

Pre-Exposure Prophylaxis (PrEP) for HIV Infection

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Disclosures

- In the past 12 months, I and UCLA Regents have received:
 - Research funding from Gilead Sciences

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Outline

- What is PrEP
- How well does it work
- Is it safe
- How to offer PrEP
- Risk reduction counseling
- Cost and access
- Resources



What is PrEP?

- Antiretroviral medication to prevent HIV acquisition
- Emtricitabine/tenofovir (FTC-TDF)
- FDA-approved as Truvada, July 2012
- One pill, once a day



Question #1

How well does PrEP work to prevent HIV?

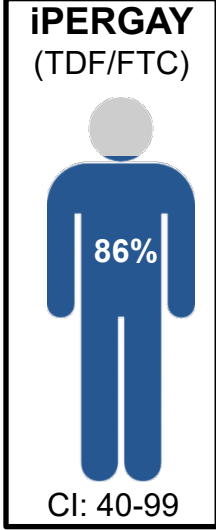
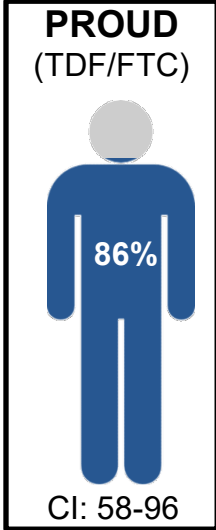
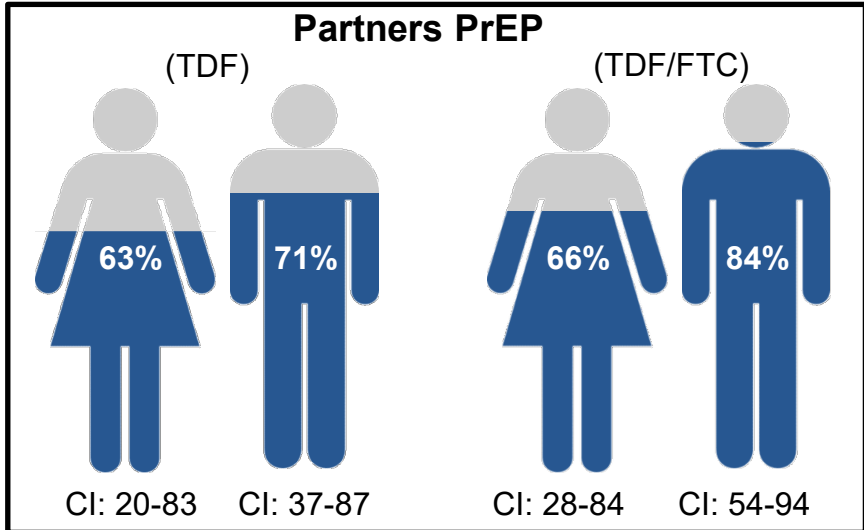
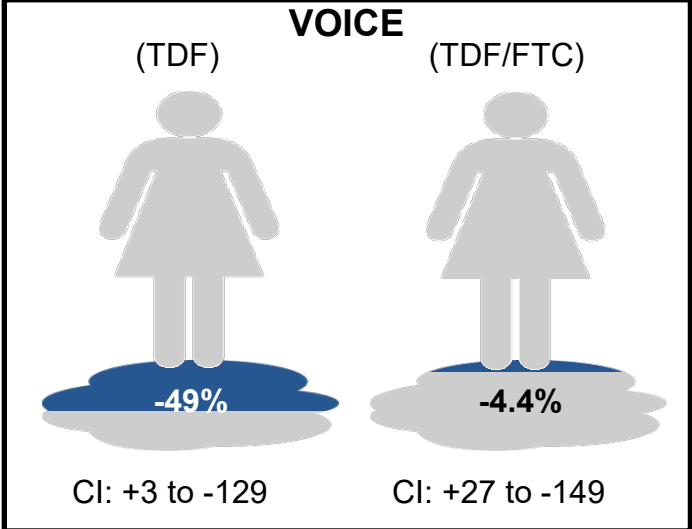
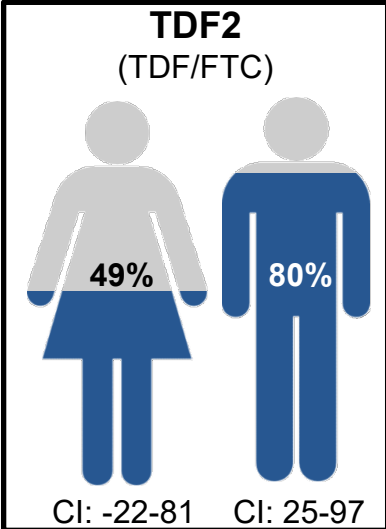
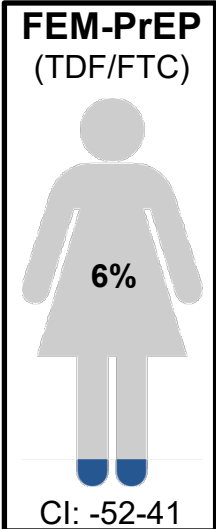
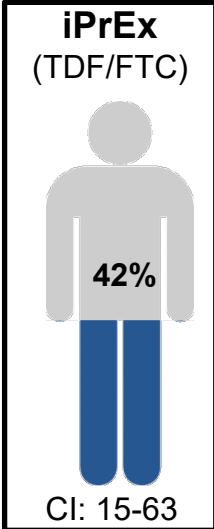
- 1) 100% effectiveness
- 2) 65% effectiveness
- 3) 85% effectiveness
- 4) It depends

