

San Francisco Health Network
Pre-Exposure Prophylaxis (PrEP) Management Guidelines

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1.0 Introduction

After San Francisco became one of the first cities to report HIV/AIDS cases in the world, the San Francisco Department of Public Health (SFDPH) and researchers/clinicians at San Francisco General Hospital have served as world leaders in advancing HIV treatment and prevention for the past 30 years. The SFDPH continues to be a national leader in HIV-based public health measures, most recently (in January 2010) being the first jurisdiction in the United States, in conjunction with HIV/AIDS Division leadership at UCSF, to recommend antiretroviral therapy (ART) to all patients at the time of diagnosis regardless of CD4 cell count. The SFDPH also supports the use of antiretroviral agents for primary HIV prevention through support of HIV post-exposure prophylaxis (PEP) for occupational and non-occupational exposures.

Pre-exposure prophylaxis (PrEP) is an effective HIV prevention tool for men who have sex with men (MSM), women at risk for HIV, transgender individuals, and people who inject drugs¹⁻⁶. In the largest study of MSM conducted, fixed dose combination of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) was associated with a 44% reduction in HIV infections, with estimates of >90% protection for those with drug concentrations indicating adequate adherence^{1,7}. In July 2012, TDF/FTC was approved by the US Food and Drug Administration for use as PrEP in individuals at risk for HIV infection with recently-updated guidelines (May 2014) from the Centers of Diseases Control citing broad indications.⁸

PrEP programs have been developed within large health systems throughout San Francisco with the provision of specialty evaluation and initiation of PrEP for those at high risk for HIV infection. However, patients within the San Francisco Health Network (SFHN), or individuals without health insurance in San Francisco, have not had regular and systematic access to this important HIV prevention option within the SFHN. It is essential to ensure coordinated access to PrEP for those disproportionately at risk for HIV infection within the SFDPH health system, as well as for special populations including young MSM of color, injection drug users, and women with risk factors or seeking preconception care.⁹ This clinical protocol is designed to provide guidance on evaluation, initiation, and monitoring of PrEP for patients within the SFDPH health system, and could be adapted for use in any primary care setting.

2.0 Eligibility for PrEP

The following criteria should be used to determine if PrEP is appropriate for patients within SFDPH primary care clinics.

2.1 Inclusion Criteria

1. Age \geq 18 years^a
2. HIV uninfected based on laboratory evidence by both the ELISA OR 4th generation assay AND HIV viral load (RNA) (performed in the past 7 days).
3. Individuals at risk for HIV infection:
 - Men who have sex with men (MSM)** or transgender individuals who have sex with men who are at ongoing, high risk for sexual acquisition of HIV.
 - 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-positive male partner.
 - Exchanges sex for money, gifts, or resources.

- Anticipated risk.

Heterosexual men and women reporting any sex with opposite sex partners in the last 6 months; not in a monogamous partnership with a recently tested HIV-negative partner;

AND at least one of the following:

- Is a man who has sex with both women and men (evaluate indications for PrEP use above).
- Uses condoms infrequently during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or MSM).
- Is in an ongoing sexual relationship with an HIV-positive partner.
- Exchanges sex for money, gifts, or resources.
- Anticipated risk.

Individuals who inject substances.

AND at least one of the following:

- Any sharing of injection or drug preparation equipment in past 6 months.
- Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months.
- Risk of sexual acquisition (also assess two above criteria).
- Anticipated risk.

2.2 Exclusion Criteria

1. Evidence of confirmed HIV infection by laboratory testing;
2. Clinical symptoms consistent with possible acute HIV infection [fatigue, fever, rash, vomiting, diarrhea, headache, arthralgia, pharyngitis, rash, night sweats, and adenopathy (cervical, axillary and inguinal)];
3. Underlying renal disease (CrCl < 60 ml/min, significant proteinuria);
4. Underlying bone disease (osteopenia/osteoporosis);
5. Unwilling to attend quarterly follow-up visits which will include counseling for ongoing risk reduction, safer sex practices (such as regular and correct condom use), and adherence to PrEP regimen, as well as repeat laboratory testing.

