

Ensuring health care decisions are informed by all of the evidence: the role of trial registration

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), the World Health Organization's International Clinical Trials Registry Platform (WHO-ICTRP) and the revised World Medical Association's Declaration of Helsinki. Registration of all trials with meaningful disclosure of the 20 item dataset mandated by WHO and the ICMJE is an important step towards reducing publication bias (*JAMA* 2003; 290:516-23), where studies with statistically significant positive or favourable results are preferentially published. A third of clinical trials presented as conference abstracts do not have results published (*Cochrane Database Syst Rev* 2007:MR000005). Trial registration can also help prevent the selective reporting of favourable outcomes over those that are less favourable or harmful (*PLoS ONE* 2008; 3:e3081). Failure to publish research has been described as scientific misconduct. If we are not to be misled, decisions about health care need to be informed by all the available evidence.

Other potential advantages of making information about all trials easily available are that it becomes easier to prevent wasteful duplication of research, as researchers, funders and ethics committees are more able to assess whether similar studies have already been conducted, or are ongoing. Similarly, it is easier to identify gaps in knowledge, where new studies need to be conducted.

The ICMJE requirement for registration led to a rapid increase in the number of trials registered; the quality and completeness of information provided also improved.

Trial registration does not ensure that all studies will publish their results in a timely manner. Worryingly, less than one in five registered cancer trials that had been completed or terminated, have published results (*Oncologist* 2008; 13:925-9). Terminated trials and industry-sponsored studies were the least likely to be published. Nevertheless, an easily accessible international comprehensive register of trials would at least allow unpublished studies to be identified. The hope is that allowing anyone with an interest to find out whether a trial has taken place could lead to more information about such studies becoming available.

National and regional trials registers that are linked to the WHO-ICTRP and integrated into local ethics and regulatory processes, and are in languages understood by local researchers and the public, are ideally placed to ensure complete and comprehensive registration of all trials in their domain. The requirement for trials registration by journals indexed in the LILACS and SciELO databases is a major step towards ensuring registration of all trials conducted in Latin America. The concerted action of funding agencies, medical journal editors, ethics committees and regulators and ongoing audit of compliance with the requirements of registration and reporting of trial results will also be needed to help ensure that health-care decisions in Latin America, and elsewhere, are informed by all the available evidence.

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