

# 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.”

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

### Disclosures

- 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.

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- 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

Released: May 17, 2012  
Type: Workshop Summary  
Topics: Biomedical and Health Research, Public Health  
Activity: Forum on Medical and Public Health Preparedness for Catastrophic Events  
Board: Board on Health Sciences Policy

[http://www.nap.edu/catalog/13104\\_public\\_engagement\\_on\\_facilitating\\_access\\_to\\_antiviral\\_medications\\_and\\_information\\_in\\_an\\_influenza\\_pandemic](http://www.nap.edu/catalog/13104_public_engagement_on_facilitating_access_to_antiviral_medications_and_information_in_an_influenza_pandemic)

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## Perspective from Patients...

- “Pharmacists 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.”

[http://www.nap.edu/catalog/13104\\_public\\_engagement\\_on\\_facilitating\\_access\\_to\\_antiviral\\_medications\\_and\\_information\\_in\\_an\\_influenza\\_pandemic](http://www.nap.edu/catalog/13104_public_engagement_on_facilitating_access_to_antiviral_medications_and_information_in_an_influenza_pandemic)

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## Perspective from Public Health...



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

Released: October 29, 2010  
Type: Workshop Summary  
Topics: Biomedical and Health Research, Public Health  
Activity: Forum on Medical and Public Health Preparedness for Catastrophic Events  
Board: Board on Health Sciences Policy

<http://om.nationalacademies.org/Reports/2010/The-2009-H1N1-Influenza-Vaccination-Campaign.aspx>

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## Perspective from Public Health...

- “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.”

<http://om.nationalacademies.org/Reports/2010/The-2009-H1N1-Influenza-Vaccination-Campaign.aspx>

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## 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
- Leads to important difference in terms of pharmacy implementation

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## CLIA-waived Tests

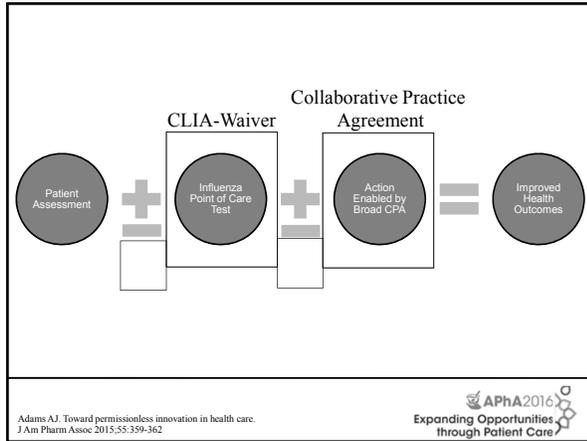
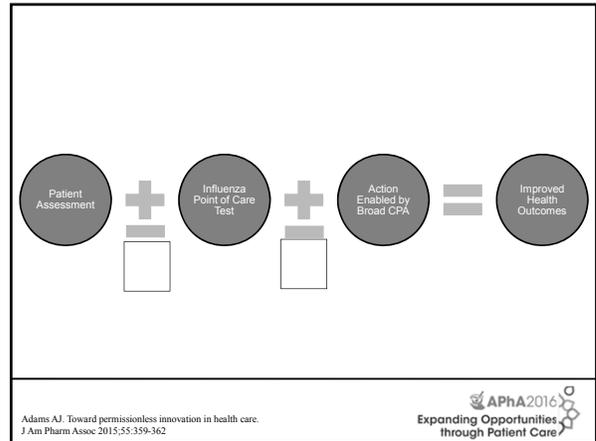
- The number of analytes for which CLIA-waived tests are available has grown:
  - 9 in 1993
  - 123 in 2015
- Tests are available for both acute and chronic diseases

## CLIA-waived Tests

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

## 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.



## Obtaining a CLIA-Waiver

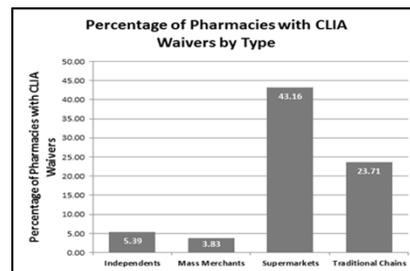


## Top CLIA-waived facilities in U.S.

Rank	Facility	# of Facilities	% of Facilities CLIA-Waived Only
1.	Physician Office	122,634	61.90
2.	Skilled Nursing Facility/ Nursing Facility	14,948	99.13
3.	Home Health Agency	14,467	99.77
4.	Pharmacy	10,838	99.85
5.	Hospital	9,060	20.87

Klepser M, Adams AJ, Smith P, et al. U.S. Community Pharmacies as CLIA-Waived Facilities: Prevalence, Dispersion, and Impact on Patient Access to Diagnostic Testing. Research in Social & Administrative Pharmacy (2015). doi: 10.1016/j.sapharm.2015.09.006.

## CLIA-Waivers by Pharmacy Type



Klepser M, Adams AJ, Smith P, et al. U.S. Community Pharmacies as CLIA-Waived Facilities: Prevalence, Dispersion, and Impact on Patient Access to Diagnostic Testing. Research in Social & Administrative Pharmacy (2015). doi: 10.1016/j.sapharm.2015.09.006.

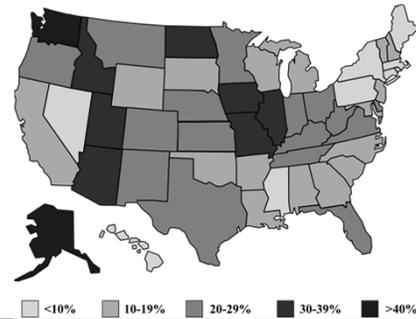
## Current Pharmacy Uptake

Rank	State	% of Community Pharmacies with CLIA Waiver
1.	Alaska	60.00%
2.	Washington	48.60%
3.	North Dakota	37.61%
49.	New York	0.40%
50.	Massachusetts	0.27%
51.	Nevada	0.00%
<b>National Percentage</b>		<b>17.94%</b>

Klepser M, Adams AJ, Smitz P, et al. U.S. Community Pharmacies as CLIA-Waived Facilities: Prevalence, Dispersion, and Impact on Patient Access to Diagnostic Testing. *Research in Social & Administrative Pharmacy* (2015). doi: 10.1016/j.sapharm.2015.09.006.

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## Current Pharmacy Uptake



<10% 10-19% 20-29% 30-39% >40%

Klepser M, Adams AJ, Smitz P, et al. U.S. Community Pharmacies as CLIA-Waived Facilities: Prevalence, Dispersion, and Impact on Patient Access to Diagnostic Testing. *Research in Social & Administrative Pharmacy* (2015). doi: 10.1016/j.sapharm.2015.09.006.

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## 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)

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## Collaborative Practice Agreement



<http://aapha.us/resources/cpa-report/>

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## 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.



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## 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 Healthcare



## 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.

Klepper DG, et al. Innovations in Pharmacy. 2014;5:1

## 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

## 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



<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf>

## 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.

## 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.

ME Klepser, et al JAPhA 2016.



## 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.

ME Klepser, et al JAPhA 2016.



## 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.

DG Klepser, et al. JAPhA 2016.



## 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.

DG Klepser, et al. JAPhA 2016.

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## 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.

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## 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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**Which of the following is the greatest barrier to implementing a successful disease management program?**

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- Pharmacist training
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- Workflow

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