Commentary on case for BJOG compliance with prospective trial registration

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Prospective registration of clinical trials ***before*** enrolment of the first participant is an ethical and scientific imperative required by the International Committee of Medical Journal Editors (ICMJE) (De Angelis et al, Lancet 2004;364:911-2), the World Health Organization's International Clinical Trials Registry Platform (WHO-ICTRP) and the revised World Medical Association's Declaration of Helsinki. Registering clinical trials reduces duplication of research and aids better identification of gaps in our knowledge, as when all research on a topic can be identified it is easier to know when a new study is not needed, as the question has already been answered; and if all research is identified it becomes easier to see where there are gaps, and so where new studies are needed. ***Prospective*** registration of clinical trials reduces publication bias and bias due to selective reporting of studies with equivocal or 'negative' results, since studies are identified and registered before their results are known, and there is less likelihood that our understanding of research evidence is distorted by studies that have disappeared without a trace, or are slow to appear. Prospective registration of trials additionally reduces bias due to selective reporting of outcomes that are 'positive' as outcomes are disclosed at registration and can be compared with published reports. Prospective registration thus contributes to less scientific misconduct, as failure to report research findings accurately and make them publicly available, is a betrayal of trust of the people who participated in that research, and can lead to harm in patient care. Prospective

registration also makes it harder to fabricate research results, and can result in less scientific fraud (Abaid LN et al. Obstet Gynecol 2007;109:1434-7).

Since its implementation in 2005, the ICMJE requirement for prospective trial registration has led to a rapid increase in the number of trials registered, but the quality and timing of registration still needs improvement. For example, in one recent survey just under half the trials published in high impact journals had been adequately registered, and trials published in general medical journals were more often properly registered than those published in speciality journals (Mathieu et al, JAMA. 2009;302:977-984). Adequate registration for all trials requires the entire scientific community to endorse and adhere to the requirement for trial registration before the first participant is enrolled in a trial. Trial registration is not enough, registration needs to be prospective and provide adequate information about the study design to ensure that what is reported was what was intended. Submitting an unpublished study protocol along with the trial manuscript does not adequately fulfil the requirements of transparency, and does not eliminate doubts about reporting biases.

To ensure publication of unbiased results the BJOG needs to ensure that its editors, authors and reviewers comply with its policy of requiring prospective trial registration. Trials which have failed to register prospectively should make their results publicly available, but should not be rewarded with publication in a mainstream journal such as BJOG.

Declaration of Interest

Lisa Askie is the manager of the Australian New Zealand Clinical Trials Registry.
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