The Present and Future of Infectious Disease Management

Michael Klepser, Pharm.D., FCCP, FIDP
Professor
Ferris State University
College of Pharmacy
Disclosures

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:

**Affiliation/Financial Interest:**

- **Grant/Research Support:**
  - National Association of Chain Drug Stores Foundation
  - Roche Diagnostics

**Consultant:**

- Arkray Diagnostics
- Lexi-Comp
- ScriptGuide Rx

**Advisory Board:**

- National Association of Chain Drug Stores Foundation
- POCT Certificate
CPE Information

- Target Audience: Pharmacists
- ACPE#: 0202-0000-19-080-L04-P
- Activity Type: Knowledge-based
Pharmacist Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

1. Propose best practices for community pharmacist management of infectious diseases.
2. Assess the potential benefits and risks of community pharmacist management of infectious diseases in the outpatient setting.
3. Summarize safety and efficacy data from community pharmacy-based infectious diseases management programs.
4. Design a business model to support community pharmacist management of infectious diseases and identify potential payment for services.
Assessment Questions

1. Where would be a good place to look for examples of evidence-based community pharmacy focused management protocols?
   A. The CMS website
   B. The Idaho Board of Pharmacy website
   C. The CDC webpage on collaborative practice
   D. Klepser’s Facebook page
2. Currently, who is most likely to pay for community pharmacy disease management services?

A. Private insurance companies
B. Medicaid
C. Patients
D. Nobody
3. Which of the following sources highlights that all pharmacists should have the skills necessary to offer infectious diseases disease management services?
   A. JACHO accreditation standards
   B. The CDC White Paper on community pharmacy innovations
   C. ACPE accreditation standards
   D. White House Strategic Plan on Combating Drug-Resistant Bacteria
4. Which of the following conditions would make the most sense to develop a pharmacy disease management program for?
   A. HIV
   B. Uncomplicated UTI’s
   C. Pneumonia
   D. The common cold
Pharmacists are providing care to patients with minor ailments. 

Overview

The Clinical Community Pharmacist (CCP) is the newest patient care development for pharmacists practicing in community pharmacies. Using collaborative drug therapy agreements, pharmacists can help their patients with minor ailments and conditions to receive timely care. More than offering a screening, or recommending an OTC, this allows pharmacists to utilize protocols to prescribe therapies for patients in acute situations to reduce urgent care and emergency room visits.

The Clinical Community Pharmacist Service is a tool to allow community pharmacists to meet the urgent needs of their communities. The clinical community pharmacist can provide after office hours and weekend care for their community, and care for their patients closer to home.

Disease states included in the Clinical Community Pharmacist Training

- Allergic rhinitis treatment
- Anaphylaxis (treatment of acute condition, and refill epinephrine autoinjectors)
- Bronchospasm (treatment of acute conditions, and provision of fast acting beta agonist refill)
- Burns
- Emergency Refills for insulin, contraception, inhalers and epinephrine auto-injectors
- Headaches (including prescribing triptans)
- Human, canine and feline bite prophylaxis
- Insulin refills
- Oral fluoride
- Herpes zoster treatment
- Insect sting treatment
- Swimmer's ear treatment
- Urinary tract infection (UTI) treatment
- Vaginal yeast infection treatment

Cold sores: To provide treatment for low-risk patients 16 years of age with recurrent herpes labialis who present with prodromal symptoms that are typical of a cold sore; or a lesion that is typical of a cold sore that has lasted ≥48 hours.

Seasonal influenza treatment: To provide treatment of influenza for low-risk patients 16 years of age exhibiting influenza-like illness for ≥48 hours or who test positive to a CLIA waived test for influenza, in consideration of the Infectious Diseases Society of America (IDSA) guidelines.

Seasonal influenza prophylaxis: To provide prophylactic therapy to high-risk household contacts of a patient being treated for active influenza in accordance with guidelines of the Centers for Disease Control and Prevention. Eligible patients include those ≥65 years of age who meet at least 1 of a list of designated criteria.

Group A streptococcal pharyngitis (Strep Throat): To provide treatment of group A streptococcal (GAS) pharyngitis for low-risk, symptomatic patients in consideration of the IDSA clinical guidelines. Eligible patients must be between 6 and 45 years old and score ≥2 on the Center Score and test positive to a CLIA waived test indicated for GAS pharyngitis.

