



An amnesty for unpublished trials

Reports of properly conducted randomized controlled trials are the foundation of effective health care, yet many are never submitted for publication.^{1,2} This reduces the power of systematic reviews to detect moderate but clinically important treatment effects, and patients are thus denied effective forms of health care. In addition, since trials that show more promising effects are more likely to be submitted for publication, research syntheses based on published studies can give misleading conclusions about treatment effectiveness, and patients may thus be exposed to useless or even harmful therapies.³ Finally, patients may be asked to participate in new studies designed to address questions that have already been answered.⁴

Trials go unreported for a myriad of reasons: investigators may think that the results are “not interesting,” and it is well documented that trials with nonsignificant results are substantially less likely to be submitted for publication.¹ Recruiting participants sometimes takes longer than anticipated at the expense of resources set aside for report writing; investigators may change jobs and leave important work unfinished; or they may discover a recently published trial on the same topic and conclude that their own results are redundant. Editors must also take some of the responsibility, since there is a limit to the number of reports we can publish. Many investigators regret not having published their results and are delighted to provide unpublished data when asked to do so.

Because of the important consequences of unreported trials, the editors of nearly 100 international medical journals are calling for what amounts to an unreported trial “amnesty.” We hope that investigators will see this as an opportunity to make the results of previously unreported trials publicly accessible and thus potentially contribute to the scientific foundation of health care. We urge all investigators with unreported

trial data to register their trials by returning a copy of the registration form shown below. We would like to register any unreported controlled trial, including those that have been published only in abstract form. Registration can be undertaken by anyone able to provide the registration information, even if they cannot provide the actual trial data. We expect a degree of duplicate registration. Registration information can be posted or faxed to the editorial offices of *CMAJ*. Alternatively, registration information can be sent by email (meta@ucl.ac.uk). The information will be made available on the World Wide Web 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 information directly from the trialist. Some of the trials may be suitable for full publication, and we will be happy to consider these, provided they are submitted in accordance with our instructions for authors.

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.

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for the Medical Editors’ Trial Amnesty

References

1. Dickersin K, Min YI. NIH clinical trials and publication bias. *On-line J Curr Clin Trials* [serial online] 1993;28 Apr: doc no 50.
2. Easterbrook PJ, Berlin JA, Gopalan R, Matthews 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 that has not already been published in full, including trials that have been published only in abstract form. Registration can be undertaken by anyone able to provide the registration information, even if they cannot provide the actual trial data. Please complete one form for each trial being registered.

Contact details

Surname: _____

Postal address: _____

Given name(s): _____

Phone (with area code): _____

Fax (with area code): _____

Email address: _____

Trial details

Approximate number of participants: _____

Inclusion criteria (e.g., head injury, at risk of breast cancer): _____

Type of intervention (e.g., steroids v. placebo, annual mammography v. standard practice): _____

versus _____

Please mail or fax completed registration forms to: Medical Editors’ Trial Amnesty, c/o Canadian Medical Association Journal, 1867 Alta Vista Dr., Ottawa ON K1G 3Y6; fax 613 523-0937. Alternatively, send the information by email to meta@ucl.ac.uk