Quick Read: Do Point-of-Care Tests Add Value?

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Disclosures

- Alex Adams: “declare(s) no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.”

- Michael Klepser:
  - Developer of the NACDS certificate program on the use of Community Pharmacy-Based Point-of Care Testing.
  - Received research funding from the NACDS Foundation to study the development of disease management programs in community pharmacies using CLIA-waived POC tests for influenza, Group A streptococcus, HIV, and HCV.

Target Audience: Pharmacists

ACPE#: 0202-0000-16-071-L04-P

Activity Type: Knowledge-based

Learning Objectives

- Identify opportunities for pharmacists to expand their services in the community pharmacy practice setting through the utilization of POC tests.
- Explain what it means for a diagnostic test, as defined by CLIA, to be waived and the requirements to use CLIA-waived tests in the community pharmacy setting.
- Identify currently available CLIA-waived tests that could be used by pharmacists.
- Explain the legal, regulatory, and liability issues involved in offering a pharmacy-based POC testing program.
- Discuss specific strategies for designing and implementing a successful pharmacy-based POC testing program.
- Discuss operational issues (e.g., workflow, reimbursement, education, liability) regarding the use of POC tests by pharmacists.
CLIA-waived tests currently cover how many analytes?
• <10
• 25-50
• 75-100
• >120

What percentage of pharmacies in the U.S. currently hold a CLIA-waiver?
• 1%
• 5%
• 18%
• 50%

Which of the following statements is true?
• All point-of-care tests are categorized as diagnostic.
• CLIA-waived facilities are subject to inspections by state laboratory bureaus.
• A CLIA-waived test is one that requires specialized advanced technique to operate.
• A separate CLIA-waiver is needed for each test that a pharmacy intends to perform.

Which of the following may result secondary to implementation of POC testing in pharmacies?
• Improved patient outcomes
• Enhanced public health efforts
• Improved appropriateness of medication use
• Reduced healthcare costs
• All of the above

Which of the following is the greatest barrier to implementing a successful disease management program?
• Cost
• Pharmacist training
• Patient awareness
• Workflow

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Perspective from Patients...

Public Engagement on Facilitating Access to Antiviral Medications and Information in an Influenza Pandemic – Workshop Series Summary

- Pharmacies are trusted medical professionals.
- Familiarity of the public with pharmacist immunization and expanded scope of practice.
- Pharmacists are knowledgeable and have the best training of any medical professional on antivirals and other medications.
- Face-to-face strategies benefit the sick by offering reliable assessment and diagnosis and by creating an opportunity for a health care professional to advise people on their treatment and answer other questions.
- Convenience of ‘one-stop shopping’ for diagnosis and antiviral medication, if indicated.
- Pharmacist involvement in public health responses increases the capacity of the health care system.

Perspective from Public Health...

The 2009 H1N1 Influenza Vaccination Campaign – Summary of a Workshop Series

- Many arguments can be given for the use of retail pharmacies in administering vaccine, but the most compelling is availability: Large numbers of immunizers are ready and available to administer vaccine...Pharmacies know their markets; they are in the community and have established relationships with local, state, and national public health. Distribution networks are already in place and easily accessed by high-risk individuals. Also, pharmacies are open during evening, weekend, and holiday hours, when public health clinics and doctors’ offices may be closed.

Unmet Patient Need

- CDC reports
  - More than 8 million people have undiagnosed diabetes
  - More than 150,000 people have undiagnosed HIV
  - More than 800,000 people have undiagnosed Hepatitis C

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CLIA-Waived Test

- Tests waived by CLIA:
  - Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible
  - Pose no reasonable risk of harm to the patient if the test is performed correctly
  - Are cleared by the FDA for home use
  - Conduct testing that is considered non-technical requiring little or no difficulty

CLIA-waived Tests

- Point-of-care tests are a subset of CLIA-waived tests
  - Performed outside of a laboratory
  - Conducted at or near the site of the patient
  - Provides a rapid and reliable result
  - Aids in disease screening, diagnosis, and/or patient monitoring

CLIA-waived Tests

- Tests can be:
  - Screening
  - Diagnostic

CLIA-waived Tests

- Leads to important difference in terms of pharmacy implementation

CLIA-waived Tests

- The number of analytes for which CLIA-waived tests are available has grown:
  - 9 in 1993
  - 123 in 2015

- Tests are available for both acute and chronic diseases

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CLIA-waived Tests

- Examples:
  - Cholesterol
  - Group A Streptococcus
  - H. pylori
  - Hemoglobin A1C
  - Influenza
  - INR
  - Serum Chemistries (sodium, potassium, chloride)
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Patient Assessment

