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

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1.0 Introduction

Since San Francisco became one of the first cities in the world to report cases of HIV/AIDS in the early 1980s, the San Francisco Department of Public Health (SFDPH) and researchers/clinicians at San Francisco General Hospital have served as world leaders in advancing innovations in HIV treatment and prevention. The SFDPH, in conjunction with the leadership of the HIV/AIDS Division at UCSF, became the first jurisdiction in the United States, (in January 2010) to recommend universal 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 via 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 drugs[1-6]. In the largest study conducted in MSM, a fixed dose combination of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) was associated with a 44% overall reduction in HIV infections, and estimates of >90% protection for persons with drug concentrations indicating adequate adherence[1,7]. Subsequent open label studies, where participants knew the effectiveness of PrEP, demonstrated even higher levels of protection.[8,9] 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 guidelines (May 2014) from the Centers of Diseases Control cite broad indications for PrEP use.[10] [Although tenofovir alafenamide fumarate and emtricitibine (TAF/FTC) has been approved for HIV treatment, it has not yet been studied for use as PrEP and should not be used.]

PrEP programs have been developed within large health systems throughout San Francisco (e.g. Kaiser Permanente) 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), patients with coverage through Healthy SF, and individuals without health insurance, have not had regular and systematic access to this important HIV prevention option within the SFHN prior to this initiative. 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 for HIV infection and women seeking preconception care.[11] These clinical guidelines are designed to provide guidance on evaluation, initiation, and monitoring of PrEP for patients within the SFDPH health system, and can be adapted for use in any primary care setting.

These guidelines are also available on the following websites:

- SF Health Network Treatment and Referral Guidelines (intranet): **insidechnsf.chnsf.org/practiceguidelines/**
- Positive Health Program (Ward 86) PrEP Clinic: **https://hiv.ucsf.edu/care/prep.html**

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[a]

1. HIV uninfected based on laboratory evidence (performed in the past 7 days), either by:
    a. Negative 4th generation assay with or without HIV viral load (RNA);
    OR
    b. Negative ELISA and HIV viral load.

2. 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 (e.g., 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.
   - Has NOT 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 [e.g., fatigue, fever, rash, vomiting, diarrhea, headache, arthralgia, pharyngitis, rash, night sweats, or adenopathy (cervical, axillary and inguinal)];
3. Underlying renal disease (CrCl < 60 ml/min, 2+ or more proteinuria);
4. Significant underlying bone disease;
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, and clinical trials evaluating safety and efficacy of TDF/FTC for PrEP in patients under the age of 18 years are currently ongoing. In the absence of available clinical trial safety 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, including our pediatric HIV specialist Dr. Ted Ruel. Please see Appendix D for additional considerations for providing PrEP to adolescents and young adults.

3.0 Initial Evaluation

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

1. History of or current kidney or 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, clinicians 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/antigen test within 7 days AND HIV viral load (RNA) testing within 7 days, if possible.
   - 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 B core antibody (HBcAb) if not currently documented.
   - Hepatitis B (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.
   - Hepatitis A (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.

** Use the following online calculator to calculate creatinine clearance: http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault. 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., creatine, protein drinks). If repeat CrCl is ≥ 60 ml/min, patient may initiate PrEP per provider judgment. If not, the patient should not be initiated on PrEP and should receive close follow-up from their PCP and consideration of nephrology consultation as appropriate.

***Self-collection swabs are an accepted method for conducting Sexually Transmitted Infection screenings and may be a more comfortable method for the patient. For patient instructions on how to self-collect specimens, please use the links below, courtesy of San Francisco City Clinic:

Pharyngeal collection instructions in English and Spanish
Rectal collection instructions in English and Spanish
Vaginal collection instructions in English and Spanish

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 and Prevention (CDC) guidelines for details on possible changes to bone mineral density (BMD) associated with TDF/FTC as appropriate.[10]

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 persons with chronic HBV infection detected at screening to participate. Patients who stop TDF/FTC for PrEP should be started on alternative HBV treatment in consultation with Infectious Disease specialist as appropriate.

Pregnancy/Breastfeeding: We recommend discussing pregnancy intentions with women of reproductive age who are considering PrEP, providing access to contraception or safer conception options when desired, and offering PrEP during pregnancy or breastfeeding if indicated. In clinical trials examining the efficacy of PrEP, the protocols called for the cessation of PrEP if participants became pregnant, so we do not have data on the safety of PrEP if used throughout the duration of pregnancy. Although no definitive statements about the safety of PrEP during pregnancy and breastfeeding can be made yet, studies have not shown an increased risk of birth defects among infants of HIV-infected women who took TDF/FTC during pregnancy.[12,13] Some observational studies have suggested a possible risk of lower bone mineral content among infants of HIV-infected women who took TDF as part of 3-drug combination ART (cART).[14] However, a recent randomized study did not find an increased risk of bone mineral density loss in infants of mothers randomized to start TDF- compared to AZT-containing cART at >14 weeks gestation.[15] For additional questions on the use of PrEP in the periconception period or during pregnancy or lactation, please contact HIVE (hiveonline.org) or the Perinatal HIV Hotline (http://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/) for expert consultation.