- ^a. **For patients under 18 years:** There are safety data on TDF/FTC as treatment in pediatric patients 12 years of age and older, however there are no clinical trial data evaluating safety and efficacy of TDF/FTC for PrEP in patients under the age of 18 years. In the absence of available clinical trial data, clinicians should use their clinical judgment when assessing the risks of HIV infection and safety of TDF/FTC for PrEP in this population, and consider consultation with Ward 86 PrEP clinicians.

3.0 Initial Evaluation

The clinician should conduct a complete medical history to assess whether or not the patient has any medical relative or absolute contraindications to PrEP, including:

1. History of or current kidney/liver disease,
2. Current or chronic hepatitis B, osteoporosis or other bone disease, or
3. Symptoms of acute HIV infection.

For patients who have complicated medical conditions, the clinician should use their clinical judgment when assessing the safety of starting PrEP and consider consultation with the Medical Director of the PrEP Clinic (Dr. Hyman Scott) or the Medical Director of Ward 86 (Dr. Monica Gandhi) as appropriate.

Before initiating PrEP, patients should have the following laboratory testing performed:*

1. HIV antibody test within 7 days AND HIV viral load (RNA) testing within 7 days.
 - The patient must have a nonreactive HIV antibody result no longer than 7 days before TDF/FTC is dispensed for the first time.
2. Serum creatinine for creatinine clearance calculation (>60 mL/min for initiation) no more than 60 days prior to the PrEP dispensation visit.**
3. Hepatitis B Surface Antigen (HBsAg), Hepatitis B surface Antibody (HBsAb), and Hepatitis Core Antibody (HBcAb) if not currently documented.
 - HBV vaccination should be offered if appropriate.
 - Patients with chronic HBV should be managed as outlined below in Special Considerations for initiation of PrEP.
4. Hepatitis C Antibody if not previously documented.
5. Hepatitis A Total Antibody if not previously documented.
 - HAV vaccination should be offered if appropriate.
6. Sexually Transmitted Infection screening if not conducted within the prior 3 months.
 - Gonorrhea/Chlamydia – Urine, Rectal, and Pharyngeal.
 - Syphilis – RPR or VDRL.
7. Pregnancy test for women of reproductive age if appropriate.

* Consider obtaining all laboratory testing 7 days prior to the initial PrEP evaluation visit.

**Patients with an estimated CrCl <60 ml/min should have the test repeated. Assess use of potentially nephrotoxic medications (e.g., NSAIDs, acyclovir, valacyclovir) and body building substances (e.g., creatinine, protein drinks). If repeat CrCl is ≥ 60 ml/min, patient may initiate PrEP. If not, patient will need close follow-up with PCP and consideration of nephrology consultation as appropriate.

Counseling: Counselors or clinicians should review with patients the basics of PrEP, provide client-centered risk reduction counseling, condoms, and medication adherence counseling (see Appendix). Refer to package insert and Centers for Disease Control (CDC) guidelines for details on possible changes to bone mineral density (BMD) on TDF/FTC as appropriate.⁸

Initial TDF/FTC Rx: Tenofovir 300mg+Emtricitabine 200mg (Truvada) 1 tab PO Daily #30, Refill #2

- Alternative: Can give RF #0 at the initiation visit and have patient follow-up at 1 month for HIV testing, adherence counseling, and additional refills.

3.1 Special Considerations

Chronic HBV infection: Patients with chronic HBV infection, or newly identified with HBV, should have review of possible use of TDF/FTC for both PrEP and treatment of HBV infection. Chronic HBV infection is not a contraindication to PrEP, and a large study of MSM and transgender women (iPrEx) allowed for participation in study despite detection of chronic HBV infection during screening. Patients stopping TDF/FTC for PrEP should be started on alternative HBV treatment in consultation with Infectious Disease or Gastroenterology as appropriate.

Pregnancy/Breastfeeding: There are no well-controlled trials in pregnant women on the safety of TDF/FTC or the efficacy of PrEP. TDF/FTC should be used during pregnancy only if clearly indicated. If an uninfected individual becomes pregnant while taking TDF/FTC for a PrEP indication, careful consideration should be given to whether use of TDF/FTC should be continued, taking into account the implications of an increased risk of HIV infection during

pregnancy. Women taking TDF/FTC for a PrEP indication should be instructed not to breast-feed; the components of TDF/FTC are excreted in breast milk, and it is not known if these can harm the infant.

