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A Step-by-Step Guide To Setting up a HIV PEP/PrEP Clinic

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Pharmacist and Technician Learning Objectives

1. Review the latest standards of care for HIV, including screening, prevention, and treatment guidelines.
2. Outline strategies for launching an HIV PEP/PrEP Clinic.
3. Discuss best practices for incorporating screening, education and connection to care into workflows.
4. Discuss communication approaches for educating patients on HIV topics.

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EPIDEMIOLOGY & PATHOPHSYSIOLOGY

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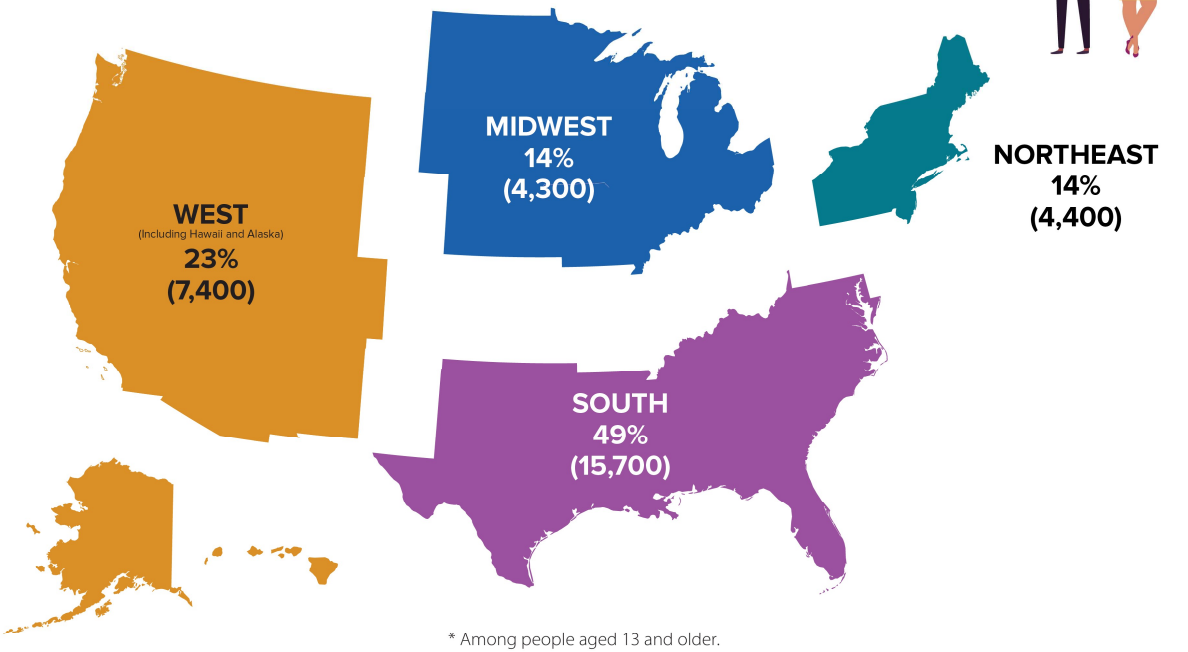
HIV in the United States

Estimated HIV infections in the US by region, 2022*

Nearly half (49%) of new HIV infections were in the South.



* Among people aged 13 and older.

Source: CDC. Estimated HIV incidence and prevalence in the United States, 2018–2022. *HIV Surveillance Supplemental Report*, 2024; 29(1).

