Reviewer’s report

Title: Responsible Data Sharing in International Health Research: A Systematic Review of Principles and Norms

Version: 0 Date: 25 Nov 2018

Reviewer: Effy Vayena

Reviewer's report:

The authors of this paper state that they conducted a systematic review of principles and norms that are relevant in data sharing for international health research. The topic of international data sharing is of high importance and so are the regulatory frameworks that can support sharing. Despite the intention of the authors to contribute to the debate, unfortunately, their approach has severe methodological flaws that undermines their conclusions.

First, there is no definition of what they define as "norms" and "principles" which would have helped us understand what they looked for in the sources they used, and in what way this distinction is relevant for policy.

Second, the authors claim "systematicity" in their search but this is not sustained by what they present as their search methods. This applies mostly to the selection of guidelines. (It is indeed difficult to systematically identify policy guidelines, but then either avoid a systematic review, or develop a systematic approach.)

For example:

(a) the use of Google Scholar - which is not a static database - warrants further explanation (how did the author delimited their search?) in order to claim systematicity?

(b) "National and EU laws and regulations were excluded from this study because we were primarily interested in elements of a governance framework that provides comprehensive moral guidance, not only enforces legal compliance." And yet laws and regulation are expected to be developed on the grounds of moral principles and norms, so this is not adequate justification for excluding them.

(c) "Relevant guidelines and policy documents on data sharing in international health research were identified with help from academic and industry consortium partners with expertise in health law, regulatory science and research ethics." This is not sufficiently descriptive, who were the partners? Why these partners and not some others? Why this method? How are the
authors confident that they have not left out important guidelines? The consultation process with experts in itself is not described.

(d) Inclusion criteria are poorly described and, based on what the reader can understand, are not appropriate: how can one judge the 'purpose' of a publication (line 93) and what does 'preferably' mean (line 94)?

(e) Why were sources discussing benefits, imperatives and challenges (line 97) excluded? If the authors are looking for ethical principles and norms, such sources could have been relevant.

(f) "For inclusion, publications were required to present a coherent set of principles and/or norms that could potentially function as or at least be construed as part of a model or framework for responsible data sharing. Documents were included if the content was developed with the purpose to inform policy decision-making and preferably by or in collaboration with (international) working groups or professional organisations active in the field of health data sharing." Are these criteria connected by an "and" or an "or"? The fact that the authors intended for their work to impact on policy tells us very little about whether any policy was impacted by them. It seems very arbitrary to use this criterion if the objective of the study is to show which principles and norms have been used in actual guidelines.

Third, the authors claim that this systematic review of the academic literature and research guidelines provides a unique overview. This is a rather puzzling claim: first the review of principles and norms (and again here we are missing the definition, but we assume them to be ethical principles) has already been published. Most recently by Blasimme et al. 2018 in Health Affairs. Another paper reviewing policies was published in 2017 by Burton et al. The authors ignore this work which generates two problems for the paper: The authors fail to place their work in the context of current literature and therefore fail to tell us what their review adds to what is already published; second, if they missed these two publications in their search, this shows weaknesses in their search strategy. They claim that their approach has limitation e.g. the expert recommendations of guidelines. This is a surmountable limitation. The Blasimme et al. paper identified 230 relevant guidelines in a replicable way. If others have been able to be more comprehensive in their selection than the authors here, then the authors have to argue what their approach with the limitations they state still does better.

Fourth, even if we had assumed that the finding were valid (based on flawed methods) then they make a final unjustified leap on the basis of assertions. Why do they consider the existing principles "haphazard, non-uniform" (in the conclusions). What makes a principle haphazard and why did they ought to be uniform? There is no explanation, no reasonable inference to be made here.
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?
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No

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Not relevant to this manuscript

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