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

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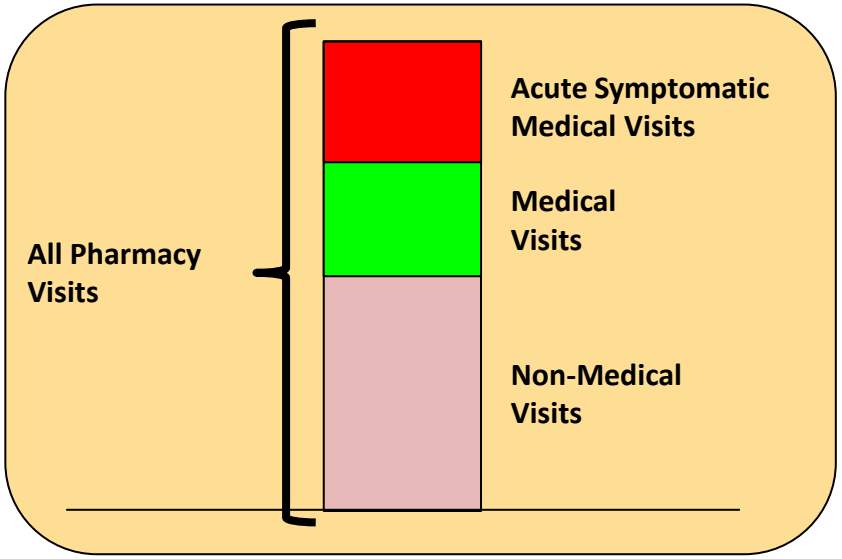
The Case for Collaborative Disease State Management

- 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.



Adequacy of Pharmacist Supply:2004 to 2030. Department of HHS. 2008

Pharmacist Education

- **All pharmacists not graduate with a Doctor of Pharmacy degree.**
- **CAPE 2013 Educational Outcomes**

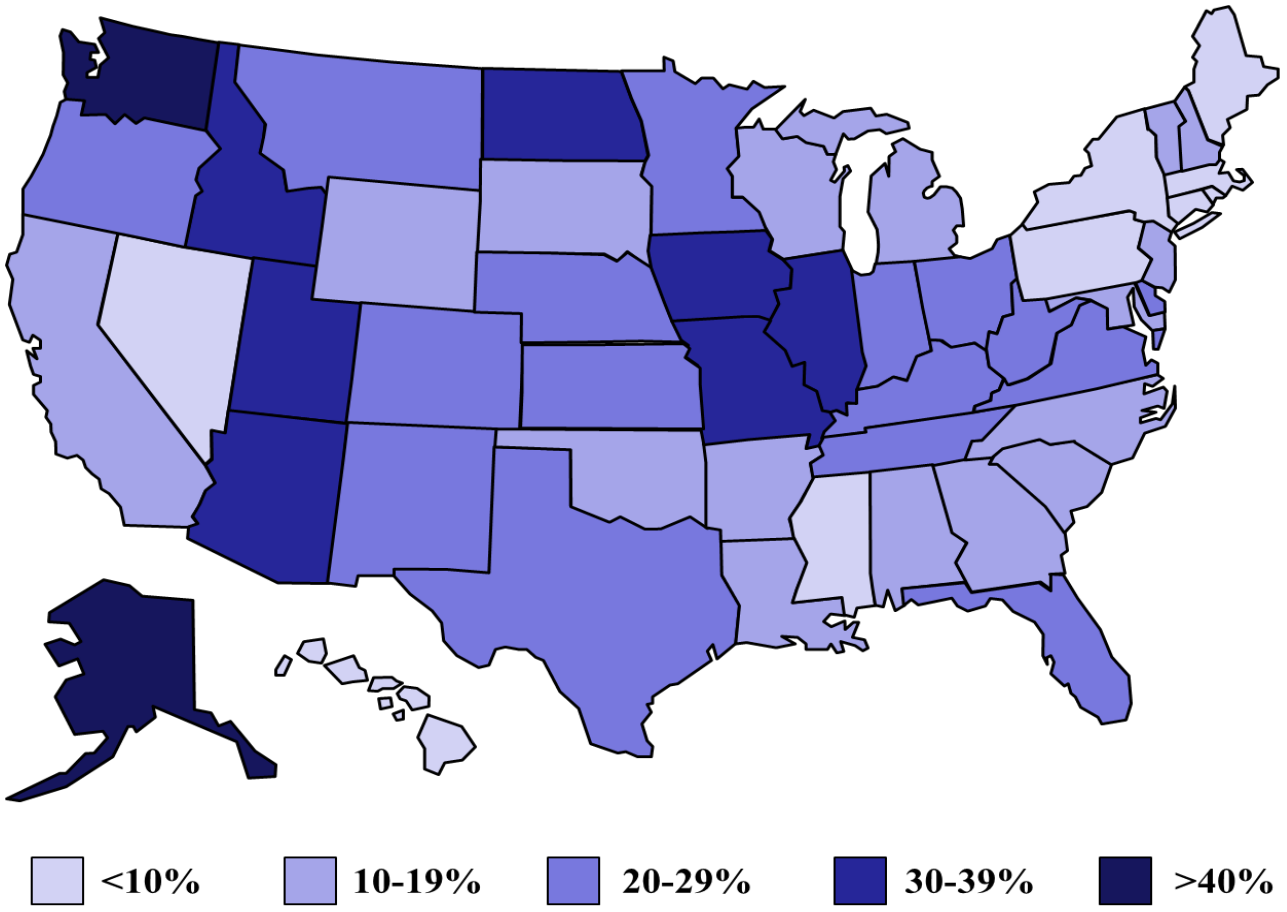
  Domain 2.1. Patient-centered care (Caregiver) - Provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities)
- **ACPE 2016 (Draft Standards)**