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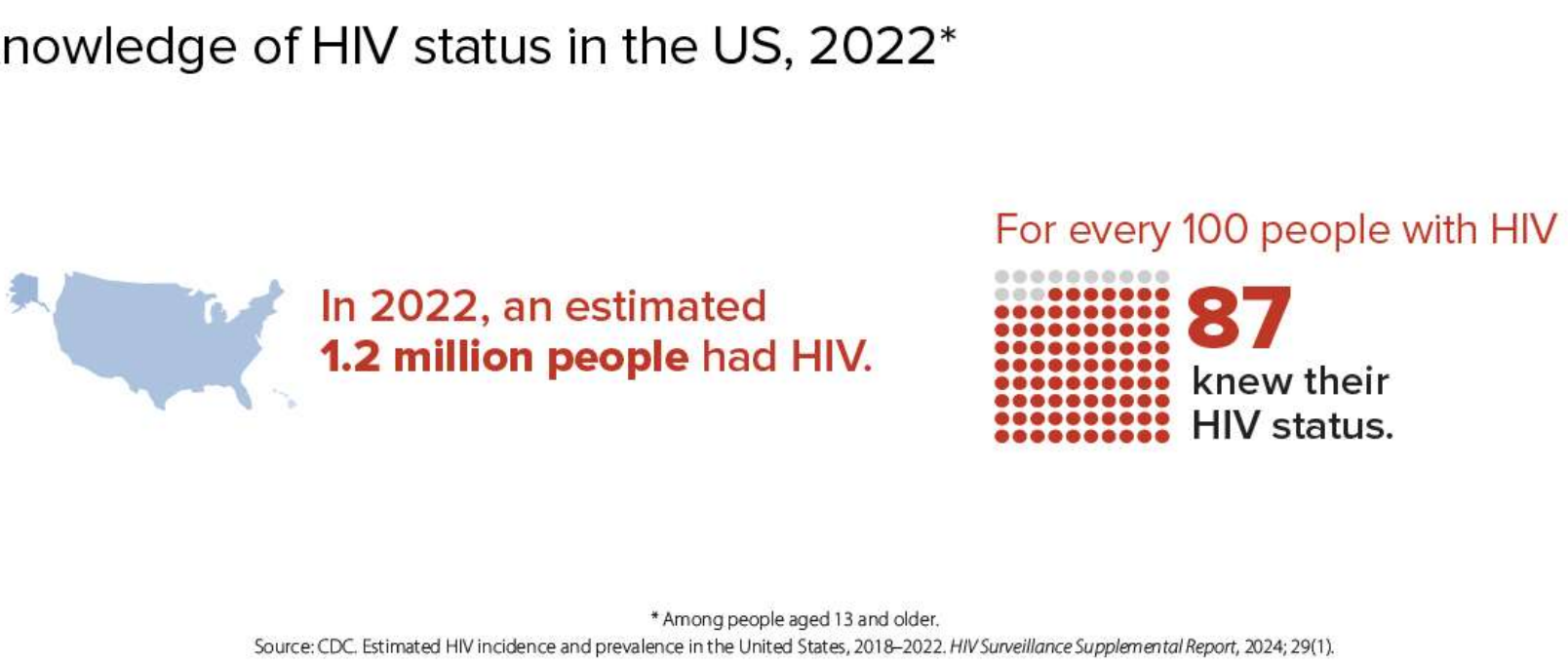
Centers for Disease Control and Prevention. (2024, April 22). *Fast facts: HIV in the United States*. U.S. Department of Health and Human Services. https://www.cdc.gov/hiv/data-research/facts-stats/index.html

CDC's Ending the HIV Epidemic wants to increase testing



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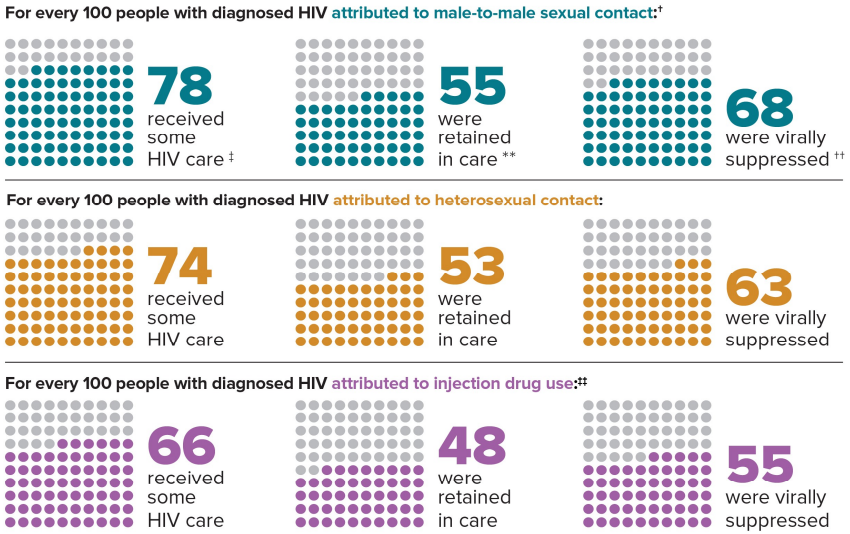
Centers for Disease Control and Prevention. (2024, April 22). *Fast facts: HIV in the United States*. U.S. Department of Health and Human Services. https://www.cdc.gov/hiv/data-research/facts-stats/index.html

Why Pharmacy can Close the Gap

HIV care continuum among people with diagnosed HIV in 48 states and the District of Columbia by transmission category, 2022*

People with diagnosed HIV attributed to male-to-male sexual contact or heterosexual contact had similar rates of viral suppression to people overall with diagnosed HIV. People with diagnosed HIV attributed to injection drug use had lower rates of viral suppression. More work is needed to increase these rates.



