Improving the flow of diagnostic information

The importance of STARD for authors and readers

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Neurology has adopted the Standards for Reporting of Diagnostic Accuracy (STARD) initiative.¹ The STARD Steering Committee and Working Group has published a checklist and a prototypical flow diagram to help authors describe the design, execution, analysis, interpretation, and implications of research on diagnostic tests (see the *Neurology* Web site, www.Neurology.org).² The STARD initiative, to improve the quality of reporting of diagnostic studies, is long overdue and follows the success of the CONSORT initiative, published in 1996 and updated in 2001, to improve the reporting of clinical trials.³

The need for STARD is clear. The methodological quality of studies of diagnostic accuracy is often poor, making judgments about validity, bias, and applicability to patients in clinical settings difficult.⁴ Studies of diagnostic accuracy in the neurologic literature are no exception.^{5,6} Such misinformation can lead to both test overuse, increasing patient risk and costs, and to test underuse, missing opportunities to improve health. The hope of the STARD initiative is to improve the quality of reported studies and to standardize information flow to optimize the use of both established and novel diagnostic tests.

The list of neurologic tests and technologies needing assessment is long and growing longer: neurologic examination findings, neuroimaging studies, neurophysiologic studies, auto-antibody tests, blood, tissue, and genetic markers, and many others. In addition, studies of diagnostic accuracy will be needed for biomarkers, functional imaging studies, proteomics and gene expression profiling.⁷ This research will provide clues about disease pathogenesis and risk factors, and better insights into disease diagnosis, prognosis, and novel therapies. The usefulness of these studies, however, depends upon “translational” research—translating these basic sci-

ence advances into applied and tangible improvement in health and disease. In many cases, the research “language,” which will allow the basic science community to communicate with the clinical researchers, and the clinical researchers to communicate with health care providers and patients, will be the study designs of diagnostic accuracy. Whether they be imaging biomarkers, serum markers, or the complex, mind-numbing possibilities of microassays to assess gene expression profiling, many of the advances embedded in this information will arise from the study design and basic research elements articulated by STARD.

Most issues of *Neurology* have articles reporting studies of diagnostic accuracy: two in the May 13th issue and three in May 27th issue. *Neurology* authors should complete the 25-item STARD checklist when submitting a study of diagnostic accuracy. This checklist will standardize information about study design, conduct and analysis to allow a reader to judge the presence and magnitude of bias. Authors should also submit a flow diagram explaining the study design, sampling procedures, and the timing and results of the index test and reference standard, as such details are often difficult to interpret in the narrative.

A particularly important aspect of STARD is the explanation and elaboration document, a comprehensive guide clarifying the meaning, rationale and optimal use of each item on the checklist.⁸ Researchers will find STARD, including the explanation document, useful both in preparing research for journal submission and in planning new studies of diagnostic accuracy. Peer reviewers will find STARD helpful in their critical appraisal and feedback for authors.

The STARD initiative will be a learning process for all—authors, readers, peer reviewers, and editors—who are currently more familiar with the study designs to evaluate new therapies (e.g., randomized controlled trials). The ultimate success of the STARD initiative however, will depend on the

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collaboration of basic scientists, clinical researchers, peer reviewers, journal editors and health care providers. The field of diagnostic technology assessment continues to mature, and better reporting of diagnostic information has the promise to improve the efficiency and quality of neurologic care.

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