Transitioning from Non-Occupational Post-Exposure Prophylaxis (nPEP) to PrEP:

1. Individual already on nPEP, requesting to transition directly to PrEP:
2. If possible, check baseline PrEP safety labs and HIV viral load (RNA) within the first week of starting nPEP to rule out acute HIV infection.
3. If the HIV viral load is below the limit of quantification and it is deemed appropriate for the patient to start PrEP, recheck HIV antibody at completion of nPEP and transition directly to PrEP without interruption.

4.0 Follow-up

All patients initiating PrEP should have a one-month follow-up visit (in-person or via phone, if appropriate) after PrEP initiation. At this visit, the counselor or clinician should assess the patient for acute HIV and STI symptoms, review TDF/FTC side effects and adherence, and order HIV testing (a blood-based rapid HIV test can be used if available). HIV testing should be completed within 7 days of this visit, or drawn at this visit if possible.

After the one-month follow-up visit, the patient should be evaluated at least every 3 months for assessment of acute HIV or STI symptoms, possible side effects, creatinine and HIV tests, and STI screening.

1. Patients should have a negative HIV antibody result within 7 days of dispensing TDF/FTC at all follow-up visits.
 - A blood-based rapid HIV test, if available, can be used at the follow-up visit.
 - If patient reports symptoms of acute HIV infection, HIV viral load (RNA) testing should be ordered.
2. Patients initiating PrEP for the first time should have creatinine testing after taking TDF/FTC for 3 months and, if creatinine is stable, every 3-6 months thereafter. No patient receiving PrEP should go longer than 6 months without having a creatinine level checked.
 - Creatinine clearance should be calculated for every creatinine result. Use the following online calculator:
<http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault>.
 - See Section 6.0 below for management of patients with CrCl <60 ml/min.
3. STI screening for Gonorrhea/Chlamydia (Urine, Rectal, and Pharyngeal) and Syphilis (RPR or VDRL) as appropriate.
4. Consider annual HCV Ab screening for MSM, and people who inject drugs.
5. Pregnancy testing for women of reproductive age if appropriate.

Pharmacist Referral: Community Oriented Primary Care (COPC) primary care pharmacists are available for follow-up visits to order and monitor labs, and provide counseling between provider visits.

Counseling: Condoms and risk reduction and medication adherence counseling should be provided to patients at each 3 month follow-up visit. The clinician or counselor should check in with the patient regarding HIV/STI risk and medication adherence and provide counseling as needed or desired (see Appendix).

1 Month Follow-up TDF/FTC Rx (if needed): Tenofovir 300mg+Emtricitabine 200mg (Truvada) 1 tab PO Daily #30, Refill 1

3 Month Follow-up TDF/FTC Rx: Tenofovir 300mg+Emtricitabine 200mg (Truvada) 1 tab PO Daily #30, Refill 2

5.0 Management of patients with CrCl <60 ml/min

If the CrCl is <60 ml/min, TDF/FTC should be discontinued immediately and the creatinine should be repeated in 2-4 weeks. If the CrCl is \geq 60 ml/min, may restart PrEP and check creatinine in 1 month.

If the creatinine is greater than 1.5x baseline (but CrCl is still \geq 60 ml/min), discuss with the patient if there are any other potential causes for the creatinine elevation (e.g., dehydration, body building supplements, new medications, NSAIDs) and repeat creatinine in 2 weeks. If creatinine elevation is sustained, discontinue PrEP for 2-4 weeks and recheck creatinine. If creatinine has normalized, may restart PrEP and check creatinine in 1 month.

Patients who want to be on PrEP but have elevated creatinine, should be referred to a nephrologist for further evaluation. Patients should have their creatinine testing completed in sufficient time prior to their referral appointment so that the results can be reviewed and discussed at their visit.

6.0 Discontinuation of PrEP

If a patient discontinues PrEP due to HIV seroconversion, they should be offered immediate linkage to care and antiretroviral therapy through the RAPID program (see RAPID Standard Operating Procedures).

If a patient discontinues PrEP secondary to concern for possible acute retroviral syndrome, HIV viral load and HIV antibody testing should be conducted within 7 days prior to reinitiating PrEP.