Influenza Point of Care Test

Action Enabled by Broad CPA

Improved Health Outcomes

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Obtaining a CLIA-Waiver

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Top CLIA-waived facilities in U.S.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Facility</th>
<th># of Facilities</th>
<th>% of Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Physician Office</td>
<td>122,634</td>
<td>61.90</td>
</tr>
<tr>
<td>2.</td>
<td>Skilled Nursing Facility</td>
<td>14,948</td>
<td>99.13</td>
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<tr>
<td>3.</td>
<td>Home Health Agency</td>
<td>14,467</td>
<td>99.77</td>
</tr>
<tr>
<td>4.</td>
<td>Pharmacy</td>
<td>10,838</td>
<td>99.85</td>
</tr>
<tr>
<td>5.</td>
<td>Hospital</td>
<td>9,060</td>
<td>20.87</td>
</tr>
</tbody>
</table>

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CLIA-Waivers by Pharmacy Type

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Current Pharmacy Uptake

<table>
<thead>
<tr>
<th>Rank</th>
<th>State</th>
<th>% of Community Pharmacies with CLIA Waiver</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Alaska</td>
<td>60.00%</td>
</tr>
<tr>
<td>2.</td>
<td>Washington</td>
<td>48.60%</td>
</tr>
<tr>
<td>3.</td>
<td>North Dakota</td>
<td>37.61%</td>
</tr>
<tr>
<td>49.</td>
<td>New York</td>
<td>0.40%</td>
</tr>
<tr>
<td>50.</td>
<td>Massachusetts</td>
<td>0.27%</td>
</tr>
<tr>
<td>51.</td>
<td>Nevada</td>
<td>0.00%</td>
</tr>
</tbody>
</table>

National Percentage 17.94%


Collaborative Practice Agreement

- Creates formal relationship between pharmacists and physicians or other providers
- Defines certain patient care functions that a pharmacist can provide under specified situations and conditions, and to specified patient populations
- Many are used to expand the depth and breadth of services the pharmacist can provide to patients and the healthcare team
- Note: Not required to perform many patient care services (e.g. medication reviews, patient education and counseling, disease screening, referral)

Learning Objectives (Cont’d)

- Explain the legal, regulatory, and liability issues involved in offering a pharmacy-based POC testing program.
- Discuss specific strategies for designing and implementing a successful pharmacy-based POC testing program.
- Discuss operational issues (e.g., workflow, reimbursement, education, liability) regarding the use of POC tests by pharmacists.

There Must be a Business Case

- Pharmacy has not always been good about this.
- The service must be sustainable.
- The business case does not take away from good patient care. It allows it to happen.
Opportunities for POC Testing

- 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

Examples of the Use of CLIA-Waived POCT by Community Pharmacists

- Screening for asymptomatic diseases.
  - Infectious (HIV/HCV) and non-infectious diseases (Diabetes and dyslipidemias)
- Identification of patients with active diseases and triage to appropriate care.
- Monitor medication adherence.
  - TDM, opioids
- Conduct medication therapy management services.
  - Renal function, hepatic function, serum chemistries
- Support of public health initiatives.
  - Surveillance, pandemics, bioterror events

Reality of Healthcare

- Patient access to information has changed the world.
- Providing care that meets patient expectations.
  - When they need it
  - Where it is convenient
  - At a reasonable and established price

Reality of Health Care

- Healthcare is patient centered and patient led.
  - Patients have choices.
  - Patients are the final decision makers.
  - We need to help patients make the best decisions.
- Community pharmacies have a distinct advantage.

The Market

- What is the target market?
  - Uninsured and underinsured
  - Busy families
  - No primary care provider
  - People who need care outside of normal office hours
  - Travelers
  - Businesses

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Workflow and Logistical Considerations for Point-of-Care Testing Services

Pharmacists Have Limited Time

- No appointments
  - Most pharmacy business is walk up
- Some days are busier than others
  - Mondays and the first of the month
- Must fit into the existing workflow
  - Why immunizations has been embraced

Pharmacists Have Limited Time

- According to a recent time and motion study of a POC testing program
- The average time to complete the entire patient encounter for an influenza assessment utilizing a POC test was 35.5 minutes.
- On average, the pharmacist spent 9.4 minutes per encounter or about 26.5% of the entire encounter.
  - When the pharmacy technician collected the vital signs, the pharmacist-required time was reduced to 4.95 minutes.

Limited Space

- Consultation room may not be a room
- No place to “stockpile” patients
- Space is unlikely to be dedicated to a single purpose

Community Pharmacy Workforce

- Multiple pharmacists at each store
- Floating pharmacists (PRN, as needed)
- Technicians
  - 335,300 technicians in 2012
  - 20% growth rate
Training

- More than just how to run the POCT.
  - Specimen collection
  - Vital sign collection
  - Record keeping
  - Laboratory manager
- Training on offering a disease management program that utilizes CLIA-waived POCT is advisable.
  - Community-based pharmacy POCT certificate program offered by NACDS

A Collaborator

- Depends on the test and follow up
- Pharmacists cannot prescribe in most states
- A new POC test means a new collaborative practice agreement

Changing Expectations

- This is a new idea for most patients
  - This may be the biggest barrier initially to a new service.
- Insurers may not pay initially
- The tests will play a more prominent role than in a traditional setting
- Marketing and education will be key

