Pharmacy-Based Infectious Disease Management Programs Incorporating CLIA-Waived Point-of-Care Tests

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ABSTRACT There are roughly 48,000 deaths caused by influenza annually and an estimated 200,000 people who have undiagnosed human immunodeficiency virus (HIV). These are examples of acute and chronic illnesses that can be identified by employing a CLIA-waived test. Pharmacies across the country have been incorporating CLIA-waived point-of-care tests (POCT) into disease screening and management programs offered in the pharmacy. The rationale behind these programs is discussed. Additionally, a summary of clinical data for some of these programs in the infectious disease arena is provided. Finally, we discuss the future potential for CLIA-waived POCT-based programs in community pharmacies.

KEYWORDS CLIA waived, POCT, pharmacy, point-of-care

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) are federal standards that were enacted to establish quality standards for laboratory testing of clinical specimens for patient diagnosis and treatment (https://www.cms.gov/Regulations -and-Guidance/Legislation/CLIA/). The objective of CLIA was to ensure the accuracy, reliability, and timeliness of diagnostic test results regardless of where they are performed. CLIA empowered three federal agencies, i.e., the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC), with the authority to regulate clinical laboratory testing. Under its mandate, the FDA was authorized to categorize tests based on complexity, develop rules and guidance for complexity categorization, and review requests for waiver. As such, a subset of laboratory tests that are referred to as CLIA waived was established. CLIA-waived tests are those tests and testing systems that are simple to perform and carry a low risk of an erroneous result. These tests include those that are cleared by the FDA for home use or those for which the manufacturer has applied for waived status to the FDA. There are currently more than 120 different CLIA-waived analytes that have been approved by the FDA (https://www.accessdata .fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm). Approved tests range from those used to monitor electrolytes and hemoglobin A1c to tests intended to diagnose the presence of an infectious agent. A number of CLIA-waived point-of-care tests (POCT) have been developed to support the diagnosis of, and screening for, infectious entities (Table 1) (1, 2). Community pharmacies have used CLIA-waived POCT such as those for assessing cholesterol and blood glucose to offer clinical services for decades (3). Recently, however, there has been increased interest in utilizing infectious disease-focused CLIA-waived POCT to improve patient care for a variety of communicable diseases. This interest stems from many factors, including the education and training of pharmacists, accessibility of pharmacies, and realization that many patients go to pharmacies early in the course of infectious diseases in an attempt to gain symptom relief before going to other health care facilities. It should be noted that all pharmacists in the United States graduate with the Doctor of Pharmacy degree (PharmD). According

TABLE 1 CLIA-waived analytes for infectious diseases[a]

Analyte/method(s)	Intended use
Adenovirus antigens	Local (in tears) adenovirus detection associated with acute infectious conjunctivitis
Aerobic/anaerobic organisms—vaginal fluid	Detection of sialidase activity, an enzyme produced by bacterial pathogens such as *Gardnerella vaginalis*, *Bacteroides* spp., *Prevotella* spp., and *Mobiluncus* spp. in vaginal fluid in women suspected of having bacterial vaginosis
GAS antigen and PCR	Aid in rapid diagnosis of GAS infection of the oropharynx
Helicobacter pylori and *H. pylori* antibodies	Most aid in diagnosis of infection by *H. pylori*; some aid in presumptive identification of *H. pylori* in gastric biopsy specimens from patients
HCV antibody	Screen for HCV in asymptomatic, high-risk individuals
HIV antibodies; HIV-1 antibody; HIV-1 and HIV-2 antibodies; HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen	Screen for HIV in asymptomatic, high-risk individuals
Infectious mononucleosis IgM heterophile antibodies	Aid in diagnosis of infectious mononucleosis
Influenza virus A and B antigens and PCR	Aid in rapid diagnosis of influenza A and B viral infections
Borrelia burgdorferi antibodies	Qualitative presumptive detection of IgG and IgM antibodies to *B. burgdorferi* in human serum or blood
RSV antigen and PCR	Aid in diagnosis of RSV infections in pediatric patients
Treponema pallidum antibodies	Aid in diagnosis of individuals with syphilis
Trichomonas vaginalis antigen	Qualitative detection of *Trichomonas* antigens in patients with symptoms or suspected exposure

[a]GAS, group A *Streptococcus*; HCV, hepatitis C virus; HIV, human immunodeficiency virus; RSV, respiratory syncytial virus.

to the educational standards for the profession (4), all pharmacy graduates are trained to evaluate patient function and dysfunction through the systematic gathering of objective (physical assessment and laboratory data) and subjective (patient interview) data important to the provision of care.

