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

Paul O. Gubbins, Michael E. Klepser, Allison M. Dering-Anderson, Karri A. Bauer, Kristin M. Darin, Stephanie Klepser, Kathryn R. Matthias, and Kimberly Scarsi

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.

J Am Pharm Assoc. 2014;54:163–171.
doi: 10.1331/JAPhA.2014.13167

Received August 13, 2013, and in revised form September 30, 2013. Accepted for publication September 30, 2013.

Paul O. Gubbins, PharmD, FCCP, is Professor and Associate Dean, University of Missouri–Kansas City School of Pharmacy at Missouri State University, Springfield. **Michael E. Klepser, PharmD, FCCP,** is Professor, Department of Pharmacy Practice, College of Pharmacy, Ferris State University, Kalamazoo, MI. **Allison M. Dering-Anderson, PharmD,** is Clinical Assistant Professor, Department of Pharmacy Practice, College of Pharmacy, University of Nebraska Medical Center, Omaha. **Karri A. Bauer, PharmD, BCPS**, is Specialty Practice Pharmacist, Infectious Diseases, Ohio State University Medical Center, Columbus. **Kristin M. Darin, PharmD, BCPS,** is Research Assistant Professor in Medicine–Infectious Diseases, Center for Global Health, Northwestern University Feinberg School of Medicine, Chicago, IL. **Stephanie Klepser, PharmD,** is Director of Clinical Services, Kalamazoo Center for Medical Studies Pharmacy, Kalamazoo, MI. **Kathryn R. Matthias, PharmD, BCPS (AQ-ID),** is Assistant Professor, Pharmacy Practice & Science, College of Pharmacy, University of Arizona, Tucson. **Kimberly Scarsi, PharmD, MS, BCPS,** is Associate Professor, Pharmacy Practice, College of Pharmacy, University of Nebraska Medical Center, Omaha.

Corresponding Author: Paul O. Gubbins, PharmD, FCCP, Professor and Associate Dean, University of Missouri–Kansas City School of Pharmacy at Missouri State University, 327 West Mill Street, #425, Springfield, MO 65806. Fax: (816) 235–5190. E-mail: gubbinsp@umkc.edu

Disclosure: Drs. M. Klepser and Dering-Anderson have developed a Certificate Program for Community Pharmacists interested in performing point-of-care testing and/or screening for infectious diseases in a community pharmacy. Drs. Gubbins, M. Klepser, Bauer, Darin, S. Klepser, Matthias, and Scarsi were members of the Society of Infectious Diseases Pharmacists Rapid Diagnostic Testing in Infectious Diseases Task Force.

Acknowledgments: To the Society of Infectious Diseases Pharmacists Board of Directors for their review and approval of this work; to Justin Kuhns, Danny Anderson, and Eric Hackbarth for assistance in contacting state boards of pharmacy for this paper.

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.[1] Furthermore, rapidly identifying the cause of an infection and promptly initiating appropriate therapy may reduce inappropriate antimicrobial use in the community.[2]

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.[3–5] 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.[6]

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.[7,8]

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.

At a Glance

Synopsis: Point-of-care (POC) testing for infectious diseases provides a unique opportunity for community pharmacists to expand their patient care services while also benefitting patients and developing in the public health role of the profession, according to the authors of this Tools for Advancing Pharmacy Practice article. Through a literature review and research into state laws and regulations, the authors determined that pharmacists in many states could apply for Clinical Laboratory Improvement Amendments (CLIA) waivers for POC testing and offer such testing for common infectious diseases such as influenza, group A streptococcal pharyngitis, human immunodeficiency virus, and hepatitis C virus. Existing barriers to the implementation of POC testing 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.

Analysis: *Challenges to the implementation of POC testing for infectious diseases are not insurmountable if pharmacists obtain the proper training, understand their state regulations and statutes, and work with regulators and stakeholders to ensure such services and follow-up care are provided legally, safely, accurately and efficiently. POC testing for infectious diseases has many potential patient and population level benefits and could expand community pharmacy's patient care service offerings.*

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.[9] Nearly 200,000 pharmacists practice in the community setting in the United States.[10,11] 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.[12,13] Despite their ubiquity, pharmacies are currently an underused health care resource staffed with highly trained health care professionals.[14]

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.[14] 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.[14] Given the knowledge, skills, and accessibility of community pharmacists, POC-testing services for