Reviewer's report

Title: Recruitment and informed consent of research participants in the extremely high density multicultural population of Doha, Qatar in the Arabian Gulf Region

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Reviewer: Jihad Makhoul

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Major Compulsory Revisions

This is an important topic of research especially of significance in non-western settings. The following are comments that I hope will be useful to the authors to improve the quality of the current manuscript.

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

The research question is clear in the abstract but it is not well articulated in the text of the manuscript.

2. Are the methods appropriate and well described?

The methods appearing in the manuscript are not fully described; the abstract gives an impression that the manuscript will be about the qualitative aspect of the larger study, however, that section lacks background information on the methods of the larger study explaining how qualitative and quantitative methods were staged and the relationship between the two.

The methods section can benefit from the reduction of the number of subtitles for the reader to understand the trail of thoughts and the justification of the research process. That being said, the manuscript will benefit from more detail about the process of recruitment, consenting procedure and role of the researchers in the study. A bit more description on the kind of interviews that were used and the rationale behind using this kind of method may be helpful to the reader.

The authors need to elaborate on the informed consent seeking process and the informed consent document itself, since this is apparently a part of the data collection process. A question the reader asks: were the participants informed that whatever reaction or information they provide such as reasons for declining will be considered as data collected and did they approve of this to happen? It is unclear whether the translated consent forms were tested to check the accuracy of the translation and the clarity of the information in there. It seems throughout the manuscript that the recruitment process itself was problematic and violated a few ethical principles. This is uncertain at this stage due to the lack of clarity of the research process.

In the methods' section, the subheading “setting” needs to be expanded to include more information on the inequalities experienced or pertaining to the
groups in the study in comparison with other sectors of the Qatari population. What kind of health care is offered by the Hamad Corporation? Is it public or private and who pays for services? Part of the information found under the results' section should be moved to the setting to complete the picture about the background to the study, such as information in the interview “environment”.

The section on compensation for participation is not very clear. Was it financial, in kind and how much compensation was given or was offered and was that discussed in the consent form as well?

It is unclear how many interviews were actually conducted. In the manuscript (page 10) it is mentioned that there were 153 individuals who were approached, 90 were initially enrolled and 84 were then included as research subjects. Is this the total number in the larger study or the number of participants in the qualitative study?

The abstract describes 30 declines, and then the declines were analyzed and revealed key themes about hesitation to participate. Does this mean that data were collected from the 30 who declined? If so, then there seems to be a problem in the informed consent seeking procedures where participants should have been consented about the collection of data even about refusal.

The readers would like to know if the study has been approved by an institutional review board. If so this should be mentioned in the methods section and if not, then a justification may be warranted.

3. Are the data sound?

The whole description pertaining to the data although seems to be around qualitative data, is described using quantitative research concepts and terms, for example, data cleaning (What does this mean for qualitative interviews); the calculation of statistics and percentage of participation should be explained referring to the original research question. There is no description of the kinds of questions that the research assistants used in the in-depth interviews with participants, for the reader to understand the type of emerging themes that have been reported.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

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

The data analysis section needs much improvement to outline to the reader the iterative process which moves from actual interviews to analysis. It is unclear how the observational data made by the RAs became part of the data set pertaining to the interviews. How much of that was part of the data being analyzed? How were observational data validated and analyzed? It is unclear how the “reported percentages represent a minimum estimate” (page 9). Again here we see the mix of quantitative terminology and thinking with qualitative data and analysis.
The results section requires much improvement and lacks interpretation, again the way the themes are presented stem from quantitative thinking where results are usually very descriptive and no depth discussion or interpretation is found. Quotations need to be cited only to support a finding that is well-presented and described. Again, in the results section, it is unclear whether the results pertaining to the qualitative aspect of the research (which seems to be more about issues of recruitment and consent) includes data about the health system (page 15). This reflects the lack of internal cohesion of the manuscript and the lack of clarity regarding which methods were used for what research question.

Conclusions about themes such as vulnerability are not grounded and are not explained, for example, how did the authors conclude that a sense of vulnerability emerged through recruitment and informed consent processes. Aren’t the participants from groups which are originally socially marginalized to begin with? Vulnerability as an emerging theme cannot be linked to the recruitment process itself, and should not be an emerging theme from the research project.

Also recording the interviews appears also under the broad theme of vulnerability. In the results' section (page 17), among all the 153 subjects...displayed hesitation due to the recording...whereas 84 were described to be enrolled. It does not seem that vulnerability should be a recurrent theme from the findings, because it should have showed up in the consent form. Didn’t the consent form ask the participant’s agreement for recording the interview?

The discussion of the results does not match, as most of what appears is either a summary of the results or a citation of some of the literature on recruitment and informed consent. The discussion section suddenly presents implications for practice which should be an independent section by itself which should appear only after the full interpretation of findings is presented; it is a confusing mix of implications, lessons and findings and needs revision.

The conclusions that the manuscript makes are not grounded and there is too much stress on the concept of vulnerability, yet this is not founded in the data or at least is not explained. There is a lot of interpretation that is not linked to the results, a number of possibilities show in the discussion section which follows a quantitative writing approach. The researcher “suspects” and tries to find explanations referring to the data which defeats the purpose of qualitative data analysis.

6. Are limitations of the work clearly stated?

Is unclear what is meant by the limitation statement, that data may not be generalizable due to the sample size. What data are the authors referring to? This is a quantitative style of writing and qualitative research never seeks generalizability.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
The authors refer to the relevant body of knowledge on the application of research ethics in non-Western settings.

8. Do the title and abstract accurately convey what has been found?

The title and the abstract do not fully match, because the abstract does not clearly outline the qualitative research study in question.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.