Author’s response to reviews

Title: Recruitment and informed consent of research participants in Doha, Qatar

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Author’s response to reviews: see over
July 5, 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

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. We have carefully considered the detailed comments of the three reviewers, and below, we provide a point-by-point explanation of how we have edited the manuscript. We have combined similar comments for easier reading.

Specifically, we have focused this revision to have greater precision and concept clarification. Briefly, the word counts are: 5756 for the manuscript; 282 words for the abstract; and 6 tables. To make it easy for you and the thoughtful reviewers to see our changes, we have used blue font in the manuscript where changes were made.

We confirm that none of the authors have a conflict of interest.

We appreciate your extension of the deadline given our circumstance. Thank you again for the consideration of our work in your journal.

Sincerely,

Michael D. Fetters, MD, MPH, MA

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

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

R.1. The research question is clear in the abstract but it is not well articulated in the text of the manuscript.

- **Response:** We have modified the text in the manuscript to match the text in the abstract. See pg. 5 in the manuscript.
- **Revised text:**
  
  *The purpose of this paper is to address the gap in the literature on recruitment and informed consent for research based on the project team’s experience and observations in a multistage research project about health care quality assessment in Qatar.*

R.2. First I like to express my appreciation to the authors trying to highlight and evaluate the problem of informed consent and recruitment in the gulf area where minimal publication are there. The study question is well defined by the authors.

- **Response:** Thank you.

R.3. I think that the title is long and this is unnecessary to mention since all your readers will know where Qatar is on the map! On the other hand, more important amendment is suggested for the title (see below-major revisions). In addition, the title is general and does not clearly reflect the work.

- **Response:** We modified the title as follows: *Recruitment and informed consent of research participants in Doha, Qatar.*

Abstract/Results/1ns paragraph: You don't start a sentence with a number, please write in words.

- **Response:** This has been corrected.

Abstract/Conclusions: "Although we achieved 80% participation among subjects approached, barriers to recruitment and informed consent still emerged."

--> This sentence is NOT a "conclusion". I prefer to delete it. Also, the sentence: "North American recruitment and consent procedures are compatible but with caveats" stands out and probably has no place in the abstract. It is not clear or relevant to the text before or after. I prefer to delete it.
• Response: We re-wrote the conclusion in the abstract to achieve further clarity. See pg. 2.

• Revised text:
This is the first study to provide empirical data on recruitment, informed consent, and other research procedures in a general adult population in the Middle East and Arabian Gulf. This investigation illustrates how potential research participants perceive research participation. With particular cultural adaptations, the investigation achieved a very good participation rate. Fundamentally, Western ethical research principles were applicable, but required flexibility and culturally informed adaptations.

2. Are the methods appropriate and well described?

R.1 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.

• Response: We have completely re-written the methodology. For specifics on the larger study and relationships between the two, see pg. 5 under Design and pg. 7 under Data collection procedures in manuscript.

• Revised text:

Design (pg. 5)

This research utilized an ethnographic approach to conduct a qualitative study as one component within a multistage, mixed methods parent study focused on developing a self-administered healthcare quality assessment instrument in the four languages of Arabic, English, Hindi, and Urdu. Briefly, the project involved cultural adaptation of the adult survey of the Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS). The second stage of the parent study involved qualitative interviews regarding patient perspectives on health care quality. Extensive field notes were collected about recruitment and informed consent procedures during the recruitment for these interviews. Human subjects approval for the study was granted from the University of Michigan, Weill Cornell Medical College in Qatar, and Hamad Medical Corporation (HMC).

Data collection procedures (pg. 7)

Field observations. Field observations served as the primary source of data for this study and were conducted under the human subjects approvals for the project. The RAs collected field jottings [28] about the environment and recruitment procedures that they expanded into full field notes after return to the research office. During recruitment, the RAs recorded detailed information regarding the number of individuals who were approached, declined, enrolled, excluded, and reasons for exclusions. The RAs discreetly recorded gender, cultural affiliation, approximate age, and reason for declining that individuals volunteered without prompting. No identifiable personal health information was collected from individuals who declined. For
individuals who were enrolled, the RAs tracked how many of them retained the information/waiver of written informed consent sheet, how many provided contact information, and how many spontaneously shared their name with the RA as an indication of trust.

**In-depth interviews.** The interviews were conducted primarily for the parent study on developing a culturally adapted survey on health care quality. The interview guide included questions about individual’s health and illness experiences, healthcare practices, challenges encountered to receive health care, recommendations for improvement in services, and demographic information. While the interviews were not focused on the recruitment and consent process, many discussions provided supplementary information to the field observations. The RAs interviewed participants in the outpatient waiting area of the general medicine clinic of HMC. The waiting area was chosen as the location for interviews for two reasons after a careful discussion amongst team members. First, cultural norms in Qatar dictate that interactions between genders occur in public space in view of others except for purely medical reasons or necessity depending on the task. The mostly Muslim and all-female RAs felt it would be culturally inappropriate for them to be in a private room with a man. Second, participants were interviewed while waiting for their doctor’s appointments. Since the hospital uses a number system, participants preferred to stay in the waiting area with full visibility of the number display used to call patients. When available and deemed to be culturally acceptable, the RAs occasionally used vacant patient rooms for interviews.

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.

- **Response:** This is a stylistic point. However, we reduced the number of subtitles.

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.

- **Response:** We describe this process in more detail in the methods section. See pg. 6 under Sampling and enrollment procedures.

- **Revised text:**

**Sampling and enrollment procedures**

We targeted the recruitment of approximately 20 participants per language for in-depth interviews. Our study employed all-female research assistants (RAs) because it is culturally more acceptable in public places in Qatar, including healthcare settings, for women to move into both male and female waiting areas, and thus more efficient for the study. The RAs wearing an official white research coat approached patients or family members in the outpatient waiting room of the clinic to inform them about the study. Inclusion and exclusion criteria are depicted in Table 1. Recruitment sought roughly equal representation within each group by literacy (low versus high). After careful consideration of primary populations in the region, low literacy was defined as 9th grade and below and high literacy as some high school education or greater.
While most linguistic groups corresponded with specific cultural groups, English serves as the lingua franca for many cultural groups in Qatar that speak English as a second language. The team exercised maximum variation sampling to achieve cultural diversity in the English language group to avoid over-representation of any specific groups. Eligible individuals who enrolled for interviews gave verbal consent that was audio recorded. These individuals received the information/waiver of written informed consent sheet at this time. This sheet included a statement that participation in the study would not impact participants’ receipt of health care. Additionally, the RAs emphasized this point when recruiting and interviewing participants. Interviews ranged from 15-60 minutes in duration.

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.

- **Response:** We have further explained this point on pg. 8 under In-depth interviews.
- **Revised text:**
  
  **In-depth interviews.** The interviews were conducted primarily for the parent study on developing a culturally adapted survey on health care quality. The interview guide included questions about individual’s health and illness experiences, healthcare practices, challenges encountered to receive health care, recommendations for improvement in services, and demographic information. While the interviews were not focused on the recruitment and consent process, many discussions provided supplementary information to the field observations.

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.

- **Response:** This information is provided with full details on pg. 6 under Data collection instruments and Sampling and enrollment procedures.
- **Revised text:**

  **Data collection instruments**
  
  The project instruments included a recruitment script, an interview guide, and a single sheet containing both information about the research and a waiver of written informed consent. All documents were developed with the goal of a fifth grade reading level. All documents (except the waiver of informed consent template that was already available in Arabic and English) were developed in English and then independently translated. Each translated document was reviewed by two translators who compared the translations to develop a best final version.

  **Sampling and enrollment procedures**
  
  We targeted the recruitment of approximately 20 participants per language for in-depth interviews. Our study employed all-female research assistants (RAs) because it is culturally more acceptable in public places in Qatar, including healthcare settings, for women to move into both
male and female waiting areas, and thus more efficient for the study. The RAs wearing an official white research coat approached patients or family members in the outpatient waiting room of the clinic to inform them about the study. Inclusion and exclusion criteria are depicted in Table 1. Recruitment sought roughly equal representation within each group by literacy (low versus high). After careful consideration of primary populations in the region, low literacy was defined as 9th grade and below and high literacy as some high school education or greater. While most linguistic groups corresponded with specific cultural groups, English serves as the lingua franca for many cultural groups in Qatar that speak English as a second language. The team exercised maximum variation sampling to achieve cultural diversity in the English language group to avoid over-representation of any specific groups. Eligible individuals who enrolled for interviews gave verbal consent that was audio recorded. These individuals received the information/waiver of written informed consent sheet at this time. This sheet included a statement that participation in the study would not impact participants’ receipt of health care. Additionally, the RAs emphasized this point when recruiting and interviewing participants. Interviews ranged from 15-60 minutes in duration.

