Are You PrEPin’?
For Patients and Providers

Hosted by PROCEED Inc.: National Center for Training, Support and Technical Assistance

Presented by San Francisco Department of Public Health and San Francisco AIDS Foundation

January 15, 2015
Welcome and Opening Remarks
WEBINAR PARTICIPANT GUIDELINES

• Your phones will be placed on mute until we open the lines for discussion or questions.

• The session is being recorded. If you would like the recording please e-mail us.

• You will be asked to answer several questions during the session, please click the “raise your hand” icon or select your answer directly on the screen.

• We will have a Question & Answer period at the end of the session. Make note of any questions that you may have.
PROCEED, Inc.: NCTSTA’s CBA Solutions program provides services in the following areas:

• Organizational Development and Management

• HIV Testing and Prevention with Positives

• Effective Behavioral Interventions and Public Health Strategies
PROCEED, Inc.: National Center for Training, Support and Technical Assistance

For more information on our program and services visit our website at www.proceedinc.com/our-services/national-training/request-capacity-building

Also “Like/Follow” us on Facebook (www.facebook.com/pages/ProceedNCTSTA/1525761844326609) and Twitter (twitter.com/ProceedNCTSTA)
Let’s get to know each other. Please answer these 3 poll questions before we get started.

Please read the question and use your keyboard to respond to the question on your screen.
Learning Objectives

By the end of the session, participants will be able to:

• Describe PrEP and how it fits into the HIV prevention care toolkit (what gap does it fill, what gaps does it leave, How do we talk about it?).

• Understand PrEP's effectiveness and the importance of its adherence.

• Describe the basic timeline of a patient's involvement in PrEP.
Join the Conversation at our simultaneous Twitter Chat now!

Twitter: @ProceedNCTSTA

Twitter: @getSFcba

Use the Hashtag: #PrEP and #PrEPTalkSF
Agenda

- Why PrEP?
- Does PrEP Work? Is it Safe?
- How to PrEP
- CBOs and PrEP: SFAF experience
- Future Directions
- Questions
Welcome!

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San Francisco Priority Areas

- HIV Testing
- Prevention for High Risk Negative Persons
- Policy/Planning
Ready to find out more?

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Email: get.SFcba@sfdph.org
Call: 415.437.6226
Are You PrEPin’? A Practical Approach to Implementing HIV Pre-Exposure Prophylaxis

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15 January 2015
Why New HIV Prevention Tools are Needed

- Despite testing, counseling, condoms, and ART, 40,000-50,000 new infections annually in the U.S.

- Incidence especially high in certain U.S. populations
  - Men who have sex with men (MSM)
  - Transwomen (FTM)
  - Racial and ethnic minorities, especially youth
  - Injection drug users (IDU)

- Incidence far higher in Sub-Saharan Africa, Southeast Asia, Eastern Europe
Diagnoses of HIV Infection among Adults and Adolescents, by Sex, 2008–2012—United States and 6 Dependent Areas

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2012—United States and 6 Dependent Areas

N = 48,651

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

a Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

b Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
## Current HIV Prevention Methods: where are the gaps?

<table>
<thead>
<tr>
<th>Method</th>
<th>(+)</th>
<th>(-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing/Counseling + Condoms</td>
<td>Counseling: individual benefits? Condoms: 67%-80% efficacy if used correctly, consistently</td>
<td>Condom <strong>efficacy drops off quickly if not used correctly, consistently</strong> Questionable efficacy of counseling in RCTs</td>
</tr>
</tbody>
</table>
| **ART as Prevention (“TasP”)**      | 96% risk reduction in serodiscordant heterosexual couples (HPTN052)                                                                                                                                                                                                                                                                                                           | -likely efficacy in MSM but %RR unknown  
-**Does not protect partners of infected-unknowns**  
-intermittent viremia?                                                                                                                                                                                                                     |
| PEP (Post-exposure Prophylaxis)     | 80% risk reduction (AZT monotherapy in occupational exposure)                                                                                                                                                                                                                                                                                                 | -underutilized  
-requires initiation within 72h of recognized risk                                                                                                                                                                                                                                     |
| **Serosorting:**                    | • Positive serosorting: limits HIV transmission if both partners truly HIV+  
• Negative serosorting: Better than nothing? Maybe?                                                                                                                                                                                                                                                                                      | Depends on:  
• Both partners’ **accurate** understanding of status  
• **Frequent testing of HIV**  
• No recent exposure since last negative test                                                                                                                                                                                                                                      |
How effective are condoms?

