PrEP-ing Primary care
Expanding access to HIV pre-exposure prophylaxis

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Always Be PrEPared
The time is now.

- **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 PrEP and syringe services programs (SSPs).
- **Respond quickly** to potential HIV outbreaks to get needed prevention and treatment services to people who need them.
Objectives:

▷ Gain general knowledge for evidence supporting provision of PrEP and its effectiveness in prevention of HIV transmission.

▷ Describe current gaps and barriers to PrEP prescription in primary care.

▷ Be able to counsel your patients on oral PrEP and incorporate oral PrEP into your practice
Pre-exposure prophylaxis (PrEP)

- HIV prevention method that uses anti-retroviral medication to prevent HIV in HIV-negative individuals.

- 3 FDA approved regimen:
  - TDF/FTC (Truvada), once daily regimen
  - TAF/FTC (Descovy), once daily regimen
  - Cabotegravir (Apretude), Q2 months IM injectable
In 2020:

1,069,948 people living with HIV

30,636 new HIV infections
In 2020, men made up **82%** of all new HIV diagnoses. Of that, **Gay and Bisexual Men** made up **83%** of new HIV diagnoses.
In 2020, **30,632** people were newly diagnosed with HIV. **Black** individuals made up nearly half (42%) of new HIV diagnoses and had a new diagnosis rate 7 times higher than **White** individuals.

*Due to rounding, percentages may not add up to 100%.*

Percentage of New HIV Diagnoses, by Race/Ethnicity, 2020

Due to the COVID-19 pandemic, data from 2020 should be interpreted with caution.
Black people represented only **14% of PrEP users (2021)** but accounted for **42% of new HIV diagnoses (2020)**, indicating a significant unmet need for PrEP.
Preliminary CDC data\(^1\) show that in 2020, about 25% of the 1.2 million people for whom PrEP is recommended were prescribed it, compared to only about 3% in 2015.

New HIV Diagnoses Among Men in the US and Dependent Areas by Transmission Category, 2018*

Most new HIV diagnoses among men were attributed to male-to-male sexual contact.

Male-to-Male Sexual Contact: 81% (24,933)
Heterosexual Contact: 10% (2,916)
Injection Drug Use: 5% (1,434)
Male-to-Male Sexual Contact and Injection Drug Use: 4% (1,372)
Other \(^{1}\): <1% (21)

*Based on sex at birth and includes transgender people.
\(^{1}\) Includes hemophilia, blood transfusion, perinatal exposure, and risk factors not reported or not identified.

Tdf/ftc as PrEP: Mechanism of Action
PrEP effectiveness directly relates to adherence.
Barriers

85% PCP favors incorporation of PrEP into primary care

Most commonly identified barriers:
• Lack of provider familiarity
• Access to resource/guidelines/protocol
• Peers who are knowledgeable about or supportive for PrEP provision in your practice

Purview Paradox

PrEP training is associated with increased provision of PrEP

Residency programs with significant training in PrEP are $7\times$ more likely to have majority of “PrEP-appropriate” patients receiving PrEP.

(Jasper et al., 2022)
Baseline:
- Comfortable prescribing PrEP: 78%
- Not comfortable: 22%

Correctly identify appropriate PrEP candidate: 30%
Lacked adequate screening: 70%

Intervention:
- 1hr didactics + learning modules
- Order set/note template
- 2 page pocket guide

Results:
- Initiated PrEP in new patients: 50%
- Had not initiated PrEP: 50%

(Gregg et al., 2020)
Barriers: provider attitude

Informed him PrEP is effective only 50% of the time, maybe less.

I suggested a monogamous relationship.

Tested for HIV, was neg. I informed him this medication is not provided for preventive measures, needs to protect himself by practicing safe sex and avoiding risky behaviors.

I am not comfortable prescribing for this purpose.

Racial bias

Black patients were rated as more likely than White patients to engage in increased unprotected sex if prescribed PrEP, which, in turn, was associated with reduced willingness to prescribe PrEP to the patient.¹

Addressing barriers:

- Provider and staff training on cultural competency and bias.
- Developing clinic protocol or adopt existing protocol.
- Discuss PrEP with anyone who has sex or who asks for it.
History

5-P’s

- Partners
- Practice
- Protection/Past history of STI
- Pregnancy
- Injection drug use history
USPSTF: Grade A recommendation
Contraindications:

- HIV +
- Signs and symptoms of acute HIV infection/Or suspect HIV
- Renal impairment: GFR< 30 -> Consider Injectable PrEP
# CDC PrEP clinical guideline

**Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use**

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

▷ Appropriateness for therapy

▷ Choice of agent (Truvada/Descovy)

▷ Counseling

▷ Do not prescribe more than 30 days at the time of initiation.
Labs at initial visit

▷ Required-Determine eligibility:

HIV- 4th gen ag/ab– documented HIV negative within 1 week of initiation.

