PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Extending the RIGHT statement for Reporting Adapted Practice Guidelines in Health Care: the RIGHT-Ad@pt Checklist protocol
AUTHORS	SONG, YANG; Darzi, Andrea; Ballesteros, Monica; Martínez García, Laura; Alonso-Coello, Pablo; Arayssi, Thurayya; Bhaumik, Soumyadeep; Chen, Yaolong; Cluzeau, Francoise; Ghersi, Davina; Fuentes, Paulina; Langlois, Etienne V.; Schünemann, Holger; Vernooij, Robin W.M.; Akl, Elie

VERSION 1 – REVIEW

REVIEWER	Anna Phillips University of South Australia, Australia
REVIEW RETURNED	18-Jun-2019

GENERAL COMMENTS	Thank you for asking me to review the study protocol, extending the RIGHT statement for Reporting Adapted Practice Guidelines in Health Care; the RIGHT-Ad@pt Checklist protocol. I would like to congratulate the authors on this study protocol. The extension proposed by the authors to the RIGHT statement has the potential to be a very important and useful checklist for researchers, clinicians and end users in health care. Furthermore, with the right methodology would enable adapted health care guidelines to be developed using a rigorous, transparent and trustworthy process. There are a several points in this study protocol that that I believe would benefit from further clarification. These are outlined below. Essential, major points to address. Abstract The abstract requires further clarification. The key areas that are unclear are the introduction and the methods and analysis sections. The introduction is difficult to follow and does not provide the reader with a clearly articulated or compelling reason for creating an extension to the RIGHT statement. There is information about adapting and adopting but not on extensions to reporting guidelines. This seems an important distinction to me and should be explained. Some more information could be included in the methods here if the word count allows to capture the intended process more clearly. I found it confusing the concept of an initial checklist in step 2 which I presume is a modified checklist based on the RIGHT statement? This was not clear to me and would benefit from further clarification / explanation. I wasn't sure if it is expected to have so much information about ethics and dissemination in the abstract? This takes up a large

	proportion of the abstract which may be better served in setting the scene and stepping through the methods and analysis more explicitly. It appear to be almost verbatim at the end of the manuscript? I note the ethics exemption from the Hospital de la Santa Creu I Sant Pau from biomedical research, however you are collecting information from human participants in the delphi survey which may require ethics review / approval? Can you clarify if this is the case. Methods: Can you provide more information to explain why the working group is comprised of 3 subgroups and the reasons / justification for the inclusion in each of these groups? Was this based on the process used in a previously developed extension statement? The references used for your Delphi process are from 2005. There has been considerable development since this time in the recommendations for undertaking and reporting a delphi process and I would recommend that you review these and update the delphi methodology accordingly, one more recent example is that from Sinha et al 2011; https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000393; Substantially more explanation and justification is needed in the methods to explain the process that will be used and why this is important. For example how will you idenitfy the delphi panel members? What are the attributes that you are seeking from these panel members and how will you approach them? What was the reasoning behind the panel size of 20-30 members and the profiles similar to the advisory group? Some more information regarding the generation of the initial checklist is needed as this is quite vague. For example, how many meetings do you plan to conduct for the generation of the initial checklist? Is there a planned timeline for this to occur? I wasn't sure why you intended to assess a convenience sample of 10 adapted guidelines using an adhoc form? The reasons for this process and intended outcomes from the process are not clearly explained. For your semi structured interviews can you explain how you will identify suitable participants, the recruitment process as well as how you will ensure rigor in this process? E.g Will you fact check the interviews with participants? The methodology and analysis for the delphi process needs to be reconsidered in line with more recent recommendations. For example what is the definition of consensus you will use? Recruitment and reminder process? Data storage, analysis etc. Why did you select a 7 point likert scale? This may be problematic, particularly when you are planning to calculate the median score and will be excluding items with a score of 0-3 which is a large (4 point range). . I can see that you may be basing this on the methodology used by Vernooij et al 2017, however they asked participants to rate (1) the completeness, (2) the usability, and (3) the quality of a clinical guideline would be influenced if the item was reported as well as including a free text box for suggestions to modify the items, the explanation, or the examples. It was unclear to me the process that will be followed for the external review for both guideline developers and users. I am concerned that it would be difficult to replicate the process you are proposing based on the limited information that is provided here. Minor points: Is there are reason why the a in adapt is written as @?