  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.

Center for the Advancement of Pharmacy Education (CAPE) 2013 Educational Outcomes
Accreditation Council for Pharmacy Education Accreditation Standards and Guidelines (2016 draft standards
National Association of Boards of Pharmacy Competency Statements

Percent of Pharmacies with CLIA-waivers



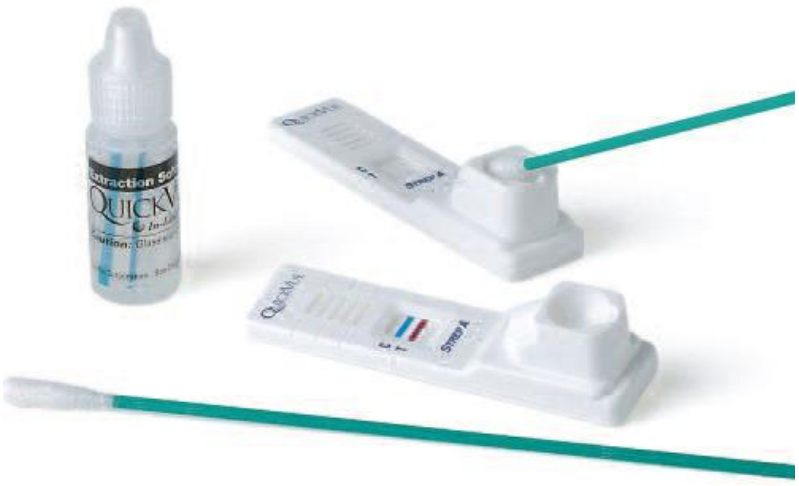
ME Klepser, et al. Res Soc Admin Pharm. 2015.

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.**



Barnett ML. JAMA Intern Med. 2014;174:138-40.
Smith SS. Otolaryngol Head and Neck Surg. 2013;148:852-9.

