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EDITORIALS

The BMJ requires data sharing on request for all trials

Heeding calls from the Institute of Medicine, WHO, and the Nordic Trial Alliance, we are extending our policy

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The movement to make data from clinical trials widely accessible has achieved enormous success, and it is now time for medical journals to play their part. From 1 July *The BMJ* will extend its requirements for data sharing to apply to all submitted clinical trials, not just those that test drugs or devices.[1] The data transparency revolution is gathering pace.[2] Last month, the World Health Organization (WHO) and the Nordic Trial Alliance released important declarations about clinical trial transparency.[3 4]

These announcements come on the heels of the US Institute of Medicine's (IOM) report on sharing clinical trial data, which called for a transformation of existing scientific culture to one where "data sharing is the expected norm."[5] The efforts of industry, too, must be acknowledged, some of which caught many people by surprise. In particular, Medtronic's cooperation with the Yale University Open Data project and GlaxoSmithKline's leadership on data disclosure efforts stand out.[6 7]

WHO's statement on public disclosure of clinical trial results and the accompanying rationale reiterate the organisation's support for registration of clinical trials.[8] WHO declares that the main results of clinical trials should be posted on a clinical trial registry or other acceptable website and submitted for journal publication within a year of study completion. The expectation is that results will be "made available publicly at most within 24 months of completion." The statement does not call for mandatory sharing of primary data from trials but instead "encourages" sharing of research datasets "whenever appropriate."

In a move that is particularly welcomed by Ben Goldacre, cofounder of the AllTrials campaign,[2] WHO also recommends disclosure of previously conducted but unreported clinical trials in a searchable and free registry and says it is "desirable" that these trials should be published in a peer reviewed journal. Goldacre notes that this is important because "the overwhelming majority of prescriptions today are for treatments that came onto the market—and were therefore researched—over the preceding decades rather than the past five years."[9]

The Nordic Trial Alliance report is bolder and far more visionary than the WHO statement. Its authors declare their ambition "to make clinical research conducted in the Nordic region the most trusted clinical research in the world." They outline the current state of data transparency in individual Nordic countries and then provide a detailed account of what needs to change. This includes "public upload of . . . individual participant data" after the report of the clinical trial is published. The alliance envisages a "Nordic transparency council" to serve as a "central, trusted public party" that would oversee the storage and dissemination of trial data.

Finally, it calls on a range of public, private, and academic institutions and citizens to "formulate clear laws, regulations, and guidelines." Such regulations "must specify that lack of transparency and trial registration is a serious offense and that attempts to re-identify . . . participant data are a breach of law, with severe consequences."[4]

Extending *The BMJ's* data sharing policy to all clinical trials

The BMJ was one of the first medical journals to require sharing of individual patient data for trials of drugs or devices. That policy took effect in January 2013 and specified that such trials would be considered for publication only if the authors agreed to make the relevant anonymised patient level data available on reasonable request.[10] We are very pleased that, to date, all authors have agreed, and we have not rejected a single paper for non-compliance. The Dryad data repository is an option for any authors who want a place to store their open, anonymised datasets.[11]

Our initial data sharing policy focused on trials of drug and devices because many high profile, serious allegations of selective or non-reporting of trial results related to such products.[12 13] Growing experience and evidence show, though, that reporting problems are not limited to the corporate sector but affect academic and government sponsored trials as well.[14] Additionally, tighter regulation of drugs and devices has produced an explosion of commercial interest in more lightly regulated "apps" and other non-pharmacological treatments.[15] It is difficult to argue that these studies should be exempt from the imperative to share data.

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Hoarding data and limiting access to them is inimical to the data sharing society envisioned in the IOM report. Making anonymised patient level data from clinical trials available for independent scrutiny allows other researchers to replicate key analyses, reduces the possibility that studies will be unnecessarily duplicated, and maximises use of the information from trials—an important moral obligation to trial participants. An initial investment of time and money is needed to prepare trial data for sharing, but after the first use there are few additional costs; in essence, the value of the data increases with each use.

Competing interests: We have read and understood BMJ policy on declaration of interests and declare *The BMJ* is a cofounder of the AllTrials campaign.

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