Novel Community Pharmacy Service

“Tamiflu Clinic”

About the Authors

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Pre-Assessment Questions

1. Tamiflu® (oseltamivir) is the most effective when initiated within how many hours of onset of symptoms? SELECT THE MOST APPROPRIATE ANSWER.
   A. 12 hours
   B. 36 hours
   C. 48 hours
   D. 72 hours

2. Within how many hours from the onset of symptoms must patients present to the pharmacy to be eligible to obtain oseltamivir?
   A. 36 hours
   B. 48 hours
   C. 72 hours
   D. 120 hours

3. Initiating Tamiflu Clinic in the community pharmacy would be beneficial for which of the following reasons?
   A. Increase accessibility to oseltamivir
   B. Increase the pharmacists’ presence in the community
   C. Control influenza transmission
   D. All of the above
Learning Objectives

• Describe annual direct and indirect costs associated with influenza illness in the U.S.
• Describe efficacy of Tamiflu® (oseltamivir) in 12 and 48 hours of symptoms onset
• Describe steps necessary to start “Tamiflu” Clinic in a community pharmacy setting
• Assess a patient presenting with influenza-like symptoms to determine eligibility for Tamiflu® (oseltamivir)
• Discuss billing and reimbursement

Background

• Influenza (“flu”) is a highly contagious respiratory illness
• Caused by a variety of influenza viruses that infect the nose, throat, and lungs
  – 5-20% of people in the U.S. get the flu each year
  – ~31.4 million outpatient visits per year
  – > 200,000 of these visits resulting in hospitalizations

Background cont.

• The flu kills 3,000 - 49,000 people annually in the US
• Annual costs
  – $10.4 billion in direct medical expenses
  – Additional $16.3 billion in lost earnings
Background cont.

- Vaccination can ↓ the risk of contracting the flu ~ 50% to 60%
  - 32% of adults aged 18–49 receive annual flu vaccine
  - 48% for adults 50–64 years
  - 69% for adults 65 and older
- Seasonal vaccine effectiveness can vary
  - 2015-16 ~ 19%
  - 2016-17 ~ 47%
  - 2017-18 ~ <30%

Vaccination Effectiveness Studies 2005-2016

Background cont.

- Most people that get the flu only require rest and plenty of fluids
- Some patients may benefit from oseltamivir
- Can reduce the total duration of illness by greater than three days if taken within 12 hours of onset
  - Can reduce total duration of illness by one day if taken at 48 hours after the onset of symptoms

Oseltamivir MOA

- Reversible competitive inhibitor of influenza neuraminidase
- Blockade of enzyme inhibits virion release from infected cells and spread within the respiratory tract
- Influenza A > Influenza B
Tamiflu® (oseltamivir) Indication

- Patients 2 weeks of age and older
- Uncomplicated illness due to influenza A & B
- Symptomatic for no more than 48 hours

Oseltamivir Side Effects

- Nausea, vomiting, headache and skin rashes
  - Nausea and vomiting were reported to occur between 3.7 to 4.7% more than placebo
- Other than GI side effects, it is well tolerated
Access to Care

- Shortage of PCPs and the long average appointment-waiting period prevents patients from obtaining the medication in a timely manner
  - Average appointment wait time for a PCP is 19.5 days
  - Average ED wait times ~ 30 min
    - Treatment times ~ 90 min
  - Urgent care wait time ~ 30 min

1. Wait Time for Treatment in Hospital Emergency Departments.
2. Urgent Care Association of America. "2012 Urgent Care Benchmarking Survey Results."
3. Healthy People 2020: Access to health services.

Additional Barriers

- Costs associated with physician appointments and ER/urgent care visits
  - Median cost ~ $1,233
  - Urgent care average cost ~ $50 - $150

2013 National Institute of Health study.

Community Pharmacists

- Pharmacists remain the most accessible health care providers in the community
  - 90% of Americans live within 5 miles of a community pharmacy
  - Patients are able to seek help on a walk-in basis
    - Eliminates long waits to see primary health care providers or spending hours in the ER

Pharmacy Workforce Center. Pharmacy Workforce Center Aggregate Demand Index. 2011.
Pilot “Tamiflu” Clinic

• Pharmacy-based clinic initiated in 2016
• Western University of Health Science Patient Care Center (WesternU PCC) Pharmacy
• Collaboration with primary care providers

Purpose of Tamiflu Clinic

• To provide support services to physicians and healthcare providers
• Alleviate the burden of flu in the community
• Make oseltamivir accessible to patients that otherwise could not get it

Goals of Tamiflu Clinic

• Identify patients who are eligible for treatment with oseltamivir within appropriate time frame
• Provide treatment for eligible patients who are presenting with signs and symptoms of influenza
Description of the Practice Model

• Requirements necessary to initiate a “Tamiflu Clinic” in a community pharmacy
  – Establish a collaborative practice agreement (CPA)
  – Develop a procedure and screening tools
  – Obtain the proper equipment
  – Train staff on use of the equipment and workflow
  – Implement proper documentation process

SB493 and Expanded Scope of Practice

• Advance Practice Pharmacists (APh) can enter into a CPA in a community setting and perform clinical services as specified in an established protocol

