

## Standards of Reporting Biomedical Research: What's New?

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"The whole of medicine depends on the transparent reporting of clinical trials." So said David Moher, who began the session on new standards of reporting biomedical research with a review of the CONSORT (Consolidated Standards of Reporting Trials) statement.

Since the 2001 revision of CONSORT, several design extensions have become available that increase the statement's scope and use, particularly in evaluating different trial designs. For example, extensions now address the quality of randomized-cluster trials, noninferiority designs, and multiarm parallel-group studies.

Moher reviewed several studies addressing the use and impact of CONSORT in the biomedical literature. Although the quality of reporting of clinical trials has improved, conformance to standards is far from ideal, particularly in journals that do not explicitly endorse the CONSORT guidelines. Moher recommended that journals include in their guidelines for authors a statement about how CONSORT is adhered to in the editorial process and report on the level of adherence in the studies they publish. Discussion of this topic addressed journals' challenges in acknowledging researchers' desire for auton-

omy and dislike of being told how to report their studies, in contrast with the perception that younger researchers may actually desire guidelines and instruction.

Moher also reviewed QUOROM (Quality of Reporting of Meta-analyses), which addresses meta-analyses of randomized controlled trials; MOOSE (Meta-analyses of Observational Studies in Epidemiology); and STRICTA (Standards for Reporting Interventions in Controlled Trials of Acupuncture). The QUOROM and MOOSE statements are available on the CONSORT Web site. Forthcoming statements include TREND (Transparent Evaluations with Nonrandomized Designs), which addresses evidence-based behavioral medicine, and STROBE (Standards for the Reporting of Observational Studies in Epidemiology), for research in botanic medicine.

The multitude of standards for reporting biomedical research can be attributed to funding challenges, Moher said. He pointed out an irony: millions of dollars are spent on the conduct of randomized clinical trials, but "we can't get \$30 for the reporting" of these trials. The financial difficulties account for inefficiencies in multiple working groups and individuals developing reporting standards, Moher said.

The CONSORT statement is used for evaluating clinical trials, but reports of new diagnostic tests have another standard: the STARD (Standards for Reporting of Diagnostic Accuracy) initiative. Harold Sox said that the role of a diagnostic test is "to move probabilities (of an event or condition) up or down". The objectives of STARD are to promote transparency from authors in the reporting of diagnostic tests and to allow readers to assess bias potential and evaluate generalizability. Like the CONSORT statement, STARD relies on full disclosure and explanation of trial methods, including recruitment, sampling, and data-gathering. After reporting of results,

the process calls for a discussion of clinical applicability.

Sox acknowledged the challenge of persuading authors to conform to the new reporting standards and observed that in evaluating use in the literature, CONSORT appears much more established. The difficult balance for journal editors lies in the need to establish standards vs the desire to publish important work rapidly. "Maybe if all journals [rejected items without a checklist], it would eliminate the competitive disadvantage of being the tough guy", Sox said.

Virginia Barbour discussed the evolving standards of reporting research in genetics studies. The challenge facing these standards, Barbour said, is the sheer size and growth of the data available in the field: at the current rate, 1 terabyte of data is produced every 3 years.

Consistent reporting standards in these burgeoning fields would allow for a needed controlled vocabulary and nomenclature, Barbour said. However, an open question is who should decide on the standards—journals (which must enforce them) or the scientific community (which must abide by them).

Data on proteomics in particular are mushrooming, Barbour said. Proposed standards for proteomics-research reporting (the Proteomics Standards Initiative) that call for a data repository would be useful for high-quality studies that are not published by allowing future researchers to mine the data. This repository would also address the lack of publication of negative studies and perhaps lead to a form of "deep" citation: the citation would link to the original data and the accompanying analysis program. However, the repository may prove controversial for commercial and academic entities, which may be reluctant to grant access to their data via a repository before they have had the opportunity to publish. 