If a patient discontinues PrEP by personal choice, non-adherence to laboratory follow-up, intolerance to TDF/FTC, or reduction in HIV risk they should receive counseling on HIV risk reduction strategies, as well as education on safely restarting PrEP. If the patient has not yet stopped PrEP, discuss continuing PrEP for 30 days after a high risk exposure if that exposure occurred within the past 7 days.

7.0 Positive Health Program (Ward 86) PrEP Referral Clinic

The Positive Health Program (known as Ward 86), the first integrated HIV/AIDS care clinic in the world, also houses a PrEP Clinic referral center. HIV negative individuals in the city of San Francisco may be referred by their provider, or self-refer, to the Ward 86 PrEP clinic for navigation services. The Ward 86 PrEP Clinic Coordinator/Navigator will conduct the initial evaluation for PrEP and provide navigation to primary care, if appropriate, as described below:

HIV-negative patients who have primary care providers within the SFHN:

Patients can be referred by their provider, or self-refer, to Ward 86 for PrEP evaluation. The PrEP Clinic Coordinator/Navigator, in conjunction with Ward 86 clinicians, will conduct the initial evaluation including HIV testing, initial laboratory screening, and HIV prevention counseling. After labs are reviewed by the clinician, PrEP may be initiated, if appropriate, and the patient referred back to their primary care provider (PCP) after the initial consult and provision of follow-up recommendations. The patient will have the option to follow-up with Ward 86

clinicians or their PCP at 1 month; subsequent quarterly follow-up for further risk reduction counseling, prescription refills, and laboratory monitoring will be performed by their PCP at their medical home. The Ward 86 clinicians will be available for specialty consultative questions as well as re-referrals as needed for management. Ward 86 will also serve as a specialty referral resource for SFHN based PCPs.

HIV-negative patients who are not yet linked to primary care:

The Ward 86 PrEP Clinic Coordinator/Navigator will conduct the initial evaluation and assist with determining medical eligibility. After determining eligibility, initial HIV testing, laboratory screening, and HIV prevention counseling will be offered; labs will be reviewed by the Ward 86 clinician, and PrEP may be initiated if appropriate. The PrEP Clinic Coordinator/Navigator and Ward 86 social workers will also work with these individuals to link them with a new primary care provider within the SFHN if appropriate or as directed by insurance eligibility. Ward 86 will manage PrEP until a primary care provider has been identified, after which PrEP will be managed by the primary care provider with Ward 86 continuing to be available in a consultative capacity.

HIV-negative patients who are not yet linked to primary care and whose partner is a patient at Ward 86:

Ward 86 will conduct the initial evaluation and assist with determining medical eligibility. After confirmation of eligibility, initial HIV screening, laboratory testing, and HIV prevention counseling will be offered; labs will be reviewed by the clinician, and PrEP may be initiated if appropriate. A Ward 86 clinician will serve as the primary care provider for HIV negative partners (on PrEP) (and who qualify for a plan accepted at W86) of currently-engaged HIV positive partners at Ward 86.

8.0 Additional PrEP Resources

- <http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>
- <http://www.cdc.gov/hiv/pdf/preprovidersupplement2014.pdf>
- sfcityclinic.org/services/prep.asp
- projectinform.org/prepresources/
- prepfacts.org/
- myprepexperience.blogspot.com/
- cdc.gov/hiv/basics/prep.html
- Clinician Consultation Center PrEPLine: (855) HIV PrEP (855-448-7737)
nccc.ucsf.edu/clinical-resources/pep-resources/prep/
- Gilead: truvadapreprems.com (for clinicians)

9.0 PrEP Billing Codes

Currently there are no specific ICD-10 billing codes for PrEP. The billing codes below are commonly used and should be used to facilitate standardized billing for PrEP services.

