4 POINT-OF-CARE TESTING

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OBJECTIVES

After completing this chapter, the reader should be able to

- Describe clinical opportunities for point-of-care testing in a community pharmacy or ambulatory care setting for both population and patient-specific applications
- Differentiate between the values of sensitivity, specificity, accuracy, precision, positive predictive value, and negative predictive value when interpreting the results of a point-of-care test
- Discuss the limitations for CLIA-waived point-of-care testing
- Identify potential resources for CLIA-waived point-of-care testing options
- Identify potential resources for maintaining good laboratory practices

The pharmacy profession's role in the healthcare system is continually evolving. Over time, the profession has shifted from being product-focused to delivering patient-oriented pharmaceutical care. Today, pharmacists are on the frontline of providing patient-centered care and wellness. Moreover, their role in delivering care has tremendous potential to expand as healthcare delivery becomes more patient-centered and team-based. Pharmacists are highly trained, accessible healthcare professionals who are second only to registered nurses in terms of the number of practicing professionals. They are also underutilized in the U.S. healthcare delivery system.[1] However, in collaboration with physicians and other healthcare professionals, the role and ability of pharmacists can be maximized to deliver quality patient-centered care and improve public health.[1]

Clinical Laboratory Improvement Amendments of 1988 (CLIA)-waived point-of-care (POC) testing (POCT) represents one means by which pharmacists can improve the delivery of healthcare.[2] Working in collaboration with other providers and public health officials, pharmacists can leverage their knowledge and accessibility to offer CLIA-waived POCT services to manage chronic illnesses, improve access to healthcare services, rapidly initiate appropriate therapy, and screen for diseases of public health significance.[2] Chapter 1 defines POCT and differentiates it from home testing, and provides an overview of the advantages and disadvantages of these testing paradigms. The objective of this chapter is to identify opportunities to perform CLIA-waived POCT in ambulatory care clinics and community pharmacies. This chapter will focus on POC tests and POCT by expanding on the overview of common CLIA-waived POC tests provided in Chapter 1; in addition, this chapter will discuss available tests, review their performance measures and practical limitations, discuss their use in current practice, and identify potential future applications for their use in practice.

REGULATORY OVERSIGHT OF CLIA-WAIVED POC TESTS AND TESTING

The U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) are the federal agencies charged with oversight of CLIA. The FDA is responsible for classifying tests based on their level of complexity and potential for risk to public health. During the premarket approval process, the FDA classifies tests based on complexity (high, moderate, or waived) using criteria in the CLIA regulations. Waived tests are low-complexity methods that are simple to use, and their risk of producing erroneous results is negligible or poses no reasonable risk of harm to the patient if performed incorrectly.[3]

CMS regulates facilities that conduct laboratory testing on human specimens for health assessment, diagnosis, prevention, or treatment of disease, including all POC tests. Waived laboratories, such as community pharmacies or ambulatory care clinics, can only perform waived tests and are not subject to regular inspections, personnel requirements, or proficiency testing. To perform such tests, these sites must obtain a CLIA Certificate of Waiver from CMS, pay applicable fees biannually, and follow the manufacturers' test instructions. In most states the process is

similar; however, CMS has exempted New York and Washington from CLIA so some of the processes and regulations to perform CLIA-waived tests are different. More information on how to apply for a CLIA Certificate of Waiver can be found at the CMS website (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html).

COMMON CLIA-WAIVED POC TESTS

Resources

Because of recent technological advances, the market for CLIA-waived POC tests is continually and rapidly growing and changing. Therefore, it is important for a pharmacist in a community pharmacy or ambulatory care clinic that has obtained a CLIA waiver to be aware of the most current information on the available tests. In addition to FDA and CMS regulatory oversight, the Centers for Disease Control and Prevention (CDC) provide support for the CLIA program and offer an additional resource for information on CLIA-waived testing. Useful and current information on CLIA-waived tests is available on the websites of all three agencies.

FDA Website

Perhaps the most up-to-date, comprehensive, and readily searchable resource is the FDA's list of analytes that are used in waived laboratory test systems, which is located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm. This resource is an alphabetically organized list of analytes hyperlinked to test and regulatory information. When a specific analyte (e.g., cholesterol) is selected, a list of waived test systems that measure the analyte appears (each with hyperlinks to regulatory information and documentation). The advantage of this resource is that it is updated frequently. However, it contains more regulatory information than most clinicians in a clinical practice site need.

CMS Website and Guidance Document

A document listing tests that have been granted a waived status under CLIA may be downloaded from the CMS website at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf. This resource is a list of tests organized by Current Procedural Terminology (CPT) code. Although this resource does not contain as much information as that found on the FDA website, it contains the basic information (e.g., CPT code, test name, and manufacturer) that clinicians may find useful in a clinical setting in an easy-to-read tabular format.

CDC Website

The CDC's website (https://wwwn.cdc.gov/clia/default.aspx) is a good resource to search for professional information and educational resources regarding the analytical and technical aspects of a test for a given analyte. In addition, the CDC's website is specific for CLIA-waived POC tests (https://www.cdc.gov/clia/Resources/WaivedTests/) and contains links to documents that outline good laboratory practices for sites performing waived tests and a booklet that details the practical considerations for performing CLIA-waived POC tests or developing CLIA-waived POCT services.[4,5]

Specimens Used in CLIA-Waived POC Tests for Chronic Disease State Management

Waived tests are approved for use only with unprocessed specimens that require no manipulation (e.g., centrifugation, precipitation, dilution, and extraction). Specimens, such as serum or plasma, require manipulation during sample preparation or training in their handling such that they are not suitable for use in CLIA-waived POC tests.[6] Clinicians should be aware that some test systems provide instructions for processed and unprocessed specimen types, but waived use is intended only for the testing of unprocessed specimens. In addition, depending on the type of specimen the test analyzes, not all CLIA-waived POC tests used for disease state management are suitable or feasible for use in a community pharmacy or ambulatory care clinic. The most commonly obtainable specimen types for POCT in disease state management are urine and whole blood.

Urine

The urine dipstick and tablet reagent urinalysis are common CLIA-waived POC tests found in many ambulatory care settings. The urinalysis test provides pharmacists with values for bilirubin, glucose, hemoglobin (Hgb), ketone, leukocytes, nitrite, pH, protein, and specific gravity. This test can be used to detect an acute urinary tract infection. The pharmacist involved in a smoking cessation program might use a nicotine detection test. This test detects nicotine and its metabolites in urine and could indicate the smoking status of an individual as a low or high nicotine consumer. Urine tests can also be used for toxicological screenings and for drug metabolism phenotyping. However, these uses are beyond the scope of this chapter.

Whole Blood

Pharmacists obtain whole blood samples through a finger stick method for a variety of CLIA-waived POC tests. Blood conservation is one advantage of POC tests; as such, tests analyze whole blood analytes using volumes typically measured in drops of blood rather than milliliters. Each testing device may require varying amounts of a blood sample for a given analyte, making it critical for pharmacists to follow the manufacturer's guidelines for blood sample collection as required by CLIA-waived testing regulations. The minimal amount of blood required by POC tests may also reduce the chance of errors that can occur when using larger volumes. As described in Chapter 1, a quick turnaround time (TAT) is also a major advantage to POCT. The TAT is the time interval from sample collection to test performance, and it is a critical step in ensuring test accuracy for some CLIA-waived POC tests. Ambulatory care clinics and community pharmacies are often very