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?

- **Response:** Individual declines when volunteered were recorded as field observations. Field observations were specifically planned in the study and covered by the IRB applications. We further note that no personally identifying information was collected; collecting reasons for refusal when volunteered is an important procedure on a routine basis for understanding the generalizability of the data acquired. Obtaining consent is impracticable in the context of a substantive number of subjects expressing a concern about vulnerability, as obtaining written consent could actually place subjects at unnecessary risk. We emphasize that all information in this report was volunteered by the subjects and not elicited through questioning by research assistants. We clarify this point on pg. 7 under Field observations.

- **Revised text:**
  
  Field observations. Field observations served as the primary source of data for this study and were conducted under the human subjects approvals for the project. The RAs collected field jottings about the environment and recruitment procedures that they expanded into full field notes after return to the research office. During recruitment, the RAs recorded detailed information regarding the number of individuals who were approached, declined, enrolled, excluded, and reasons for exclusions. The RAs discreetly recorded gender, cultural affiliation, approximate age, and reason for declining that individuals volunteered without prompting. No identifiable personal health information was collected from individuals who declined. For individuals who were enrolled, the RAs tracked how many of them retained the
information/waiver of written informed consent sheet, how many provided contact information, and how many spontaneously shared their name with the RA as an indication of trust.

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.

- Response: We provide details about accurate development of all project instruments on pg. 6 under Data collection instruments.

Revised text:

**Data collection instruments**

The project instruments included a recruitment script, an interview guide, and a single sheet containing both information about the research and a waiver of written informed consent. All documents were developed with the goal of a fifth grade reading level. All documents (except the waiver of informed consent template that was already available in Arabic and English) were developed in English and then independently translated. Each translated document was reviewed by two translators who compared the translations to develop a best final version.

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.

- Response: The methods section previously lacked detail as noted by the reviewer. The study was conducted in an ethical manner. Individual declines when volunteered were recorded as field observations. Field observations were specifically planned in the study and covered by the IRB applications. We further note that no personally identifying information was collected; collecting reasons for refusal when volunteered is an important procedure on a routine basis for understanding the generalizability of the data acquired. Obtaining consent is impracticable in the context of a substantive number of participants expressing a concern about vulnerability, as obtaining written consent could actually place them at unnecessary risk. We emphasize that all information in this report was volunteered by the individuals in the study and not elicited through questioning by research assistants. We describe the recruitment and data collection procedures on pgs. 6-7. These procedures were approved by the IRBs at three institutions.

Revised text:

**Sampling and enrollment procedures**

We targeted the recruitment of approximately 20 participants per language for in-depth interviews. Our study employed all-female research assistants (RAs) because it is culturally more acceptable in public places in Qatar, including healthcare settings, for women to move into both male and female waiting areas, and thus more efficient for the study. The RAs wearing an
official white research coat approached patients or family members in the outpatient waiting room of the clinic to inform them about the study. Inclusion and exclusion criteria are depicted in Table 1. Recruitment sought roughly equal representation within each group by literacy (low versus high). After careful consideration of primary populations in the region, low literacy was defined as 9th grade and below and high literacy as some high school education or greater. While most linguistic groups corresponded with specific cultural groups, English serves as the lingua franca for many cultural groups in Qatar that speak English as a second language. The team exercised maximum variation sampling to achieve cultural diversity in the English language group to avoid over-representation of any specific groups. Eligible individuals who enrolled for interviews gave verbal consent that was audio recorded. These individuals received the information/waiver of written informed consent sheet at this time. This sheet included a statement that participation in the study would not impact participants’ receipt of health care. Additionally, the RAs emphasized this point when recruiting and interviewing participants. Interviews ranged from 15-60 minutes in duration.

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.

- Response: We agree with the reviewer that understanding inequalities in Qatar is important. We address this issue in the results and discussion, as these are findings of the research. Demonstrating healthcare inequality among various cultural groups was not the purpose of this study. We cannot comment explicitly on the presence or absence of healthcare inequalities based on our findings. However, the idea that a sense of vulnerability could be linked to healthcare inequalities is implied by the results and discussion about vulnerability.

What kind of health care is offered by the Hamad Corporation? Is it public or private and who pays for services?

- Response: We added a statement describing this under Setting on pg. 6.
- Revised text: Health care services at HMC are subsidized and considered a governmental public service for Qatari nationals and Qatari residents.

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”.

- Response: We have moved information from the results section to the methods section on pg. 8 under In-depth interviews.
- Revised text:
The RAs interviewed participants in the outpatient waiting area of the general medicine clinic of HMC. The waiting area was chosen as the location for interviews for two reasons after a careful discussion amongst team members. First, cultural norms in Qatar dictate that interactions between genders occur in public space in view of others except for purely medical reasons or necessity depending on the task. The mostly Muslim and all-female RAs felt it would be culturally inappropriate for them to be in a private room with a man. Second, participants were interviewed while waiting for their doctor’s appointments. Since the hospital uses a number system, participants preferred to stay in the waiting area with full visibility of the number display used to call patients. When available and deemed to be culturally acceptable, the RAs occasionally used vacant patient rooms for interviews.

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?

- **Response:** We clarified the procedures regarding compensation and how it was offered on pg. 8.
- **Revised text:**

**Compensation for participation**

Participants who completed interviews were offered a pre-paid mobile phone card called a Hala Card in the amount of 100 QR= $30, as compensation for their participation. Compensation was not offered until the end of the interview because during pilot testing, concern emerged that the offer of compensation might offend individuals of financially sound backgrounds or others who were not accustomed to participating in research studies. The RAs were also concerned that offering the Hala cards at the beginning might put them under undue pressure to give compensation to individuals who left for appointments before completing the interview and who might not come back.

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?

- **Response:** Ninety subjects indicated a willingness to participate, and 84 were enrolled to participate in the interviews. We did not enroll for inclusion all 90 since the recruitment quotas had been met. This occurred because RAs were recruiting in multiple sites simultaneously. Based on the reviewers’ comments, we realize how confusing this was to readers and have simplified the text to consider the 6 dropped just as exclusions because the recruitment goals had been met. Leaving this information out is reasonable because their lack of participation due to a procedural
complication is not critical to understanding subjects’ perspectives on recruitment and informed consent.

- Revised text:
The research assistants approached 153 individuals; after eligibility exclusions and patient declinations, a total of 84 individuals (43 women and 41 men) were included as research participants (Tables 2 & 3).

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.

- Response: As described earlier, the information in question was all derived from field notes. The reasons for decline were recorded as field notes. We have provided greater clarity about the field notes collection and demonstrate all data were collected ethically. See pg. 7 under Field observations.

- Revised text:
**Field observations.** Field observations served as the primary source of data for this study and were conducted under the human subjects approvals for the project. The RAs collected field jottings about the environment and recruitment procedures that they expanded into full field notes after return to the research office. During recruitment, the RAs recorded detailed information regarding the number of individuals who were approached, declined, enrolled, excluded, and reasons for exclusions. The RAs discreetly recorded gender, cultural affiliation, approximate age, and reason for declining that individuals volunteered without prompting. No identifiable personal health information was collected from individuals who declined. For individuals who were enrolled, the RAs tracked how many of them retained the information/waiver of written informed consent sheet, how many provided contact information, and how many spontaneously shared their name with the RA as an indication of trust.

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.

- Response: IRB approval was gained from three institutions. Refer to page 6 in manuscript.

- Revised text:
  Human subjects approval for the study was granted from the University of Michigan, Weill Cornell Medical College in Qatar, and Hamad Medical Corporation (HMC).

R.2. The methods are confusing.
Major Compulsory Revisions: Not clear on what bases the authors decided to interview 20 from each language, with no calculation for the sample size, although they mentioned that around 100 cultures live in Qatar which would carry a wide range of differences. Mentioning that maximum variation sampling need to more explained and how variations were defined to use 20 for each group. If this could not be explained, it is better to mention that it is a convenient sample from the 4 main languages 20 of each as this would better describe the exact situation of the study.

