Cases in PrEP Implementation

Susanne Doblecki-Lewis, MD, MSPH
Associate Professor, Division of Infectious Diseases
University of Miami Miller School of Medicine
Learning Objectives
Upon completion of this presentation, learners should be better able to:

- Describe potential barriers to PrEP care in various settings
- Utilize strategies to overcome common barriers to PrEP care for priority populations
- Identify potential strategies for transitioning from PEP to PrEP

Faculty and Planning Committee Disclosures
Please consult your program book or Conference App.

Off-Label Disclosure
The following off-label/investigational uses will be discussed in this presentation:

- Intermittent or other off-label dosing strategies for PrEP may be discussed in this presentation / discussion.
Case 1

- A 29-year-old transgender woman who was notified by DOH partner services that she was identified as a recent sexual contact with an individual with infectious syphilis.
- She presents to clinic for additional evaluation and treatment.

She reports 5 male partners in the last 6 months with whom she has had condomless receptive anal sex.
- She has a history of symptomatic rectal gonorrhea 3 months prior, treated with ceftriaxone and azithromycin with resolution of symptoms
- Currently feeling well, no recent fever, chills, rash, ulcers, discharge, or other systemic or local symptoms
• No other significant medical history.
• She has plans for future gender affirmation surgery but has not yet started this process.
• Currently receiving estradiol valerate 2 mg daily and cyproterone 25 mg daily.

• A rapid HIV test is reported as non-reactive
• She is offered PrEP but mentions that she is reluctant due to concerns about potential interactions with her feminizing hormone therapy.
1. How do you respond?

A. There are no known interactions between TDF/FTC and feminizing hormones.
B. Levels of feminizing hormones may decrease with TDF/FTC.
C. TDF/FTC PrEP may be ineffective with concomitant use of estradiol.
D. Levels of TDF/FTC may be decreased with estradiol use, but levels are still adequate to confer protection with daily dosing.

TDF/FTC PrEP and Feminizing Hormones

- Concern about impact of PrEP medication on feminizing hormones may cause reluctance to use PrEP among transgender women.
- The iFACT study demonstrated that TDF/FTC PrEP, when taken concomitantly with estradiol, does not reduce estradiol levels.
- However, estradiol administration may reduce TDF levels by 17%.
- Modeling suggests levels of protection are maintained with adherence to daily dosing.
- Cottrell, et al. found that transgender women living with HIV were found to have TFV-DP rectal tissue levels 8x lower than cis-gender women, although viral suppression not compromised.

Hiransuthikul, A. AIDS 2018, Abstract 13177
Case 2

- A 19-year-old Cuban-American man presents for a STD check with a urethral discharge.
- He is sexually active with men, including approximately 15 partners in the last 6 months, both receptive and insertive, with inconsistent condom use.
- He has a history of rectal chlamydia and secondary syphilis within the last year.

- He is generally healthy and takes no medications.
- A rapid HIV test is non-reactive.
- After evaluation and treatment for his urethritis, you mention the possibility of TDF/FTC PrEP and he is interested.
- He has medical insurance through his mother’s employer-sponsored plan.
- He mentions that has not discussed his sexual activity with his mother, and is worried about what her response may be if she finds out.
How do you respond?

A. Reassure that this information is confidential and will not be disclosed to his mother.
B. Plan to enroll him in the pharmaceutical company patient assistance program so that he can obtain medication without disclosure to his mother.
C. Inform him that you will ask that the explanation of benefits received by his mother be masked but that confidentiality cannot be guaranteed.
D. Inform him that he must get his mother’s consent to receive PrEP medication.

