

# House of Delegates Policy Topic Webinar – Point of Care Testing

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## Development and Support

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# Disclosures

**Alex Adams, PharmD, CAE, MPH**, declares no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria.

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# Learning Objectives

1. Explain current available point of care and rapid diagnostic testing programs.
2. Describe the difference between a point of care and rapid diagnostic test.
3. Explain the need for point of care and rapid diagnostic testing programs to be offered to patients at a pharmacy.
4. Describe some barriers to implementing testing programs in the pharmacy setting.



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How many patients may have an undiagnosed HIV infection in the United States?

- A. >8.1 million
- B. >800,000
- C. >150,000
- D. >25,000



Which of these is not a potential barrier to the expansion of point of care testing?

- A. Reimbursement
- B. State laws (legislation and/or regulation)
- C. Cost to operator
- D. Research proving positive results from point of care tests



As of May 2015, what percentage of pharmacies conducted a CLIA waived point of care test?

- A. 14%
- B. 18%
- C. 21%
- D. 29%



Which of the following reference sources will direct you to approved point of care tests?

- A. FDA's Orange Book
- B. CLIA Waived Test Listing
- C. Pharmacists' Patient Care Process
- D. Medicare Part D Approved Test Listing



Which of the following statements is *false* regarding the differences between point of care and rapid diagnostic tests.

- A. Point of care and rapid diagnostic tests are both included within CLIA waived tests
- B. Rapid diagnostic tests are not a subset of point of care tests and have a different approval process.
- C. Rapid diagnostic tests should include assessment and follow-up with the patient and provider
- D. Rapid diagnostic tests typically test for a specific antigen related to infections



## Patient Need

- CDC Reports...
  - >8.1 million people have undiagnosed diabetes
  - >150,000 have undiagnosed HIV
  - >800,000 have undiagnosed Hepatitis C
- What do these people have in common?
  - Most Americans live within 5 miles of a pharmacy
  - Patients can receive appropriate and timely care in a pharmacy setting



<http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6424a2.htm#Tab1>  
<http://www.cdc.gov/features/HepatitisCTesting/>  
Burley E, et al. Opportunities for pharmacists to improve access to primary care through use of CLIA-waved tests. *Michigan Pharmacist*. 2014;52(2):8-11.

# Role of the Pharmacist

- Pharmacists are playing a larger role in public health
  - direct patient care activities
  - disease state monitoring programs
  - patient self-monitoring initiatives
- Expansion in point of care test (POCT) and rapid diagnostic test (RDT) use
  - RDT are part of POCT
  - Clinical services are paired with test operation



Burley E, et al. Opportunities for pharmacists to improve access to primary care through use of CLIA-waived tests. *Michigan Pharmacist*. 2014;52(2):8-11.

# Current Approved Tests

- 120 CLIA-waived laboratory tests available in the US
  - Passed in 1988, finalized in 1992
  - Laboratories are required to meet standardized certification parameters to perform tests on humans
  - If...
    - A minimal level of complexity and low risk of erroneous results can be proven
  - Then...
    - an exception could be granted to perform this testing in a non-laboratory setting
      - Pharmacy
      - Clinic
      - or other non-laboratory setting



Burley E, et al. Opportunities for pharmacists to improve access to primary care through use of CLIA-waived tests. *Michigan Pharmacist*. 2014;52(2):8-11.  
Gubbins PO, et al. Point-of-care testing for infectious diseases: Opportunities, barriers, and considerations in community pharmacy. *Journal of the American Pharmacists Association*. 2014;54(2):163-171.  
Rodis JL, Thomas RA. Stepwise approach to developing point-of-care testing services in the community/ambulatory pharmacy setting. *Journal of the American Pharmacists Association*. 2006;46(5):594-604.  
CLIA currently waived analytes. Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm>.

