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Comments on Sharing Clinical Trial Data – a Proposal from the International Committee of Medical Journal Editors

We are writing as trialists who carry out community-based randomised trials of public health interventions in resource-poor settings.

We welcome the move towards greater sharing of data from trials (and other studies), both to ensure that the findings reported in published papers can be replicated, and to facilitate secondary analyses with the aim of maximising the value derived from the resources invested in the research. We do, however, have some concerns about the details of the proposals, and the unintended adverse effects these may have - particularly in large community trials in developing country settings.

Our main concern is with the short period (6 months) proposed before data have to be made available for sharing. Our studies often take many years of intensive fieldwork before the primary results are available. Published output during the trial is often very limited because of the requirement to maintain blinding during the trial. The academic careers of the research team are therefore critically dependent on the outputs after the end of the trial. There is strong pressure for the primary results to be published at the earliest possible date, especially when they are of major policy relevance. Necessarily, therefore, the team has to focus its effort on analysing and presenting these primary findings. Following this initial publication, there will usually be a long series of pre-planned secondary and ancillary analyses. These studies – which often involve tens of thousands of research participants – will generally be conducted by large multi-disciplinary teams, which may include senior and experienced investigators as well as more junior and middle-level scientists from local institutions where research capacity is still being built. The latter will often take responsibility for preparing and publishing the secondary trial outputs, and this is very important for their career development. But if data are shared openly within 6 months of the primary publication, other groups (for example well-resourced groups in high income countries (HIC) who have contributed nothing to the conduct of the research over such a long period) may easily outpace the work of trial scientists in low and middle income countries (LMIC) and submit publications on these topics before they are able to - further exacerbating the asymmetry of opportunity between HIC and LMIC researchers.

We are aware that the ICMJE proposal only requires open sharing of the data needed to replicate the results in the primary publication. Potentially, therefore, the authors could restrict the number of variables shown in the paper so as to minimise the amount of data that needs to be shared, and thus to protect the ability of the study team to publish secondary analyses. This would be a perverse result of the proposed policy as it would reduce the value of the shared data. Moreover, many of the studies we conduct are cluster-randomised trials (CRTs), for which there are special issues. Because many CRTs have a small number of clusters randomised (often a cluster is a large community), there is always a concern over balance across study arms, and this has to be carefully checked by the investigators in the analysis. Thus, to allow for full

replication of the findings, investigators would potentially have to share *all* the study variables under the proposed requirements.

We feel that these concerns might be minimised if a 12 month rather than 6 month period of exclusive use were adopted. Particularly for large studies, taking many years to complete, this would seem to be a proportionate arrangement that protects the legitimate interests of researchers at the same time as ensuring that data can be shared without undue delay. This would also help to ensure that trial results are analysed and presented carefully, and thus maximise their value to policy-makers and other stakeholders. If the main concern of the ICMJE editors is over the transparency of findings – and the ability to carry out replication analyses to check that data have been correctly analysed and reported - we feel that this could be ensured in other ways. For example, there might be a requirement for investigators to share the data for replication on a confidential basis at an earlier stage.

Those advocating for greater data sharing correctly point out that we have a duty to the study participants to maximise the value of the data that they have voluntarily provided. But we must make sure that the proposed requirements do not make it so unattractive and unrewarding for researchers to carry out challenging long-term primary research that such studies are not carried out. This would be a grave disservice to the public.

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