Waived Testing

KATHY HANSEN, DON LAVANTY

The Government Affairs Committee of ASCLS has made it a high priority to understand and attempt to influence the process of test categorization under the Clinical Laboratory Improvement Amendments (CLIA) regulations. The regulations, published in 1992, classify tests as high complexity, moderate complexity, waived, and provider performed microscopic (PPM). The latter two categories of tests are unregulated, in the sense that laboratories that perform them are not inspected and need not perform and report proficiency testing. The Center for Medicare and Medicaid Services (CMS, formerly HCFA) does have the authority to inspect waived and PPM laboratories if it has reason to suspect that they are performing tests beyond the scope of their certificate, or are not following manufacturers' instructions in performing the tests.

Waived testing has been the subject of many newsletter articles and conference presentations recently as concerns about the quality of testing and patient safety have been raised. These concerns have fallen into two areas:

- How are tests classified as waived and do they perform reliably?
- Are the laboratories that do waived tests performing them correctly?

There is recent news on both of these fronts.

WHAT IS A WAIVED TEST?

Two sets of criteria exist for evaluating waived tests, depending upon whether they are intended for home use or for diagnostic use, such as in a physician office laboratory. Responsibility for test categorization belongs to the Food and Drug Administration (FDA).

The evaluation criteria for waived tests for diagnostic use are adequate. The FDA has announced that it will continue to use criteria that were initially developed by the Centers for Disease Control (CDC) in 1995 for evaluation of waived tests for diagnostic use. These criteria appropriately specify a 90% specificity and sensitivity rate for diagnostic testing. Accuracy data is established in a laboratory setting by professionals who can recognize potential pitfalls in the procedure. Reproducibility is determined in the hands of lay users, including relatively untrained personnel at the point of care who will be the end users of the test.

Washington Beat is intended to provide a timely synopsis of activity in the nation's capitol of importance to clinical laboratory practitioners. This section is coordinated jointly by Kathy Hansen, Chair of the ASCLS Government Affairs Committee, and Don Lavanty, ASCLS Legislative Counsel. Direct all inquiries to ASCLS (301) 657-2768 extension 3022; (301) 657-2909 (fax); or mail to ASCLS, 7910 Woodmont Avenue, Suite 530, Bethesda MD 20814, Attention: Washington Beat.

However, the criteria listed in the CLIA statute state that a waived test should:

- be cleared by the Food and Drug Administration (FDA) for home use;
- employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or
- pose no reasonable risk of harm to the patient if the test is performed incorrectly

These criteria are quite subjective and thus inadequate as a basis of test categorization. The first criterion negates the evaluation criteria for waived testing for diagnostic use, since *tests approved for home use are automatically waived* and thus not subject to the more stringent criteria used to evaluate waived tests for diagnostic use.

Tests intended for home use are evaluated essentially for reproducibility only and not evaluated for sensitivity and specificity (accuracy). Because of the loophole in the statute, the home use tests may also be used in diagnostic settings.

ASCLS believes that there is a potential for negative consequences to patient care under the current system. Data from CMS records of CLIA certificates over the past several years show that nearly 5,000 laboratories have dropped their moderate complexity certificates and converted to waived test certificates. This is understandable since it results in exemption from required proficiency testing, inspections, and other regulations. However, protection of patients demands that the waived tests in use are indeed simple, easy to perform, *and* produce accurate and precise test results, regardless of testing personnel expertise. The 'double standard' for evaluation of accuracy and precision for home use tests vs. other waived tests becomes problematic when both are being used in the diagnostic setting.

As incentives exist for manufacturers to develop technology that is categorized as waived and as there are virtually no regulatory requirements for waived tests, the public health demands that the categorization criteria for both be sufficiently stringent to ensure reliable test results. Did you realize that there are currently over 800 waived tests for more than 40 analytes? The list of waived tests can be found at www.phpoo.cdc.gov/dis/clia/waived.asp

Since the statutory language of CLIA is unlikely to be changed, the solution to these concerns appears to be to apply the same evaluation criteria to all waived tests, whether originally intended for home use or diagnostic use. This would close the loophole for products to become waived in laboratories and healthcare institutions across the country. ASCLS has been working with other pro-

fessional groups to encourage the FDA to incorporate the more stringent waived test criteria into the home use approval mechanism so that all waived tests would meet the *same* standards of accuracy and precision.

HOW ARE WAIVED LABORATORIES PERFORMING?
Those who attended the ASCLS Legislative Symposium in March 2001 heard Judy Yost, Director, Division of Laboratories and Acute Care Centers of CMS report on a small study of 100 waived laboratories in two states. Results indicated that many of them were not using the test kits appropriately and not following the manufacturers' instructions for correct performance of the tests. 50% of those laboratories had quality problems.

Last month at the Lab Institute Conference in Washington, D.C., Ms Yost updated that report with additional findings. The survey has been expanded to include a 2.5% sample of waived laboratories in eight additional states.

- 32% of these laboratories did not perform quality control as required
- 32% failed to have manufacturers' instructions
- 16% failed to follow manufacturers' instructions
- 23% had certificate issues (testing beyond the scope of their certificate)
- 20% cut occult blood cards or urine dipsticks to save money
- 19% had personnel who were neither trained nor evaluated

A total of 48% of the laboratories in this second group had some type of quality problems.

Both the Office of Inspector General (OIG) and CMS have waived laboratory surveillance in their work plans for the coming year. CMS plans to take an educational approach and survey a percentage of waived laboratories annually.

ASCLS has long been an advocate for the patients we serve and their right to accurate laboratory results. We are supportive of the efforts of CMS to ensure that the patients who receive laboratory services from waived laboratories can be confident that they are getting quality laboratory service.

In Praise of Reading

(continued from page 2)

to the profession and science. The word, contributors, means much more than "just writing". It conveys a belonging to a tradition of teaching and learning. It means participating in the most fundamental way to the community of scientists and professionals that has existed through millennia. Many reading this might say that they could not be on a par with the giants of the past; that they simply could not write anything that earth shaking. Perhaps. But equally important to the landmark leaps of knowledge is the continuous assessment of current knowledge. Did that instrument work in an unusual situation? Was that an interesting infectious disease presentation? Why did those cells react in that fashion? How can we better communicate our knowledge to others in our facilities? What is the impact of stresses and strains from external forces on our practice field? Each of these questions needs to be answered on a daily basis in our practice. Each of them also needs to be disseminated to colleagues to help them provide better patient care. In this interconnected world, we are responsible to teach and learn. For a profession, the vehicle of that enterprise is the journal.

As we have all known in our personal and professional lives, change is the only constant. The Editor-in-Chief of *Clinical Laboratory Science* for the past five years, Marian Schwabbauer, has stepped down from this position. Marian has served ASCLS in many different capacities throughout the years and her tenure on the Editorial Board has been greatly appreciated. During these past years, we have changed editorial offices–the people who actually publish the journals–three times. That she managed to maintain a consistent flow of manuscript handling and publications was no easy task, especially in light of the loss of significant numbers of manuscripts by one of the offices.

It will be no easy task to take over from her. She made the process less cumbersome and less intimidating by improving the overall infrastructure. Thank you, Marian, from all of us.

Susan J Leclair is 2001-2003 *Clinical Laboratory Science* Editor-in-Chief.