The Ins and Outs of Point-of-Care Testing

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College of Pharmacy
Target Audience: Pharmacists
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Activity Type: Knowledge-based
## Disclosure Statement of Financial Interest

I, Michael Klepser, DO have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation, they are:

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Assessment Question

1. Which agency does not have a direct role in CLIA?
   A. CDC
   B. NIH
   C. CMS
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Assessment Question

2. Which of the following can be a barrier to implementing a sustainable pharmacy-based point-of-care testing service:
   A. State regulations
   B. Lack of third party reimbursement
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Assessment Question

3. Community pharmacy based disease management programs utilizing CLIA-waived POCT have been developed for which of the following?
   A. Acute pharyngitis
   B. Hepatitis C virus
   C. Blood lead testing
   D. Influenza
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Assessment Question

4. Which of the following should be considered when designing a pharmacy-based POC testing-program?
   A. How will it impact pharmacy workflow?
   B. Can the program be sustainable?
   C. How will follow-up care be provided?
   D. All of the above should be considered.
Learning Objectives

1. Explain what it means for a diagnostic test to meet the Clinical Laboratory Improvement Amendments (CLIA)–waived requirements for use as point-of-care (POC) tests in the community pharmacy setting.
2. List currently available CLIA-waived POC tests that can be used by pharmacists.
3. Identify opportunities for pharmacists to expand their services in the community pharmacy practice setting through the utilization of POC tests.
4. Explain the legal, regulatory, and liability issues involved in offering a pharmacy-based POC testing program.
5. Discuss specific strategies for designing and implementing a successful pharmacy-based POC testing program.
6. Discuss operational issues (e.g., workflow, reimbursement, education, liability) regarding the use of POC tests by pharmacists.
Small Group Activity

- Break into small groups with those around you.
- Attempt to answer the following questions to the best of your ability.
- Discuss your answers with those in your group.
Small Group Activity

- Are pharmacists in your state able to conduct CLIA-waived tests?
  - If so, are there any restrictions?
- What can a pharmacist do with the results of a CLIA-waived test in your state?
- What types of testing programs are occurring in your state?
- Do you think your employees have the skills necessary to develop and implement a community pharmacy-based point-of-care testing program?
Pharmacy-Based Point-of-Care Testing is not new...

Establishment and Evaluation of a Serum Cholesterol Monitoring Service in a Community Pharmacy

Thomas R. Einarson, Ph.D., J. Lyle Bootman, Ph.D., William F. Mcgahan, Pharm.D., more...

First Published January 1, 1988 | Research Article
..nor is it rare...

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Out of ~60,000 community pharmacies

..., but it certainly is not common.

- The current landscape:
  - Pilot projects
  - Screening events
  - Limited hours
  - Special staffing
RESEARCH

Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness

Michael E. Klepser, Donald G. Klepser*, Allison M. Dering-Anderson, Jacqueline A. Morse, Jaclyn K. Smith, Stephanie A. Klepser

EXPERIENCE

Community pharmacist-physician collaborative streptococcal pharyngitis management program

Donald G. Klepser*, Michael E. Klepser, Allison M. Dering-Anderson, Jacqueline A. Morse, Jaclyn K. Smith, Stephanie A. Klepser

T. Thornley1,2, G. Marshall3, P. Howard3 and A. P. R. Wilson4*

1Boots UK, Nottingham NG90 1BS, UK; 2School of Pharmacy, University of Nottingham, University Park, Nottingham NG7 2RD, UK; 3Medicines Management & Pharmacy, Leeds Teaching Hospitals NHS Trust, Leeds LS1 3EX, UK; 4Department of Microbiology & Virology, University College London Hospitals, London W1T 4EU, UK

*Corresponding author. Tel: +020344-79516; Fax: +020344-79211; E-mail: peter.wilson@uclh.nhs.uk

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What is CLIA?

- The Clinical Laboratory Improvement Amendments (CLIA) were passed by Congress in 1988 to establish quality standards for all non-research laboratory testing performed on specimens derived from humans for providing information for the diagnosis, prevention, and treatment of disease or impairment, or assessment of health.
Why is CLIA Important?