- **Response:** In qualitative research, enrollment of 8-20 subjects per group of interest is generally considered adequate for reaching the criterion for saturation. In this case, we enrolled 20 or more per language group. Moreover, our sampling methodology involves intentional sampling not convenience sampling. The practice of choosing subjects in qualitative research is based on specific characteristics of the subjects. Specifically, we sought equal representation across the four most common language groups in the hospital. We sought roughly equal distribution between male and female subjects, and we sought roughly equal distribution based on literacy. Hence, the large number of exclusions, n=30. If this were a convenience sample, we would not have excluded subjects.

Major Compulsory Revisions: It is mentioned in page 10: that the authors approached 153 then the legible were 90 then 6 were dropped eligibility exclusion and patient declines. What I understood that they approached 153 then dropped those who refused and/or not legible to be included. I got confused what is the difference between those excluded earlier and those last 6 excluded later.

- **Response:** We clarified this in an earlier comment. Ninety subjects indicated a willingness to participate, and 84 were enrolled to participate in the interviews. We did not enroll for inclusion all 90 since the recruitment quotas had been met. This occurred because RAs were recruiting in multiple sites simultaneously. Based on the reviewers’ comments, we realize how confusing this was to readers and have simplified the text to consider the 6 dropped just as exclusions because the recruitment goals had been met. Leaving this information out is reasonable because their lack of participation due to a procedural complication is not critical to understanding subjects’ perspectives on recruitment and informed consent.

- **Revised text:**
The research assistants approached 153 individuals; after eligibility exclusions and patient declines, a total of 84 individuals (43 women and 41 men) were included as research participants (Tables 2 & 3).

Minor Essential Revisions: The refusal rate among Arabic speakers is a real cultural question mark as indicated in table 1 with male to female ratio 1:3 that had to be discussed more.
• Response: This is an interesting point that we hadn’t considered. We added the following to the discussion on pg. 17:

• Revised text.

We noted some interesting trends relevant to recruitment. More individuals in the Arabic language group declined participation than in any other language group, and three times more women than men in this group declined. As the number of declinations by men were close to the other groups, it is difficult to discern if there is a cultural pattern. However, the declinations among women were greater among Arabic speaking women than all other groups. One possible explanation can be found in the results from women who volunteered a reason for declining, and several individuals felt compelled to discuss with a family member whether to participate. While there were nine Qatars enrolled in the study, overall we did not notice any patterns suggesting differences between them and other Arabic speaking individuals. Future research could provide further information about gender and cultural differences.

Discretionary Revisions: having the interview done in the waiting room with the presence of others waiting in the same room is usually a difficult sitting to get the answers for the in depth interview. Private place would reduce the vulnerability that was the main finding.

• Response: This point highlights the complexity of recruitment and informed consent in Arab countries that we are trying to improve understanding about. We explain this further in the discussion section on p. 20.

• Revised text:

Cultural adaptations also meant compromising privacy during interviews to respect cultural norms around gender interaction and to alleviate participants’ fears of losing their place in queue for their appointment. Although Western ethical standards may suggest privacy to be critical, we found that conducting interviews in a public space generally did not inhibit the responses of the majority of our participants.

Minor Essential Revisions: Nothing mentioned about the number of the Qatari subjects who accepted to participate in the study. This may show how they think about being subjects of research and this also will show if they feel vulnerable like others or not.

• Response: This is an interesting question, so we conducted additional analyses to see if there were any substantive differences between the Qatars and other Arabs. There were 9 Qatars enrolled in the study. We did not note any trends from the qualitative data. We mention this in the discussion on pg. 17.

• Revised text:

While there were nine Qatars enrolled in the study, overall we did not notice any patterns suggesting differences between them and other Arabic speaking individuals. Future research could provide further information about gender and cultural differences.
Discretionary Revisions: Regarding compensation in open places I think it would be shameful as well specially for some cultures and specially if offered from woman to man in some cultures as well. Nothing mentioned if there is any deference between offering the compensation in privacy than in open areas. If this data is there it might be helpful

- **Response:** This is an interesting comment. We do not have any data to support this conclusion, but we also were not explicitly seeking such data. We added a statement to the discussion on pg. 19.

- **Revised text:**

  Unanswered questions remain as to the optimal timing and location of offering compensation.

Discretionary Revisions: In the last paragraph of the data transformation section page 9. It is mentioned that some data is based on the observation of the RAs which would be a real source of bias.

- **Response:** The RAs were systematically trained in how to conduct qualitative interviews and field observations. Field observation is a critical methodology in anthropology and utilized as a standard procedure. As the data was not dependent solely on RA observations, and RA observations are consistent with the interview data, we believe the data to be robust.

R.3. Background/1st paragraph: The authors keep using the word "Western" standards, which is a bit vague! Do you mean the standards of ICH guidelines of GCP? OR Declaration of Helsinki OR Nuremberg Code? Especially when talked about Dawson and Kass's study: " found that most researchers believed US regulations should allow more flexibility in informed consent regulations compared to current Western standards." which ones are 'Western'? The International ones? In addition, the term that is commonly used in the literature is 'International' guidelines such as in the following publication:


- **Response:** We appreciate the excellent paper suggestion which we have incorporated in the introduction and discussion. While there are of course exceptions such as the citation offered by the reviewer, the predominant terminology used in the literature we found is Western and non-Western. In addition, the researchers are being held accountable to Western standards. While we considered “North American” where many of these principles were promulgated, we believe in this context Western is preferred to North American. As suggested, we have clarified what is meant. We currently use the terminology of Western research principles.

- **Revised text:**
Fadare and Porteri illustrate how Nigeria incorporates cultural considerations for human subjects in its national research guidelines in accordance with the Helsinki Declaration of the World Medical Association and the International Ethical Guidelines for Biomedical Research of the Council for International Organizations of Medical Sciences.

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We agree with Fadare and Porteri’s position, who state, “While international research ethics guidelines have an important role in setting basic and acceptable standards, there remains a window for local adaptation, especially in resource-poor and culturally diverse countries.”

Background/3rd paragraphs: when talking about the 10 articles found in literature: I take it that these are references 13-21 as denoted in the text. Well, these are 9 not 10. Please add the 10th reference in the text.

- **Response:** We have clarified the text to make it clear which ten articles we are referring to. We also added another reference per the reviewers’ suggestion, for a total of 11 articles.

Background/3rd paragraph and throughout the Background: It is still unclear to the reader if we are talking about 'research' or 'clinical care'. In this paragraph, it is confusing as some of the studies searched in the literature where described to have had discussed "influence of cultural idiosyncrasies on the level of disclosure and the informed consent process in clinical care" while the last sentence of the same paragraph talked about "None of the articles addressed subject reactions to compensation for participating in research" !!

- **Response:** We have clarified that there is little information on this topic, and of the information that exists, it is virtually all about clinical care. As we articulate, there is only one study providing empirical data on recruitment and informed consent particular to the Middle East and Arabian Gulf. This is exactly the issue we found when searching the literature. That there really weren’t many articles addressing the PROCESS of recruitment and consent, but tended to 1) be editorials/thought pieces, 2) a study of people’s thoughts about informed consent, and/or 3) a discussion about informed consent in clinical care. This illustrates why this research is filling an important gap.

3. Are the data sound?

R.1. 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.
• Response: Data cleaning is not exclusive to quantitative data. In qualitative research, after data are transcribed, data also need to be “cleaned”. This is done because the transcriptionist may make errors during transcription. Cleaning in the qualitative context refers to a second person listening to the audio recording, checking the accuracy of transcription, and making corrections where there is an error. While not all projects do so because of cost, this is an extra step we employed to ensure the integrity of our qualitative data. While we do provide percentages and descriptive statistics of the quantitative demographic data, we do not calculate inferential statistics on the qualitative data, as this would not be appropriate. We have clarified this in the text. See pg. 9 under Data analysis.

• Revised text:
To make the large qualitative dataset manageable, data transformation was employed whereby the coded qualitative themes were counted. Major codes were used to generate a summary for review, and then the search was refined for output by language and gender. After the initial analysis of the textual data from the transcripts and field observations, and numerical data from the demographic instrument and recruitment procedures, we integrated these diverse sources of data from observations and transcripts into a narrative format for the results.

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.

• Response: The focus of this paper is on observations regarding the process of recruitment and informed consent, and not on the content of the interview questions. As there are so many pages of data, including information about other emerging themes is beyond the scope of the paper, and the subject of four other papers currently in development. See pg. 8 under In-depth interviews.