## Current Approved Tests

- Subset of these are more commonly seen as POCT programs
  - Cholesterol
  - Group A *Streptococcus* (RDT)
  - *Helicobacter pylori* (RDT)
  - Hemoglobin A1C
  - Influenza (RDT)
  - INR
  - Serum chemistries (e.g., sodium, potassium, chloride)
- For a full list of the CLIA-waived tests available in the United States, visit:
  - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm>



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Gubbins PO, et al. Point-of-care testing for infectious diseases: Opportunities, barriers, and considerations in community pharmacy. *Journal of the American Pharmacists Association*. 2014;54(2):163-171.

## Definition of a Point of Care Test

- Robust test 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
- Examples include:
  - Serum creatinine to gauge renal function
  - Hemoglobin A1c to monitor blood glucose control
  - Rapid diagnostic tests to confirm or screen for infectious diseases (e.g., Group A Strep, influenza, Hep C, HIV, etc.)



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## Rapid Diagnostic Test

- Subset of point of care tests
- Fast, accurate, reliable, and accessible
  - Results typically within 30 minutes
  - Tests for an antigen related to an infection
  - Newer technology
    - Improved specificity
    - Decreased cost
  - Provided in settings with a CLIA waiver at the time of need
- Test is accompanied by an action plan
  - In collaboration with a physician
  - Includes immediate treatment measures and follow-up
  - Referral to advanced care



## Case studies on point of care and rapid diagnostic tests

- Project IMPACT: Hyperlipidemia
- Project IMPACT: Diabetes
- HIV Rapid Diagnostic Test Study
- Pharmacy Based Influenza Testing





## Case study - Cholesterol

**Study:** Project ImPACT: Hyperlipidemia

**Objective:** Demonstrate pharmacists' ability to promote medication compliance and achievement of therapeutic goals through pharmacist administered POCT

**Participants:** 26 community pharmacies equipped with Cholestech devices working collaboratively with physicians and patients

**Results:** 397 patients over an average period of 2 years

- Observed rate of compliance = 90.1%

- Rate achieving and maintaining target lipid goal = 62.5%



Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia. *Journal of the American Pharmacists Association*. 2000;40:157-65.

## Case study - Diabetes

**Study:** Project ImPACT: Diabetes

**Objective:** To improve patient health by integrating pharmacists into diabetes care teams in 25 communities that are underserved and/or have a high prevalence of diabetes.

**Participants:** Community and university-affiliated pharmacies, clinics, health centers, self-insured employers and other organizations.

**Results:** Aggregate interim data from all 25 participating communities showed statistically significant improvements across key diabetes indicators, including A1C (blood sugar) control, Systolic Blood Pressure, LDL Cholesterol and Body Mass Index (BMI).



Bluml BM, Watson LL, Skelton JB, et al. Improving outcomes for diverse populations disproportionately affected by diabetes: Final results of Project ImPACT: Diabetes. *J Am Pharm Assoc*. 2014;54:477-485. doi: 10.1331/JAPhA.2014.13240

## Case study - HIV

**Study:** Pharmacist Provided Rapid HIV Testing in two Community Pharmacies

**Objective:** To evaluate the acceptability and feasibility of pharmacist-provided rapid testing for human immunodeficiency virus (HIV) infection in community pharmacies.

**Participants:** Two independent pharmacies located in Michigan cities of different size and with different prevalence of HIV infection.

**Results:** 69 participants with 1 immediate referral for a confirmatory test. Participants and pharmacists reported favorable perceptions of the HIV testing experience.



Darin KM, Klepser ME, Klepser DE, et al. Pharmacist-provided rapid HIV testing in two community pharmacies. *J Am Pharm Assoc.* 2015;55:81–88. doi: 10.1331/JAPhA.2015.14070

## Case Study - Influenza

**Study:** Antimicrobial Stewardship in Outpatient Settings: Leveraging Innovative Physician-Pharmacist Collaborations to Reduce Antibiotic Resistance

**Objective:** To evaluate the impact of pharmacy-based influenza testing and treatment under a Collaborative Practice Agreement

**Participants:** 55 independent and chain pharmacies in 3 states.

**Results:** Screened 121 patients. Only 11% had a positive influenza test and received antivirals. Achieved >90% patient satisfaction, 39% of tests provided after physician office hours, and 35% of patients had no primary care physician.



