Reviewer's report

Title: Key stakeholder perceptions about consent to participate in acute illness research: a rapid, systematic review to inform epi/pandemic research preparedness

Version: 2
Date: 14 September 2015

Reviewer: Don Willison

Reviewer's report:

Thank you for the opportunity to review this paper. The authors address a very important issue – stakeholder perspectives on consent to participate in acute illness research in the context of a pandemic. In particular, the authors focus on: prospective consent by the research participant, third-party consent; deferred consent and waiver of consent. Overall, this is an easy-to-read paper. The recommendations within the Discussion section are constructive and follow logically out of the reported findings from the literature.

Major compulsory revisions

The authors are commended for taking on a particularly challenging topic. I do have concerns with some of the overarching assumptions in and approach to the analyses in the manuscript.

1. The authors set out to identify literature that could inform research in the context of a pandemic. Only one paper was found that was specifically in the context of a pandemic. The remaining were settings like cardiac arrest, stroke, ICU, etc., involving emergency medical situations for individuals. While some lessons can be drawn from these cases to that of pandemic, the larger context of a public emergency involving mass casualties is very different. Under circumstances of pandemic or mass emergency, the regular norms around consent will likely be very different, as will be the capacity to invoke the usual protocols for development and implementation of the consent. Research during a pandemic may also involve individuals not immediately acutely ill but also at risk. In addition, research in a pandemic may involve interventions on a population-wide basis and not just on select individuals within the population. These concerns about generalizability of findings to a pandemic context are not given sufficient attention. While the authors touch briefly on this in the Conclusion section of the paper, there is a need to address this more completely and directly in the Discussion, Limitations, and Conclusion sections of the paper.

2. The authors identified 52 papers they considered relevant. The papers are quite varied. Thirty-eight of these are quantitative papers, 13 are qualitative, and 1 used mixed methods. The settings vary across studies. Some address hypothetical cases while others address actual patient experiences. This heterogeneity represents a challenge to summarize the findings. However, within
the manuscript, there was very little description of these papers. While Table 1 summarizes each of the papers, an additional table that summarized common features across the papers would be helpful. Granted, the authors have made some statements about certain factors such as: actual cases vs. hypotheticals and the impact of risk of the research on responses, but it would be helpful to have a richer discussion around the papers themselves.

3. In addition to the setting, how a question is framed can strongly influence how a survey participant responds to the question. This is particularly the case in the context of questions around third party, deferred, and waived consent for research. Therefore, before one can compare findings across papers, it is important to establish that the study contexts and framing of questions were sufficiently similar to be able to draw direct comparisons. Unfortunately, there is insufficient information provided to ascertain whether there is sufficient homogeneity in the framing of the questions across studies to draw comparisons.

Currently, the paper is framed as a quantitative statistically-focused summary of the extant literature. Comments 2 and 3 above call for the addition of substantially more qualitative analysis of the data. For example, on page 13, under “waived consent”, in the paragraph titled “potential research participants”, the authors state: “Some studies suggest greater number of participants would be willing to take part [49, 53, 56], while others showed fewer numbers being willing to participate [55, 61]”. However, there is no further analysis of those five papers to examine what may be the cause of those differences.

While there are further comments that I could make to specific points in the paper, I think there is initially need for a substantial re-framing of the manuscript to provide a richer description of the papers and in-depth analysis of the findings in the Results section. I look forward to reviewing a revised manuscript.

**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.