Primary Billing Codes

ICD-9	Description	ICD-10	Description
V01.79	Exposure to other viral diseases	Z20.6	Contact with and (suspected) exposure to HIV
V69.2	High-risk sexual behavior	Z72.5	High risk sexual behavior

Counseling Codes

CPT	Description
99401	Prevention Counseling (15 minutes)
99402	Prevention Counseling (30 minutes)
99403	Prevention Counseling (45 minutes)
99404	Prevention Counseling (60 minutes)

10.0 References:

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- Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med.* 2012;367(5):423-434.
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- Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet.* 2013;381(9883):2083-2090.
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- McCormack S, Dunn D. Pragmatic Open-Label Randomised Trial of Preexposure Prophylaxis: The PROUD Study. Conference on Retroviruses and Opportunistic Infections (CROI) 2015. Abstract 22LB.
- Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis.* 2014.
- Centers for Disease Control (CDC). New HIV Pre-Exposure Prophylaxis Guidelines. Press Release issued May 15, 2014. <http://www.empr.com/cdc-new-hiv-pre-exposure-prophylaxis-guidelines/article/347053/> (Accessed August 25, 2014).

9. Liu A, Cohen S, Follansbee S, et al. Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. *PLoS Med.* 2014;11(3):e1001613.

Appendixes:

A. Paying for PrEP

B. Initial and Follow-up PrEP Appointment Counseling Prompts

C. Basics of PrEP – Patient Information

Paying for PrEP

Patient Insurance	PrEP Access
Uninsured and <500% FPL	Gilead will provide PrEP through patient assistance (see below) May need to pay for office visit and labs
Uninsured and >500% FPL	\$1250/month for PrEP alone, without office visits and lab costs Gilead offers \$300/month co-pay assistance (see below)
Medi-Cal	Covered; no prior authorization required Phone number: 1-855-355-5757 May use Patient Access Network if <500% FPL (see below)
Medicare	Most plans cover, some require prior authorization Plans tend to have higher co-pays; can't use Gilead co-pay card Contact specific plan for more information May use Patient Access Network if <500% FPL (see below)
Healthy SF	Will work through patient assistance first, otherwise prior authorization required \$0-\$50 co-pay; cannot use Gilead co-pay card http://www.healthysanfrancisco.org Phone number: 415-615-4555 May use Patient Access Network if <500% FPL (see below)
Healthy Workers	Prior authorization required \$0-\$50 co-pay; cannot use Gilead co-pay card www.sfhp.org/members/healthy-workers Phone number: 1-800-288-5555 May use Patient Access Network if <500% FPL (see below)
Employer-sponsored health insurance	Most cover, some require prior authorization, cost sharing varies Gilead offers \$300/month co-pay assistance (see below) May use Patient Access Network if <500% FPL (see below)
Covered California	Bronze plans: High deductible, 30-40% co-pay for specialty drugs after deductible met; PrEP costs about \$800/month with Gilead co-pay card Silver and Gold plans: Most have no cost for PrEP with Gilead co-pay card Gilead offers \$300/month co-pay assistance (see below) May use Patient Access Network if <500% FPL (see below)

Gilead patient assistance (for patients without insurance)

- The Gilead PrEP patient assistance program will provide TDF/FTC at no cost for those who are uninsured and meet income guidelines
- Fax application and proof of income to the program:
 - Application: https://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf
 - Fax number: 1-855-330-5478
 - Phone number: 1-855-330-5479
- One bottle (30 day supply) shipped to providers office

- Patients have to re-apply (resubmit proof of eligibility) every 3-6 months
- Contact Jason Sison with SFDPH for assistance (e-mail jason.sison@sfdph.org, phone 415-206-5934)

Gilead co-pay assistance (for patients with non-government insurance)

- Patients sign up through website: <http://www.gileadcopay.com/>
- Website generates co-pay card, and patients take card to pharmacy when picking up PrEP
- Phone number: 1-877-505-6986
- Contact Jason Sison with SFDPH for assistance (e-mail jason.sison@sfdph.org, phone 415-206-5934)

Patient Access Network Foundation (for patients with insurance and <500% FPL)

- Patients sign up through website: www.panfoundation.org/hiv-treatment-and-prevention
- Phone number: 1-866-316-7263
- Patients can sign-up on their own or be enrolled by a healthcare provider.

Prior Authorization Language to Justify PrEP

- Patient is high risk because [LIST PATIENT SPECIFIC RISK FACTORS]. Truvada for HIV pre-exposure prophylaxis is indicated. Lab evaluation shows a negative HIV test from [DATE] and normal kidney function from [DATE]. The patient is regularly followed at [NAME OF CLINIC] clinic, and will be scheduled for counseling visits and ongoing monitoring of HIV status, kidney function, and STI screening every 3 months.

