PrEP 101: Increasing Uptake of PrEP in the Hispanic and Latinx Community

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This activity is jointly provided by the Postgraduate Institute for Medicine and the American Academy of HIV Medicine.

This activity is supported by independent educational grants from Gilead Sciences, Janssen Therapeutics, and ViiV Healthcare.
Target Audience
This activity has been designed to meet the educational needs of physicians, physician assistants, nurse practitioners, and pharmacists; other healthcare providers, such as nurses, nutritionists, social workers, and case managers are also encouraged to attend.

Statement of Need/Program Overview
Academy credentialed providers and members are very adept at prescribing and retaining patients on PrEP, however, shelter in place and stay at home orders from the early COVID pandemic in the U.S. interrupted patients abilities to test for HIV and STIs and have associated laboratory monitoring. Recognizing that the recommended quarterly testing and monitoring requirements may serve as a barrier to engaging and retaining “hard to reach” patients that may benefit rom PrEP. This series will serve as an elevated discussion on higher-level PrEP topics including different formulations of PrEP and when to use them; HIV testing, laboratory monitoring, and taking a sexual health history; interpreting clinical laboratory information for the rare adherent patient that fails on PrEP and recommendations for initial ARV treatment therapies, future PrEP formulations, and how to reach and retain hard to engage PrEP patients.
In support of improving patient care, this activity has been planned and implemented by the Postgraduate Institute for Medicine and the American Academy of HIV Medicine. Postgraduate institute for Medicine is accredited by the American Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.
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• Postgraduate Institute for Medicine designates this continuing education activity for 0.75 contact hour(s) (0.075 CEUs) of the Accrediting Council for Pharmacy Education. Universal Activity Number #UAN - JA4008162-9999-22-189-L02-P.

• Type of Activity: Knowledge
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- Carly Floyd has nothing to disclose.
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The Academy planners and managers have nothing to disclose

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Fee Information

There is no fee for this educational activity.
Program Learning Objectives

• Differentiate HIV pre-exposure prophylaxis (PrEP) from HIV post-exposure prophylaxis (PEP) and identify the indications for each.

• Identify appropriate candidates for HIV PrEP and PEP.

• Recognize the key counseling points & monitoring parameters for HIV PrEP regimens.

• Understand challenges and opportunities to reach populations in need of HIV prevention, including Hispanic and Latinx communities.
Diagnose all people with HIV as early as possible.

Treat people with HIV rapidly and effectively to reach sustained viral suppression.

Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

Reducing Acquisition of HIV

- Increased testing & linkage to care
- Delayed or fewer partners
- Less risky activities
- Increased condom use
- Empowerment & negotiation skills
- Reducing alcohol & drug use
- Reduce psychosocial barriers
- Circumcision
- STI treatment
- HIV PEP & HIV PrEP
Let’s Talk About Sex

Recognizing and Supporting Patients Who May Benefit From PrEP

New prescriptions for bacterial STIs or HIV post-exposure prophylaxis can prompt assessment for PrEP eligibility

Sexual history taking

<table>
<thead>
<tr>
<th>Partners</th>
<th>Practices</th>
<th>Past History of STDs</th>
<th>Protection From STDs</th>
<th>Pregnancy Plans</th>
</tr>
</thead>
</table>

HIV risk reduction counseling

- Limiting number of sexual partners
- Ask partner about their sexual partners
- Consistent condom use
- Ask HIV-positive partner(s) about their HIV medications and viral load \(U = U\)

- Regular HIV testing
- Testing and treatment of other STIs

1.2 million people are at increased risk for acquiring HIV and would benefit from PrEP

Barriers:
- Misinformation about HIV risk within sexual networks and via social media
- Lack of access to healthcare (COVID-19 impact)
- HIV stigma
- Lack of discussions on importance of HIV & STI prevention in healthcare

Risks of HIV

https://www.cdc.gov/stophivtogether/campaigns/hiv-stigma/index.html
Potentially infectious fluids:

