Improving the Quality of Reporting of Randomized Controlled Trials

The CONSORT Statement

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THE RANDOMIZED controlled trial (RCT), more than any other methodology, can have a powerful and immediate impact on patient care. Ideally, the report of such an evaluation needs to convey to the reader relevant information concerning the design, conduct, analysis, and generalizability of the trial. This information should provide the reader with the ability to make informed judgments regarding the internal and external validity of the trial. Accurate and complete reporting also benefits editors and reviewers in their deliberations regarding submitted manuscripts. For RCTs to ultimately benefit patients, the published report should be of the highest possible standard.

For editorial comment see p 649.

Evidence produced repeatedly over the last 30 years indicates a wide chasm between what a trial should report and what is actually published in the literature. In a review of 71 RCTs with negative results published between 1960 and 1975, the authors reported that the vast majority of them had too few patients to observe moderate or large differences.[1] Twenty years later, THE JOURNAL reported research indicating few improvements in this situation and expressed a concern about the reporting of RCTs in general.[2]

In an effort to correct these and other problems, the Standards of Reporting Trials (SORT) group met on October 7 and 8, 1993. At the conclusion of the 2-day workshop, the SORT group put forth a new proposal for the reporting of RCTs: structured reporting.[3] The proposal set out 24 essential items that needed to be included in the report of a trial, provided empirical evidence as to why the items should be included, and provided a format showing how they could be included.

Independently, approximately 5 months later (March 14 to 16, 1994), another group, the Asilomar Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature, met to discuss similar challenges facing the reporting of clinical trials. Their proposal[4] consisted of a checklist of items that should be included when reporting a clinical trial, along with a suggestion that editors add it to the Instructions for Authors.

A subsequent Editorial[5] urged both groups to meet and decide which recommendations from each group's proposal should be retained. Besides being pragmatic, this suggestion had the potential for increasing consensus, which in turn might afford a greater chance of improving the quality of reporting of clinical trials to a wider audience.

On September 20, 1995, a total of 9 members (including editors, clinical epidemiologists, and statisticians) of the SORT group and the Asilomar Working Group met in Chicago, Ill. Two other people participated in the meeting: a journal editor (R.H.) who had expressed interest in helping to improve the reporting of RCTs and one of the authors (D.S.) of a trial report that used the SORT approach.[6]

METHODS

We started the day by reviewing both the SORT and Asilomar checklists to ascertain which items covered similar content areas and which ones were unique. Those items having similar content areas we then reviewed individually. We decided, a priori, to keep only those items for which there was empirical evidence, when available, that not reporting them resulted in bias in the estimates of the effects of interventions. We used common sense for those items included for which there was no empirical evidence. The selection of items was achieved using a modified Delphi process. We also emphasized the need to keep the number of items to a minimum, while maintaining adequate standards of reporting RCTs. We used a similar approach in deciding which of the unique items should remain in the resulting checklist. The day ended with a discussion on the use of the flow diagram proposed by the SORT group and the format of a trial report. Within a week or so following the meeting, a draft report was circulated to the entire group for further refinement. This process was continued until we felt the report accurately represented what had gone on during the meeting.

RESULTS

This meeting resulted in the Consolidated Standards of Reporting Trials (CONSORT) statement—a checklist (Table) and a flow diagram (Figure). The checklist consists of 21 items that pertain mainly to the methods, results, and discussion of an RCT report and identify key pieces of information necessary to evaluate the internal and external validity of the report. We have included at least 1 reference for each item, when appropriate (Table). The flow diagram provides information about the progress of patients throughout a 2-group parallel-

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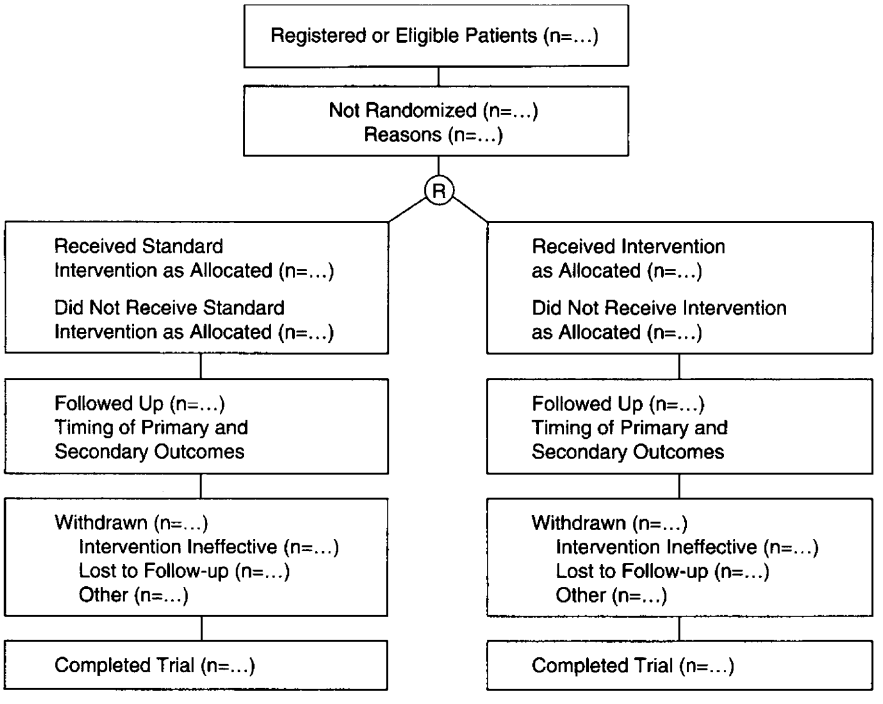
Consolidation of Standards for Reporting Trials—CONSORT[3,4]