Transitioning from Non-Occupational Post-Exposure Prophylaxis (nPEP) to PrEP:
New nPEP guidelines by the CDC were published in April 2016. Please see http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf . Our guidelines endorse the statement that most individuals who qualify for nPEP by risk factors should be transitioned to PrEP following the nPEP course

1. 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.
2. 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/antigen test at completion of nPEP and transition directly to PrEP (TDF/FTC) 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 done at this visit if possible, or at least within 7 days of this follow-up visit, or drawn at this visit if possible.

Patients should be evaluated at least every 3 months (after their initiation visit) for assessment of acute HIV or STI symptoms, possible side effects, creatinine and HIV tests, and STI screening.

1. **HIV Testing:** 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 a patient reports symptoms of acute HIV infection, HIV viral load (RNA) testing should be ordered.
2. **Creatinine:** 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. More frequent testing (every 3 months) should be based on the presence of other risk factors for renal insufficiency (e.g. hypertension, diabetes mellitus, older age). No patient receiving PrEP should go longer than 6 months without having a creatinine level checked.
    - Estimated creatinine clearance (CrCl) via the Cockcroft Gault equation should be calculated for every creatinine result. Use the following online calculator: http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault.
    - See Section 5.0 below for management of patients with CrCl <60 ml/min.
3. **STI screening:** Gonorrhea/Chlamydia (urine, rectal, and pharyngeal) and Syphilis (RPR or VDRL) as appropriate (every 3 months for MSM or other patients with multiple sexual partners).
4. **Hepatitis C (HCV):** Consider annual HCV Ab screening for MSM, and people who inject drugs.
5. **Pregnancy testing:** Women of reproductive age every 3 months 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 about medication adherence and should provide counseling (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 ≥ 60 ml/min, TDF/FTC may be restarted and creatinine should be rechecked in 1 month.

If the creatinine is greater than 1.5x baseline (but CrCl is still ≥ 60 ml/min), discuss with the patient and evaluate the medical record to understand if there are any other potential causes for the creatinine elevation (e.g., dehydration, body building supplements, new medications,

NSAIDs, trimethoprim/sulfamethoxazole, other nephrotoxins, newly-diagnosed conditions that can lead to renal insufficiency such as hypertension and diabetes) and repeat creatinine in 2 weeks. If creatinine elevation is sustained, discontinue PrEP for 2-4 weeks and recheck creatinine. If creatinine has normalized, it is possible to restart PrEP and check creatinine in 1 month.

Patients who want to be on PrEP but have elevated creatinine should be worked up for other etiologies of renal insufficiency and referred to a nephrologist when appropriate. 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. These guidelines discourage the use of TDF/FTC-based PrEP for patients with persistent CrCl < 60ml/min and close monitoring when CrCl approaches this value.

6.0 Discontinuation and Restarting PrEP

If a patient is found to be infected with IHV on follow-up testing, PrEP should be discontinued and the patient should be started on antiretroviral therapy. The patient they should be offered immediate linkage to care and antiretroviral therapy through the San Francisco-based 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 28 days after a high risk exposure if that exposure occurred within the past 7 days.

Restarting PrEP after discontinuation: If a patient has discontinued PrEP for 7 days or more, and wishes to restart, they should have repeat HIV antibody/antigen testing (with HIV viral load, if possible) prior to reinitiating TDF/FTC. If there is a concern for acute HIV, HIV viral load testing should be completed, and PrEP delayed until test results are available. Furthermore, if there has been a potential HIV exposure within the past 72hrs, start nPEP and consider transiting to PrEP without interruption.

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 may 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:

<u>HIV-negative patients who have primary care providers within the SFHN:</u>
Patients can be referred by their provider, or they can self-refer, to Ward 86 for PrEP evaluation. The PrEP Clinic Coordinator/Navigator (415-206-2453), 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. The Ward 86 clinician will provide the primary caer provider (PCP) with recommendations for PrEP follow-up. 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 primary 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 for any questions on PrEP.

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 eligibility is established, initial HIV testing, laboratory screening, and HIV prevention counseling will be offered; labs will be reviewed by the Ward 86 clinician, and PrEP 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 at Ward 86 (if insurance eligible) or another clinic within SFHN for PrEP management and primary care.

