

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

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| TITLE (PROVISIONAL) | How Novice, Skilled and Advanced Clinical Researchers Include Variables in a Case Report Form for Clinical Research:A Qualitative Study |
| AUTHORS | Chu, Hongling; Zeng, Lin; Fetters, Micheal; Li, Nan; Tao, Liyuan; Shi, Yanyan; Zhang, Hua; Wang, Xiaoxiao; Li, Fengwei; zhao, yiming |

VERSION 1 - REVIEW

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| REVIEWER | Adrian Barnett Queensland University of Technology Australia |
| REVIEW RETURNED | 21-Apr-2017 |

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| GENERAL COMMENTS | <p>This is an interesting idea for a paper. The results were not that surprising, but are still potentially useful as designing good studies is a vital part of the research process. It was good to see an overall concern for collecting too much data, with a focus on collecting the right data.</p> <p>There was no research checklist. I suggest completing: Consolidated criteria for reporting qualitative research (COREQ).</p> <p>See the instructions to authors: "An 'Article summary' section consisting of the heading: 'Strengths and limitations of this study', and containing up to five short bullet points, no longer than one sentence each, that relate specifically to the methods of the study reported. They should not include the results of the study and should be placed after the abstract."</p> <p>A reference to the literature on the proliferation of badly designed studies could be useful. For example, John P A Ioannidis, et al DOI: http://dx.doi.org/10.1016/S0140-6736(13)62227-8 "Increasing value and reducing waste in research design, conduct, and analysis".</p> <p>Were the interviewers and transcribers unaware of the researchers' experience? And were they aware of the study's hypothesis? It's potential that confirmation bias could creep in here. It may have been too difficult to blind, but this issue should at least be acknowledged.</p> <p>The first few paragraphs of the discussion simply repeat the results and could be cut. The instructions for authors are: "We also recommend, but do not insist, that the discussion section is no longer than five paragraphs and follows this overall structure (you do not need to use these as subheadings): a statement of the principal findings; strengths and weaknesses of the study; strengths and</p> |
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| | <p>weaknesses in relation to other studies, discussing important differences in results; the meaning of the study: possible explanations and implications for clinicians and policymakers; and unanswered questions and future research."</p> <p>The paper needs a good edit for grammar and clarity.</p> <p>Minor comments</p> <ul style="list-style-type: none"> - inclusion criterion b is unusual, how was it judged? Were any researchers excluded by this criterion? - Table 1, the summary stats for age could be shown as a whole number |
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| REVIEWER | Simon Watmough Edge Hill University UK |
| REVIEW RETURNED | 21-Apr-2017 |

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| GENERAL COMMENTS | <p>Introduction is nice and succinct and sets the scene for the research nicely. could be improved by a short section (referenced) on why clinical research is important and any problems with undertaking clinical research currently.</p> <p>Methods A little bit more information about the academic institution in Beijing would be useful, for example is this a teaching hospital and so on? Data collection: How many staff were eligible to take part in the interviews?</p> <p>Was the group interview not a focus group? If not, how was it different to a focus group? "We developed a semi-structured interview guide based on group discussion and a preliminary pilot study in 2 clinical researchers." Again, this needs more clarity. What is for "parent study"? How was the following measured? "b. Being able to express themselves with well-articulated stories and to deeply reflect on their stories"</p> <p>Methods More details needed about how all researchers agreed the final results. The following needs more explanation: illustrating the three identified models and illustrative quotes from the interviews. Are the results illustrated from the main themes which were used as questions/prompts? The ethics are fine.</p> <p>Results: At the start of b page 9 Experienced clinical researcher needs to be plural. Page 10, lines 11-14 - the quote is in italics whereas the other quotes aren't. Consistency is needed.</p> <p>Discussion: "The main findings from this study are that novice, experienced and</p> |
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| | <p>expert clinical researchers have three progressively sophisticated approaches for selecting variables in a CRF for clinical research." Did you expect this before you started the research? "garbage in garbage out" is not really academic language so please re phrase.</p> <p>The discussion so far is fine and relevant but a more general discussion within the literature about how these results are applicable elsewhere is also needed.</p> <p>The final section is fine, bit within the limitations and the methods sections a discussion about whether saturation of themes was reached with the numbers interviewed. Personally, I think all papers should finish with a nice short succinct conclusion (titled as such) given the reader clear take home messages.</p> <p>General note - "we" is used a lot - third person is always preferable where at all possible.</p> <p>I would like to acknowledge the hard work put in by the authors so far but feel changes as listed above are required before it can be considered for publication.</p> |
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1: There was no research checklist. I suggest completing: Consolidated criteria for reporting qualitative research (COREQ).

