Reporting Diagnostic Accuracy

The following draft of guidelines was presented for comments at the 1997 Annual Meeting of the Council of Biology Editors. Useful advice has been received from editors of medical journals, epidemiologists, and others. We request comments from our readers as we revise the document for dissemination to editors and investigators, who will, we hope, find it useful:

Toward a Checklist for Reporting of Studies of Diagnostic Accuracy

(1997 CBE Meeting, Session E6, D.E. Bruns, E.J. Huth, E. Magid, and D.S. Young: Supported by the International Federation of Clinical Chemistry and the American Association for Clinical Chemistry)

Diagnostic testing is a critical part of modern medicine. Despite the importance of testing for diagnosis, prognosis, and monitoring, the methodology for evaluations of clinical (diagnostic) accuracy of tests has received only modest attention. Recent studies have documented that most published studies of diagnostic accuracy of clinical tests fail to meet (or fail to document adherence to) reasonable methodological standards.

Assessments of diagnostic accuracy of tests are likely to attract increasing attention. Diagnostic testing accounts for 10–25% of healthcare expenditures, and assessment of the diagnostic accuracy of a test is a logical prerequisite to studies of the test’s cost-effectiveness.

The Table below is a step toward a checklist for reporting of studies of diagnostic accuracy. It specifically does not address studies of analytical accuracy (which may accompany reports of diagnostic accuracy), studies of nonanalytical sources of variation, or studies of cost-effectiveness (which may require a distinct protocol).

Checklist for Studies of Clinical Performance of Laboratory Tests

Title: Identify the study as an evaluation of a test for diagnosis or prognosis; include disease or condition and name(s) of test(s).

Abstract: Use structured abstract.

Search terms: List evaluated test or test(s); disease or outcome (or both); criterion (gold) standard test; sensitivity; specificity; diagnosis; study design.

Introduction: Include: Research question and why it came up; hypothesis; specific objectives of study.

Study Protocol and Methods:
1. Study design—prospective cohort, retrospective cohort, etc.
2. Patient care setting (ambulatory, practice, inpatient, volunteers).
3. Criteria for (a) inclusion and (b) exclusion of subjects. When the main inclusion criterion is a clinical indication for use of the test, explain in detail the justification for any exclusion criteria, especially any that involve results of preceding tests.
5. Planned sample size; statistical power; resource considerations.
6. Planned subgroup analyses.
7. Methods to avoid spectrum bias
   (e.g., consecutive series).
8. Methods (and references) for (a) evaluated test(s) and (b) criterion (gold) standard test(s). When an outcome (e.g., death) is used as the criterion standard, indicate duration and methods of follow-up.
9. Methods for blinding of those performing (a) evaluated test(s) and (b) criterion standard test(s) to avoid reviewer bias.
10. Methods to avoid verification bias
    (usually by application of criterion standard to all subjects) or to deal with its consequences.
11. Methods (and references) for statistical analysis, including steps to deal with repeated or serial measures.
12. Indicate that these guidelines were followed.

Results:
1. Study subjects
2. Specific interpretation of study findings, including sources of imprecision and bias (e.g., fallibility of criterion standard).
3. General interpretation vis-a-vis other studies (e.g., does test add to other tests and to clinical observations?).

Pericardial Access Device: A New Challenge for TDM?

Chiron Technologies and Comedixus Inc. announced an agreement under which Chiron will receive an (exclusive) license to use Comedixus’ PerDUCER™ pericardial access device for delivery of proprietary therapeutic agents for selective purposes inside the pericardium. A representative of Chiron indicated a belief “that the pericardial sac offers potentially very significant advantages over systemic and other local delivery approaches for the therapeutic and diagnostic management of patients with a wide variety of cardiovascular diseases. Particularly in the case of cardiovascular therapeutic agents, many of which suffer from narrow therapeutic indices, suboptimal pharmacokinetics and biodistribution, high cost of manufacture, or inconvenient administration regimen, the pericardium as a local cardiovascular drug depot site may offer unique opportunities.”

This approach appears to be yet
another challenge for TDM. How will concentrations of drugs be monitored in the pericardial sac? Is monitoring needed? How will the volume of pericardial fluid be estimated to permit calculation of dose?

The potential diagnostic utility of assays of pericardial fluid seems to have been little explored. Will this fluid prove to be another “routine” sample (like CSF) in the clinical laboratory?

These questions and others seem ripe for asking. Careful study will be required to determine which pericardial fluid assays, if any, will be useful in patient care.

Public Servants Speak Out

“I haven’t committed a crime. What I did was fail to comply with the law.”—David Dinkins, New York City Mayor

“Outside of the killings, Washington has one of the lowest crime rates in the country.”—Mayor Marion Berry, Washington, DC.

“Beginning in February 1976 your assistance benefits will be discontinued . . . Reason: it has been reported to our office that you expired on January 1, 1976.”—Letter from the Illinois Department of Public Aid.

“The streets are safe in Philadelphia. It’s only the people who make them unsafe.”—Frank Rizzo, former Police Chief and Mayor of Philadelphia.

“After finding no qualified candidates for the position of principal, the school board is extremely pleased to announce the appointment of David Steele to the post.”—Philip Streifer, Superintendent of Schools, Barrington, RI.