Reviewer's report

Title: Mixed-Methods Study on Perceptions Towards Use of Rapid Ethical Assessment to Improve Health Research Informed Consent Processes in a Low-Income Setting

Version: 1  Date: 16 December 2013

Reviewer: sisira siribaddana

Reviewer's report:

I have few philosophical comments about this paper. Ethics and informed consent originated in the west and was exported to developing countries in the east, preceded by western medicine and research.

Supposedly consent and community consultation or engagement is two instruments to make western medical research more democratic and humane! (To authoritarian savages in the east). However when needed even sacred vaccination campaigns can be subverted by western military.

I also believe that independent Ethiopian researcher-clinicians (or any other country for that matter) should be facilitated to conduct research without bureaucratic ethics enterprise. Ultimately it is the researchers who have to design and conduct recruitment that are appropriate to their own research. If researchers develop longer term bond with their participants (such as clinician researchers who recruit their patients for research) they are bound to treat their subjects compassionately. However it is the duty of the IRB to monitor the research, discern therapeutic misconception and weed out the black sheep!

New tool such as REA may be stumbling block for independent local investigators that can be easily hurdled over by researchers from west (or collaborators) who are well funded and resourced.

Increasing the capacity of local IRBs also may be better way than REA. They can provide better advice on how to conduct recruitment process with cultural sensitivity.

Leaving these musings aside I think this is an excellent study particularly in the qualitative aspect and should be published with revisions.

Major Compulsory Revisions

1. Presentation of results undermines the mixed methods. Quantitative first and qualitative second undermining the authors' statement on triangulation. If it is mixed it should be truly mixed and not layered.

2. “Respondents were randomly selected from e mail list”-how many was in the original lists? How many selected randomly? How many responded? How many are incomplete? Kindly provide. Then the authors say “… eligible respondents i.e. researchers and academics having the experience of independent research with at least post graduate degree” I was puzzled by this statement. Was the original
Did they really use random numbers??

3. What was the EXCEL version? What function did you use to generate random numbers?

4. Translation was by back translation after the data collection. This may have led to loss of meanings of many rich Amharic words and phrases. I understand this was done for the convenience of using NVIVO software. But in qualitative data collection carried out in one language I believe analysis also should be from the same language (however tedious it is!) and then translating the text-only pieces that are embedded in the manuscript. Lack of semantic, conceptual and normative equivalence across language, culture and society prevent the real meaning getting across. The classical example of lack of normative experience is there are no terms to describe research in local language as mentioned in the results section of this manuscript. I think this should be described as a limitation. There are ways to overcome this such as using modified Delphi technique for cultural adaptation.

5. REA does not seem to be different from formal qualitative inquiry. Only data seems to be analysed rapidly!!!

6. Data collection was top down only – researchers’ investigators and field workers. No data were collected from research participants. I didn’t see any limitation section in the discussion.

7. Although the study seems to be well conducted it does not add anything new about informed consent process in the third world.

Minor Essential revisions

8. Background section 1st paragraph “communities where personal choices are very limited…” This is very condescending statement. Is the society that places community before individual inferior?

9. Results 1st para – 87% has post grad degrees-how many had research degrees ?. The researchers should be aware that clinician-researcher with post graduate research degree is different from specialist clinician with completed specialist training in UK it can be MRCP/FRCP and CST/CCST and in Sri Lanka it can be MD. Clinician completing specialist training may have little research specific knowledge. Also there are little nuances such as MSc by research and by taught course.

10. At the end of the first part of the results (3rd para) there is a description of the 14 in-depth interviewees. Did all of them have post graduate degrees??

Discretionary revisions

1. “I also think Table number one should go to appendix and brief description of the subjects are sufficient.

2. Discussion 1st para 1st line research consent process” is a noun salad it should be consent process in research.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:

I declare that I have no competing interests. I chair Ethics Review Committee in the university.