Biomedical Interventions for HIV Prevention

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Los Angeles County Department of Public Health
Disclosures

• No financial disclosures
Learning Objectives

• Describe current PrEP and PEP treatment regimen and its efficacy.
• Identify who is eligible for PreP and high priority populations for PrEP.
• Describe how providers can ensure that at-risk patients obtain PrEP treatment.
• Discuss how to support adherence and maintenance of PrEP regimens.
Agenda

• Avoiding the “Faux Pas” of Sexual Health: Taking a Good Sexual History
• Making the case for PrEP: Quick research review
• Guidelines Overview: Who should receive PrEP?
• Starting the conversation about PrEP: Addressing barriers and myths
• PrEP Patient Management: How to PrEP?
• PrEP Challenges: Adherence and Special Populations
• Educating your patient: Tools to promote self-efficacy
Avoiding the “Faux Pas” of Sexual Health:

Taking a Good Sexual History
Taking a good sexual history

- Provider comfort level in asking sexual health questions influences patients’ willingness to disclose information about their sexual practices.
Taking a good sexual history

• Introduce the topic
  – Normalize the questions and state importance
  – Acknowledge it sensitive and confidential
• Remember the “Five P’s” of sexual history:
  – Partners
  – Practices
  – Protection from STDs
  – Past History of STDs, and
  – Prevention of Pregnancy.
5 P’s of Sexual History Taking

• **Partners/Practices**
  - Do you have sex with men, women, or both?
  - Tell me more about your sexual practices...
  - Do you have vaginal sex? Anal sex? Oral sex?
  - Do you give and receive oral sex?
  - When you have anal sex, how much of the time are you the bottom, the top, or vers?

• **Prior STDs**
  - Have you ever been diagnosed with a sexually transmitted disease?
  - If so, which disease(s) and when?
5 P’s of Sexual History Taking (continued)

• Protection from STDs/HIV
  – How are you keeping yourself safe from STDs/HIV?
  – Do you use condoms sometimes, always, or never? Ever used PEP or PrEP in the past?

• Protection from pregnancy (if applicable)
  – How are you keeping yourself or your partner from getting pregnant?
Helpful Hints: For sexual history taking (and other conversations!)

• Make no assumptions
• Recognize patient anxiety
• Talk less.. And listen more
• Recognizing our own biases
  – Something is pushing your buttons
• Avoid value laden language
  – “You should...“
  – “Why didn’t you...”
  – “I think you...”
• FIX YOUR FACE!
Why is gathering this information important?

1. Helps you determine where to conduct STD screening (i.e. vagina, pharynx, rectal, urine)
2. Helps you determine which patients would benefit from PrEP
Proportion of CT and GC infections **MISSED** among 3398 asymptomatic MSM if screening only urine/urethral sites, San Francisco, 2008-2009

Marcus et al, STD Oct 2011; 38: 922-4
STDs consistently associated with 2 to 3-fold increased risk of HIV acquisition

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any STI</td>
<td>3.87</td>
<td>(2.8-5.3; p&lt;.01)</td>
</tr>
<tr>
<td>Any Ulcerative STD</td>
<td>2.76</td>
<td>(2.3-3.3; p&lt;.01)</td>
</tr>
<tr>
<td>- Herpes</td>
<td>2.71</td>
<td>(2.1-3.5; p&lt;.01)</td>
</tr>
<tr>
<td>- Syphilis</td>
<td>2.31</td>
<td>(1.9-2.8; p&lt;.01)</td>
</tr>
<tr>
<td>- Chancroid</td>
<td>2.25</td>
<td>(1.4-3.6; p&lt;.01)</td>
</tr>
<tr>
<td>Any non-ulcerative STD</td>
<td>1.69</td>
<td>(1.4-2.0; p&lt;.01)</td>
</tr>
<tr>
<td>- Gonorreahe</td>
<td>2.31</td>
<td>(1.9-2.8; p&lt;.01)</td>
</tr>
<tr>
<td>- Chlamydia</td>
<td>2.83</td>
<td>(1.8-4.5; p&lt;.01)</td>
</tr>
<tr>
<td>- Trichmoniasis</td>
<td>1.59</td>
<td>(1.3-2.0; p&lt;.01)</td>
</tr>
</tbody>
</table>

