



UNIVERSITY OF CENTRAL FLORIDA

## Pre-Exposure Prophylaxis:

# An Overview of An Emerging Clinical Approach to Preventing HIV in High-Risk Adults

Christopher W. Blackwell, Ph.D., ARNP, ANP-BC, AGACNP-BC, CNE

*Associate Professor*

College of Nursing

University of Central Florida

Orlando, Florida

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# Disclosure

- I have no association or relationship whatsoever with any related entity, including Gilead Pharmaceuticals, the manufacturer of emtricitabine/tenofovir disoproxil fumarate (Truvada®)

# Introduction

- The FDA recently approved the HIV antiretroviral drug emtricitabine/tenofovir disoproxil fumarate as pre-exposure prophylaxis (PrEP) therapy for adults at high risk for sexually acquired HIV infection

**Truvada® Tablets**  
Each tablet contains 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, which is equivalent to 245 mg of tenofovir disoproxil.

Store at 25 °C (77 °F) (see insert).  
Keep container tightly closed. Dispense only in original container.  
See package insert for dosage and administration.

**Manufactured for:**  
Gilead Sciences, Inc.  
Foster City, CA 94404  
Made in Canada

NDC 61958-0701-1

**Truvada®**  
(emtricitabine and tenofovir disoproxil fumarate)  
**Tablets**  
30 tablets

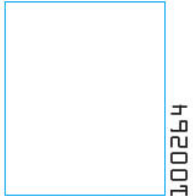
**Rx only**

DISPENSER: Each time Truvada® is dispensed give the patient the attached Medication Guide.

**GILEAD**  
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# Introduction

- To support their approval, the FDA evaluated data from several studies that assessed the use of either tenofovir disoproxil fumarate (TDF) alone or in combination with emtricitabine (FTC) as a once-daily regimen to prevent HIV in individuals at high risk.



# Clinical Trials: iPrEx

- The 2010 Preexposure Prophylaxis Initiative (iPrEx) study showed the combination regimen of FTC plus TDF was highly efficacious
- Data indicated that, in addition to a comprehensive preventive approach (providing condoms, monthly HIV testing, and risk reduction counseling), the once-daily regimen provided an additional 44% protection for the traditionally high-risk sample of men who have sex with men
- Those enrolled in the study that had detectable serum levels of the medication showed up to a 90% reduction in HIV transmission
  - This emphasized the significance of adherence



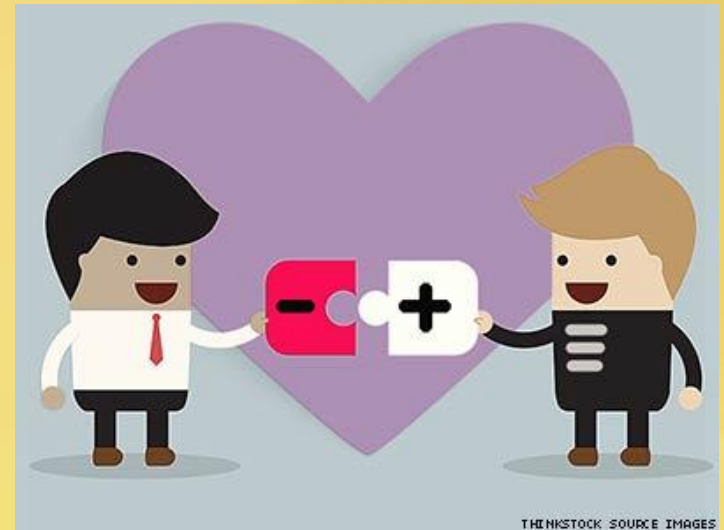
# Clinical Trials: TDF2

- The tenofovir disoproxil fumarate and emtricitabine study (TDF2) found the combination therapy was 62% effective at reducing the risk of acquiring HIV in uninfected, heterosexually active men and women
- Similar to the iPrEx study, data from the TDF2 study also indicated regimen adherence as significantly increasing its efficacy, with a 90% reduction of infection in participants with detectable serum medication levels

The logo for TDF2, featuring the letters 'TDF2' in a bold, orange, sans-serif font with a slight shadow effect, set against a white rectangular background.

# Clinical Trials: Partners 2

- Partners 2 Study:
  - Compared TDF with combination TDF and FTC
  - This trial found that among HIV serodiscordant couples (in which one partner is HIV infected and the other is not), the TDF and FTC combination reduced overall HIV transmission by 75%
  - This study also found efficacy to be equal in both men and women



# Clinical Trials: Summary of Findings

- Commonality among the studies was the finding that the efficacy of the regimen was highly related to its adherence
- The iPrEx study found a high level of efficacy variance depending on how well participants adhered to the regimen





# Clinical Trials: Summary of Findings

- Similarly, in the TDF2 study, only half of the participants taking the TDF and FTC combination became infected with HIV, and these participants were found to have very low serum levels of the drug therefore, regimen adherence is essential



# Determining Risk and Evaluation for Treatment

- Risk evaluation is salient in the determination of patients' appropriateness for PrEP therapy
- Clinicians must possess the skills necessary to obtain an appropriate sexual history from patients to assess their risk for sexually acquired HIV infection
- Approaching the subject of sexuality can be sensitive
- Clinicians should avoid any assumptions about their patients' sexual orientation and should use language that is neutral and nonjudgmental



# Determining Risk and Evaluation for Treatment

- Instead of asking “Are you married?” or “Do you have a girlfriend?” a more direct approach is preferred
- Asking the patient to “Tell me about our sexual practices” or asking “Do you have sexual relationships with men, women, or both?” are both open-ended and nonjudgmental approaches that can yield a great detail about one’s sexual history and facilitate the construction of an appropriate plan of care.



