Letter from 336 investigators in 28 countries

April 10, 2016

Dear Members of the International Committee of Medical Journal Editors:

We are writing regarding your proposed plan for "Forced Data Sharing" that will require authors to freely share with individuals who had nothing to do with a trial, the de-identified individual patient data (IPD) underlying the results presented in an article within 6 months of its publication.[1] In the article that reported the International Committee of Medical Journal Editors (ICMJE) data sharing proposal, you stated the following. "Sharing data will increase confidence and trust in the conclusions drawn from clinical trials. It will enable the independent confirmation of results, an essential tenet of the scientific process. It will foster the development and testing of new hypotheses. It will help to fulfill our moral obligation to study participants, and we believe it will benefit patients, investigators, sponsors, and society."[1]

We support data sharing in an appropriate and timely manner, but we do not support the proposal of the ICMJE, as it currently stands. We believe that the **current** proposed plan of forced data sharing will not result in a **net** benefit to patients, investigators, sponsors, or society. Our concern regarding possible net harm arises from likely unintended adverse consequences of the proposal (Table 1). These possible adverse consequences are based on several concerns which are summarized below. This leads us to propose alternative approaches to achieving the benefits of data sharing while minimizing the adverse consequences.

1) The ICMJE proposal does not assure the intended goals will be achieved. An alternative would do better.

Our first concern with the ICMJE proposal is that making data freely available does not guarantee confirmatory analyses will be undertaken. Moreover, the proposed plan will not provide readers the assurance they want regarding data confirmation, at the time they are reading an article. A solution to this issue is to have authors provide the data to statisticians affiliated with journals. These statisticians would ideally conduct confirmatory analyses before a paper is published, or later should there be questions that challenge the basic findings of the study. Alternatively, authors could be required to obtain confirmatory analyses by accredited independent statisticians before submitting a paper. If such an approach were required, there would be a need to establish mechanisms to fund this activity. We strongly support developing parallel approaches for studies that are not submitted for regulatory approvals. This would appropriately enhance the confidence healthcare providers have in the results of a trial, when they read an article. At present, studies that are submitted for regulatory approvals are required to submit the entire database to the regulatory bodies (e.g., the US FDA) who conduct extensive independent analyses before approval is granted for marketing. For such trials the standardized Clinical Study Report should be made publicly available.[2]

2) The time frame is too short to allow the appropriate analyses and publication of the data by the individuals who have created the new knowledge.

The proposed timeline for the release of de-identified IPD is too short. Major trials often take between 5-10 years or more to conceive, fund, establish, recruit patients, complete follow-up, analyse, and report. Six months is far too short a time for the investigators in a trial to fully

analyse all planned analyses and report the results. In our experience, important findings often require a few years of analyses and drafting reports for publication. The current proposal of 6 months to release data deprives investigators who actually invested many years (often a decade or more) of efforts, the rightful opportunity to utilize the data for both fully understanding their results as well as reaping justifiable scientific credit for their many years of efforts.

These investigators should be given a reasonable timeline to undertake the analyses of the relevant reliable data, submit the resulting papers, and get them published. Six months is not a realistic timeline, and it would result in situations where various groups simultaneously submit similar analyses to different journals, resulting in duplicate publications, some of which are likely to be incorrect and misleading (Table 1). We propose instead that every study be provided a minimum of 2 years after the first publication of the results and up to an additional 6 months for every year that it took to complete the study (i.e., write the protocol, obtaining funding, obtain ethics and regulatory approvals, recruit the patients, complete the patient follow-up, and clean the database).

Further, a large trial is completed based on the efforts of several hundred investigators. At the end of a study, few funding bodies provide adequate resources for extended data analyses and so the investigators often have to raise additional resources and this takes further grants. The situation may be more difficult for investigators from poorer countries. If data were released within 6 months of the publication, this could lead to a situation where investigators (who had nothing to do with the study) from well-resourced countries could exploit the data as a priority that were generated by the investigators from poorer countries. This would lead to furthering the inequities between investigators in poor and rich countries.

Many studies conduct extended follow-up of their trials after reporting the main results. Others that utilize a factorial design may report on one arm of the trial while other arms continue. Early disclosure of the data could compromise the integrity of further follow-up or the continuation of some arms.

