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POSITION STATEMENT

Modernization of CLIA: Certificate of Waiver Testing Sites

November 2018

Introduction

Over the past few decades there has been a significant increase in near-patient laboratory testing sites outside of the traditional clinical laboratory. These sites, which often perform only waived testing, include physician offices, pharmacies, home health care agencies, and skilled nursing facilities (SNFs), among others. Since 1993, the number of registered facilities performing only waived testing has grown from 44% (67,294) of all clinical laboratory testing sites to 71% (186,746). A benefit of near-patient testing is that test results are typically available more quickly than if the test is sent to an off-site laboratory. However, studies have shown that many near-patient testing sites perform clinical tests incorrectly (1). More research is needed to assess the extent and impact of these problems and to determine where improvements are necessary. AACC believes that all laboratories, regardless of where they are located and the level of testing performed, should have processes in place that facilitate reliable testing and quality patient care.

Background

Laboratory Oversight

Under the Clinical Laboratory Improvement Amendments (CLIA), laboratory tests are assigned to one of three categories: high complexity, which are the most difficult and thoroughly regulated tests; moderate complexity, which are less challenging and therefore have less stringent requirements; and waived, which are tests considered to be simple and easy to perform and therefore have few regulatory constraints. Laboratories performing high and moderate complexity testing must obtain a Certificate of Compliance or Certificate of Accreditation, whereas testing facilities conducting only waived testing must obtain a Certificate of Waiver (CoW).[1] Near-patient testing sites generally perform only waived testing and therefore operate under a CoW.

AACC POSITION:

The American Association for Clinical Chemistry (AACC) supports greater federal monitoring of laboratories performing only Certificate of Waiver (CoW) testing. AACC recommends that the Centers for Medicare and Medicaid Services expand its oversight of facilities performing waived testing and exhort them to adopt good laboratory practices. Further, the association urges Congress to direct the Department of Health and Human Services to conduct a study on the state of testing performed by CoW facilities to evaluate current practices and make recommendations for improvement. AACC also recommends enhanced training for CoW testing personnel, and voluntary proficiency testing for CoW labs.

Emergence of Point of Care Testing

When CLIA was initially implemented, there were only eight tests on the waived category list of tests. That

1. Certificate of Compliance and Registration Certificates are issued by the Centers for Medicare and Medicaid Services (CMS), whereas Certificates of Accreditation are issued by private sector organizations that are authorized to act on behalf of CMS.

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number has now increased to more than 130 (2). Much of the increase in waived testing at near-patient sites is due to technological advances in point-of-care (POC) testing devices. These test devices are considered easy to operate, provide quick results, and permit healthcare professionals to bring testing to the patient rather than requiring centralized laboratory testing. With proper oversight, POC testing can be a high-quality, high-value tool to manage the care of patients (3). The number of POC tests likely will continue to increase with technological advances.

Current CoW Regulatory Requirements

Facilities performing only waived testing operate with limited federal oversight. The owners of these laboratories are required to complete and submit a form that describes the tests they perform and to pay a biennial fee of $150 to obtain and maintain a Certificate of Waiver. These laboratories are not subject to CLIA personnel, quality control (QC), and proficiency testing (PT) requirements, nor do they undergo regular inspections. In lieu of these standards, CoW facilities are required to follow the manufacturer's instructions for the tests they perform, which prescribe QC and maintenance requirements for the devices, instructions on how to properly store reagents, the testing protocol, and other procedures.

Personnel Performing the Tests

Individuals performing testing in near-patient healthcare settings often have little to no formal education or training in laboratory medicine (4). Training on protocols and use of the devices is provided by a variety of personnel—the manufacturer's sales representatives, current employees of the facility, and nurses, for example—or through self-education by reading the package insert (4). These multiple training approaches lead to inconsistent quality in POC testing in CoW facilities. CMS survey data indicate a high turnover among individuals performing testing at CoW testing sites, further exacerbating quality issues (4).

Considerations

Quality of CoW Testing

Over the past few decades, CMS has documented significant, widespread deficiencies among CoW laboratories, such as:

- Not having the manufacturer's instructions;
- Not performing QC as directed by the manufacturer;
- Not reporting patient test results correctly; and
- Not storing and handling the reagents properly (1).

A separate study conducted by the New York Department of Health found similar problems (5). These deficiencies can result in patient harm from testing errors (4). The Centers for Disease Control and Prevention (CDC) has developed several practical resources to help CoW laboratories improve their testing.