• Revised text:
The interview guide included questions about individual’s health and illness experiences, healthcare practices, challenges encountered to receive health care, recommendations for improvement in services, and demographic information. While the interviews were not focused on the recruitment and consent process, many discussions provided supplementary information to the field observations.

R.2. Although the sample size is convenient and data could not be generalized still the data is carrying new knowledge which is sound.

• Response: As mentioned above, our sampling methodology involves intentional sampling not convenience sampling. The practice of choosing subjects in qualitative research is based on specific characteristics of the subjects. Specifically, we sought
equal representation across the four most common language groups in the hospital. We sought roughly equal distribution between male and female subjects, and we sought roughly equal distribution based on literacy. Hence, the large number of exclusions, n=30.

R.3. Results section/Motivation to participate: In some instances, the authors mentioned the nationality of the interviewee (e.f. an Indian woman stated...) while this was not mentioned in the rest. I think out of consistency and importance to link to motivation to participate, this should be included.

• Response: We believe providing the nationality of subjects is important since we are providing cross-cultural comparisons. We provided the nationality as consistently as possible. However, we withheld nationality for specific controversial statements as we did not want to implicate a particular cultural group when negative comments were made.

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

R.2. Major Compulsory Revisions:
The manuscript does not really adhere to the relevant standards for reporting and data deposition.

Response: Due to the relatively complex methodology of research, the previous draft required clarifications. We feel the paper now fully complies with relative standards for reporting and data deposition. Specifically,

- The project received IRB approval from three institutions. The IRB applications included specific information regarding protecting confidentially, reporting, and data storage.
- We have composed our report in the usual format of background, methods, results, and discussion. We have followed the specific structure expected of qualitative study and provided full disclosure of our methodology. The format followed is typical for a qualitative study.

The result section is the most confusing section. It includes in some parts e.g. page 13 the first paragraph is mainly methodology.

• Response: We moved this information from the results section to the methods section. See p. 8 under In-depth interviews.
• Revised text:
The RAs interviewed participants in the outpatient waiting area of the general medicine clinic of HMC. The waiting area was chosen as the location for interviews for two reasons after a careful discussion amongst team members. First, cultural norms in Qatar dictate that interactions between genders occur in public space in view of others except for purely medical reasons or necessity depending on the task. The mostly Muslim and all-female RAs felt it would be culturally inappropriate for them to be in a private room with a man. Second, participants were interviewed while waiting for their doctor’s appointments. Since the hospital uses a number system, participants preferred to stay in the waiting area with full visibility of the number display used to call patients. When available and deemed to be culturally acceptable, the RAs occasionally used vacant patient rooms for interviews.

In the same page 13 the second paragraph (having all the RAs females) and last paragraph (using crowded waiting rooms) are mainly limitation rather than results.

- Response: As suggested, this information has been incorporated into the paragraph on limitations. See pg. 22.
- Revised text:
  All studies have possible limitations. As the study was conducted in one healthcare 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. 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.

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

R.1. 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.
• Response: We have clarified our research methodology in the Methods Section on pg. 9 of the manuscript under Data analysis. As mentioned in our earlier comments, we also clarified our use of RA observations.

• Revised text:

Data analysis

Based on the RA observations, we calculated percentages of participation as well as descriptive statistics of the enrolled participants. The audio-recorded interviews were transcribed in the native language, and the transcription checked by a second reviewer. To protect the privacy of individuals, place names and any possible identifying information were changed. For Arabic, Urdu, and Hindi, the transcripts were independently translated into English, compared for similarity, and differences were reconciled by consulting with a third bilingual researcher. Iteratively, three team members (AK, HE, and MF) immersed themselves in the data by reading and open coding transcripts independently to develop preliminary codes. They reviewed and refined the codes and definitions during regular meetings. Emergent themes were incorporated into the coding scheme, and coding definitions were refined using general consensus of team members. Two analysts (AK and HE) independently coded and compared the coding of two transcripts for calibration, while a third (MF) resolved any disagreements. With calibration complete, the primary analyst (AK) coded all remaining transcripts and had weekly consultations with team members to clarify any concerns. The qualitative analysis software ATLAS.ti was used for data management and analysis procedures.

To make the large qualitative dataset manageable, data transformation was employed whereby the coded qualitative themes were counted. Major codes were used to generate a summary for review, and then the search was refined for output by language and gender. After the initial analysis of the textual data from the transcripts and field observations, and numerical data from the demographic instrument and recruitment procedures, we integrated these diverse sources of data from observations and transcripts into a narrative format for the results.

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.

• Response: We have completely re-written the results with careful consideration of all the suggestions, and believe that these issues are now clear. The revisions involved making it more clear how the quotations were being used to support specific findings.

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.
• Response: We have clarified that the focus of this paper is to delineate issues related to recruitment and informed consent procedures for research, and not on the participant responses to the interview questions, including data about the healthcare system. The emphasis is on understanding recruitment and informed consent procedures. We emphasize that the interviews about health care quality are the focus for the parent study.

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.

• Response: We agree that many of the participants in this research are from groups that are socially marginalized. Specifically, we sought roughly equal distribution between low and high literacy subjects. The research findings help give a voice to concerns of these individuals rather than just inferring it. We stand by the claim that a sense of vulnerability emerged DURING (note we have changed from through) the recruitment, informed consent, enrollment, and compensation processes. We believe the field observations, examples, and quotations support this argument. Refer to pg. 14 under Vulnerability.

• Revised text:

**Vulnerability**

Despite many individuals being forthcoming with information about their experiences, a sense of vulnerability from participating emerged as a recurring theme throughout the recruitment and informed consent process among a sizeable minority of participants.

**Name sharing**

Through the normal discourse in a conversational style approach to interviewing, conversations sometimes shifted to the participant’s name. Most participants (n=71, 85%) shared their names with the RAs, with men (n=36) and women (n=35) equally sharing. However, a minority of participants (n=13, 15%) did not share with some expressing concerns about revealing their identity; participants in the Hindi language group (n=8) were proportionately the least likely to share their name.

**Interview recording**

Individuals had a range of responses upon learning that the interviews would be recorded. During recruitment, some individuals declined to participate outright, and others consented after assurance from the RAs that the recordings would be deleted and that participants were not required to reveal their identity. Concern about the recording was also raised during the interview phase. In addition to the nine women who expressed concern during
recruitment and informed consent as noted earlier, an additional five women expressed concern during the actual interview. There were concerns about the recording in all language groups, with the most concern expressed by individuals in the Arabic (n=8) and Hindi (n=7) language groups.

Some participants requested the RAs to pause the recording at different times during the interview, as illustrated by a Qatari man: “Before- (I) raise this, I want to tell you a word, don’t record it.” An Indian woman paused the recorder every time she wanted to share a negative experience: “No. I don’t want all this to be recorded. I believe you but please don’t record. You can write down if you want.” A British woman used hand gestures to convey negative feelings and did not complete her sentences, as observed by the RA: “she...(left her) sentences incomplete...and (used) gestures to avoid saying. . . words. The interviewer had to say these words so that these expressions also get recorded. . . She spoke more openly when (the) conversation was not being recorded.” Some participants shared more about their experiences after the interview was finished and the recorders were turned off. For example, a Pakistani woman shared a negative experience, but would not allow the RA to turn the recorder back on, even though she had no objection to the RA writing about it in her presence.

Concern about negative consequences

A few people expressed concern about participation in the study resulting in negative consequences for them or their families. Among all 153 individuals approached, four women and three men expressed this concern, with the issue being raised mainly in the Hindi language group (n=5), followed by the Urdu (n=1) and English (n=1) groups, and no observed references in the Arabic group. Concern about negative repercussions was expressed at multiple points during the interview process, specifically during recruitment, the interview, member checking, and compensation.

During the interviews, a few participants were cautious in voicing negative feedback about the healthcare system. A British woman apologized for giving generalized answers, as she was worried about where her answers might end up. A Pakistani woman wondered about her husband’s job being impacted. An Indian woman was cooperative, but was not willing to fully share when the recorder was on ‘because they may consider it as a complaint and something will happen to us.’ She incidentally ran into the RA a few days after the interview, and inquired about sharing further information.