Uncomplicated urinary tract infections (UTI): To provide timely and accessible treatment of uncomplicated urinary tract infections (UTI) for low-risk patients in accordance with the clinical guidelines of the IDSA or the American Congress of Obstetricians and Gynecologists. Eligible women must be ≥18 years old and have at least 2 of the following symptoms: dysuria, urinary frequency, urinary urgency, or suprapubic pain.

Sections for Patients with Diabetes: To reduce cardiovascular risk in accordance with the guidelines of the American College of Cardiology/American Heart Association. Eligible patients include those between the ages of 45 and 75 years who report a previous diagnosis of diabetes.
Practice Innovation?

Has This Ever Happened to a Pharmacist?

Florence comes into the pharmacy and asks to talk to the pharmacist because:

1. She has a rash on her back and wants to know what she should do about it.
2. Has a cough and wants to know what she should take for it.
3. Has a fever and wants to know if she should see her doctor.
4. Her legs are swollen and painful and wonders what you can recommend.
But Pharmacists Are not Qualified to:

- Conduct a physical exam
- Collect vital signs
- Interpret laboratory tests
- Develop a differential diagnosis
- Select a drug regimen to treat a condition

Are they?
Pharmacists Are not Qualified to:

<table>
<thead>
<tr>
<th>Element</th>
<th>Required Elements of the Didactic Doctor of Pharmacy Curriculum and Expected Competency for NAPLEX</th>
</tr>
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These elements constitute approximately 67% of the NABPLEX.

Pharmacists are Qualified

- Pharmacists are qualified to manage patients with various illnesses.
  - Skills and competencies are required by ACPE and assessed by the NAPLEX.
- Why is pharmacist management of ailments being touted as novel?
  - State regulations and practice acts limit pharmacy practice.
  - Groups outside pharmacy are not familiar with contemporary pharmacy education.
Infectious Diseases Affect Millions

- 60%-80% of antibiotic use in the United States occurs in the outpatient setting
- 13% of all physician office visits result in the prescribing of an antibiotic.
  - Translates into 154 million antibiotic prescriptions
  - 30% of antibiotic prescriptions are unnecessary
- High rates of misuse.
- 1 in 3 antibiotics is unnecessary
  - 80% of adults with rhinosinusitis and >60% of adults with pharyngitis get antibiotics

Antibiotic resistance threats in the United States, 2013, Center for Disease Control and Prevention
Public Health Agency of Sweden and National Veterinary Institute
Outpatient Infections Prone to Misuse of Antibiotics

- Upper respiratory tract infections
- Urinary tract infections
- Pneumonia
- Skin and skin structure infections

https://www.cdc.gov/niosh/topics/indoorenv/moldsymptoms.html
Pharmacists Can Help

• 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.
  • 530-570 visits per pharmacy each day.
• Educated to manage acute medical conditions.

# Risks and Benefits of Pharmacy Disease Management Programs

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Pharmacy</th>
<th>Patient</th>
<th>Physician</th>
<th>Health Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk</strong></td>
<td>Liability • Time away from dispensing</td>
<td>Out of pocket cost</td>
<td>Potential lost revenue • Liability</td>
<td>Overuse of services</td>
</tr>
<tr>
<td><strong>Benefit</strong></td>
<td>New revenue • Professional satisfaction • Patient satisfaction</td>
<td>Convenient • Less costly • Increased access to care • Improved satisfaction</td>
<td>Ability to see patients who need expertise • Extend reach to patients</td>
<td>Lower costs • Improved use of antibiotics</td>
</tr>
</tbody>
</table>
Scope of Practice

• **This should not be a scope of practice issue!**
  • Pharmacists are trained to do this.
  • Pharmacists have been doing this.
  • Pharmacists are not diagnosing they are following a protocol/algorithm.

