Author’s response to reviews

Title: Procedures of recruiting, obtaining informed consent, and compensating research participants in Qatar: Findings from a qualitative investigation

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Author’s response to reviews: see over
November 6, 2013

Re: 1785337553861114 - Recruitment and informed consent of research participants in the extremely high density multicultural population of Doha, Qatar in the Arabian Gulf Region
Corresponding author: Prof. Michael Fetters

New Title: Procedures of recruiting, obtaining informed consent, and compensating research participants in Qatar: Findings from a qualitative investigation

To: Adrian Aldcroft—Executive Editor of BMC Medical Ethics

Dear Esteemed Editor,

Thank you for the invitation to provide a revision of the above manuscript. This is our second revision, and the reviewers asked for only a few changes which we address below with a point-by-point explanation. Where appropriate, we provide the actual revised text. The remaining concerns on the part of the reviewers primarily were related to the use of terminology. We have complied with their recommendations to the extent possible. For some comments, we added clarity to illustrate that our use of terminology was correct based on actual procedures in our study.

Specifically, we have further honed the title and purpose statement, and we emphasized these points in the conclusions as requested by Reviewer 1. A suggested discretionary change to use the phrase 'notes from the interviews' does not accurately describe our work, so we did not make that change, though we provided clarification to make it clear that we used field observations. We clarified the sampling procedures as requested by Reviewer 2 using the references the reviewer suggested. Reviewer 3 had no further requested changes. In short, we believe you will find we have fully addressed all remaining concerns. To make it easy for you and the thoughtful reviewers to see our changes, we used yellow highlight in this letter and the manuscript where changes were made.

We confirm that none of the authors have a conflict of interest. The author contributions were included in the previous submission, and we highlighted them in yellow for your reference. Thank you again for considering what appears to be based on our best knowledge, the first study on recruitment, informed consent, and compensation for research participation by adults in the Middle East and Arabian Gulf Region.

We look forward to your decision. If at all possible, we would appreciate a response at your earliest possible convenience as we are in the process of submitting our final report to the funding agency.
Reviewer#1: Jihad Makhoul

1. Is the question posed by the authors well defined?

Major Compulsory Revisions: The authors state that the purpose is "to address the gap in the literature on recruitment and informed consent for research..". The 'gap' is still unclear. It needs further qualification on what kind of gap the manuscript is addressing and how it will address it. There is a sentence about a gap in knowledge about compensation and this is not further explained to lead the reader to a conclusion on what to expect in the paper. Is the gap contextual, procedural, or so on.. Along the same lines, the literature review focuses on the processes and approaches related to seeking/obtaining informed consent with a focus on nonwestern settings. Informed consent itself is an outcome of the process of seeking it. This should be amended in the manuscript. The title should reflect that as well. The revised title is "Procedures of informed consent.." which could be also benefit from describing the informed consent: is it the process of seeking informed consent, or the concept, or the forms used or all the above?

Response:

• The reviewer’s comments helped us further clarify the title and study purpose. Thank you. Consequently, we have clarified that the purpose of this report is to address the gap in the literature about procedures of recruiting, obtaining informed consent, and compensating participants in health care research in Qatar. The reviewer’s point compelled us to consider again more carefully, and we added the issue of compensation to the title as well. This is appropriate since we have an entire Table 5 dedicated to the topic of compensation, and there are no papers on this topic in the literature. Currently, there are two somewhat similar studies on the topics of recruitment and informed consent (neither address compensation): one on adolescents conducted in the Region,
and another conducted in the US with an Arab population. We have added wording about “procedures” and “compensation” throughout the manuscript to clarify this focus.

- The title has been amended to reflect these specifics, “Procedures of recruiting, obtaining informed consent, and compensating research participants in Qatar: Findings from a qualitative investigation”

- Revised text: “The purpose of this paper is to address the gap in the literature on procedures for recruiting, obtaining informed consent, and compensating participants in health research in the Middle East and Arabian Gulf Region. The findings are based on the research team’s field observations and interviews of participants during one stage of a multistage research project about health care quality assessment in Qatar.

2. Are the methods appropriate and well described?

Discretionary Revisions: Interviews are now clearer. Yet the authors continue to refer to field notes on interviews as observations and use these as a major source of data collected emphasizing responses to the researchers' Qs as observations. I suggest replacing this with terms such as 'notes from the interviews' rather than observations, a method used in ethnographic studies to mean collecting data about the behaviors, gestures and the environment where the participants naturally exist.