	Page 8, line 3, notable should read notably. Page 8, line 52 rigorousness could be replaced with rigour.

REVIEWER	Zhaoxiang, Bian Hong Kong Baptist University, School of Chinese medicine
REVIEW RETURNED	22-Jun-2019

GENERAL COMMENTS	1. How long this study will last for? 2. How about the ratio of different stake holders among the participants and working groups? 3. How many round of delphi survey? How to deal with the disagreement ? 4. When the checklist finalized, any pilot survey to check whether it can fit for the original purpose?

VERSION 1 – AUTHOR RESPONSE

Response to Reviewers

Reviewer 1 - Anna Phillips

Comment 1 (Abstract - Introduction)

> The abstract requires further clarification. The key areas that are unclear are the introduction and the methods and analysis sections. The introduction is difficult to follow and does not provide the reader with a clearly articulated or compelling reason for creating an extension to the RIGHT statement. There is information about adapting and adopting but not on extensions to reporting guidelines. This seems an important distinction to me and should be explained.

Response 1: We have modified the text in the "Abstract - Introduction" section; it now reads: *"The adaptation of guidelines is an increasingly used methodology for the efficient development of contextualised recommendations. Nevertheless, there is no specific reporting guidance. The Essential Reporting Items of Practice Guidelines in Healthcare (RIGHT) statement could be useful for reporting adapted guidelines, but it does not address all the important aspects of the adaptation process. The objective of our project is to develop an extension of the RIGHT statement for the reporting of adapted guidelines (RIGHT-Ad@pt Checklist)."*

Comment 2 (Abstract - Methods)

> Some more information could be included in the methods here if the word count allows to capture the intended process more clearly. I found it confusing the concept of an initial checklist in step 2 which I presume is a modified checklist based on the RIGHT statement? This was not clear to me and would benefit from further clarification / explanation.

Response 2: We have modified the text in the "Abstract - Methods" section; it now reads: *"To develop the RIGHT-Ad@pt Checklist, we will use a multistep process that includes: 1) establishment of a Working Group; 2) generation of an initial checklist based on the RIGHT statement; 3) optimisation of the checklist (an initial assessment of adapted guidelines, semi-structured interviews, a Delphi consensus survey, an external review by guideline developers and users, and a final assessment of adapted guidelines); and 4) approval of the final checklist. At each step of the process, we will calculate absolute frequencies and proportions, use content analysis to summarise and draw conclusions, discuss the results, draft a report, and refine the checklist."*

Comment 3 (Abstract - Ethics and Dissemination)

I wasn't sure if it is expected to have so much information about ethics and dissemination in the abstract? This takes up a large proportion of the abstract which may be better served in setting the scene and stepping through the methods and analysis more explicitly. It appears to be almost verbatim at the end of the manuscript? I note the ethics exemption from the Hospital de la Santa Creu I Sant Pau from biomedical research, however you are collecting information from human participants in the Delphi survey which may require ethics review / approval? Can you clarify if this is the case?

Response 3: We have modified the text in the "Abstract - Ethics and Dissemination" section; it now reads: *"We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain). We will disseminate the RIGHT-Ad@pt checklist by publishing into a peer-reviewed journal, presenting to relevant stakeholders, and translating into different languages. We will continuously seek feedback from stakeholders, surveil new relevant evidence and, if necessary, update the checklist."*

We have also modified the text in the "Discussion - Ethics and Dissemination" section; it now reads*: "The protocol obtained a waiver of approval (did not involve patients, biological samples, or clinical data) from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain). Nevertheless, we will request written informed consent from all participants and anonymize all data."*

Comment 4 (Methods - Establishment of the RIGHT-Ad@pt Working Group)

Can you provide more information to explain why the working group is comprised of 3 subgroups and the reasons / justification for the inclusion in each of these groups? Was this based on the process used in a previously developed extension statement?

