PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A Protocol of Reporting Items for Public Versions of Guidelines: RIGHT-PVG
AUTHORS	Wang, Xiaoqin; Chen, Yao-Long; Liang, Yao; Zhou, Qi; Wang, Qi; Wang, Mengshu; Yang, Kehu; Norris, Susan L

VERSION 1 – REVIEW

REVIEWER	Caroline Moore University College London, United Kingdon
REVIEW RETURNED	13-May-2018

GENERAL COMMENTS	This paper reports a protocol for developing a checklist of reporting items for public versions of guidelines. This is a topic which does not yet seem to have been addressed directly, and the work proposed would do this. There is some lack of clarity regarding how much of the work has been done to date, with present and past tense used in the methods section of the abstract in particular.

REVIEWER	Emma McFarlane National Institute for Health and Care Excellence, United Kingdom
REVIEW RETURNED	11-Jul-2018

GENERAL COMMENTS	Further detail is needed on the methodology used to develop and validate the checklist. It's not clear currently what the role of the participants is, how they will be identified and what breadth of experience is required. Remove the sentence 'We took methods recommended by the EQUATOR network as a starting point, and will also try to develop our own methods as appropriate' as this is not describing a repeatable methodology. Replace this text with details about the methods planned. Give more details about how you plan to survey literature reflecting patient opinion about PVGs or decision aids. Consider adding a feasibility study before the validation test to check whether the whole premise is possible, and refine the initial version of the tool before the Delphi. Further detail is needed in the methods section to explain the objective of each process step, type and number of participants, the key outcomes and how you will minimise bias. It seems like a gap in this study to not include patients as they would be the intended audience and users of the guides. Consider

	how you could obtain patient views as it would seem that the checklist should improve reporting in PVGs that would benefit patients but without obtaining their views it's not possible to assess impact of the checklist. Consider making reference to the Checkup tool which is a tool focusing on reporting items for updated guidelines - so similar premise to this work. Change National Institute for Health and Clinical Excellence to National Institute for Health and Care Excellence. Page 9, row 26 - remove the letter t before 'panelists'.

VERSION 1 – AUTHOR RESPONSE

Reviewers' Comments to Author:

Reviewer: 1
Reviewer Name: Caroline Moore
Institution and Country: University College London, United Kingdom
Competing Interests: None declared

This paper reports a protocol for developing a checklist of reporting items for public versions of guidelines. This is a topic which does not yet seem to have been addressed directly, and the work proposed would do this.
Authors' response: Thank you.

There is some lack of clarity regarding how much of the work has been done to date, with present and past tense used in the methods section of the abstract in particular.
Authors' response: Thank you for the comment. Since some of the tasks that have already been done and some are planned for future, there is a mix of past and future tense. We have now checked the manuscript thoroughly to ensure that the appropriate tense is used. We have also updated the timeline in Table 1.

Reviewer: 2
Reviewer Name: Emma McFarlane
Institution and Country: National Institute for Health and Care Excellence, United Kingdom
Competing Interests: None declared

1. Further detail is needed on the methodology used to develop and validate the checklist. It's not clear currently what the role of the participants is, how they will be identified and what breadth of experience is required. Remove the sentence 'We took methods recommended by the EQUATOR network as a starting point, and will also try to develop our own methods as appropriate' as this is not describing a repeatable methodology. Replace this text with details about the methods planned.
Authors' response: We have added more details to make the methods clearer.
First, we have added the planned methods in Table 1, elaborating on each step. Because we did refer to and adapt the methods described in the "Guidance for developers of health research reporting guidelines", which is recommended by the EQUATOR network to develop reporting guidelines, we kept this overall description with minor revision to make it clearer. We also now refer to CheckUp. The revised overall description is:

"We will use methods recommended by the EQUATOR network as the starting point [19], refer to the methods used in the RIGHT statement and the Checklist for the Reporting of Updated Guidelines (CheckUp) [17, 20], and adapt these methods as appropriate. Table 1 shows the detailed process with the proposed timeline. (lines 8-10, page 4)"
Second, we have made appropriate revisions for each step to make the progress more repeatable. The major revisions could be found in the responses for the specific points below.

