



Pre-Exposure Prophylaxis (PrEP): A primer for primary care providers

Daily emtricitabine/tenofovir (Truvada®) is safe and effective for reducing the risk of HIV acquisition in sexually active men and women and injection drug users. This primer will serve as a brief “how to guide” for providers interested in providing PrEP to their patients.

1) Identify patients who may benefit from PrEP

The CDC guidance recommends that PrEP be offered to patients with “ongoing, very high risk for acquiring HIV infection.” In practice, this can be difficult to determine and risk varies depending on local epidemiology. Identifying potential PrEP candidates begins with taking a sexual and drug use history. Some groups that may benefit from PrEP include:

- Men who have sex with men (MSM) who engage in condomless receptive anal sex
- MSM with multiple anal sex partners
- MSM with syphilis or rectal STDs (e.g. rectal gonorrhea (GC) or Chlamydia (CT))
- MSM with one or more HIV-positive sex partners, particularly if the HIV-positive partner is not in care or does not have an undetectable viral load
- Heterosexual men and women with one or more HIV-positive sex partners
- Injection drug users

2) Discuss PrEP with your patient

Ask your patient what he is currently doing to protect himself from HIV-infection. Inform your patient about the potential risks and benefits of PrEP and explain that only studies of daily dosing have proven the efficacy of PrEP. Important counseling points to include:

- Discussion of side effects identified in the iPrEx study: **nausea** which improved in first few weeks; **mild worsening of kidney function** which improved with discontinuation of truvada in all patients; **decreased bone density** greater in truvada arm, but no increase in fractures
- Effects of non-adherence with PrEP on efficacy: overall risk of HIV acquisition 44% lower in PrEP arm in iPrEx study; protective efficacy was 92% in those with detectable drug in plasma. It is critical to discuss adherence and consider giving patient pillbox.
- Risks of development of resistance to HIV medications if acute HIV is not identified quickly while on PrEP
- Patient should report immediately to clinic if they develop symptoms compatible with acute HIV infection (fever, fever with sore throat; fever with rash; fever with headache)

3) Take a medical and social history and conduct a review of symptoms. Check specifically for:

- Any history of renal or liver disease or osteoporosis: caution or avoid using tenofovir
- Recent symptoms of a mono-like illness: Test for acute HIV (HIV RNA or 4th generation HIV Ag/Ab test) and defer PrEP until results are back

4) Assess how patient will pay for PrEP

Insured patients

- Medi-Cal no longer requires a prior authorization for PrEP as of April 2014
- Many private insurers cover PrEP but may require prior authorization
- ICD9 codes include:

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- i. V01.79 – contact with or exposure to viral disease
- ii. V69.2 – high risk sexual behavior
- iii. V65.44 – HIV counseling
- If patient has a high co-pay, Gilead (maker of Truvada) has a co-pay assistance program: <http://www.truvada.com/truvada-patient-assistance> or 1-877-505-6986

Uninsured patients

- The Gilead PrEP patient assistance Program will provide Truvada® at no cost for those who are uninsured and meet income guidelines
- Fax application and proof of income to the program: https://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf or 1-855-330-5479
- One bottle (30 day supply) shipped to providers office
- Patients have to re-apply (i.e. resubmit proof of eligibility) every 3-6 months

5) Obtain baseline testing:

| Tests | Comments & rationale |
|---|--|
| HIV test: Rapid HIV Ab test, OR 4 th generation (Quest #91431), OR HIV RNA PCR (Quest #40085) | Consider testing for acute HIV infection in ALL patients who are initiating PrEP with either an individual HIV RNA, a pooled HIV RNA or a 4 th generation combined HIV Ag/Ab assay, especially if they have had a high risk exposure in the prior month. Test for acute HIV infection in all patients with symptoms concerning for acute HIV infection. If the patient has acute or chronic HIV infection, they must receive 3 active HIV medications for treatment and risk resistance if taking only PrEP. |
| Creatinine | CrCl should be ≥ 60 ml/min (Cockcroft Gault) to safely use tenofovir. |
| Hepatitis B surface antigen | Truvada is active against hepatitis B virus (HBV). Patients with chronic HBV CAN use Truvada for PrEP, but should have liver function tests monitored regularly during PrEP use and after discontinuing PrEP, and should be cautioned that hepatitis can flare if Truvada is discontinued. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized. |
| STDs (based on patient's self-reported sexual practices) | MSM should be tested for syphilis, urethral, rectal and pharyngeal GC and CT. Heterosexual men and women should be tested for syphilis and genital GC and CT. |
| Pregnancy test for women | PrEP should be coordinated with pre-natal care. HIV-negative pregnant women in serodiscordant relationships who want to get pregnant can use PrEP to assist with safe conception: http://hiv.ucsf.edu/care/perinatal/pro_men/safer_conception_hiv-neg_female_hiv-pos_male_12-4-2013.pdf |

Note: It is not necessary to obtain liver function tests or a CBC when initiating or monitoring a patient using PrEP.



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6) Initiate PrEP

- If there are no contraindications to PrEP use and the patient is interested in using PrEP as an HIV-prevention tool, PrEP can be initiated.
- Consider prescribing a 30-day supply, and no more than 90 days, for first dispensation.
- Provide risk reduction and adherence counseling, review adherence starter pack (attached), provide anticipatory guidance about common side effects when Truvada is started, and suggest a pill box to help patient with adherence.
- If it has been more than 2 weeks since baseline labs were obtained, repeat an HIV test. *We strongly suggest testing for acute HIV infection on the day the initial PrEP prescription is written.*

7) Monitor and provide ongoing support for patients using PrEP

| Timeframe | Action |
|--|---|
| 30 days after initiation: Follow-up visit | <ul style="list-style-type: none"> • Assess side effects and the patient's interest in continuing • Adherence counseling: reinforce importance of daily use and address any challenges patient has faced. |
| Every 3 months: labs visit refills | <ul style="list-style-type: none"> • HIV test: 4th generation preferred • If the patient has been off PrEP form more than a week, consider screening for acute HIV at time of PrEP re-initiation • Creatinine: stop if CrCl < 60 ml/min • STD screening • Pregnancy test for women; If pregnant, ensure that the patient has been informed about use during pregnancy and that she discusses PrEP use with her prenatal provider. • Renew prescription for 90 days only if HIV test negative • At visit: adherence and risk reduction counseling |

8) What if my patient has a positive HIV antibody test while on PrEP?

- Discontinue Truvada to avoid development of HIV resistance
- Order and document results of an HIV genotype (resistance test)
- Report the test to your local health department
- Ensure that the patient is linked to an HIV-primary care provider for care and possible immediate initiation of antiretroviral therapy

See: <http://www.sfcityclinic.org/services/prep.asp> for additional information