CLIA-WAIVED TESTING IN THE UNITED STATES

CLIA-waived POCT can be performed in any facility in possession of a certificate of waiver; however, some states require additional elements of testing sites (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/). As of 2015, physician offices hold the highest number of certificates of waivers for conducting CLIA-waived tests. Pharmacies rank fourth in facilities in possession of certificates of waiver (5). The number of pharmacies with certificates of waiver is increasing, indicating an increased interest in using CLIA-waived tests to provide patient care programs. This growth has been driven by the publication of data supporting various pharmacy practice models that utilize CLIA-waived POCT (2, 6–19). A recent report of the North American POCT market projected that the POCT market will exceed $6.84 billion by 2024 and that this growth is being driven largely by CLIA-waived tests in the United States (54). Furthermore, it has been suggested that pressure from payers to detect high-cost diseases early will help speed up the growth of pharmacy-based CLIA-waived diagnostic screening services (https://www2.deloitte.com/us/en/pages/risk/articles/retail-health-care-and-wellness.html). As a result, revenue projections related to CLIA-waived POC testing in pharmacies in the United States is expected to continue to grow and exceed that generated by other pharmacy services, including administration of immunizations.

COMMUNITY PHARMACY-BASED POC TESTING FOR INFECTIOUS DISEASES

Pharmacies are often identified as the most accessible entry point for patients into the health system in the United States (8, 20). There are roughly 62,000 retail pharmacies and more than 180,000 pharmacists practicing in the community setting (20). Furthermore, it has been estimated that 91% of all Americans live within 5 miles of a community pharmacy (8). It has been estimated that more than 13 billion pharmacy visits occur each year. This is more than 10 times the number of patient contacts that occur with all other primary care providers combined (20). Of these patient encounters, many are patient initiated and for nonmedical or low-acuity medical needs. Owing to this level of patient interaction and the manner in which patients frequent pharmacies, community pharmacies provide a unique opportunity for the implementation of disease management programs for various infectious diseases and other conditions of public concern. A number of recent studies have demonstrated the positive impact that

collaborative pharmacy-based disease management programs that employ CLIA-waived POCT can have on patient care and outpatient antibiotic utilization (2, 6–19).

As of March 2016, 9,110 pharmacies possessed a CLIA certificate of waiver (21). Although a number of factors are likely to have spurred interest in CLIA-waived POCT services in pharmacies, a primary driver has been the development of a nation-wide certificate program developed by the National Association of Chain Drug Stores (NACDS) aimed at educating pharmacists on the appropriate use of CLIA-waived POCT. This 20-h program consists of a number of live and self-study modules that provide training on all aspects of developing pharmacy-based disease management programs, including developing collaborative practice agreements, running tests, performing physical assessments, and managing a CLIA-waived laboratory (http://nacds.learnercommunity.com/Point-of-Care-Testing-Certificate). To date, more than 5,000 pharmacists have completed the program (NACDS, personal communication). Although few states mandate completion of training programs for pharmacists who perform CLIA-waived POCT, some do require pharmacists to be adequately trained. It is important to recall that CLIA-waived POCT are intended to be used by nonlaboratory personnel with no training. This being said, the NACDS certificate program recognizes the importance of pharmacists being comfortable and competent with collecting specimens, running tests, running quality controls, and functioning as a CLIA-waived laboratory. Personal communication with state laboratory inspectors who have audited some of the pharmacies conducting these tests in Michigan has suggested that the training provided by the NACDS program represents a higher standard than is currently in place for other health professionals.