Concerns about negative consequences emerged even with inquiries about member checking as two participants refused to provide their contact information to receive the study results. A Pakistani man cited concern about his visa being cancelled, and a Bangladeshi man seemed conflicted and eventually, he decided not to share his address: “No, if I give my address it is not good no? ...If something wrong happens to me then it is not correct to give it no?...I will not give. I have all addresses. I have (in) Bangladesh, (in) Qatar also...I am (a) company person (company worker)...Now if.... I give you my address, then what will people say? Eating food of Qatar and not saying good to it. He is saying that India, Bangla(desh) is good...That’s why I don’t want to give.” During the compensation phase, two participants were concerned that accepting the Hala Card would result in negative ramifications
as expressed by a Nepali man, “We will not fall into trouble because of this, no?” Even though the majority of participants were willing to give their suggestions for improving healthcare, a minority of participants specifically confided a sense of vulnerability.

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?

- **Response:** While the consent form did state that the interview will be recorded, we still found that a minority of participants confided a sense of vulnerability particularly related to the interview recording. We believe the field observations, examples, and quotations support this argument. We clarify this on pg. 14 under Vulnerability.

- **Revised text:**

  *Interview recording*
  
  Individuals had a range of responses upon learning that the interviews would be recorded. During recruitment, some individuals declined to participate outright, and others consented after assurance from the RAs that the recordings would be deleted and that participants were not required to reveal their identity. Concern about the recording was also raised during the interview phase. In addition to the nine women who expressed concern during recruitment and informed consent as noted earlier, an additional five women expressed concern during the actual interview. There were concerns about recording in all language groups, with the most concern expressed by individuals in the Arabic (n=8) and Hindi (n=7) language groups.

  Some participants requested the RAs to pause the recording at different times during the interview, as illustrated by a Qatari man: “Before- (I) raise this, I want to tell you a word, don’t record it.” An Indian woman paused the recorder every time she wanted to share a negative experience: “No. I don’t want all this to be recorded. I believe you but please don’t record. You can write down if you want.” A British woman used hand gestures to convey negative feelings and did not complete her sentences, as observed by the RA: “she...(left her) sentences incomplete…and (used) gestures to avoid saying. . . words. The interviewer had to say these words so that these expressions also get recorded. . . She spoke more openly when (the) conversation was not being recorded.” Some participants shared more about their experiences after the interview was finished and the recorders were turned off. For example, a Pakistani woman shared a negative experience, but would not allow the RA to turn the recorder back on, even though she had no objection to the RA writing about it in her presence.

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. R.2. Discussion section is a nice section although the authors sometimes jump to conclusions that is not really measured well.

- **Response:** We have revised the discussion and conclusion sections to address these concerns. See pgs. 17-22 in the manuscript.
- **Revised text:**

**Discussion**

There are few empirical studies on recruitment and informed consent in countries other than the United States and Western Europe, with none in particular to the Middle East and Arabian Gulf other than a single study with adolescent refugees. To our knowledge, this is the first study in the Middle East and Arabian Gulf to provide empirical data on recruitment and informed consent procedures in a general adult population invited to participate in research. Our study also provides the only empirical data available about the responses of participants in the Middle East and Arabian Gulf to member checking and compensation procedures.

We noted some interesting trends relevant to recruitment. More individuals in the Arabic language group declined participation than in any other language group, and three times more women than men in this group declined. As the number of declinations by men were close to the other groups, it is difficult to discern if there is a cultural pattern. However, the declinations among women were greater among Arabic speaking women than all other groups. One possible explanation can be found in the results from women who volunteered a reason for declining, and several individuals felt compelled to discuss with a family member whether to participate. While there were nine Qataris enrolled in the study, overall we did not notice any patterns suggesting differences between them and other Arabic speaking individuals. Future research could provide further information about gender and cultural differences.

We believe our success in recruitment and enrollment was possible because we culturally adapted data collection procedures. We utilized the expertise of the Qatari research team members to ensure implementation of recruitment and consent procedures that were culturally adapted to Qatar’s cultural, political, and social practices. We also employed culturally competent and language concordant RAs familiar with the cultural dynamics of individuals living in Qatar. We employed all-female RAs primarily to avoid breaching cultural sensitivities about gender interactions. Utilizing male RAs to recruit female individuals is more likely to affront cultural sensitivities about gender interactions and thus have a negative impact on the research, compared to female RAs recruiting male individuals. Although we had to recruit in gender specific waiting areas, having the female RAs wear white research coats conveyed their
official status and helped to temper cultural guidelines of gender separation. Our RAs were also cognizant of the fact that in many non-Western collectivist societies, individuals may be bound to others in a web of social relations which can impact decision-making processes. Thus, the RAs allowed individuals, especially women, to seek input from family members before participation, and they allowed family members to contribute to the interviews as “incidental research participants” if acceptable to the enrolled participant. While the team considered whether incidental research participants should provide separate informed consent, the team felt this would be too burdensome and disruptive to the discussions as they naturally unfolded.

Our study is the first to offer empirical data about the responses of participants in Qatar to compensation and member checking procedures. Most returned to complete the interview despite having no knowledge about the compensation, although there were varying degrees of interest in accepting the compensation. The data demonstrated that there were some participants who were taken aback and adamantly declined compensation. Unanswered questions remain as to the optimal timing and location of offering compensation. As for the member checking invitation, most participants were willing to provide contact information to receive study results. There was a difference between groups, with participants in the Arabic group most often sharing their contact information and the Hindi group least often doing so. This may reflect a greater sense of vulnerability among participants in the Hindi group.

Approximately half of all recruited individuals had low literacy, but we overcame this by having the RAs work directly with participants in their own language. Generally, we did not encounter difficulties obtaining informed consent from low literacy individuals in Qatar, in contrast to previous findings. Although most participants retained the information/waiver of written informed consent sheet, we are unsure if the others were just not interested, preferred not to retain any linkage to the study, could not read, or had other reasons. We obtained verbal consent instead of written informed consent because in many non-Western societies, signatures are usually reserved for formal transactions associated with major life events. Requests for written consent could rouse suspicion or concern, and asking illiterate participants to sign documents they are unable to read or fully comprehend can be threatening or imply lack of trust. Signatures would leave a record of participation, so individuals who preferred anonymity would have been precluded from participating. Interestingly however, we found that enrolled participants did not hesitate to provide their verbal consent despite it being audio-recorded. If executed as intended, written and verbal consent are ethically equivalent; thus, written consent shouldn’t be necessary. The willingness to provide verbal consent while hesitating to provide written consent illustrates the cultural aversion to signing documents.

Cultural adaptations also meant compromising privacy during interviews to respect cultural norms around gender interaction and to alleviate participants’ fears of losing their place in queue for their appointment. Although Western ethical standards may suggest privacy to be critical, we found that conducting interviews in a public space generally did not inhibit the responses of the majority of our participants. Despite the gender norms of the country, we found that in the five instances of female RAs interviewing male participants in a room, individual preferences ultimately determined whether a participant was comfortable being
interviewed in private. Gender norms may not have applied as rigidly since the RAs were viewed as part of the healthcare staff and because it is more acceptable for men and women to interact in healthcare settings when there is no reasonable alternative.

Although many participants openly discussed their opinion of the healthcare system, a few expressed trepidation that their participation might result in negative consequences for them or their families. We suspect that vulnerability fears may be due to a number of reasons. First, many of the participants were expatriate workers from countries where human rights cannot be assumed, and this lens could inevitably carry into Qatar. Second, there is relatively less public knowledge about research participation in the Arabian Gulf and in many of the developing countries that the expatriates call home, so lack of familiarity with research could cause mistrust. Third, it is possible that some individuals may have had negative experiences in society, e.g. in the workplace, and through this lens interpreted that their research experiences might be similar. Fourth, particularly in the case of a working spouse, some may not want to contradict or compromise preferences or policies of a spouse’s employer. The RAs quickly learned the importance of confidentiality of personal information, and adapted by emphasizing that private information would not be collected and that information given could not be linked to the participants. Regardless of the low probability of negative implications for such individuals, it is important for researchers working in the Arabian Gulf, especially given so many expatriates, to be aware of how people may perceive the consequences of participating in research. We recommend that research procedures be designed to address the underlying concerns that participants, even though a minority, may have about vulnerability throughout all stages of the process. Overall, we did find that many participants felt empowered to provide information to the researchers and appreciated the opportunity to discuss their experiences and offer recommendations to improve the Qatari health system.