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.**

The Case for Collaborative Disease State Management

- **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.**

Cranor CW, et al. J Am Pharm Assoc. 2003;43:173-90.

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**

Collaborative Influenza Disease State Management Program

- This study examined a collaborative physician-community pharmacist influenza management program with respect to clinical outcomes and healthcare utilization.
- A multi-center, project funded by the NACDS Foundation.
- Investigators:
  - Michael E Klepser, Pharm.D.
  - Donald G. Klepser, Ph.D.
  - Allison Dering-Anderson, Pharm.D
  - Jacqueline A. Morse, Pharm.D.
  - Jaclyn K. Smith
  - Stephanie A. Klepser, Pharm.D.

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 od the encounter.**
    - **Appropriate patients were managed in the pharmacy according to a collaborative practice agreement.**

ME Klepser, et al ASM Biodefense and Emerging Diseases Research Meeting. 2015.

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

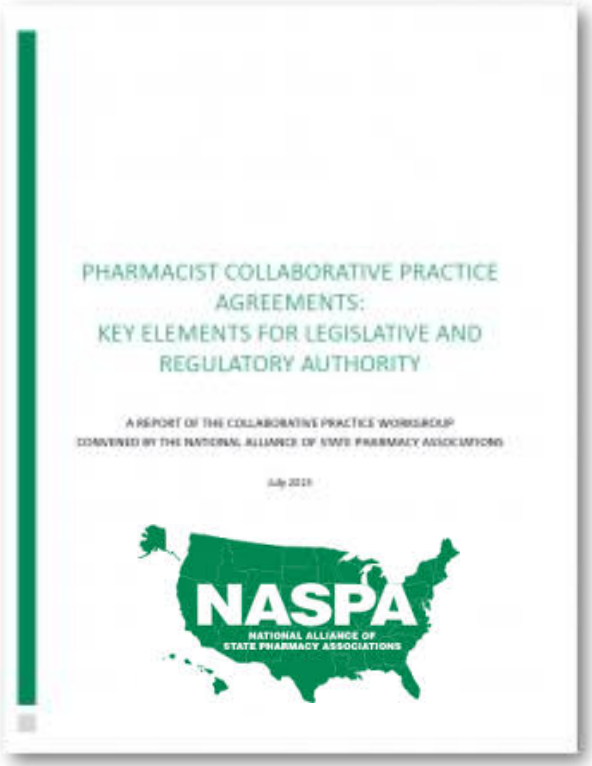
- Question and answer regarding self-study.
- Physical assessment review, practice, and assessment of proficiency.
- Specimen collection review, practice, and assessment of proficiency.
- Case studies

Currently:

- **More than 3,000 pharmacists have been trained nationwide.**
- **More that 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.**

ME Klepser, et al J Am Pharm Assoc. 2016; 56:14-21.

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.**

ME Klepser, et al. J Am Pharm Assoc. 2016; 56:14-21.

Collaborative Influenza Disease State Management Program

	n/N (%)
Total Number of Patients Screened	**121**
• Excluded from participation • Eligible for participation	45//121 (37.2%) 76/121 (62.8%
Patients Tested for Influenza	
• Did not have a primary care provider • Seen outside of regular clinic office hours	26/75 (34.6%) 29/75 (38.7%)
POC Test Result	
• Positive • Negative	8/75 (10.7%) 67/75 (89.3%)
Patient Receipt of Oseltamivir	

• Positive test
  ○ CPA Site
  ○ Physician Call
• Negative test
	
	5/5 (100%)
	1/3 (33.3%)
	0/67 (0%)

ME Klepser, et al. J Am Pharm Assoc. 2016; 56:14-21.

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. J Am Pharm Assoc. 2016; 56:14-21.

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. J Am Pharm Assoc. 2016;In Press.

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. J Am Pharm Assoc. 2016;In Press.

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"**
  - **March 2015 - "National Action Plan 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_antibotic-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.**

Going Forward