Question #1

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Effectiveness of PrEP



Question #2

What are some common side effects of FTC/TDF (PrEP) to prevent HIV?

- 1) Mild skin rash or fever, occasional vomiting
- 2) Mild nausea, diarrhea, weight loss
- 3) Cardiac arrhythmias, liver abnormalities
- 4) Birth defects, if used in first trimester

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FTC/TDF Side Effects

- Clinical
 - Mild short-term nausea +/- diarrhea (10%)
 - Decreased appetite + weight loss (5-10%)
 - Reversible small decrease in bone density (1%)
 - Reversible small decrease in kidney function (0.5%)
- Sexual health
 - Decrease in condom use
 - Increase in syphilis and rectal gonorrhea/ chlamydia



Is Emtricitabine-Tenofovir Disoproxil Fumarate Pre-exposure Prophylaxis for the Prevention of Human Immunodeficiency Virus Infection Safer Than Aspirin?

Noah Kojima¹ and Jeffrey D. Klausner^{1,2}

¹David Geffen School of Medicine, and ²Fielding School of Public Health, University of California Los Angeles

PrEP compares favorably with aspirin
regarding safety



Case 1

- 22 year old man, recent syphilis treatment, reports sex with other men
- Tested HIV-negative 2 months ago
- What additional history is needed?
- What tests are needed?
- Should PrEP be prescribed?



Question #3

When will protection from HIV from PrEP likely occur?

- 1) After 1 days of use
- 2) After 3 days of use
- 3) After 7 days of use
- 4) After 14 days of use
- 5) After 28 days of use

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CDC Recommended Indications for PrEP Use by Men who have Sex with Men

- Adult man without acute or established HIV infection
- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- Any STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-infected partner



Case 2

- 42 year old woman with HIV-infected partner
- Partner's viral load is unknown
- Has condomless sex when he's in town
- Is PrEP indicated?
- Risks vs. benefits?
- Baseline history and testing?