Data source: meta-regression & meta-analysis of 31 longitudinal studies; adjusted estimates of STD effect

# Early Syphilis* Cases by Sex and Gender of Sex Partners

California, 2017

<table>
<thead>
<tr>
<th>MSM (HIV Positive)</th>
<th>MSM (HIV Neg/Unk)</th>
<th>MSW/Unk</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>28%</td>
<td>32%</td>
<td>27%</td>
<td>13%</td>
</tr>
</tbody>
</table>

* Includes primary, secondary, and early latent syphilis.
MSM=Men who have sex with men
MSW/Unk=Men who have sex with women plus men of unknown sexual orientation

Provisional Data as of 4/7/18
Making the case for PEP and PrEP:
Epi/Research Review
Lifetime Risk of HIV Diagnosis by Race/Ethnicity

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Lifetime Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American Men</td>
<td>1 in 20</td>
</tr>
<tr>
<td>African American Women</td>
<td>1 in 48</td>
</tr>
<tr>
<td>Hispanic Men</td>
<td>1 in 48</td>
</tr>
<tr>
<td>Hispanic Women</td>
<td>1 in 227</td>
</tr>
<tr>
<td>White Men</td>
<td>1 in 132</td>
</tr>
<tr>
<td>White Women</td>
<td>1 in 880</td>
</tr>
</tbody>
</table>

Source: Centers for Disease Control and Prevention
Lifetime Risk of HIV Diagnosis by Transmission

- **MSM**: 1 in 6
- **Women Who Inject Drugs**: 1 in 23
- **Men Who Inject Drugs**: 1 in 36
- **Heterosexual Women**: 1 in 241
- **Heterosexual Men**: 1 in 473

Source: Centers for Disease Control and Prevention
Lifetime Risk of HIV Diagnosis among MSM

![Bar Chart]

**Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity**

- African American MSM: 1 in 2
- Hispanic MSM: 1 in 4
- White MSM: 1 in 11

Lowest Risk: White MSM
Highest Risk: African American MSM

Source: Centers for Disease Control and Prevention
Proportion of HIV-MSM Aware of PrEP by Survey Cycle, Race/Ethnicity and Language

Collected at baseline in April 2016 and in all follow-up surveys (October 2016, February 2017, August 2017, February 2018 and July 2018)

*February 2018 91% of Spanish language respondents were recruited by Agency. App respondents only included 3 HIV-MSM who responded in Spanish
Proportion of HIV- MSM Willing to Use PrEP by Survey Cycle, Race/Ethnicity and Language

Collected at baseline in April 2016 and in all follow-up surveys (October 2016, February 2017, August 2017, February 2018, and July 2018)
<table>
<thead>
<tr>
<th>Reason</th>
<th>Black MSM N=91</th>
<th>Latino (English) MSM N=279</th>
<th>Latino (Spanish) MSM N=61</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need more Info</td>
<td>35 (38%)</td>
<td>120 (43%)</td>
<td>6 (10%)</td>
</tr>
<tr>
<td>No need for PrEP</td>
<td>30 (33%)</td>
<td>68 (24%)</td>
<td>13 (21%)</td>
</tr>
<tr>
<td>Can’t afford PrEP</td>
<td>18 (20%)</td>
<td>62 (22%)</td>
<td>8 (13%)</td>
</tr>
<tr>
<td>Don’t know where get PrEP</td>
<td>16 (18%)</td>
<td>58 (21%)</td>
<td>7 (11%)</td>
</tr>
<tr>
<td>Side Effects</td>
<td>29 (32%)</td>
<td>88 (32%)</td>
<td>8 (13%)</td>
</tr>
<tr>
<td>Stigma</td>
<td>4 (4%)</td>
<td>31 (11%)</td>
<td>9 (15%)</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>11 (12%)</td>
<td>32 (11%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>My risk behaviors will increase</td>
<td>12 (13%)</td>
<td>35 (13%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Tried/Didn’t Like PrEP</td>
<td>3 (3%)</td>
<td>2 (1%)</td>
<td>3 (5%)</td>
</tr>
</tbody>
</table>

