Point-of-Care Testing: An Opportunity to Provide Patient-Centered and Collaborative Care

John T. Holmes, PharmD, BCPS
Idaho State University
2017 Spring Continuing Education

In support of improving patient care, Idaho State University Kasiska Division of Health Sciences is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.
Disclosure Statement

• The planners and presenter of this presentation have disclosed no conflict of interest, including no relevant financial relationships with any commercial interests.
Objectives

• Examine the risks and benefits of implementing a community pharmacy based point-of-care testing (POCT) program from the patient, provider and payer perspectives

• Utilize previously implemented community pharmacy based POCT programs to gain institutional support for dissemination of a POCT program in your practice

• Design and implement an evidence-based POCT program in your practice setting
What is Point-of-Care Testing (POCT)?

- Laboratory testing that takes place at or near the site where the patient is located

- Common traits:
  - Minimally invasive
  - Quick to perform
  - Immediate results

- Screening, diagnostic, and monitoring

Terminology

• Clinical Laboratory Improvement Amendments (CLIA) – waived tests
  – Over 120 CLIA-waived tests
  – “minimal level of complexity and low risk of erroneous results”
    • Waiver for testing in a nonlaboratory setting
Terminology

• Rapid Diagnostic Tests
  – A subset of POCT
  – Diagnostic test that is done easy and quick to perform
  – Infectious Diseases
Common Pharmacy-Based POCTs

- Hemoglobin A1c
- Blood Glucose
- Cholesterol
- Serum chemistries
- Group A Streptococcus (RDT)
- Influenza (RDT)
- Helicobacter pylori (RDT)
- Thyroid Stimulating Hormone
Do you currently have POCT available at your practice site?

A. Yes
B. No
How often do you perform POCT?

A. Daily
B. Weekly
C. Monthly
D. A couple times a year
E. Never
I would be comfortable discussing tests or test results with patients or prescribers.

A. Strongly agree
B. Agree
C. Neutral
D. Disagree
E. Strongly disagree
Pharmacists and Public Health

• Screening
  – 7 million people with undiagnosed diabetes
  – 240,000 people with undiagnosed HIV
  – 800,000 people with undiagnosed Hepatitis C

• Diagnostic
  – Access to care, costs, early diagnosis/treatment

• Chronic Disease Monitoring and Management
  – Inappropriate drug therapy
  – Achievement of clinical outcomes
Access to Pharmacy Care

• Approximately 260,000 pharmacists in the US
• Between 59,000 and 67,000 community pharmacies in the US
• 13 billion visits to a pharmacy per year
  – 275 million patient visits to a pharmacy each week
    • 4,000 patient visits a week per pharmacy
• 92% of people live within 1.6 miles of a pharmacy

Each visit to a pharmacy represents a possible encounter!!
Pharmacy-Based POCT

• In March 2016, 9110 pharmacies held a CLIA-waiver
  – Approximately 14% of all community pharmacies
  – Majority of waivers held by chains and supermarkets
• 5th leading CLIA-laboratory site
• 10.7% increase in non-Walgreens pharmacies holding a CLIA-waiver between 5/15 and 3/16

Historical Barriers to POCT

- Pharmacists’ lack of familiarity with POCT programs processes
- Pharmacists’ lack of physical assessment and specimen collection skills
- Feasibility incorporating into workflow
- Fragmentation of care and acceptability
- Administrative burden
- Limited financial incentives

For those with POCT available, what barriers to performing POCT have you encountered??
HIV Screening Example

• **Objective:** Test feasibility of offering POC HIV testing in community pharmacies and retail clinics

• **Setting:** 21 community pharmacies and retail clinics

• **Intervention**
  – Conceptual model for counseling and testing
  – Training materials
  – Relationship with health department (stakeholder)
  – Point-of-care HIV testing
  – Referral for confirmatory and HIV care if needed
  – Marketing

HIV Screening Example

• **Results:**
  – 1540 test performed between 2011 and 2013
  – Time
    • 4 minutes pretest counseling, consent and collection
    • 23 minutes waiting for result
    • 3 minutes for posttest counseling
  – 17/21 sites planned to continue HIV testing

Influenza RDT Example

• **Objective:** Examine effectiveness of physician-pharmacists collaboration to treat influenza-like illness