• **This is a pharmacy rules and regulations issue**
  • States permit or prohibit actions by pharmacists.
  • Many states have been too prescriptive developing rules and regulations.
  • Go home and challenge your Board of Pharmacy to clean up its pharmacy practice act and ensure that policies reflect contemporary pharmacy practice. Nothing changes without a champion.
The comprehensive pharmacy service is enabled by action on the result of the test, either through CPA or independent prescribing.
Basis for the Pharmacist’s Authority

Collaborative Prescribing

- Patient-Specific CPA
- Population-Specific CPA (18 states)

Autonomous Prescribing

- Statewide Protocol
- Unrestricted (Category-Specific)

Most Restrictive  Least Restrictive

Best Practices for Developing Infectious Diseases Management Services

• Partnership between pharmacy and physicians and/or public health
  • Establish an evidence-based collaborative practice agreement
  • Enable provision of follow-up care
• CLIA-waived POC tests

• Trained personnel
  • NACDS POC certificate program for pharmacists
  • WSPA CCP training
  • APhA programs
  • Informatics
• Plan for patient follow-up
• Data sharing plan
• Good business plan
Opportunities for ID POCT in Pharmacies

Acute Conditions

• Conjunctivitis
• Vaginosis
• Sexually transmitted infections
• Lyme Disease
• Viral respiratory infections
• Urinary tract infections
• Skin infections
• Mononucleosis
• Traveler’s diarrhea
• GI parasites
• Priority pathogens (bioterrorism)

Screening

• Hepatitis A/B/C
• HIV
• *H. pylori*
• Malaria
• Zika virus
• West Nile virus

Recognizing a Good Business Opportunity

- Fundamentally a product or service must fill a real or perceived need.
  - Consumers’ core jobs/interests do not change.
  - How a core job/interest is fulfilled does change.

Thirst is a fundamental need. Quenching thirst is an interest.
What Makes a Good Business Opportunity?

• The product/service meets a need.
  • Market inefficiency.
  • Remove a key barrier or hassle.
  • Customers want something new.
  • Make solutions simpler, more convenient, and cheaper.

• The product/service will work at your location.

• You have the resources available to succeed.
  • Financial, physical, personnel, customers
What Makes a Good Business Opportunity?

• You can offer the product/service at a reasonable price.
  • Need to be able to meet the need of the consumer at a price they will pay and still make a profit.
    • Customers will pay for things that they believe add value or satisfy a need.
    • Healthcare is tricky because of insurance. Many customers are used to paying nothing.
• The timing is right in terms of the market and resources.
  • Market and competitor analyses
    • Who else is providing the product/service and at what price?
    • Is the market growing or shrinking?
    • Are there barriers to entering the market?
    • Be able to tailor a product/service rather than force it.
    • Are consumers ready for your product/service?
Opportunities for ID POCT in Pharmacies

Acute Conditions
- Conjunctivitis
- Vaginosis
- Sexually transmitted infections
- Lyme Disease
- **Viral respiratory infections**
- **Urinary tract infections**
- Skin infections
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Screening
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- HIV
- *H. pylori*
- Malaria
- Zika virus
- West Nile virus

Infectious Diseases Affect Millions

• Influenza
  • In 2016-17, it was estimated that 30,900,000 individuals in the United States were infected with influenza resulting in 14,500,00 medical visits. Estimated to have cost the health system >$10 billion dollars.
  • A survey reported that 69% of patients went to the pharmacy because of their illness.

• Acute Pharyngitis
  • Acute pharyngitis results in >40 million medical visits annually.
  • Most are caused by viruses.
  • Identified as one of the most common conditions for which antibiotics are inappropriately used in the outpatient setting.

Infectious Diseases Affect Millions

- Uncomplicated Cystitis
  - Results in 10.5 million office visits (0.9% of all ambulatory visits) and 2-3 million ED visits in the United States annually.
  - Uncomplicated infections occur annually at an incidence of 102 per 100,000 women.
  - Estimated that 85%-95% of women with a recurrent UTI can reliably self-diagnose.
  - Associated with $3.5 billion in health care costs annually.

Impact of Common infections

• Management of influenza, acute pharyngitis and uncomplicated UTIs
  • Consumes billions of dollars of health care resources annually.
  • Results in shifting of ambulatory care resources and delays access to care.
  • Needlessly exposes at risk populations to viral infections.
The Idaho Patient Assessment Protocol Model

• This legislation did not give pharmacists the authority to diagnose.
• Provided criteria that allows them to prescribe and dispense a medication.
• Format:
  • Purpose
  • Patients eligible for treatment
  • Patients ineligible for treatment
  • Guidance for follow-up with the patient
Evidence Supporting Management of Influenza

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
• 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.

Influenza Model

• **Purpose:**
  • To provide accessible and timely treatment of influenza for low-risk patients in consideration of the clinical guidelines of the Infectious Diseases Society of America (IDSA).