- blood, breast milk, tissue, semen, vaginal secretions, visibly bloody fluids
- exposure across mucosal surface, open wound, or injection

HIV Transmission Risks

Not infectious:

- Urine
- Saliva
- Sweat
- Tears
- Nasal secretions
- Sputum vomitus
- Stool

Image: https://healthylife.werindia.com/your-road-to-healthy-life/hiv-is-not-transmitted-by
HIV Transmission Risks

Higher Risk

- receptive anal sex
  - per episode: 0.3 - 3%

- needle sharing
  - per episode: 0.67%

Lower Risk

- oral sex
  - per episode: 0.06%

- insertive sex
  - per episode: 0.03 – 0.14%

### Average Risk of HIV Transmission Per Exposure to Infected Source

<table>
<thead>
<tr>
<th>SOURCE</th>
<th>PERCENTAGE</th>
<th>ODDS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NONSEXUAL MODES</strong>*</td>
<td>Blood transfusion</td>
<td>90%</td>
</tr>
<tr>
<td>Needle-sharing (injection drug use)</td>
<td>0.67%</td>
<td>1 in 149</td>
</tr>
<tr>
<td>Needlestick (percutaneous through the skin)</td>
<td>0.30%</td>
<td>1 in 333</td>
</tr>
<tr>
<td>Fingering, spitting, throwing body fluids (including semen or saliva), sharing sex toys</td>
<td>negligible</td>
<td>negligible</td>
</tr>
<tr>
<td><strong>ORAL SEX</strong>*</td>
<td>Recipient partner (example, giving a blow job)</td>
<td>0% - 0.04%</td>
</tr>
<tr>
<td>Insertive partner (example, getting a blow job)</td>
<td>~0%</td>
<td>about zero</td>
</tr>
<tr>
<td><strong>VAGINAL SEX</strong>*</td>
<td>Risk to female with HIV-positive male partner</td>
<td>0.08%</td>
</tr>
<tr>
<td>High-income countries</td>
<td>0.30%</td>
<td>1 in 333</td>
</tr>
<tr>
<td>Low-income countries</td>
<td>0.04%</td>
<td>1 in 2,500</td>
</tr>
<tr>
<td>Risk to male with HIV-positive female partner</td>
<td>0.38%</td>
<td>1 in 263</td>
</tr>
<tr>
<td>High-income countries</td>
<td>0.11%</td>
<td>1 in 909</td>
</tr>
<tr>
<td>Low-income countries</td>
<td>0.05%</td>
<td>1 in 154</td>
</tr>
<tr>
<td><strong>ANAL SEX</strong>*</td>
<td>Insertive partner’s risk (uncircumcised)</td>
<td>0.62%</td>
</tr>
<tr>
<td>Insertive partner’s risk (circumcised)</td>
<td>0.85%</td>
<td>1 in 154</td>
</tr>
<tr>
<td>Receptive partner’s risk (without ejaculation)</td>
<td>1.43%</td>
<td>1 in 70</td>
</tr>
<tr>
<td>Receptive partner’s risk (with ejaculation)</td>
<td>1.0%</td>
<td>1 in 100</td>
</tr>
</tbody>
</table>

### Other Numbers to Know

**INCREASE HIV RISK**
- Acute infection, roughly the 12 weeks after contracting HIV, can increase transmission likelihood 26 times, raising a 14% risk to 37%—higher than 1 in 3. This is because viral load skyrockets during the acute phase.
- Presence of other sexually transmitted infections (STIs) can amplify risk by as much as 8 times.
- Exposure to gender inequality and intimate partner violence can raise a woman’s HIV risk 3.5 times.