Klepser ME, Adams AJ, Klepser DG. Antimicrobial Stewardship in Outpatient Settings: Leveraging Innovative Physician-Pharmacist Collaborations to Reduce Antibiotic Resistance. *Health Security*, Volume 13(3):166-173.

# Implementation Barriers

- Education and understanding:
  - Lack of familiarity with, or education regarding, POCT program processes
  - Lack of physical assessment and specimen collection skills
  - Low level of acceptance by other health care providers
- Administrative burden of meeting state regulations, federal requirements, and other third party demands
- Feasibility of incorporating POCT programs into the pharmacy workflow



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# Implementation Barriers

- Financial feasibility of investing in equipment, supplies, and documentation programs necessary for point of care testing programs
- Relatively limited financial incentives to provide such testing, including low or no reimbursement for pharmacists
- Patient utilization of point of care influenced by insurance coverage and payment
  - HIV Study: 69 participants screened (37 commercially insured, 13 Medicare, 3 Medicaid, and 14 uninsured)
    - 63 participants indicated that they would pay for point of care testing
      - 80% of participants indicated they would be willing to pay \$16–\$20 or less for the HIV test
      - 9% of participants would pay \$30 or more



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## Resources for Implementation

- Patient Care Process
- Collaborative Drug Therapy Management
- CLIA waivers
- Laws & Policies



## Resources for Implementation

- Pharmacists' Patient Care Process
  - Approved by the Joint Commission of Pharmacy Practitioners (JCPP) in May 2014
  - Consensus document between national pharmacy associations
  - Framework for delivering patient care in any practice setting
  - Point of care testing and related services fit directly within this approved process
  - Available at:
    - <http://www.pharmacist.com/sites/default/files/files/PatientCareProcess.pdf>



## Resources for Implementation

- Collaborative Practice Agreements
- Also known as collaborative drug therapy management agreements
  - As of 2012:
    - 44 states had a provision to allow for CDTM
    - 19 of these states have language for pharmacist participation in POCT programs
    - Of these 19, 7 also had POCT-related provisions included in their state scope of practice outside of CDTM language
- Opportunity for inclusion in state scope of practice acts



Gubbins PO, et al. Point-of-care testing for infectious diseases: Opportunities, barriers, and considerations in community pharmacy. *Journal of the American Pharmacists Association*. 2014;54(2):163-171.

## Resources for Implementation

- Key Elements for CPA Legislative and Regulatory Authority
  - July 2015, NASPA convened the Collaborative Practice Workgroup
  - Goal: develop recommendations for CPAs
  - State and national organization participation
  - Available at:
    - <http://naspa.us/wp-content/uploads/2015/07/CPA-Workgroup-Report-FINAL.pdf>
- Collaborative Practice Agreements and Pharmacists' Patient Care Services
  - 4 documents created for:
    - Pharmacists
    - Nurses, physicians assistants, and other providers
    - Government and private payers
    - Decision makers
  - Available at:
    - <http://www.aphafoundation.org/collaborative-practice-agreements>



# Resources for Implementation

- CLIA Waived Tests

- As of May 2015

- 18% of pharmacies are conducting CLIA waived tests

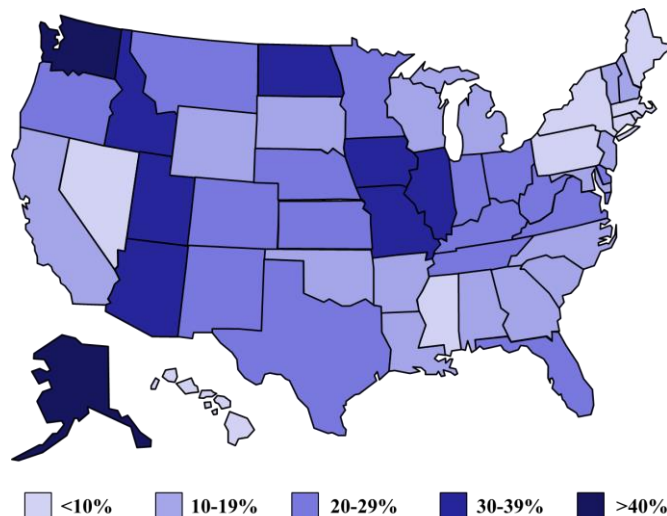
## Top CLIA-waived facilities in U.S.