• **Patients Eligible for Neuraminidase Treatment Under this Protocol (Inclusion Criteria):**
  • Patients 6 years of age or older exhibiting signs of influenza-like illness (e.g., fever, cough, sore throat, nasal congestion, muscle/body aches, etc.) for 48 hours or less who test positive to a CLIA-waived test indicated for influenza.

Influenza Model

• Patients Ineligible for Neuraminidase Treatment Under this Protocol (Exclusion and Referral Criteria):
  • Patients exhibiting signs of influenza-like illness (ILI) for greater than 48 hours
  • Patients who report they are pregnant or breastfeeding
  • Patients who report they are immunocompromised by medication or condition
  • Patients who have one or more of the following:
    • Systolic hypotension <100mgHg
    • Tachypnea >25 breaths/min (>20 breaths per minute for patients <18 years)
    • Tachycardia >100 beats/min (>119 beats/min for patients <18 years)
    • Oxygenation <90% via pulse oximetry
    • Body temperature >103°F (>102°F for patients <18 years)

Influenza Model

• **Patients Ineligible for Neuraminidase Treatment Under this Protocol (Exclusion and Referral Criteria, continued):**
  
  • Patients who report any of the following:
    
    - History of renal dysfunction
    - History of allergic reaction to any previous neuraminidase therapy
    - History of psychologic side effects from any previous neuraminidase therapy
    - Use of antiviral therapy in past 4 weeks

• **Follow-up within 48 hours after initial interaction to determine efficacy of treatment initiated or need for referral.**

Evidence Supporting Management of GAS Pharyngitis

A feasibility service evaluation of screening and treatment of group A streptococcal pharyngitis in community pharmacies

T. Thornley1,2, G. Marshall3, P. Howard4 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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J Antimicrob Chemother
doi:10.1093/jac/dkw264
# Evidence Supporting Management of GAS Pharyngitis

<table>
<thead>
<tr>
<th>Study</th>
<th>Program Details</th>
<th>Number of Patients Treated/Screened</th>
<th>Key Findings</th>
</tr>
</thead>
</table>
| Klepser     | • Adult patients  
• Collected vitals  
• Calculated a Centor score  
• Used a POCT  
• No cost to patient | 48/316 (15.2%)                     | • 37% did not have a PCP  
• 44% used service outside physician office hours  
• High patient satisfaction |
| Thornley    | • Patients ≥12 years  
• Collected vitals  
• Calculated a Centor score  
• Used a POCT  
• Charged £7.50 ($10.00 USD) | 36/367 (24.2%)                     | • Payment did not appear to be a barrier  
• 88% would have self-treated or gone to physician if service not available |
| Papastergiou| • Retrospective  
• Patients ≥ 5 years  
• Used POCT  
• Charged $20 | 1,318/7,050 (18.7%)                 | • 86% would have gone to a clinic, physician, or ER if service was not available  
• Patient satisfaction was 80% |
Group A Streptococcal Pharyngitis Model

• Purpose:
  • To provide accessible and timely treatment of group A streptococcal (GAS) pharyngitis for low-risk patients in consideration of the clinical guidelines established by the Infectious Diseases Society of America (IDSA).

• Patients Eligible for Antibiotic Therapy Under this Protocol (Inclusion Criteria):
  • Symptomatic patients between the ages of 6 and 45 who score a 2 or higher on the Centor Score and then test positive to a CLIA-waived test indicated for GAS pharyngitis.

Group A Streptococcal Pharyngitis Model

• Patients Ineligible for Neuraminidase Treatment Under this Protocol (Exclusion and Referral Criteria):
  • Patients younger than 6 years of age or older than 45 years
  • Patients who received antibiotic therapy within the previous 30 days
  • Patients who report they are pregnant or breastfeeding
  • Patients who report they are immunocompromised by medication or condition
  • Adult patients who have one or more of the following
    • Systolic hypotension <100mgHg
    • Tachypnea >25 breaths/min (>20 breaths per minute for patients <18 years)
    • Tachycardia>100 beats/min (>119beats/min for patients<18years)
    • Oxygenation <90% via pulse oximetry
    • Body temperature >103°F (>102°F for patients <18 years)
    • History of renal dysfunction

Group A Streptococcal Pharyngitis Model

• Follow-up within 48 hours after initial interaction to determine efficacy of treatment initiated or need for referral.
Evidence Supporting Management of Uncomplicated Urinary Tract Infections

