Point-of-care testing for infectious diseases: Opportunities, barriers, and considerations in community pharmacy


Abstract

Objectives: To identify opportunities to perform point-of-care (POC) testing and/or screening for infectious diseases in community pharmacies, provide an overview of such tests and how they are used in current practice, discuss how the Clinical Laboratory Improvement Amendments of 1988 (CLIA) affect pharmacists performing POC testing, and identify and discuss barriers and provide recommendations for those wanting to establish POC testing for infectious diseases services in community pharmacies.

Data sources: PubMed and Google Scholar were searched from November 2012 through May 2013 and encompassed the years 2000 and beyond for the narrative review section of this article using the search terms rapid diagnostic tests, POC testing and infectious diseases, pharmacy services, CLIA waiver, and collaborative drug therapy management. All state boards of pharmacy in the United States were contacted and their regulatory and legislative websites accessed in 2012 and January 2013 to review relevant pharmacy practice laws.

Data synthesis: POC testing for infectious diseases represents a significant opportunity to expand services in community pharmacies. Pharmacist education and training are addressing knowledge deficits in good laboratory practices and test performance and interpretation. Federal regulations do not define the qualifications for those who perform CLIA-waived tests, yet few pharmacists perform such services. Fewer than 20% of states address POC testing in their statutes and regulations governing pharmacy.

Conclusion: POC testing for infectious diseases could benefit patients and society and represents an opportunity to expand pharmacy services in community pharmacies. Existing barriers to the implementation of such services in community pharmacies, including deficits in pharmacist training and education along with state regulatory and legislative variance and vagueness in statutes governing pharmacy, are not insurmountable.

Keywords: Rapid diagnostic tests, Clinical Laboratory Improvement Amendments, collaborative practice, pharmacy services, laws and legislation.

Point-of-care (POC) tests can potentially improve the detection and management of infectious diseases by reducing the time between testing for and the diagnosis of an infection. Rapidly diagnosing an infection benefits the patient by facilitating timely access to care and initiation of therapy; it may also benefit the population at large by reducing the probability of disease transmission. Furthermore, rapidly identifying the cause of an infection and promptly initiating appropriate therapy may reduce inappropriate antimicrobial use in the community.

Although no universally accepted definition of POC testing exists, it typically involves performing a robust diagnostic test outside of a laboratory at or near the patient that produces a reliable result rapidly to aid in disease screening, diagnosis, and/or patient monitoring. To improve clinical management (e.g., triage, referral, and treatment decisions), such tests must be convenient and simple to perform, and have a rapid turnaround of results. With POC testing, the screening or diagnostic process can be completed during a single clinical encounter, a key difference from laboratory-based testing. While being convenient, simple, and quick are important, these POC testing characteristics are meaningless if the test result does not improve access to care, counseling, and/or patient outcomes.

Community pharmacies represent an ideal setting to perform POC testing for infectious diseases. POC tests for infectious diseases are waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Pharmacists can charge patients directly or bill third-party payers for services using these tests as they would with other CLIA-waived POC tests. For a more comprehensive discussion about establishing POC-testing services and pharmacist compensation for providing services, including CLIA-waived tests, in a community pharmacy, the reader is referred to two excellent reviews on these topics.

The purpose of this Tools for Advancing Pharmacy Practice article is to identify opportunities to perform POC testing and/or screening for infectious diseases in a community pharmacy, provide an overview of POC infectious disease tests and how they are used in current practice, and discuss how CLIA affects pharmacists performing POC testing. We also identify and discuss barriers community pharmacists may encounter when establishing infectious disease POC-testing services and provide recommendations for those considering implementation of such services.

**POC-testing opportunities in community pharmacies**

In 2010, an estimated 274,900 pharmacists were practicing in the United States, and this figure is expected to grow at least 25% by 2020. Nearly 200,000 pharmacists practice in the community setting in the United States. By virtue of patient volume and diverse locations nationwide, community pharmacies are highly visible health care facilities that are easily accessible to the public without appointment. Despite their ubiquity, pharmacies are currently an underused health care resource staffed with highly trained health care professionals.

