

How to Report Randomized Controlled Trials

The CONSORT Statement

The best evidence on the efficacy of medical interventions comes from well-conducted, randomized controlled trials (RCTs), but unless such trials are reported adequately, it is impossible to assess that information. In response to increasing evidence that reporting of RCTs is imperfect, there has been a concerted effort to set standards for reporting RCTs, the process described by Begg et al¹ in this issue of THE JOURNAL.

See also p 637.

In December 1994, *JAMA* published the Standards of Reporting Trials (SORT) statement.² We followed this with the publication of a trial using all the SORT headings.³ In an accompanying Editorial,⁴ I called for the SORT group to agree on common standards with another group that had met in Asilomar.⁵ Representatives of both groups were brought together by David Moher, MSc, of the University of Ottawa. Their discussions were informed by comments from readers, many of whom had found the SORT format cumbersome and restrictive. In this issue of THE JOURNAL, we publish the resultant Consolidated Standards of Reporting Trials (CONSORT) statement and flow diagram.

The editors of *JAMA* endorse this statement. As of January 1, 1997, we intend to incorporate the statement and its requirements in our Instructions for Authors. Until then, the CONSORT statement, flow diagram, and checklist are

available on our home page on the World Wide Web (<http://www.ama-assn.org>).

From the beginning of next year, we expect manuscripts reporting RCTs to include all the information in the CONSORT checklist and to be accompanied by the checklist together with the page number in the manuscript where each item may be found. The completed checklist will be sent on to our reviewers but will not be published. This last modification, which was suggested by a *JAMA* peer reviewer, Douglas G. Altman, not only will be useful to the editors, but will also allow considerable freedom of style for authors and journals and still ensure that all relevant information is identified. We hope that the CONSORT format, with its subheadings, appeals both to authors submitting reports of trials to THE JOURNAL and to our readers.

We expect that the CONSORT statement will not only be of great use to our reviewers, but will also increase the completeness of reporting of RCTs and help improve their design and conduct. We intend to join with other journals in testing CONSORT's efficacy and, once more, call for comments from our readers.

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1. Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA*. 1996;276:637-639.
2. The Standards of Reporting Trials Group. A proposal for structured reporting of randomized controlled trials. *JAMA*. 1994;272:1926-1931. Correction: *JAMA*. 1995;273:776.
3. Williams JW Jr, Holleman DR Jr, Samsa GP, Simel DL. Randomized controlled trial of 3 vs 10 days of trimethoprim/sulfamethoxazole for acute maxillary sinusitis. *JAMA*. 1995;273:1015-1021.
4. Rennie D. Reporting randomized controlled trials: an experiment and a call for responses from readers. *JAMA*. 1995;273:1054-1055.
5. Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature. Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature: a position paper. *Ann Intern Med*. 1994;121:894-895.

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