Outcomes of Urinary Tract Infection Management by Pharmacists (RxOUTMAP): A study of pharmacist prescribing and care in patients with uncomplicated urinary tract infections in the community

Antibiotic treatment of urinary tract infection by community pharmacists: a cross-sectional study
## Evidence Supporting Management of Uncomplicated Urinary Tract Infections

<table>
<thead>
<tr>
<th>Study</th>
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</tr>
</thead>
</table>
| Beahm | • New Brunswick (authority to prescribe)  
• >19 years with signs consistent with uncomplicated UTI  
• Nitrofurantoin 100 mg BID x 5 days  
  • Alternatives: trimethoprim/sulfamethoxazole, fosfomycin, cefuroxime axetil | 656 | • Mean age 41 years  
• Clinical cure 89%  
• Patient satisfaction was >80% |
| Booth | • Glasgow and Clyde (patient group direction)  
• Uncomplicated UTI (symptoms)  
• Trimethoprim 200 mg BID x 3 days | 56 | • 41/56 (73%) received trimethoprim  
• 33% of patients sought care on the weekends |
| Hind  | • Scotland (patient group direction)  
• Uncomplicated UTI aged 16-65 years (symptoms and dipstick)  
• Trimethoprim 200 mg BID x 3 days | 349 | • 299/349 (86%) received trimethoprim  
• Dipstick not required if patient has dysuria and frequency  
• 90% of patients seen within 10 minutes  
• 35% of patients sought care on weekends |

Uncomplicated Urinary Tract Infection Model

• **Purpose:**
  • To provide accessible and timely treatment of uncomplicated urinary tract infections (UTI) for low-risk patients in consideration of the clinical guidelines of the Infectious Diseases Society of America or the American Congress of Obstetricians and Gynecologists.

• **Patients Eligible for Treatment Under this Protocol (Inclusion Criteria):**
  • Women aged 18 or older who present with at least two of the following symptoms: dysuria, urinary frequency, urinary urgency, or suprapubic pain.

Uncomplicated Urinary Tract Infection Model

• Patients Who Must Be Referred By the Pharmacist to a More Appropriate Venue of Care (Exclusion and Referral Criteria):
  • Men
  • Women who meet or report one or more of the following:
    • Under the age of 18
    • Pregnant
    • Post-menopausal
    • Immunosuppressed by medication or condition
    • No previous history of uncomplicated UTI
    • Has had previous antibiotic therapy within the past 4 weeks
    • Has had surgical changes or birth defects relevant to the urinary tract
    • Has undergone urinary tract instrumentation in the past 4 weeks or has any current catheterization

Uncomplicated Urinary Tract Infection Model

• Women who meet or report one or more of the following (continued):
  • Has or reports any symptoms suggestive of systemic illness, including:
    • Fever
    • Sweating
    • Flank pain
    • Shaking chills
    • Nausea
    • Vomiting
    • Systolic hypotension <100 mgHg
    • Tachypnea >25 breaths/min
    • Tachycardia >100 beats/min
    • Oxygenation <90% via pulse oximetry
    • Body temperature >103°F
  • Abnormal vaginal discharge or other symptom suggestive of a sexually transmitted infection
  • Poorly controlled diabetes

Best Practices for Developing Infectious Diseases Management Services

- Partnership between pharmacy and physicians and/or public health
  - Establish an evidence-based collaborative practice agreement
  - Enable provision of follow-up care
- CLIA-waived POC tests

- Trained personnel
  - NACDS POC certificate program for pharmacists
  - WSPA CCP training
  - APhA programs
  - Informatics
- Plan for patient follow-up
- Data sharing plan
- Good business plan
Sustainability and Payment

• Sustainability
  • Know your patient population – what services do they want
  • Find a champion and conduct a pilot project
  • Have a clearly articulated mission
  • Know your price point
  • Do not bite off too much at one time

• Payment
  • CASH – patients pay for convenience
  • Health savings accounts
  • Insurance companies – probably in the future
Community pharmacy-based management of infectious diseases has been going on for decades.

Data are readily available demonstrating that pharmacists can safely and effectively manage patients for influenza, GAS pharyngitis, uncomplicated UTI and other conditions.

Push your boards of pharmacy to push to allow for contemporary practice to occur.
1. Where would be a good place to look for examples of evidence-based community pharmacy focused management protocols?
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