As community pharmacies continue to evolve toward a primary mission of provision of patient care services, the profession has a clear opportunity to expand pharmacist services beyond medication dispensing and patient counseling to encompass convenient, accessible, and affordable primary care services. In fact, many community pharmacies have expanded their services by implementing on-site health care clinics or “retail clinics” that provide preventive health care services such as health screenings, diagnostic services, and vaccinations, as well as treatment for many common illnesses or complications.

Given the knowledge, skills, and accessibility of community pharmacists, POC-testing services for
infectious diseases represent a focused means through which community pharmacies can expand their services to improve the prevention and treatment of infectious diseases.

Data demonstrate that community pharmacists and pharmacies can significantly improve the prevention and management of infectious diseases, such as influenza, herpes zoster, and streptococcal pharyngitis.\textsuperscript{15-18} Community pharmacists have become critical to population-based vaccination efforts. With their ubiquity, community pharmacies are proven important elements of efforts to reach populations that might otherwise go unvaccinated (e.g., medically underserved, healthy young and middle-aged adults).\textsuperscript{12,15-21}

Performing POC testing for common infectious diseases in community pharmacies could also produce a significant societal benefit by lessening inappropriate antimicrobial use, reducing transmission of these pathogens in the community, and improving the capacity to monitor population exposure to an infectious agent (e.g., influenza). In addition to situations in which pharmacists can initiate POC management (e.g., needle-exchange programs for injection drug users, clinical services for chronic diseases), limited data have emerged to suggest that community pharmacists’ screening for diseases such as human immunodeficiency virus (HIV), hepatitis C virus, and other communicable diseases of public health interest could improve linkage to care and have a positive impact on disease identification and outcomes.\textsuperscript{22,23}

**Overview of POC infectious disease tests**

POC tests for infectious diseases are based on a variety of microbial particle-based or antibody-based detection methods, including agglutination, enzyme-linked immunosorbence, optical immunoassays, or lateral flow immunochromatography.\textsuperscript{24} Common POC tests for infectious diseases can detect a variety of infections or microorganisms from patient specimens. Although data describing the use of POC tests for infectious diseases are limited at this time, such tests can likely be incorporated into community pharmacy practice in two ways.

First, POC infectious disease tests can be used in community pharmacies to screen for communicable diseases of public health interest. For example, performing POC screening tests for HIV and hepatitis C virus can improve linkage to appropriate care or counseling services for patients with reactive test results.\textsuperscript{25} Expanded surveillance through the use of these tests may also provide more accurate data on disease prevalence as well as increase public health agencies’ ability to reach targeted populations for screening.\textsuperscript{1}

For example, some pharmacies are performing POC testing for influenza and group A streptococci and piloting work to augment public health efforts by reporting positive cases and outbreaks.\textsuperscript{25} A 2013 report by the National Association of County and City Health Officials on partnerships between community pharmacies and public health departments recognized the potential for POC testing for infectious diseases to improve data sharing and facilitate collaboration that would inform disease surveillance efforts.\textsuperscript{26}

With the rapid changes now under way in available technology, some equipment used for infectious disease POC tests can store data and also facilitate data sharing and communication with public health agencies. Using these tests to screen for communicable diseases of public health interest could also extend antimicrobial stewardship activities to the community practice setting. For example, having more accurate data on the prevalence of influenza in the community could improve the allocation of vaccines to areas in highest need or help curtail inappropriate use of antibacterial agents.\textsuperscript{2,26,27}

A second way that POC infectious disease tests can be used in community pharmacies is as an aid in the rapid identification or diagnosis of treatable infectious diseases in individual patients. For example, POC testing for influenza and group A streptococcal pharyngitis can yield information that rapidly leads to initiation of cost-effective treatment.\textsuperscript{17,18}

**Overview of CLIA’s certificate of waiver**

All facilities that conduct laboratory testing on human specimens for health assessment, diagnosis, prevention, or treatment of disease, including all POC tests, are regulated by the Centers for Medicare and Medicaid Services (CMS) through CLIA.\textsuperscript{28} Locations that perform only CLIA-waived tests, including community pharmacies, are considered “laboratories” and must obtain a CLIA Certificate of Waiver before initiating testing services.

