

Novel Community Pharmacy Service

“Tamiflu Clinic”






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**About the Authors**

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- Dr. Micah Hata, PharmD, is an Associate Professor of Pharmacy Practice and Administration at Western University of Health Sciences, College of Pharmacy. Dr. Hata has no bias or conflict of interest to report.

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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. 48hours
  - 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

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## 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



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## 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

Influenza statistics 2017. <https://www.cdc.gov/flu/> Accessed January 10 2017.



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## 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

Influenza statistics 2017. <https://www.cdc.gov/flu/> Accessed January 10 2017.



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### 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




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### 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

Dobson J, Whitley, RJ, Pocock S. Oseltamivir treatment for influenza in adults: a meta-analysis of randomized controlled trials. The Lancet. 2015;385:1729-37.




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### 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

Oseltamivir (Tamiflu®)[package insert]. San Francisco, CA .Genentech, Inc.,2016




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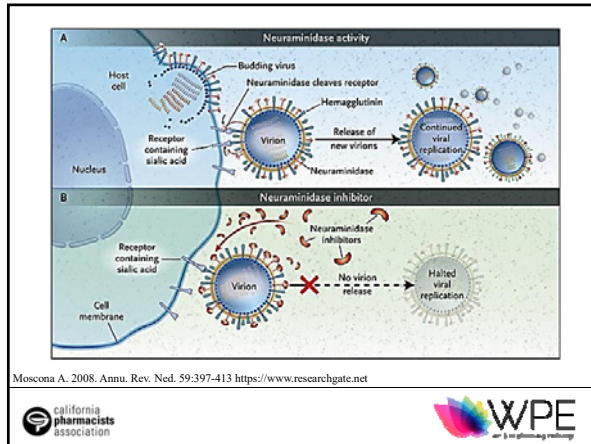
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### Tamiflu® (oseltamivir) Indication

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

Osetamivir (Tamiflu®)[package insert]. San Francisco, CA :Genentech, Inc.:2016

california pharmacists association WPE *art of pharmacy reality*

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### 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

Dobson J, Whitley, RJ, Pocock S. Oseltamivir treatment for influenza in adults: a meta-analysis of randomized controlled trials. *The Lancet*. 2015;385:1729-37.

california pharmacists association WPE *art of pharmacy reality*

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### 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.




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### 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




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### 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.




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### 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



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### 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



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### 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



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### 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




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### 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




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### 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

Hernandez E. California Senate Bill 493, Hernandez. Pharmacy Practice.; 2013.




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### 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



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### Tamiflu Clinic Inclusion Procedure

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



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### 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



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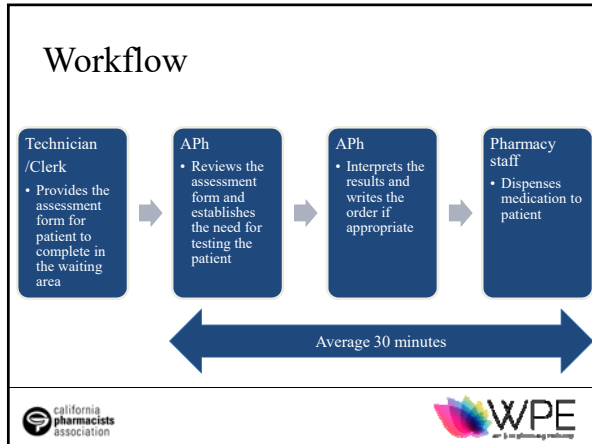
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### CLIA Waivers

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

Clinical Laboratory Improvement Amendments (CLIA) <https://www.cms.gov/RegulationsandGuidance/>

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### 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

CLIA-waived Tests <https://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm>

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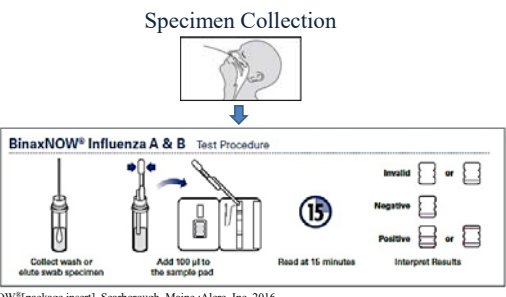
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### Test Procedure

Specimen Collection



**BinaXNOW<sup>®</sup> Influenza A & B** Test Procedure

Collect wash or elute swab specimen

Add 100 µl to the sample pad

Read at 15 minutes



Invalid or

Negative or

Positive or

Interpret Results

BinaXNOW<sup>®</sup> [package insert], Scarborough, Maine :Alere, Inc. 2016


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### 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


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### 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


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### 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



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### Marketing and Advertising

