Point of Care Testing Opportunities in Pharmacy

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What is point of care and rapid diagnostic testing
Describe the difference
Explain the need
Why Pharmacy
Barriers to implementation
What to expect
Point of Care Testing

* Robust test performed outside a laboratory
* Conducted at or near the site of the patient
* Provides a rapid and reliable result
* Results aids in
  * Disease screening
  * Diagnosis
  * Patient monitoring

**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
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

Current Approved Tests

* Subset of more commonly seen POCT within 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:

Current CLIA Landscape

* CLIA Waived Tests
  - As of May 2015
  - 18% of pharmacies are conducting CLIA waived tests

Top CLIA-waived facilities in the U.S.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Office</th>
<th># of Facilities</th>
<th>% of Facilities CLIA-Waived Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Physician Office</td>
<td>122,634</td>
<td>61.90</td>
</tr>
<tr>
<td>2</td>
<td>Skilled Nursing Facility/Nursing Facility</td>
<td>14,948</td>
<td>99.13</td>
</tr>
<tr>
<td>3</td>
<td>Home Health Agency</td>
<td>14,467</td>
<td>99.85</td>
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<tr>
<td>4</td>
<td>Pharmacy</td>
<td>10,838</td>
<td>99.85</td>
</tr>
<tr>
<td>5</td>
<td>Hospital</td>
<td>9,060</td>
<td>20.87</td>
</tr>
</tbody>
</table>

Percentage of Pharmacies with CLIA-Waivers by State

Projects supporting POCT & RDT

* Project IMPACT: Hyperlipidemia
* Project IMPACT: Diabetes
* HIV Rapid Diagnostic Test Study
* Pharmacy Based Influenza
Case Study – Cholesterol - 2000

* **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%

Case study- Diabetes - 2013

* **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).
Case study – HIV - 2014

* **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.

**Pharmacy Based Influenza**

**Case Study – Influenza - 2014**

* **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.

The Need in Healthcare

* CDC Reports...
  * >8.1 million people have undiagnosed diabetes
  * >150,000 have undiagnosed HIV

* 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/mmwr/preview/mmwrhtml/mm6424a2.htm#Tab1
http://www.cdc.gov/features/HepatitisCTesting/
The Need in Healthcare

* Diabetes
  - Treatment is more complicated the longer a patient goes untreated.
  - Annual treatment costs exceed $116 billion.
  - Can be identified by determining a Hgb A1C

* Hyperlipidemia
  - 8% of the population of the United States has an undiagnosed dyslipidemia.
  - Many more are not managed appropriately.
  - Primary risk factor for heart attack and stroke
The Need in Healthcare

* HIV
  - Estimated that 240,000 individuals in the United States are undiagnosed with HIV.
  - These individuals tend to have a poorer prognosis and can spread infection.
  - CDC recommends that everyone in the United States be tested for HIV at least once.

* Influenza
  - 3,000 – 49,000 people die each year from influenza in the United States.
  - Most cases are not identified in time to treat (48 hour window).
  - Early diagnosis and treatment reduces complications and transmission.
The Need in Healthcare

- **Streptococcal Pharyngitis**
  - 15 million visits for acute pharyngitis each year in the United States.
  - 1.8 – 3.6 million (5%-15% adults and 20%-30% children) cases of streptococcal pharyngitis.
  - More than 60% of adults with pharyngitis receive an antibiotic.
  - Annual economic burden is $224-$539 million.
  - Early identification and treatment reduces complications and transmission

Centers for Disease Control and Prevention JAMA 2014; 174:139-140
Why Pharmacy?

* Access to care
* Pharmacists qualification
* Cost
Access to Care

* Estimated 225,000 active pharmacists in the United States in 2010.
  • 208,000 primary care physicians
  • 30,000 physician’s assistants
  • 56,000 nurse practitioners
* By 2030 it is projected that there will be 368,000 active pharmacists.
* 59,000-67,000 community pharmacies in the United States.
* 92% of Americans live within 1.6 miles of a pharmacy.

Access to Care

* Estimated to be 13 billion pharmacy visits annually.
  • 470 million annual physician office visits.
  • 3,700-4,000 visits per pharmacy each week (530-570 daily).
* Not all visits are for an identifiable medical purpose.
* Many patients come into pharmacies each day with asymptomatic forms of diseases like diabetes, hyperlipidemia, and hypertension.

MTM – Medication Therapy Management

Current Pharmacy practice calls upon pharmacists to help manage patients’ medications to optimize therapy and avoid drug misadventures with limited information.

* Serum creatinine
* Liver function
* Serum electrolytes
* INR
* TSH
* A1C
Pharmacist Qualification

- **CAPE 2013 Educational Outcomes**
  
  **Domain 2 – Essentials for Practice and Care**
  
  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 Standards 2016**
  
  Evaluation of patient function and dysfunction through the performance of tests and assessments leading to objective (e.g., physical assessment, health screening, and lab data interpretation) and subjective (patient interview) data important to the provision of care.

- **National Association of Boards of Pharmacy - NAPLEX**
  
  **Area 1 Assess Pharmacotherapy to Assure Safe and Effective Therapeutic Outcomes**
  
  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.
Pharmacist Qualification

* Current Pharmacy Practice
  * Pharmacists routinely gather data about patient symptoms and ailments and make recommendations regarding OTC products or refer patients.
  * Many pharmacies currently offer some point-of-care testing or disease screening/monitoring services
Disease State Management

- Owing to existing infrastructure and availability, pharmacists are a cost-effective resource for disease screening and management.
- Cost for Access
  - ER visit - $406
  - Hospital Clinic - $245
  - Physician Office Visit - $89
  - Pharmacy Visit - $0
- Patients trust pharmacists and recognize their accessibility.

Cost

* Antibiotic stewardship
  - Group A Strep
    - More than 60% of adults with pharyngitis receive an antibiotic
    - Only 20 to 30% of children with acute pharyngitis have GAS;
      5 to 15% in adults

* Antiviral initiation
  - Early diagnosis and treatment reduces complications and transmission
  - Treat with neuraminidase inhibitor within 48 hours or less
Barriers to implementation

* Economic
* Training
* Laws and Policy
* Time in current pharmacy models
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 Medicare, 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
* 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

* Programs developed to meet the need
  - APhA Certificate Training Programs
  - NACDS Point-of-Care Testing Program
  - APhA ADAPT – Online patient care skills development program for practicing pharmacist in all settings
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
- Currently New York and Rhode Island are not able to provide POCT

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

According to a recent time and motion study of a POC testing program, the average time to complete the entire patient encounter for an influenza assessment utilizing a POC test was 35.5 minutes. On average, the pharmacist spent 9.4 minutes per encounter or about 26.5% of the entire encounter.

- When the pharmacy technician collected the vital signs, the pharmacist-required time was reduced to 4.95 minutes.
What can we Expect?

* Pharmacists’ use of POCT to collect patient information will increase dramatically over the next 5-10 years.
* POCT will become commonplace like pharmacy-based immunizations.
* Pharmacists will serve as key providers in the identification of disease activity.
Questions??