Implementation and evaluation of an innovative pharmacist-physician collaborative Influenza and Group A Streptococcal pharyngitis management program

Ferris State University and University of Nebraska Medical Center
in association with BlueCross BlueShield of Nebraska and Quidel Corporation

Investigators:
University of Nebraska Medical Center: PI - Donald G. Klepser, PhD, MBA; Allison Dering-Anderson, PharmD. *Ferris State University*: Michael E. Klepser, PharmD; Jacqueline A. Morse, PharmD. *OptiMed Pharmacy*: Stephanie A. Klepser, PharmD.

Consultant: John Tamerius, PhD, Quidel Corporation.

Study period:
Influenza: June 2013 – May 2014
Group A Streptococcal: September 2013 – August 2014

Purpose: This multi-site study compares two models of pharmacy-based influenza and Group A Streptococcal (GAS) pharyngitis management with respect to clinical outcomes, healthcare utilizations, patient and pharmacist satisfactions, physician perceptions of pharmacist collaboration, and impact on pharmacy workflow and resources.

Primary Objective: The primary objective is to compare the clinical outcomes and healthcare utilization of patients presenting to a community pharmacy with symptoms consistent with influenza like illness or GAS pharyngitis under two models of care: (1) a point-of-care location, requiring a collaborative practice agreement or (2) a physician consult location.

Methodology: This prospective, block randomized multi-center clinical study will be conducted from October 1, 2013 to May 1, 2014 for influenza management and September 11, 2013 through August 1, 2014 for GAS management. Based on the assessment of the programs during the pilot phase, a broader program will be implemented for 2014-15.

Study setting: Patient recruitment and screening will occur in multiple community pharmacy sites in Michigan, Minnesota, and Nebraska. Sites were selected based on the availability of an appropriate patient population, walk-in patient volume, and a pharmacist at the site with the skills and training necessary to assess and test patients. Keystone Pharmacy, HomeTown Pharmacy, Hy-Vee, Meijer, OptiMed Pharmacy, Spartan Stores, Thrifty White and University Pharmacy (Detroit) have committed stores.

Study population: Screening of patients for influenza will occur only when influenza activity in the state where stores are located is classified as “local” according to weekly surveillance data published by the CDC or “moderate” according to Google Flu Trends. Screening of patients for GAS pharyngitis will occur during the entire study period.

Inclusion criteria: During the study period, pharmacists at the study sites will offer to screen all individuals if they meet the following inclusion criteria:

Influenza:
- ≥ 18 years of age (≥ 19 years of age in Nebraska) and
- Present seeking over-the-counter products to alleviate cough or cold symptoms or who complain of signs/symptoms consistent with influenza-like illness (fever/feverish AND cough OR sore throat) within the past 48 hours.

Group A Streptococcal pharyngitis:
- 18-45 years of age (19-45 years of age in Nebraska) and
- Present seeking over-the-counter products to alleviate symptoms of pharyngitis or who complain of signs/symptoms consistent with pharyngitis and
- Modified Centor score of ≥1.

This research is funded in part by a grant from the
National Association of Chain Drug Stores Foundation.

Exclusion criteria:
A patient would be excluded from study participation if exhibiting any of the follow criteria:

Exclusion criteria	Influenza	GAS
Symptoms that are not consistent with influenza-like illness	X	
Symptoms that are not consistent with GAS pharyngitis (modified Centor score of 0 or below)		X
Immunocompromised state [patients with hematologic malignancies, patients currently receiving immunosuppressant therapy including long-term oral corticosteroids (defined as patients currently receiving oral corticosteroid at a dose equivalent to oral prednisone ≥20mg/day for greater than 2 weeks duration), and patient with HIV/AIDS]	X	X
Women who are pregnant/breastfeeding or who plan to become pregnant during the study period;	X	X
Presence of known renal disease or dysfunction	X	X
Received the live attenuate influenza vaccine (LAIV) within the previous 2 weeks	X	
Presence of influenza-like illness for ≥48 hours	X	
Receipt of influenza prophylaxis with an antiviral agent currently or within the previous 2 weeks	X	
Pulmonary disease requiring home oxygenation therapy	X	
Known hypersensitivity to oseltamivir or any component of the product	X	
History of asthma, COPD and/or heart failure	X	
History of rheumatic fever and/or rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis		X
Known hypersensitivity to beta-lactam antibiotic AND azithromycin		X
Patients taking medication with clinically significant drug interactions with amoxicillin AND azithromycin		X
Antibiotic treatment within previous 3 months		X

Study Design: Following an initial eligibility screening, informed consent will be collected from all eligible patients. Once consent is obtained, contact information, demographic data, past medical history, and history of present illness will be collected.

Intervention Groups: Consented patients will have a baseline assessment performed and pertinent vital signs collected including pulse, blood pressure, respiratory rate, temperature, and oxygen saturation. If the patient is clinically unstable, the patient's primary care physician will be contacted by the pharmacist to discuss appropriate treatment.