Although there are more than 120 FDA-approved and CLIA-waived analytes, tests for infectious diseases have been identified as having an important role in the community pharmacy setting (11). As mentioned, pharmacies represent a convenient contact point with the health care system for patients. This convenience is significant to a busy individual suffering an acute symptomatic illness. A pharmacy offering disease management services for an acute illness such as acute pharyngitis represents a location where a patient can not only get information about the cause of their illness but also potentially receive symptomatic relief and antibiotics when appropriate. This type of patient care can be realized is some states through collaborative practice agreements or statewide protocols. In addition to the benefits afforded the patient, various studies have reported that pharmacy-based disease management is also associated with decreased rates of inappropriate antibiotic use (18, 19). In spite of the promise pharmacy-based disease management services have, these services may not be appropriate for implementation in every pharmacy. Likewise, just because there is a CLIA-waived test available for a pathogen does not mean that every CLIA-waived POCT should be used in a pharmacy (12). Prior to offering a service, careful consideration should be given to a number of pharmacy, test, patient, and procedural elements (Table 2). Special training in infectious diseases is not required for a pharmacist to determine when and how to employ a CLIA-waived POCT. All pharmacists, like physicians, are trained as generalists and receive significant training on common infectious conditions. Additionally, those who complete the NACDS program receive a refresher regarding the epidemiology, signs and symptoms, diagnosis, and treatment of several common infectious conditions for which CLIA-waived POCT may be considered. When possible, the pharmacy should also communicate with a laboratorian or public health entity to discuss potential uses and limitations of given tests.

Accessibility of a pharmacy alone does not make it an appropriate place to conduct laboratory testing. For several decades, pharmacies have provided patient care, including health screenings and immunizations. To accommodate these services, pharmacies have been renovated to include private or semiprivate areas to allow patient examination and/or counseling. These same areas are often used to ensure patient comfort and privacy during physical assessments and for conducting CLIA-waived POCT. Typically, an encounter is initiated by a patient speaking with a pharmacist or technician. The patient is then asked to complete a medical intake form that is reviewed by the

TABLE 2 Considerations prior to utilizing a CLIA-waived POCT in a pharmacy

Element	Consideration(s)
CLIA-waived test	Is an appropriate CLIA-waived test available?
	Does the test have adequate performance characteristics?
	What types of specimens are required to perform the test?
Data sharing	How will data be shared with the patient, their primary care provider, and public health (if necessary)?
Education and training	Are staff trained to identify and manage patients with the diseases of interest?
	Are staff trained to collect the appropriate specimens required for the test?
	Have staff been trained to counsel patients on diseases of interest (e.g., HIV, HCV)?
Partnerships	Is a collaborative practice agreement required to provide follow-up care to patients?
	Has public health been consulted regarding reporting reportable diseases?
Patient follow-up	Has a plan been developed to check in with patients once they leave the pharmacy to ensure their safety?
Permissibility	Do state rules or regulations that may prohibit a CLIA-waived test from being performed in a pharmacy exist?
	Do state rules or regulations that prohibit the pharmacist from providing follow-up care to the patient based on the test results exist?
Physical space	Is an appropriate exam and testing space available?
	Is a private room required for counseling?
Sustainability	How will the pharmacy recover its investment in the service?

pharmacist to determine if provision of care in the pharmacy is appropriate. If care in the pharmacy is deemed appropriate, the appropriate vital signs are collected and a physical examination is performed. If the patient meets testing criteria, a CLIA-waived POCT may be performed and care provided according to a collaborative practice agreement of statewide protocol. It is encouraged that the pharmacy provide a follow-up call to each patient within 24 to 48 h of the encounter regardless of test results. Additionally, the pharmacist is encouraged to send a summary of the encounter to the patient's primary care provider, if one is identified by the patient. Typically, the initial encounter can be completed within 30 min of a patient presenting to the pharmacy (22). Additionally, the impact on workflow is similar to that experienced by pharmacists when administering immunizations. Total hands-on time for providing these services ranges from 2.6 to 12.7 min, depending on the degree to which trained pharmacy technicians or interns are utilized (22–24).