Author Response : We have now added the research checklist as a supplementary file.

Reviewer 1: See the instructions to authors: "An 'Article summary' section consisting of the heading: 'Strengths and limitations of this study', and containing up to five short bullet points, no longer than one sentence each, that relate specifically to the methods of the study reported. They should not include the results of the study and should be placed after the abstract."

Author Response :

This part has been changed as requested (page2):

- The study used qualitative interviews to explore the novel topic of how researchers create a case report form.
- The study involved the development of three visual models to depict the approach of novice, excellent, and expert clinical researchers.
- The expert clinical researchers shared guiding principles they use to conduct research.
- A limitation of our study concerns the potential selection bias of our sample as clinician participants are from a premier academic hospital in Beijing, and these participants might have greater knowledge, cognitive skills, and opportunities for research than clinicians in many other hospitals in China.

Reviewer 1: A reference to the literature on the proliferation of badly designed studies could be useful. For example, John P A Ioannidis, et al DOI: [http://dx.doi.org/10.1016/S0140-6736\(13\)62227-8](http://dx.doi.org/10.1016/S0140-6736(13)62227-8)
"Increasing value and reducing waste in research design, conduct, and analysis"

Author Response : This reference has been included on page 18.

Reviewer 1: Were the interviewers and transcribers unaware of the researchers' experience? And were they aware of the study's hypothesis? It's potential that confirmation bias could creep in here. It may have been too difficult to blind, but this issue should at least be acknowledged.

Author Response : The interviewers were aware of the researchers' experience and study's

hypothesis. But transcribers were unaware of the researchers' experience and study's hypothesis.

Reviewer 1: The first few paragraphs of the discussion simply repeat the results and could be cut. The instructions for authors are: "We also recommend, but do not insist, that the discussion section is no longer than five paragraphs and follows this overall structure (you do not need to use these as subheadings): a statement of the principal findings; strengths and weaknesses of the study; strengths and weaknesses in relation to other studies, discussing important differences in results; the meaning of the study; possible explanations and implications for clinicians and policymakers; and unanswered questions and future research."

Author Response : As requested, the discussion has been rewritten with these suggestions used as a guide on pages 13 and 14.

Reviewer 1: The paper needs a good edit for grammar and clarity.

Author Response : As requested, we have do some edit in the paper.

Reviewer 1: inclusion criterion b is unusual, how was it judged? Were any researchers excluded by this criterion?

Author Response : Purposive sampling was used in this study, so there were not any researchers excluded by this criterion. However, we did not have an objective standard to judge the criterion b. Therefore, the criterion b was deleted from page 5 in the revision.

Reviewer 1: Table 1, the summary stats for age could be shown as a whole number

Author Response : This part has been changed as requested in Table 1 on page7.

Reviewer 2: A little bit more information about the academic institution in Beijing would be useful, for example is this a teaching hospital and so on?

Author Response : This part has been clarified as requested on page 4 and 5.

Reviewer 2: Data collection: How many staff were eligible to take part in the interviews?

Author Response : All physicians in an academic institution have some expectation for participation in research. There are over 1000 clinician researchers in these institution, information added to give context.

Reviewer 2: Was the group interview not a focus group? If not, how was it different to a focus group?

"We developed a semi-structured interview guide based on group discussion and a preliminary pilot study in 2 clinical researchers." Again, this needs more clarity.

What is for "parent study"?

Author Response : A focus group interview was used in this study. In reference to, "We developed a semi-structured interview guide based on group discussion and a preliminary pilot study in 2 clinical researchers." In this sentence, the information was related to conducting a group discussion to develop the interview guide. This was not a formal "focus group" interview.

"parent study" has been changed as requested on page 4.

Reviewer 2: How was the following measured? "b. Being able to express themselves with well-articulated stories and to deeply reflect on their stories"

Author Response : It did not have an objective standard to judge the criterion b. Therefore, the criterion b was deleted in the revision, on page 5.

