Reviewer’s report

Title: Data Access Committees

Version: 0 Date: 19 Jun 2019

Reviewer: Angela Ballantyne

Reviewer's report:

Thanks for the opportunity to review this paper. I think it makes a valuable and timely contribution to the literature on data sharing. It is well written and the arguments have a clear and logical flow. The paper is well-referenced and draws appropriate links to existing literature. I recommend Acceptance with minor revision.

Below I have made some suggestions for minor revisions. (sorry in advance, the copy I reviewed had no page numbers so it has been tricky trying to specific the location of specific comments in the manuscript)

I think it would help to be really explicit at the beginning that the scope of the paper is 'research data'; you are not talking about sharing health data collected in a clinical context or health administrative data, insurance data etc.

In the "Introduction" you describe positions in the existing literature that advocate for a public health ethics approach to data sharing. From the rest of the paper, it seems you endorse these arguments but this is never explicitly stated. So it would be easier for the reader if you could clarify your position here.

Can you please also clarify whether you are assuming that any research data potentially available for sharing already has broad consent for future use from the data subjects at the point of data collection; or whether the DAC can also grant consent waivers for the re-use of research data where subjects did not give consent for future use? If both types of data sharing are to be considered, can you please specify whether the same standards should apply (social value, minimal harm, institutional priorities etc) to both?

I think there is more debate about the 'proper' role of RECs than the paper suggests. See for example 'The job of ethics committees' by Andrew Moore, https://jme.bmj.com/content/44/7/481.short; and the responses by Schaefer and Holm and others. Moore argues that the proper role of ethics committees is to assess whether proposed research complies with national policy. Furthermore, I agree with you that a primary role of RECs is to protect research subjects, but personally I would argue they should also play a role in promoting and facilitating socially valuable research. I suggest that you could be more explicit about the degree of debate concerning the appropriate role of RECs; and that some of what you suggest DACs should do differently to RECs, is consistent with what other writers think that RECs should actually be doing in the first place.

In "Functions" you describe the primary question that DACs should consider. I think it would help to clarify here that you see DACs as only assessing consequences (harms and benefits), and not assessing rights. This will set you up for the conversation on privacy later in the paper, where you state that you are not interested in privacy breaches per say, but whether any harm arises from such rights violations.
In "protecting data subjects" - here you talk about the risks to communities and data subjects, I think it is worth acknowledging that part of the epistemic challenge with data sharing is that we don't necessarily know what these risks will be if we don't get consult with communities. In the end, it often won't be practical to require consultation, but it is worth being explicit about the risk of underestimating or misidentifying risks to data subjects if we don't consult. On this same point, in "Composition" it may be worth noting that DACs can always consult on an ad-hoc basis with people familiar with the community or data subjects where necessary; they don't need to be standing members of the DAC.

Also in "protecting data subjects" - you make the point that the magnitude of risks to participants in research is different to the magnitude of risks to data subjects in data sharing. I agree, but I think it is not simply the magnitude but also the nature of the risks in research v data sharing that differ.

In the abstract you mention that DACs should assess the social value of the research and ensure research is low risk. In the body of the paper you argue that benefit should be proportional to potential harm. Does this mean there is no upper limit on the potential harm a study could involve? Or are you assuming that all data sharing is low risk? You also argue that DAC should promote institutional interests; what would happen when there is a conflict between the interests of the institution and value of the research - e.g. a really value data sharing arrangement is proposed, but the institution fails to recognise this value, or the value doesn't correspond to institutional priorities - what takes precedent here?

"Goal of review"…" the main goal of an ethics committee review…" here you state the researchers may overlook aspects of a study because of COIs, but more often this happens because of research inexperience or lack of familiarity with the specific law or research ethics policy for a certain type of research.

Can you please clarify whether you think DACs should assess the methodology (scientific integrity, data analysis plan) of the secondary analysis, or is this outside the scope of DAC review?

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

Yes

**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

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

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