CDC Recommended Indications for PrEP Use by heterosexually active women

- Adult woman without acute or established HIV infection
- Any sex with opposite sex partner in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status **who are known to be at substantial risk of HIV infection** (IDU or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-infected partner



Others at HIV risk

- **Transgender Adults**

- Ask every person their gender identity
- Ask every person if they have had sex with men, women or both in past 12 months
- If sexually active with men, ask about types of partnerships, relationships and HIV status of partners

- **Injection Drug Users**

- Any sharing of injection or drug preparation equipment in past 6 months
- Been in an opiate substitution program in past 6 months
- Risk of sexual acquisition (also evaluate by MSM and heterosexual criteria)

Case 3

- 36 year old man with fever, chills, mild rash
- Reports condomless receptive anal sex 3 weeks ago at a sex club
- Interested in PrEP



Signs and symptoms of acute HIV

- Fever
- Rash
- Sore throat
- Headache
- Swollen glands
- Diarrhea



Source: www.etsu.edu

Question #4

How common is HIV drug resistance among PrEP users?

- 1) There are at least 100 reported cases
- 2) Resistance has never happened
- 3) Rare and usually associated with poor adherence
- 4) Rare and usually associated with undiagnosed HIV

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FTC/TDF for PrEP and Resistance

TRIAL	RESISTANCE AMONG THOSE INFECTED AT ENROLLMENT	RESISTANCE AMONG THOSE INFECTED LATER IN THE STUDY
iPrex	1 of 8 in the placebo arm 2 of 2 in the PrEP arm	0 of 64 in the placebo arm 0 of 36 in the PrEP arm
Partners PrEP	0 of 6 in the placebo arm 2 of 8 in the PrEP arms	0 of 52 in the placebo arm 0 of 30 in the PrEP arms
TDF2	0 of 2 in the placebo arm 1 of 1 in the PrEP arm	1 of 24 in the placebo arm 0 of 9 in the PrEP arm
TOTAL	1 of 16 in placebo arms 5 of 11 in PrEP arms	1 of 140 in placebo arms 0 of 75 in PrEP arms

7 with resistance: 5 of 7 with HIV **before starting FTC/TDF**

No resistance developed in treatment arm



Typical Clinical Evaluation

- Baseline
 - HIV testing 4th gen HIV Ab/Ag*
 - STI screening for syphilis, rectal chlamydia/ gonorrhea and pharyngeal gonorrhea
 - Hepatitis B & C screening
 - HBV vaccine if non-immune
 - Kidney function testing
- Every 3 month follow-up
 - HIV testing 4th gen HIV Ab/Ag
 - STI screening for syphilis, rectal chlamydia/ gonorrhea and pharyngeal gonorrhea
 - Kidney function testing (3 months then 6-monthly)
 - Bone scan not recommended
 - Pregnancy test for women who may become pregnant

*Any suspicion acute HIV = HIV RNA testing



Prescribe PrEP

- FTC/TDF 1 tab daily by mouth, #30, refills x 2
- Follow-up visit at 1 month to review dosing, adherence, side-effects
- Manage other interventions, vaccinations, etc.
- Risk-reduction counseling
 - How do you keep yourself at low risk from STIs?
 - Any substance use issues?
 - How does substance use impact sexual behavior?
 - Strong recommendation for condom use
 - Identify at least one concrete step to reduce risk



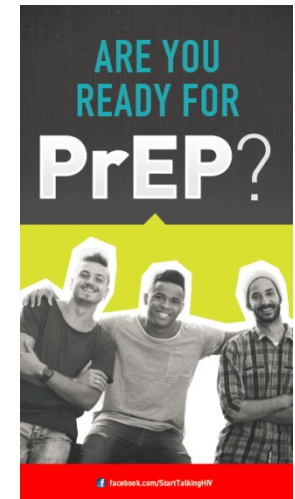
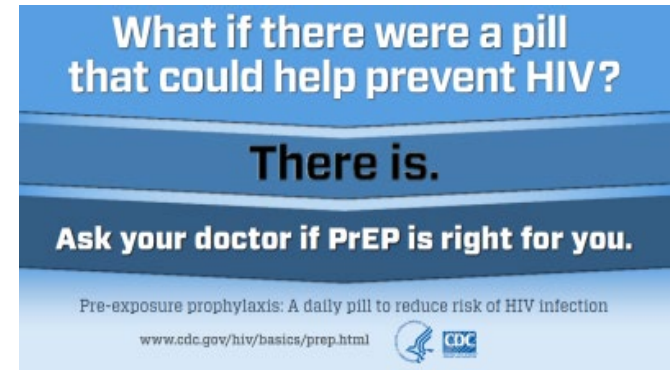
Possible Concrete Risk Reduction Steps

