

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Current practices and Challenges in adaptation of Clinical Guidelines: A qualitative study based on semi-structured interviews
<b>AUTHORS</b>	Song, Yang; Ballesteros, Monica; Li, Jing; Martínez García, Laura; Niño de Guzman, Ena; Vernooij, Robin W.M.; Akl, Elie; Cluzeau, Françoise; Alonso-Coello, Pablo

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Stokes, Tim Otago University, General Practice & Rural Health
<b>REVIEW RETURNED</b>	12-Jul-2021

<b>GENERAL COMMENTS</b>	<p>This paper reports current practices and challenges in adaptation of clinical guidelines - that is the adaptation of a clinical guideline in one health care setting (usually regional or national) for use in a different health care setting. This is important - as guidelines should be able to be adapted for use in other settings in a transparent and rigorous manner. It is also important that organisations without the financial resources to develop guidelines de novo are able to adapt other regional/national guidelines for their own setting. The paper also adds to the existing literature in the field and will be of interest to those developing and adapting clinical guidelines.</p> <p>Overall the paper is of acceptable quality. The one main caveat is that at times the quality of the english is below that expected - there are frequent wrong tenses and at times some of the sentence meaning is unclear (see below).</p> <p>Essential minor revisions</p> <ol style="list-style-type: none"><li>1. Thorough review of written english and correction if identified grammatical errors.</li><li>2. Review of extensive use of abbreviations, some of which are not intelligible to non-guideline developers (e.g., EtD), and use of terms in full as appropriate.</li><li>3. Abstract: It is recommended for intelligibility purposes that Clinical Guidelines is used in full (not CGs). This can be achieved by removing LL15-16 ("we report the study ....").</li><li>4. Introduction LL54-56. Re-word and shorten "Therefore .... to better understand", to "This study aimed to better understand ..."</li><li>5. Results LL12-18. Need to make it clear why you interviewed individuals (10) and organisations (9) - I assume there were single interviews from 8 organisations and 2 from 1 organisation.</li><li>6. Results LL16-18 "Finally we conducted ten .... until data saturation was complete. " It does not appear from figure 1 that</li></ol>
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	interviewing continued until data saturation was reached - it appears that only 10 participants agreed to take part, and all were interviewed.
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<b>REVIEWER</b>	de Melo, Daniela Universidade Federal de Sao Paulo
<b>REVIEW RETURNED</b>	26-Jul-2021

<b>GENERAL COMMENTS</b>	<p>Congratulations on an excellent paper. I really enjoyed reading it and find the topic very relevant. I have a few comments/suggestions.</p> <p>Page 5 – Lines 38 – 40: “A recent review described several limitations of published adaptation frameworks and showed that the time to adapt CGs using the same framework varies between 18 months and three years (7, 10, 21)” - The authors talk about a review but there are three references. I suggest leaving only the reference of the review they refer to.</p> <p>Page 5 – Line 21 – the ADAPTE reference seems to be inappropriate here.</p> <p>Page 7 – Line 49: “Six participants reported they used their own adaptation methodology (8, 33-38).” - The authors talk about 6 participants but there are 7 references. Check if there is one more reference or if two of them talk about the same adaptation.</p> <p>Page 10 – Line 14: “Most of the identified methodologies were not previously discussed.” - I think you could make it clearer: discussed or published in advance?</p> <p>Figure 1 - there seems to be an error in the picture regarding "No response/Not eligible" - is it 17 or 18?</p> <p>Figure 2 – I suggest that in the same way that you put the options in the second stage, you also describe the options for the third and fourth stages as well.</p> <p>The most important limitation of this study was the choice of respondents. This limitation could be better explored for two reasons: 1) choosing among adapted published guidelines makes it necessary to choose interviewees who have sufficiently large experience in the process of critical appraisal and/or publication of scientific articles. Among G-I-N participants brings an even greater bias. They are already people very involved in the guideline development/adaptation process; 2) the language limitation also leads to a very important bias, making the interviewees already present a very qualified profile, which certainly influenced the results.</p> <p>I think it would be important to be more emphatic about this in the discussion and conclusion. It is not just an issue about the lack/poor presence of LMCI representatives.</p>
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### VERSION 1 – AUTHOR RESPONSE

Comments from the Reviewers 1: Prof. Tim Stokes

Comment 1: General comments

This paper reports current practices and challenges in adaptation of clinical guidelines - that is the adaptation of a clinical guideline in one health care setting (usually regional or national) for use in a different health care setting. This is important - as guidelines should be able to be adapted for use in

other settings in a transparent and rigorous manner. It is also important that organisations without the financial resources to develop guidelines de novo are able to adapt other regional/national guidelines for their own setting. The paper also adds to the existing literature in the field and will be of interest to those developing and adapting clinical guidelines.