According to CDC and University of Texas studies looking at how well condoms work at preventing HIV transmission:

• For people who report 100% condom use for vaginal sex, their estimated level of protection is 87%.
• For people who report 100% condom use for anal sex, their estimated level of protection is 70%.
• For people who sometimes use condoms for anal sex, their estimated level of protection is 4.4% ≈ 0%.
  – More research being done to define frequency of sometimes

Only 1 in 6 gay men reported 100% condom in CDC study.

What is PrEP?

- FDA approved emtricitabine/tenofovir (FTC/TDF, or Truvada®) 16 July 2012 for use as PrEP in combination with safer sex practices to reduce the risk of sexually-acquired HIV infection in adults at elevated risk
- Taken daily regardless of plans for sex
- As part of a comprehensive HIV prevention plan
- PLUS regular monitoring for HIV infection, STIs, drug safety, adherence
If Effective, PrEP may:

- Provide a partner-independent prevention method
  - totally controlled by the user
  - independent of the state of mind immediately prior to and during sex

- Fill gaps in current prevention methods
PrEP and the test/treat model

I. Universal, accessible HIV/STI testing
   - Frequency determined by risk
   - Testing for acute infection in high-risk populations/settings

III. COMBINATION PREVENTION
   - Condoms and Risk Reduction coaching
   - Referrals for Substance use treatment, Mental health care
   - PEP for occasional exposures
   - PrEP for Pts with elevated risk:
     - Inconsistent condom use
     - Multiple partners/non-monogamous steady partnerships
     - Serodiscordant partners especially periconception
     - h/o Rectal STIs

II. IMMEDIATE ART
   - Eliminate OIs/AIDS
   - ↓ nonAIDS complications
   - ↓ transmission to heterosexual partners (HPTN052)
   - Likely ↓ transmission in MSM

IF (+)
Polling Question: by how much does PrEP reduce the risk of HIV infection?

1. 44%
2. >90%
3. 67%
4. 92%
5. All of the above, depending on adherence and population studied
Does PrEP Work?
Efficacy results from Randomized Controlled Trials (RCT)
Design of PrEP RCTs

- Rapid HIV Ab testing at screening, enrollment
- Randomized to daily drug vs. placebo
- Monthly follow-up visits for rapid HIV testing, adherence counseling and measures, prevention counseling, STI testing/treatment
- If rapid(+) at a f/u visit, HIV RNA performed retrospectively on stored plasma to determine infection window
- Outcomes: efficacy, safety, adherence, behavior, resistance
# Phase III PrEP Studies

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>POPULATION</th>
<th>LOCATION</th>
<th>Active arm(s)</th>
<th>EFFICACY If High Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>2499 MSM and MTF</td>
<td>South America, USA, Thailand,</td>
<td>FTC/TDF</td>
<td>44% (95% CI 18-60) 48 vs. 83 &gt;90%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South Africa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDF-2</td>
<td>1219 heterosexual men and women</td>
<td>Botswana</td>
<td>FTC/TDF</td>
<td>63% (95% CI 21-83) 9 vs. 24</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>4758 serodiscordant heterosexual couples</td>
<td>Kenya and Uganda</td>
<td>FTC/TDF</td>
<td>73% (95% 49-85) 90% 62% (95% CI 44-81) 13 FTC/TDF, 17 TDF, 52 placebo</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>2120 heterosexual women</td>
<td>Kenya, Tanzania, Zimbabwe,</td>
<td>FTC/TDF</td>
<td>No difference 33 FTC/TDF vs. 35 placebo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South Africa</td>
<td></td>
<td>Stopped early due to lack of efficacy</td>
</tr>
<tr>
<td>VOICE</td>
<td>5000 heterosexual women</td>
<td>Uganda, Zimbabwe, South Africa</td>
<td>FTC/TDF TDF</td>
<td>No Difference</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vaginal TDF gel</td>
<td></td>
</tr>
</tbody>
</table>

