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Opinion

Pharmacy-based point-of-care testing for infectious diseases: Considerations for the pharmacy curriculum ☆

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Abstract

With the recent changes in U.S. health care delivery, patients and public health officials are embracing opportunities for pharmacists to provide more clinical services, expand access to care, and improve public health. Point-of-Care (POC) testing for infectious diseases and other Clinical Laboratory Improvement Amendments (CLIA)-waived tests are useful tools that may guide the clinical decision-making process. When used appropriately, these tests can result in significant health care cost savings and improved health outcomes. We identify this as an opportunity to further incorporate POC tests into the pharmacy curriculum and present considerations that may be useful to schools and colleges of pharmacy in developing such coursework. Key areas highlighted include the role of CLIA-waived POC tests in pharmacy practice, curricular considerations, training, and legal/privacy concerns.

Keywords: Point-of-Care testing; CLIA-waived testing; Screenings; Community pharmacy

Recently, trade and consumer press articles have highlighted various national and regional pharmacy chains launching Point-of-Care (POC) Testing services for influenza and Group A Streptococcus (GAS) by community pharmacists; others have launched POC testing for Hepatitis C and Human Immunodeficiency Virus (HIV).[1–3] Some have hypothesized that POC testing services for infectious disease may become a valuable public health service in community pharmacies in a manner similar to pharmacy-based immunizations, where one in five immunized patients have turned to in the years after the 2009 H1N1 influenza pandemic.[4,5] Indeed, pharmacy groups representing chain and independent pharmacies have included such POC testing among the competencies needed in entry-level pharmacists, and the Accreditation Council for Pharmacy Education (ACPE) has included this requirement in its draft curricular guidance.[6,7]

The goal of this article is to present an opinion piece based on research experience with POC testing for infectious disease in community pharmacies to highlight opportunities to further integrate POC into the pharmacy curriculum and to discuss the unique administrative and logistical concerns associated with classroom instruction of POC testing from experience at two schools of pharmacy.

☆Conflicts of interest: Dering-Anderson and Klepser have partnered with the Michigan Pharmacists Association (MPA) to create a community pharmacy-based rapid diagnostic testing certificate program that is mentioned in the article. MPA provided no input or direct support in the preparation of this article.

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Role of POC testing in pharmacy practice

Many POC tests currently performed by pharmacists are regulated under the Clinical Laboratory Improvement Amendments (CLIA). The Food and Drug Administration defines a CLIA-waived test as one that is "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."[8] Common examples of CLIA-waived tests currently utilized in pharmacy practice include blood glucose tests and those that measure total cholesterol, HDL cholesterol, and triglycerides, among others. Many of these tests are also utilized by patients to self-monitor and manage their own disease states.

Rapid diagnostic tests (RDTs) are a subset of CLIA-waived POC tests, and these provide rapid and objective information to confirm or rule out a diagnosis.[9] Common RDTs that can be implemented in the community pharmacy setting include tests for acute infections such as influenza and GAS.[10] In addition, POC tests for chronic infections such as HIV and Hepatitis C are available. Importantly, the natural course of each of these diseases has the potential to be altered by early detection and intervention. All also represent significant public health needs. For example, the Centers for Disease Control and Prevention (CDC) has recommended a one-time Hepatitis C screening for anyone born between 1945 and 1965, and some have raised concerns about the ability of the traditional office-based model of medical care to meet this goal.[11]

Recently, pharmacies have begun offering RDTs for influenza and GAS in select markets.[1–3] One approach to providing these services involves pairing the RDT with a physician-led collaborative practice agreement (CPA) that permits the initiation of the appropriate antibiotic or antiviral medication if the patient meets clinical criteria and has a positive test.[12] Patients for whom a test result is negative are given supportive care with appropriate follow-up in order to minimize false negatives. Modeling has shown that this framework for pharmacy-based RDT can lead to cost-effective treatment.[13] Expansion of this model will build off the education and training of the pharmacist, including their understanding of RDTs, proper specimen collection techniques, an understanding of clinical utility, ability to interpret tests in the context of the patient's clinical presentation, and proper adherence to a prescriber-led collaborative practice agreement. While these elements are included in various sections of the pharmacy curriculum for several non-infectious disease states, a coordinated and comprehensive POC-focused training module coalescing these elements could be further incorporated into the curriculum.

POC testing curricular considerations

Course outline

A sample course outline for a POC-themed class is provided in Table 1. It shows an option for a one semester hour course (750 min contact time) that may be used as either an elective or a required course. This type of curricular content fits well into a pharmacotherapy curriculum or a pharmacists' advanced practice curriculum and is synergistic with POC training already provided. While much of this outline is amenable to the flipped classroom strategies being used in pharmacy schools and colleges today, physical examination and specimen collection skills must be conducted in the live classroom setting with appropriately trained assessors. The proposed outline emphasizes a comprehensive understanding of POC testing and not just the specimen collection technique. It is important for pharmacists to know when and why to perform the tests, not just how to perform them. It is also important for pharmacists to know how to interpret tests in the context of the patient's clinical presentation. For example, the current model that some community pharmacies are using for influenza includes a CPA that requires pharmacists to assess for evidence of patient instability that triggers an automatic referral to more advanced care settings. This requires the pharmacist to assess the patient's blood pressure, temperature, respiratory rate, and oxygen saturation, among other clinical information, in addition to the RDT for influenza itself.

While Table 1 provides an overview of a one semester hour course, we recognize there are many options available to schools to build this into the curriculum. Some options include the following:

(1) Provide didactic content in Table 1 but limit the practical experience of the four main specimen collection techniques (oral fluid, nasal, throat, and whole blood) to use of control solutions or specimens, not real RDT or POC tests.
(2) Provide didactic content in Table 1 but limit the practical experience to student observation of a demonstration of the techniques with no student-to-student sampling.
(3) Alternatively, many schools and colleges engage students in health fairs and community wellness events. POC testing for chronic infectious diseases may be incorporated into these pre-existing opportunities as another learning opportunity.

Practice requirements

In order to build assessment of POC into the curriculum, schools and colleges must obtain a CLIA waiver. This involves the submission of a federal application form (CMS-116) and a $150 biennial certificate fee through a recognized state agency. Information regarding the state agencies and the entire CLIA certification process can be found at www.cms.hhs.gov/clia. Additional registration at the state level may be required.[14] Most schools and colleges may find that they have already completed both these steps since many CLIA-waived tests are already conducted in