¹Includes all HIV negative MSM/TGP who were not interested in using PrEP
Collected in all follow up surveys (October 2016, February 2017, August 2017, February 2018 and July 2018)
### HIV- Respondents Who Report No Need to Use PrEP by Receptive CAI

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Total Unwilling (n=295)</th>
<th>No CAI (n=167)</th>
<th>Any CAI (n=128)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Need for PrEP</strong></td>
<td>106 (36%)</td>
<td>70 (41%)</td>
<td>36 (28%)</td>
</tr>
<tr>
<td>Use Condoms</td>
<td>29 (27%)</td>
<td>16 (23%)</td>
<td>13 (36%)</td>
</tr>
<tr>
<td>Not Sexually Active</td>
<td>26 (25%)</td>
<td>19 (27%)</td>
<td>7 (19%)</td>
</tr>
<tr>
<td>Perceived low risk</td>
<td>6 (6%)</td>
<td>4 (6%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Sero Sort Partners</td>
<td>17 (16%)</td>
<td>11 (16%)</td>
<td>6 (17%)</td>
</tr>
<tr>
<td>Other risk reduction methods</td>
<td>7 (7%)</td>
<td>4 (6%)</td>
<td>3 (8%)</td>
</tr>
</tbody>
</table>

**Risk factors among respondents reporting no need for PrEP**

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Median Number CAI Partners (range)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Positive/Unknown Status Partner</td>
<td>17 (16%)</td>
<td>10 (14%)</td>
</tr>
<tr>
<td>History of STD (past 12-months)</td>
<td>8 (10%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>SY</td>
<td>2 (2%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>GC</td>
<td>5 (5%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>CT</td>
<td>4 (4%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

1Includes all HIV negative MSM/TGP who reports receptive CAI with at least 1 partner and unwilling to use PrEP
2Respondents with no receptive CAI partners were significantly more likely to report no need for PrEP (p<0.02)

Collected in follow up survey 4 and 5 (February 2018-July 2018)
• The use of *daily* oral antiretroviral medication in *HIV-negative persons* to reduce the risk of acquiring HIV infection.

• The only medication currently approved for PrEP is a combination of two antiretroviral medications: Emtricitabine and Tenofovir.

• When taken daily as prescribed, can decrease risk of HIV infection by up to 99%.
Using ART Medications for HIV Prevention

**PrEP**: Pre-Exposure Prophylaxis
- TDF/3TC daily
- 92-99% reduction in HIV risk if taken daily

**PEP**: Post-Exposure Prophylaxis
- 28 day course of 2 or 3 drug ART regimen

**TasP**: Treatment as Prevention
- Individuals with suppressed viral load 96% less likely to infect partner with HIV
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
<table>
<thead>
<tr>
<th>TRIAL</th>
<th>POPULATION</th>
<th>LOCATION</th>
<th>Active arm(s)</th>
<th>EFFICACY</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>2499 MSM and MTF TG</td>
<td>South America, USA, Thailand, South Africa</td>
<td>FTC/TDF</td>
<td>44% (95% CI 18-60) 48 FTC/TDF vs. 83 placebo</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 22-83) 9 FTC/TDF vs. 24 placebo</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>4758 serodiscordant heterosexual couples</td>
<td>Kenya and Uganda</td>
<td>FTC/TDF</td>
<td>75% (95% CI 55-87) 67% (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, South Africa</td>
<td>FTC/TDF</td>
<td>No difference 33 FTC/TDF vs. 35 placebo 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</td>
<td>No difference</td>
</tr>
<tr>
<td>Bangkok IDU</td>
<td>2413 IDU</td>
<td>Bangkok</td>
<td>TDF DOT or monthly visits, by choice</td>
<td>48.9% (95% CI 9.6-72.2, P=0.01) 17 FTC/TDF vs. 33 placebo</td>
</tr>
<tr>
<td>PROUD</td>
<td>545 MSM Q3m visits</td>
<td>Public GUD clinics in UK</td>
<td>FTC/TDF</td>
<td>86% (90% CI 58-96, P=0.0002) 3 immediate arm, 19 deferred NNT=13</td>
</tr>
</tbody>
</table>

Courtesy of Dr. Stephanie Cohen, SF DPH
• Study of MSM and transgender women on intermittent dosing regimen based on sexual activity