Courtesy of Stephanie Cohen, adapted
Facilitators and Barriers to Adherence

Facilitators

- Altruism towards community
- Regular contact with study staff
- Open, nonjudgmental relationship with staff
- Accurate information about side effects and mitigation, how to handle missed doses
- Prior pill-taking (vitamins, other daily meds)
- Having a predictable daily routine

Barriers

- Predictable disruptions: travel
- Unpredictable disruptions: illness, stress, changes in mental health/job/housing
- Not sleeping at home
- Intentional skipped doses
- Stigma (hiding pill taking)

Gilmore et al. AIDS PATIENT CARE and STDs: 27(10), 2013
Adherence, Drug levels and Efficacy

<table>
<thead>
<tr>
<th>Dosing</th>
<th>Estimated PrEP Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>2x/week</td>
<td>76%</td>
</tr>
<tr>
<td>4x/week</td>
<td>90%</td>
</tr>
<tr>
<td>Daily</td>
<td>99%</td>
</tr>
</tbody>
</table>


Grant RM, Anderson PL et al. Lancet Inf Dis 2014
Time to effectiveness

- Starting PrEP: Data from PK studies\(^{[1,2]}\) in HIV-uninfected volunteers, looking at time to maximal intracellular drug levels (time to clinically protective levels unknown)
  - 7 Days for rectum
  - 20 days for cervicovaginal tissue
  - 20 days for blood

- Discontinuing PrEP: Continue 30 days after last exposure
PrEP for Injection Drug Users (IDU)

- Bangkok Tenofovir Study
- 2413 IDU randomized to TDF vs Placebo 2005-10
- Could switch between DOT or monthly visits; followed for 4 yrs
- 48.9% (95%CI 9.6-72.2, P=0.01) incidence reduction TDF vs. Placebo
- Incidence reduction of 70% (95%CI 2.3-90.6, P=0.04) if detectable levels*
- Could not distinguish between HIV protection by transmission route (sex or IDU)

Choopanya et al. Lancet 2013; 381: 2083–90
2 Recent Studies to watch.....

1. **PROUD** (2014) - British study that assigned people to start PrEP right away or to delay for 48 months. This was a smaller pilot study of 500 people. A second larger phase of the study to measure efficacy and safety was planned, but the initial study has now determined that PrEP was so much more effective than delay that all participants are being offered PrEP. We do not yet know how effective.

2. **IPERGAY** (2014)- Study of demand-based PrEP. Take 2 pills before sex, one pill right after sex and a fourth pill the next day. Based on PROUD announcement, a safety board did a similar analysis and found that PrEP worked significantly better than a placebo. We do not yet know how effective.
Standard daily dosing

Emtricitabine/tenofovir 200/300mg daily
Alternative Dosing

IPERGAY Study

Emtricitabine/tenofovir 200/300mg Dosed
As 2 pills 2-24 hours before sex then 2 days after

Wanna hook up on Friday?

http://www.ipergay.fr/
PrEP Efficacy: Summary

- PrEP found to be moderately to highly efficacious in MSM, MSW, IDU
  - Highly efficacious in those who take it consistently
  - Adherence is the key variable: doesn’t have to be PERFECT, but has to be better than good

- Efficacy results in women mixed
  - Adherence is a major factor
  - Differential cervicovaginal vs rectal tissue penetration?
  - Other local tissue phenomena: STDs, trauma, tissue integrity.......
  - Stage of infection in source partner?
  - Perception of risk?

- Do women need to be *more* adherent than men?
- Need more data in Transwomen: effect of hormone therapy, adherence, uptake

PrEP Safety: Summary

- **Safety (vs. Placebo)** *
  - Studied rates of death, serious adverse events, and laboratory abnormalities
  - no significant difference in kidney toxicity;
  - increased nausea and wt loss in FTC/TDF (P=0.04 for both)
  - small but sig. decrease in bone mineral density (BMD), without difference in fractures

- **PrEP was well tolerated** *
  - Adverse effects occurred in minority of subjects
  - GI adverse effects (eg, nausea) more common in those receiving PrEP than placebo
    - Occurred in < 10% and primarily during the first month only (PrEP “start up” symptoms)

*data from iPrEx, but similar results reported in other RCTs*
How to PrEP (in 2014/2015)
Polling Question: Which of the following persons is NOT eligible for immediate PrEP?