# Determining Risk and Evaluation for Treatment

- PrEP therapy is indicated for patients considered high risk for sexually acquired HIV
- Examples of such individuals might include a non-HIV-infected partner of an HIV infected individual



## **Initiation of PrEP: Pretreatment evaluation<sup>3,13</sup>**

Prior to initiation of therapy, perform the pretreatment evaluation to determine eligibility for therapy.

- Document HIV-negative antibody test:
  - Test for HIV if patient reports unsafe sex with an HIV-infected partner
  - Test for HIV if patient reports symptoms of acute HIV infection (symptoms include fever, chills, malaise, anorexia, nighttime diaphoresis, lymphadenopathy, dysphagia, nausea, emesis, diarrhea, and/or myalgia)
- In females, document a negative urine pregnancy test
- Provide education regarding possible risks of using PrEP during pregnancy
- Do not prescribe PrEP for female patients who are breastfeeding
- Confirm creatinine clearance of 60 mL/min or greater (use Cockcroft-Gault formula)
- Assess status of care in HIV-infected partners and provide referral as needed
- Screen for hepatitis B and initiate treatment when indicated
- Screen for and treat any sexually transmitted infections

# PrEP Treatment Regimen

- The PrEP dosage is one tablet (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg)
- The drug is taken orally with or without food and should be prescribed with a frequency of once daily
- In addition to the medication, which should be prescribed in no more than a 90-day supply, the patient should be educated about risk reduction strategies, particularly consistent use of condoms during every sexual encounter



## Treatment monitoring recommendations<sup>3</sup>

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- Document HIV-negative antibody test every 2 to 3 months
  - Review adherence and provide safer sex counseling at each follow-up visit
  - Screen for bacterial STIs, even if asymptomatic, every 6 months
  - In females, document a negative urine pregnancy test and counsel pregnant patient regarding possible risks if PrEP is continued
  - Assess creatinine clearance 3 months after treatment initiation and then every 6 months while on PrEP
-

# Co\$t Con\$ideration\$

- The financing of antiretrovirals for PrEP is emerging as an important healthcare policy issue
- A 2011 cost-effectiveness model by the CDC estimated the daily cost of PrEP at \$22, which equals \$8,030 per year
- Additional monitoring and screening costs per person were estimated to be \$1,300 per year.
- Unfortunately, most private insurance companies do not currently cover PrEP





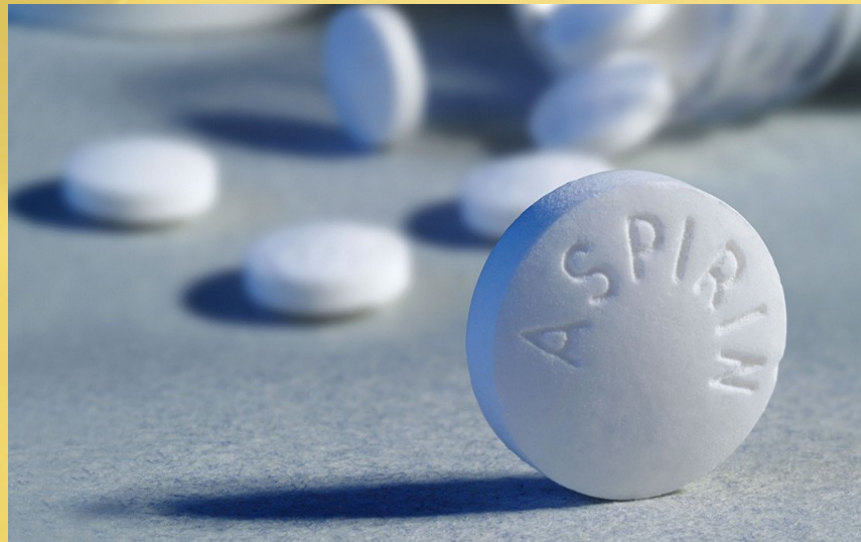
# Co\$t Con\$ideration\$

- The Patient Protection and Affordable Care Act requires insurers to cover preventive services with an A or B rating from the United States Preventive Services Task Force (USPSTF)
- Therefore, a significant step toward private insurance coverage for PrEP in the United States is to nominate it for review by the USPSTF



# Co\$t Con\$ideration\$

- However, approval of chemoprophylaxis by the USPSTF has been challenging, as the panel has only approved 2 out of 45 proposals
- Consequently, cost could continue to be a significant impedance to the implementation of PrEP in those who may need it most



# Moving Forward

- PrEP therapy with the use of FTC/TDF is a newly approved approach to preventing HIV in individuals at high risk for sexually acquired infection
- The once-daily regimen has been shown as significantly effective at preventing HIV in both men and women including heterosexual and bisexual persons



# Moving Forward

- Evaluating patient appropriateness for PrEP, performing pretreatment evaluations prior to initiation of treatment, and close monitoring of therapy are all responsibilities NPs will assume as this treatment becomes more widespread in the U.S. healthcare system.
- Cost of the therapy is also a major blockade to its implementation, and this will continue to be a prevalent issue in the foreseeable future



# How to Learn More

Blackwell, C.W. (2014). Pre-exposure prophylaxis: An emerging clinical approach to preventing HIV in high-risk adults. *The Nurse Practitioner: The American Journal of Primary Healthcare* 39(9), 50-53. DOI: 10.1097/01.NPR0000452976.92052.fa.

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