Collaborative Practice Agreement

• Include specifics about:
  – Patient population
  – Medication the pharmacist will use
  – Communication steps necessary to document and inform the physician
• Stepwise procedure to provide guidance to the pharmacy staff
  – Ensure the process is integrated into the workflow

Patient Presentation

- Acute symptoms of influenza
- Going from feeling well to ill in a short period of time
- Headache, minimal nasal secretions, loss of appetite, harsh unproductive cough, sore throat, nausea and/or vomiting

Tamiflu Clinic Inclusion Procedure

- Patients 18-64 years old
- Acute symptoms of influenza
- Able to start therapy within 48 hours of symptom onset

Tamiflu Clinic Staffing

- Conducted in the community pharmacy during normal business hours
- Staffed by an APh and other pharmacy-related personnel
- Additional space is not required
Workflow

Technician/CLerk
- Provides the assessment form for patient to complete in the waiting area

APh
- Reviews the assessment form and establishes the need for testing the patient
  - Obtains consent of patient

APh
- Interprets the results and writes the order if appropriate

Pharmacy staff
- Dispenses medication to patient

Average 30 minutes

CLIA Wavers

- CLIA-waived tests are noncomplex
  - Do not require special training or licensures
- Only the facility required to have CLIA-waved certificates
  - Submit an application for laboratory status
  - Assign a laboratory director
  - An authorizing physician on the CPA
- Cost of application: $150.00 biennially

RIDT

- Personnel conducting the tests should receive training from the manufacturer:
  - Specimen collection and handling
  - Performing the test
  - Necessary clinical utility for the specific test chosen
- RIDTs provide results within ~15 minutes
- >10 RIDTs approved by FDA for influenza testing
  - Vary in sensitivity (50-70%) & specificity (90-95%)
  - Average cost is between $13.00-$15.00 per test
Test Procedure

Specimen Collection


Documentation

• If oseltamivir is initiated, documentation is faxed to the PCP
• Patient receives a copy of the assessment
• Original assessment form and Treatment Order form are kept in the pharmacy in accordance to the state law

Billing

• Pharmacists can not bill directly for CLIA-waived tests
  – During the pilot, service was initiated as “cash-only”
  – Fee covered the cost of the test and personnel time
  – Similar to a physician office visit copayment
Billing cont.

• Some insurance companies may reimburse patients
• Potential billing opportunities might be available once APh status is recognized
• Patients who receive oseltamivir also pay their copayment for the medication

Marketing and Advertising

During the pilot
• Mass emails
• Handing out flyers

In community pharmacy setting
• Information board
• Placing flyers in prescription bags

Additional marketing avenues
• Direct mailers
• Social media
• Brochures at physician’s office

Needs Assessment

• “Needs Assessment Survey on Pharmacists Provided Point-of-Care Diagnostic Testing for Influenza”
• Conducted at Western University Of Health Sciences in 2017
• Surveyed 510 WesternU students, staff and faculty members from the 11 colleges
Needs Assessment Survey

1. If you had flu-like symptoms (i.e. chills, fevers, aches), where would you most likely go to get treatment?
   a. Doctor’s office
   b. Pharmacy
   c. Urgent Care
   d. Not seeking any help
   e. I don’t know

2. How willing are you to take Tamiflu® (oseltamivir)?
   a. Very willing
   b. Somewhat willing
   c. Unsure
   d. Very unwilling

3. If you had flu-like symptoms, how willing would you be to utilize the services at the pharmacy?
   a. Very willing
   b. Somewhat willing
   c. Unsure
   d. Very unwilling

4. How much are you willing to pay to get tested if you think you might have the flu?
   a. Would not be willing to pay for the test
   b. <$30
   c. $30
   d. >$30

Participants’ History with Flu

Have you ever had the flu in the past? (n=510)

- 26% No, never had the flu
- 17% Yes, missed school/ work
- 26% Yes, less productive
- 41% Yes, not severe enough
Participant's History with Tamiflu®

Have you had any prior experience of taking Tamiflu® (oseltamivir)? (n=510)

- Taken/Helped: 36%
- Taken/Not Helped: 10%
- Not Taken/Seen: 13%
- Not Taken/Not Seen: 38%
- Not heard of Tamiflu®: 3%

Seeking Treatment

Where would you most likely go to get treatment? (n=510)

- Doctor's Office: 51%
- Urgent Care: 16%
- Pharmacy: 13%
- Will not seek any treatment: 3%
- I don't know: 31%

Participants’ Willingness

- Very willing: 244
- Somewhat willing: 154
- Unsure: 87
- Very unwilling: 25

Willingness to take Tamiflu® (oseltamivir)
Willingness to utilize the clinic
Tamiflu Clinic 2018

- 10 patients – none tested positive

Conclusion

- Public health benefit
  - Increase accessibility to oseltamivir
  - Control influenza transmission
  - Minimize duration of the flu and the costs
- Support providers
  - Decrease patient load
  - Minimize exposure to influenza
- Allow pharmacists to integrate themselves into an interprofessional patient-centered team approach
- Increase the pharmacists’ presence and impact in the healthcare arena

Post Assessment Questions

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Thank You!

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References