| Rank | Physician's Office                            | # of Facilities | % of Facilities CLIA-Waived Only |
|------|---|-----------------|----------------------------------|
| 1.   | Physician Office                              | 122,634         | 61.90                            |
| 2.   | Skilled Nursing Facility/<br>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, Srnis 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.

## Percentage of Pharmacies with CLIA-Waivers by State



Klepser M, Adams AJ, Srnis 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.

## Resources for Implementation

- **Laws & Policies**
  - Variations exist from state to state related to POCT
    - Important to follow existing laws when conducting POCT
  - POCT is not specifically mentioned within NABP Model Practice Act
  - Company policies should also be used as an outline for conducting POCT



## Resources for Implementation

- **APhA ADAPT** – Online patient care skills development program for practicing pharmacist in all settings
  - Skills and processes ADAPT covers include:
    - Conducting thorough medication assessments;
    - Collaborating successfully with other health care providers;
    - Interviewing and assessing your patients (incorporating physical; assessment and laboratory data);
    - Making evidence-based clinical decisions;
    - Using validated documentation practices to support patient care; and
    - Developing and implementing care plans.
- Information: [www.APhAADAPT.com](http://www.APhAADAPT.com).



## Resources for Implementation

- **APhA Certificate Training Programs** – Practice-based continuing pharmacy education (CPE) activities primarily constructed to instill, expand, or enhance practice competencies through the systematic achievement of specified knowledge, skills, attitudes, and performance behaviors.
  - Current programs:
    - [Delivering Medication Therapy Management Services](#)
    - [Pharmacy-Based Cardiovascular Disease Risk Management](#)
    - [Pharmacy-Based Immunization Delivery](#)
    - [The Pharmacist and Patient-Centered Diabetes Care](#)



## Resources for Implementation

- **NACDS Point-of-Care Testing Program**—Partnership with clinicians from Ferris State University College of Pharmacy, the University of Nebraska Medical Center College of Pharmacy, and the Michigan Pharmacists Association to offer a 20-hour certificate training course related to point of care testing.
  - Training course provides community pharmacists, academicians, and other interested practitioners with the skills necessary to develop and implement a collaborative testing program for influenza, Group A *Streptococcus*, HIV, and Hepatitis C.
  - Available at:
    - <http://nacds.learnercommunity.com/Point-of-Care-Testing-Certificate>





## Future Expansion

- **ACPE standards** - In its *Guidance for Standards 2016*, ACPE encouraged schools to implement requirements related to point of care testing.
  - Specifically, schools and colleges of pharmacy should ensure graduates are competent to “collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests.”



Guidance for the accreditation standards and key elements for the professional program in pharmacy leading to the doctor of pharmacy degree.  
Accessed at: <https://www.acpe-accredit.org/pdf/GuidanceforStandards2016FINAL.pdf>.

## Conclusion

- There is a broad need for POCT services in the United States due to growing numbers of patients who could benefit from POCT
- Pharmacists are in a good position to contribute to the care of patients through participation and leadership of POCT services.
- Positive patient outcomes have been demonstrated through the delivery of POCT programs.



## Conclusion

- Barriers exist to the expansion of POCT services, but are being reviewed and addressed on a state and national level through the creation of resource documents.
- Opportunities also exist for the expansion and implementation of POCT services through the efforts of national organizations.



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- D. >25,000



Which of these is not a potential barrier to the expansion of point of care testing?

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