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## Utilization of influenza and streptococcal pharyngitis point-of-care testing in the community pharmacy practice setting

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#### ABSTRACT

*Background:* One way to reduce the complications and costs of influenza like illness and pharyngitis is to improve access to testing and treatment in early stages of infection. Pharmacy-based screening and treatment of group A streptococcus (GAS) infection and influenza has the potential to improve patient care and population health.

*Objective:* To improve patient care and population health, the objective of this retrospective study was to assess if a previously validated service model could be implemented by pharmacy chains without mandated standardization.

Methods: Researchers utilized a certificate program to provide initial training to pharmacists and shared templates from previous validated models. Pharmacy companies were responsible for navigation of all implementation within their company. Researchers analyzed the de-identified data from patients seeking point-of-care testing from the participating pharmacies.

Results: Participating pharmacies reported 661 visits for adult (age 18 and over) patients tested for influenza for GAS pharyngitis. For the GAS patients, 91 (16.9%) tested positive. For the Influenza patients, 22.9% tested positive and 64 (77.1%) testing negative. Access to care was improved as patients presented to the visit outside normal clinic hours for 38% of the pharmacy visits, and 53.7% did not have a primary care provider.

*Conclusion:* A collaborative care model for managing patients with symptoms consistent with influenza or group A streptococcus can be successfully implemented, and improve access to care outside of normal clinic hours and for those without a regular primary care provider.

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#### 1. Background

It has been estimated that one in five visits to a physician's office are for acute pharyngitis, with 15%–30% of those cases originating from Group A Streptococcus (GAS) infection and 2% from influenza. One study found that over a ten-year period there were 78 million visits to a physician's office for acute pharyngitis and antibiotics were prescribed approximately 63% of the time. While each of these illnesses may be self-limiting, there are many patients that require treatment. Treatment for influenza with neuraminidase

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inhibitors is found to reduce mortality and patient outcomes improved when treatment was provided within 48 h of symptom onset.<sup>3</sup> A study by Hughes et al., determined the annual cost for hospitalizations due to GAS infection in England totaled approximately \$5 to 7 million US dollars, or over \$2000 dollars per patient.<sup>4</sup> These illnesses can lead to a significant financial burden for patients.

One way to reduce the risk of hospitalization from infection and the subsequent costs is to improve access to testing and treatment in early stages of infection. As stated previously, early treatment can limit the duration of illness, subsequently lowering the risk of further complications and associated costs. Unfortunately, not all patients have reliable access to care. A 2011 national survey found

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that 57% of patients who were sick and needed medical attention could not obtain access to care promptly.<sup>5,6</sup> The screening and treatment of GAS infection and influenza can be managed in community pharmacies, using a collaborative practice agreement (CPA). Obtaining a collaborative practice agreement (CPA) or similar document was necessary for each pharmacy chain based on the locations of their pharmacies where the POC testing services were offered. The CPA allows the pharmacists from each organization to follow a single prescriber's protocol for POC testing and/or treatment based upon the POC test results.<sup>5–7</sup> Pharmacists can use point-of-care (POC) tests to screen patients, and if positive, can provide patients the adequate treatment under the prescribing authority of a licensed prescriber. It has been observed that pharmacist management of patients for GAS infection improved patient care by decreasing the time to prescription medications.<sup>8</sup> The objective of this study was to assess if a previously validated model<sup>7,9</sup> could be utilized to improve patient care and population health outside the structure of a prospective research study.

#### 2. Methods

This was a multisite implementation project, with retrospective data analysis, conducted from July 2014 to May 2016. Based upon the successes of the previous prospective studies, <sup>7,9</sup> a total of 7 pharmacy chains expressed interest in developing POC testing services acute illnesses, such as pharyngitis and influenza. In addition to these 7 new chains, 2 pharmacy chains from the prospective studies supplied de-identified data.

The researchers provided initial training for pharmacists and corporate leadership via a 20-hour training program that includes physical assessment, disease state cases, specimen collection, pharmacy law and risk management, developing and implementing a POC testing service, test utilization and interpretation, culminating in a proficiency assessment.