- CLIA establishes quality standards for laboratories to ensure the accuracy, reliability, and timeliness of the patient’s test results.

- CLIA requires the Department of Health and Human Services to certify clinical laboratories.
How Does CLIA Work

Centers for Medicare & Medicaid Services (CMS)
- Collects fees
- Conducts inspections
- Enforces compliance
- Issues laboratory certificates
- Monitors proficiency testing
- Publishes CLIA rules and regulations

Food and Drug Administration (FDA)
- Categorizes tests based on complexity
- Develops rules and guidance for CLIA complexity categorization
- Reviews requests for waiver by application
How Does CLIA Work

Centers for Disease Control and Prevention (CDC)

- Conducts laboratory quality improvement studies
- Develops professional information and educational resources
- Develops technical standards and practice guidelines

- Manages CLIA Advisor Committee
- Monitors proficiency testing practices
- Provides analysis, research, and technical assistance
Test Categorization

The FDA categorizes laboratory tests based on the complexity of the methods.

- Amount of interpretation
- Calibration and quality control requirements of the instruments
- Degree of independent judgment
- Difficulty of calculations
- Examination, procedures, and methodologies used
- Training required to operate the instruments for the methods.
Test Categorization

- Based on their assessment, the FDA classifies tests as:
  1. Waived complexity (aka CLIA-waived tests)
     - Waived tests are so simple and accurate that little risk of error exists when done correctly.
     - Note: This does not take into account specimen collection!!!!
  2. Moderate complexity
  3. High complexity
CLIA-Waived POCT Already in some Pharmacies

- Influenza
- Group A *Streptococcus*
- HIV
- HCV

- Cholesterol
- Blood glucose
- Hgb A1C
- Blood lead
- Genetic tests
<120 CLIA-Waived Tests in U.S.

**Chronic**
- Blood glucose
- Fecal occult blood
- Pregnancy
- Cholesterol
- Triglycerides
- Thyroid Stimulating Hormones
- Hemoglobin A1C
- HIV
- Hepatitis C

**Acute**
- Influenza
- Group A Streptococcus
- Respiratory Syncytial Virus
- Mononucleosis
- H. Pylori
Obtaining a CLIA-Waiver

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

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Nationally, roughly 18% of community pharmacies have a CLIA-waiver.
Federal Requirements for Obtaining a CLIA-Waiver

- Waived laboratories must meet only the following requirements under CLIA:
  - Enroll in the CLIA program;
  - Pay applicable certificate fees biennially; and
  - Follow manufacturers' test instructions.

Accessed January 17, 2018
State Limitations on CLIA Waivers

- Preventing pharmacies outright
- Limiting who can serve as a lab director
- Limiting what tests can be performed
- Limiting tests to being performed under a CPA
Opportunities for Pharmacy-Based Point-of-Care Testing

- “Point-of-care testing services are anticipated to surpass immunizations to drive revenue. Pressure from payers to detect high-cost diseases early will help speed up the growth of pharmacy-based diagnostic screening services.”

Benefits of Pharmacy Testing in Support of Clinical Care

- Accessibility
  - Expanded hours
  - Convenient locations
  - Walk in service model
  - Patients without PCP
  - Lower costs

- Supporting new practice models that promote team-based and patient-centered care
  - ACOs and PCMHs
  - Value-based purchasing
  - High deductible health plans
Benefits of Pharmacy Testing in Support of Clinical Care

- Collaborative practice agreements as a means of supporting primary care in:
  - Chronic disease management
  - Acute illness care
  - Early detection of disease
Opportunities for Pharmacy-Based Point-of-Care Testing

- Chronic Disease Management and Prevention
  - Cholesterol and HbA1c
  - Affect large patient populations
  - Clearly defined guidelines for treatment and goals
  - Pharmacists have been using these tests for decades
  - In many ambulatory clinic settings, pharmacists utilize CPAs to manage patient therapy based on laboratory values.
Opportunities for Pharmacy-Based Point-of-Care Testing

