Author’s response to reviews

Title: Researcher and study participants’ perspectives of consent in clinical studies in four referral hospitals in Vietnam

Authors:

Jennifer Van Nuil (jvannuil@oucru.org)
Thuy Nguyen Thi Thanh (thuyntt2977@gmail.com)
Nhan Le Nguyen Thanh (drnhanbvnhidong1@gmail.com)
Vinh Chau Nguyen Van (chaunvv@oucru.org)
Mary Chambers (mchambers@oucru.org)
Ngan Ta Thi Dieu (dr.dieungan@gmail.com)
Laura Merson (laura.merson@ndm.ox.ac.uk)
Dung Nguyen Thi Phuong (dungntp@oucru.org)
Van Hoang Minh Tu (vanhmt@oucru.org)
Michael Parker (michael.parker@ethox.ox.ac.uk)
Susan Bull (susan.bull@dph.ox.ac.uk)
Evelyne Kestelyn (ekestelyn@oucru.org)

Version: 2 Date: 27 Sep 2019

Author’s response to reviews:

Dear Editor,

Thank you very much for considering our manuscript for publication in BMC Medical Ethics. We responded to the editor and reviewer comments below and revised the paper accordingly, which is included in the submission in both track changes and clean versions. If additional information is needed, please contact me via email.

Best,

Jennifer
Editor Comments:

1. Please consider the list of authors as it currently stands with reference to our guidelines regarding qualification for authorship (http://www.biomedcentral.com/submissions/editorial-policies#authorship).

Currently, the contributions of some of the authors do not automatically qualify them for authorship. In the section “Authors’ contributions”, please provide further clarifications on their contributions, and see our guidelines for authorship below.

[author response] We consulted with each author and clarified their roles for this work, as well as divided the contribution sub-sections into smaller categories to better reflect the division of work among co-authors. The revised author contributions are listed in the revised paper.

Reviewer reports:

Johannes Van Delden (Reviewer 1): I think the authors have adequately addressed my concerns.

Henry J. Silverman (Reviewer 2): I appreciate the additional information provided by the authors.

I have several additional comments.

The authors state in their introduction the following: "The data from this study will inform future consent research and guide the revisions of policies that inform the consent processes for specific studies within our research context, as well as pointing to several larger issues surrounding researcher-participant expectations, communication, and trust."
I recommend that in their discussion section the authors should suggest what changes in consent policies are in order. This is key as it appears that many researchers do not consider that several of the basic elements of informed consent are necessary (survey results) and many provided limited amount of information "so that the participants feel 'comfortable' and 'safe' but not too much so that they become scared of the research".

[author response] Thank you for your extensive re-review of our paper.

Your suggestion above is a good suggestion, therefore, we added more to the end of the discussion section regarding potential policy changes that could enhance the consent process in our setting, based on the results. See final paragraph of the conclusion section.

1. In their conclusion section, the authors state "To maximize the development of valid consent, it is important to engage the hospital-based communities…". The authors should explain more how this conclusion emanated from their results.

[author response] We added how this point was developed from our data in the conclusion (revised text page 18).

2. On page 17, the authors mention that "participants relied on the physicians to help them make the decision, which is not a unique finding to Vietnam….." and then provide several questions that deserve further exploration. As the authors' intent was to investigate the practice of consent in the context of the hospital setting in Vietnam, I need to ask why this contextual issue was not pursued in the present study?

[author response] These issues were not elaborated upon in this current study for two main reasons: the idea of trust and reliance on physicians was noted as a topic during analysis but was not probed upon in detail during the data collection (a large missed opportunity) and second, the literature cited in the discussion section was published within the past two years and these data for this particular paper were collected prior to these publications (from 2013-2014).
3. On page 14, the authors mentioned "However, in practice…..the line between care and research was easily blurred.". From where did the authors obtain this insight about "practice"?

[author response] Though we did not use observation as a method to determine how the consent process occurs in practice, we collected narratives, as part of the interviews, of how consent was practiced (and imagined) by both physicians and participants. These are the data that informed our insight about practice – whether or not this is what happens in actual practice would require additional data collection, e.g. direct observation of the process or participant observation within the sites for an extended period. To clarify the point in the text about practice, we removed the word “practice” from the first part of the sentence and moved the first sentence so that it is after the finding that helped us to reach the conclusion.

4. On page 10, the authors state that the survey results showed that a large majority of participants believed that the idea of voluntariness is essential in the consent process. However, the survey asked about the concept of voluntariness in the consent "form" rather than practice. It appears from the results of their interviews there are many questions about researchers' practice of informed consent.

[author response] Yes, in the survey we asked about the concept of voluntariness – how essential is it that the voluntariness be included in the consent forms. But during the interviews, discussions revolved around how to portray the concept of voluntariness in practice. It’s important to include these ideas in the consent process, that is, that participants have a choice. Additionally, there were several other ways to achieve this idea, e.g. using specific words to show that they do indeed have a choice (research instead of programme). The finding that we want to highlight is that conceptually, a majority of participants stated that voluntariness is essential (survey data). But what voluntariness means and how that plays out during clinical studies in the hospital, (according to our interview data), is messy and unclear and involves different perceptions from different stakeholders.

5. In the authors' response to my comments, they state that the sample size was dependent on timeline/budget, "as well as the point at which saturation occurred" (during interviews). However, they mentioned later on that the "interviews were analyzed after the data were collected...". If the latter is true, then how did the authors determine when there was data saturation?
[author response] The second author kept notes about each interview and summarized some of the key questions within her notes (which arguably could “count” as a first step of analysis, I suppose). Based on these notes and being the sole interviewer in the study, she assessed that saturation (of the sample – not necessarily the analytical categories/codes or ‘theoretical sampling’) was reached after a certain number of participants were interviewed and the responses were starting to sound more alike than different.

6. In the authors’ discussion of their limitations they should also mention that the interviews were analyzed after the data were collected and as such, as stated by the authors, the interviewer "missed some of the probing opportunities". The authors stated that they would mention this limitation in their discussion.

[author response] Added to discussion.

7. The authors state on page 6 that they coded all interviews "with a predefined codebook based on the specific areas we wanted to investigate". Did the interviews reveal other 'codes' that were unexpected?

[author response] The initial codebook included topics of interest, which we coded as a first step. Had there been any major gaps in the codebook, we would have included it as a code as we would not want to limit the analysis to our own preconceived notions of what is important after reviewing the notes and transcripts. However, in the next step, we used more inductive/open coding to break down these larger codes into more specific topics. This step was data driven. Finally, we grouped these into the themes that are presented in the paper. I edited the analysis text a bit to better reflect the process.

Thank you for this opportunity to re-review this manuscript.

[author response] Thank you for taking the time to re-review the paper.