USING CLIA-WAIVED POCT FOR PHARMACY-BASED PATIENT MANAGEMENT

Regulation of medical professions resides at the state level in the United States, and each state determines what professional services are permissible within their borders. Unfortunately, this means that there is virtually no continuity among states regarding the pharmacist's authorization to provide care to a patient pursuant to the results of a CLIA-waived POCT. Some states authorize pharmacists to provide care independently under statewide protocols. Some specifically prohibit pharmacists from initiating drug therapy based on the results of laboratory tests. Some are silent on the matter. Others require that the pharmacist enter into a collaborative practice agreement (CPA) with a prescriber in order to have prescriptive authority delegated to them. The CDC describes CPAs as collaborations that allow pharmacists and prescribers to create formal protocols that outline responsibilities and tasks within the scope of their respective practices (25). However, states may vary on the requirements and restrictions of CPAs. For example, delegation of prescriptive authority in some states is restricted to only patients with whom the collaborating prescriber has a preexisting relationship. This would make the care for patients with various acute conditions difficult, since patients who go to a pharmacy are rarely all seen by the same prescriber. In contrast, a number of states offer population-based CPAs. Under this model, one prescriber may delegate prescriptive authority for any patient who fulfills the criteria set forth in the CPA (16). Authorization afforded by this type of CPA would make delivery of care for acute conditions viable, as described by the National Alliance of State Pharmacy Associations (https://naspa.us/resource/swp/). Table 3 provides a few examples of pharmacy practice acts regarding initiation of drug therapy by a pharmacist.

Regardless of the means by which permission is granted to the pharmacist to engage in these activities, all provide a framework to guide testing and patient

TABLE 3 Examples of pharmacy practice acts related to provision of follow-up care by a pharmacist

Type of prescriptive authority	Characteristic(s)	Example state
Prohibited	CPAs are not authorized or may not allow for a diagnostic component Most restrictive	Delaware
Patient-specific CPA	Initiation and modification of drug therapy are allowed under a CPA if the patient is under the care of the signing prescriber Limited value for acute conditions	Illinois
Population CPA	A single prescriber can authorize a pharmacist to initiate and modify drug therapy for any patient that meets criteria set forth in the CPA Allows for management of patient with acute conditions	Michigan
Population CPA with specifications	States may limit the conditions to be managed under the CPA (e.g., influenza and group A streptococcal pharyngitis)	Kentucky
Statewide protocol	Authorization granted by a protocol approved by the state and signed by an authorizing prescriber Many states authorize the dispensing of naloxone by protocol Currently, no states authorize management of patients with infectious conditions by protocol	
Unrestricted (category specific)	Idaho Prescriptive authority for a limited range of medications Least restrictive	

management. As a result, patients need to meet criteria in order to be tested and must have a positive test prior to a medication being dispensed. These elements help mitigate concerns regarding inappropriate testing and treatment by the pharmacist.

DISEASE MANAGEMENT MODELS

Characteristics of successful models. Advancements in CLIA-waived POCT technology has provided community pharmacies powerful resources related to the detection of various infectious disease etiologies. However, a number of factors have hindered the adoption of this technology. First, data supporting pharmacy-based disease management models are still emerging. Currently, the most data exist for management of acute conditions such as pharyngitis, influenza, and urinary tract infections and for screening for human immunodeficiency virus (HIV) and hepatitis C virus (HCV) (7, 9, 13, 14, 17–19, 26–29). Although other tests may be well suited for deployment in community pharmacies, the disease management models incorporating these tests have not been developed and the impact on patient or pharmacy workflow has not been described. Second, variable pharmacy practice acts among states have made it difficult for chains with pharmacies in multiple states to develop models that can be applied across state lines. This fact results in the need for the pharmacy to expend a significant amount of resources in each state in which they wish to offer a service. Lastly, the onus of identifying a collaborating prescriber(s) can be a significant impediment, especially for smaller pharmacies. A prescriber who is hesitant to enter into a CPA regarding a service for which they do not have a good understanding is behaving responsibly. A prescriber who is fearful of entering into a CPA for a service because they are fearful of repercussions from peers or professional societies is a sign of a broken system.

The following common criteria have been identified regarding successful CLIA-waived POCT-inclusive disease management programs:

- Availability of a test with good performance characteristics

- Ability to offer population-based services

- Business plan established

- Clearly articulated criteria for the patient population that is eligible for the service

- Marketing plan to raise service awareness

- Pharmacy staff trained in providing the service (e.g., physical examination, collection of vital signs, specimen collection, test performance, laboratory management)

- Plan for data sharing (i.e., primary care provider, public health)

- Plan for linkage to care when appropriate (e.g., patients that are too ill to be managed in the pharmacy, patients with reactive HIV or HCV tests)
- Plan for patient follow-up
- Plan for patient management subsequent to positive and negative test results
- Prescriber support

Services that fulfill these criteria have been shown to benefit prescribers, pharmacists, and the patients they serve. A few examples of the benefits that have been realized include increased patient access to care, reduced health care costs, increased patient satisfaction with health care, improved antimicrobial use, improved access to prescribers by higher-acuity patients, reduction in unnecessary utilization of emergency departments, and identification of patients without identified primary care providers (1, 2, 5, 7, 8, 10, 11, 30).