3) The proposal fails to consider important differences between large and small trials; there are adverse consequences of applying the proposal to large trials.

Applying the requirement to provide IPD within 6 months of publication to both small and large clinical trials is problematic.

Small trials involve moderate efforts. Further, the data permit limited secondary analyses that investigators should be able to undertake within a relatively short time frame. In contrast, large, multicentre, international trials commonly take 5-10 years of investigators' time to complete.[3-7] Before conducting a trial, investigators have to develop a protocol, obtain funding, and overcoming regulatory and bureaucratic challenges. These processes themselves take between 2 and 3 years. The recruitment, follow-up, data cleaning, and database locking of the trial often takes an additional 5-7 years. If the investigators are not able to obtain the academic outputs commensurate for their efforts, it is likely that fewer investigators will invest the necessary time and effort to conduct large trials of important questions, especially if they are difficult to fund. Over time, investigators will be reluctant to conduct such large trials and might shift their focus to other endeavours. This could harm the generation of new knowledge.

To complete a large clinical trial, there is invariably the need for many centres. Site principal investigators are likely to appear only in an appendix of the primary publication of a trial, in comparison to the members of the steering committee who are most likely to appear on the byline. It is usually in secondary publications that site principal investigators can participate

and be recognized for their contributions. If this is limited, then there is a real risk with the current ICMJE proposal that fewer investigators from recruiting centres will participate in subsequent trials, because the likelihood that they can author a secondary paper will substantially decrease since many more individuals not involved in the trial, and who have not contributed to the efforts, will have the same access to the data. If the number of investigators willing to recruit patients into a trial decreases, it will be harder to complete large studies of important questions; many of these address questions of great public health or clinical importance and have limited or no funding.

4) The ICMJE proposal provides a motivation to delay publication of key results.

If the ICMJE proposal for forced data sharing were to be implemented, there is a substantial risk that investigators will delay publishing their primary trial results, to allow the study investigators to prepare secondary papers that can undergo submission to a journal as soon as the primary paper is accepted.

Delay or failure to publish the primary results of clinical trials is already a substantial problem. Gordon and colleagues published a paper in 2013 that evaluated 244 trials funded by the National Heart, Lung, and Blood Institute.[8] More than a third remained unpublished 30 months after data collection was completed, and among the published trials, the median time from completion of data collection to publication was >2 years. Other studies, not restricted to peer-reviewed funded trials, support this finding of a substantial proportion (i.e., ≥30%) of clinical trials going unpublished 4 years after completion of data collection.[9,10] The ICMJE's current plan to require data sharing within 6 months of a publication is likely to exacerbate this problem; investigators may delay submission of their primary publication by many months to allow themselves time to prepare several secondary papers that can undergo submission to a journal as soon as the primary paper is accepted.

This potential unintended consequence of the ICMJE's proposed plan may also differentially impact the larger trials that are currently published the quickest. Relative to small trials, large clinical trials have the greatest impact on clinical care,[11] typically are of higher quality,[12] and are published more quickly regardless of whether they have a positive or negative result (i.e., they minimize the risk of publication bias).[8] Because often these large trials can yield many useful secondary publications, these are the very trials at risk of delayed publication of the primary results based on the ICMJE proposal.

Delaying primary publications is problematic. Patients consenting for a clinical trial are told about the primary question the trial is addressing. Investigators' primary moral obligation to patients is to answer this question and get the results out in a timely fashion. Furthermore, it is the primary results of clinical trials, not the secondary analyses – often focused on questionable subgroups[13] – that are paramount to clinical practice.

5) The proposal imposes financial penalties on clinical trial investigators.

Many trialists conducting investigator-initiated trials spend substantial amounts of money they have generated from other activities, to cross-subsidize trials addressing questions that are not of interest to business sponsors. If individuals want to access these data the investigators should be able to recoup some of their costs through charges to other investigators accessing the data.

Moreover, the process of preparing the data for investigators not involved in the trial is onerous and involves substantial time and effort. Imposing this additional cost on investigators is problematic. Doing so without consideration of investigators legitimate interests is unfair.

