Reviewer’s report

Title: Protocol publication, transparency, and selective reporting: increasing value and reducing waste in clinical trials

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Reviewer: Catriona McDaid

Reviewer’s report:

This commentary paper mainly provides an overview of existing publications in this field. It is clearly written and outlines some key issues currently under discussion in the field. However, I think it is limited in the extent to which it moves the debate on from papers that have gone before it. There are a lot of general statements about the publication of protocols, which I am in full agreement with, but I wonder whether some more in-depth discussion of the practicalities around implementation would strengthen the paper and give it more impact.

For example what do you mean by "publication" of the protocol - do you mean that it is in the public domain or do you mean published in a peer reviewed journal - what are the advantages and disadvantages of the different approaches, does it matter which it is? For example if researchers are to ensure that the protocol is published in a journal before participant enrolment this has actually considerable consequences for several stakeholders e.g. for trials teams there is generally a relatively small window between ethical approval (which may require protocol changes) and recruitment of first participant and this is an extremely busy time for trials teams. Equally the considerable length of time it can take journals to process submissions is another factor that may affect the timeliness of the publication - how might some of these practicalities be tackled?

Do protocol amendments need to be publicised and how should this be done? Lines 189-191 need to also give some consideration of the known limitations of peer review and the practicalities of how much a protocol can be changed by the time it gets to a journal having been approved by an ethics committee and often a funder.

There is suggestion in the paper that publication of protocols will get around the limitations of poor reporting in registries and published papers of results - is there an argument for improving these and using these existing structures more effectively?

Similarly, with some of the other general statements made it would be useful to have some more 'unpacking' of the issues.

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