Response 4: We have included in the "Methods and analysis - Establishment of the RIGHT-Ad@pt Working Group" section the following references that support this step of the process:

- Moher D, Schulz KF, Simera I, Altman DG. Guidance for Developers of Health Research Reporting Guidelines. Plos Med. 2010; 7(2):e1000217.
- Vernooij RW, Alonso-Coello P, Brouwers M, Martínez García L; CheckUp Panel. Reporting Items for Updated Clinical Guidelines: Checklist for the Reporting of Updated Guidelines (CheckUp). PLoS Med. 2017;14(1):1002207.
- Martínez García L, Pardo-Hernandez H, Niño de Guzman E, Superchi C, Ballesteros M, McFarlane E, et al. Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol. BMJ Open. 2017;7(8):e017226.

Comment 5 (Methods - Delphi Panel)

The references used for your Delphi process are from 2005. There has been considerable development since this time in the recommendations for undertaking and reporting a Delphi process and I would recommend that you review these and update the Delphi methodology accordingly, one more recent example is that from Sinha et al 2011; https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000393 Substantially more explanation and justification is needed in the methods to explain the process that will be used and why this is important. For example how will you identify the Delphi panel members? What are the attributes that you are seeking from these panel members and how will you approach them? What was the reasoning behind the panel size of 20-30 members and the profiles similar to the advisory group?

Response 5:

- Akins et al. 2005 reference and the size of Delphi panel: As far we know, the Akins et al. 2005 reference is the most recent methodological study to supports the sample size of the Delphi panel. Akins et al. 2005 concluded that *"Panels of similarly trained experts (who possess a general understanding in the field of interest) provide effective and reliable utilization of a small*

sample from a limited number of experts in a field of study to develop reliable criteria that inform judgment and support effective decision-making."

- Sinha et al. 2011 reference: We have checked the text accordingly using the recommended checklist from Sinha et al. 2011 (please, see the following table). In addition, we have included the reference in the text.

	Broad Aspect of Reporting	**Specific Items for Which the Reporting Quality Was Assessed**	**RIGHT-Ad@pt Checklist protocol**
1	Size and composition of the panel	Number of participants	*"The Delphi Panel will be comprised of 20 to 30 members, with profiles similar to those of the members of the Advisory Group (guideline methodological experts, guidelines developers, guideline users, and journal editors of guideline related journals) [33, 34]."*
2		Types of participants (e.g., clinicians, patients)	*See item 1*
3		Proportion of each type of participant	*"We will aim for country income, gender and profile representativeness of participants."*
4		How participants were identified/sampled	*"We will identify participants from the Guidelines International Network (GIN) Adaptation Guidelines Working Group (http://www.g-i-n.net/working-groups/adaptation), WHO, authors of adapted guidelines [25], and expert colleagues."*

- Identify the Delphi panel members: We describe how to identify the Delphi panel in "Methods and analysis - Establishment of the RIGHT-Ad@pt Working Group" section: *"We will identify participants from the Guidelines International Network (GIN) Adaptation Guidelines Working Group (http://www.g-i-n.net/working-groups/adaptation), WHO, authors of adapted guidelines [25], and expert colleagues."*

- Attributes and profiles of Delphi panel members: We have included the profiles of Delphi panel in “Methods and analysis - Establishment of the RIGHT-Ad@pt Working Group” section; the text now reads: *“The Delphi Panel will be comprised of 20 to 30 members, with profiles similar to those of the members of the Advisory Group (guideline methodological experts, guidelines developers, guideline users, and journal editors of guideline related journals) [33, 34].”*
- Approach to Delphi panel members: We describe how to approach the Delphi panel in “Methods and analysis - Delphi consensus survey” section: *“We will use online software to design the survey and collect responses (http://www.clinapsis.com/).”*

Comment 6 (Methods - Generation of the initial checklist)

Some more information regarding the generation of the initial checklist is needed as this is quite vague. For example, how many meetings do you plan to conduct for the generation of the initial checklist? Is there a planned timeline for this to occur?