PrEP for Adolescents & Young Adults

• TDF/FTC PrEP is approved by the FDA for use in adolescent minors weighing 35 kg or more
• Stigma regarding same-sex behavior can particularly affect youth
• Building family / community support is essential
• CDC findings show that no jurisdiction explicitly prohibits access to PrEP without parental consent
• Some jurisdictions allow minors of a particular age to access PrEP independently, others do not have explicit statutes regarding minors’ access to PrEP.
• Explanation of benefits (EOB) and other insurance communications can “out” young adults who receive insurance through their parents (and adults who receive through a spouse or partner).
• EOB communications may be suppressed only in some states (NY, California)

https://www.cdc.gov/hiv/policies/law/states/minors.html
Case 3

- You are evaluating a 32-year-old woman with risk for HIV due to injection drug use and exchanging sex for money and drugs.
- She is a regular attendee at a syringe exchange program and presents as usual to exchange syringes.
- She reports that she “usually” insists on condom use when having vaginal sex with men but on the previous night the condom broke and her partner informed her that he was HIV positive.
- She did not know whether the man was receiving /adherent to antiretroviral therapy.

She knows that PrEP is offered at your site, and after this experience is interested in starting PrEP.
- A rapid HIV test is performed and is non-reactive.
- She is feeling well and has no fever, chills, rash, ulcers, discharge, or other STI symptoms.
- You offer 3-drug post-exposure prophylaxis for 28 days with TDF/FTC and raltegravir, given her exposure <72 hours before presentation.
- Baseline lab-based 4th generation (Ag/Ab) HIV test, Hepatitis testing, and STI testing is also performed and returns as negative.
She returns 4 weeks later for follow-up, and is interested in initiating PrEP. After a non-reactive HIV test result is obtained, what would you do?

A. Stop medication as planned and follow-up in 1 week for repeat HIV test and consideration of TDF/FTC PrEP.
B. Stop medication as planned and follow-up in 4 weeks for repeat HIV test and consideration of TDF/FTC PrEP.
C. Transition directly to TDF/FTC PrEP without any gap in receipt of medication and follow-up in 3 months for quarterly testing.
D. Transition directly to TDF/FTC PrEP without any gap in receipt of medication and follow-up monthly for HIV testing for next 3 months, then transition to quarterly testing.

Transition from PEP to PrEP

• However, no increase in risk of resistance & majority of infections were detected by 3 months
• CDC clinical guidance for PrEP suggests that patients may be directly transitioned from PEP to PrEP without delay or gap in therapy.
• Risk for seroconversion when off medication waiting to start PrEP can be substantial and favors direct transition to PrEP when desired & appropriate.

Center for Disease Control and Prevention Guidelines – 2017 update
Case 4

• Ronaldo is a 54-year-old man who presents for sexual health screening.
• He says he has sex with men, occasionally with anonymous partners that he meets through dating apps, 1-2 times/month.
• He uses condoms, but not consistently.
• He is usually the receptive partner.
• He has a remote history of syphilis.

• You recommend that he consider PrEP as part of his HIV prevention strategy.
• He is interested but does not want to take a pill every day, given his pattern of sexual activity.
How do you counsel him regarding PrEP?

A. Daily dosing of TDF/FTC is the only recommended PrEP strategy.
B. He may consider taking 2 tablets of TDF/FTC 2-24 hours before sex, and 1 tablet daily for the next 2 days (2-1-1 dosing)
C. He may consider taking 1 tablet of TDF/FTC before sex and 1 tablet after sex.
D. He should be more consistent with condoms and consider nPEP after condomless exposures rather than PrEP.

Intermittent / “on-demand” PrEP

- The IPERGAY study demonstrated 86% risk reduction with use of 2-1-1 TDF/FTC dosing.
- Follow-up open-label studies have shown high efficacy of this strategy, including for men who have less frequent sexual activity.
- CDC guidelines currently recommend only daily dosing of TDF/FTC for PrEP
- IAS-USA guidelines allow 2-1-1 dosing as an alternative to daily dosing for men who have sex with men with infrequent sexual activity (evidence rating AIA).
- Only daily dosing recommended for cis-gender or transgender women and people with chronic active Hepatitis B.

Center for Disease Control and Prevention Guidelines – 2017 update
Discussion