Requirements for a CLIA Certificate of Waiver vary from state to state. State CMS offices are a resource from which to gain specific information about obtaining and maintaining a CLIA Certificate of Waiver. Information on how to apply for a CLIA Certificate of Waiver can also be obtained from the CMS website at www.cms.hhs.gov/cla.

The U.S. Food and Drug Administration (FDA) classifies laboratory tests into one of three categories based on their level of complexity and potential for risk to public health.\textsuperscript{29} Waived tests are those defined as simple laboratory examinations and procedures that are cleared by FDA for home use, use 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.\textsuperscript{29} CLIA-waived tests are available for 120 analytes. A complete list of these can be accessed at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/anlyteswaived.cfm.

Currently, 16 analytes are used in CLIA-waived tests for infectious diseases, and not all of them have...
In the past decade, the number of pharmacies with a certificate to offer CLIA-waived laboratory services increased nearly threefold, and the percentage of waived facilities that are pharmacies increased from 2% to 5%.28,30 Although the reasons for these increases have not been studied, the trend may reflect a need to enhance nondispensing revenues to compensate for declining prescription reimbursement rates, a means to improve patient services and public image, or a way of gaining a competitive advantage in the changing health care delivery environment.31 Perhaps the successes observed with the expansion of clinical services in community pharmacy practice to include immunizations have prompted pharmacists and health care systems to explore a greater role in primary care.12

### Table 1. CLIA-waived analytes for infectious diseases

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Intended use</th>
<th>Required specimen</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus</td>
<td>Local (in tears of the eye) adenovirus detection associated with acute infectious conjunctivitis</td>
<td>Tears</td>
<td>Intended for use in an office, clinic, or hospital.</td>
</tr>
<tr>
<td>Aerobic/anaerobic organisms–vaginal</td>
<td>Detection of sialdase activity, an enzyme produced by bacterial pathogens such as <em>Gardnerella vaginalis</em>, <em>Bacteroides spp.</em>, <em>Prevotella spp.</em>, and <em>Mobiluncus spp.</em> in vaginal fluid</td>
<td>Vaginal fluid</td>
<td>Intended for use in an office, clinic, or hospital. Because of the means of specimen collection, this test may not be appropriate for all pharmacies.</td>
</tr>
<tr>
<td>Group A streptococcus</td>
<td>Aid in rapid diagnosis of group A streptococcal infection</td>
<td>Throat swab</td>
<td>Some tests are only intended for in-vitro diagnostic use in clinical and physician office laboratories.</td>
</tr>
<tr>
<td>Helicobacter pylori and Helicobacter pylori antibodies</td>
<td>Most aid in diagnosis of infection by H. pylori. Some aid in presumptive identification of H. pylori in gastric biopsy specimens from patients.</td>
<td>Whole blood</td>
<td>Not all tests are suitable for use at point-of-care testing sites.</td>
</tr>
<tr>
<td>Hepatitis C virus (HCV) antibody</td>
<td>Aid in diagnosing HCV</td>
<td>Whole blood</td>
<td>Intended for use in public health settings, physician office, community health clinic, laboratories, and emergency departments.</td>
</tr>
<tr>
<td>Human immunodeficiency virus (HIV) antibodies; HIV-1 antibody; HIV-2 antibodies</td>
<td>Aid in the detection of HIV. Used for initial screening. Tests detect either the HIV-1 antibody or both the HIV-1 and HIV-2 antibodies</td>
<td>Whole blood, oral fluid</td>
<td>Only one currently approved test is suitable for in-home testing. Results from tests from two different manufacturers can be used to confirm HIV infection.</td>
</tr>
<tr>
<td>Infectious mononucleosis antibodies</td>
<td>Aid in diagnosis of infectious mononucleosis</td>
<td>Whole blood</td>
<td>Tests are intended for point-of-care and other use by health professionals.</td>
</tr>
<tr>
<td>Influenza A, B, or B virus</td>
<td>Aid in rapid differential diagnosis of influenza A and B viral infections</td>
<td>Nasal swabs or washes</td>
<td>Test could be performed in a community pharmacy. Any follow-up of negative test results by cell culture would require a laboratory.</td>
</tr>
<tr>
<td>Lyme disease antibodies (Borrelia burgdorferi antibodies)</td>
<td>For qualitative presumptive detection of IgG and IgM antibodies to B. burgdorferi in human serum or blood</td>
<td>Whole blood</td>
<td>Intended for use in clinical and physician office laboratories.</td>
</tr>
<tr>
<td>Respiratory syncytial virus (RSV)</td>
<td>Aid in diagnosis of RSV infections in pediatric patients</td>
<td>Nasal swabs or washes</td>
<td>Negative test results should be confirmed by cell culture.</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>For qualitative detection of <em>Trichomonas</em> antigens in patients with symptoms or suspected exposure</td>
<td>Vaginal swab</td>
<td>Intended for use in clinical and physician office laboratories.</td>
</tr>
</tbody>
</table>