* Among people aged 13 and older.
† Includes infections attributed to male-to-male sexual contact only.
‡ At least 1 viral load or CD4 test.
** Had 2 viral load or CD4 tests at least 3 months apart in a year.
†† Based on most recent viral load test.
‡‡ Includes infections attributed to injection drug use only. For every 100 men with HIV attributed to male-to-male sexual contact and injection drug use, 81 received some HIV care, 19 were retatained in care, and 62 were virally suppressed.

Source: CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 territories and freely associated states, 2022. *HIV Surveillance Supplemental Report* 2024;29(2).

Centers for Disease Control and Prevention. (2024, April 22). ***Fast facts: HIV in the United States***. U.S. Department of Health and Human Services. https://www.cdc.gov/hiv/data-research/facts-stats/index.html

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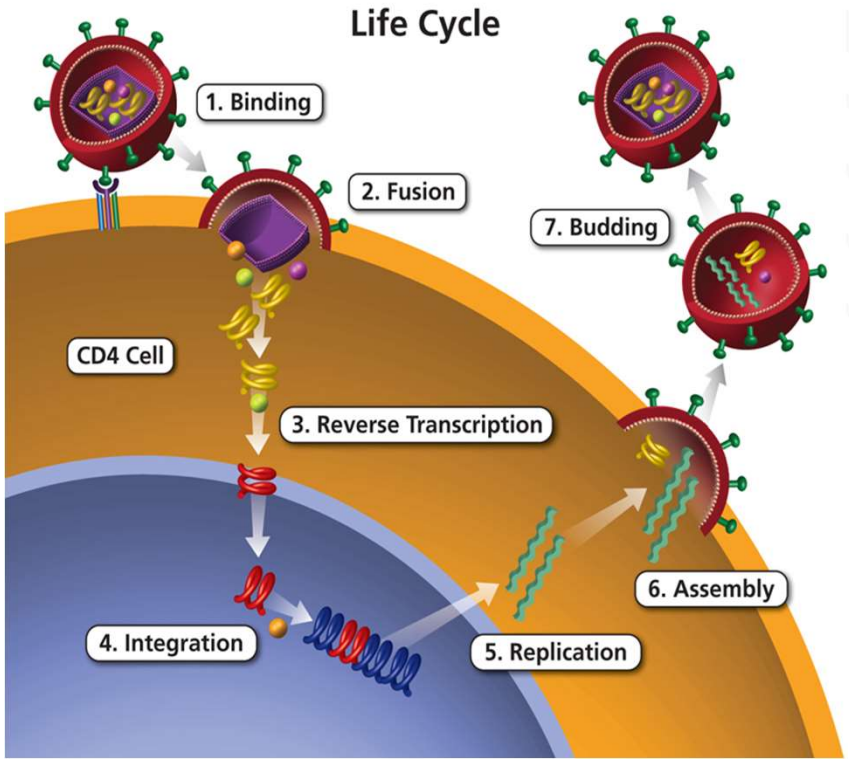
How Does PrEP Work?

- PrEP is comprised of several medications, that block an enzyme called HIV reverse transcriptase.

- HIV uses this enzyme to make new copies of HIV, so PrEP prevents HIV from multiplying in the body.



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SIGNS
SYMPTOMS
DIAGNOSIS

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Signs and Symptoms of Acute HIV Infection

- Fever
- Fatigue
- Myalgias
- Skin rash
- Headache
- Lymphadenopathy
- Arthralgia
- Night sweats
- Diarrhea

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What is PrEP?

- Pre-exposure prophylaxis
  - ONE of the tools for preventing HIV
  - For people at high risk of HIV acquisition
  - Tenofovir disoproxil fumarate (TDF) 300 mg/Emtricitabine (FTC) 200 mg 1 tablet daily
    - Truvada®
  - Tenofovir alafenamide (TAF) 25 mg/Emtricitabine (FTC) 200 mg 1 tablet daily
    - Descovy®
  - Cabotegravir 200mg/mL injection every 2 months after initial 2 doses which are 1 month apart
    - Apretude®
  - Prescriptions only written for 3 months at a time to ensure regular monitoring

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Center for Disease Control and Prevention: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2017 Update: a clinical practice guideline. https//www.cdc.gov/hivpdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.