- Response: The field notes taken during field observations were more than just notes on interviews, and more than just behaviors, gestures and environment. Field observations are defined as “the systematic description of events, behaviors, and artifacts in the social setting chosen for study (Marshall & Rossman, 1989, p.79)\(^1\). The research assistants kept track of everything from the beginning of the recruitment process to the end of the interview. Specifically, they collected information about all individuals who were approached, even if they were not enrolled. They recruited information about non-participants and actual comments about the study procedures including compensation. We have expanded our description to make it more clear that it involved more than just behaviors, gestures and the environment.

- Revised text: The RAs collected field jottings [29] about the events, behaviours, and environment during recruitment and data collection procedures that they expanded into full field notes after return to the research office.

3. Are the data sound?

Discretionary Revisions: The kinds and sources are clearer. However, the data cleaning explanation can easily be referred to as cross-validation or validation or checking or editing..

• **Response:** In the current manuscript, we do not use the word “data cleaning”, but rather the word “checked”. The audio-recorded interviews were transcribed in the native language, and the transcription checked by a second reviewer.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? *It is clearer now.*

• **Response:** Thank you.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

**Major Compulsory Revisions:** The conclusions will benefit from a summary of gaps the research has identified in the relevant body of knowledge and what the research has concluded as the major findings; a recap of take-home messages will be useful for the reader. Implications for researchers and for further research should be presented in the conclusions. The manuscript will benefit from a quick review to pick these messages up and place them at the end.

• **Response:** Thank you for your suggestion. We revised our conclusion to summarize take-home messages and the implications of this study as suggested by the reviewer.

• **Revised text:**

**Conclusion**

This empirical study from Qatar provides the first comprehensive consideration of recruitment, informed consent, compensation, and other research procedures in Middle East and Arabian Gulf Region. Based on these findings, we conclude that Western approaches to recruitment, consent, and compensation are compatible in Qatar but with the caveat that researchers should consider potential cultural influences. Specific issues merit the consideration of data collection environment, gender relations, preferred informed consent procedures, sensitivity about compensation, possible involvement of family members as incidental research participants, and privacy concerns due to a perceived sense of vulnerability. With attention to these cultural influences, our investigation achieved a very good participation rate. Given the limited literature about research participation in the Middle East and Arabian Gulf Region, additional studies on the perspectives of researchers and research participants would be helpful in exploring the challenges of conducting research in non-Western contexts, abiding by Western IRB standards, and ethically incorporating cultural adaptations. We conclude that researchers embarking on health research in the Middle East and Arabian Gulf Region should consult closely with colleagues on the ground to assess and account for local cultural sensitivities.

6. Are limitations of the work clearly stated?

*Yes, they are acceptable.*

• **Response:** Thank you.
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Yes.

- **Response:** Thank you.

8. Do the title and abstract accurately convey what has been found?
Minor Essential Revisions: Yes, if the title is revised to include a word or two specifying what about informed consent is being addressed. as suggested in point 1.

- **Response:** We modified the title as follows: “Procedures of recruiting, obtaining informed consent, and compensating research participants in Qatar: Findings from a qualitative investigation.”

9. Is the writing acceptable?
Yes.

- **Response:** Thank you.

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**Reviewer #2: Maged El-Setouhy**

1. Regarding the response to my first comment about the sample size. I know that many researchers think that no need to calculate the sample size however, in 2000 there was a nice publication on that, please read:
   Sample size for qualitative research by Peter DePaulo 2000
   I did not hear intentional sample before. We used to use convenient sample instead. Please read:
   a. Sampling for qualitative research by Martin N Marshall 1996
   and
   b. An Introduction to Qualitative Research. The NIHR RDS for the East Midlands / Yorkshire & the Humber 2009 Qualitative Research
   So I think it is better to consider the term "convenient sample" which is acceptable for qualitative research.
Response: Thank you for searching out and sharing these articles. We are in agreement about the importance of sampling. However, in our study, we did not use “convenience sampling”. As indicated in our manuscript, we used “maximum variation sampling” (Methods, paragraph 4 “Sampling and Enrollment Procedures”, sentence 8). Our use of “intentional sampling” in our cover letter was confusing to the reviewer. Maximum variation sampling is one type of intentional or purposeful sampling (reference “a” by Marshall describe and “b” by NIHR describe this). These “intentional” and “purposeful” terms are used somewhat interchangeably by qualitative researchers, and contrast with “convenience sampling”, generally, the weakest form of qualitative sampling (reference “a” Marshall, states this explicitly). Both reference “a” by Marshall (lists 2 other “general” strategies including several sub-categories including of maximum variation sampling) and reference “b” by the NIHR (lists 6 other specific strategies) provide a variety of qualitative sampling strategies besides convenience sampling. Of the three articles, “reference b” is the newest, most definitive and respected because its source, is the National Health Service of the UK. As stated in the manuscript, we used maximum variation sampling as discussed in reference (b) as follows:

“Maximum variation sampling: here researchers identify cases with different characteristics to maximise diversity in the sample, usually to get the widest range of views possible. This is best done using quota methods (see “strategy determined in advance”) and iteratively (e.g. refine your quotas based on the emergent analysis – you may decide you need to investigate one group in more depth). Any common themes that emerge can capture “core” experiences or views.” SOURCE: “b”. An Introduction to Qualitative Research. The NIHR RDS for the East Midlands/ Yorkshire & the Humber 2009 Qualitative Research. http://www.rds-yh.nihr.ac.uk/wp-content/uploads/2013/05/5_Introduction-to-qualitative-research-2009.pdf

In short, this trustworthy reference describes exactly what we did, and what we refer to in the paper itself, maximum variation sampling.

Regarding a “sample calculation”, we used a “quota method”, also appropriate for the maximum variation sampling as described above in the NIHR report. We did not the term “quota method” this in the paper. In some of Dr. Fetters’ early qualitative studies, he was criticized for using too much technical jargon, as it would be confusing to readers. Thus we are concerned that this methodological jargon “quota method” might alienate readers. We have cited the NIHR reference on maximum variation sampling which includes a description of the quota method, and believe this will suffice for the interested reader particularly interested in research methodology.

We have chosen not to cite the first article by Peter DePaulo on calculating a sample size. This paper takes a highly unorthodox view on sampling for qualitative studies. We don’t
believe this article to be an appropriate reference for this paper because: (1) the author is mixing quantitative and qualitative paradigms by using a quantitative calculation strategy with qualitative data, (2) the author is writing in the context of focus groups, (3) the article is published in Quirk, which is a non-peer reviewed magazine, and (4) the article doesn’t include a single reference to support this approach. Thus, we do not feel it is a credible source to cite in this paper.

• Regardless, these articles suggest a sample size of 30-60 should be adequate and our sample, n=84, actually exceeds. To make this more clear, we clarify our sample size in the text that we have highlighted as follows. “We targeted the recruitment of approximately 80 subjects, about 20 participants per language for in-depth interviews.” (Methods, Para 4, Sentence 1)

• To summarize, (1) we characterize our sampling according to the preferred terminology, maximum variation sampling, (2) we used a sample calculation described in a most trustworthy source, and finally, our sample size of 84 exceeds the range of expected size of 30-60 cited in the references from the reviewer. We have added the NIHR reference for the interested reader.

2. I think it would be good to include the responses to my 4th and 5th comments in a paragraph under the title "limitation of the study". Otherwise I think the manuscript will be ready for publication after correction the name of the sample to be convenient to make it easy for the readers.

• Response: Thank you for your recommendation. Since you suggested this previously, we had already partially incorporated this information. Since it was unclear, we have further emphasized these points in the limitations paragraph of the revised manuscript. Please see below.

• Revised text: All studies have possible limitations. As the study was conducted in one health care setting in Doha, the degree that recommendations from this study will hold in other settings needs further exploration. Our study employed all-female RAs; utilizing male RAs may have had different implications for the recruitment and informed consent process. Interviewing participants in a busy outpatient waiting room rendered data collection feasible, though this choice may have limited the information participants provided, such as criticisms or private information [further addresses 4th comment and 5th comment]. Future research could compare outcomes such as participation rates and data quality when data collection occurs in public vs private settings to clarify the advantages each setting might offer. While the RAs endeavored to observe carefully, there may have been other meaningful events that they did not notice or document. Finally, qualitative text from interviews was volunteered by the participants in response to open-ended questions, so the reported numbers represent minimum estimates when qualitative responses were
quantified. Caution should be exercised in generalizing the prevalence of the various positions stated since participants were not randomly sampled.

Reviewer #3: Mayyada Wazaify
I think that the authors have adequately answered the raised questions and addressed the comments. The title has been changed and references have been modified. I also appreciate the respect of not revealing the nationality with negative comments etc. In conclusion, I am satisfied with the changes/comments that the authors have made and think that the manuscript can be published in its current format.

- **Response:** Thank you!