• Overall efficacy = 86%

• Great variability in use of PrEP

• Current recommendation: Daily PrEP
PrEP Works if You Take It — Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention

Percentage of participants' samples that had detectable drug levels

- CAPRISA 004 (tenofovir gel, BAT-24 dosing)
- FEM-PrEP
- IPERGAY (TDF/FTC)
- iPrEx
- Partners PrEP (TDF)
- Partners PrEP (TDF/FTC)
- PROUD (TDF/FTC)
- TDF2
- VOICE (TDF)
- VOICE (TDF/FTC)
- VOICE (tenofovir gel, daily dosing)
DOES ADHERENCE HAVE TO BE PERFECT?

<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>96%</td>
</tr>
<tr>
<td>Daily</td>
<td>99%</td>
</tr>
</tbody>
</table>

HIV Incidence and Drug Concentrations

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


NO infections seen w/ ≥ 4 doses/week
Adherence even more important in women

- Pharmacokinetic evidence shows that PrEP concentrations are lower in the vagina (compared to the rectum)

- IPrEx: PrEP did protect cisgender women from infection, but data indicates that 6 - 7 doses a week would be needed to fully protect them.

- Takes 21 days to reach maximum efficacy in vaginal tissue vs. 7 days in rectal tissue
Real World Data

- **Kaiser NorCal**
  - One of the first and largest evaluations of PrEP in a clinical practice setting (different from a research study)
  - 657 people (majority MSM)
  - Followed for 2.5 years
  - Average length of use during the study was 7.2 months
  - More likely to report multiple sex partners
  - Self report of condom use was unchanged in 56%, decreased in 41%
    - At 6 months, 30 percent of PrEP users had been diagnosed with an STD
    - At 12 months, 50 percent of PrEP users had been diagnosed with an STD

No new HIV infections among this population
Have their been any cases of HIV in people adherent to PrEP?

- **2 HIV Cases in Highly Adherent MSM**
  - **Case 1:**
    - 43 year old Canadian MSM
    - Adherent to PrEP for 24 months (DBS confirmed)
    - Infected with multi-class resistant strain of HIV-1 (NRTIs, NNRTIs, and INSTI)
    - Now undetectable on treatment
  - **Case 2:**
    - MSM in his 20’s in serodiscordant relationship (partner undetectable)
    - Adherent to PrEP for 4 months (DBS confirmed)
    - 2 remote sexual encounters with partners of unknown HIV status
    - Infected with multi-class resistant strain of HIV
    - Now undetectable on treatment
Putting breakthrough HIV cases in context

• Of PrEP users: $2/79,684 = 0.0026\%$ failure or $99.99\%$ success!

PrEP is a lifesaver, but not infallible.
PrEP Safety

• Safety (vs. Placebo) *
  – Small but clinically significant decrease in creatinine clearance; resolved after interruption, usually w/o recurrence
  – 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)
Guidelines Overview:

Who should receive PrEP?
Los Angeles County PrEP Guidelines

Identifying Persons in Whom to Consider PrEP
- Public Health recommends that medical providers routinely ask all adolescent and adult patients if they have sex with men, women or both men and women.
- Providers should ensure that all of their male and transgender patients who have sex with men know about PrEP.

Guidelines for Initiating PrEP in HIV-Uninfected Persons
Medical providers should recommend that patients initiate PrEP if they meet the following criteria:
1. Men who have sex with men (MSM) or transgender persons who have sex with men if the patient has any of the following risks:
   - Diagnosis of rectal gonorrhea or early syphilis in the prior 12 months.
   - Methamphetamine or popper use in the prior 12 months.
   - History of providing sex for money or drugs in the prior 12 months.
2. Persons in ongoing sexual relationships with an HIV-infected person who is not on antiretroviral therapy (ART) or is on ART but is not virologically suppressed or who is within 6 months of initiating ART.