Patients deemed clinically stable will be administered an appropriate rapid diagnostic test and informed of their rapid test results and pharmacist's assessment of their clinical condition.

Point-of-Care Sites	
Positive Influenza Rapid Test Results	***Positive GAS Rapid Test Results***
▪ Patient will be dispensed a treatment of oseltamivir (75 mg by mouth twice daily for 5 days for a total of 10 doses) in accordance with a pre-arranged physician collaborative practice agreement and will receive appropriate counseling from a pharmacist.	▪ Patient will be dispensed a treatment course of amoxicillin (500mg by mouth twice daily for 10 days, or azithromycin 500mg orally once daily for 5 days for those with a history of beta-lactam hypersensitivity) in accordance with a pre-arranged physician collaborative practice agreement and will receive appropriate counseling from a pharmacist.
Negative Influenza Rapid Test Results	***Negative GAS Rapid Test Results***
▪ Patient is counseled and provided with OTC products when appropriate. Patient immunization history is reviewed and appropriate immunizations are offered and provided.	▪ Patients will receive counseling and medical care from a pharmacist as consistent with standard care for patients presenting to the pharmacy with pharyngitis.

This research is funded in part by a grant from the
National Association of Chain Drug Stores Foundation.

<table>
<tr><th colspan="2">Physician Consult Sites</th></tr>
<tr><td colspan="2">Positive Influenza or GAS Rapid Test Results</td></tr>
<tr><td colspan="2">▪ Pharmacist will call the patient's primary care physician to discuss the patient's presenting symptoms, vital signs, and rapid test result.
▪ If the patient does not have a primary care physician or their physician cannot be reached in a timely manner, patients will be referred to an urgent care facility.</td></tr>
<tr><td>Negative Influenza Rapid Test Results</td><td>Negative GAS Rapid Test Results</td></tr>
<tr><td>▪ Patient is counseled and provided with OTC products when appropriate. Patient immunization history is reviewed and appropriate immunizations are offered and provided.</td><td>▪ Patients will receive counseling and medical care from a pharmacist as consistent with standard care for patients presenting to the pharmacy with pharyngitis.</td></tr>
</table>

Patients are responsible for the cost/copayment of any medication (oseltamivir, antibiotic or over-the-counter). Patients enrolled in the study will receive a voucher for the cost of the rapid diagnostic test ($75).

Regardless of the test result, the pharmacy will complete a follow-up call to any study participant within 24-48 hours of the patient's presentation at the pharmacy to assess clinical status/need for additional medical evaluation.

Rapid Diagnostic Testing: All study pharmacists have completed the Community Pharmacy-Based Rapid Diagnostic Testing certificate program offered through the Michigan Pharmacists Association. All study pharmacies possess a valid CLIA waiver.

Influenza: The Sofia Influenza A+B FIA system or QuickVue Influenza A+B test (Quidel, Corp.) will be utilized for rapid diagnostic screening. The nasal swab collected from each patient is tested on site using these CLIA-waived testing systems which are described by the manufacturer as Sofia: 90% sensitive and 95% specific for the detection of influenza A and 89% sensitive and 96% specific for the detection of influenza B; QuickVue: 94% sensitive and 90% specific for the detection of influenza A and 70% sensitive and 97% specific for the detection of influenza B. The Sofia test system provides automated, objective interpretation of test results and allows for hard copy and electronic reporting/sharing of test results as well as de-identified test results for public health surveillance and inventory management. The QuickVue Influenza test technology utilizes the principle of antibody specificity for the influenza virus nucleoprotein. A positive test result is visually detected as a single red colored test line. The test has an internal control that appears as a visually detected blue colored line.

Group A Streptococcal: The QuickVue In-Line A Strep testing system (Quidel, Corp.) will be utilized for rapid diagnostic screening. The throat swab collected from each patient is tested on site using this CLIA-waived testing system which described by the manufacturer as 92% sensitive with overall accuracy of 96% for the detection of GAS.

Patient, Pharmacist and Physician Surveys: Patients will be asked to complete a survey one week following their initial presentation to the pharmacy to capture information related to the duration of illness, severity of symptoms, all health care utilized, and the time away from work, school, or regular activities. The patient survey will also assess their attitude and satisfaction with their disease management experience. Pharmacists will be asked to complete a survey to assess their attitude and satisfaction with the practice model to which they were assigned and focus groups will be conducted to discuss workflow issues and integration of the RDT service. Physicians who are contacted as part of these treatment models will be asked to complete a survey to determine their perceptions of the physician-pharmacist collaborative disease state management programs.

Time and Motion Study: A time and motion study will be conducted within the RDT study to assess the efficiency of intervention.

This research is funded in part by a grant from the
National Association of Chain Drug Stores Foundation.