1. 35 y.o. MTF with normal kidney function, no evidence of active hepatitis B, and rectal chlamydia; tested fingerstick(-) for HIV 3 days ago.

2. 22 y.o. MSM with normal kidney function, no evidence of active hepatitis B, and rectal gonorrhea. He tested fingerstick(-) for HIV 3 days ago and has a fever, fatigue, and a sore throat.

3. 27 y.o. woman who is trying to get pregnant with her HIV + male partner, who has an undetectable viral load. She tested fingerstick(-) for HIV 3 days ago and has normal kidney function and no evidence of active hepatitis B.
Sample PrEP Visit Schedule

**Screening**

- Enrollment: 1-2 weeks

**First Visit: Assessment**

- Sexual Risk Assessment
- Basic Medical History, exam
  - Sx of acute HIV?
- PrEP Basics: how it works, adherence, side effects
- Labs: HIV, STI, Safety (renal function, HBV)
- Navigation services: Provider/Clinic referrals as needed; Financial Case Management

**Follow-up:**

- Symptom review: Sx of acute HIV?
- Assessment, counseling:
  - Behavior
  - Adherence
- HIV testing
- STI testing
- Renal function testing
- Dispense 90 Tabs

- Repeat HIV testing if >7 days since last test
- Review PrEP basics
- Dispense 30 tabs
Taking a Sexual History

The 5 P’s

- Partners (#, gender) over given time
- Practices (oral, anal, vaginal)
- Protection (condoms, when, how often; status discussions)
- Past STI Hx (pathogen, location, frequency)
- Pregnancy (desire for it, prevention methods)

Some Tips

- Safe patient environment
- Confidentiality
- Be non-judgmental
- Be sensitive, but matter-of-fact
- Avoid assumptions
Counseling: Sexual behavior

- Deemed important by iPrEx participants in US: Nonjudgmental, open ended, data-driven, motivational

- Sexual behavior/HIV risk reduction: Probe for Pt’s knowledge of risk, prevention measures:
  - “What’s been going on sexually in last X months?”
  - “In the past 12 months, have you had vaginal sex? Anal sex? How many partners”
  - “When you have anal sex, how much of the time are you the bottom, the top?”
  - “What are the elements of your HIV prevention plan and how does PrEP fit into them?”
Empiric data on risk compensation in those receiving active PrEP

- In the Partners PrEP Study, no increase in unprotected sex in serodiscordant couples, STIs, or pregnancy after July 2011 (when placebo stopped and all received active PrEP).

Mugwanya et al., Lancet Infectious Diseases 2013

Average frequency of unprotected sex, \( \leftarrow \) before & after \( \rightarrow \) July 2011

Slide courtesy of Al Liu
From the initial iPrEx study, those who believed they were receiving Truvada, no risk compensation.

- ↓ Rates of HIV infections
- ↓ Rates of syphilis infections
- No increase in sexual risk behavior
What Demo Project Participants Say about Risk

Before PrEP
- “I am more comfortable barebacking with a positive guy who’s undetectable than with a guy who says he’s negative”
- “I usually start off using condoms, but then as I get to know a guy and trust him, and know his testing habits, the condom comes off”
- “I’ll use a condom if a guy seems sketchy. Or I just won’t have sex with him”

On PrEP
- “It’s easier to talk about HIV status with partners”
- “I am much less anxious about sex than I used to be”
- “I don’t tell my clients I’m on PrEP, because I don’t want them to ask me to do things I’m not comfortable with” (sex worker)
- “I wasn’t really using condoms before, and I’m not now”
Eligibility assessment: MSM

Box B1: Recommended Indications for PrEP Use by MSM

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- 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
Eligibility Assessment: Heterosexual

Box B2: Recommended Indications for PrEP Use by Heterosexually Active Men and Women

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 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 (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
Counseling: Medication issues

- **Adherence**
  - Ask about pill taking several ways
  - What makes it easier to take your pills daily?
  - What makes it more difficult?
  - What could you do to make it easier?
  - Tools: alarms, pillboxes, combining PrEP with other daily meds or activities

- **Discussion of most common side effects, mitigation strategies**
  - With/without food, bedtime dosing, waiting it out
  - Anticipatory guidance
**PrEP and risk of ARV-Resistance**

