

Voluntary registration of unreported randomised trials: an initiative from medical editors

Reports of properly conducted randomised controlled trials are the foundation of safe and effective health care. However, a substantial proportion of all controlled trials never contribute to this knowledge base because they are not submitted for publication.^{1,2} This fact has a number of important implications for patient care. Firstly, under-reporting of trials reduces the power of systematic reviews to detect moderate but clinically important treatment effects. As a result, patients may be denied effective forms of health care. Secondly, as trials that show more promising treatment effects are more likely to be submitted for publication, research syntheses based on published studies can give misleading conclusions about treatment effectiveness, thus exposing patients to useless or even harmful treatments.³ Finally, patients may be asked to participate in new research studies designed to consider questions that have, in truth, already been answered.⁴

Trials go unreported for a myriad of reasons; the most common is that investigators think the results are “not interesting”, and it is well documented that trials with non-significant results are substantially less likely to be submitted for publication.¹ Sometimes participant recruitment takes longer than expected at the expense of time and resources set aside for report writing; investigators may change jobs with the result that important work remains unfinished; or investigators may discover a recently published trial on the same topic and conclude that their own results are now redundant. Editors must also take some of the responsibility. There is a limit to the number of reports we can publish and sometimes we are forced to decline publication.

Many investigators regret not having published their trial results, and almost all investigators when contacted about unreported data are delighted to provide it.

Because of the important consequences of unreported trials, the editors of nearly 100 international medical journals have joined together to call an unreported trial “amnesty”. Although amnesty is perhaps not quite the

right term, we hope that investigators will appreciate the spirit of the initiative and see this as an opportunity—namely, to make the results of previously unreported trials publicly accessible, thus having the potential to contribute to the scientific foundation of health care. We urge all investigators with unreported trial data to register their trial or trials by filling in and returning an unreported trial registration form. We would like to register any unreported controlled trial, including trials that have only been published as an abstract. Registration can be undertaken by anyone able to provide the registration information, even if they are unable to provide the actual trial data. We expect a degree of duplicate registration. Registration information can be posted or sent by email (meta@ucl.ac.uk). The information will be made available by listing the trial details on a web site, and in other ways as appropriate. If specific trial data are required, for example by those conducting systematic reviews, then the reviewer will be able to seek this information directly from the trialist. Some of the trials may be suitable for full publication, and the journal will be happy to consider these.

Medical editors are acutely aware of the trials and tribulations of research reporting, but on this occasion, because of the serious implications of unreported research, we are endeavouring to cleave the trials from the tribulations. We cannot confidently estimate the total number of unreported trials, but we are confident of a good response.

RICHARD SMITH

Editor, *BMJ*

- 1 Dickersin K, Min YI. NIH clinical trials and publication bias. *Online J Curr Clin Trials* [serial on-line] 1993;Apr 28:Doc No 50.
- 2 Easterbrook PJ, Berlin JA, Gopalan R, et al. DR. Publication bias in clinical research. *Lancet* 1991;337:867-72.
- 3 Egger M, Davey Smith G. Misleading meta-analysis. *BMJ* 1995;310:752-4.
- 4 Savulescu J, Chalmers I, Blunt J. Are research ethics committees behaving unethically? Some suggestions for improving performance and accountability. *BMJ* 1996;313:1390-3.

Unreported trial registration form

Register any controlled trial which has not been published in full, including trials that have only been published as an abstract. Registration can be undertaken by anyone able to provide the registration information, even if they are unable to provide the actual trial data. Please complete one form for each trial being registered.

Contact details

Surname: _____ Forename(s): _____

Postal address: _____ Phone (with regional codes): _____

_____ Fax (with regional codes): _____

_____ email: _____

Trial details

Approximate number of participants in the trials: _____

Type of participants (for example, people with head injury, women at risk of breast cancer): _____

Type of intervention (for example, steroids versus placebo, annual mammography versus standard practice): _____

_____ versus _____

Please post or fax completed registration forms to: The Editor, *Journal of Medical Screening*, Wolfson Institute of Preventive Medicine, St Bartholomew's and the Royal London School of Medicine and Dentistry, Charterhouse Square, London EC1M 6BQ. Fax: 44 171 982 6272