If symptoms of acute HIV/High risk exposure – sent HIV RNA

Renal function

▷ Recommended:

STI testing

HBV/HCV

Pregnancy
STI Testing:

▶ Syphilis testing for all adults prescribed PrEP, at initial and semi-annual.

▶ GC/Chlamydia – MSM (Quarterly), Women (Semi-annual)
  ○ For MSM: 3-site test approach is recommended.
  ○ Urine testing alone would have missed most infections with CT (74.6%) and GC (82.3%)\(^1\).
  ○ Patient self-collected swabs has been shown to be equivalent to clinician collected swabs.

1 in 15 MSM patients with rectal Gc/Ct acquires HIV within 1 year.
Hepatitis B

▷ Routine screening prior to initiating PrEP.

▷ Tenofovir and Emtricitabine are both used to treat chronic HepB. Possible flare when discontinued.

▷ +HepB is not a contraindication, but consultation with infectious disease should be considered.
Truvada (FTC-TDF) vs Descovy (FTC-TAF)
Renal function

- Small/mild decrease in eGFR has been reported for both Truvada/Descovy.
- Rare, but reported cases for acute renal failure and Fanconi syndrome.
- No difference in clinically significant renal outcome between Truvada/Descovy.
Bone health

24% to 29% of participants in this substudy had osteopenia or osteoporosis at baseline

Mean % change in lumbar spine and hip BMD at Weeks 48 and 96 by DXA scans

The long-term clinical significance of changes in BMD is not known.

CDC currently does not recommend DEXA scan
# Truvada (FTC-TDF) vs Descovy (FTC-TAF)

<table>
<thead>
<tr>
<th></th>
<th>Truvada/Generic</th>
<th>Descovy $</th>
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<tbody>
<tr>
<td><strong>Regimen</strong></td>
<td>Daily, 2-1-1 (Not FDA approved)</td>
<td>Daily</td>
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<tr>
<td><strong>Indication</strong></td>
<td>Gay &amp; bisexual cis men</td>
<td>Gay &amp; bisexual cis men</td>
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<td></td>
<td>Trans women</td>
<td>Trans women</td>
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<tr>
<td></td>
<td>Trans men</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Heterosexuals</td>
<td></td>
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<tr>
<td></td>
<td>Cis women</td>
<td></td>
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<tr>
<td></td>
<td>People who inject drugs</td>
<td></td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>- May consider avoid at risk of kidney disease or osteoporosis -min eGFR&gt;60 -Small weight loss</td>
<td>- Safer in patient with or at higher risk of kidney disease or osteoporosis -min eGFR&gt;30 -Small weight gain/Increase LDL</td>
</tr>
</tbody>
</table>
Time to effectiveness

How long does PrEP take to work?

- For **receptive anal sex (bottoming)**, PrEP pills reach maximum protection from HIV at about **7 days** of daily use.
- For **receptive vaginal sex** and **injection drug use**, PrEP pills reach maximum protection at about **21 days** of daily use.
- No data are available for PrEP pill effectiveness for **insertive anal sex (topping)** or **insertive vaginal sex**.
- We don’t know how long it takes for PrEP shots to reach maximum protection during sex.
1 Month follow-up visit

1 Month

• Assess/counsel on adherence to daily dosing

• Assess risk behaviors; counsel

• Labs: HIV test, Renal function, STI testing as needed

• Prescribe 90 day supply, no refills.
3-6 Month follow-up visit

3 Month

- Assess adherence to daily dosing, risk behaviors.
- HIV every 3 months

STI testing:
- Every 3 months for MSM
- Semi annually for heterosexual men/women even if asymptomatic

Renal function:
- Every 6 months: Age >50, baseline abnormal eGFR, risk factor (DM, HTN...etc).
- Every 12 month for all PrEP patients

Lipid panel: Annually if prescribed Descovy.
At discontinuation of therapy

- Protection wane within 7-10 days.
- Continuing until 1 month post last high risk activity
- HIV test at time of discontinuation.
- Document reason for discontinuation, recent medication adherence, and risk behaviors.
Pregnancy and breastfeeding

▷ World Health Organization (WHO)

• WHO supports provision of PrEP to pregnant and breastfeeding people (PBFP) who are at continuing substantial risk of HIV infection.

▷ ACOG

• Can use PrEP when trying to become pregnant, and during pregnancy. Esp if partner viral load is detectable or unknown.

