality assurance process of WHO guidelines: a cross-sectional study." This manuscript examines the guideline approval process within WHO and summarizes the proportion of guidelines delayed and for what reasons.

Major comments:

1. This manuscript provides detailed information on reasons for conditional and non-approval of guideline proposals and documents. While an important issue, the manuscript is very specific to the WHO process and could provide more information to generalize these issues of explore whether or not they are common to other institutions producing guidelines. While the authors state that this is the first manuscript to explore internal quality measures produced by a major
organization, it would be beneficial to see what the literature has related to this topic and highlight instruments available to support the development of high-quality guidelines.

*The reviewer makes an important point regarding the applicability of our findings to other guideline development groups and we have elaborated on this important issue (page 12). We have not included additional information on instruments and guidance on how to develop a high-quality guideline, as we feel that is outside of the scope of our research paper.

2. This study would benefit from the disaggregation of conditionally approved and non-approved documents. While the authors address the limitations of their approach, it would be beneficial to perform this additional analysis and report disaggregated results. Conditionally approved documents would be more likely to receive approval in a shorter time period since they did not require formal GRC review. Disaggregated results would highlight information to help guideline developers meet the standards of the GRC. Disaggregated results would also inform researchers developing guideline tools to facilitate the process.

We now present stratified analyses: conditionally approved and not approved guideline proposals and final guidelines.

3. How much did internal and external efforts influence trends of approval, such as training, update of the WHO handbook, inclusion of methodologists? Any exploration of trends by topic area?

It is not possible from our observational data to determine the factors which may be responsible for temporal changes: we can only speculate which we note in the limitations section (page 11). It is also not possible to determine if there are differences across topic areas due to the small number of documents submitted from each WHO department (responsible for specific topics).

4. How will the findings from this manuscript be implemented at WHO or how could they be used to improve the quality of guidelines at other organizations? I think additional details would be needed to provide actionable guidance.

We have added a section to the end of the Discussion on the potential implications of this study for other organizations that develop guidelines (page 12). We have also augmented discussion of the GRC Secretariat’s efforts to implement quality improvement efforts in response to the findings in this study.
Minor comments:

5. Consider including the Secretariat checklist or template as an appendix.

We have not included the Secretariat checklist and template as they are currently under revision. When finalized, we plan to post them in the GRC intranet site for public review and use.

6. Page 10, line 7: I think the authors are trying to outline the domains in the GRADE evidence to decision framework. Is human rights a separate domain or is that considered under equity? If considered within equity, it could be removed from the sentence.

At WHO we generally use an evidence-to-decision framework that is adapted from the original GAGE-DECIDE framework. Human rights is a critical and separate issue from equity in that framework. We plan to publish this framework in 2018.

7. Could the paper be updated to include documents submitted in 2016 or through 1 March 2017? It would be helpful to see if there is any change in the trend or reasons why the documents were not approved.

We have updated the manuscript to include data from January 2016 to December 2017 and have re-done all the analyses.

8. Page 7, lines 41-44, consider stating the years in chronological order to display the trends.

We have revised the results section considerably. We still present the range with low and high rates of conditional and non-approval; the data are presented in temporal order in Table 1.

9. Did the schedule of the GRC meetings influence the time interval until approval? For documents requiring full GRC review, this would be dependent on the regular meetings versus documents that could be reviewed with the Secretariat.

The schedule of GRC meetings has very little effect on time interval for approval as meetings are monthly except August and December (starting in 2015). The 2-month lag would only affect documents that were not approved and where the guideline developer might have had the document ready in August or December. Conditionally approved documents are essentially always reviewed with a decision provided within 3 workdays. We now note in the background
that meetings occur on a regular basis ten times per year. The analysis section notes the timing of issuing decisions by the GRC.

Reviewer #3:

This is a well written and concise paper. It is important that policy makers, health care providers and others better understand the results of the guideline development process, so that they maintain confidence in the process.

1. Please clarify whether and how the authors of the paper are involved in the process, and whether/to what extent their involvement many contribute to their interpretations of the results.

Thank you for raising this important issue. We have added clarification that Ms Porgo (who is external to WHO) independently extracted the data and performed all analyses, with subsequent checking by Dr Beller Ferri or Dr Norris. We have added to the declaration of completing interests that Dr Norris is WHO staff and is responsible for the guideline quality assurance process at WHO. We have also added a remark to the section on limitations.

2. Please explain the justification for selecting the 2012 - 2015 time period for review? Why not start in 2007, when the Guideline Review Committees were established?

We have revised the paper to focus only on 2014 to 2017 because these data are recent and therefore the most relevant, and much more detailed information was available on the reasons for non-approval and conditional approval for these years.

3. Please clarify the first and second sentences of the methods section --- did you actually include proposals and guidelines from 201-2014? And if so, how were they treated differently from proposals and guidelines submitted from 2014 - 2015?

The study now focuses on data from 2014 to 2017. We have analysed rates of and reasons for all guideline proposals and final guidelines submitted during that period.
4. The discussion focuses on a few key issues. Why did you not include problems with methods for the literature review in your discussion — noted, as problems in nearly 3/4 of the non-approvals at both stages? Clearly the methods used for the review are as important as key questions and recommendations —- indeed, the methods link the two and are deserving of more attention in the discussion.

We thank the reviewer for this important comment and omission on our part. We have added text on page 10 on how we are addressing this (staff training, more attention to contractors’ work and to their terms of reference, and collaboration with WHO information scientists).

5. Why is it difficult to address problems with the scope/key questions (pg 9). Surely, it is important to clarify key questions early in the process.

We agree that it is critical to get the key questions right early in the process and the fact that so many proposals have an issue with these questions is concerning. We have revised this paragraph, removing the statement that it is difficult to address problems with key questions.