Medical providers should discuss PrEP with patients who have any of the following risks:
- MSM and transgender persons who have sex with men if the patient has either of the following risks:
  1. Condomless anal sex outside of a long-term, mutually monogamous relationship with a man who is HIV-negative.
  2. Condomless receptive anal sex outside of a long-term, mutually monogamous relationship with a man who is HIV-negative.
  3. Diagnosis of urethral gonorrhea or rectal chlamydial infection in the prior 12 months.
  4. Persons in HIV-discordant relationships in which the female partner is trying to get pregnant.
  5. Persons in ongoing sexual relationships with HIV-infected persons who are on ART and are virologically suppressed.
  6. Black MSM
  7. Latino MSM
  8. Women who exchange sex for money or drugs.
  9. Persons who inject drugs that are not prescribed by a medical provider.
  10. Persons seeking a prescription for PrEP.

As with all medical therapies, patients and their medical providers ultimately need to decide what treatments and preventive measures are best for them. Providers should evaluate patients’ knowledge and readiness to initiate PrEP prior to prescribing it, and should counsel and educate patients to facilitate their success taking PrEP. Medical providers should refer to national guidelines for information on how to prescribe PrEP and monitor persons on PrEP.¹

Manufacturer copayment assistance and medication assistance programs are available. More information is available at: http://www.truvada.com/truvada-patient-assistance.
A list of LA County providers who prescribe PrEP is available at: http://getprepla.com

http://getprepla.com/for-providers.html
## CDC recommendations for PrEP use

<table>
<thead>
<tr>
<th>MSM</th>
<th>Transgender Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HIV positive sex partner</td>
<td>• HIV positive sex partner;</td>
</tr>
<tr>
<td>• History of a bacterial STD in the past 12 months</td>
<td>• History of a bacterial STD in the past 12 months</td>
</tr>
<tr>
<td>• History of multiple sex partners of unknown HIV status</td>
<td>• History of multiple sex partners of unknown HIV status</td>
</tr>
<tr>
<td>• Engages in unprotected anal intercourse</td>
<td>• Other risk factors that increase HIV risk</td>
</tr>
<tr>
<td>• Other risk factors that increase HIV risk</td>
<td>• Sharing injection equipment</td>
</tr>
<tr>
<td>• History of PEP use</td>
<td></td>
</tr>
</tbody>
</table>
CDC recommendations for PrEP use (continued)

<table>
<thead>
<tr>
<th>Heterosexual Women</th>
<th>Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HIV positive sex partner;</td>
<td>• Injection drug users who share injection equipment, inject one or more times per day, inject cocaine or methamphetamine, or engage in high-risk sexual behaviors.</td>
</tr>
<tr>
<td>• History of syphilis diagnosed in the past 12 months;</td>
<td></td>
</tr>
<tr>
<td>• A male partner who may be having sex with men.</td>
<td></td>
</tr>
<tr>
<td>• Other risk factors that increase HIV risk</td>
<td>• Use of stimulant drugs associated with high risk behaviors</td>
</tr>
</tbody>
</table>
What are the behavioral determinants of HIV/STI risk among LAC Women?
The Challenge

• Particularly among women, HIV surveillance data, data from STD clinic patients as well as data from HIV+ and HIV- persons has not supported using self-reports of risk behavior as the basis for determining HIV risk – i.e., women are unaware of their risk factors.
HIV Surveillance Data

Adult Women Diagnosed with HIV infection in 2012 - 2016 by Transmission Category

- Injection drug use: 6.0%
- Heterosexual contact: 21.7%
- NIR/Others/Unknown: 72.2%
• In a survey of STD clinic patients participating in the HIV Testing Survey (all of whom were presenting for evaluation of a suspected STD and who therefore were presumably at risk for HIV infection), 54% of women reported 1 sex partner in the past 12 months.

• A separate survey of recently diagnosed HIV-infected persons participating in the Supplement to HIV/AIDS Surveillance (SHAS) Project found 74% of women had 1 partner in the year preceding their HIV diagnosis.

At the root of our failure to observe correlations between women reported behavior and HIV infection is the fact that it is their partners behavior rather than their own, that places women at risk.
Partner’s race/ethnicity by respondent’s race/ethnicity.

