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

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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


Literature Review

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 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
- 17/21 sites planned to continue HIV testing


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
  - **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?

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**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

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**Workflow Diagram**

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**Research and Organize**

- 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

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

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.
Timeline

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<th>Person Responsible</th>
<th>Date Due</th>
<th>Completed</th>
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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!!!
Useful Resources

• Centers for Disease Control and Prevention
  – https://www.cdc.gov/clia/Resources/WaivedTests/
  – 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.


• Burley E, Klepser S, Klepser M. Opportunities for pharmacists to improve access to primary care through use of CLIA-waived tests. Mich Pharm. 2014;52(2):8–11.