**DECREASE HIV RISK**
- Circumcision can lower heterosexual men’s risk by 60%.
- Treatment as prevention, TAVI! when HIV-positive people on meds maintain an undetectable viral load, can reduce transmission risk by 90%. Some research hints that the number may approach 100%.
- Pre-exposure prophylaxis, PrEP, when HIV-negative people take daily Truvada, can decrease risk by upwards of 92%, depending on adherence. Post-exposure prophylaxis, PEP, works similarly.
- Condoms, according to the CDC, lower risk on average by 80%.
- Forms of serosorting, such as having condomless sex only with people of your same sero status, can also lower risk, but the benefits vary.

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[https://www.poz.com/pdfs/P04-14p53.risk_transmission.pdf](https://www.poz.com/pdfs/P04-14p53.risk_transmission.pdf)

- Print and laminate
- Review with patients while rapid test is processing
Low in populations *actually* at risk

- 5871 individuals in Philadelphia 2007-2009 rapid HIV tested
  - Those with no condom use – 90% *thought* they had no or low risk
  - 66% of those who tested positive *thought* they were no or low risk
A person who knows they have HIV is able to:

- Protect others from becoming infected
- Make safer decisions about sex, needle use, & their health care

People with HIV (PWH) who know their status may avoid behaviors that spread infection

Those at high risk but test negative can start PrEP

CDC 2006
- Test *all* pts 13-64 yo
- Test *all* pregnant women
- Test all pts with TB or STI
- Test high risk patients at least annually

USPSTF 2013
- Test *all* 15-65 yo
- Test *all* pregnant women
- Test <15 & >65 yo if at risk
- Grade A recommendation

Studies from 2008-2016 show zero linked HIV transmissions after >100,000 condomless sex acts

- PWH had a **durably undetectable viral load**

**UNDETECTABLE = UNTRANSMITTABLE**
Nationally, 23% of the people who are considered at considerable risk of HIV infections are receiving pre-exposure prophylaxis.
PrEP Coverage is Unequal – 2017

- **Knowledge of HIV status**
  - Black/African American: 9,000
  - Hispanic/Latino: 8,900
  - White: 6,900

- **Discussed PrEP**
  - with a healthcare provider in the past 12 months
    - Black/African American: 45%
    - Hispanic/Latino: 47%
    - White: 59%

- **Used PrEP**
  - in the past 12 months
    - Black/African American: 27%
    - Hispanic/Latino: 31%
    - White: 42%

- **Taking HIV Medicine as prescribed**
  - Black/African American: 48%
  - Hispanic/Latino: 59%
  - White: 64%

- **Viral Suppression**
  - Black/African American: 62%
  - Hispanic/Latino: 67%
  - White: 74%

Source: [https://www.cdc.gov/vitalsigns/hivgaybimen/index.html](https://www.cdc.gov/vitalsigns/hivgaybimen/index.html)
PrEP Coverage is Unequal – 2019

**PREP COVERAGE IN THE U.S. BY RACE/ETHNICITY, 2019**

*Ending the HIV Epidemic in the U.S. 2030 Target Goal*

- Overall: 23%
- Black/African American: 8%
- Hispanic/Latino: 14%
- White: 63%
Need PrEP to Reach Most at Risk

- Continued disparities among certain populations with new HIV infections and lack of access to HIV PrEP
- Interventions to improve metrics at each step of PrEP Care Continuum could reduce disparities

Jenness, S et al. CROI2018. Abstract 1149
PEP vs. PrEP

- **Post-exposure prophylaxis**
  - Given *after* high-risk exposure to reduce risk of HIV infection
  - Start within 72 hours of exposure
  - 28-day course of daily 3-drug regimen

- **Pre-exposure prophylaxis**
  - Given *before* high-risk exposure to reduce risk of HIV infection
  - Start at least 7 days prior to exposure
  - Daily 2-drug regimen or q 2 month long-acting regimen

HIV Infection

- PEP must be given <72 hours after exposure
- PrEP requires therapeutic levels of drug at site of infection
  - Rectal tissue: 7 days
  - Vaginal tissue: 20+ days

Considerations Before Prescribing

• What was the exposure?
• Is the source known/unknown?
• Likelihood of HIV infection in the source?
• Antiretroviral therapy (ART) resistance in the HIV infected source?
• What is the time period since exposure?
• What is the health of contact & are they taking any medications?
Acute Seroconversion

Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016
Figure 2 Assessing Indications for PrEP in Sexually Active Persons

Sex with men, women, or both?

