



Improvement of Symptoms in Medications Prior to the Spread of Infectious Diseases before Obtaining Therapy

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DESCRIPTION

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are federal regulations created to provide quality requirements for clinical specimen laboratory testing for patient diagnosis and treatment. CLIA's goal was to assure the accuracy, dependability, and timeliness of diagnostic test findings no matter where they were done. CLIA gave three federal agencies the ability to oversee clinical laboratory testing: the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). The FDA was given the authority to categorize tests based on their difficulty, to set guidelines and recommendations for complexity classification, and to examine waiver petitions. As a result, a subset of laboratory tests known as CLIA exempted was formed. CLIA-waived tests are those that are straightforward to perform and have a minimal risk of producing an incorrect result. These tests include those that have been cleared by the FDA for home use or for which the manufacturer has submitted to the FDA for waived status. The FDA has currently authorized more than 120 distinct CLIA-waived analytes. A variety of CLIA-compliant Point-of-Care Tests (POCT) have been developed to aid in the diagnosis and screening of infectious organisms.

For decades, community pharmacists have provided clinical services using CLIA-waived POCT, such as those used to check cholesterol and blood glucose. Yet, there has recently been a surge in interest in using infectious disease-focused CLIA-waived POCT to improve patient care for a wide range of communicable disorders. This interest derives from a variety of causes, including pharmacist education and training, pharmacy accessibility, and the understanding that many patients seek symptom alleviation at pharmacies early in the course of infectious illnesses before seeking treatment at other health care institutions. It should be mentioned that in the United States, all chemists receive the Doctor of Pharmacy Degree (Pharm D). According to the profession's training criteria, all pharmacy graduates are educated to evaluate patient

function and dysfunction through the systematic collection of objective (physical examination and laboratory data) and subjective (patient interview) data relevant to care delivery. In the United States, pharmacies are frequently regarded as the most accessible entrance point for patients into the health system. There are around 62,000 retail pharmacies and over 180,000 pharmacists working in the community. Nevertheless, 91% of all Americans are predicted to live within 5 miles of a community pharmacy. It is estimated that more than 13 billion pharmacy visits take place each year. This is more than ten times the total amount of patient encounters with all other primary care physicians.

As of March 2016, 9,110 pharmacies had a CLIA waiver certificate. Although a variety of causes are likely to have fueled interest in CLIA-waived POCT services in pharmacies, the National Association of Chain Drug Stores (NACDS) launched a nation-wide certificate programme focused at teaching pharmacists on the proper use of CLIA-waived POCT. This 20-hour programme includes a variety of live and self-study modules that cover all elements of building pharmacy-based illness management programmes, such as developing collaborative practice agreements, running tests, completing physical exams, and operating a CLIA-waived laboratory.

More than 5,000 pharmacists have completed the programme so far (NACDS, personal communication). Although few states require pharmacists who do CLIA-waived POCT to complete training programmes, some do require pharmacists to be well trained. It is vital to remember that CLIA-waived POCT are designed to be utilized by untrained non-laboratory staff. Having said that, the NACDS certificate programme recognizes the need of chemists being familiar and proficient with collecting specimens, performing tests, doing quality controls, and operating as a CLIA-waived laboratory. Personal contact with state laboratory inspectors who have inspected some of the pharmacies doing these tests in Michigan has led to the conclusion that the training offered by the NACDS programme is of a better calibre than that already in place for other health professionals.

Despite the fact that there are over 120 FDA-approved and CLIA-waived analytes, infectious disease tests have been recognized as

playing an essential role in the community pharmacy context. As previously said, pharmacists provide patients with a convenient point of contact with the health care system. Its convenience is critical for a busy person suffering from an acute symptomatic sickness. A pharmacy that provides disease management services for an acute illness, such as acute pharyngitis, is a place where a patient can not only acquire information regarding the source of their sickness, but also potentially receive symptomatic relief and antibiotics if necessary. Several states can provide this level of patient care through collaborative practice agreements or statewide protocols. Apart from the advantages to the patient, some studies have found that pharmacy-based illness management is related with lower rates of inappropriate antibiotic usage. Despite its potential, pharmacist-based illness management services may not be suited

for deployment in every pharmacy. Similarly, just because a pathogen has a CLIA-waived test available does not indicate that every CLIA-waived POCT should be utilized in a pharmacy. A variety of pharmacy, test, patient, and procedural components should be carefully considered before providing a service.

A chemist does not need special knowledge in infectious illnesses to identify whether and how to use a CLIA-waived POCT. Like physicians, all pharmacists are trained as generalists and undergo extensive training in common infectious diseases. Those who finish the NACDS programme also receive a refresher on the epidemiology, signs and symptoms, diagnosis, and management of a number of prevalent infectious illnesses for which CLIA-waived POCT may be considered.