In the following sections, we describe a few of the more common pharmacy-based disease management programs.

Pharmacy-based disease management programs. (i) Influenza. There are currently two CLIA-waived methods available to aid in the detection of influenza virus in the United States, namely immunoassays and PCR. Both test methods have been studied in community pharmacy disease management programs; however, the majority of data have been generated using immunoassays, with or without accompanying analyzers. Historically, lateral flow immunoassays for influenza virus have been criticized for exhibiting suboptimal sensitivities. As a result, the tests were of limited value in ruling out the presence of influenza virus because of high false-negative rates. In January 2017, the FDA announced its decision to require all marketed CLIA-waived rapid influenza tests to meet more stringent parameters with respect to sensitivity (31). As of 2018, tests that do not have a sensitivity point estimate of at least 80% (95% confidence interval [CI] lower bound of 70%) for influenza virus A and B in comparison to a molecular comparator must be withdrawn from the U.S. market. As a result, when coupled with clinical judgement and appropriate patient selection, influenza immunoassays are now more reliable tools for identifying influenza virus.

A prospective cohort study examined the effectiveness of a collaborative physician-pharmacist disease management program to care for individuals presenting with influenza-like illness (ILI) with respect to clinical outcomes and health care utilization (7). This study enrolled patients from 55 pharmacies during the 2013-2014 influenza season. Patients were eligible for inclusion in the study if they exhibited signs and symptoms consistent with ILI for less than 48 h and were deemed to be clinically stable and not a high risk for influenza-related complications as outlined in a CPA. Patients who were eligible for the service had a rapid influenza immunoassay performed (Sofia influenza A+B fluorescent immunoassay system or QuickVue influenza A+B test; Quidel, San Diego, CA). Patients with positive test results were offered oseltamivir, and those with negative test results were managed with over-the-counter medication. Pharmacy staff attempted to contact all patients 24 to 48 h following the pharmacy encounter for a follow-up assessment. If a patient identified a primary care prescriber, a summary of the visit was sent within 24 h of the encounter. A total of 121 patients were screened for the service. Of note, approximately 35% of the patients did not have a primary care physician and 39% sought care outside normal physician office hours. Forty-five (37%) patients did not meet criteria for pharmacy-based management and were referred to their prescriber or urgent care for further evaluation. Seventy-five (62%) of the patients were eligible for pharmacy-based care services. Eight (11%) patients had a positive influenza test and were offered oseltamivir. At follow-up, 3% of patients reported worsening of symptoms and were advised to seek additional care. No appointments were needed for patients seen in this study. Even in this walk-up model, patients were seen quickly and typically discharged from the pharmacy within 30 to 40 min.

Another study described the performance of rapid influenza tests by pharmacists (26). This study also noted that the rates of positive influenza test results were comparable to the trends of the epidemic that year.

(ii) Acute pharyngitis. Acute pharyngitis is among the most common infectious diseases in the United States. Although 13 million medical visits for acute pharyngitis are reported each year, this figure likely greatly underestimates the true prevalence of this condition (32). Although group A *Streptococcus* (GAS) is the most common bacterial agent that causes pharyngitis, it is the source of illness for only 10 to 15% of adults and 15 to 30% of children (10, 33). Differentiation among GAS and nonbacterial causes of pharyngitis cannot be made by symptoms alone. As a result, antibiotics are prescribed for >70% of patients who present with symptoms of acute pharyngitis (33). Use of rapid antigen detection tests (RADTs) can greatly improve the accuracy with respect to identifying GAS and thus decrease inappropriate antibiotic use by clinicians. Unfortunately, since RADTs do not have a sensitivity of 100%, many negative test results in pediatric patients must be followed up with a throat culture. However, as CLIA-waived PCR tests for GAS become more widely used, follow-up cultures will become unnecessary.