Reviewer 2: More details needed about how all researchers agreed the final results.

Author Response : We have added the following to page 6: "Member checking was used to share the results with all the interviewees by email--they raised no objections or new considerations, and agreed with the findings."

Reviewer 2: The following needs more explanation:
illustrating the three identified
models and illustrative quotes from the interviews.

Are the results illustrated from the main themes which were used as questions/prompts?

Author Response : The results are illustrated through the main themes. The questions are on page 4: "What process do you use to design a case report form for clinical research?" The results emerged primarily from this question and key probes were, "What are the difficulties and challenges encountered when you designed case report form for your project?" and "What is your previous experience joining a clinical research project?"

Reviewer 2: result: At the start of b page 9 Experienced clinical researcher needs to be plural. Page 10, lines 11-14 - the quote is in italics whereas the other quotes aren't. Consistency is needed.

Author Response : This part has been changed as requested on page 9 and 10.

Reviewer 2: Discussion:

"The main findings from this study are that novice, experienced and expert clinical researchers have three progressively sophisticated approaches for selecting variables in a CRF for clinical research."

Did you expect this before you started the research?

Author Response : While we expected to see differences in the approaches of novice, experienced and expert researchers, we were not sure how they would differ. The main findings are refined from this study. The findings are consistent with our hypothesis at a general level, but we found the details to be quite interesting.

Reviewer 2: "garbage in garbage out" is not really academic language so please re phrase.

Author Response : This part has been removed and changed as requested on page 13.

Reviewer 2: The discussion so far is fine and relevant but a more general discussion within the literature about how these results are applicable elsewhere is also needed.

Author Response : This part has been changed as requested on page 13. "These findings speak to fundamentals of conducting high quality research, and while based on research in a single institution, can reasonably be expected to hold true in a broad range of settings."

Reviewer 2: The final section is fine, but within the limitations and the methods sections a discussion about whether saturation of themes was reached with the numbers interviewed.

Author Response : This part has been changed to reflect how saturation was addressed as requested on page 4.

Reviewer 2: Personally, I think all papers should finish with a nice short succinct conclusion (titled as such) given the reader clear take home messages.

Author Response : This part has been changed as requested on page 14. "In sum, this research illustrates that increasing levels of sophistication in research planning reflect increasing levels of sophistication in the selection of variables for inclusion in a case report form. Thus, novice and intermediate-level researchers alike could benefit by emulating the comprehensive planning procedures utilized by expert clinical researchers."

Reviewer 2: General note - "we" is used a lot - third person is always preferable where at all possible.

Author Response : This has been changed in the revision to minimize the use of "we".

VERSION 2 – REVIEW

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| REVIEWER | Adrian Barnett Queensland University of Technology Australia |
| REVIEW RETURNED | 08-Jul-2017 |

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| GENERAL COMMENTS | <p>The authors have answered my queries. The paper still needs a grammar edit.</p> <p>Grammar edits</p> <ul style="list-style-type: none">- page 3, line 48, change 'should keep privacy for' to 'should maintain the privacy of'- page 4, line 47, 'question developed' singular- page 8, line 33, 'said' not 'opined'- page 8 line 39, 'follow' instead of 'are doing like this'- page 10, line 57, 'important' in place of 'crucial'- page 12, line 36, spelling 'Ioannidis'- page 12, line 45, 'greatly increasing' not 'exploding'- page 14, line 37, 'a case' not 'as case'- Figure 3, typos 'Orgnize' and 'domins' |
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| REVIEWER | Simon Watmough Edge Hill University, Uk |
| REVIEW RETURNED | 09-Jul-2017 |

