Reviewer’s report

Title: "We all want to succeed, but we've also got to be realistic about what is happening": An ethnographic study of relationships in trial oversight and their impact

Version: 0 Date: 03 Sep 2017

Reviewer: annmarie nelson

Reviewer's report:

Thank you for the opportunity to review this very interesting paper. From my personal experience, the findings seemed very familiar and well worth highlighting to the general trial audience who may otherwise easily accept some of the more negative reported dynamics as custom and practice.

I was particularly pleased to see the COREQ reporting guidelines checkbox completed, which makes my job a lot easier and demonstrates the overall rigour of this article. However, the entry for Methodological orientation and Theory referred to an unreferenced paper, which needs expanding within the manuscript.

It took me a while to figure out the sample selection. There are eight trials but there are five groups of interviews and 51 interviewees. As a qualitative research study, data collection and analysis relies on homogeneous groups, with each representing a perspective. The authors acknowledge this in lines 54 to 56 but that doesn't seem to follow through to the allocation of groups, which seems mixed - what are the defining criteria of the interviewed groups?

It was refreshing to see fieldnotes being used appropriately and referenced throughout the paper, so often there is a mention of them with regard to data collection but these are not referenced in the results.

In terms of the standardised observation schedule, it would be interesting to know how that was developed and whether it took account of non-verbal language as well.

The authors have paid careful attention to research rigour and have co-coded a subset of interviews transcripts, it would be useful to reference the percentage of the full set. I'm not sure about the word triangulation is applicable here, I'm more used to hearing that in relation to multimethods research, to enhance convergance. I understand what the authors mean and maybe reference to cross case/sample analysis is a better phrase to use.
There is a good spread of data from the various trials and the various professionals but I feel there is that little attention paid to PPI representation, who are integral members of trials teams at all levels. I would have thought PPI reps should have sat within all five of the interview groups. It would certainly be good to see an extract from the PPI representative in the paper.

I think the most powerful theme is the Communication theme, which is the root cause of issues across many different topics, but I was particularly taken with Page 16 and the key question about overall responsibility, with its divergent and very telling responses. I felt that this could have come through far more strongly in the recommendations.

The intelligent discussion leads to a box of recommendations regarding trial oversight, these feel quite tentative in parts and, given the data, I think that there is an opportunity to emphasise the issues in a stronger way and maybe consider taking wider consultation on an eventual definitive set of recommendations for increased impact.

The authors have been careful to retain the anonymity of the participants but it might be worth checking the use of gender throughout the manuscript so that he/she is used consistently in preference to single gender references.

Overall, congratulations to the authors on a very good paper, which will be of interest to a wide audience, and has the potential for high impact by the promotion of the resulting recommendations.

Finally, outwith this paper, it may be worthwhile to collaborate with http://www.trialforge.org whose position paper has been published in Trials https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-16-S2-P231.
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