Best practices for implementing CLIA-waived point-of-care testing services in community pharmacies

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The Case for Collaborative Disease State Management

- There are between 59,000-67,000 community pharmacies in the United States.
  - 92% of Americans live within 1.6 miles of a pharmacy
- Estimated to be 13 billion pharmacy visits annually.
  - 470 million annual physician office visits.
  - 530-570 visits per pharmacy each day.

Pharmacist Education

- All pharmacists not graduate with a Doctor of Pharmacy degree.
- CAPE 2013 Educational Outcomes
  
  *Domain 2.1. Patient-centered care (Caregiver) - Provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities)*

- ACPE 2016 (Draft Standards)
  
  *Evaluation of patient function and dysfunction through the systematic gathering of objective (physical assessment and lab data interpretation) and subjective (patient interview) data important to the provision of care.*

- National Association of Boards of Pharmacy - NAPLEX
  
  *Area 1.1.0 Identify, interpret, and evaluate patient information to determine the presence of a disease or medical condition, assess the need for treatment and/or referral, and identify patient-specific factors that affect health, pharmacotherapy, and/or disease management.*
Percent of Pharmacies with CLIA-waivers

The Case for Collaborative Disease State Management

- Pharmacists have been helping to manage patients with various medical conditions for decades.
  - POC tests now provide more objective data.
  - Data sharing barriers are eroding.
The Case for Collaborative Disease State Management

• For acute illnesses such as influenza and streptococcal pharyngitis, early identification and intervention are associated with better outcomes and reduced transmission.

• Data suggest that antimicrobials are overused in the outpatient setting.

The Case for Collaborative Disease State Management

- Untold numbers of patients of patients with asymptomatic forms of diseases like diabetes, hyperlipidemia, HIV or HCV come into pharmacies every day.
  - The course of these diseases is complicated by delayed identification and intervention.
  - POC tests allow pharmacists to screen patients and link to care.
MTM services are routinely performed by pharmacists to insure the safe use of medications.

- $76.6 billion dollars are spent annually to manage drug-related problems.
- POC tests provide timely laboratory data allowing pharmacists to make data-based recommendations.

Pharmacy-Based Disease Management Programs

• Goals of disease management programs.
  – Improve patient outcomes
    • Early detection ➔ Early and appropriate intervention/linkage to care
  – Improve overall public health
    • Disease surveillance and containment
  – Improve appropriate medication use
    • “MTM on steroids”
  – Reduce costs to the healthcare system
    • Reduced ER visits and hospitalizations
This study examined a collaborative physician-community pharmacist influenza management program with respect to clinical outcomes and healthcare utilization.

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Collaborative Influenza Disease State Management Program

• Program design:
  – All participating pharmacists completed a 20-hour POC testing certificate course* and CITI training.
  – Only offered when influenza activity was documented in the state (“Local” or higher according to CDC).
  – Pharmacists used a clinical algorithm to identify patients who were candidates for the program.
    • If symptoms were consistent with influenza, a POC test was performed and vital signs were collected.
    • Patients that were at high risk for complications or clinically unstable were referred to their primary care provider or urgent care along with a summary of the encounter.
    • Appropriate patients were managed in the pharmacy according to a collaborative practice agreement.

POC Certificate Program

Self-Study Modules

• Overview of Point-of-Care Testing (POCT) in Community Pharmacies
• Pharmacy Practice Acts and CLIA Regulations
• Overview of POC Technology
• Ready? Set? Test! Patient Testing is Important. Get the Right Results
• Overview of selected disease states for which CLIA-waived tests are available to assist with management
• Physical Assessment
• Specimen Collection
• Maximizing Test Performance
• Developing collaborative disease management programs
• Using POC tests in pharmacies to promote antimicrobial stewardship and combat antimicrobial resistance
• Collaborating with state and local health departments
• HIV/HCV Testing and Counseling

Live Modules

• Question and answer regarding self-study.
• Physical assessment review, practice, and assessment of proficiency.
• Specimen collection review, practice, and assessment of proficiency.
• Case studies

Currently:
• More than 3,000 pharmacists have been trained nationwide.
• More than 600 trainers have been trained.
Collaborative Practice Agreement

- Identify patient population to screen.
- Identify clinically unstable patients or those at high risk for complications and refer them to appropriate care.
- Allow for point-of-care management with OTC or prescription medications as appropriate.
- Provide communication with the patient’s primary care provider.
- Provide patient follow-up.
- Communicate with public health departments for disease reporting and surveillance.

http://naspa.us/resource/cpa-report/
Collaborative Influenza Disease State Management Program

• All participating sites agreed to actively promote the program.
Collaborative Influenza Disease State Management Program

• Program design (continued):
  – Informed consent was obtained for each patient.
  – A summary of the encounter was transmitted to the patient’s primary care provider within 24 hours.
  – All patients evaluated in the pharmacy were followed up with within 24-48 hours after the encounter.
  – Patients were administer a satisfaction survey following the encounter.
Participating Sites

- 55 pharmacies in 3 states (Michigan, Minnesota, Nebraska).
  - Meijer, Hometown, Hy-Vee, Thrifty White
- All pharmacists completed the POC certificate training program and CITI training.
- All pharmacies identified a physician to sign a collaborative practice agreement.