During the pilot	<ul style="list-style-type: none"><li>• Mass emails</li><li>• Handing out flyers</li></ul>
In community pharmacy setting	<ul style="list-style-type: none"><li>• Information board</li><li>• Placing flyers in prescription bags</li></ul>
Additional marketing avenues	<ul style="list-style-type: none"><li>• Direct mailers</li><li>• Social media</li><li>• Brochures at physician's office</li></ul>



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### 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



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### 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




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### Needs Assessment Survey

- 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




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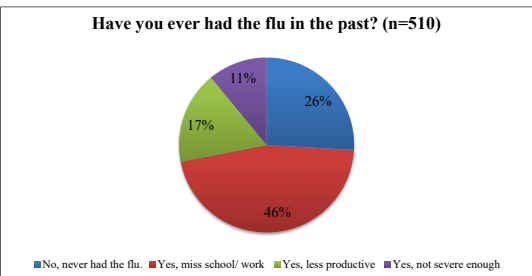
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### Participants' History with Flu




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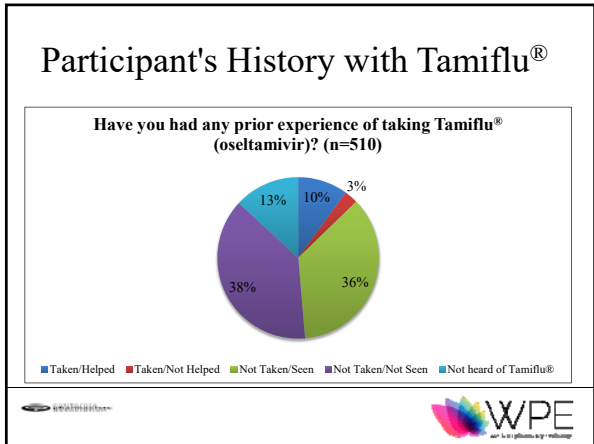
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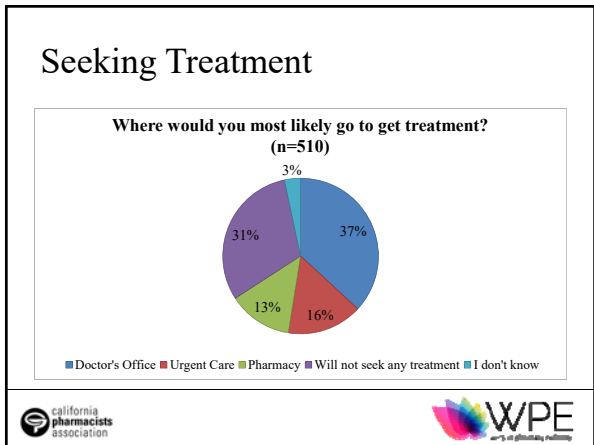
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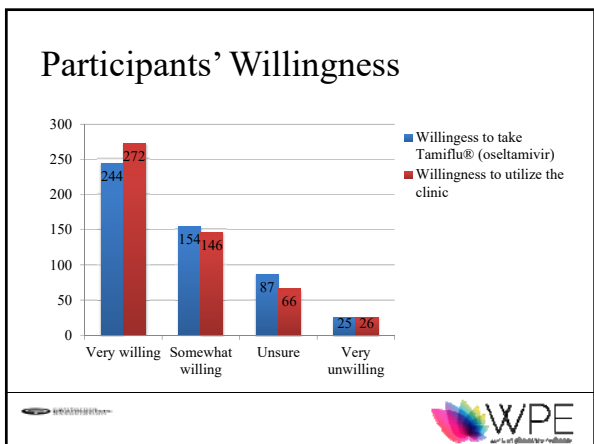
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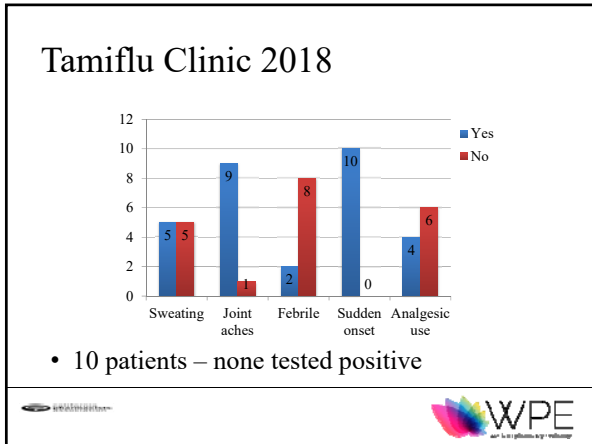
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### Conclusion

- 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



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### Post Assessment Questions

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# Thank You!

## Speaker Contact Information:

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