• **Setting:** 55 pharmacies in Michigan, Minnesota, and Nebraska

• **Intervention:**
  – Brief physical exam and rapid influenza diagnostic test
  – Referred or treated per collaborative practice agreement (CPA)
  – Patient f/u in 24-48 hours

Influenza Example

• **Results:** 121 patients screened
  – 45 (37%) excluded and referred to PCP or urgent care
  – 75 (62%) eligible for participation
    • 8 (11%) tested positive and treated per CPA
  • Approximately 35% of patients tested had no PCP
  • 38.7% of patients tested outside of normal business hours

STEP-WISE APPROACH TO POCT DEVELOPMENT AND IMPLEMENTATION

Needs Assessment

Research and Organizing

Materials Development

Implementation

Evaluation
Needs Assessment

• SWOT Analysis
  – Strengths (internal)
    • Location, students, pharmacist desire
  – Weaknesses (internal)
    • Coverage, no CLIA certificate, training
  – Opportunities (external)
    • Community demographics, collaborative providers
  – Threats (external)
    • Cost, patient acceptance
Needs Assessment

• “Who are the patients that visit my pharmacy?”
  – Prescription record reports
    • Age, gender, zip codes, medications as disease surrogates, etc.
  – Patient Survey
  – Focus Groups
    • Patients, staff, medical neighborhood, etc.
Stakeholder Engagement

• Health Departments
• Community Advocacy Groups
• Medical Providers
• Pharmacy Staff
• Patients
• Other Pharmacies?
Research and Organize

• Go look at other sites conducting POCT
  – Ask LOTS of questions!!!!

• Partner with other entities
  – University faculty and students
  – Other groups already conducting screenings

• Begin to work out logistics
  – Students
  – Residents
Research and Organize

• “How will this POCT service fit into my current environment?”

• Practice site restructuring
  – Assessment of current and future state workflow
  – Consider staffing, time, space, etc.

• Other wellness and quality improvement programs
  – Example: Screening for ADEs
Workflow Diagram

Exclusion Criteria

- Symptoms >48 hours
- Symptoms not consistent with ILI
- Receipt of LAIV within the previous 2 weeks
- Immunocompromised state
- Presence of pulmonary or cardiovascular disease (excluding hypertension)
- Pulmonary disease requiring home oxygen therapy
- Women who are pregnant or breastfeeding
- Receipt of a neuraminidase inhibitor within the previous 2 weeks
- Known hypersensitivity to oseltamivir

Patient ≤18 years of age

Not eligible for study participation. Manage appropriately.

Screening Questions

- Do you have a cough?
- Do you have a fever or feel feverish?
- Do you have unexplained body aches?
- Do you have a sore throat?

Answered Yes to any Screening Question

Unlikely to be influenza

Presence of Exclusion Criteria

Not eligible for study participation. Manage appropriately.

Perform Influenza rapid test (RIDT)

Automatic Referral Criteria

Clinical instability defined as the presence of any of the following:
- Altered mental status
- Pulse >125 beats/minute

Research and Organize Regulations

• State Regulations
  – State Board of Pharmacy
  – Idaho Bureau of Laboratories
  – Disease reporting (Infectious Diseases)

• Federal Regulations
  – Occupational Safety and Health Administration (OSHA)
    • Bloodborne pathogens - PPE
  – HIPAA
Does the Idaho State Board of Pharmacy allow pharmacists to conduct POCT?

A. Yes
B. No
Idaho Board of Pharmacy

• Definition of “Pharmaceutical Care Services” (updated 2016)
  – “ordering and interpreting laboratory tests”
CLIA Certificate of Waiver

• State of Idaho Clinical Laboratory Registration form

• Federal CMS Form 116 laboratory registration form
CLIA Certificate of Waiver

- General information
- Type of certificate (CoW)
- Setting (pharmacy)
- Hours of testing
- Number of sites
- Approx. number of tests per year
- Name, address and signature of “laboratory director”
CLIA Certificate of Waiver

• Both forms must be completed for each pharmacy
• Cost
  – State registration is no charge
  – CMS registration (Form 116) is $150
• Time
  – Expect 1-3 weeks for processing
• Renew every 2 years

Idaho Board of Pharmacy. How to Obtain a CLIA Waiver and Begin Testing. 2016.
Training

• “What are the basic qualifications each pharmacist should have to be able to provide care within this new POCT service?”