# Collaborative Influenza Disease State Management Program

<table>
<thead>
<tr>
<th></th>
<th>n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Number of Patients Screened</strong></td>
<td>121</td>
</tr>
<tr>
<td>• Excluded from participation</td>
<td>45/121 (37.2%)</td>
</tr>
<tr>
<td>• Eligible for participation</td>
<td>76/121 (62.8%)</td>
</tr>
<tr>
<td><strong>Patients Tested for Influenza</strong></td>
<td></td>
</tr>
<tr>
<td>• Did not have a primary care provider</td>
<td>26/75 (34.6%)</td>
</tr>
<tr>
<td>• Seen outside of regular clinic office hours</td>
<td>29/75 (38.7%)</td>
</tr>
<tr>
<td><strong>POC Test Result</strong></td>
<td></td>
</tr>
<tr>
<td>• Positive</td>
<td>8/75 (10.7%)</td>
</tr>
<tr>
<td>• Negative</td>
<td>67/75 (89.3%)</td>
</tr>
<tr>
<td><strong>Patient Receipt of Oseltamivir</strong></td>
<td></td>
</tr>
<tr>
<td>• Positive test</td>
<td></td>
</tr>
<tr>
<td>o CPA Site</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>o Physician Call</td>
<td>1/3 (33.3%)</td>
</tr>
<tr>
<td>• Negative test</td>
<td>0/67 (0%)</td>
</tr>
</tbody>
</table>

Collaborative Influenza Disease State Management Program

• Key findings:
  – Using a collaborative practice agreement and judicious use of an influenza POC test, pharmacists were appropriately able to identify and management patients with influenza.
  – Approximately **11%** of patients evaluated tested positive for influenza and received an antiviral.
    • Inline with national data for 2013-14.
    • Most patients received recommendations for management of symptoms.
  – No adverse clinical outcomes were noted.
  – Patient satisfaction was >92%.
  – Time and motion studies demonstrated that this model fit nicely into pharmacy workflow.

Collaborative GAS Pharyngitis Disease State Management Program

- GAS pharyngitis management program
  - Pharmacists use a clinical algorithm to identify patients who are candidates for the program.
    - If symptoms are consistent with GAS pharyngitis, vital signs are collected, a Centor score is calculated and a POC test is performed, if appropriate.
    - Patients at high risk for complications or who are clinically unstable are referred to their primary care provider or urgent care along with a summary of the encounter.
    - Appropriate patients are managed in the pharmacy according to a collaborative practice agreement.

Collaborative GAS Pharyngitis Disease State Management Program

• Preliminary data
  – 316 patients were screened and 273 (86.3%) were eligible for participation.
  – 48 (17.5%) had a positive POCT result and were dispensed an antibiotic.
  – 37.3% did not identify a primary care provider.
  – 43.9% visited the pharmacy outside of established physician’s office hours.

Antimicrobial Stewardship in the Outpatient Setting

• The White House recently published two documents that focus on combating antibiotic resistance.
  – September 2014 “National Strategy for Combating Antibiotic-Resistant Bacteria”

https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf
https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf
National Goals for Antimicrobial Stewardship

• Anticipated outcome by 2020
  – Inappropriate outpatient antibiotic use for monitored conditions/agents will be reduced by 50% from 2010 levels.

• The pharmacy-based influenza and GAS disease management models have already exceeded this goal
Ongoing Initiatives

- HIV/HCV screening with linkage to care (NACDS Foundation, MDHHS, CDC)
  - Detroit, MI; Atlanta, GA; West Virginia.
  - Pharmacists use a clinical algorithm to identify patients who are candidates for screening.
  - All patients receive counseling on HIV and HCV.
  - All patients with reactive test results are linked to care.
Ongoing Initiatives

• HIV/HCV screening with linkage to care
  – Key features of the program:
    • Partnership with departments of community health.
    • The pharmacist provides disease education to all patients.
    • The pharmacist is trained to give test results.
    • The pharmacist facilitates linkage to care.
Ongoing Initiatives

• Lead testing of children in Flint
  – Partnership between pharmacies, Michigan Pharmacist Association, and MDHHS.
  – Using CLIA-waived lead test to identify children with elevated lead levels.
Components of a Successful Disease Management Program

- Partnership between pharmacy and physicians and/or public health
  - Establish a collaborative practice agreement
  - Enable provision of follow-up care
- CLIA-waived POC tests

- Trained personnel
  - NACDS POC certificate program for pharmacists
  - Tests are only a component of a disease management program
- Plan for patient follow-up
- Data sharing plan
Summary

• Access to patient laboratory data in the community pharmacy has several broad applications:
  – Use in screening for asymptomatic diseases.
  – Use in identification of patients with active diseases and triage to appropriate care.
  – Use for improved medication therapy management services.
    • Renal function, hepatic function, serum chemistries
  – Support of public health initiatives.
    • Surveillance, pandemics, bioterror events

• Collaboration is key.