#### Response 1

We appreciate reviewer's confirmation about the importance of guideline adaptation and the value of our study.

#### Comment 2: English checking

Overall the paper is of acceptable quality. The one main caveat is that at times the quality of the English is below that expected - there are frequent wrong tenses and at times some of the sentence meaning is unclear (see below).

#### Response 2

We have reviewed the English thoroughly with the help of an English Professional and marked all the modifications in blue words, including modifications in the title.

#### Comment 3: Essential minor revisions - English

Thorough review of written English and correction of identified grammatical errors.

#### Response 3

Please see reply 2.

#### Comment 4: Essential minor revisions - Abbreviations

Review of extensive use of abbreviations, some of which are not intelligible to non-guideline developers (e.g., EtD), and use of terms in full as appropriate.

#### Response 4

We have substituted the "EtD" with its full term "Evidence to Decision" and marked the modifications in blue words. We also clarified the abbreviations of "ADAPTE", "GRADE-ADOLOPMENT", and "RAPADAPTE" using their full names to avoid confusion. Now it reads: "Resource Toolkit for Guideline Adaptation - ADAPTE, Adapted ADAPTE, Alberta Ambassador program adaptation phase, GRADE Evidence to Decision frameworks for adoption, adaptation, and de novo development of trustworthy recommendations (GRADE-ADOLOPMENT), Making GRADE the irresistible choice (MAGIC), RAPADAPTE for rapid guideline development, Royal College of Nursing (RCN), and Systematic Guideline Review (SGR)." Please see page 4, line 14-18.

#### Comment 5: Essential minor revisions -Abstract

Abstract: It is recommended for intelligibility purposes that Clinical Guidelines is used in full (not CGs). This can be achieved by removing LL15-16 ("we report the study ....").

#### Response 5

Thanks to reviewer's suggestion. We have substituted the "CGs" with its full term "Clinical guidelines" in the abstract and marked modifications in blue; please see page 2, lines 12-29. We also took out the sentence "we report the study following the COREQ checklist" according to the reviewer's suggestion and to fit the abstract format of the BMJ Open.

#### Comment 6: Essential minor revisions -Introduction

Introduction LL54-56. Re-word and shorten "Therefore .... to better understand", to "This study aimed to better understand ..."

#### Response 6

We have shortened this sentence as suggested by the reviewer and marked the modification in blue words, now it reads: "This study aims to better understand the current practice of CGs adaptation and identify the challenges raised in this process, thus providing accordance for the improvement of the adaptation process." Please see page 4, line 42-43.

#### Comment 7: Essential minor revisions - Results

Results LL12-18. Need to make it clear why you interviewed individuals (10) and organisations (9) - I assume there were single interviews from 8 organisations and 2 from 1 organisation.

#### Response 7

Thanks to reviewer for highlighting this point. Our study included two interviewees that are from one single organisation. As stated in the methods section, we analysed organisations' methodologies on the adaptation process, and individuals' views and experiences about challenges. In the Results section, we have included one sentence to clarify this point and marked in blue words, it reads: "Data from published methodologies of different participating organisations were included in framework analysis to avoid individual bias. In addition, data from individuals were included in thematic analysis to reflect participants' views and experiences." Please see page 6, lines 17-19.

#### Comment 8: Essential minor revisions – Results and Figure 1

Results LL16-18 "Finally we conducted ten .... until data saturation was complete. " It does not appear from figure 1 that interviewing continued until data saturation was reached - it appears that only 10 participants agreed to take part, and all were interviewed.

#### Response 8

We appreciate the reviewer point out the confusion. As stated in Figure 1, one reason for the "Unable to participate" is the duplicated institution, reflecting the continuous recruitment process. To avoid confusion, we made clarification in Figure 1 by substituting "Unable to participate" with "Non-participation" and "Consent to participate" with "Participation - Obtain participation consent and signed COI form". Please see the new Figure 1.

We also included one sentence to clarify the data saturation point and marked in blue words, it reads: "we conducted ten semi-structured interviews between November 2019 and January 2020 until data saturation on the reason for CG adaptation and methodology was reached." Please see page 6, lines 16-17.

#### Comments from the Reviewers 2: Prof. Daniela de Melo

##### Comment 1: General comments

Congratulations on an excellent paper. I really enjoyed reading it and find the topic very relevant. I have a few comments/suggestions.

##### Response 1

We appreciate the reviewer's interest on our study.

##### Comment 2: Introduction - references

Page 5 – Lines 38 – 40: "A recent review described several limitations of published adaptation frameworks and showed that the time to adapt CGs using the same framework varies between 18 months and three years (7, 10, 21)" - The authors talk about a review but there are three references. I suggest leaving only the reference of the review they refer to.

#### Response 2

Thanks for reviewer's suggestion, we have taken out the references 10 and 21. Please see page 4, line 33.