Abbreviations used: HCV, hepatitis C virus; HIV, human immunodeficiency virus; RSV, respiratory syncytial virus; IgG and IgM, immunoglobulins G and M, respectively.

Source: Adapted in July 2013 from CLIA (Clinical Laboratory Improvement Amendments) Currently Waived Analytes, available on the website of the Food and Drug Administration, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

### Barriers to infectious disease POC testing in community pharmacies

#### Lack of training
Although CLIA-waived POC tests are classified as simple to use with low risk for erroneous results, they are not error-proof.29 Regardless of how POC infectious disease tests are used in the community pharmacy setting, they should be performed only by trained individuals and according to the manufacturer’s instructions. Studies by the Centers for Disease Control and Prevention (CDC) and CMS indicate that, in general, CLIA-waived sites (including pharmacies) usually take measures to perform testing correctly. However, available data raise quality-control concerns about practices that could lead to errors in testing and adverse events.32 Specific concerns include lack of understanding about good

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laboratory practices and inadequate training on how to perform a test, the interpretation and knowledge of test shortcomings, and requirements treatment, record keeping, and disease reporting.28

While such deficits exist, current standards and proposed competencies for educating and training pharmacists have begun to address these gaps in knowledge. The most recent Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy degree from the Accreditation Council for Pharmacy Education (ACPE), effective in 2011, list diagnostic tests among the elements of the science foundation about which pharmacy practitioners should be knowledgeable and competent before receiving their degree.33

A joint National Association of Chain Drug Stores (NACDS) Foundation–National Community Pharmacists Association–ACPE Task Force formulated practice competencies for entry-level practitioners in 2012. These require each entry-level graduate to be able to apply public health policy in clinical situations and list specific objectives to “collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests” and “describe the need for CLIA waiver and describe documentation of testing done in the community pharmacy.”34

Regulatory variability and vagueness

The scope of practice for pharmacists varies among states based on laws and board of pharmacy regulations. The actions of pharmacy and other health regulatory boards are subject to legislative and regulatory oversight, and the political process adds to the variability in state statutes governing the practice of pharmacy.

Because of these legal realities, it remains unclear from a national perspective which states may allow pharmacists to provide POC tests for infectious diseases and what role, if any, pharmacists may have in performing these services. Legislative and regulatory variability and vagueness may produce confusion among practitioners and therefore presents a barrier to pharmacists performing POC tests for infectious diseases in the community setting.

Interestingly, a national survey of 194 licensed pharmacists from 40 different states regarding their knowledge and perceptions of POC tests used for the identification of infectious diseases found that more than 85% of respondents were unaware if their state practice acts allowed them to conduct such tests (unpublished data, personal communication with Danielle Daunais, principal investigator).

Even if POC testing is addressed in the state statutes and regulations governing the practice of pharmacy, individual provisions may lack specificity or be worded vaguely. To evaluate the variability in the United States with regards to such regulations, we assessed the scope of practice for all 50 states and the District of Columbia by reviewing the websites of the boards of pharmacy and/or contacting representatives of state boards of pharmacy via e-mail. This review took place from January 2012 to January 2013. Only 8 (16%) states (California, Colorado, Delaware, Georgia, New Jersey, North Dakota, Pennsylvania, and Washington) explicitly address POC testing in their respective pharmacy practice acts, and in Maryland, it is addressed in the regulations governing laboratories. In five of these eight states, the practice act specifies POC tests that pharmacists are allowed to perform.