Yes

HIV+ partner?

Yes

Unknown or detectable viral load?

Yes

Prescribe PrEP

No

Discuss PrEP

Yes

Prescribe if requested

No

Discuss PrEP

Always used condoms?

Yes

Prescribe PrEP

No

Discuss PrEP

Had bacterial STI in past 6 months?

Yes

MSM: GC, chlamydia, or syphilis

No

Discuss PrEP

MSW and WSM: GC or syphilis

Yes

Prescribe PrEP

No

Discuss PrEP

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline

Figure 3  Assessing Indications for PrEP in Persons Who Inject Drugs

Assess sexual risk for all PWID

Ever Injected Drugs?

Yes

Injected past 6 months?

Yes

Shared injection equipment?

Yes

Prescribe PrEP

No

Prescribe if requested

No

Prescribe if requested

No

Prescribe if requested

No
FDA-approved daily oral formulations:

- Tenofovir/emtricitabine (F/TDF* or F/TAF**)
- 1 tablet by mouth once a day
- Prescribe for ≤ 90-day supply
- Approved for adolescents & adults ≥ 35kg (77 lb)*

*F/TDF FDA-approved indication in adults 7/2012 and for youth 5/2018
**F/TAF FDA-approved for PrEP (except receptive vaginal sex) 10/2019
USPSTF Grade A Recommendation, 6/2019
TDF vs. TAF

TDF vs. TAF

**F/TDF**
- Use if receptive vaginal sex or if IDU is only risk factor (i.e., no sexual risk)
- Renal & bone toxic
  - Do not start if eCrCl <60mL/min
- Generic available

**F/TAF**
- Not indicated for receptive vaginal sex or IDU alone
- Less renal & bone toxicity
  - Can use if eCrCl > 30 mL/min
  - Consider use if hx of osteoporosis or related bone disease
- Weight gain
  - 1 - 1.7kg vs. 0 - 0.5kg (F/TDF)
- Smaller tablet
# Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use

<table>
<thead>
<tr>
<th>Sexually-Active Adults and Adolescents</th>
<th>Persons Who Inject Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identifying substantial risk of acquiring HIV infection</strong></td>
<td>HIV-positive injecting partner OR Sharing injection equipment</td>
</tr>
<tr>
<td>Anal or vaginal sex in past 6 months AND any of the following:</td>
<td></td>
</tr>
<tr>
<td>- HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</td>
<td></td>
</tr>
<tr>
<td>- Bacterial STI in past 6 months&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>- History of inconsistent or no condom use with sexual partner(s)</td>
<td></td>
</tr>
<tr>
<td><strong>Clinically eligible</strong></td>
<td></td>
</tr>
<tr>
<td>- Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP</td>
<td></td>
</tr>
<tr>
<td>- No signs/symptoms of acute HIV infection</td>
<td></td>
</tr>
<tr>
<td>- Estimated creatinine clearance ≥30 ml/min&lt;sup&gt;4&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>- No contraindicated medications</td>
<td></td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
<td></td>
</tr>
<tr>
<td>- Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR</td>
<td></td>
</tr>
<tr>
<td>- For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply</td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up care</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up visits at least every 3 months to provide the following:</strong></td>
<td></td>
</tr>
<tr>
<td>- HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support</td>
<td></td>
</tr>
<tr>
<td>- Bacterial STI screening for MSM and transgender women who have sex with men&lt;sup&gt;2&lt;/sup&gt; – oral, rectal, urine, blood</td>
<td></td>
</tr>
<tr>
<td>- Access to clean needles/syringes and drug treatment services for PWID</td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up visits every 6 months to provide the following:</strong></td>
<td></td>
</tr>
<tr>
<td>- Assess renal function for patients aged ≥50 years or who have an eCrCl &lt;90 ml/min at PrEP initiation</td>
<td></td>
</tr>
<tr>
<td>- Bacterial STI screening for all sexually-active patients&lt;sup&gt;3&lt;/sup&gt; – [vaginal, oral, rectal, urine- as indicated], blood</td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up visits every 12 months to provide the following:</strong></td>
<td></td>
</tr>
<tr>
<td>- Assess renal function for all patients</td>
<td></td>
</tr>
<tr>
<td>- Chlamydia screening for heterosexually active women and men – vaginal, urine</td>
<td></td>
</tr>
<tr>
<td>- For patients on F/TAF, assess weight, triglyceride and cholesterol levels</td>
<td></td>
</tr>
</tbody>
</table>