Investigators conducting international health research may face multiple challenges during the research process, particularly if Western ethical standards are used without consideration of local traditions and social contexts. Table 6 provides recommendations for researchers conducting research in the Arabian Gulf Region. There have been many efforts to establish national research ethics guidelines in the Middle East and Arabian Gulf, with most of the Arabian Gulf countries making more advanced steps than other countries in the Middle East. Researchers are expected to balance universal ethical standards with local standards; therefore, ethical research principles should be upheld in as much as they are appropriate to the local context. We agree with Fadare and Porteri’s position, who state, “While international research ethics guidelines have an important role in setting basic and acceptable standards, there remains a window for local adaptation, especially in resource-poor and culturally diverse countries.”

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. 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.

**Conclusion**

This study provides empirical data on the recruitment, informed consent, and other research procedures that can inform others who are interested in conducting research in the Middle East and Arabian Gulf Region. Moreover, the investigation illustrates how potential research participants perceive research participation. With particular cultural adaptations, the investigation achieved a very good participation rate. Given the limited literature, 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 offering further cultural adaptations. In conclusion, Western ethical research principles were applicable, but required flexibility and culturally informed adaptations. The Western ethics approach to recruitment and informed consent in this region of the world is compatible but with caveats that should be considered by researchers and human subjects regulators.

Major Compulsory Revisions: Page 21 first paragraph: the authors concluded that the interviews successfully occurred in public place without comparing the outcome of interviews occurred in public places versus in private places

- **Response:** As described earlier, the choice to conduct the interviews in a public place was based on feasibility issues. It is appropriate to describe what we did and how it worked. We do not make any conclusions that this approach is better, as this would require a comparison with a private place. We explain this further in the discussion section on p. 20.
- **Revised text:**

  Cultural adaptations also meant compromising privacy during interviews to respect cultural norms around gender interaction and to alleviate participants’ fears of losing their place in queue for their appointment. Although Western ethical standards may suggest privacy to be critical, we found that conducting interviews in a public space generally did not inhibit the responses of the majority of our participants.

Major Compulsory Revisions: The main finding was the vulnerability as mentioned by the authors. However vulnerability is a very general term that need to be carefully used. I am not sure also to what extent the subjects are vulnerable in Qatar and if they are vulnerable because they are expatiate and if this would convey the message that just by being expatriate in Qatar
you are vulnerable and need more protection?? If this is true this is only in research or generally and to what extent?

- **Response:** We attempted to explain this further in the discussion section. As stated earlier, we stand by the claim that a sense of vulnerability emerged DURING (note we have changed from through) the recruitment, informed consent, enrollment, and compensation processes. We believe the field observations, examples, and quotations support this argument. Refer to pg. 20 in the Discussion.

- **Revised text:**
  Although many participants openly discussed their opinion of the healthcare system, a few expressed trepidation that their participation might result in negative consequences for them or their families. We suspect that vulnerability fears may be due to a number of reasons. First, many of the participants were expatriate workers from countries where human rights cannot be assumed, and this lens could inevitably carry into Qatar. Second, there is relatively less public knowledge about research participation in the Arabian Gulf and in many of the developing countries that the expatriates call home, so lack of familiarity with research could cause mistrust. Third, it is possible that some individuals may have had negative experiences in society, e.g. in the workplace, and through this lens interpreted that their research experiences might be similar. Fourth, particularly in the case of a working spouse, some may not want to contradict or compromise preferences or policies of a spouse’s employer. The RAs quickly learned the importance of confidentiality of personal information, and adapted by emphasizing that private information would not be collected and that information given could not be linked to the participants. Regardless of the low probability of negative implications for such individuals, it is important for researchers working in the Arabian Gulf, especially given so many expatriates, to be aware of how people may perceive the consequences of participating in research. We recommend that research procedures be designed to address the underlying concerns that participants, even though a minority, may have about vulnerability throughout all stages of the process. Overall, we did find that many participants felt empowered to provide information to the researchers and appreciated the opportunity to discuss their experiences and offer recommendations to improve the Qatari health system.

R.3. Discussion: A typo--> please be consistent in referencing. You mention here Khan and Tamimi, 2009 while the rest are numbers e.g. [17].

- **Response:** We corrected this oversight.


- **Response:** As stated earlier, the predominant terminology used in the literature is Western and non-Western. While we consider North America where many of these principles were promulgated, we believe Western is preferred to North American. As
suggested, we have clarified what is meant. We currently use the terminology of Western research principles, and thus no reference is required.

Discussion/statement:" As in many studies, the skills and the charisma of the RAs can influence recruitment rates" also needs referencing and more clarification in light of previous studies as mentioned.

- Response: We removed this statement from the manuscript.

In general, I like Table 5. However, I think participants in addition to confidentiality, should have been assured that their participation in the study would never affect their receipt of health care, despite any negative comments that may have been mentioned during the interview.

- Response: Our consent form included a statement that participation in the study would not impact participants’ receipt of health care. Additionally, our RAs emphasized this point when recruiting and interviewing participants.
- Revised text. The waiver of written informed consent form included a statement that participation in the study would not impact participants’ receipt of health care. Additionally, the RAs emphasized this point when recruiting and interviewing participants.

6. Are limitations of the work clearly stated?

R.1. 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.
R.2. The limitation section include the inability to generalize the data because of the sample size which is true as it is mostly convenient sample. However, many limitations are included in the result section and as I mentioned earlier.

- Response: The conflicting viewpoints of these reviewers illustrate the challenge we have about trying to provide sufficient information with terminology that is understood, but not confusing to reviewers who may not be familiar with qualitative methodology. We agree with reviewer #1, and clarify the risk of making inferences about the generalizability of the positions stated by participants.
- Revised text. Caution should be exercised in generalizing the prevalence of the various positions stated since participants were not randomly sampled.

R.3. The title should reflect that the 'recruitment and informed consent' we are talking about here are for "Research" NOT "Medical Practice". Important! While reading through the text and
up until I got to the end of Background section, I was still confused whether this is asking about IC of research or medical procedures.

- **Response:** We clarify this in the title: *Recruitment and informed consent of research participants in Doha, Qatar*, and further in the background section of the manuscript on pg. 5.
- **Revised text:**
  Surprisingly, only two of these 11 papers provide a glimpse of empirical data on outcomes of recruitment and informed consent procedures for research with Arab populations.

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The purpose of this paper is to address the gap in the literature on recruitment and informed consent for research based on the project team’s experience and observations in a multistage research project about health care quality assessment in Qatar.

Methods/data collection procedures: It is not clear to the reader whether these interviews were for the sake of this study OR for the main goal of the whole project which is to develop a self administered tool to evaluate health services. It is confusing to the reader. I think this should be re-written in a clearer format.

- **Response:** We clarified this earlier. For specifics on the larger study and relationships between the two, see pg. 5 under Design and pg. 7 under Data collection procedures in manuscript.
- **Revised text:**

*Design (pg. 5)*

This research utilized an ethnographic approach to conduct a qualitative study as one component within a multistage, mixed methods parent study focused on developing a self-administered healthcare quality assessment instrument in the four languages of Arabic, English, Hindi, and Urdu. Briefly, the project involved cultural adaptation of the adult survey of the Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS). The second stage of the parent study involved qualitative interviews regarding patient perspectives on health care quality. Extensive field notes were collected about recruitment and informed consent procedures during the recruitment for these interviews. Human subjects approval for the study was granted from the University of Michigan, Weill Cornell Medical College in Qatar, and Hamad Medical Corporation (HMC).

*Data collection procedures (pg. 7)*

*Field observations.* Field observations served as the primary source of data for this study and were conducted under the human subjects approvals for the project. The RAs collected field jottings [28] about the environment and recruitment procedures that they expanded into full field notes after return to the research office. During recruitment, the RAs recorded detailed information regarding the number of individuals who were approached, declined, enrolled, excluded, and reasons for exclusions. The RAs discreetly recorded gender, cultural affiliation,
approximate age, and reason for declining that individuals volunteered without prompting. No identifiable personal health information was collected from individuals who declined. For individuals who were enrolled, the RAs tracked how many of them retained the information/waiver of written informed consent sheet, how many provided contact information, and how many spontaneously shared their name with the RA as an indication of trust.

**In-depth interviews.** The interviews were conducted primarily for the parent study on developing a culturally adapted survey on health care quality. The interview guide included questions about individual’s health and illness experiences, healthcare practices, challenges encountered to receive health care, recommendations for improvement in services, and demographic information. While the interviews were not focused on the recruitment and consent process, many discussions provided supplementary information to the field observations. The RAs interviewed participants in the outpatient waiting area of the general medicine clinic of HMC.