Response 6: We have modified the text in the “Methods and analysis -Generation of the initial checklist” section; it now reads: *“We will conduct this step via monthly face-to-face and online meetings within the Coordination Team.”*

In addition, we have included a Figure with the timeline in “Methods and analysis”; the text now reads: *“Figure 1 illustrates the development process, and Figure 2 presents the timeline.”*

Comment 7 (Methods - Initial assessment of adapted guidelines)

I wasn’t sure why you intended to assess a convenience sample of 10 adapted guidelines using an ad hoc form? The reasons for this process and intended outcomes from the process are not clearly explained.

Response 7:

- The reasons and outcomes of the process: We have included the definition of “adequacy” in “Methods - Initial assessment of adapted guidelines” section; the text now reads: *“We will survey published adapted guidelines using initial checklist. We will explore the adequacy of each item (defined as overall completeness of reporting as well as the quantity of example supporting the item [35]), and refine the checklist.”*

- Convenience sample: We have included the following reference to support the sampling method that will be used in "Methods - Initial assessment of adapted guidelines" section: *"Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Med Res Methodol. 2010;10:67."*
- *Ad hoc* form: We have removed the text *"using an ad hoc form"* in the "Methods and analysis - Initial assessment of adapted guidelines" section; it now reads: *"Two reviewers from the Coordination Team will independently apply the initial version of the checklist to adapted guidelines."*

Comment 8 (Methods - Semi structured interviews)

For your semi structured interviews can you explain how you will identify suitable participants, the recruitment process as well as how you will ensure rigor in this process? E.g Will you fact check the interviews with participants?

Response 8:

- Rigor of the process: We have modified the text in the "Methods and analysis - Semi-structure interviews" section; it now reads: *"The interview transcripts will be sent to interviewees for approval."*
- Identification and recruitment: We have modified the text in the "Methods and analysis - Semi-structure interviews" section; it now reads: "*We will identify the participants with the support of the Advisory Group. We will contact via email and conduct online interviews. We will continue recruitment and collect data until information becomes repetitive and no new information emerges (sampling saturation) [38, 39]."*

Comment 9 (Methods - Delphi consensus survey)

The methodology and analysis for the Delphi process needs to be reconsidered in line with more recent recommendations. For example what is the definition of consensus you will use? Recruitment and reminder process? Data storage, analysis etc.

Response 9:

- Definition of consensus: We have modified the text in the "Methods and analysis - Delphi consensus survey" section; it now reads: *"We will conduct additional Delphi rounds until consensus regarding items inclusion is reached (median score of 6-7) and no more relevant comments on the items are provided (two or three rounds, as needed)."*

- Recruitment process: Please, see comment 5.
- Reminder process: We describe the reminder process in “Discussion - Strengths and Limitations” section: *“To minimise non-response bias, we will make the survey available online for four weeks and we will send two reminders prior to the round closing date.”*
- Data analysis: We describe the data analysis in “Methods and analysis - Delphi consensus survey” section: *“For quantitative variables (response rate, characteristics of participants and workplaces, inclusion score, participants’ understanding of each item, and participants’ overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative data (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [37].”*
- Sinha et al. 2011 reference (from comment 5): We have check the text according recommended checklist from Sinha et al. 2011 (please, see the following table).

	Broad Aspect of Reporting	**Specific Items for Which the Reporting Quality Was Assessed**	**RIGHT-Ad@pt Checklist protocol**
1	Methodology of the Delphi process	Administration of questionnaires (e.g., postal)	*“We will use online software to design the survey and collect responses (http://www.clinapsis.com/).”*
2		How items were generated for first questionnaire	*“In the first Delphi round, we will ask participants to rate whether each item should be included in the checklist using a seven-point Likert scale (1=strongly disagree and 7=strongly agree) [31, 32, 40].”*
3		What was asked in each round	*“We will conduct additional Delphi rounds until consensus regarding items inclusion is reached (median score of 6-7) and no more relevant comments on the items are provided (two or three rounds, as needed).”*
4		Information provided to participants before the first round	*“Before the first Delphi round, we will provide the Delphi Panel Members with a brief background material on the topic.”*

