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Sharing Clinical Trial Data

"Sharing Clinical Trial Data: a Proposal From the International Committee of Medical Journal Editors" (ICMJE) published in several journals in 2016,[1] raises serious concerns and should not be accepted. The sharing of data is sensible but, in general, this should be with the consent and participation of the primary researchers. The ICMJE proposal gives an automatic right to access someone else's clinical trial data. This goes too far.

Setting up, conducting and analysing clinical trial data is a major investment of a researcher's time and effort. For the trial data to be automatically available to others is not fair to the researcher, a disincentive to conduct trials and will encourage secondary research at the expense of primary research.

Whether a reported trial finding is true is better determined using independent primary research evidence than by re-analyses of the same data by different groups. Clinical trialists are sometimes asked to perform subgroup analyses which lack statistical power and are not scientifically justified. If the proposal were accepted, the primary researchers would be unable to prevent this abuse which, if published, could be misleading and would also be linked to the primary research and potentially damage its credibility. There may be vested interests with considerable resources that seek to show that a given trial result is flawed. With access to the data, these interests could subject the primary research to a relentless argument that would be distracting and may be financially unsustainable.

Guidelines, including journal rules on the conditions of publication of primary research, should simplify the processes involved in carrying out primary research so that such research is not discouraged and so that unnecessary obligations to third parties and obstacles are avoided. The ICMJE proposal will tend to do the opposite. It is also possible that, if this proposal proceeds unmodified, observational studies will become subject to the same rules, so exacerbating the problems.

A proposal along the following lines would be better and avoid the problems with the current proposal:

i. A request for access to trial data is put to the principal investigators with a statement of the scientific question being asked by the data applicant and details of how it will be answered.
ii. If the principal investigators agree to release the data, the new analyses should be a collaborative endeavour.
iii. If the principal investigators do not see the reason for the secondary analysis or do not believe the questions can be answered by re-examination of the primary data, or do not have confidence in the team requesting the data, the latter can approach the steering committee.
iv. If this receives a negative response, the matter can be referred to the data monitoring committee.
v. If this committee declines access, the matter could be passed for arbitration to the research ethics committee that originally considered the project.
vi. If an agreement is made to share data, the recipient should bear the reasonable costs of doing so; analyzing and anonymizing raw data so that it is understandable and useable by third parties requires time, effort, and funding.

A stepped approach such as this would help ensure that data sharing is conducted responsibly and not regarded as an automatic right for any person or for any purpose. It would be fair and the primary researchers would retain their involvement and judgment over the use of the data, while ensuring that a denial of access to data was justified and subject to independent review. The approach would serve the public interest by encouraging both primary research and the use of existing data for further research with others.

Reference

1. Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors. *JAMA* 2016; 315: 467–468.

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