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<sup>1</sup> Adolescents weighing at least 35 kg (77 lb)
<sup>2</sup> Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated
<sup>3</sup> Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs
<sup>4</sup> Estimated creatinine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

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Labs Before Prescribing Oral PrEP

Consider pregnancy screening for people of childbearing potential

Hep B serologies
- Surface antigen
- Surface antibody
- Total core antibody

Table 5  Timing of Oral PrEP-associated Laboratory Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Screening/Baseline Visit</th>
<th>Q 3 months</th>
<th>Q 6 months</th>
<th>Q 12 months</th>
<th>When stopping PrEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Test</td>
<td>X*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>eCrCl</td>
<td>X</td>
<td></td>
<td>If age ≥50 or eCrCl &lt; 90 ml/min at PrEP initiation</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Syphilis</td>
<td>X</td>
<td></td>
<td>MSM / TGW</td>
<td></td>
<td>MSM / TGW</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>X</td>
<td></td>
<td>MSM / TGW</td>
<td></td>
<td>MSM / TGW</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>X</td>
<td></td>
<td>MSM / TGW</td>
<td></td>
<td>MSM / TGW</td>
</tr>
<tr>
<td>Lipid panel (F/TAF)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep B serology</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep C serology</td>
<td>MSM, TGW, and PWID only</td>
<td></td>
<td>MSM, TGW, and PWID only</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Assess for acute HIV infection (see Figure 4)
### Interpreting Hepatitis B Blood Test Results

<table>
<thead>
<tr>
<th>Interpretation &amp; Action Needed</th>
<th>HBsAg \nHepatitis B Surface Antigen</th>
<th>HBsAb (anti-HBs) \nHepatitis B Surface Antibody</th>
<th>HBCab (anti-HBc) \nHepatitis B Core Antibody</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not Immune - Not Protected</strong></td>
<td>―</td>
<td>―</td>
<td>―</td>
</tr>
<tr>
<td>Has not been infected, but still at risk for possible hep B infection.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Vaccine is needed.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immune Controlled - Protected</strong></td>
<td>―</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Surface antibodies present due to natural infection. Has recovered from a prior hep B infection. Cannot infect others.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>No vaccine is needed.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immune - Protected</strong></td>
<td>―</td>
<td>+</td>
<td>―</td>
</tr>
<tr>
<td>Has been vaccinated. Does not have the virus and has never been infected.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>No vaccine is needed.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Infected</strong></td>
<td></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Positive HBsAg indicates hep B virus is present. Virus can spread to others. Find a doctor who is knowledgeable about hep B for further evaluation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>More Testing Needed.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Could be Infected</strong></td>
<td></td>
<td>―</td>
<td>+</td>
</tr>
<tr>
<td>Result unclear - possible past or current hep B infection. Find a doctor who is knowledgeable about hep B for further evaluation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>More Testing Needed.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Inform all doctors about a prior or current hepatitis B infection and include this information as part of your health history. Talk to doctors before taking immune system suppressing medications to understand the risk for possible hep B reactivation.*
Lessons learned from studies:

• Safe, well tolerated (nausea)
• Adherence is key
  • iPrEx study: 44% reduction in HIV
  • 92% reduction in those with good adherence
• PrEP as bridge to ART: 95% reduction
• Important to screen & treat STIs

Cost effective if used among high risk
### Figure 5: Adherence and F/TDF PrEP Efficacy in MSM

<table>
<thead>
<tr>
<th>Weekly Medication Adherence Estimated by Drug Concentration</th>
<th>HIV Incidence per 100 person/years</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>4.2</td>
</tr>
<tr>
<td>≤2 pills/week</td>
<td>2.3</td>
</tr>
<tr>
<td>2-3 pills/week</td>
<td>0.6</td>
</tr>
<tr>
<td>≥4 pills/week</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**A brief medication adherence question**

“Many people find it difficult to take a medicine every day.

Thinking about the last week; on how many days have you **not** taken your medicine?”
Box B: Key Components of Oral Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education
- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence
- Tailor daily dose to patient’s daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence
- Reinforce benefit relative to uncommon harms

Monitor medication adherence in a non-judgmental manner
- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side effects and plan how to manage them
Bangkok Tenofovir Study (2013) investigated the effects of a PrEP strategy for HIV prevention in 2,413 Thai PWID

Kaplan-Meier Estimates of Time to HIV Infection in the Modified Intention-to-Treat Population

- 48.9% reduction in HIV incidence (95% CI, 9.6-72.2; P = .01)
- 73.5% reduction in HIV incidence in individuals with detectable drug levels (95% CI, 16.6-94.0; P = .03)
Women who inject drugs (WWID) have higher odds (OR, 1.18) of HIV infection than men who inject drugs (MWID) (95% CI, 1.10-1.26)

- WWID are more likely to have higher risk of sexual and injection exposures than MWID
  - Concomitant or overlapping exposures

- WWID who are unable to negotiate safe sex practices are especially at risk of HIV transmission and could benefit greatly from PrEP for HIV prevention

On-Demand F/TDF / “2-1-1” Method

Only for adult men who have sex with men (MSM), if:
- sex is less than twice weekly and
- can anticipate sex

https://apps.who.int/iris/rest/bitstreams/1239070/retrieve
Injectable Pre-Exposure Prophylaxis

FDA-approved injectable formulation:

- Cabotegravir (CAB) 600mg/3mL every 2 months
- Optional 30mg daily oral CAB 4-week lead-in
- Approved for adolescents & adults ≥ 35kg (77 lb)*

*CAB FDA-approved indication in 12/2021
CAB LAI q8weeks for MSM and transwomen who have sex with men (TGWSM) at high risk for HIV

- 4,570 MSM & TGWSM (12%) double-blinded
- CAB LAI HIV incidents - 13
- Daily oral F/TDF HIV incidents - 39
- 66% fewer HIV infections in LAI CAB vs. F/TDF
- Well-tolerated: injection site reactions (ISRs) – 2.2% discontinued

https://www.hptn.org/research/studies/hptn083
CAB LAI q8weeks for sexually active cisgender women (not pregnant or breastfeeding, on contraception) at high risk for HIV

- 3,224 participants in Sub-Saharan Africa
- CAB LAI HIV incidents - 4
- Daily oral F/TDF HIV incidents - 34
- 89% fewer HIV infections in LAI CAB for cisgender women vs. F/TDF
- Well-tolerated: ISRs – no discontinuations due to ISRs

https://www.084life.org/study-results/
Guidance for Injectable PrEP

<table>
<thead>
<tr>
<th>Identifying substantial risk of acquiring HIV infection</th>
<th>Sexually-Active Adults</th>
<th>Persons Who Inject Drugs¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anal or vaginal sex in past 6 months AND any of the following:</td>
<td>HIV-positive injecting partner OR Sharing injection equipment</td>
<td></td>
</tr>
<tr>
<td>• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Bacterial STI in past 6 months²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• History of inconsistent or no condom use with sexual partner(s)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Clinically eligible**