If the practice act of a state does not explicitly address POC testing directly, such tests may be addressed under collaborative drug therapy management (CDTM) provisions in state regulations or statutes. At the start of 2012, according to the National Association of Boards of Pharmacy Survey of Pharmacy Law, 43 states had some form of CDTM provisions in their regulations or statutes. In late 2012, Missouri became the 44th state to have such provisions, leaving Alabama, Delaware, the District of Columbia, Illinois, Kansas, Oklahoma, and South Carolina as the only states without enabling CDTM provisions.35 In 19 of these 44 states (42%) (Arkansas, California, Colorado, Georgia, Idaho, Iowa, Louisiana, Maryland, Michigan, Montana, New Jersey, Nebraska, New Mexico, North Dakota, Oregon, Texas, Vermont, Washington, and Wyoming), the CDTM provisions explicitly state that pharmacists are allowed to perform POC testing. One other state, Pennsylvania, specifically allows pharmacists in institutional practice settings to order laboratory tests and order and perform other diagnostic tests needed to manage drug therapy with a CDTM protocol as long as such activities are consistent with the standards of the institution. The CDTM provisions in Pennsylvania are silent on whether pharmacists in the community setting could engage in similar practices. In 7 of these 19 states, POC testing is also addressed in pharmacy practice acts: California, Colorado, Georgia, New Jersey, North Dakota, Pennsylvania, and Washington.

The variability in how POC testing is addressed in state statutes and regulations governing the practice of pharmacy is not surprising, given that the regulatory oversight for CLIA and its Certificate of Waiver program is a responsibility of state agencies or departments other than state boards of pharmacy.

Limited implementation of services

Without more widespread implementation of community pharmacy services involving POC tests for infectious diseases, individual efforts to establish such services may be stifled because stakeholders will likely continue to fail to recognize their potential benefits and value. CLIA does not define the professional qualifications for the director or testing personnel at waived sites.29
Data indicate that these tests are not commonly being performed in pharmacies or by pharmacists. In 2002–04, a national survey with 3,788 respondents indicated that the majority (86%) of the directors of their CLIA-waived sites were either physicians or nurses. The other 14% of site directors had a variety of medical or nonmedical training, including some with only a general educational development (GED; high school equivalency) degree. Only 76 (2%) respondents indicated the directors of CLIA-waived sites were pharmacists.28

In a CMS study, 5,511 respondents provided information about the professional training of the individuals who performed the testing at their CLIA-waived site. The top four categories were nurses (46%), medical assistants (25%), physicians (9%), and high school graduates or persons with a GED (7%). Only 55 (1%) respondents indicated the testing personnel at their CLIA-waived sites were pharmacists. According to data from 2004, only 3,294 (3%) of the 109,820 CLIA-waived sites were identified as pharmacies.28

Currently, an estimated 64,000 community pharmacies are operating in the United States; data indicate that 8,856 (14%) of all community pharmacies have a CLIA Certificate of Waiver.5,9,20 Given the minority of community pharmacies possessing a CLIA Certificate of Waiver, and the small number of pharmacists identified in the past as being directors of CLIA-waived sites or even as testing personnel, the potential for pharmacies to offer such services or for pharmacists to provide these tests has clearly not been realized.

**Recommendations for pharmacy-based POC testing for infectious diseases**

Based upon the opportunities and barriers identified above and after considering sound business planning practices, we believe pharmacists should consider the following when contemplating whether to establish services for POC testing for infectious diseases in community pharmacies (Table 2).

**Obtain education and training**

In late 2005, CDC published a report that provided recommendations developed by the Clinical Laboratory Improvement Advisory Committee for conducting quality waived testing. These recommendations include considerations before introducing waived testing, including outlining the management responsibility for testing, regulatory, safety, physical, and environmental requirements along with determining how the tests will benefit care offered at the testing site and the associated costs, staffing, and documentation.