- Hispanic women: 86.8% Hispanic, 13.2% Afr. Am.
- Af. Am. women: 4.8% Hispanic, 95.2% Afr. Am.
PrEP Patient Management:
How to PrEP?
Sample PrEP Visit Schedule

Screening/Enrollment

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
- Prescribe 30 tabs

Follow-up:
- Symptom review: Sx of acute HIV?
- Assessment, counseling:
  - Behavior
  - Adherence
- HIV testing
- STI testing
- Renal function testing
- Prescribe 30 tabs with 2 refills

4 weeks
12 weeks
24 weeks
36 weeks
48 weeks

Courtesy of Dr. Stephanie Cohen, SF DPH
Clinical Assessment

• PMH, Medication Hx, allergies, review of symptoms, focused physical exam

• Osteoporosis and liver disease are relative contraindications to TDF/FTC

• Moderate kidney dysfunction is an absolute contraindication

• Patients with recent symptoms of a mono-like illness should be tested for acute HIV. Wait to start PrEP until test results are back
Obtain Baseline Testing

- HIV Antibody test (rapid if available).
- Strongly suggest obtaining a viral load to test for acute HIV when PrEP initiated.
- Creatinine (CrCl should be ≥ 60 ml/min)
- HBsAg
- STDs
- Pregnancy test, if applicable
- Offer Hep B immunization if not immune
- Offer HPV immunization if < 26
PrEP Clinical Tools

PrEP Service Delivery Checklist

**PrEP Initiation Visit**

- Perform an HIV risk assessment to determine whether PrEP is indicated for patient.
- Provide basic education about PrEP.
- Obtain past medical history. Query specifically about history of kidney and liver (e.g., hepatitis B) disease, bone disease, and fractures. For women of child bearing age, assess pregnancy desires.
- Review current and recent symptoms. Assess for symptoms of acute HIV infection.
- Order all laboratory results to assess for contraindications. If laboratory tests were already performed, review at this visit.
  - HIV test: 4th generation Ag/Ab test (or HIV viral load) to rule out acute HIV
  - STD (GC/CT urine, GC/CT rectum, GC pharynx, RPR)
  - Serum Creatinine to calculate CrCI
  - HBSAg and HBSAb and HCV Ab
  - Check patient weight for CrCI
  - Pregnancy test (if applicable)
- Provide prescription for Truvada (#30 tabs).
- PrEP education/counseling with patient; ask questions to elicit patient understanding. Ensure all questions answered regarding substance abuse and mental health needs and that referrals are made as appropriate.

**1 Month Follow-Up Appointment**

- Assess the following at this visit
  - Patient’s desire to continue on PrEP.
  - Side effects
  - Medication adherence
  - Signs/symptoms of acute HIV
  - Possibility of pregnancy (if applicable)
- Provide prescription for two-month supply of Truvada (#60 tabs).
- Provide medication adherence counseling, if needed.
- Schedule 4 visits. Provide reminder card with appointment and contact information.

**3. 6. 9. 12 Month Follow-Up Appointments**

- Assess the following at each visit
  - Patient’s desire to continue on PrEP
  - Side effects
  - Medication adherence
  - Signs/symptoms of acute HIV
  - Possibility of pregnancy (if applicable)
- Order Laboratory tests at each visit
  - HIV test: 4th generation Ag/Ab test is best; if not available, 3rd generation test is sufficient as long as concern for acute HIV or seroconversion is low
  - STD (GC/CT urine, GC/CT rectum, GC pharynx, RPR)
  - Serum Creatinine to calculate CrCI (every 3-6 months)
  - Pregnancy test (if applicable)

Available at http://getprepla.com/for-providers.html
What if my patient has a positive HIV test?

• Discontinue PrEP to avoid development of resistance
• Order and document results of an HIV genotype
• Ensure patient is linked to an HIV-primary care provider for care and possible early initiation of ART.
• Inform Division of HIV and STD Programs (213) 351-8146 and please let us know the patient was on PrEP.
PrEP Challenges:

Special Populations
Patients with Chronic Active Hepatitis B Virus Infection (HBV)

- TDF/FTC active against both HIV and HBV infection

- All persons with +HBsAg should be further evaluated, including obtaining HBV DNA

- Co-management with Infectious Disease or Hepatology based on comfort level of primary provider

- There has been concern that discontinuation of TDF/FTC may lead to a rapid flare Hepatitis B infection.
Analysis of data from study participants with Active Hepatitis B from the iPrEX study

6 patients with active Hepatitis B were randomized to FTC/TDF arm

No patients experienced Hepatitis B flare following discontinuation of PrEP

Risk of flares seems to be limited to people with advanced liver disease (i.e. cirrhosis)²

Patients with Chronic Renal Failure

• Patients with eCrCL < 60 ml/min should **not** take PrEP because safety below this level was not evaluated in clinical trials.