Acute Conditions

- Influenza and Group A Strep
  - Usually minor illness
  - Symptomatic
  - Seasonal
  - Patients seek OTC treatments at the pharmacy
  - Potential for complete management of care in the pharmacy

Influenza and Group A Strep

- Why is the patient seeking care at a community pharmacy?
  - Triage
  - Alternative to wait-and-see or self-care
  - Lack of primary care option
  - Cost
  - Convenience

Screening for Chronic Conditions

- HIV or Hepatitis C
  - Potentially severe illnesses
  - Likely asymptomatic at time of screening
  - Social stigma, emotional, and privacy concerns
  - Recent CDC recommendations for increased screening
  - CDC pilot of community pharmacy screening
  - Referral network
  - Reporting and surveillance requirements

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HIV & HCV Screening
• Why is the patient at a community pharmacy?
  – Public pressure, raised awareness
  – At risk population
  – Peace of mind
  – Lack of primary care option
  – Cost
  – Convenience

Monitoring Chronic Diseases
• Dyslipidemias and diabetes
  – Common chronic diseases with established drug therapies
  – Opportunities to monitor lab values for medication therapy management
  – Clinical pharmacists have existing role
  – POC tests are being done in many community pharmacies

Liability
• Key points of liability & liability insurance:
  – Practice insurance will cover legal activities conducted in a legal manner
  – Collaborating partners are liable only for their component of the collaboration
  – Collaborating partners are not liable for the actions or inactions of another partner.

What Does a POC Testing Service Look Like?

What will the Patient Experience?
• A collaborative care experience
• Healthcare is a business that requires patients to be sustainable
• Customer service
  – Patient focus
  – Fast service
  – Little or no wait time
  – Reasonable price

Initial Contact
• Screen for those that are not candidates for the service
• Setting expectations (time, price, payment terms, sharing of results with physician etc.)
Information Gathering

- Symptoms, health status, medication history
- Patient filling out form or interview
- Screening to make sure you are providing care to patients described in the protocol
  - What to do with ineligible patients
  - Referrals for high risk patients
  - OTC options for others

Time Expectations

- Patients do not want to wait.
- The average time to complete the entire patient encounter for an influenza assessment utilizing a POC test was 35.5 minutes.
  - One regional chain has a goal that the entire patient encounter for group A strep pharyngitis assessment will be less than 30 minutes.

Test Results

- How and where they are provided
- Interpretation
- Treatment options
- Reporting

Treatment

- Depends on results and collaborative practice agreement
  - Fill prescription
  - Referral or phone call
  - OTC products
- Counseling
- Brochure or other education material
- Follow-up

Payment and Reimbursement

- Full payment due at time of service
- Provide forms necessary for 3rd party reimbursement (CMS 1500)
- Health savings accounts
- Pharmacies can register to bill to the medical arm of insurance plans to bill for laboratory tests

3rd Party Reimbursement

- Two part reimbursement.
  - Lab tests are likely to be reimbursed.
  - Professional service is less likely to be reimbursed since most insurers do not recognize pharmacists as medical providers.
  - Provider status will not guarantee reimbursement.
- Patients will pay for services they value.
- Insurers will pay for services that show value and that consumers demand.


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CPT Codes and Reimbursement Rates

- Influenza
  - CPT: 87449 QW; 87804 QW
  - Reimbursement: $16.36 x 2
- Strep Throat
  - CPT: 87880 QW
  - Reimbursement: $16.36
- HIV
  - CPT: 86701 QW; 86703 QW
  - Reimbursement: $12.58; $19.43
- HCV
  - CPT: 86803 QW
  - Reimbursement: $19.47

*CPT codes are for specific lab tests.

**2014 CMS average reimbursement for lab test.

Documentation, Reporting and Surveillance

- Patient care summary/progress note
  - Electronic or paper
  - Primary care provider or collaborating physician
  - Patient
  - Follow up
- Billing
- Business reporting and tracking
- Public health surveillance

Pricing

- Influenza - $75 - $126
- Strep Throat - $59 - $96
- HIV - $40 - $65
- HCV - $40 - $65
- Some tests may be free through public health departments

Influenza/GAS POC Studies

- 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

- Key findings:
  - Using a collaborative practice agreement and judicious use of an influenza POC test, pharmacists were appropriately able to identify and manage patients with influenza.
  - Approximately 11% of patients evaluated tested positive for influenza and received an antiviral.
  - In line 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.


Influenza/GAS POC Studies

- Patient satisfaction with pharmacist provided service was ~90%
  - Dissatisfaction was linked to protocol adherence
  - Patients were willing to pay out of pocket for the service.

Key Points

- Pharmacists are ideally positioned to offer disease management services to patients.
- Pharmacists have been using CLIA-waived POCT for quite some time.
- Almost 11,000 pharmacies already are registered as a CLIA-waived testing site.
- Disease management programs that use CLIA-waived POCT fit into workflow.
- Patient satisfaction and quality of care are high.

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