The recommendations provide good laboratory practices to follow at each testing phase: before (e.g., test ordering and specimen collection), during (e.g., control testing, test performance, result interpretation and recording), and after (e.g., result reporting, documentation, confirmatory testing, and biohazard waste disposal). These recommendations can be used to form the basis of standard operating procedures for the testing facility. Overall, the recommendations are intended for those who would benefit from improving their knowledge of good laboratory practices.28

Pharmacists considering implementing POC infectious disease testing need to ensure that patients receive appropriate post-test follow-up or counseling services. For this reason, pharmacists performing POC infectious disease testing should possess adequate training in infectious diseases or collaborate with another infectious disease-credentialed health care professional. Pharmacists should also be adequately trained on the performance and interpretation of waived tests.

In addition to these recommendations, faculty from the colleges of pharmacy at University of Nebraska Medical Center and Ferris State University (including authors MEK and AMD) have collaborated to develop an ACPE-approved professional development certificate program to provide pharmacists with exposure to the practice skills and policy requirements necessary to safely and effectively incorporate POC testing into their clinical practice. This program has been endorsed by the Society of Infectious Diseases Pharmacists and NACDS. The program is managed by the Michigan Pharmacists Association.

**Table 2. Checklist of resources for community pharmacists considering offering infectious disease point-of-care testing services**

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtain education and training on CLIA waivers and performance of waived tests.</td>
</tr>
<tr>
<td>- Attend continuous professional development programs.</td>
</tr>
<tr>
<td>- Be familiar with local statutes and regulations governing pharmacy practice and CDTM agreements.</td>
</tr>
<tr>
<td>- Review pharmacy practice act and state board rules and regulations.</td>
</tr>
<tr>
<td>- Be familiar with other state and federal regulations.</td>
</tr>
<tr>
<td>- CLIA regulations (<a href="http://www.cms.gov">www.cms.gov</a>) and regional or state CMS offices</td>
</tr>
<tr>
<td>- Occupational Safety and Health Administration regulations for health care workers and needlestick precautions (<a href="http://www.osha.gov">www.osha.gov</a>)</td>
</tr>
<tr>
<td>- Centers for Disease Control and Prevention28</td>
</tr>
<tr>
<td>- Develop standard operating procedures that address documentation of testing and follow-up of test results.</td>
</tr>
<tr>
<td>- Centers for Disease Control and Prevention28</td>
</tr>
<tr>
<td>- Consider partnering with stakeholders to pilot services.</td>
</tr>
<tr>
<td>- National Association of County and City Health Officials (<a href="http://www.naccho.org)26">www.naccho.org)26</a></td>
</tr>
<tr>
<td>- State professional organizations, state agencies, nonprofit and/or nongovernmental quality improvement organizations</td>
</tr>
<tr>
<td>- Check liability insurance.</td>
</tr>
</tbody>
</table>

**Abbreviations used:** CLIA, Clinical Laboratory Improvements Amendments; CDTM, collaborative drug therapy management; CMS, Centers for Medicare and Medical Services; MMWR, Morbidity and Mortality Weekly Report.
**Review governance of pharmacy practice and CDTMs**

The lack of reference to CLIA-waived POC testing in state regulations and statutes governing pharmacy practice does not preclude pharmacists from performing these tests; rather, permission for testing is granted by CMS through issuance of CLIA Certificates of Waiver. The process of applying for and maintaining a CLIA waiver is not difficult. In general, it involves completing a standard form (CMS-116), which can be obtained from the CMS website (www.cms.gov). Once completed, the form must be sent to the applicable state agency, which will process it and issue a fee remittance coupon listing the CLIA identification number and the amount due for the certificate. The process takes approximately 2–3 months. The waiver is renewed by fee every 2 years.

Pharmacists performing POC testing in community pharmacies must ensure that the pharmacy has a valid CLIA waiver just as they would look for a valid pharmacy license. Although pharmacists practicing in CLIA-waived pharmacies do not need board of pharmacy permission to perform a POC test, it would be prudent to check local statutes and regulations to determine what, if any, additional approvals are needed, such as CDTM agreements or exemptions from other state agencies governing laboratory practices.