2. Give more details about how you plan to survey literature reflecting patient opinion about PVGs or decision aids.
Authors' response: We have added more details for the survey of literature reflecting patients' opinions about PVGs or other patient materials (e.g decision aids):
"We plan to conduct a search of the relevant literature on patients' opinions about PVGs and other patient materials. The methods for the literature search are outlined in step 4." (lines 2-3, page 5)

"In order to identify any existing guidance for conducting and reporting PVGs, we conducted a pilot review of the literature on the standards for reporting guidelines and other related methodological articles to refine the search strategies. In the subsequent, formal search, we will focus on potential sources of checklist items in PVGs .
In addition to searching for guidance specifically on PVGs, we will seek information on developing and reporting of other evidence-based patient tools. Search strategies will be developed with the assistance of an information scientist (Junqiao Chen, University of Oxford). We will search PubMed to identify relevant papers. All search results will be screened in duplicate. Due to the variety of names that can be used to describe PVGs, we will use the snowballing method to conduct reference and citation searches [22]. The following sources will be collected for possible items. The third type of study will be used to further support the rationale for a checklist for PVGs (step 1):" (lines 1-11, page 6)

3. Consider adding a feasibility study before the validation test to check whether the whole premise is possible, and refine the initial version of the tool before the Delphi.
Authors' response: We have planned to do a formal feasibility study, but the RIGHT-PVG working group and the RIGHT working group have discussed and evaluated the feasibility with of this project thoroughly. We discussed this issue mainly from the technical, resource and financial aspects, which were the main challenges for this project, and clarified the methods that will be used and got the approval from the funders. For the technical need, we established a multidisciplinary development group and a consensus group, which covered technical expertise in guideline development, PVGs, GRADE, knowledge translation, reporting guidelines, and plain language editing. The representatives of the public were also invited to the consensus group to reflect the views and perspective of users of PVGs. For the resource and financial aspects, we applied for the funding and obtained enough support from two research projects supported by the government. In addition, before collecting the items, we invited the consensus experts to review the protocol and provide feedback on the plan, including consideration of feasibility.
For refining the initial version of the tool before the Delphi process, we added the following content into step 4 of the development process:
"This step will provide a list of potential items for reporting in a PVG, and the RID group will discuss the items one by one to refine them." (lines 23-24, page5)

4. Further detail is needed in the methods section to explain the objective of each process step, type and number of participants, the key outcomes and how you will minimise bias.
Authors' response: According to the comments and the plan of our work, we added for each step the objective and clarification of the "responsible groups" in Table 1. To make it clearer, we reorganized the description of the three working groups without changing the main content in step 3, and added

information on the members of each group (page 5). We also provided a supplementary file with details on the institutions and research interests of the members of each of the three groups.

We also now specify the information scientist for the literature search (step 1 and step 4), and note that literature screening and data abstraction will be done by two independent reviewers (step 4).

For control of the potential biases:
In the funding sources, all funders are from the research department of the Chinese government. The funders will have no role in the planning and implementation of this project. We now clarify this as follows:
“The funders will have no role in the study design, data collection and analysis, writing of the article or the decision to submit it for publication.” (lines 9-10, page 5)
In the literature search, we first did a pilot search and consulted with an information scientist to develop an appropriate search strategy. The screening and abstraction will be completed by two independent reviewers. The updated content about the search is presented in our response to comment 2.
In the Delphi consensus process, we will send an email to each expert separately and the responses will be analyzed anonymously by a biostatistician. We have updated the content as follows:
“To minimize potential biases, the responses will be analyzed anonymously by a biostatistician who is not a member of the panel and who will be blinded to the identities of panel members. After the 3-round consensus survey, we will get a checklist of included reporting items for PVGs, which will be discussed in step 6.”(lines 2-5, page 9)