- Resistance not seen in clinical trials of PrEP showing efficacy, except for those with acute infection at baseline (monthly monitoring)
- FEM-PrEP: 3 cases of FTC resistance seen in participants who likely acquired HIV post-baseline (possibility of acute infection at baseline not ruled out)[5]
- Resistance mutations seen: K65R (TDF) or M184V/I (FTC)

<table>
<thead>
<tr>
<th>Trial</th>
<th>HIV Infected After Enrollment, n/N</th>
<th>Seronegative Acute HIV Infection at Enrollment, n/N</th>
<th>HIV Infections Averted, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx[1,2]</td>
<td>0/36</td>
<td>2/2</td>
<td>28</td>
</tr>
<tr>
<td>Partners PrEP[3]</td>
<td>0/30</td>
<td>2/8</td>
<td>74</td>
</tr>
<tr>
<td>TDF2[4]</td>
<td>0/10</td>
<td>1/1</td>
<td>16</td>
</tr>
</tbody>
</table>

## Screening for Acute HIV Infection

**Table 7: Clinical Signs and Symptoms of Acute (Primary) HIV Infection**

<table>
<thead>
<tr>
<th>Features (%)</th>
<th>Overall (n = 375)</th>
<th>Male (n = 355)</th>
<th>Female (n = 23)</th>
<th>Sexual (n = 324)</th>
<th>Injection Drug Use (n = 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>75</td>
<td>74</td>
<td>83</td>
<td>77</td>
<td>50</td>
</tr>
<tr>
<td>Fatigue</td>
<td>68</td>
<td>67</td>
<td>78</td>
<td>71</td>
<td>50</td>
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<tr>
<td>Myalgia</td>
<td>49</td>
<td>50</td>
<td>26</td>
<td>52</td>
<td>29</td>
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<tr>
<td>Skin rash</td>
<td>48</td>
<td>48</td>
<td>48</td>
<td>51</td>
<td>21</td>
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<tr>
<td>Headache</td>
<td>45</td>
<td>45</td>
<td>44</td>
<td>47</td>
<td>30</td>
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<tr>
<td>Pharyngitis</td>
<td>40</td>
<td>40</td>
<td>48</td>
<td>43</td>
<td>18</td>
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<tr>
<td>Cervical adenopathy</td>
<td>39</td>
<td>39</td>
<td>39</td>
<td>41</td>
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<tr>
<td>Arthralgia</td>
<td>30</td>
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<td>26</td>
<td>28</td>
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</tr>
<tr>
<td>Night sweats</td>
<td>28</td>
<td>28</td>
<td>22</td>
<td>30</td>
<td>27</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>27</td>
<td>27</td>
<td>21</td>
<td>28</td>
<td>23</td>
</tr>
</tbody>
</table>

PrEP Monitoring and HIV Testing

GOAL:
- Detect acute HIV infection (ab-/rna +) as soon as possible
  - at Baseline
  - acquired on PrEP
- Decrease risk of drug resistance

GOAL:
- ↑ Sustainability
- ↓ Costs
- ↓ Technical needs
- ↓ Program complexity

More frequent, more complex........................................................................Less frequent, less complex
Approximate Sensitivity of HIV Tests for Acute/Recent Infection

- **LAB RNA**
- **LAB-based p24 antigen/antibody Combo: (4th gen)**
- **LAB-based Antibody: (3rd gen)**
- **RAPID Ag/Ab (4th gen)**
- **RAPID Antibody (blood test reactive before oral)**

**INFECTION**

0 11 16 22 28-35 days

Acute Symptoms (+/-)
CDC recommendations for HIV testing

- Document nonreactive antibody test within ONE week prior to starting/restarting PrEP, and every 3 months on PrEP
  - Lab-based antibody (EIA) on blood or
  - Rapid FDA approved fingerstick antibody
  - NOT oral rapid antibody test
  - NOT patient self-reported test
  - NOT anonymous test

- Standard confirmatory testing, CD4, viral load if antibody-reactive

- If AHI suspect, delay PrEP, send RNA

Thought experiment: Possible HIV Testing Strategies for PrEP

- **Goal:**
  - Screen out acute HIV-infections at initiation
  - Detect acute infections after PrEP interruption

- “Basic package:” Serum antibody at screening and q3m; RNA for acute HIV if sxs

- “Basic Plus:” add test for acute infection (RNA) if Ab(-) at screening, or at re-initiation if off drug ≥ 7 days, or if sxs of AHI

- “Deluxe package:” Add test for acute HIV at all visits if Ab(-)?
  - Which acute test: 4\text{th} \text{ gen} Ag/Ab vs. RNA?