• New version of Tenofovir, *Tenofovir Alafenamide*, with less renal effects currently being studied but not yet FDA-approved to be used as PrEP.
PrEP in Adolescent Minors

• PrEP is an important HIV prevention tool for adolescents.

• Truvada as PrEP is now FDA approved for adolescents.

• NOTE: Minors ages 12 or older may request testing and consent to medical care related to the diagnosis and treatment of Sexually Transmitted Diseases/HIV (Cal. Family Code § 6926)
PrEP in Adolescent Minors

- Adolescents can be referred to the following clinics for PrEP services.
  - Children’s Hospital Los Angeles
    5000 Sunset Blvd. 4th Floor, LA 90027
    (323)-361-7522

Client should ask for the “PrEP Navigator”!
Educating Your Patient

Tools to Promote Self-Efficacy
"Basics of PrEP" Handout

- Patient education sheet
- Available in both English and Spanish
- For this document and more, visit http://getprepla.com/for-providers.html

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 than once a day would still help to protect people from HIV, but there are no results from these studies yet. Based on what we know right now, we recommend taking PrEP as close to daily as possible.

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...
Take PrEP daily to block HIV from your cells

PrEP (Pre-exposure Prophylaxis)

PREP

PROTECT YOURSELF FROM HIV EVERY DAY

PEP (Post-exposure Prophylaxis)

PREVENT HIV AFTER EXPOSURE
Get Protected with PrEP

PrEP is a Daily Pill That Helps You Stay HIV Negative

GetPrEPLA.com

Funded by the U.S. Centers for Disease Control and Prevention and the County of Los Angeles, Department of Public Health, Division of HIV and STD Programs.
# PrEP Provider Directory

Enter an address, city, or zip code [search input]

## Clinics/Practices

<table>
<thead>
<tr>
<th>Clinic/Practice</th>
<th>Provider(s)</th>
<th>Address</th>
<th>Contact Info</th>
<th>Insurance Accepted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Public Health Center</td>
<td>Multiple Providers</td>
<td>241 N Figueroa Street, Los Angeles, CA 90021</td>
<td>Sebastian Mancas 323-469-823</td>
<td>No cost</td>
</tr>
<tr>
<td>Curtis Tucker</td>
<td>Multiple Providers</td>
<td>1041 W. Manchester Boulevard, Inglewood, CA 90301</td>
<td>Roberto Mena and Cheena Tizon 310-410-2559</td>
<td>No cost</td>
</tr>
<tr>
<td>North Hollywood Public Health Center</td>
<td>Multiple Providers</td>
<td>9500 Tujunga Ave, North Hollywood, CA 91605</td>
<td>Mary and Lourdes 818-906-0646</td>
<td>No cost</td>
</tr>
<tr>
<td>Ruth Temple Public Health Center</td>
<td>Multiple Providers</td>
<td>387 E. Western Ave, Los Angeles, CA 90062</td>
<td>Graciela or Blas 310-795-9537</td>
<td>No cost</td>
</tr>
<tr>
<td>Torrance Public Health Center</td>
<td>Multiple Providers</td>
<td>2141 Del Amo Boulevard, Torrance, CA 90402</td>
<td>Yaela Peets and Theresa Martinez 310-603-6936</td>
<td>No cost</td>
</tr>
<tr>
<td>AltaMed Health Services Corp</td>
<td>William Dunne, MD, Scott Kim, MD, Kevin Liao, MD</td>
<td>8007 Melrose Ave, Los Angeles, CA 90039</td>
<td>Bryan Halper 323-909-0020</td>
<td>No cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Marie Nanavati 310-807-0012</td>
<td>No cost</td>
</tr>
</tbody>
</table>

This clinic provides PrEP services at no cost to people who do not have insurance.
PrEP Materials

Targeted client education materials (wallet brochures)

Available via online order

Email prepinfo@ph.lacounty.gov
Questions?

Leo Moore, MD, MSHPM
lmoore@ph.lacounty.gov