Laboratory Testing in the 1990s

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In this issue of the Journal, three studies report on tests that are commonly performed in office laboratories: the serum cholesterol test (Erickson et al),[1] the white blood count (WBC) (Kikano et al),[2] and the urinalysis (Abyad).[3] These articles raise two issues that have been at the center of heated debates by regulators, third-party payers, and physicians: how accurate are office laboratory tests, and when is it appropriate to order a test?

In the late 1980s a series of media reports "uncovered" the problem of errors in clinical diagnostic testing. Much of this media attention was focused on cholesterol testing and coincided with the promotional activities of the National Cholesterol Education Program of the National Institutes of Health (NIH). A front-page story in *The Wall Street Journal* of February 2, 1987 ("Inaccuracy in Testing Hampers War on Heart Disease"), by Walter Bogdanich, was the first in a series of reports in newspapers and magazines and on television. This attention by the press and the subsequent concern of the public directly resulted in a series of congressional hearings that eventually led to the passage of the Clinical Laboratory Improvement Amendments (CLIA) in October of 1988.[4] This legislation for the first time regulated laboratory testing no matter where the testing was performed. CLIA broadly defined a laboratory as any facility for the "examination of material, derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings."

The Health Care Financing Administration (HCFA) was given responsibility to write the detailed regulations for CLIA. Their first attempt was published as proposed regulations and resulted in 60,000 comments being submitted to HCFA.[5] These letters from physicians and other health care professionals expressed outrage about the following:

1. HFCA failed to consider the costs of regulation. Some estimates indicate that CLIA would cost up to $4 billion per year.[6]
2. HFCA failed to consider CLIA's impact on access to care. The proposed regulations would very likely have resulted in the closure of laboratories in many rural hospitals and physicians' offices.
3. HFCA failed to consider the rapid changes in laboratory technology. The proposed CLIA regulations would have forced laboratories to use quality assurance methods that were both outdated and inflexible.

Revised regulations for CLIA are being prepared through a cooperative effort by the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), and HCFA. They should be released in early 1992 and are likely to be more acceptable to family physicians.

This regulatory activity has occurred despite the fact that there has been almost no research on the quality of testing in decentralized laboratories in the United States. Congress realized this fact and stipulated that studies be conducted on the quality of laboratory tests. These studies have only recently been started, and their results will undoubtedly not be available in time to have an impact on the wording of the CLIA regulations.

In this regard, the study by Erickson et al[1] is both timely and important. It is the first study to be published that reports on the test performance of a large number of office laboratories. The findings indicate that in 1988 the laboratories of family physicians in Iowa did exceptionally well in testing an unknown specimen for cholesterol. This study also identified several factors that predicted good performance:

- *The testing of controls.* Controls are simply one way to ensure that the test methods are working. This check on test performance is a routine part of good laboratory practice. There has been debate about the frequency with which laboratories should "run" controls. This frequency should depend on the sta-

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bility of the instrument and its reagents, the skills of the person performing the test, and the intended use of the test result.

- *Participation in proficiency testing.* Fifty years ago a group of 12 pathologists, who were laboratory directors in 12 Philadelphia hospitals, decided to share the results they obtained from testing pooled, unknown specimens. They found that each hospital had a few test results that were not in agreement with the other laboratories, and this finding helped them to identify analytical problems. The idea grew and eventually led to a formal program organized by the College of American Pathologists (CAP). Two years ago, the American Academy of Family Physicians worked with CAP to develop a proficiency-testing program specifically designed for office laboratories. Any physician who directs an office laboratory should consider participating in this program.
- *Using high-quality instruments.* Testing conducted in office laboratories can be equal in quality to that attained by hospital or reference laboratories.[7] But not every test system is of high quality. The easiest way to find out about the quality of an instrument is to look at its performance in the summary results from a proficiency testing program.

The second issue raised by the studies in this issue of the Journal relates to the clinical utility of testing. When should a test be ordered? How should the test information be used? Can test ordering be made more efficient?

A growing number of studies have shown that physicians vary greatly in their test-ordering behaviors. George Lundberg, MD, Editor of *The Journal of the American Medical Association*, has listed 32 different reasons for ordering a test, including "frustration at nothing else to do."[8] While it is true that physicians vary in how they order tests, it is not clear exactly why this is so. And more to the point, it is not at all clear when the ordering of a test represents overutilization and when not ordering a test represents underutilization.

Should a physician order a white blood count on a 10-month-old child with a temperature of 38.8°C and no obvious source of infection? The answer is unknown, but it is clear from the study by Kikano et al[2] that given this information, physicians treat patients in very different ways.

One recent trend has been to try to quantify the appropriateness of testing based on a critical evaluation of data from the medical literature regarding a test's sensitivity, specificity, and predictive value. This approach has been led by the efforts of the American College of Physicians, which received funds from the Blue Cross and Blue Shield Association to prepare testing guidelines.[9] These guidelines are extremely conservative in their view of test utilization and are untempered by the humility that comes from the ambiguity of clinical practice. ("The utility of each test in specific situations depends on . . . whether the test results enable the clinician to cross a diagnostic or therapeutic threshold.")[9,p144]

It is very likely that future efforts at health-care cost containment will continue to be directed at test utilization. One reason for this is that tests are more easily studied than other sources of clinical information such as the elements of the medical history or the physical examination. It is unlikely that health care payers would be interested in the "appropriate utilization" of the questions a physician asks in obtaining a patient's history.

So what is the state of medical testing in 1991? First, it is clear that despite the regulatory clamor, physicians can now offer the highest quality of testing that has ever been available to patients. Furthermore, rapid advances in technology will outdistance our greatest expectations. Twenty years ago a rabbit had to die for a physician to diagnose pregnancy. Today, any woman can test her own urine specimen at home and diagnose pregnancy before the first missed menses. In many cases, her home test will use the same technology and provide the same level of accuracy as the pregnancy tests in the best clinical laboratories.

Concerns about analytic accuracy will ultimately be dwarfed by our lack of understanding of the many proper roles that tests can play in excellent patient care. We must try harder to understand why physicians order tests. In some cases, it may well be appropriate to order a test because "there is nothing else to do."

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