Other resources for patients to access PrEP

- My Prep Experience: <http://myprepexperience.blogspot.com/p/truvada-track.html>
 - Patients can e-mail problems in gaining access to myprepexperience@gmail.com. They have an online community that can work to help patient gain access to PrEP and report it on the website.
- Clinical Trials: <http://www.avac.org/trial-summary-table/prep>
 - Patients can enroll in ongoing clinical trials and access PrEP for free.
- San Francisco AIDS Foundation: www.prepfacts.org
 - Additional information on clinical trials.

Initial and Follow-up PrEP Appointment Counseling Prompts

Initial PrEP Appointments

Opener: Let's talk about your sexual health for a few minutes.

Sexual Behavior and Substance Use:

- What has been going on for you sexually in the past couple months?
- How much of the time did you use condoms for anal sex?
- What made it easier to use condoms for anal sex? What made it more difficult?
- What, if any, concerns do you have about your sexual activities?
- In what ways does substance use impact your risk activity, if at all?
- What, if any, concerns do you have about your substance use?
- How, if at all, might taking PrEP impact your risk activity?

Plan(s) for Staying HIV/STI Negative:

- In what ways are you reducing your risk for getting HIV/STIs?
- If you could list the steps you are taking to stay HIV negative as a series of bullet points, what would they be?
- You are reducing your risk for HIV by deciding to take PrEP, Let's talk about how PrEP fits into your risk reduction efforts.
- What other ideas/plans, if any, do you have for staying HIV/STI negative?

HIV Testing and Results:

- How are you feeling about getting your HIV test result in a few minutes?
- What, if anything, would you like to discuss before I provide your results?
- *After negative result obtained:*
 - What are your thoughts/feelings about your negative test result?
 - How, if at all, does this negative test result impact your plans/efforts to remain HIV negative?
- *After positive result obtained:*
 - Provide post-test counseling and linkage to care.
 - Refer to RAPID.

Adherence counseling:

- What is your experience with taking a daily medication?
- What helps you remember to take your pills?
- When you've taken medications in the past, how did you remember to take them?
- What will you do about taking your pill if you are away from home for a night or two?
- What do you do if you miss a dose of Truvada?
- What is your understanding of possible Truvada side effects? How will you address side effects if you have them?

PrEP Follow-Up Appointments

Opener: Let's check in about your sexual health and what it has been like taking PrEP since your last visit.

Pill Taking Experience:

- How has it been taking PrEP? Have you experienced any side effects?
- What helps you remember to take your pill?
- What challenges do you experience in taking the pill? When are you more likely to forget? How many pills have you missed in the past month?
- Thinking about the past 7 days, how many doses do you think you may have missed completely? On average, how many doses do you miss per week?
- What might help you take your pills more regularly? (Helpful strategies may include: using a pill box, taking Truvada with other daily medications, using a phone alarm, marking doses taken on a calendar, keeping bottle in a visible location associated with a daily activity like brushing teeth)
- What keeps you motivated in taking the PrEP pills?
- What, if anything, might help make taking PrEP even easier?

Discussing PrEP with others:

- Since your last visit, have you had any positive or negative social experiences that you think are related to taking PrEP (for example, improved relationship with a friend or sex partner, such as ability to have a more open discussion with a partner about HIV status, *or* stigma/discrimination, such as someone not wanting to use condoms with you after finding out you are on PrEP)?

Behavior and Activity:

- What has been going on for you sexually since your last visit?
- How does taking PrEP impact your risk activity?
- Has taking PrEP changed what you do to protect yourself from getting HIV/STIs (for example: topping vs bottoming, condom use, discussing HIV/STI status and/or testing with partners)?

Plan(s) for Staying HIV/STI Negative:

- What I hear you saying is that you currently reduce your risk by...and you talked about your desire/plan to also.... Have I understood you correctly?
- What other ideas/plans, if any, do you have for staying HIV/STI negative?

