Reviewer’s report

Title: Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel

Version: 0 Date: 02 Nov 2018

Reviewer: Angus Dawson

Reviewer's report:

Thanks for the opportunity to read this paper. It reports on discussions and a series of recommendations from an expert panel looking at research ethics during outbreaks.

My main comment relates to the fact that the purpose of the paper is not clear and there is a sliding around in relation to the focus. The structure of the paper could be improved to better reflect the overall aims. I take it that the purpose of the paper is to report the finding of the workshop (in terms of what topics were discussed and what was said in relation to each of them). However, there is also a set of recommendations that purportedly arose through a process of consensus building. I accept, and am guided in my review, by the explicit claim that this is a descriptive report and that it does not seek to engage in discussion of substantive ethical issues. (There is a lot to say about the substantive content - but that's for another day).

What do you want to achieve in this paper? What's your aim(s)? At the moment this is unclear.

Probably the clearest statement is at the bottom of p.8. where it is stated that 'the objective of the workshop was to identify practical processes and procedures related to ethics review that support national and international outbreak preparedness and response and facilitate the timely implementation of research'.

* I think this is an aim not an objective (an objective is a means to achieving an aim).

* This assumes that research is (always?) a good thing. This is never justified.

I think the aim is to produce recommendations to assist relevant committees with the ethics review processes in the light of outbreaks etc.

This is achieved via the objectives of:

* Outlining five key issues
* Discussing challenges etc
* Reaching consensus on what ought to be implemented…etc

I would suggest a clearer structure for the paper as follows:

1. Report on the background to the workshop (who was invited, aims etc) - i.e. current pp.8-9.

2. Report on what was the focus of the content and what was discussed (the five 'sessions') - i.e. current pp.10-17.

3. Report recommendations

The current 'background' section (current pp.4-8) should be dropped and the abstract revised to reflect this.

This proposed structure would make it much clearer that this is a descriptive report. The current background is mostly a mixture of vaguely worded summary claims, unnecessary detail and occasional quite contentious substantive normative claims (that are not defended - e.g. some things are held to be 'beneficial', 'reasonable' etc). This is not needed for the paper.

In reviewing the content, assuming the proposal above is adopted, special care should be taken to only use descriptive language (e.g. 'The groups discussed…') and not employ any normative language (e.g. '(N)RECs should…'). Or if normative language is used - reasons need to be provided why the authors might think such a claim should be made.

One thing missing is that I could not see any reasons given for the focus on the five 'session' topics. Was this the result of prior discussion, a review of the literature, expert opinion, lack of time? Why were some other obvious topics excluded? Why were these ones included?

Something needs to said about the building of consensus. How was this done? Was it done formally using some variant of a Delphi method? Why is *consensus* as such the focus? There is no discussion of these methods.

I take the point that the focus is here on process. However, procedures still require justification - there is an implicit set of values at work here and they are not made explicit or justified. For example, the assumption is that being transparent etc is easy to do, uncontroversial, and should be done. This is hardly obvious.
It could be clearly stated what the proposed force or status of the recommendations is supposed to be. Is this general advice? Or is it a proposal for further discussion? Or are they a firm and formal proposal for global action to be implemented immediately?

Why is there a list of substantive ethical issues in the first paragraph of session 5 and not elsewhere in the reported 'sessions’? It is far from obvious to me that these are the sum total of relevant ethical issues and they have a suspiciously 'usual suspects' feel to them. Again, there is a danger of commitments in relation to substantive ethical claims here - whether explicitly or implicitly - and this needs to be avoided in a descriptive paper.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Unable to assess

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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Please indicate the quality of language in the manuscript:

Acceptable

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