- Minor acute illnesses
  - Influenza and pharyngitis
  - Patients already seek care in the pharmacy
  - CPAs can allow for complete management in the pharmacy for suitable populations
- Potential to relieve burden on PCPs
Opportunities for Pharmacy-Based Point-of-Care Testing

- Disease Screening and Public Health
  - HIV and Hepatitis C screening
    - Public health partnerships
    - Linkage to confirmatory testing
    - Pre-exposure prophylaxis (PrEP) programs

- Lead testing
  - Rapid response and access points
Point-of-Care Testing in Pharmacies

1. Pharmacy-based retail clinics
2. Pharmacy-based labs/specimen collection
3. Pharmacist provided care
Safeway expands Quest Diagnostics diagnostic testing offering to 12 locations

JUNE 16, 2016 | BY MICHAEL JOHNSEN

Walgreens partners with LabCorp on in-store lab testing services

JUNE 28, 2017 | BY MICHAEL JOHNSEN
Pharmacy-Based Collaborative 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
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
Model for Acute Conditions...

The test is a piece of the puzzle.

The comprehensive pharmacy service is enabled by action on the result of the test, either through CPA or independent prescribing.

Continuum of Pharmacist Prescriptive Authority

Collaborative Prescribing
- Patient-Specific CPA
- Population-Specific CPA

Autonomous Prescribing
- Statewide Protocol
- Unrestricted (Category-Specific)

The History of Pharmacy-Based Testing

- Total cholesterol and HDL
- Blood Glucose
- Vitamin D
- A1c

- Some pharmacies have been doing this type of testing for over 20 years.
- In many of these cases, the pharmacy was simply a lab.
The History of Pharmacy-Based Testing

- Wide adoption, but generally not for diagnostic or treatment purposes.

- May not be connected to a disease management service
The Opportunity

- May be part of a patient specific collaborative practice agreement to manage chronic disease patients.

- Could be used to inform/improve MTM programs
Acute Disease Management

- Requires population based CPA or greater autonomy

- Opportunity for complete management in the pharmacy
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Influenza and Group A Strep Studies

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


Influenza Study

- Eighteen (18) years of age or older
- Complain of signs/symptoms consistent with influenza-like illness (fever/feverish AND cough OR sore throat) that began within the past 48 hours
- Positive nasal swab rapid diagnostic influenza test
- Clinical stability, defined as the absence of the following:
  - Altered mental status
  - Systolic blood pressure < 90mmHg or diastolic blood pressure < 60mmHg
  - Pulse > 125 beats/minute
  - Respiratory rate > 30 breaths/minute
  - Oxygen saturation < 92% on room air
  - Temperature > 103°F

Influenza Study

- Approximately 11% of patients evaluated tested positive for influenza and received antiviral.
- Zero patients received an antibiotic.
- No adverse clinical outcomes were noted.
- 44% of patients visited the pharmacy outside of established physician office hours.
- 37.3% of patients did not identify a primary care provider.
- Patient satisfaction with pharmacist provided service was >90%.

Group A Strep Study

- Between Eighteen (18) and Forty-five (45) years of age
- Centor score of 1 or greater
- Positive throat swab rapid diagnostic strep test
- Clinical stability, defined as the absence of the following:
  - Altered mental status
  - Systolic blood pressure < 90mmHg or diastolic blood pressure < 60mmHg
  - Pulse > 125 beats/minute
  - Respiratory rate > 30 breaths/minute
  - Oxygen saturation < 92% on room air
  - Temperature > 103°F

**Group A Strep Study**

- Approximately 18% of patients evaluated tested positive for group A strep and received an antibiotic.
- Zero patients who tested negative received an antibiotic.
- No adverse clinical outcomes were noted.
- 44% of patients visited the pharmacy outside of established physician office hours.
- 43% of patients did not identify a primary care provider.
- Patient satisfaction with pharmacist provided service was >90%.