**ALL OF THE FOLLOWING CONDITIONS ARE MET:**

- Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection
- No signs/symptoms of acute HIV infection
- No contraindicated medications or conditions

**Dosage**

- 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle
  - Initial dose
  - Second dose 4 weeks after first dose (month 1 follow-up visit)
  - Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)

p 48: “Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an HIV-1 RNA assay

Guidance for Injectable PrEP

<table>
<thead>
<tr>
<th>Follow-Up Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>At follow-up visit 1 month after first injection</strong></td>
</tr>
<tr>
<td>• HIV Ab/Ag test and HIV-1 RNA Assay</td>
</tr>
<tr>
<td><strong>At follow-up visit every two months (beginning with third injection – month three)</strong></td>
</tr>
<tr>
<td>• HIV Ab/Ag test and HIV-1 RNA Assay</td>
</tr>
<tr>
<td>• Access to clean needles/syringes and drug treatment services for PWID</td>
</tr>
<tr>
<td><strong>At follow-up visits every four months (beginning with the third injection – month three)</strong></td>
</tr>
<tr>
<td>• Bacterial STI screening for MSM and transgender women who have sex with men – oral, rectal, urine, blood</td>
</tr>
<tr>
<td><strong>At follow-up visit every six months (beginning with the fifth injection – month seven)</strong></td>
</tr>
<tr>
<td>• Bacterial STI screening for all heterosexually active women and men – (vaginal, rectal, urine - as indicated), blood</td>
</tr>
<tr>
<td><strong>At follow-up visits at least every 12 months (after the first injection)</strong></td>
</tr>
<tr>
<td>• Assess desire to continue injections as PrEP</td>
</tr>
<tr>
<td>• Chlamydia screening for heterosexually active women and men – vaginal, urine</td>
</tr>
<tr>
<td><strong>At follow-up visits when discontinuing cabotegravir injections provide the following</strong></td>
</tr>
<tr>
<td>• Re-educate patients about the “tail” and the risks of declining CAB levels</td>
</tr>
<tr>
<td>• Assess ongoing HIV risk and prevention plans</td>
</tr>
<tr>
<td>• If PrEP is indicated, prescribe oral, daily F/TAF or F/TDF beginning within eight weeks of the last injection</td>
</tr>
<tr>
<td>• Continue follow-up visits with HIV testing quarterly for 12 months</td>
</tr>
</tbody>
</table>
Guidance for Injectable PrEP

CAB “tail” – may need oral PrEP to protect from HIV
Labs Before Prescribing CAB for PrEP

Consider pregnancy screening for people of childbearing potential

Hep C screening!

Hep B serologies
- Surface antigen
- Surface antibody
- Total core antibody

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### Table 7: Timing of CAB PrEP-associated Laboratory Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Initiation Visit</th>
<th>1 month visit</th>
<th>Q2 months</th>
<th>Q4 months</th>
<th>Q6 months</th>
<th>Q12 months</th>
<th>When Stopping CAB</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV*</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Syphilis</td>
<td>X</td>
<td></td>
<td></td>
<td>MSM/TGW^ only</td>
<td>Heterosexually active women and men only</td>
<td>X</td>
<td>MSM/TGW only</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>X</td>
<td></td>
<td></td>
<td>MSM/TGW only</td>
<td>Heterosexually active women and men only</td>
<td>X</td>
<td>MSM/TGW only</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>X</td>
<td></td>
<td></td>
<td>MSM/TGW only</td>
<td>MSM/TGW only</td>
<td>Heterosexually active women and men only</td>
<td>MSM/TGW only</td>
</tr>
</tbody>
</table>

* HIV-1 RNA assay
X = all PrEP patients
^ men who have sex with men
* persons assigned male sex at birth whose gender identification is female

