Editorial

The International Committee of Medical Journal Editors proposal for sharing clinical trial data and the possible implications for the peer review process

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The recent proposal by the International Committee of Medical Journal Editors (ICMJE) for the sharing of clinical trial data will surely be a topic of much discussion within and outside academic circles (1). It is difficult to argue against the principle behind this proposal. Open and accessible data from a clinical trial may permit others to validate the findings, thereby increasing confidence in the results and importantly directing scarce resources to future work in the reproducible fields/areas that have clinical benefit. In fact, sharing data may be beneficial for all of science, not just clinical trials (2-4).

With every change there is resistance and obstacles to overcome. The ICMJE is accepting feedback on this topic (www.icmje.org) and have identified several areas where input is required and where potential roadblocks exist. One important stakeholder that appears to be neglected in this process is the role of peer reviewers. The ICMJE proposal permits sharing data no later than 6 months after publication (1); however, in doing so it is clear that the objective is for transparency and not necessarily for the scientific assessment during the peer review process. Peer reviewers are vital for the successful dissemination of scientific results. So wouldn't it be reasonable to have the individual-patient data (IPD) available for their review rather than after the publication of the study? Moreover, if there is a lack of confidence in scientific literature (1-4), one could question how low the confidence would be if there was no peer review process?

There are *Pros* and *Cons* to this approach of having IPD available for peer review:

(I) *Pro:* reviewers take on assignments with the understanding that the manuscript and findings need to be treated confidentially; having access to the IPD would be the next logical step in the scientific review.

Con: reviewers would be the earliest potential users to gain access to the IPD, thus possibly obtaining an unfair advantage to either enhance their own studies or possibly delaying the peer review process even further with additional, even trivial, analyses on the IPD;

(II) *Pro:* reviewers are selected based on many criteria, with a common criterion being established skills/expertise in the field/area; thus making these individuals ideally suited to evaluate the IPD.

Con: demonstrating expertise is not equivalent to expertise in evaluating and performing the complicated statistical analyses performed within the study;

(III) *Pro:* allowing reviewers' access to the IPD may prevent an erroneous finding from being published or a paper from being retracted after publication based on scientific error.

Con: scientific fraud and error may still occur as the IPD itself may be corrupt and the additional assessment and review of the IPD may further contribute to reviewer fatigue, burden and burnout;

(IV) *Pro:* reviewers may focus critiques and comments based on the actual dataset rather than blindly asking for analyses that cannot be performed.

Con: presently, the acknowledgment and the importance for the reviewers' role in the scientific publication process in academia and beyond is undervalued; with the many demands on these

experts' time why would they wish to do more work in assessing the IPD?

There are additional points and arguments besides those listed above with respect to the availability of the IPD for the peer review process. Notwithstanding this scenario, there are important practical aspects that will need to be addressed if the sharing of the IPD after the clinical trial publication becomes truly open and widely accessible as envisioned by the ICMJE. First, the survey findings of the United Kingdom publically funded Clinical Trials Units have highlighted significant concerns for sharing data including the misuse of data/incorrect secondary analysis, resource requirements/implications, loss of ability to publish, additional consent requirements, and identification of patients (3). Second, even in journals that require data to be shared at the time of publication, such as the *PLOS* journals (4), there can be wide variation and expectation of the actual data available when the article is published. A quick search on topics in *PLOS* revealed datasets that require specific commercial statistical software programs to open the files (i.e., thereby limiting the accessibility of the data) while other publications stated for the data availability section that "All relevant data are within the paper"; yet the publication consisted of thousands of patients with no IPD available (i.e., a contrast to the statement). Third, IPD sharing may need to occur in other scientific fields/areas outside of the clinical trial realm in order to maximize on this initiative. As an illustration of this third point, assume a study is published on a clinical trial that demonstrates a favourable intervention for patients with a diagnosis of a non-ST elevation acute myocardial infarction (NSTEMI). By definition, for the diagnosis of NSTEMI the patient's cardiac troponin result (a diagnostic laboratory test) is required to exceed the 99th percentile upper reference limit (URL) from a healthy population (5). Evaluating the IPD from the clinical trial indicates that indeed all NSTEMI patients fulfil this criterion, reassuring other investigators and the public that the inclusion criteria were met and the intervention was beneficial in NSTEMI patients. Yet, there is no guarantee that the actual clinical study that established the cardiac troponin cut-off used in the clinical trial was correctly calculated (6,7); and without the requirement to provide the IPD for this clinical study one will not be able to evaluate this important point.

Herein lies the problem, science is fluid and builds on data obtained from correctly designed experiments. Siloing off or placing different criteria for one particular scientific field/area and not others will not eliminate errors in scientific publications. However, sharing IPD after publication as the ICMJE proposes for clinical trials or possibly even during the peer review process is an important first step. Sometimes one area/field needs to be a leader for others to follow; it appears yet again that the ICMJE is ready to take this important next step in medical research.

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Footnote

Provenance: This is a Guest Editorial commissioned by Executive Editor Zhi-De Hu(Department of Laboratory Medicine, General Hospital of Ji'nan Military Region, Ji'nan, China).

Conflicts of Interest: Dr. Kavsak is currently the Editor-in-Chief for *Clinical Biochemistry*.

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