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| GENERAL COMMENTS | <p>This is much better than the original version and I note that the authors have made good attempts to improve the paper. Still use of "our" page 3 line 39. Introduction is much better and sets the scene now for the study.</p> <p>Methods</p> <p>"We" used again on page 4 instead: As little is known about how clinicians determine variables to include in a CRF it was deemed appropriate to use a qualitative approach" for example. Setting - is this a University hospital? reference needed for Purposive sampling and a brief explanation of what this is and why useful for this study. Same with "maximum variation sampling" b for recruitment isn't needed as it is obvious. Study population still needs more explaining. How many approx. of staff fitted into the 3 categories for example? Did only 17 out of a 1000 potentially research active staff volunteer or as suggested was recruitment targeted? Data collection - were the RAs clinicians? Did they work on a day to day basis with the participants? More about saturation of themes. In analysis: "All research team members agreed with the final results" How did this happen and who were the research team members? Not sure what Member checking is?</p> |
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| | <p>the following should go at the start of the section ethical considerations: The institutional review board (IRB) at Peking University ThirdHospital approved the study.</p> <p>Results: Cleary presented and easy to follow.</p> <p>Discussion: Again improved. More could have been put in about limitations ie the small numbers. Perhaps more could have been put in about whether the authors feel the results are "obvious" and expected.</p> <p>As said earlier this is a much improved paper for the first submission and does clearly have merit, but I would leave it to the editorial team if they think the results have far enough implications beyond the institution in question to be published in this journal.</p> |
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VERSION 2 – AUTHOR RESPONSE

Reviewer 1: The authors have answered my queries. The paper still needs a grammar edit.

Grammar edits

- page 3, line 48, change 'should keep privacy for' to 'should maintain the privacy of'
- page 4, line 47, 'question developed' singular
- page 8, line 33, 'said' not 'opined'
- page 8 line 39, 'follow' instead of 'are doing like this'
- page 10, line 57, 'important' in place of 'crucial'
- page 12, line 36, spelling 'Ioannidis'
- page 12, line 45, 'greatly increasing' not 'exploding'
- page 14, line 37, 'a case' not 'as case'
- Figure 3, typos 'Orgnize' and 'domins'

Author Response : Thank you very much for your carefully modification. As requested, we have changed all above in the paper.

Reviewer 2 : This is much better than the original version and I note that the authors have made good attempts to improve the paper. Still use of "our" page 3 line 39. Introduction is much better and sets the scene now for the study.

Author Response : Thank you very much for your review. We have changed the "our" on page 3 line 39.

Reviewer 2 : Methods

"We" used again on page 4 instead: As little is known about how clinicians determine variables to include in a CRF it was deemed appropriate to use a qualitative approach" for example.

Author Response : As requested, we have changed in the paper.

Reviewer 2 : Setting - is this a University hospital?

Author Response : Yes, this is a University hospital. And we have added this in the paper.

Reviewer 2 : reference needed for Purposive sampling and a brief explanation of what this is and why useful for this study. Same with "maximum variation sampling"

Author Response : Actually, "Purposive sampling" in this paper is "maximum variation sampling". We have changed in the paper.

Reviewer 2 : b for recruitment isn't needed as it is obvious.

Author Response : We have deleted this in the paper.

Reviewer 2 : Study population still needs more explaining. How many approx. of staff fitted into the 3 categories for example? Did only 17 out of a 1000 potentially research active staff volunteer or as suggested was recruitment targeted?

Author Response : I think the study population in this study have the high homogeneity for this topic. And data collection was complete after 17 interviews, the point when saturation of themes was reached.

Reviewer 2 : Data collection - were the RAs clinicians? Did they work on a day to day basis with the participants?

Author Response : RAs are not clinicians, they are majored in clinical research methodology.

Reviewer 2 : In analysis: "All research team members agreed with the final results" How did this happen and who were the research team members?

Author Response : All research team members agreed with the final results in a final discussion meeting. We have add the "in a final discussion meeting" in the paper. The team members are the authors of this paper, they were involved in the design, data collection, transcribe and analysis.

Reviewer 2 : Not sure what Member checking is?

Author Response : Member checking is to send the interview result to the interviewee and get their reply to the result.

Reviewer 2 : the following should go at the start of the section ethical considerations: The institutional review board (IRB) at Peking University Third Hospital approved the study.

Author Response : As requested, we have changed in the paper.

Reviewer 2 : Discussion: Again improved. More could have been put in about limitations ie the small numbers.

Author Response : I think the study population in this study have the high homogeneity for this topic. And data collection was complete after 17 interviews, the point when saturation of themes was reached.

Reviewer 2 : Perhaps more could have been put in about whether the authors feel the results are "obvious" and expected.

Author Response : We have added "This is consistent with our research expectations" in the paper.

VERSION 3 - REVIEW

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| REVIEWER | Simon Watmough Senior Lecturer Edge Hill University UK |
| REVIEW RETURNED | 24-Jul-2017 |

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| GENERAL COMMENTS | The manuscript is much improved now |
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