

The revised CONSORT statement: honing the cutting edge of the randomized controlled trial

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A revision of the CONSORT (Consolidated Standards of Reporting Trials) statement is being published this week in major medical journals.¹ Although randomized controlled trials provide our best evidence of the relative efficacy of competing treatments, they are not without controversy. Sometimes debate can help further our understanding; however, debate that springs from confusion about what actually took place in a trial constitutes a diversion of intellectual resources that could be better spent elsewhere. Such debates can generate considerable heat to produce relatively little light. The revised CONSORT statement is designed to help minimize such confusion and promote clarity in reporting the methods and results of randomized controlled trials.

Both the original CONSORT statement, which was published in 1995,² and the revised version¹ comprise a checklist and flow diagram intended to help ensure the clear reporting of key elements of parallel clinical trials. Several of the differences between the revised and original checklists are stylistic. Many result from the unbundling of compound items. For example, the original checklist included a rather ambitious item relating to a study's primary and secondary outcome measures as well as to the way the target sample size was projected. This item has been deconstructed into 2 separate items in the revision. The flow chart has also been modified. Its revisions introduce a clear demarcation between the different stages of a trial: enrolment, treatment assignment, follow-up and analysis. The changes serve to increase transparency and reduce lingering ambiguity as to who is or is not included in the analysis of a trial.

An explanatory document designed to assist authors in using the revised statement is available on the CONSORT Web site.³ In addition to providing annotated examples of the use of the statement, it contains a helpful glossary. The document should prove a useful adjunct for trial consumers as well as trial producers.

Although the CONSORT statement was designed to improve the reporting of clinical trials, it can also play a role at an earlier stage of trialing. In their introduction to the revised CONSORT statement, David Moher and colleagues note that the report of a trial should indicate why the study was undertaken.¹ This objective is reflected in the second item in the checklist: scientific background and explanation

of rationale. Although potentially complex, there is an element of the trial background that can be easily conveyed, and should be conveyed, not only to journal readers but also to the research ethics board and institutional review board members, journal reviewers and grant reviewers who are involved before the final report is published. This element relates to a structured review of the pertinent literature to document all previously published trials. Unfortunately, there have recently been cases in which researchers have selectively reported the existing literature, leaving out pivotal studies that would call into question the need for their own study. The CONSORT explanatory document does comment on this aspect of trial reporting;³ however, it would be desirable to see the requirement for a structured review explicitly incorporated into the CONSORT checklist.

Is the current statement perfect? Of course not. The crafting of CONSORT is an ongoing activity; the CONSORT Group has probably already started to work on the next revision. Another aspect of the statement that could be strengthened relates to the transparency of certain analytic choices, in particular the strategy used to deal with missing data. Investigators now seem to realize the importance of reporting on all trial participants who were randomized, irrespective of their subsequent degree of compliance with the intervention. However, despite best intentions one often has to contend with people who not only cease treatment but also cease to participate in follow-up. A variety of options are available to handle missing data from participants who drop out of the trial and it is important for readers to know what strategy the investigators adopted. Without such information, the fact that an intent-to-treat analysis was carried out is only partially informative.

Authors of trial reports can remove another level of ambiguity for readers by explicitly indicating how they assessed noncompliance. Compliance is typically difficult to capture, involving both timing and quantity, but it still seems to be most frequently reported as a simple compliant/noncompliant dichotomy. Even in the simplest of cases readers should know whether the assessment of compliance was based on physicians' suspicions, participants' self-reports, pill counts, markers or monitoring devices.

We have recently commemorated the 50th anniversary of the modern randomized controlled trial. Since the first trial was conducted a variety of innovations, such as med-

ication event monitoring systems, data entry mechanisms that exploit the Internet and flexible interim analysis plans, have helped to sharpen an already powerful tool. The revised CONSORT statement aims to provide a template to help ensure that the increasingly sharp cutting edge of the randomized controlled trial remains well honed. Some potential improvements notwithstanding, CONSORT provides an extremely useful sharpening stone for the task.

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