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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: More on why not to publish protocols until trials are done

I wrote previously on this topic just the other day (25 March 2020). It generated comments from several people.

Richard Chappell (chappell@biostat.wisc.edu)

I like Friedman, Furberg, & DeMets' recommendation that block size be random (e.g., interspersed 4, 6, and 8 for a two-arm trial). That way we can publish complete details of the allocation method in the protocol. We wouldn't need to state the exact sequence of block sizes any more than we ought to give the randomization sequence.

I do agree with Curt's warning about needing to publish amendments.

An-Wen chan (anwen.chan@utoronto.ca)

Providing certain details of random sequence generation (e.g. block size) in the protocol is indeed problematic. The SPIRIT protocol guidance recommends that such details be provided in a separate document so that early protocol publication does not facilitate bias.

Tianjing Li (TIANJING.LI@CUANSCHUTZ.EDU)

I would argue that there has never been a more important time for trialists to be sharing their protocols during the global pandemic. As of last Friday, there are over 300 COVID-19 “trials” ongoing. It’s chaotic if one reviews the registration records of some of these trials (and many unfunded). The journal *Trials* argue that it is essential to have the fullest record of trials to ensure that we maximally learn from them (and avoid being misled by shoddy research). The journal took on an initiate to provide fast track publications for COVID-19 trial protocols with article procession fees reduced or waived. It’s an important step to support research integrate to minimize waste, avoid post hoc changes, and keep our promise to patients.

Marc Buyse (marc.buyse@iddi.com)

I am a bit puzzled by your position on publishing protocols after trials are completed: isn’t there a requirement to make the trial protocol publicly available as soon as patient accrual is opened (e.g. in ClinicalTrials.gov)? With the current (and most welcome) trend of increased patient engagement, I would find it rather a good thing for patients to be fully aware of all ongoing trials. To me, that is far more important than, say, masking randomization, which can easily be done by not providing such level of detail in the protocol.

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To be clear, I favor posting protocols to CT.gov when trials are started and updates as they occur! But I do not regard posting as the equivalent of publication in peer-reviewed indexed medical journals.

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I also recognize that there are journals, such as *Trials*, that publish protocols as standalone publications.

The problem I have with publishing protocols (not to be confused with posting on registration websites) as standalone publications before trials are done is then I am committed to publishing updates when changes occur for fear of being crucified if I failed to do so when results are published.

I am of the mind that, as a researcher, I was born with a specified number of publications in me and when that number is reached my paper writing is over. That being so, I am reluctant to spend chips from that account writing updates to protocol publications detailing changes I know will come. For me, the better plan is to publish protocols and changes as supplemental material in initial results publications.