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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: An NLM-indexed website for nil and negative results?

Not every trial deserves to be published. Some are so poorly conceived and done so as to not generate any useful results.

But even if a trial produces worthwhile results the results will be hidden to the public if not written up or if rejected by journal editors.

The work of meta-analysts and systematic reviewers is colored by publication bias because of differences in the publication behavior of authors and editors, depending on the nature and direction of results. Indeed, the Cochrane Collaboration devotes considerable time and energy to finding studies, whether published or not, before undertaking systematic reviews. Part of the reason for the requirement of registration as a condition for publication by medical editors was to help the meta-analysts and systematic reviewers find trials.

All trialists can do is try to get their results published. If medical editors reject them they are counted among those who failed to publish and as contributors to publication bias.

A step forward would be establishment of an NLM-indexed website for manuscripts rejected for publication.

Conditions for acceptance of manuscripts for repose on the website would be:

- 1. Registration on clinicaltrials.gov or a similar registration website
- 2. Ethical review and approval of the trial
- 3. Evidence of submission to and rejection by at least two NLM-indexed medical journals

The existence of such a website would:

- 1. Make it possible for trialists to meet their ethical obligation to publish results when journals reject them and still appear in an NLM-indexed medium
- 2. Provide a measure of the amount of publication bias due to medical editors rejecting results

3. Make results of trials available in a more timely fashion than possible now with multiple submissions and rejections

One of the benefits of such a website is that it would give trialist, committed to publishing regardless of the nature or direction, something to ensure investigators that their efforts will not be for naught. I know, as one committed to publishing, that it is a lonesome journey convincing fellow colleagues to write-up nil or negative results. Invariably what you hear is "no journal will be interested". At least with an NLM-indexed website, there would be a place for publication regardless of the nature or direction of results.

My wish is that the signatories of the registration manifesto of medical editors, the Cochrane Collaboration, and the Society for Clinical Trials will work for the establishment of such a website. We would all be better off knowing how investigators report and analyze their results than by meta-analysts and systematic reviewers digging them out and analyzing them for us.

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