Reviewer's report

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

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Reviewer: Bartha Knoppers

Reviewer's report:

This article provides both an excellent review of international data sharing norms and an insightful analysis. The regrouping of trends into four over-arching themes in especially helpful and original.

The only weakness is Section 4. Line 366 uses the term "outright contradiction" concerning data anonymization. A closer reading of the original texts/sources on anonymization reveals more granular and contextual approaches rather than contradictions. For example, irrespective of whether total anonymization is ever possible, the data sharing research context may well require pseudonymization for longitudinal studies or in those studies that wish to return results. Again, the conflation by the authors of anonymized, anonymous, pseudonymized and de-identified approaches is also evident in lines 390-406. As the GDPR rightly states "anonymous" date is not personal data so the legal obligations and protections of personal data do not apply. Most recommendations do not and cannot apply to "anonymous" data (line 394). I would argue that rather than "sparse guidance" (line 390), the analysis points to a confusion in the meaning of the terms used to describe the degree and type of data de-identification and hence, could affect both the sharing and the confidentiality and security of that data. (See Phillips, M, Knoppers BM. The discombobulation of de-identification. Nature Biotechnology. 2016; 34(11); 1102-1103). In short, the "Conclusions" section should be more nuanced. Rather than using terms such as "haphazard" or "contradictory", the language of "confusion" and "incoherence" in the terminology describing guidance on de-identification processes would be more appropriate.

Overall, this confusion stands in contrast to the greater convergence and clarity of the emerging normative frameworks for data governance and sharing as illustrated by this excellent paper.
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