6) The ICJME proposal for forced data sharing fails to consider fair alternatives that could achieve the goals without the adverse consequences (Table 1).

Trial investigators themselves should be afforded the first opportunity to undertake analyses proposed by investigators who were not involved in a trial. Often it is only after the main trial results have emerged that follow-up questions are identified. This requires significant effort, money (which often requires additional grants), and time on the part of the original investigators. Only if the investigators cannot undertake the proposed analyses and submit the paper for publication within an 18 month time period, should the investigators who were not involved with the trial be given the opportunity to access the data for the proposed analyses. An independent entity like ClinicalTrials.gov could facilitate such a process.

Proposed modifications of the ICMJE plan to avoid the adverse consequences in Table 1.

There is a need to modify the ICMJE plan to ensure: a balanced approach where the accuracy of the data can be verified; the original investigators' legitimate scientific rights are protected; the data can be explored in a systematic and fair way for the public good; and the avoidance of disincentive for investigators to develop and undertake trials and site investigators to participate in recruiting patients. We are requesting that you modify the ICMJE proposed plan on data sharing as follows:

1. To enhance readers' confidence in published data, an independent statistician should be offered the opportunity to conduct confirmatory analyses before publication of a paper.
2. The timeline for providing de-identified IPD should be a minimum of 2 years after the first publication of the results and up to an additional 6 months for every year that it took to complete the study (i.e., write the protocol, obtaining funding, obtain ethics and regulatory approvals, recruit the patients, complete the patient follow-up, and clean the database).
3. Individuals who were not involved in an investigator-initiated trial but want access to the data should have to financially compensate the original investigators who conducted the trials, so they can recoup some of their costs of conducting the trial, for the efforts of making the data available, and to support further analyses of their data.
4. Trial investigators should be afforded 18 months to undertake any analyses and submit the resulting paper proposed by investigators who were not involved in a trial.

Sincerely,

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Table 1: Potential unintended consequences of the ICMJE data sharing plan

Groups that could experience a net negative effect due to proposed plan	**Outcomes that would result in a net negative effect**
Trial participants	Investigators delay publication of primary results to allow time to prepare secondary papers that can undergo submission to a journal as soon as the primary paper is accepted.
	Individuals not part of the investigators who conducted the trial will undertake data dredging exercises and publish spurious subgroup analyses that can mislead and negatively impact clinical care. Further, analyses may be motivated to undermine results, to further other interests and can lead to unwarranted doubts about the findings.
Investigators	Investigators are unable to publish secondary analyses because other investigators who were not involved with the trial obtain the data and publish such results before the trial investigators themselves are able to do so. This will undermine motivation for participation in the research enterprise that produces the data in the first place.
	Trialists have less opportunity for career advancement (e.g., university promotion) because their productivity is limited because they are not able to capitalize on their investments in conducting a large trial. Often students or junior investigators who were involved in the trial and use the study data for their thesis or early papers will have their opportunities curtailed.
Sponsors	The decreased motivation for investigators will make mounting a large trial more difficult.
	Fewer investigators from participating centres are willing to enroll patients because the likelihood that they can author a secondary paper has substantially decreased.
Society	Fewer large clinical trials are undertaken because investigators are unwilling to spend 5-10 years of their time developing an idea and protocol, obtaining funding, overcoming regulatory and bureaucratic challenges (which often takes several years), and conducting the trial only to have other individuals obtain the data within 6 months of the primary publication and limit their ability to publish papers from the trial. This would widely be seen as restricting the ability of the original investigators to have a

	reasonable opportunity to fully explore the data they have been central to generating.
	Many trialists spend substantial amounts of money they have generated from other activities to cross-subsidize peer reviewed grants addressing generic questions. Fewer trials (not funded by commercial organizations) will be initiated because fewer investigators will be willing to invest their resources subsidizing clinical trials because their scientific opportunities are limited.
Editors	It is likely that various groups will simultaneously submit similar analyses to different journals that will result in duplicate publications.
	If journals accept papers from authors who analyze data from a trial in which they were not involved, the results may not be robust. The authors will not realize which data points are not robust and as a result some findings will be subsequently found erroneous.

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