

A need to stand united: reply to the WAME secretary

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I believe Dr Winker and I agree more than differ about the need for authors of medical journal reports of randomised controlled trial (RCT) findings to acknowledge when they make post hoc adjustments to the original content that they submit to obtain FDA marketing approval for a new drug or medical device (1).

Medical journals have a critical role to play in assuring truth in research labelling. Indeed, as its membership implements the WAME policy, Principles of Transparency and Best Practice in Scholarly Publishing (2), its task will be made easier by enactment of reinforcing national laws and regulations requiring truth in research labelling. Success in this endeavour will enable us to achieve our common goal of promoting the integrity of biomedical science in support of evidence-based medicine.

I'm encouraged by Dr Winker's disclosure that some journals do require submission of research protocols and statistical analysis plans to enable editors to compare submitted manuscript outcomes with outcomes originally provided at the time of trial registration. Ideally, such scrutiny should happen without exception. Unfortunately, limited compliance with the registration and reporting requirements of Section 801, Public Health Service Act (42 U.S.C. 282) makes it impossible to do so in all cases (3, 4).

I think we agree that journal editors should require authors of published reports to make explicit how peer-review required changes differ from registered RCT content. Journal readers need to know and decide for themselves whether post hoc adjustments to the registered RCT are justified.

The truth-in-research-labelling petition (5) reaches beyond the problem of limited compliance with the Section 801 registration mandate. It addresses with supporting documentation the disparity between RCT content submitted to the FDA to obtain marketing approval, and that submitted to www.clinicaltrials.gov. Eliminating the disparity will enable journal editors to rely on registered RCT content as a reliable source of information. Medical editors and peer-reviewers will "regularly fail" to know for sure which version they are vetting of RCT content until the loophole in existing law is closed.

The WAME policy, Principles of Transparency and Best Practice

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in Scholarly Publishing (2) by embrace of the COPE Code of Conduct for Journal Editors (6) is committed to high quality peer-review, and thus to what we learn from the Chauvin et al (7) report about the tasks most highly rated by peer-reviewers. They explicitly value risk assessment of RCT bias, the reliability, validity and reporting of all outcome measures, the search for any attempts to distort outcome reporting, and evaluation of the study's importance. This is consistent with what is known about the effectiveness of peer-review in discerning research quality (8).

I would like to address the concern Dr Winker raised about follow-up expectations. We seem to have had a different interpretation and expectation about what was to happen on the basis of my follow-up email to which she refers. I sent it hoping that WAME would reconsider after receipt of additional evidence (9, 10) that an estimated 85% of the medical research is an untrustworthy guide to evidence-based medicine. I suggested a change from "high frequency" to "many."

Because the petition had already been launched, the change could not be made. Once activated and gathering signatories, it is not ethical to make post hoc adjustments to a petition midstream. The final petition is the message to be read and decision made whether to endorse. I accepted, therefore, her email of September 30, 2016 as definitive refusal to endorse or distribute it to the WAME membership.

In passing, let me say that I'm sorry our exchange has become side-tracked by the obvious error in my losing of Dr Winker's "bolding" of the petition's text and numbering differently of her objections. I should have numbered the first objection as 1a and 1b instead of 1 and 2. For this I apologise, and have requested that the *Indian Journal of Medical Ethics* correct these formatting errata. There was no substantive change to what she had to say, nor did the bolding of the petition's text alter its meaning.

I am hopeful that in light of the fact that we agree on the fundamental principles of transparency, consistency, validity and integrity in data reporting, WAME can now lend its support to the petition. Given the massive challenge ahead of incentivising and changing how biomedical research is organised, managed and reported (11), there is more to be gained in standing united in reaching our common goal of truth in research labelling than in remaining divided over perceptions of magnitude or frequency. I believe we have more to gain than lose in collectively supporting a petition to amend legislation to prevent misleading or biased scientific reports from growing in numbers.

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