Often the vagueness of state statutes and regulations governing the practice of pharmacy regarding POC testing in community pharmacies may be addressed by specifically including the performance and interpretation of such tests in a CDTM agreement with a licensed physician or other licensed diagnostician. For example, the ability of the pharmacist to render a professional opinion about a POC test result likely depends on the scope of practice defined by individual state regulations and statutes governing pharmacy practice. Thus, before developing services to provide POC testing for infectious diseases in a community pharmacy, pharmacists must understand what their state regulations and statutes governing pharmacy practice allow with regard to test result interpretation and application to clinical care.

In many cases, such actions may be allowed under the CDTM provisions of state regulations and statutes governing pharmacy practice. However, CDTM regulations vary in scope across states and still do not exist in a few states. In our examination of the scope of practice of all 50 states and the District of Columbia, 12 states with CDTM provisions did not allow pharmacists to perform POC testing (Connecticut, Hawaii, Indiana, Kentucky, Maine, Massachusetts, New York, North Carolina, Ohio, Rhode Island, Utah, and Virginia). Therefore, in states with very limited or no CDTM provisions in their statutes and regulations governing the practice of pharmacy, community pharmacies may not be able to offer such services unless POC testing is explicitly addressed in their respective pharmacy practice acts.

**Develop follow-up and documentation procedures**

Performing POC testing for infectious diseases in the community pharmacy setting will be meaningless to the patient and wasteful for the health care system if a follow-up plan to address the test result is not included as part of standard operating procedures. Because of the variability in CDTM provisions that exists across the United States, pharmacists must understand their state regulations and statutes to determine how to legally and efficiently provide follow-up care as a result of performing POC tests for infectious diseases. In some cases, follow-up may be mandated as a necessary element of a CDTM agreement and allow for follow-up of specific diseases in any patient, while in other states CDTM regulations may require issuance of a prescription for each patient.

**Consider partnering with stakeholders to pilot services**

State boards of pharmacy and legislative bodies often require data and experience to expand the scope of practice. While gaining regulatory support and endorsement is ultimately vital to changes in practice, it is not the starting point. Rather, pharmacy demonstration projects in collaboration with physicians and other stakeholders, such as third-party payers and patients, may be needed to advance practice and expand services to include POC testing for infectious diseases in community pharmacies.

To ensure such efforts are productive, state boards of pharmacy and other state regulators must be involved.

**Check for liability insurance**

Pharmacists planning on providing POC testing for infectious diseases under a CDTM must understand that they will incur more liability. Depending on how the CDTM is structured, the collaborating physician is generally not liable for the actions of the pharmacist, just as they are not liable for the pharmacist’s action in the administration of a vaccine or the dispensing of a prescription. In addition to understanding state regulations, the pharmacist should also contact their liability insurance carrier to determine whether an individual or pharmacy policy covers performing and/or interpreting POC tests.

In doing so, pharmacists must understand that insurance companies cannot insure an illegal activity. Even if an activity is legal, a given carrier still may not underwrite it. Thus, pharmacists may need to involve their state board of pharmacy representative in discussions with their insurance representative so that the company has a full understanding of and is comfortable with the proposed practice.

**Conclusion**

POC testing for infectious diseases has many potential patient and population-level benefits. Offering such ser-
vices in a community pharmacy represents an opportunity to expand pharmacy services beyond medication dispensing and patient counseling to encompass convenient, accessible, and affordable primary care services. Challenges facing the widespread implementation of POC testing for infectious diseases in community pharmacies include deficits in pharmacist training and education and the variance and vagueness in state statutes and regulations governing the practice of pharmacy. However, these challenges are not insurmountable if pharmacists obtain proper training, understand their state regulations and statutes, and work with regulators and stakeholders to ensure that such services and follow-up care are provided legally, safely, accurately, and efficiently.

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28. Centers for Disease Control and Prevention. Good laboratory practices for waived testing sites; survey findings from testing sites holding a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 and recommendations for promoting quality testing. MMWR. 2003;54(RR-13):1–22.

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