Consolidated Standards of Reporting Trials (CONSORT): An Update

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The Consolidated Standards of Reporting Trials (CONSORT) statement,\textsuperscript{1,2} issued in 1996, specifies types of content to include in papers reporting clinical trials. At the current session, two members of the group revising the CONSORT statement provided an update and discussed related items.

Tom Lang began the session with historical background. He noted that studies since the 1960s have shown that poor reporting of clinical trials has produced biased estimates of treatment effects. He also described how efforts of previous groups led to the work of the CONSORT group and noted that at least 70 journals have adopted or endorsed the CONSORT statement.

In his opening remarks, Frank Davidoff raised the question of how journals are using the CONSORT statement, and he proposed undertaking research to answer it. He also asked what effect the statement has had, and he summarized a small study by David Moher and others suggesting that adoption of the statement is associated with more complete reporting.

Davidoff described work by the group that met in 1999 and 2000 to revise the CONSORT statement. Whereas the initial version consisted largely of a checklist, the revised version will be accompanied by more explanatory text. The group has added some items to the checklist (for example, a reminder to include a report of adverse effects in the results section) and deleted others (such as the directive to state in the title that a study was a randomized controlled trial).

Davidoff mentioned two other recent sets of standards for reporting research. One, known as the QUOROM statement,\textsuperscript{3} deals with reporting meta-analyses of randomized controlled trials. The other, the MOOSE statement,\textsuperscript{4} deals with reporting meta-analyses of observational studies in epidemiology. Davidoff also said that a group was developing guidelines for reporting studies of diagnostic tests.

Davidoff characterized the various statements as parts of an effort to promote “consistency and transparency in reporting”. Although these statements are concerned primarily with reporting, they can also aid in designing research, editing reports, shaping readers’ expectations of content, and preparing systematic reviews and meta-analyses. He noted, however, that such guidelines should not become too rigid.

In closing the session, Lang posed questions about the purposes of the CONSORT statement and other standards for reporting: What is quality in a scientific article? What is, or should be, the purpose of such an article? What is, or should be, the purpose of a scientific journal? What role do stated standards play?

The updated CONSORT statement, CONSORT 2000, and explanatory text will probably be published in the spring of 2001.

References