Follow Up Study

- 661 patients tested at 86 pharmacy locations in 7 states.
  - 102 influenza with 23% testing positive and receiving an antiviral
  - 559 group A strep with 17% testing positive and receiving an antibiotic
- 38% of patients visited the pharmacy outside of established physician office hours
- 46% of patients did not identify a primary care provider
- 3 chains were unable to participate because they could not find a willing collaborator

Screening Tests

- HIV or HCV
  - Need for additional testing
- Requires a different kind of collaboration
  - Public Health
  - Specialist care
- Patients linked to care rather than managed in the pharmacy
Challenges - Finding a willing collaborator

- Particular challenge for independent pharmacies
- Cost relative to true oversight
- Need for permission stifles uptake
Challenges – Differences in State Laws

- Challenge for organizations operating in multiple states

- Generally, a bigger concern for providing follow up than to providing testing

- Inhibits the ability to create a standardized service

- Makes it impractical in some states and impossible in others.
Challenges - Workflow

- Unpredictable demand?
  - Some services can be scheduled

- Staffing

- Time per encounter
  - May vary greatly depending on test result

- Use of technicians
Challenges – Payment/Sustainability

- Reimbursement in 2018
  - Medical versus pharmacy benefit
  - Move away from the fee-for-service model
  - The goal is to get paid, not reimbursed
- Service must make sense economically
  - It may drive foot traffic or other sales
- Competitive pricing
  - Competing with clinic/ED copays
Challenges – Education

- Few pharmacists received significant training on point-of-care testing or collaborative practice agreements in school.
- Some states require demonstration of knowledge and proficiency through an approved certificate program or other form of credentialing.
Challenges – Liability

- Any time you practice pharmacy you have professional liability
- Adding point-of-care testing disease management program will increase your liability, albeit only slightly
- Collaborating physicians will also have concerns about their own liability
Challenges - Demonstrating value and improved patient outcomes

- What do patients expect?
  - Antibiotic?

- Fragmentation of care or part of a patient-centered medical home?
Solutions/Strategies for Designing and Implementing a Successful Program

- Find out what is allowable in your state in terms of POC testing and CPAs
  - Unfortunately, there is no single source for this
  - Talk with your state association, schools/colleges of pharmacy, and board
  - Be willing and prepared to advocate for change
- Get the training you need to provide the service
Solutions/Strategies for Designing and Implementing a Successful Program

- Build a business case for the service
  - Define the service and market
  - Find out if insurer’s will cover the services provided
  - Begin thinking about cash pricing for the service
  - Think about potential partners (large employer, schools, etc.) who would support the service
Solutions/Strategies for Designing and Implementing a Successful Program

- Develop a protocol and find a willing collaborator
  - Template protocols are available (dklepser@unmc.edu)
  - Consider public health and infectious disease physicians
  - Have a plan for patients regardless of the test result
  - Collaborate on the final protocols and be sure they meet both parties’ needs
- File/Submit to appropriate Board(s) if necessary
Solutions/Strategies for Designing and Implementing a Successful Program

- Select the appropriate tests
  - Talk to the manufacturers
  - There is more to consider than just the price
  - Understand what the test results mean and be prepared to explain that to your patients

- Develop appropriate data collection tools
  - Templates are available
  - What information is necessary for patient care, billing, reporting?
Solutions/Strategies for Designing and Implementing a Successful Program

- Training and education of your staff
- Marketing
- Evaluation of the service
Solutions/Strategies for Designing and Implementing a Successful Program

- Be prepared for pushback and resistance
- Be prepared for lower than expected patient volume
- Be prepared for the unexpected

- Stay focused on the patient!!!
Flu & Strep Testing

When you or someone you care about isn't feeling well, you need to take action right away. Our pharmacist will run a quick test so you will know to see if you or your family member have the flu or strep. In just a few minutes, you'll leave our pharmacy with the proper medication so you can get better, faster.

Pricing:

- $25 for a strep test
- $35 for an influenza test

Flu and strep tests are offered to adults and children, ages 5 & up. Prescription treatment is offered when test results are positive. To learn more, talk to your pharmacist.

https://www.blountdiscountpharmacy.com/services/flu-strep-testing

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