5		How the overall group response was feedback to participants	*"After each Delphi round, we will provide feedback to Delphi Panel Members (data reported will be anonymised)."*
6		Level of anonymity (total or quasi-anonymity)	*See item 5*
7		A priori definition of ''consensus'' about whether an outcome should be measured)	*See item 3*
8		Were non-responders invited to subsequent rounds	*"We will not invite non-responders or partial responders (questionnaires with no response for more than 20% of the items) to subsequent Delphi rounds."*

Comment 10 (Methods - Delphi consensus survey)

Why did you select a 7 point likert scale? This may be problematic, particularly when you are planning to calculate the median score and will be excluding items with a score of 0-3 which is a large (4 point range). I can see that you may be basing this on the methodology used by Vernooij et al 2017, however they asked participants to rate (1) the completeness, (2) the usability, and (3) the quality of a clinical guideline would be influenced if the item was reported as well as including a free text box for suggestions to modify the items, the explanation, or the examples.

Response 10:

- Seven-point Likert scale: We have corrected an error in the range of values; the text now reads: *"We will calculate the median score for inclusion of each item and will classify them as 1) excluded (median score of 1-3 points); 2) review, modify and retest (median score of 4-5 points or with substantial comments); and 3) included (median score of 6 to 7 points and without substantial comments) [31, 32]."*
- Vernooij et al 2017 reference: When we developed the CheckUp, we included in the Delphi consensus survey "median score for inclusion, completeness, usability, and quality" with nonspecific results for each outcome (similar scores). After this experience, when we developed another tool (UpPriority), we included in the Delphi consensus survey "median score for inclusion, and understanding" with more consistent results between outcomes.

- Free text box for suggestions: We describe the option to provide free text suggestions in Table 2. We have included the option in the "Methods and analysis - Delphi consensus survey" section; it now reads: *"We will also record response rate, characteristics of participants and workplaces, participants' understanding of each item, suggestions to improve the checklist, and participants' overall assessment of the checklist (Table 2)."* We have also included this text in the following sections: "Initial assessment of adapted guidelines", "Semi-structure interviews", "External review by guidelines developers and users", and "Final assessment of adapted guidelines".

Comment 11 (Methods - External review)

It was unclear to me the process that will be followed for the external review for both guideline developers and users. I am concerned that it would be difficult to replicate the process you are proposing based on the limited information that is provided here.

Response 11: We have modified the text in the "Methods and analysis -External review" section:

- The text in "External review by guidelines developers" section now reads: *"We will survey guideline developers who were involved in guideline adaptation over the past three years. We will explore usefulness of each item (defined as provision of enough and clear information in order to be used with effectiveness, efficiency and satisfaction to check the reporting of adapted guidelines [41]) using a seven-point Likert scale (1=strongly disagree and 7=strongly agree) [40], and refine the checklist. We will also record response rate, characteristics of participants and workplaces, participants' understanding of each item, suggestions to improve the checklist, and participants' overall assessment of the checklist (Table 2)."*
- The text in "External review by users" section now reads: *"We will conduct external review semi-structured interviews with guidelines users who have used adapted guidelines over the past three years. We will explore participants' views and experiences using the checklist, and refine the checklist. We will also record the characteristics of participants and workplaces, participants' understanding of each item, suggestions to improve the items, and participants' overall assessment of the checklist (Table 2). Each interview will last approximately one hour and will be recorded and transcribed with participant´s permission. The interview transcripts will be sent to interviewees for approval."*

Comment 12 (Other comments)

Is there are reason why the “a” in adapt is written as @? Page 8, line 3, notable should read notably. Page 8, line 52 rigorousness could be replaced with rigour.

Response 12:

- We used “ad@pt” to address both “adapt” and “adopt”.
- We have replaced “notable” with “notably”.
- We have replaced “rigorousness” with “rigour”.