A number of studies have documented the safety and efficacy of the use of CLIA-waived RADT in pharmacies to assist in the management of patients with acute pharyngitis. In the largest study conducted in the United States, Klepser and colleagues described the results of a collaborative disease management model of acute pharyngitis (15). Prospective adult patients were evaluated by a pharmacist, and a modified Centor score for each was calculated. If the patient's Centor score was greater than 1, a RADT was performed. Patients with Centor scores of ≥1 and negative RADT results were managed with over-the-counter medications. Patients with positive test results were treated with an appropriate antibiotic as outlined in a CPA. Of the 316 patients screened by pharmacists, 278 were deemed eligible for management in the pharmacy. Of the eligible patients, 46 (17%) had a positive RADT result and provided an antibiotic. Almost half (44%) visited the pharmacy during hours in which a physician's office would be closed, and 43% of the patients that were studied did not have a primary care provider. These data suggest that community pharmacists who utilize a RADT under a CPA can safely and effectively manage adults with acute pharyngitis and that their service results in a significant reduction in inappropriate antibiotic use.

Similarly, Thornley and colleagues published findings from a study conducted in the United Kingdom that examined the ability of pharmacists to assess patients with sore throats who visited a pharmacy (34). Presenting adult and adolescent patients were initially screened for the appropriateness of RADT use by conducting a physical assessment, collecting vital signs, and calculating a Centor score. Individuals with a score of ≥3 had a RADT performed. Patients with a positive GAS test were offered antibiotics. The authors screened 367 individuals and identified 149 patients who were eligible for a throat swab and RADT. Of the eligible patients, 24% tested positive and were offered antibiotics. Participants reported a high level of satisfaction with the program. Additionally, it was estimated that the health system saved £67 (U.S. $87.80) for each patient that was managed in the pharmacy.

Papastergiou et al. reported their experience with a community pharmacist-directed GAS management program in Canada (9). Of 7,050 patients identified retrospectively, 25.5% had tested positive for GAS with an RADT and approximately 70% of these individuals received an antibiotic from the pharmacy as a result. The majority of the patients for whom data were collected stated that they would have gone to a clinic, physician, or emergency department had these services not been available in the pharmacy. Therefore, the improved accessibility of the service did not appear to result in increased testing but resulted in provision of services in a more cost-efficient setting.

(iii) HIV. Although the CDC recommends that all persons aged 13 to 64 years get tested for human immunodeficiency virus (HIV), only 54% of adults have acknowledged that they have been tested (6). Many individuals tested for HIV, especially those in nontraditional sites, are typically screened initially with a CLIA-waived immunoassay. If

the initial results are positive, the individual is referred for confirmatory testing. The currently available CLIA-waived POCT for HIV have sensitivities and specificities of >99%. However, most of the currently available tests detect only antibodies to HIV-1 and HIV-2. As a result, individuals that have experienced a recent exposure may provide a nonreactive test result if they have not yet seroconverted. Therefore, these individuals may require repeat testing and slow the detection of infection. A few CLIA-waived tests can detect HIV-1 p24 antigen as well as antibodies (https://www.cdc.gov/hiv/pdf/testing/rapid-hiv-tests-non-clinical.pdf). These tests may allow for detection of HIV-1 several weeks earlier than antibody tests. According to public health officials, the limiting factor in treating patients with HIV is having them get an initial screen. A number of factors, including accessibility, stigma, and mistrust of the health system, are all likely reasons that many individuals do not get screened. Pharmacies are highly accessible, and pharmacists are trusted by members of the community (8, 20, 35). This makes HIV screening in pharmacies an attractive option. Several studies have been published that support the use of pharmacies as sites to increase the accessibility for HIV screening (6, 36–39). Prior to initiation of screening services, the pharmacist should be trained on how to counsel patients on their results, have a plan in place to link patients with reactive results to care, and be familiar with disease reporting requirements in their state.

Some pharmacies have begun to support HIV pre-exposure prophylaxis (PrEP) services by offering quarterly HIV screening prior to dispensing antivirals (https://www.clinicaloptions.com/hiv/programs/pharmacy-care/pre-exposure-prophylaxis/ivp1) (40, 41). Data from reported studies suggest a high acceptance rate among patients.

(iv) HCV. Over 4 million Americans are estimated to be infected with hepatitis C virus (HCV). Unfortunately, more than half of the individuals infected with HCV are unaware of their status (42). The CDC recommends HCV antibody testing for a variety of individuals with high risk and risk exposures and individuals born between 1945 and 1965. Many of the members of this population are likely to be homeless, not have access to medical care, or may not return to view their results. A CLIA-waived POCT for the detection of HCV antibodies has been approved for use as a screening tool for HCV infection. If individuals yield a reactive result with the screen, referral for confirmatory testing is required. Offering HCV screening in community pharmacies has been proposed as a means to increase accessibility of the test for individuals that may otherwise not be screened. Studies describing HCV screening services in community pharmacies have highlighted the successes of this approach (12, 14). As with HIV screening, it is important for the pharmacy to have a plan in place to link individuals with reactive results to the appropriate care and to be familiar with disease reporting requirements in their state.