The pharmacy companies were provided with templates for patient screening, data collection forms, a policy and procedure manual, and collaborative practice agreement examples. Each pharmacy company was responsible for initial patient care and follow-up; compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations; navigating the practice acts of the state(s) where the POC testing services were to be offered; identifying a collaborating prescriber; selecting and purchasing the POC test utilized by their pharmacists; securing physical assessment equipment, personal protective equipment, and patient comforts; and implementing the service in with the company structure and workflow, including advertising, customizing the patient forms, and pricing of the service.

The onboarding of each company occurred on a rolling basis with the expectation that POC testing services would be implemented on a timeline to yield data by May 2016. The researchers requested de-identified data including the number and type of tests run along with test result and treatment outcome (Appendix A). The University of Nebraska Medical Center Institutional Review Board deemed this activity did not meet the definition of human subjects research as defined by 45CFR46.102 and was not subject to regulation because the researchers reviewed existing de-identified data, which excluded any protected health information (PHI).

#### 3. Results

De identified POC testing data was obtained data from 6 pharmacy chains representing 6 states were contacted by the researchers and provided de-identified POC testing data. Five were chains who planned implementation during the current study period (December 2014 through April 2016). The 2 chains who had

previously participated continued testing in 3 states (Michigan, Minnesota, and Nebraska) at 51 store locations. Of the 7 new chains, 5 began offering POC testing services in 4 states (Minnesota, Utah, Vermont, and Wisconsin) at 35 store locations. No patient data was available from the remaining 2 of 7 new chains because they had not started POC testing services at the time data was requested in May 2016.

De-identified data shared by 6 pharmacy chains, noted 661 visits for adult (age 18 and over) patients tested for influenza for GAS pharyngitis (Table 1). Each company's implementation details varied as did their criteria for inclusion or exclusion for testing. For the 661 patients eligible for testing, 559 were tested for GAS and 102 were tested for influenza.

For the GAS patients, 91 (16.9%) tested positive. Most patients who tested positive were prescribed an antibiotic (98.9%) per a CPA. Nearly all the GAS patients who tested negative were treated symptomatically with over-the-counter recommendations. One patient with a negative result was referred to urgent care.

For the influenza patients, results were reported for 83 with 19 (22.9%) testing positive and 64 (77.1%) testing negative. For the 19 patients with a positive influenza test, treatment result was reported for 16 (84.2%) of whom 15 (93.8%) were prescribed oseltamivir per a CPA at the pharmacy. One of the 16 patients whose test result was reported as positive refused the oseltamivir prescription due to cost and opted for over-the-counter treatment options.

The patient population was ranged in age from 18 to 85 years old with an average of 29.22 years (Table 2). The gender composition included a higher proportion of female patients (61.75%) than male patients (38.25%). The patients presented at the visit outside normal clinic hours for 38% of the visits. Of the 661 patients tested, data for 123 patients noted the status of a primary care provider with 66 (53.7%) indicating they did not have a primary care provider.

For the companies that included a 24–48-hour follow-up with the patient and reported the results, 90 patients were reached for follow-up with most (94.4%) patients indicating they felt better. Those feeling worse (5) were advised to seek additional care. Of the patients contacted, 2 who felt better had sought additional care. In both of these instances, the patients reported having a second test for influenza or GAS that was also negative, but each patient secured a prescription for an antiviral or antibiotic from the provider. For the patients who indicated they felt the same, 2 reported seeking additional care with one having a second negative test for GAS and the other receiving an antibiotic prescription from a provider without additional testing. Of the patients who indicating feeling worse, 3 had already sought additional care with one noting a diagnosis of mononucleosis.

#### 4. Discussion

The current study validates a model of increased access for patients to receive appropriate care under collaborative practice for influenza and GAS pharyngitis treatment and demonstrates that the model can be successfully implemented in a variety of community pharmacy settings. In particular, the study showed that the model could be implemented outside of the guidance and design of a prospective research study. In this study, a collaborative care team, was able to successfully implement this service and provide care to patients. Our findings, including the rates of positive test results for both influenza and GAS pharyngitis, were consistent with earlier work in the United States and United Kingdom. <sup>7,9,10</sup> As in the previous studies, the rates of positive test results were consistent with existing literature on the incidence and prevalence of disease. <sup>1,7,9</sup>

Our results demonstrated that a collaborative care model

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