HIV Testing and Results:

- How are you feeling about getting your HIV test result in a few minutes?
- What, if anything, would you like to discuss before I provide your results?
- *After negative result obtained:*
 - What are your thoughts/feelings about your negative test result?
 - How, if at all, does this negative test result impact your plans/efforts to remain HIV negative?
- *After positive result obtained:*
 - Provide post-test counseling and linkage to care.
 - Refer to RAPID.

The Basics of PrEP – Patient Information

1. Medication Instructions

- There are 30-pills of Truvada in each bottle (30-days of PrEP).
- Store the bottle at room temperature (not in refrigerator/hot car). Keep pills in bottle with desiccant, except for pills kept in 7-day pill box.
- This medication can be taken with or without food.
- This medication can be taken when drinking alcohol or using drugs.
- Do not share your Truvada with others; it may seem like a generous thing to do, but could actually cause harm. PrEP is not safe for everyone.

2. One Pill Per Day

- Take 1 pill every day.
- Only studies of daily dosing have shown PrEP to be effective. People who use PrEP more consistently have higher levels of protection against HIV.
- It takes about 1 week on Truvada before there is enough medication in your body to decrease your chance of getting HIV.
- We have **no** evidence that taking more than one pill a day gives any additional protection. In fact, taking too many can be bad for your health or make you feel sick.
- There are studies currently investigating if taking PrEP less frequently than once a day would still help to protect people from HIV, but final results from these studies are not yet available. Based on what we know right now, we recommend taking PrEP as close to daily as possible.

3. Getting into a Routine

- Many people find it helpful to take their pills at the same time as something else they regularly do each day (e.g., eating breakfast, brushing teeth).
- Reminders (alarms or seeing the bottle somewhere you look each day) can also help.
- Pill boxes are available if you want to try one.
- When routines are disrupted (e.g., staying out overnight, going on vacation, skipping meals), consider carrying extra pills on you.

4. Sometimes Doses Are Missed

- People sometimes forget or skip doses. It is not uncommon.
- If you forget a dose just take it when you remember. For example:
 - *If you usually take in AM, but realize at 10pm that you forgot, it's ok to take 1 pill then and continue with your usual schedule the next day.*

5. Potential Side-Effects

- Some people experience side effects when starting Truvada for PrEP. This may involve gas, bloating, softer/more frequent stools, or nausea.
- These symptoms are usually mild and go away after the 1st month on PrEP.
- Strategies to deal with stomach related symptoms:
 - take pill with food/snack
 - take pill at night before bedtime
- Contact the PrEP staff if you have side effects (see phone number at end of handout). We can help.

6. Discussing PrEP with Others

- People sometimes find it helpful to tell friends or family that they are taking PrEP (can help support pill taking).
- Think carefully about whom you might want to tell you're taking PrEP (you want it to be someone who will be supportive).
- It's your personal decision. You should not feel pressured to tell anyone.

7. Stopping PrEP

- If you choose to stop PrEP, please call the PrEP staff to let us know.
- Consider taking Truvada as PEP (post-exposure prophylaxis) for 1 month after your last high-risk exposure. The PrEP staff will be happy to talk with you more about this.
- Please come to the clinic for HIV testing 4 weeks after stopping PrEP.

8. Restarting PrEP

- If you have stopped PrEP for more than 7 days and would like to restart, please call us and let us know so that we can help you do this safely.
- Getting an HIV test before you restart PrEP is very important. If you are already infected with HIV and take Truvada, the virus could become resistant to this medication which means that the medication will not work for HIV treatment.
- Report any flu-like symptoms or rashes to your health care provider or PrEP staff as they could be symptoms of early HIV infection.

9. Combining PrEP with other prevention strategies

- PrEP isn't 100% effective and also doesn't protect against other STIs, so should be combined with other prevention strategies, such as condoms, lube, and regular STI testing.

10. Health monitoring while on PrEP

- Your health should be monitored by a health care provider while taking Truvada
- HIV testing every 3 months and creatinine testing every 3-6 months while on PrEP is recommended.

Questions/Concerns

- Call your provider during business hours if you have any questions or concerns, or if you're going to run out of pills before your next visit. If you have an emergency, call 911 or go to the hospital emergency room.

Additional resources

- sfcityclinic.org/services/prep.asp
- prepfacts.org
- myprepexperience.blogspot.com/
- projectinform.org/prep/
- cdc.gov/hiv/basics/prep.html