- More frequent testing during screening/initiation period? For all clients? Only for those reporting recent exposure risk?

- May change with new CDC HIV testing algorithm: Lab-based 4\text{th}-gen Ag/Ab may replace antibody/confirmatory testing
HIV Testing and Monitoring Scenarios: Basic and Basic-Plus

- **Basic:** Per CDC: Lab-based EIA or rapid blood EIA
- **Basic-plus:** Add test for acute infection at baseline, or if patient restarting PrEP after ≥ 7 day interruption and Ab(-), or if sx of AHI

**HIV:**
- Ab* and, if Ab(-)
  - Test for acute HIV (RNA or Ag/Ab)**
- Ab**
- Ab**
- Ab**
- Ab**
Testing and Monitoring Scenarios: increased HIV testing frequency during initiation phase

**HIV:**

- **Ab* and, if**
- **Ab(–)**
- Test for acute HIV
  - (RNA or Ag/Ab)

*Per CDC: Lab-based EIA or rapid blood EIA

**Add test for acute infection if patient restarting PrEP after ≥ 7 day interruption and Ab(–), or if sx of AHI**
Testing and Monitoring Scenarios: increased HIV testing frequency during initiation phase

Ab and, if Ab(-), Test for acute HIV (RNA or Ag/Ab)
Toxicity Monitoring for FTC/TDF PrEP

- Rule out active HBV before starting
  - Risk of hepatitis rebound if FTC/TDF stopped

- In HIV(+)_s, TDF renal toxicity can occur at any time after starting: usually incremental rise, followed by incremental fall after drug d/c’d
  - More likely if pre-existing renal disease (in HIV+ patients)
  - RARE in PrEP RCTs
  - Usually NOT clinically significant, rarely requires drug interruption

- CDC/FDA: Serum creatinine at baseline and q3-6months
  - Goal is CrCl>60 mL/min
  - Watch the trend
  - Confirmed CrCl<60 at baseline a contraindication for PrEP

- Other: no need to routinely test blood counts, liver function
STI’s, screening

- STI incidence on PrEP: data just emerging
  - Preliminary data suggest considerable incidence, but not significantly different from baseline
  - More data needed

- Screen q3m

- Use NAAT testing for gonorrhea (GC and Chlamydia (CT))

- CRUCIAL to screen for pharyngeal, rectal GC, CT (usually asymptomatic), as well as urethral, cervicovaginal

- Serology for syphilis
Supporting providers and clients: Billing issues

- **Obtaining Truvada**
  - Many insurers cover it, including Healthy SF, Medi-Cal
  - Aetna and United Health requiring prior authorization
  - Gilead patient assistance program

- **Billing for an office visit (initial and subsequent)**
  - Visit Type (CPT): Preventive Counseling (99401-99404)
    - 99401: 15 minutes
    - 99402: 30 minutes
    - 99403: 45 minutes
    - 99404: 60 minutes
  - Diagnosis (ICD9): use both
    - V69.2: High Risk Sexual Behavior
    - V01.79: “contact with or exposure to other viral diseases”

- **Covering labs**
  - Some plans only cover one HIV test/year
  - Gilead has a program to cover HIV testing
How can I get PrEP?

- Covered by most private insurance plans (including Covered California plans), Medicaid, Medi-Cal and Medicare
  - California and Illinois formulary analysis available
  - Marketplace enrollment goes through February 15
- Out of pocket costs with copayments and deductibles can be high
- Gilead copayment assistance for up to $300 a month if privately insured or uninsured (www.gileadcopay.com)
- Gilead patient assistance if uninsured and income <5x the federal poverty level (or approximately $58,350) (www.truvada.com/truvada-patient-assistance)
- ADAP does not cover Truvada for PrEP
- If you live in Washington State, there’s a state PrEP DAP
ACA issues

- SFDPH/CA Office of AIDS analysis:
  - FTC/TDF classified as a specialty drug
  - Avoid Bronze plans (lower premiums but higher drug costs)
  - Silver plans + drug assistance programs offer lower drug costs; additional savings from federal premium reimbursement if patient qualifies
SFAF and PrEP efforts

- BETA blog ([www.betablog.org](http://www.betablog.org))
  - Prevention messaging article series around “Is PrEP right for me?”