• National guidelines (e.g. AHRQ App)
• Visit another pharmacy currently doing POCT
• Conferences
• Industry partnerships
POCT Certificate Program

• Community Pharmacy-Based Point-of-Care Testing Certificate
  – Supported by the National Association of Chain Drug Stores
  – 12 hours of home study; 8 hours of live training
  – Also have a train-the-trainer program
Entry Level Pharmacist Competencies

• Collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests

• Describe the need for Clinical Laboratory Improvement Amendments (CLIA) waiver and describe documentation of testing done in the community pharmacy

Accreditation Council for Pharmacy Education. Guidance for the accreditation standards and key elements for the professional program in pharmacy leading to the doctor of pharmacy degree. Available at: https://www.acpe-accredit.org/pdf/GuidanceforStandards2016FINAL.pdf.
Select a Device

- Device specifications
- Portability
- Testing procedure
  - Should be simple, fast and accurate
- Cost
  - Device, supplies, warranty
  - Lease versus buy versus share
Reimbursement

• Direct payment for the service
• Collaborating directly with third-party payers and other stakeholders
• Reimbursement for the test
  – Third party payers may pay for this
• Reimbursement for the pharmacists time

Develop Materials

• Standard Operating Procedures
  – Care of the machine
  – Testing procedure
  – Quality assurance testing
  – Documentation
  – Patient and provider follow-up and communication

• Checklists
Goals of the Program

• Develop short and long term goals
  – Specific, measurable, achievable, realistic, time-bound
  – “By November 30, 2017 5% of patients born between 1945 and 1965 with a prescription fill in the past 6 months will have had a hepatitis C screening test at our pharmacy.”

• Develop a timeline
  – Consider budget, staffing, competing priorities, etc.
<table>
<thead>
<tr>
<th>Task or Action</th>
<th>Person Responsible</th>
<th>Date Due</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWOT Analysis</td>
<td>Brett</td>
<td>6/1/2017</td>
<td>Yes</td>
</tr>
<tr>
<td>CLIA Certificate of Waiver</td>
<td>Brett</td>
<td>7/15/2017</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Workflow Redesign</td>
<td>Susan</td>
<td>7/15/2017</td>
<td>Yes</td>
</tr>
<tr>
<td>SOPs and Training Material</td>
<td>Joe</td>
<td>8/1/2017</td>
<td>Yes</td>
</tr>
<tr>
<td>Device Purchase</td>
<td>Brett</td>
<td>8/1/2017</td>
<td>No</td>
</tr>
<tr>
<td>Staff Training</td>
<td>Susan</td>
<td>8/15/2017</td>
<td>No</td>
</tr>
<tr>
<td>Marketing</td>
<td>Joe</td>
<td>9/1/2017</td>
<td>No</td>
</tr>
</tbody>
</table>
Documentation and Patient Visits

• Don’t recreate the wheel....
  – Ask other pharmacies doing POCT, consult potential payers, etc.
• Electronic versus paper
• Consent forms with HIPAA statement
• Medical history form
• Documentation of encounters form
Collaboration

• Consider collaborating with a local physicians office or health department on certain initiatives
  – Collaborative practice agreements
  – Standing orders
  – Implementation of treatment protocols
Implementation

• “Who is my target audience?”

• Marketing
  – Signage, messages on receipts, mailers, bag stuffers, etc.
  – Personal marketing (staff and customers)
  – Community-wide advertising

• Ask patients who receive POCT how they heard about the service and why they utilized the service
Evaluate the Program

• Continuous Quality Improvement
• Process versus patient outcomes
  – Evaluate each step of process
  – Patient satisfaction survey, chart review
  – Financial
• Feedback from stakeholders
  – What works, what needs improved
• Use students!!!
Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?

Act

Plan

Study

Do
Useful Resources

• Centers for Disease Control and Prevention
  – Ready? Set? Test!
  – To Test or Not to Test
  – MMWR R&R Good Laboratory Practices for Waived Testing Sites
Selected References

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