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: 3  Date: 29 October 2015

Reviewer: Don Willison

Reviewer’s report:

I have reviewed the revised paper, the comments of the other reviewers, and the authors’ response to the reviewers. I see there was considerable concordance among reviewers as to issues that needed to be addressed, particularly around context and generalizability to pandemics.

1. To their credit, the authors have considerably re-worked the Background and Discussion sections. However, I think the major limitations remain largely unaddressed or under-addressed. To simply state in the Discussion section: “the extent to which we can generalize these findings to pandemic emergency research requires investigation” is dodging the fact that there are very severe limitations to generalizability of the extant literature. The authors have done the investigation and the literature directly applying to a pandemic context is virtually non-existent. The low generalizability is not the fault of the authors. It is the limitation of the literature to date.

2. Immediately thereafter, in the Discussion section, the authors minimize the importance of context by simply stating that others have declared that an individual’s capacity is more important than the urgency of a pandemic context. They then cite a paper by Macklin and Cowan and provide no explanation of the arguments supporting (or opposing) this perspective. This approach to addressing this important question is simplistic and unsatisfactory.

3. While the data presented in the Results section are presented in an orderly and systematic fashion, it feels as if the analysis is only half complete. The key findings of individual studies are organized and collated but the larger job of identifying overarching themes, and areas of convergence and divergence across themes is not well developed. Some of this occurs in the Discussion section, in the paragraphs before “Strengths and Limitations”, but not in great depth. So reading through the Results section is a very tough slog. This method of reporting research findings may reflect the rapid review method, but the consequence is a Results section that is a text equivalent to reading a table of cross-tabulations when a regression analysis is in order. The analysis feels incomplete.

4. The addition in the Discussion section of the paragraph describing comparative effectiveness research and adaptive trial designs is an interesting
addition but its insertion feels forced. Further, the authors skim the surface of the ethical issues associated with these designs, which have been the subject of considerable debate in recent months. Meanwhile, issues around cluster randomization designs for intervention studies – a likely design to be encountered in the context of a pandemic have gone largely unaddressed.

5. Finally, the authors highlight a number of findings that occur in virtually all health research and are not particular to research in the context of an emergency. For example:

# Confusion over concepts such as equipoise and randomization; and therapeutic misconception (Results section: waived consent; potential research participants)

# Participants being motivated to participate by altruism, trust in the medical community, and perceptions of the risks and benefits of participating (Discussion section: paragraph 2)

As these are not unique to research in the context of an emergency, it is not clear why the authors have highlighted these particular issues. They could have pointed out that these issues persist among research participants regardless of the presence or absence of an emergency. However, they did not.

While there are several smaller issues, I feel the revised paper still requires considerable further qualitative analytic work before it is ready for publication.

Respectfully submitted.

Don Willison

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 I have no competing interests.