8.0 Additional PrEP Resources

- http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf
- http://www.cdc.gov/hiv/pdf/prepprovidersupplement2014.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)
- nPEP guidelines: http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf

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-10	Description
Z20.6	Contact with and (suspected) exposure to HIV
Z72.6	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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13. Jao J, Abrams EJ, Phillips T, Petro G, Zerbe A, Myer L. In Utero Tenofovir Exposure Is not Associated With Fetal Long Bone Growth. *Clin Infect Dis.* 2016.
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15. Siberry GK, et al. Impact of Maternal Tenofovir Use on HIV-Exposed Newborn Bone Mineral Content. CROI 2016, Abs. 36.

Appendixes:

A. **Paying for PrEP**
B. **Initial and Follow-up PrEP Appointment Counseling Prompts**
C. **Basics of PrEP – Patient Information**
D. **PrEP in Adolescents and Young Adults**

Appendix A

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
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 $3600/year 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 $3600/year co-pay assistance (see below) May use Patient Access Network if <500% FPL (see below)

FPL – Federal Poverty Limit $11,880 for individuals (2016) (www.healthcare.gov/glossary/federal-poverty-level-FPL/)

Gilead patient assistance (for patients without insurance or with Healthy SF)

- 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)

- Gilead offers $3600/year co-pay assistance.
- 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.

Appendix B

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.

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SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

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The Basics of PrEP – Patient Information

1. Medication Instructions

- There are 30-pills of Truvada in each bottle (30days 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 things 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

Appendix D

PrEP for Adolescents and Young Adults

Rationale

Adolescents and young adults (AYA) are disproportionately impacted by HIV in the United States. AYA ages 13 to 24 made up 17% of the US population in 2010 but accounted for an estimated 26% of new HIV infections that same year (CDC, 2015). The majority of new HIV infections among AYA occur among young men who have sex with men (YMSM), particularly YMSM of color (CDC, 2015). Comprehensive HIV prevention services for AYA, including access to PrEP, are integral to achieving San Francisco Getting To Zero goal of a 90% reduction in new HIV infections by 2020. However, PrEP access for AYA has particular challenges which have limited uptake among this highly impacted population. This appendix is intended to provide guidance to providers who care for AYA at risk for HIV infection for whom PrEP may be beneficial.

Minor Consent

In California, minors, young people 12 years of age or older, may legally consent for reproductive and sexual health services ("sensitive services") without parental notification or consent. This includes protection from the disclosure of sensitive services health information to parents or guardians without the written consent of the minor. Sensitive services include consent for HIV testing and treatment, and PrEP services. As of January 1, 2012 California Family Code §6926 specifically states: "A minor who is 12 years of age and older may consent to medical care related to the prevention of a sexually transmitted disease." While not specific to PrEP, this law was written to be inclusive of all sexual transmitted disease prevention, including PrEP for HIV prevention. The National Center for Youth Law has additional information on minor consent laws:
http://www.teenhealthlaw.org/fileadmin/teenhealth/teenhealthrights/ca/CaMCConfChart10-14.pdf

Maintaining Confidentiality

An Explanation of Benefits (EOB) report sent to the policyholder after a medical visit presents a unique risk to confidentiality for AYA covered by a parent's health insurance. The Confidential Communications Request law requires that, when requested, health insurers keep all or sensitive services information from the policyholder and requires the insurer to send communication directly to the insured individual instead. Request for confidential communications can be requested electronically or via mail, and must be implemented within 7 days of electronic receipt or 14 days of first class mail receipt, respectively. Providers, case managers, or other clinic staff should discuss confidentiality and submission of confidentiality communications request with AYA patients who are covered by a parental policy. Additional information about the confidential communication request form is available at http://www.myhealthmyinfo.org/.

Limits to Confidentiality

Some limitations to confidentiality exist in circumstances when the minor discloses suicidal or homicidal ideation, reports experiencing physical or sexual abuse or assault, or when certain age discrepancies exist between the patient and her or his sexual partner(s). Sexual intercourse between a minor age 13 or under and a partner age 14 or older constitutes a mandated report to appropriate authorities. Similarly, sexual

intercourse between a minor 14 or 15 years old and a partner 21 years or older must be reported regardless of stated consent by the minor. Providers are not obligated to ask patients about the age of their sexual partners, but should rely on professional judgment to guide the clinical interview. For additional information please see the Adolescent Health Working Group Toolkit on Understanding Confidentiality and Minor Consent in California:
http://www.teenhealthlaw.org/fileadmin/teenhealth/teenhealthrights/ahwg/ahwg_consent_toolkit.pdf