Methods: How long did the interview last for in average? Please add.

- **Response:** We added the following statement on pg. 7 in the section on Sampling and enrollment procedures.
- **Revised text:** Interviews ranged from 15-60 minutes in duration.

Results/Informed consent process: It is not clear what you mean by "no meaningful difference"! Do you mean they were equal or what?

- **Response:** We have removed the confusing wording. See pg. 12.
- **Revised text:** Of the 78 individuals tracked, 60 (77%) chose to keep the information/waiver of written informed consent sheet, and there was no apparent difference by language or gender.

Results/Interview recording: The way I understood the objective of this study is to qualitatively describe reasons observed and/or reported for declining participation- to the main large project- by approached individuals. The main large project was a self-administered questionnaire, wasn't it? So, it did not include tape-recording. I think this is again confusing to the reader! By this part, the researchers are describing the vulnerability of subjects to the qualitative part which included recording not the large project.

- **Response:** Our study is a very large and complex mixed methods study. For this paper, we opted to minimize the overview of the other project as we felt it would confuse the reader as to what component of the larger project we are discussing. Since the reviewers asked for further information about the entire project, we have provided it as requested. The interviews were recorded.
We clarified this earlier. For specifics on the larger study and relationships between the two, see pg. 5 under Design and pg. 7 under Data collection procedures in manuscript.

• Revised text:

**Design (pg. 5)**

This research utilized an ethnographic approach to conduct a qualitative study as one component within a multistage, mixed methods parent study focused on developing a self-administered healthcare quality assessment instrument in the four languages of Arabic, English, Hindi, and Urdu. Briefly, the project involved cultural adaptation of the adult survey of the Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS). The second stage of the parent study involved qualitative interviews regarding patient perspectives on health care quality. Extensive field notes were collected about recruitment and informed consent procedures during the recruitment for these interviews. Human subjects approval for the study was granted from the University of Michigan, Weill Cornell Medical College in Qatar, and Hamad Medical Corporation (HMC).

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**In-depth interviews.** The interviews were conducted primarily for the parent study on developing a culturally adapted survey on health care quality. The interview guide included questions about individual’s health and illness experiences, healthcare practices, challenges encountered to receive health care, recommendations for improvement in services, and demographic information. While the interviews were not focused on the recruitment and consent process, many discussions provided supplementary information to the field observations. The RAs interviewed participants in the outpatient waiting area of the general medicine clinic of HMC.

Results/Interview recording/paragraph 2/Line 2: wanted to share (not shared).

• Response: We corrected this.
Results/Negative consequences: It is obvious from the quotes that the fear of negative consequences was observed only among the non-Qatari group. Were there any among Qatari group? A point that is worth mentioning and discussing. Again this also applies to the Discussion section when the authors discussed vulnerability. Was this only linked to the Arabic language group too? Only expatriate workers? What about the Qatari participants. I think this is important since the study is being conducted in Qatar.

- **Response**: This is an interesting point, so we conducted additional analyses to see if there was any suggestion of differences between the Qatari and other groups. There were 9 Qatari enrolled in the study. We did not note any patterns suggesting differences from the qualitative data. We did not conduct inferential statistics as this would be inappropriate based on our sampling strategy.

- **Revised text**:

  While there were nine Qatari enrolled in the study, overall we did not notice any patterns suggesting differences between them and other Arabic speaking individuals. Future research could provide further information about gender and cultural differences.

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Although many participants openly discussed their opinion of the healthcare system, a few expressed trepidation that their participation might result in negative consequences for them or their families. We suspect that vulnerability fears may be due to a number of reasons. First, many of the participants were expatriate workers from countries where human rights cannot be assumed, and this lens could inevitably carry into Qatar. Second, there is relatively less public knowledge about research participation in the Arabian Gulf and in many of the developing countries that the expatriates call home, so lack of familiarity with research could cause mistrust. Third, it is possible that some individuals may have had negative experiences in society, e.g. in the workplace, and through this lens interpreted that their research experiences might be similar. Fourth, particularly in the case of a working spouse, some may not want to contradict or compromise preferences or policies of a spouse’s employer. The RAs quickly learned the importance of confidentiality of personal information, and adapted by emphasizing that private information would not be collected and that information given could not be linked to the participants. Regardless of the low probability of negative implications for such individuals, it is important for researchers working in the Arabian Gulf, especially given so many expatriates, to be aware of how people may perceive the consequences of participating in research. We recommend that research procedures be designed to address the underlying concerns that participants, even though a minority, may have about vulnerability throughout all stages of the process.

Discussion: As for the first sentence, I found through my search few papers that talked about ICF and consent preferences in some Arab countries. I believe that these could be a useful addition to the discussion:

- **Response:** This paper is a more recent one that did not appear in our literature search. We have incorporated it into the manuscript.
- **Revised text:** There have been many efforts to establish national research ethics guidelines in the Middle East and Arabian Gulf, with most of the Arabian Gulf countries making more advanced steps than other countries in the Middle East.

2. Mamoun Ahram1, Areej Othman2 and Manal Shahrouri3. Public support and consent preference for biomedical research and biobanking in Jordan. European Journal of Human Genetics advance online publication 12 September 2012; doi: 10.1038/ejhg.2012.213

- **Response:** This paper is a more recent one that did not appear in our literature search. We have incorporated it into the manuscript.
- **Revised text:** In the Middle East and Arabian Gulf, only a limited literature informs the debate about culturally adapted approaches to recruitment and informed consent. A search of PubMed’s extensive database of medical literature, of Google and Google Scholar’s archives, and of Global Health Database, Articles Plus, PsycInfo, Social Sciences Citation Index/Web of Science, and Scopus’s depository of resources revealed only 11 articles addressing methodological procedures of recruitment and informed consent for research in this region. Emanating from Qatar, Oman, Egypt, and other countries in the Middle East and Arabian Gulf, these papers provide insight on six topics: (1) influence of cultural idiosyncrasies on the level of disclosure and the informed consent process in clinical care; (2) differences in interpreting ethical research principles; (3) challenges implementing Western research principles, particularly informed consent; (4) difficulty of obtaining informed consent from illiterate individuals; (5) difficulty with recruitment, and (6) perception about informed consent specific to biobanking research.


- **Response:** This paper addresses informed consent in a clinical setting, and not informed consent for research. We therefore did not include it because it is beyond the scope of our study.


- **Response:** We incorporated this citation earlier. Thank you.
Discussion/regarding statement "Fourth, particularly in the case of a working spouse, some would not want to contradict or compromise preferences or policies of a spouse’s employer." did the authors collect information about the interviewee’s spouses?? This has not been mentioned in the Methods/Results sections.

- **Response:** We did not collect information about an interviewee’s spouse, but given that many interviewees were expatriate workers, it would behoove us to ignore this issue and how it relates to research participation.

Discussion/the last sentence: "This speaks to genuine efforts by Qatari society to be open to consumers and to reflect on making improvements to the system" How come the authors are talking about Qatari society and most of the participants were non-Qatari! This is also obvious from the respondents in Table 4.

- **Response:** As we point out in the background, nearly 80% of the population in Qatar are non-Qatari. So, while Qataris make all decisions in the country, the expatriate workers have the direct effects of the policies implemented. Thus, it is appropriate to talk about Qatari Society, where the rules are set, and to talk about participants who are non-Qatari. Qataris represent a minority in their own country.

The Discussion part involves a repletion to the Results and it lacks "discussing" the results in light of international literature.

- **Response:** We have revised the discussion to address these concerns. See pgs. 17-22 in the manuscript.
- **Revised text:**

**Discussion**

There are few empirical studies on recruitment and informed consent in countries other than the United States and Western Europe, with none in particular to the Middle East and Arabian Gulf other than a single study with adolescent refugees. To our knowledge, this is the first study in the Middle East and Arabian Gulf to provide empirical data on recruitment and informed consent procedures in a general adult population invited to participate in research. Our study also provides the only empirical data available about the responses of participants in the Middle East and Arabian Gulf to member checking and compensation procedures.

We noted some interesting trends relevant to recruitment. More individuals in the Arabic language group declined participation than in any other language group, and three times more women than men in this group declined. As the number of declinations by men were close to the other groups, it is difficult to discern if there is a cultural pattern. However, the declinations among women were greater among Arabic speaking women than all other groups. One possible explanation can be found in the results from women who volunteered a reason for declining, and several individuals felt compelled to discuss with a family member whether to participate.
While there were nine Qataris enrolled in the study, overall we did not notice any patterns suggesting differences between them and other Arabic speaking individuals. Future research could provide further information about gender and cultural differences.