PATIENT SATISFACTION WITH HEALTH CARE

Numerous studies have examined patient satisfaction with health care experiences (43–45). Regardless of medical practice or practitioner type, for noncritical ambulatory care visits, the factors that are most often related to patient satisfaction with services are wait times and providers not taking enough time to answer questions (43–45). Additionally, prescription of an antibiotic has been linked to patient satisfaction among individuals being seen for a respiratory tract infection (46, 47).

Patient wait times in physician offices, in waiting rooms and in examination rooms waiting for a provider, have been reported to be, on average, 26 min (45). In the pharmacy models described above, the entire patient encounter (i.e., time from presentation to leaving the pharmacy) was less than 30 min (7, 15, 22, 24, 48). During the pharmacy encounter, patients had minimal downtime and were typically not alone (22, 24). Both of these factors have been associated with decreased patient satisfaction in traditional care models and may be a reason that satisfaction with pharmacy care models has been high (45).

With respect to the time spent with the patient and the time taken by a provider to answer patient questions, a recent study reported that physicians spend an average of

16.5 $\pm$ 9.2 min with patients during a typical office visit (49). This represents only 46% of the entire time that a patient is in the office. The bulk of the non-face-to-face time, >60%, was the result of working on the electronic medical record. This study noted that physicians typically spend 6.9 min per patient after-hours working on the electronic medical record. As a result, many physicians feel hurried during encounters and are reluctant to discuss conditions apart from the primary diagnosis (50). In the pharmacy care models described above, the average total face-to-face time (pharmacist and pharmacy technician) for the services was approximately 12 to 14 min or roughly 40% to 47% of the total encounter (22, 24). The total amount of time spent face-to-face with patients is similar between pharmacy care programs and physician care models.

Recent data from an evaluation of patient satisfaction with direct-to-consumer telemedicine for respiratory tract infections revealed that patient satisfaction was higher when they were prescribed an antibiotic or prescribed a nonantibiotic than when they did not receive a prescription (46, 47). Similar to a pharmacy-based model, telemedicine services often improve accessibility and patient convenience over office visits. In contrast to the data for pharmacy-based treatment models described above, the telemedicine services resulted in prescription of antibiotics for 66% of encounters. In spite of this difference in antibiotic prescribing, approximately 90% of individuals managed in pharmacies reported high levels of satisfaction with the care (7, 15). In the pharmacy setting, satisfaction was not correlated with receipt of an antibiotic. The authors of the studies suggested that in pharmacy care models, patient satisfaction may have been a result of a number of elements, including the ability of the pharmacist to provide over-the-counter products for symptomatic relief.

CONCERNS RELATED TO PHARMACY-BASED PROGRAMS

As pharmacy-based disease management programs continue to expand, some groups have expressed concern about fragmentation of care. In an effort to prevent this from happening, the practice of sending an encounter summary to a patient's primary care provider has been adopted. Interestingly, 30% to 40% of the patients that utilize pharmacy disease management programs do not identify a primary care provider (7, 15). In these situations, many pharmacists have begun recommending that these individuals attempt to establish a relationship with a provider. As a whole, when best practices are followed and a summary of the encounter is shared with the primary care provider or if patients follow the pharmacist's recommendation and establish care if they do not have a medical home, it appears that these care models do not result in fragmentation of care and may actually improve patient-provider relationships.

Additionally, a concern related to ordering unwarranted or duplicative tests by pharmacists has been raised. In most states, pharmacists determine when to run a test by following an evidence-based CPA or statewide protocol. Data from the literature have determined that not only do pharmacy-based models of care not order unwarranted tests, but they often provide a great deal of transparency regarding the rationale for running a test (7, 15). Furthermore, when practicing according to a CPA or protocol, pharmacists are obligated to manage patients according to the results of the test. This has resulted in dramatic improvement in appropriate antimicrobial use and has become a means to promote outpatient antimicrobial stewardship (7, 15, 51, 52). As far as ordering duplicative tests, this is a possibility if the pharmacist is not aware of previously collected data. However, this is not just a problem for pharmacists. This is a larger problem associated with our health system that needs to be addressed.