- PrEP Facts website and social marketing campaign ([www.prepfacts.org](http://www.prepfacts.org))
  - Outdoor/print/online ads
  - Brochures
  - Palm cards/posters

- PrEP Open House event

- PrEP Program at Magnet/474 Castro (coming soon!)
  - PrEP Navigator
PrEPfacts.org website
Outdoor / online / print campaign

Getting reliable, easy-to-understand information about pre-exposure prophylaxis, or PrEP, a groundbreaking new HIV prevention strategy just got easier. Today we launched www.PREPfacts.org! Please share widely.

PrEP - Love May Have Another Protector
PrEPfacts.org
Pre-exposure prophylaxis, or PrEP, is an HIV prevention approach being studied where HIV-negative individuals take anti-HIV medications to reduce their risk of HIV.
### Common PrEP-Related Billing Codes

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>Description</th>
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<tbody>
<tr>
<td>V69.2</td>
<td>High-risk sexual behavior</td>
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<tr>
<td>V01.79</td>
<td>Exposure to other viral diseases</td>
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<th>ICD-10</th>
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<td>Z72.5</td>
<td>High-risk sexual behavior</td>
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<tr>
<td>Z20.82</td>
<td>Contact with and (suspected) exposure to other viral diseases</td>
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<tr>
<th>CPT</th>
<th>Description</th>
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<tr>
<td>99401</td>
<td>Preventive counseling (15 minutes)</td>
</tr>
<tr>
<td>99402</td>
<td>Preventive counseling (30 minutes)</td>
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<td>Preventive counseling (45 minutes)</td>
</tr>
<tr>
<td>99404</td>
<td>Preventive counseling (60 minutes)</td>
</tr>
</tbody>
</table>
Conclusions

- FTC/TDF PrEP can be highly protective against HIV infection, depending on adherence
- Safe, well tolerated
- Resistance rare in RCTs with monthly monitoring; essential to rule out acute HIV infection before starting
- Emerging data on STI’s, condom use
- Brief, nonjudgmental adherence and behavioral counseling important
- Need to increase awareness among potential clients, providers; solve financing issues
- “Real world” data from demonstration projects awaited
PrEP Research Agenda

- New oral agents
  - HPTN 069 (NEXT-PrEP)
    - Maraviroc + FTC
    - Maraviroc + TDF
    - Maraviroc alone
    - Truvada alone
- Alternate dosing
  - ADAPT
    - Daily dosing
    - Time-driven (twice weekly + dose post-exposure)
    - Event-driven (before and after exposure)
  - IPERGAY
    - Before and after sex
- Other routes of delivery
  - Vaginal microbicides, rings
  - Rectal microbicides
  - Long acting IM
    - Rilpivirine
    - GSK 1265744
- More data from Trans people
- How to improve adherence?
  - “real time” drug levels?
- Provider capacitation
  - Public Health Detailing
  - Clinical Mentoring
  - Distance learning
- Financing
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  - Sneha Patil

- UCSF
  - Shannon Weber
  - Bob Grant

- SFAF
  - Courtney Mulhern-Pearson
What questions do you have?

Please remember to complete your evaluation forms.

Thank You!
Thanks again and here’s our contact information.

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We will gladly assist you in any way we can.
HOW TO ACCESS CAPACITY BUILDING ASSISTANCE (CBA) SERVICES

1) To obtain CBA services, organizations must access the CBA Request Information System (CRIS) at www.cdc.gov/Cris2009/pages/main/l1.aspx. To request CBA through CRIS, CDC and DOH funded organizations must contact their Project Officer at the Centers for Disease Control and Prevention (CDC) or Department of Health, Monitoring Officer.

2) For all other capacity building services or assistance accessing CRIS, please contact PROCEED for assistance.

3) PROCEED’s experienced staff will assist you to design and implement a customized plan of action that will strengthen your programs and services and their impact on your clients and community.
GOOD LUCK!