- Carry condoms before going out
- Ask partner about condom use
- Reduce alcohol use when seeking sex
- Ask partner about recent HIV/STD testing
- Limit number of new sex partners of unknown status/ testing history



Clinical setting and team

- Routine primary care
 - Create PrEP friendly setting
 - Use CDC infographics
- PrEP champion
- Add tools into e-health system
 - Best practice advisories
 - Patient self-completed risk assessment
- Social worker or benefits expert



Average Wholesale Price

- \$1800 for 30-day supply FTC/TDF

Average annual cost of HIV care =\$23,000*

Medication Assistance

- Gilead will provide FTC/TDF for PrEP at no cost for individuals who qualify for the assistance program (< 500% poverty level)
- Gilead will provide Co-Pay assistance for insured patients

Program Element	PrEP Medication Assistance Program
Eligibility Criteria	US resident, uninsured or no drug coverage, HIV-negative, low income
Drug Fulfillment	Product dispensed by Covance Specialty Pharmacy, labeled for individual patient use and shipped to prescriber (30 day supply); no card or voucher option
Recertification Period	6 months, with 90 day status check

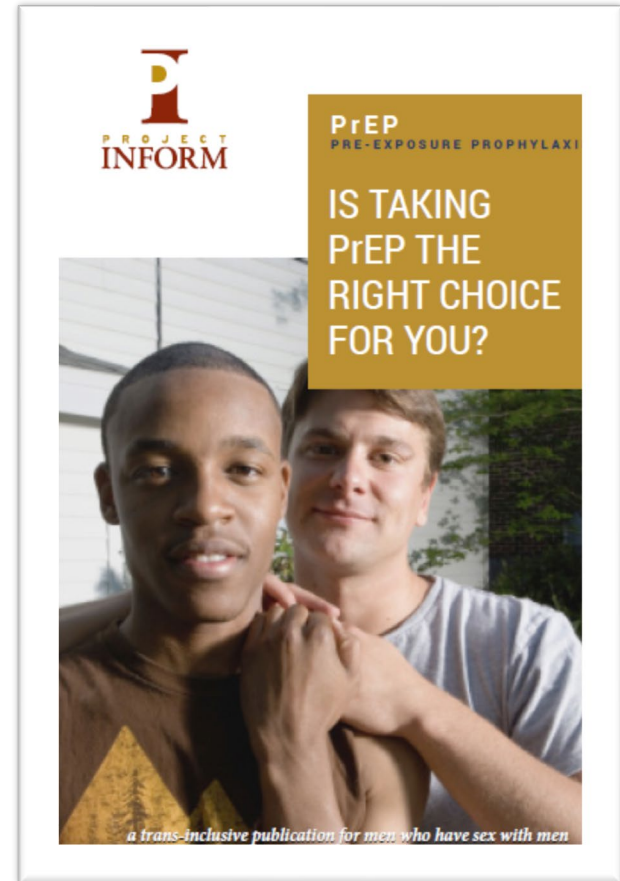


Online Resources

<https://www.cdc.gov/hiv/risk/prep/index.html>

www.projectinform.org/orderprepbooklets/

<http://prepfacts.org/>



Conclusions on PrEP

- PrEP works
- PrEP is safe
- PrEP may be prescribed by primary care and mid-level providers
- PrEP use is associated with increased risk behavior and increased number of STDs, ... regular screening and risk reduction counseling are critical

Thank you

QUESTIONS?