We believe our success in recruitment and enrollment was possible because we culturally adapted data collection procedures. We utilized the expertise of the Qatari research team members to ensure implementation of recruitment and consent procedures that were culturally adapted to Qatar’s cultural, political, and social practices. We also employed culturally competent and language concordant RAs familiar with the cultural dynamics of individuals living in Qatar. We employed all-female RAs primarily to avoid breaching cultural sensitivities about gender interactions. Utilizing male RAs to recruit female individuals is more likely to affront cultural sensitivities about gender interactions and thus have a negative impact on the research, compared to female RAs recruiting male individuals. Although we had to recruit in gender specific waiting areas, having the female RAs wear white research coats conveyed their official status and helped to temper cultural guidelines of gender separation. Our RAs were also cognizant of the fact that in many non-Western collectivist societies, individuals may be bound to others in a web of social relations which can impact decision-making processes. Thus, the RAs allowed individuals, especially women, to seek input from family members before participation, and they allowed family members to contribute to the interviews as “incidental research participants” if acceptable to the enrolled participant. While the team considered whether incidental research participants should provide separate informed consent, the team felt this would be too burdensome and disruptive to the discussions as they naturally unfolded.

Our study is the first to offer empirical data about the responses of participants in Qatar to compensation and member checking procedures. Most returned to complete the interview despite having no knowledge about the compensation, although there were varying degrees of interest in accepting the compensation. The data demonstrated that there were some participants who were taken aback and adamantly declined compensation. Unanswered questions remain as to the optimal timing and location of offering compensation. As for the member checking invitation, most participants were willing to provide contact information to receive study results. There was a difference between groups, with participants in the Arabic group most often sharing their contact information and the Hindi group least often doing so. This may reflect a greater sense of vulnerability among participants in the Hindi group.

Approximately half of all recruited individuals had low literacy, but we overcame this by having the RAs work directly with participants in their own language. Generally, we did not encounter difficulties obtaining informed consent from low literacy individuals in Qatar, in contrast to previous findings. Although most participants retained the information/waiver of written informed consent sheet, we are unsure if the others were just not interested, preferred not to retain any linkage to the study, could not read, or had other reasons. We obtained verbal consent instead of written informed consent because in many non-Western societies, signatures are usually reserved for formal transactions associated with major life events. Requests for written consent could rouse suspicion or concern, and asking illiterate participants to sign documents they are unable to read or fully comprehend can be threatening or imply lack of trust.
Signatures would leave a record of participation, so individuals who preferred anonymity would have been precluded from participating. Interestingly however, we found that enrolled participants did not hesitate to provide their verbal consent despite it being audio-recorded. If executed as intended, written and verbal consent are ethically equivalent; thus, written consent shouldn’t be necessary. The willingness to provide verbal consent while hesitating to provide written consent illustrates the cultural aversion to signing documents.

Cultural adaptations also meant compromising privacy during interviews to respect cultural norms around gender interaction and to alleviate participants’ fears of losing their place in queue for their appointment. Although Western ethical standards may suggest privacy to be critical, we found that conducting interviews in a public space generally did not inhibit the responses of the majority of our participants. Despite the gender norms of the country, we found that in the five instances of female RAs interviewing male participants in a room, individual preferences ultimately determined whether a participant was comfortable being interviewed in private. Gender norms may not have applied as rigidly since the RAs were viewed as part of the healthcare staff and because it is more acceptable for men and women to interact in healthcare settings when there is no reasonable alternative.

Although many participants openly discussed their opinion of the healthcare system, a few expressed trepidation that their participation might result in negative consequences for them or their families. We suspect that vulnerability fears may be due to a number of reasons. First, many of the participants were expatriate workers from countries where human rights cannot be assumed, and this lens could inevitably carry into Qatar. Second, there is relatively less public knowledge about research participation in the Arabian Gulf and in many of the developing countries that the expatriates call home, so lack of familiarity with research could cause mistrust. Third, it is possible that some individuals may have had negative experiences in society, e.g. in the workplace, and through this lens interpreted that their research experiences might be similar. Fourth, particularly in the case of a working spouse, some may not want to contradict or compromise preferences or policies of a spouse’s employer. The RAs quickly learned the importance of confidentiality of personal information, and adapted by emphasizing that private information would not be collected and that information given could not be linked to the participants. Regardless of the low probability of negative implications for such individuals, it is important for researchers working in the Arabian Gulf, especially given so many expatriates, to be aware of how people may perceive the consequences of participating in research. We recommend that research procedures be designed to address the underlying concerns that participants, even though a minority, may have about vulnerability throughout all stages of the process. Overall, we did find that many participants felt empowered to provide information to the researchers and appreciated the opportunity to discuss their experiences and offer recommendations to improve the Qatari health system.

Investigators conducting international health research may face multiple challenges during the research process, particularly if Western ethical standards are used without consideration of local traditions and social contexts. Table 6 provides recommendations for researchers conducting research in the Arabian Gulf Region. There have been many efforts to
establish national research ethics guidelines in the Middle East and Arabian Gulf, with most of the Arabian Gulf countries making more advanced steps than other countries in the Middle East. Researchers are expected to balance universal ethical standards with local standards; therefore, ethical research principles should be upheld in as much as they are appropriate to the local context. We agree with Fadare and Porteri’s position, who state, “While international research ethics guidelines have an important role in setting basic and acceptable standards, there remains a window for local adaptation, especially in resource-poor and culturally diverse countries.”

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. 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.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?

R.1. The authors refer to the relevant body of knowledge on the application of research ethics in non-Western settings.

- Response: Thank you.

R.2. Some of the authors names are written wrong e.g. reference #21

- Response: This has been corrected.

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

R.1. The title and the abstract do not fully match, because the abstract does not clearly outline the qualitative research study in question.

- Response: We have clarified this in the Abstract.

Revised text:

Abstract
**Background**
While research recruitment and informed consent have become routine in North America, scant literature informs such procedures in the Arabian Gulf Region. Our objective was to delineate issues related to recruitment and informed consent in the extremely high-density multicultural setting of Qatar.

**Methods**
During a multistage mixed methods project, field observations and qualitative interviews were conducted in a general medicine clinic of a major medical center in Qatar. Participants were chosen based on gender, age, literacy, and preferred language, i.e., Arabic, English, Hindi and Urdu. Qualitative analysis identified themes about informed consent and recruitment.

R.3. (Repeat of Reviewer’s 3 comment above)The title should reflect that the 'recruitment and informed consent' we are talking about here are for "Research" NOT "Medical Practice". Important! While reading through the text and up until I got to the end of Background section, I was still confused whether this is asking about IC of research or medical procedures.

- **Response:** We mentioned this earlier. We clarify this in the title: *Recruitment and informed consent of research participants in Doha, Qatar*, and further in the background section of the manuscript on pg. 5.
- **Revised text:**

  Surprisingly, only two of these 11 papers provide a glimpse of empirical data on outcomes of recruitment and informed consent procedures for research with Arab populations.

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  *The purpose of this paper is to address the gap in the literature on recruitment and informed consent for research based on the project team’s experience and observations in a multistage research project about health care quality assessment in Qatar.*

**9. Is the writing acceptable?**

R.1. The language is good but the writing is confusing specially the results section as mentioned above.

- **Response:** We clarified as requested.

**Final Comments:**

R.2. The article should be published as it includes important data not published before. Although my mother tongue is not English but the English of this article is simple and understandable which easily readable and cited. I reviewed the statistics and commented on the sample size and technique from the statistics point of view.
• Response: We have clarified that descriptive statistics are appropriate for the demographics, and how we have appropriately used data transformation to provide an honest accounting of the number of respondents who VOLUNTEERED specific comments.

I am Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions. However, I trust that the authors will do and I hope to see this paper published.

• Response: We believe this reviewer will find our careful revisions satisfactory.

R.3. Conclusions: again the term "Western"! (please refer to my previous comments above). Also, you don't expect to see references in the Conclusions section.

• Response: We have exercised caution and clarity with regard to this throughout. We also removed any references in the Conclusion section.

**Level of interest:**

All reviewer concluded the article is of importance in the field, or to those with closely related research interests.

Quality of written English: All reviewers concluded the quality of the written English as acceptable.

Statistical review: All reviewers concurred statistical review was not necessary.