

EDITORIAL

In the September 15, 2004 issue of *The Journal of the American Medical Association*, an editorial statement was published that was signed not only by the editor-in-chief of *JAMA*, but also by the editors-in-chief of *The Lancet* and *The New England Journal of Medicine*, as well as by the editors of several other internationally significant medical journals (DeAngelis *et al*, 2004). This editorial, which can be found at the following website <http://www.jama.ama-assn.org/cgi/content/full/292/11/1363>, was from the International Committee of Medical Journal Editors (ICMJE) announcing that all 11 member journals were adopting a policy of only publishing results of clinical trials that were registered in a publicly accessible database, i.e., any clinical trial not registered in such a database, no matter how well done, would not be publishable in one of their journals. An update of this editorial (De Angelis *et al*, 2005), including a minimal registration data set recently mandated by the World Health Organisation, can be formed in the 15 June 2005 issue of *JAMA* or at <http://jama.ama-assn.org/cgi/content/Full/293/23/2927>.

As stated in the *JAMA* editorial, the reason for this dramatic action was serious concern by the ICMJE over the 'selective reporting' of clinical trials by certain research sponsors and/or investigators. Many causes could result in such selective reporting. For example, some trials might go unpublished because the investigators (or certain journals) think the results mundane and not worthy of publication. In others, the interpretation of findings might not be clear at the time of study completion or even for some time thereafter. In still others, publication of results might have financial implications. We suspect the latter, and several recent, highly publicized drug-recalls prompted by the occurrence of significant adverse events that might have been anticipated from data apparently available to sponsors and/or investigators, stimulated the ICMJE action. Clearly, the ICMJE was particularly concerned that the trust of patients, which underlies the entire clinical research endeavor, was diminishing because of perceptions that clinical trial results may be published in a manner to reflect primarily self-interests of a study sponsor, e.g. a drug manufacturer, or those of an individual investigator.

As described in the *JAMA* editorial (DeAngelis *et al*, 2004), a clinical trial for the purposes of the ICMJE policy statement was defined '...as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause and effect relationship between a medical intervention and a health

outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., phase 1 trials), would be exempt.'

As noted, the ICMJE endorsed a policy favoring the registration of all clinical trials in a public database. At the time of the *JAMA* editorial, and still now, the only major such website available is at <http://www.clinicaltrials.gov>, a site sponsored by the US National Library of Medicine. Patients can access this site and find information about various clinical trials including searches by disease condition, sponsor, location, and recruitment status. Investigators or sponsors can register a trial at <http://www.prinfo.clinicaltrials.gov/>.

Among the types of information required for registration are the following:

- Sponsor
- Funding source(s)
- Contact person for participation
- Contact person for scientific inquiries
- Title of the study
- Information about ethical committee approval
- The condition being studied
- Information on the intervention and control comparison, including drug name, if applicable
- Key inclusion and exclusion criteria
- Study type (e.g., double-blind, crossover, etc.)
- Enrollment start date
- Total number of subjects to be enrolled
- Recruitment status
- Primary outcome
- Secondary outcomes

More details related to the registration of a clinical trial are available at <http://www.prinfo.clinicaltrials.gov/who-icmje-crosswalk.html>.

The type of information required is not difficult to assemble and should be part of any routine peer-reviewed clinical protocol submission. Nonetheless, we recognize that registration of a clinical trial is yet another administrative responsibility for already paper-work-weary clinical investigators. However, as the *JAMA* editorial points out, maintenance of public trust, and encouragement of the public's willingness to participate in clinical trials, requires special action.

We agree with the ICMJE statement, and we are strongly in favor of requiring that all clinical trials, as defined above, submitted for publication to *Oral Diseases*, whether dealing with prescription or over-the-counter preparations, be registered in a publicly accessible database. We accept the ICMJE arguments that such a registry promotes public trust in the clinical research endeavor. To that extent, we announce to our

readers and potential contributors, and will post on the *Oral Diseases* website, that effective with submissions beginning January 1, 2007 we will only publish the results of clinical trials that have been registered at <http://www.clinicaltrials.gov> or a similar, and readily accessible, website. The ICMJE argues that 'full transparency' is needed for the conduct and publication of clinical trials, no matter the product, no matter the condition. We at *Oral Diseases* agree fully. On our part, we pledge to publish well-conducted and well-written studies, even if results are what might be described as mundane (though true impact might not be appreciated for years), as long as the studies have been peer-reviewed prior to conduct and are publicly registered. We hope this policy will foster both high-quality science and

increasing public trust. We hope our contributing authors and readers agree.

**Bruce Baum &
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References

- DeAngelis CD, Drazen JM, Frizelle FA, *et al.* (2004). Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *JAMA* **292**: 1363–1364.
- De Angelis CD, Drazen JM, Frizelle FA *et al.* (2005). Is this clinical trial fully registered? *JAMA* **293**: 2927–2929.

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