In 2005, CDC published a *"Good Laboratory Practices for Waived Testing Sites"* that provides recommendations to CoW facilities on how to identify and address common testing problems. The agency later released a follow-up document in 2015, *"To Test or Not to Test? Considerations for Waived Testing,"* which provides more detailed guidance on how CoW laboratories can improve the quality of their testing. The agency also developed a one-hour educational training module based on the second booklet. Waived laboratories should document that they have viewed and understood these free and useful resources.

CoW facilities could take a variety of steps to implement best practices, such as:

- hiring a properly qualified laboratorian to serve as a consultant to help supervise and train the testing personnel, and to document their training; and/or
- participating in an accredited PT program for the tests it performs.

These additional steps could improve operator technique and the reliability of test results, reduce medical errors, improve the quality of care, and lead to more efficient use of healthcare resources.

Operator Training and Competency

CoW sites use waived POC testing devices to perform patient testing. While simpler than complex instruments in clinical laboratories, these instruments are not error-proof, even with built-in internal controls. Improper reagent storage, outdated reagents, variations in testing technique, or operator error can all lead to inaccurate results and adverse medical events. Therefore, it is critical that individuals

performing waived testing have adequate knowledge of laboratory best practices, including a familiarity with the devices they are using, common sources of error, and troubleshooting.

Programs exist to train individuals on how to properly perform POC testing. AACC offers education and certification in POC testing, and other organizations offer their own educational programming. Increased and expanded use of educational programs or ongoing participation in continuing education programs could reduce many of the deficiencies identified by CMS during its inspections, thereby improving the reliability of test results provided by CoW laboratories to clinicians for diagnosing and treating their patients.

Need for Ongoing Quality Assessments

In 2002, CMS initiated the CoW project, which resulted in the agency inspecting two percent of CoW laboratories each year to identify problems and help resolve them. Through these inspections, the agency detected serious quality problems that needed to be addressed (6). These data were invaluable in helping CDC and CMS develop best practice documents and modules to improve the performance of CoW facilities. In 2016, CMS discontinued this program to focus on physician-performed microscopy laboratories.

CMS should consider restarting the CoW project given the continued growth and diversity of testing performed by waived testing facilities. Inspections should include a wide variety of CoW testing sites, such as physician office laboratories, home health agencies, pharmacies, retail stores, and nursing homes, to ensure that issues unique to each type of laboratory can be identified and resolved.

Need for Broader Study of CoW Laboratories

Since 1993, the number of CoW sites has increased by more than 170%. These facilities often perform testing as an adjunct to their primary function (e.g., pharmacies). Past CMS surveys have shown that CoW facilities have quality problems and their personnel need ongoing training and guidance (4). Unfortunately, there has never been a comprehensive study to evaluate the testing performed in these sites.

The most recent official assessment of CoW laboratories was an August 2001 Department of Health and Human Services (HHS) Office of the Inspector General (OIG) report, *"Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program."* (7). A new, more comprehensive assessment of the quality of testing performed by waived laboratories is needed. This study should address all types of CoW facilities and make recommendations for improvement.

Positions

AACC is concerned that insufficient oversight and quality requirements for CLIA Certificate of Waiver testing facilities might be contributing to compromised patient care. To fully realize the potential of new technology in point-of-care and other waived testing facilities, personnel performing waived tests should be properly trained and/or credentialed, and CoW facilities should meet standards of good laboratory practices. To these ends, AACC holds the following positions:

Congress

- AACC urges Congress to direct the HHS Inspector General's Office to conduct a study on the quality of testing provided by CoW testing sites and make recommendations for improvement. This study should include the various CoW sites performing laboratory testing so that specific guidance can be directed to the differing categories of sites.

Federal Agencies

- CMS should resume its CoW Laboratory Project and annually inspect a minimum of two percent of waived laboratories – covering a representative cross-section of decentralized testing sites.
- CMS and CDC should provide CoW facilities with the CDC best laboratory practice documents and provide ongoing educational programs designed to improve the quality of testing in these laboratories.

CoW laboratories

- CoW laboratories should document the quality and reliability of their test results (e.g., through participation in proficiency testing).
- CoW laboratories should continually assure their

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personnel are properly supervised and trained to consistently and reliably perform clinical laboratory tests necessary for the provision of quality patient care. Manufacturers could provide laboratories with training checklists to document personnel training.

Laboratory Community

- Professional laboratory organizations should continue to provide training programs and materials that ensure CoW operators gain the knowledge, experience and skills needed to perform quality laboratory testing.

References

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