We have also added the following notes on key outcomes and the control of bias in the discussion:
The main outcome of the this work is a checklist of reporting items for PVGs and an explanatory document. (line 21, page 10)
The RID group will strictly oversee the process, and appropriate methods will be applied in each step to minimize potential biases.(lines 30-31, page 10)

5. It seems like a gap in this study to not include patients as they would be the intended audience and users of the guides. Consider how you could obtain patient views as it would seem that the checklist should improve reporting in PVGs that would benefit patients but without obtaining their views it's not possible to assess impact of the checklist.
Authors’ response: Thank you for pointing this out. For the patient views, we included three representatives of the public in our 19-member consensus group. After consulting with several experts in development of guidelines or decision aids, we planned to collect the literature on what kinds of information patients want and need from PVG and from other patient materials, and summarize this information. We have added the following section to the manuscript:
“Taking into account diversity of language, gender equality, and wide geographic representation, we invited 19 individuals to the DCP group, based on a review of the main authors in the field, as well as the RIGHT members (http://www.right-statement.org/home/member). We included experts with technical expertise in guideline development, PVGs, GRADE, knowledge translation, reporting guidelines (including experts of RIGHT statement), and plain language editing. To reflect the views and perspective of users of PVGs, three representatives of the public were also invited to this group. In addition, the literature on what patients want and need from PVG and other patient materials will also be explored.” (lines 28-36, page 5)
For the search and abstraction of literature, detailed methods are given in step 4 on page 6. The corresponding content is described in responses for comments 2 and 4 above.

6. Consider making reference to the Checkup tool which is a tool focusing on reporting items for updated guidelines - so similar premise to this work

Authors' response: We examined the methods used in the Checkup tool, and agree with the reviewer. We have added a reference in the overall description of the development process, which was described in response for comment 1 above. We also refined our plan for the Delphi process and now refer to Checkup.

7. Change National Institute for Health and Clinical Excellence to National Institute for Health and Care Excellence.
Authors' response: Thank you for noting this error; we have changed this accordingly.

8. Page 9, row 26 - remove the letter t before 'panelists'.
Authors' response: Thank you, we have corrected this.

VERSION 2 – REVIEW

REVIEWER	Emma Mcfarlane National Institute for Health and Care Excellence, UK
REVIEW RETURNED	07-Sep-2018

GENERAL COMMENTS	This protocol has improved significantly after the first review. The authors have taken on board the suggestions from reviewers and the protocol is now acceptable for publication. My only comment is about the Delphi group as there is no one from the UK that is a member. Consider expanding to include someone from NICE or SIGN who also have experience in working on the DECIDE project patient work and patient versions of guidelines.

VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 2

Reviewer Name: Emma Mcfarlane

Institution and Country: National Institute for Health and Care Excellence, UK

Please state any competing interests or state 'None declared': None declared.

Please leave your comments for the authors below

This protocol has improved significantly after the first review. The authors have taken on board the suggestions from reviewers and the protocol is now acceptable for publication.

My only comment is about the Delphi group as there is no one from the UK that is a member. Consider expanding to include someone from NICE or SIGN who also have experience in working on the DECIDE project patient work and patient versions of guidelines.

Authors' response: Thanks for this comment and we agree with the reviewer. Actually, we have sent invitation letters to some experts from the UK but did not receive any response. Our working group thus decided to list the ones who agreed to be the consensus experts in the protocol. We adopted the suggestion from the reviewer and are now planning to invite potential experts from UK who are from the DECIDE patient work and patient versions of guidelines. As we are now preparing the second round of the Delphi survey, the new invited expert will act as a Delphi expert or consultant expert to comment on the checklist after Delphi depending on the time.

For the time reason, we updated the timeline to ensure enough time to for the response of the potential experts.

This final expert information in the supplementary file will be updated in the EQUATOR network as well as in the final report of our project.