Another concern regarding pharmacy care models has been communication with health departments regarding reportable diseases. Pharmacists are subject to the same reporting standards as other providers; therefore, they are required to report all relevant diseases and pathogens. In the state of Michigan, pharmacists have worked with the state health department to develop procedures to facilitate reporting (53). Additionally, it was discovered during a pilot of a pharmacy care program that health officials in Michigan and pharmacists realized that pharmacists had not been given access to the state's online disease surveillance and reporting system. As a result of

pharmacists working with officials from the state health department on the development of policies and procedures related to disease reporting before the programs were launched, this error was identified and corrected. Now pharmacists in the state have the access they need to participate in reporting communicable diseases.

These models have raised several concerns from clinical microbiology professionals as well. One concern relates to who will be collecting and running the tests and the type of training they will receive. CLIA-waived tests are intended to be performed by individuals with no training and minimal instruction. That being said, the performance of the tests is predicated on the collection of a quality specimen. Most states do not restrict who may run these tests. Therefore, it is likely that pharmacists, student pharmacists, and pharmacy technicians will collect specimens and run tests. Although not mandated by all states, most pharmacists and pharmacy staff who employ CLIA-waived tests undergo training, as described earlier, to ensure competence in specimen collection and test performance.

Another concern that has been expressed is competency assessment for pharmacies performing CLIA-waived tests. For sites that perform only CLIA-waived tests, there are no proficiency requirements. These sites must apply for a certificate of waiver every 2 years. Additionally, the sites must agree to be inspected by state laboratory inspectors as requested. In order to be in compliance, the sites must have a copy of the current manufacturer's instructions for each test and be following the instructions. This includes any provisions for performing quality controls.

There is concern regarding how pharmacies will manage the handling of clinical specimens and protection against blood-borne pathogens. Pharmacists in all states have been administering immunizations for more than 10 years. As part of this aspect of practice and now with collection of specimens for POCT, pharmacists undergo routine training with blood-borne pathogens and have policies in place for safe handling of potentially hazardous materials. Additionally, pharmacies have policies in place regarding the use of gloves and masks when exposure to hazardous materials like blood and bodily secretions is likely.

The question of reporting of appropriate pathogens or cases of disease has also been raised. Each state is different with respect to its reporting requirement (i.e., what is reportable, when it needs to be reported, and how things are reported). Pharmacists in each state understand these parameters and spell out responsibilities in their CPAs or practice guidelines. Pharmacists also work closely with public health officials to ensure that proper procedures are followed.

Lastly, the procedures for managing high-risk patients has been questioned. This is often outlined in the CPAs and includes patients with positive or negative test results. Pharmacists may recommend following up with a primary care provider, going to an emergency department, or following up with the pharmacy. Most protocols have a provision for the pharmacy to follow up with all patients within 48 h of the encounter in the pharmacy.

FUTURE GROWTH

Currently, roughly 25% of all adult influenza vaccinations in the United States are administered in a community pharmacy. However, less than 20 years ago, pharmacist-administered vaccinations were not common, and many states had laws that did not allow this to occur (5). Over time, as data accumulated to support the safety and effectiveness of this service, patients, prescribers, and legislators recognized the value of this service. Slowly, state practice laws evolved, and now pharmacists in every state may administer influenza vaccines.

Pharmacy-based use of CLIA-waived POCT to support disease management programs is in the early stages of acceptance. There are roughly 9,000 pharmacies in the United States that possess a CLIA certificate of waiver. There are a growing number of analytes that have been granted CLIA-waived status by the FDA. As the body of literature regarding the safe and effective implementation of pharmacy-based collaborative disease management programs continues to expand, the value of these services

will continue to be recognized. Within the past few years, this has resulted in changes in the legislation of several states to allow pharmacists to develop POC-driven disease management services. As state laws free pharmacies up to provide these services, innovative and entrepreneurial pharmacists begin to offer them, similar to what happened with vaccines in the past 25 years. In a competitive market like community pharmacies, successful innovations are widely adopted. So, while POC testing in pharmacies still has a long way to go to achieve its potential, the future of such services certainly remains bright.

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