Heading	Subheading	Descriptor	Was It Reported?	On What Page No.?
Title		Identify the study as a randomized trial.[7]		
Abstract		Use a structured format.[8,9]		
Introduction		State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses.[10]		
Methods				
	Protocol	Describe Planned study population, together with inclusion/exclusion criteria. Planned interventions and their timing. Primary and secondary outcome measure(s) and the minimum important difference(s), and indicate how the target sample size was projected.[2,11] Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention-to-treat basis.[12,13] Prospectively defined stopping rules (if warranted).[14]		
	Assignment	Describe Unit of randomization (eg, individual, cluster, geographic).[15] Method used to generate the allocation schedule.[16] Method of allocation concealment and timing of assignment.[17] Method to separate the generator from the executor of assignment.[17,18]		
	Masking (Blinding)	Describe mechanism (eg, capsules, tablets); similarity of treatment characteristics (eg, appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful blinding among participants, person doing intervention, outcome assessors, and data analysts.[19,20]		
Results				
	Participant Flow and Follow-up	Provide a trial profile (Figure) summarizing participant flow, numbers and timing of randomization assignment, interventions, and measurements for each randomized group.[3,21]		
	Analysis	State estimated effect of intervention on primary and secondary outcome measures, including a point estimate and measure of precision (confidence interval).[22,23] State results in absolute numbers when feasible (eg, 10/20, not 50%). Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication.[24] Describe prognostic variables by treatment group and any attempt to adjust for them.[25] Describe protocol deviations from the study as planned, together with the reasons.		
Comment		State specific interpretation of study findings, including sources of bias and imprecision (internal validity) and discussion of external validity, including appropriate quantitative measures when possible. State general interpretation of the data in light of the totality of the available evidence.		



Progress through the various stages of a trial, including flow of participants, withdrawals, and timing of primary and secondary outcome measures. The "R" indicates randomization.

design RCT, perhaps the type of trial most commonly reported.[26] Appropriate adjustments will need to be made in reports of trials with a larger number of groups or trials using a different design.

We recommend, for example, that RCTs should report how the allocation sequence was generated (eg, computer generated) and concealed (eg, in sequentially numbered, opaque, sealed envelopes) until the patient was randomized, something that is possible in all trials.[17] Schulz and colleagues[17] have shown empirically that trials in which the allocation sequence had been inadequately concealed yielded larger estimates of treatment effects (odds ratios that were lower, on average, by 30%-40%) compared with trials in which the authors reported adequate allocation concealment (ie, keeping the intervention assignments hidden from all individuals participating in the trial until the point of allocation). One possible interpretation is that some trials with inadequate reporting of allocation concealment actually had faulty randomization, and faulty randomization allowed the introduction of bias.

COMMENT

Although any optimally reported trial will address the items on the checklist and embody the flow diagram, the manner in which RCTs are reported (ie, their format) is also important. The format we favor includes a combination of 5 new subheadings in the text of the trial report and the use of the checklist during the journal submission process.

Three of the subheadings fall within the "Methods" section of a trial report: protocol, assignment, and masking (blinding). For example, under the subheading "assignment" the authors would describe the unit of randomization (eg,

the individual patient). The remaining 2 subheadings are included when the authors report the results: participant flow and follow-up, and analysis. The participant flow and follow-up subheading is used in conjunction with describing details of the flow diagram. These 5 subheadings provide readers with consistency from report to report as to where they can expect to find relevant information. The completed checklist, which includes all 5 subheadings, would be required for all journal submissions. For example, corresponding authors would need to specify whether or not their trial report described the unit of randomization, and, if so, where in the report this is documented. We recognize that different trials, because of unusual or complex methods, will require modifications to the reporting structure.

The advantages of the CONSORT format include minimal change to the length and readability of the manuscript and enhanced clarity and organization in the actual report of a trial through the addition of the 5 new subheadings, while at the same time the information that is submitted to editors and reviewers is maximized through the completed checklist. This strategy avoids some of the criticisms of previously suggested reporting formats.[3,6]

Some authors, editors, and even reviewers may find our recommendations for the reporting of RCTs difficult and even restrictive. Similar concerns were also raised when more informative abstracts were first introduced.[8] Our separate group efforts[3,4] and our combined effort, CONSORT, came about because of the need to provide readers with enough valid and meaningful information concerning the design, conduct, and analysis of RCTs.

We would be remiss if we did not evaluate whether the CONSORT approach actually has its intended impact. Such an evaluation should incorporate the very design we are advocating improvements to its reporting: the RCT. The assessments need to be of both process and outcome, such as the readability of the report and its length as well as more standard quality assessments.[27] In the coming months we will work toward designing and implementing such an evaluation.

During our meeting there was unanimous agreement that the reporting of RCTs, and research in general, is frequently incomplete.[28] Many examples of inadequate reporting and their sequelae have been cited.[29-31] As a result, we decided that our deliberations should be disseminated to as wide an audience as possible in the hope that the CONSORT statement will ultimately lead to more comprehensive and complete reporting of RCTs. We recognize that the statement will need revision as new empirical evidence of bias becomes available. We invite all editors and clinical trialists to join us in using the CONSORT checklist and flow diagram. We will make the checklist and flow diagram available to all interested journal editors who wish to disseminate the information to their reviewers. Interested readers can also find the checklist and flow diagram on THE JOURNAL's World Wide Web site (http://www.ama-assn.org).

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