Reviewer2 - 卞兆祥 Zhaoxiang Bian

Comment 13 (Timeline)

How long this study will last for?

Response 13: Please, see comment 6.

Comment 14 (Methods - Establishment of the RIGHT-Ad@pt Working Group)

How about the ratio of different stake holders among the participants and working groups?

Response 14: We have modified the text in the “Establishment of the RIGHT-Ad@pt Working Group - Delphi Panel” section; it now reads: “*We will aim for country income, gender and profile representativeness of participants.”*

Comment 15 (Methods - Delphi consensus survey)

How many round of delphi survey? How to deal with the disagreement?

Response 15:

- Delphi rounds: We describe the Delphi rounds in "Methods and analysis - Delphi consensus survey" section: *"We will conduct additional Delphi rounds until consensus regarding items inclusion is reached (median score of 6-7) and no more relevant comments on the items are provided (two or three rounds, as needed)."*
- Delphi disagreement: We describe the Delphi rounds in "Methods and analysis - Delphi consensus survey" section: *"We will calculate the median score for inclusion of each item and will classify them as 1) excluded (median score of 1-3 points), 2) review, modify and retest (median score of 4-5 points or with substantial comments), and 3) included (median score of 6 to 7 points and without substantial comments) [31, 32]."*

Comment 16 (Pilot study)

When the checklist finalized, any pilot survey to check whether it can fit for the original purpose?

Response 16: We will conduct a final assessment of the validity of each item in a set of adapted guidelines (see "Methods and analysis - Final assessment of adapted guidelines" section). However, we will not conduct a complete formal validation of the checklist (see "Discussion - Strengths and Limitations" section).

Response to Editors

Comment 17 (Ethics approval)

Please provide a full justification to explain why your study does not require ethics approval in the ethics and dissemination section of the main text.

Response 17: Please, see comment 3.

Comment 18 (Timeline)

Please provide the planned dates for each phase of the study in the main text.

Response 18: Please, see comment 6.

Comment 19 (Errors)

Please complete a thorough proofread of the text and correct any spelling and grammar errors that you identify

Response 19: We have reviewed as suggested.

Comment 20 (Co-author's name)

The author "Martínez Gracía, Laura" in your main document is registered as "Martínez García, Laura" in ScholarOne. Please ensure that the author has same registered name.

Response 20: We have reviewed as suggested.

Comment 21 (Figures)

Please remove all your figures in your main document and upload each of them separately under file designation 'Image' (except tables and please ensure that Figures are of better quality or not pix-elated when zoom in). NOTE: They can be in TIFF, JPG or PDF format and make sure that they have a resolution of at least 300 dpi. Figures in DOCUMENT, EXCEL and POWER POINT format are not acceptable.

Response 21: We have modified as suggested.

Comment 22 (Appendix)

Kindly remove all your Supplementary Appendix Table in your Main Document and upload it separately under file designation "Supplementary File" in PDF Format.

Response 22: We have modified as suggested.

Comment 23 (Patient and Public Involvement)

We have implemented an additional requirement to all articles to include 'Patient and Public Involvement' statement within the main text of your main document. Please refer below for more information regarding this new instruction:

Authors must include a statement in the methods section of the manuscript under the sub-heading 'Patient and Public Involvement'.

This should provide a brief response to the following questions:

- How was the development of the research question and outcome measures informed by patients' priorities, experience, and preferences?
- How did you involve patients in the design of this study?
- Were patients involved in the recruitment to and conduct of the study?
- How will the results be disseminated to study participants?
- For randomised controlled trials, was the burden of the intervention assessed by patients themselves?

Patient advisers should also be thanked in the contributor ship statement/acknowledgements. If patients and or public were not involved please state this.

Response 23: We have included a Patient and Public Involvement statement in the "Methods and analysis" section.

VERSION 2 – REVIEW

REVIEWER	Zhao-xiang Bian Hong Kong Baptist University, School of Chinese medicine
REVIEW RETURNED	03-Aug-2019

GENERAL COMMENTS	The revised version is acceptable.