Same-Day PrEP Prescribing

NOT appropriate if patient:

• Is ambivalent about starting
• Can’t have blood drawn for lab testing
• Has possible acute HIV
• Has hx of renal disease or associated conditions (e.g., hypertension, diabetes)
• Is uninsured or can’t afford cost
• Doesn’t have a confirmed means of contact should lab tests indicate need to d/c PrEP (e.g., acute HIV infection, unanticipated renal dysfunction)

May not be appropriate if:

• Recent possible HIV exposure but no signs of acute HIV (PEP vs. PrEP)
• Person may not be easily contacted for return appointments
• Has mental health conditions severe enough to interfere with PrEP requirements (adherence, follow-up)

Sexually Transmitted Infection Screening

- GC/CT NAAT swabs
  - Test all relevant sites
  - Urine, urethral, vaginal
  - Oral
  - Rectal

- Syphilis is on the rise in US
  - T.pal Ab & RPR (blood)

https://www.cdc.gov/std/tg2015/default.htm
http://uwptc.org/
When to Stop PrEP

• **Oral PrEP**
  - F/TDF: eCrCl <60 mL/min
  - F/TAF: eCrCl <30 mL/min
    • Rise in serum creatinine **not** reason to stop if eCrCl still above cutoffs
  - New proteinuria not due to other causes
    • Discuss NSAID or protein powder use

• **HIV seroconversion**
• **Allergic reaction or severe intolerance**
• **Non-adherence to medications or visits**
• **No longer at risk**
• **Caution in chronic hepatitis B infections- risk of flare & fulminant hepatitis**

Telemedicine for PrEP

• Benefits to patient
  • Convenience: no travel to clinic
  • Easier access to personalized care

• Challenges
  • Clinic visit might be a one-stop shop (visit, labs, prescription refills)
  • Needs physical exam for STI complaints and/or treatment
  • Unable to conduct STI swabs lab (can get specimen kits online-cost to patient up front)
  • No access to phone and computer/internet

Telemedicine for PrEP

• Online PrEP options
  • MISTR/SISTR – partner clinics cover costs
  • Nurx – $15 for visit & $94-$124 for labs
  • Plush - $15/month + copay or $69-$129
  • Folx - monthly cost $90 + cost of labs ($0-$55)
  • Push - "less than insurance co-pays and costs are always clearly displayed"
  • Qcare+ - partner clinic & insurance billed

https://pleaseprepme.org/online-providers
HIV prevention methods can be used in combination to reduce risk.

It is important to ask about last potential high-risk exposure & properly interpret HIV screening test to determine use of PEP or PrEP.

PrEP is effective at reducing HIV transmission BUT not enough patients at high risk have access.

Novel strategies & practices have potential to engage & retain in PrEP care.

- Incorporate best practice strategies, such as use of telemedicine.

Anyone who asks for PrEP should GET IT!
Prescribing PrEP

• ICD-10 codes:
  • Z20.6 Contact with and (suspected) Exposure to HIV
  • Z20.2 Contact with and (suspected) Exposure to infections with a predominantly sexual mode of transmission

• NASTAD Billing & Coding Guide
  nastad.org/sites/default/files/2021-12/PDF-Billing-Coding.pdf

• PrEP Toolkit
  www.cdc.gov/hiv/clinicians/materials/prevention.html
If large copay: (however, ACA implementation part 47 should = $0)


If uninsured:

- Injectable PrEP Assistance Program: 1-844-588-3288
- State PrEP Assistance Programs: [nastad.org/prepcost-resources/prep-assistance-programs](http://nastad.org/prepcost-resources/prep-assistance-programs)
• https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview
• CDC. A guide to taking a sexual history. Available at: https://www.cdc.gov/std/treatment/sexualhistory.pdf
• https://www.cdc.gov/stophivtogether/campaigns/hiv-stigma/index.html
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  www.cmeuniversity.com

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