• Can be used during breastfeeding if mother continues to be at risk of HIV infection.

• There are no known reports of birth defects caused by PrEP.
On demand PrEP – off label use

- Endorsed in Europe/British/WHO guidelines, but not FDA approved.
- IPREGAY/PREVENIR: 87% relative risk reduction but take avg 4 or more pills weekly.
- Prescribe only 30day supply at a time.
Examples of other clinical protocol

Pre-exposure prophylaxis (PrEP) is an effective way to prevent HIV infection for people who are at high risk.

**PrEP in Primary Care**

- The FDA approved medication for PrEP consists of tenofovir (TDF) 300 mg and emtricitabine (FTC) 200 mg (Truvada) combined into a single tablet taken once daily.
- Prior to prescribing PrEP at VA, prescribers need to complete TMS training #36785 then submit certificate for approval. Prescribers will be notified when approved.

**Assess HIV Risk**

- Discuss sexual health and practices
- Discuss injection drug use

**Indications for PrEP**

- Any Veteran who has sex and/or shares injection equipment with HIV infected or HIV status unknown individuals

**Assess for Current HIV Infection**

- Order HIV testing. Negative test must result within 1 week of starting PrEP.
- Check for signs of acute HIV infection
- **Do NOT use PrEP in Veterans with positive HIV testing or strong suspicion for recent exposure***

**Check Other Diagnostic Labs**

- Creatinine clearance (Consider PrEP only in Veterans with CrCl > 60 mL/min.)
- STIs: gonorrhea/chlamydia (GC/CT), syphilis (RPR)
- Pregnancy status (not a contraindication)
- Hep B/C (not a contraindication but may need additional evaluation)

**Prescribe PrEP**

- Truvada 1 tab PO daily
- INITIATE with no more than 30-day supply & REFILL with no more than 90-day supply
- Adherence determines efficacy

**Follow-up**

- 1 month: Repeat HIV test
- Q 3 months: HIV status
- Q 6 months: STI and Creatinine clearance
- Annually: Reassess need

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**Sexual History Questions: The Five P’s**

**Partners**

- Do you have sex with men, women, or both?
- In the past 6 months, have you had unprotected sex? With anyone who’s HIV status you did not know?
- Is it possible that any of your sex partners in the past year had sex with someone else while they were still in a sexual relationship with you?

**Practices**

- Can you describe the type of sex you have with your partner(s)?
- Do you use barrier protection (condoms, dental dams, rubber gloves, etc.) or other types of protection? If not, why not? If sometimes, in what situations do you use protection?
- Have you ever had sex in exchange for something you needed (food, shelter, drugs, $$)?
- Is there anything else I should know about your sexual practices?

**Protection from and Past history of sexually transmitted infections (STIs)**

- Do you know your HIV status?
- Past history of STIs? Are you concerned about getting an STI?
- How do you protect yourself from STIs and HIV?
- Have any of your partners had STIs?

**Pregnancy**

- What are your plans regarding pregnancy?
- What (if anything) are you doing to prevent pregnancy?

**Injection Drug History Questions**

Put questions in context: “Some of my patients have used drugs, such as heroin, cocaine or methamphetamine—have you ever used drugs?”

- Have you ever injected drugs that were not prescribed for you or in a way other than were prescribed to you by a health care provider? If yes:
  - When did you last inject drugs that were not prescribed for you?
  - In the past 6 months, have you injected using needles, syringes, or other drug preparation equipment that had already been used by another person?
  - In the past 6 months, have you been in a methadone, buprenorphine/ naloxone, or other medication-based drug treatment program?

***At minimum, a sexual health hx should be performed on an annual basis OR when NEW risk factors are identified***
Examples of other clinical protocol
Summary

▷ Significant gap still exists in provision of PrEP to reach the national goal of 50% by 2030.
▷ There is inequitable provision of PrEP in racial groups, and systemic/provider bias contributes to this gap in care. Training in implicit bias must be incorporated.
▷ PrEP is highly effective and should be made available to everyone who is HIV negative.
▷ Initiating oral PrEP is oftentimes straightforward, and there are plenty of easy-to-access resources and established protocol to help with this.
Thank you!

Any questions?

You can email me at:

lwang@crhc.org
Trouble Shooting

▷ Start up syndrome
  • ~10% will experience “start up syndrome”.
  • Most commonly GI, nausea, headache.
  • Transient, self-resolves usually within 1 month.
  • Manage with OTC

▷ Missed dose
  • Not to panic.
  • Take the dose as soon as you remember it.
  • Resume normal schedule.
  • If close to normal schedule, just take the normal dose slightly earlier.