TDF/FTC Safety

Clinicians prescribing PrEP to AYA should consider the same safety issues relevant to adults, including bone mineral density, kidney function, pregnancy status, and hepatitis B status. Effects of TDF/FTC on bone mineral density (BMD) warrants closer attention in this age group as peak BMD accrues throughout young adulthood. Eighteen to 24 year old males taking TDF/FTC for PrEP experienced minimal whole body BMD loss (roughly 1% loss) over the course of about one year (Mulligan et al., 2015). This loss is comparable to the BMD loss seen among women using depot medroxyprogesterone acetate (DMPA; Depo-Provera) for birth control for one year (0.35% - 3.5%; ACOG, 2014). Importantly, similar to DMPA use, BMD among 18 -25 year olds returns to expected level for age six months after discontinuation of TDF/FTC (iPrex Study Team, 2016). More specific data on BMD changes in minors 15-22 year olds taking TDF/FTC for PrEP is currently underway. Of note, the effects of TDF/FTC for PrEP on physical development have yet to be evaluated among youth under the age of 15. The decrease in BMD should be weighed against the risk of HIV infection, which itself causes decreased BMD.

PrEP Adherence

PrEP efficacy is strongly linked to daily adherence and recent studies have shown challenges with PrEP adherence among AYA (ATN 110). This is similar to past research on HIV treatment and contraception adherence among youth which also found this to be an especially difficult issue for AYA (ATN, 2013). This population may require more intensive support and frequent communication from providers and navigators in order to stay adherent. It is especially important that adolescents have open, non-judgmental communication with their providers with the opportunity to ask questions in order to support adherence. Beyond in-clinic communication, one recommendation for improved adherence is the use of text message reminders. These have been found to be effective in the AYA population and have the benefit of being affordable and non-location dependent. The creation of peer support groups, whether in person or through social media, can also be very effective in improving adherence. By bringing those taking PrEP together, these groups can help reinforce self-efficacy and increase satisfaction of those involved which has been found to be beneficial for other AYA clinical settings (Taddeo, Egedy & Frappier, 2008).

Access to Medication

Costs associated with the access of PrEP are a common barrier, especially when considering the full retail value of the medication. There are options to help AYA cover the costs. For those aged 18 and older, the patient assistance programs and copay coverage options presented in these guidelines still apply. For those under 18 years of age, many barriers persist and unfortunately there are few options for covering the cost of the medication. We recommend addressing these on a case-by-case basis with the help of a PrEP Navigator, Case Manager or other available patient advocate. It is helpful to note that Medi-Cal will cover the cost of the medication, regardless of patient age.

Opportunity for Health Care Engagement

Many AYA at increased risk for HIV also face barriers accessing the healthcare system. PrEP can serve as an important point of entry into care for a group that may not otherwise seek medical services. Adolescence is a pivotal time in a person's life for health, especially health promotion. Though AYA may be considered healthier than their adult counterparts on traditional measures of morbidity and mortality, they generally have poor behavioral indicators of health. It is suspected that approximately half of adult deaths are due to poor health behaviors which were started in adolescence, making this an optimal time to engage in the healthcare system (NAS-IOM, 2009). PrEP allows an opportunity to engage in conversation with youth around sexual health, but also provides a gateway to address other areas of their well-being. As part of ongoing PrEP maintenance, youth receive regular testing for sexually transmitted infections, including HIV, in accordance with national guidelines and recommendations. In addition, PrEP visits are opportunities to review immunization history and screen for common AYA problems.

Select recommended vaccinations for AYA in addition to HAV and HBV:

- HPV (4- or 9- valent)
    - 3 dose series through the age of 26 for both women *and* YMSM
    - Minors may consent for this vaccine without parental consent
- MCV4
    - 1 dose of meningococcal conjugate vaccine *may* be given to YMSM if not previously immunized or immunized > 5 years ago
    - Requires parental consent for minors
    - http://www.cdph.ca.gov/HealthInfo/discond/Documents/MSM_meningococcal_vaccine_health_advisory_April15_2014.pdf
- Tdap by age 12
    - Requires parental consent for minors

Additional U.S. Preventive Services Task Force AYA screening recommendations:

- Substance use education and brief counseling
- Depression screening and referral to treatment
- Intimate partner violence assessment
- Cervical cancer screening for women >21 years old
- Obesity/BMI screening and referral
- Hypertension
- Lipid disorder >20 years old
- Nutrition and physical activity

For more guidance on the care of adolescents and young adults, please reference *Adolescent Health Care 101: The Basics- CA Edition* (http://ahwg.net/uploads/3/4/5/5/34557719/adolescent_health_care_101.pdf)

> This document from the Adolescent Health Working Group provides recommendations on how to create a youth friendly space, how to start discussions on sexual history, etc.

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