#### Comment 3: Introduction - references

Page 5 – Line 21 – the ADAPTE reference seems to be inappropriate here.

#### Response 3

We have moved reference 9 (the ADAPTE reference) behind the “ADAPTE tool”, please see page 4, line 18.

#### Comment 4: Results - references

Page 7 – Line 49: “Six participants reported they used their own adaptation methodology (8, 33-38).” - The authors talk about 6 participants but there are 7 references. Check if there is one more reference or if two of them talk about the same adaptation.

#### Response 4

Thanks to reviewer's reminder. The Appendix 04 (Identified adaptation methodologies) has clarified that one of the identified methodologies (Adopt–Contextualise–Adapt (ACA) framework) has two publications. One of the two references describes specifically the contextualisation process (reference 36). To avoid confusion, we have deleted the reference for the contextualisation stage (reference 36) since it has been cited by the ACA framework publication (reference 37). Please see page 6, line 43 and page 7, line 4.

#### Comment 5: Discussion - clarification

Page 10 – Line 14: “Most of the identified methodologies were not previously discussed.” - I think you could make it clearer: discussed or published in advance?

#### Response 5

Thanks to reviewer's suggestion. Seven of nine identified methodologies were organisation handbooks or publications that have not been discussed by previous systematic reviews. We have clarified this sentence to avoid confusion and marked the modifications in blue words. Now it reads: “Most of the identified methodologies were not discussed by previous systematic reviews.” Please see page 9, line 20.

#### Comment 6: Figure 1 - error

Figure 1 - there seems to be an error in the picture regarding “No response/Not eligible” - is it 17 or 18?

#### Response 6

Thanks to reviewer for spotting this error. We have checked the raw data and corrected the number for “No response/Not eligible” as 18. Please see the new Figure 1.

#### Comment 7: Figure 2 – Include options for third and fourth stages

Figure 2 – I suggest that in the same way that you put the options in the second stage, you also describe the options for the third and fourth stages as well.

#### Response 7

We accepted reviewer's suggestion and included two points for the third stage (Decision making process) and four points for the fourth stage (External review and follow up), please see the new Figure 02. Those points correspond with the results section, page 8 lines 2-3 and page 8 lines 10-11.

Comment 8: Limitation of the study

The most important limitation of this study was the choice of respondents. This limitation could be better explored for two reasons: 1) choosing among adapted published guidelines makes it necessary to choose interviewees who have sufficiently large experience in the process of critical appraisal and/or publication of scientific articles. Among G-I-N participants brings an even greater bias. They are already people very involved in the guideline development/adaptation process; 2) the language limitation also leads to a very important bias, making the interviewees already present a very qualified profile, which certainly influenced the results.

I think it would be important to be more emphatic about this in the discussion and conclusion. It is not just an issue about the lack/poor presence of LMCI representatives.

Response 8

We agree with the reviewer about the limitation of the participants' selection and have included one sentence in blue words to reflect the reviewer's suggestion, the limitation now reads: "Our study has some limitations. We only conducted ten interviews and hence could have missed additional adaptation methods from other countries. In addition, we recruited participants from published adapted guidelines and G-I-N attendees, limiting the study samples to experts with sufficiently large experience in the CGs adaptation or development field. Besides, we did not interview non-English-speakers, which may bias the study results. Finally, we did not conduct data analysis based on country income due to the small sample size and fewer participants from LMICs that lack resources and technical/methodological experts. The challenges highlighted by our study are likely to be universal within experienced guideline adaptation developers (e.g., intensity and complexity of adaptation process, limitations of source CGs, and implementation barriers). However, some specific challenges, such as specific contextualisation issues, would be under-reported in our study" Please see page 10, lines 2-10.

We also included the limitation of participants' selection in the "Strength and limitation" section below the "Abstract", it reads: "The challenges highlighted by our study are likely to be universal to experienced CG adaptation developers, since our participants' selection process limits the study samples to experts with sufficiently large experience in the CG adaptation or development field." Please see page 3, lines 8-10.

We believe the sentence in conclusion has reflected this limitation; it reads: "More methodological research is needed to develop rigorous international standards for adapting clinical guidelines."

**VERSION 2 – REVIEW**

<b>REVIEWER</b>	Stokes, Tim Otago University, General Practice & Rural Health
<b>REVIEW RETURNED</b>	09-Sep-2021

<b>GENERAL COMMENTS</b>	I consider that the authors have fully addressed the reviewers' comments and have improved the standard of written English up to an acceptable standard.
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<b>REVIEWER</b>	de Melo, Daniela Universidade Federal de Sao Paulo
<b>REVIEW RETURNED</b>	24-Sep-2021

<b>GENERAL COMMENTS</b>	I am satisfied with the adjustments made by the authors. Congratulations on the manuscript.
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