ONE of the Tools in the Prevention Toolbox

- Limit number of sexual partners
- Sexual risk reduction counseling
- Condoms
- Sexually transmitted infection (STI) treatment
- Never share needles
- Referral to drug treatment and mental health services when indicated
- Treatment for partners who are living with HIV (“TasP”)
- Abstinence

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https://www.cdc.gov/hiv/basics/prevention.html

Why Be Involved?

- Pharmacists
  - Improve patient understanding
  - Promote medication adherence
  - Provide key risk reduction counseling
  - Enhance PrEP efficacy

As accessibility increases hopefully the number of new HIV diagnoses decrease!

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- Farmer EK et al. al. The Pharmacist's Expanding Role in HIV Pre-Exposure Prophylaxis (PrEP). *AIDS Patient Care and STDs* 2019; 33(5):207-13.

PATIENT CASE

VA is a 32-yo cismale whose husband is living with HIV but has been in and out of care

He comes to your pharmacy asking if there's a good way to prevent HIV infection

Broken condom 3 weeks ago: HIV testing was negative

Consent for husband's medical info, request he speak with pharmacist

- He missed his last 2 clinic appointments
- Condom broken or removed more frequently

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People at Higher Risk

- **Sexual transmission** not in a mutually monogamous relationship with a partner who recently tested HIV-negative AND
  - Gay or bisexual man who has had anal sex without a condom or been diagnosed with an STI in the past 6 months; OR
  - Heterosexual person who does not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection (e.g., people who inject drugs or have bisexual male partners)
- **For people in HIV-discordant couples**
  - Especially useful when the HIV-positive partner is not taking antiretroviral medications or does not have an undetectable viral load
  - Discuss also during conception and pregnancy as one of several options to protect the partner who is HIV-negative
- **For people who inject drugs**
  - Those who have injected illicit drugs in the past 6 months AND
  - Who have shared injection equipment in the past 6 months
  - Risk of sexual acquisition

www.cdc.gov/hiv/risk/prep/index/html

Patient Centered Communication

Taking a Sexual History

- Partners
  - Number?
  - Sex?
- Practices
  - Affects risk
  - Identifies anatomical sites for testing
- Protection from STIs
  - What percent of the time do you use protection?
  - What kind of protection do you use?
- Past history of STIs
  - Affects risk
- Pregnancy Plans
  - Trying to conceive or father a child?
  - What type of protection if you want to prevent?

Taking an Injection Drug Use History

- Normalize the discussion
- i.e. “Some of my patients have used injection drugs such as heroin, cocaine, or meth…have you ever used these types of drugs?”
- Have you ever injected drugs that were not prescribed to you by a clinician?
  - (if yes), When did you last inject unprescribed drugs?
- In the past 6 months, have you injected by 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 or other medication-based drug treatment program?

- https://www.cdc.gov/std/treatment/sexualhistory.pdf
- https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

WHAT IS PrEP?

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PEP vs. PrEP – What's the Difference?

	PEP	PrEP
Timing	Within 72 hrs of exposure	Before exposure (ongoing risk)
Duration	28 days	Continuous (daily or q2mo injection)
Indication	Emergency	Prevention

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Slide 20

DR1 Should this slide include a source?
Drew Register, 2025-06-18T05:10:16.600

ED1 0 Reference slide included at the end of presentation
Elise Damman, 2025-06-27T13:52:57.907

DR1

What is PrEP?

- Pre-exposure prophylaxis is taken to prevent HIV infection
  - It does not prevent or protect against other STIs!

	Truvada (TDF/FTC)	**Descovy (TAF/FTC)**	**Apretude (cabotegravir)**
Dosing	1 tablet once a day	1 tablet once a day	IM injection every other month
Indication	Reduce risk of HIV-1 infection	Reduce risk of sexually acquired HIV-1 infection, **excluding individuals at risk from receptive vaginal sex**	Reduce risk of HIV-1 infection in people who weigh at least 77 lbs
Clinical Considerations	Small decrease in eGFR and BMD	Less impact on eGFR and BMD through 96 weeks	Drug interactions!

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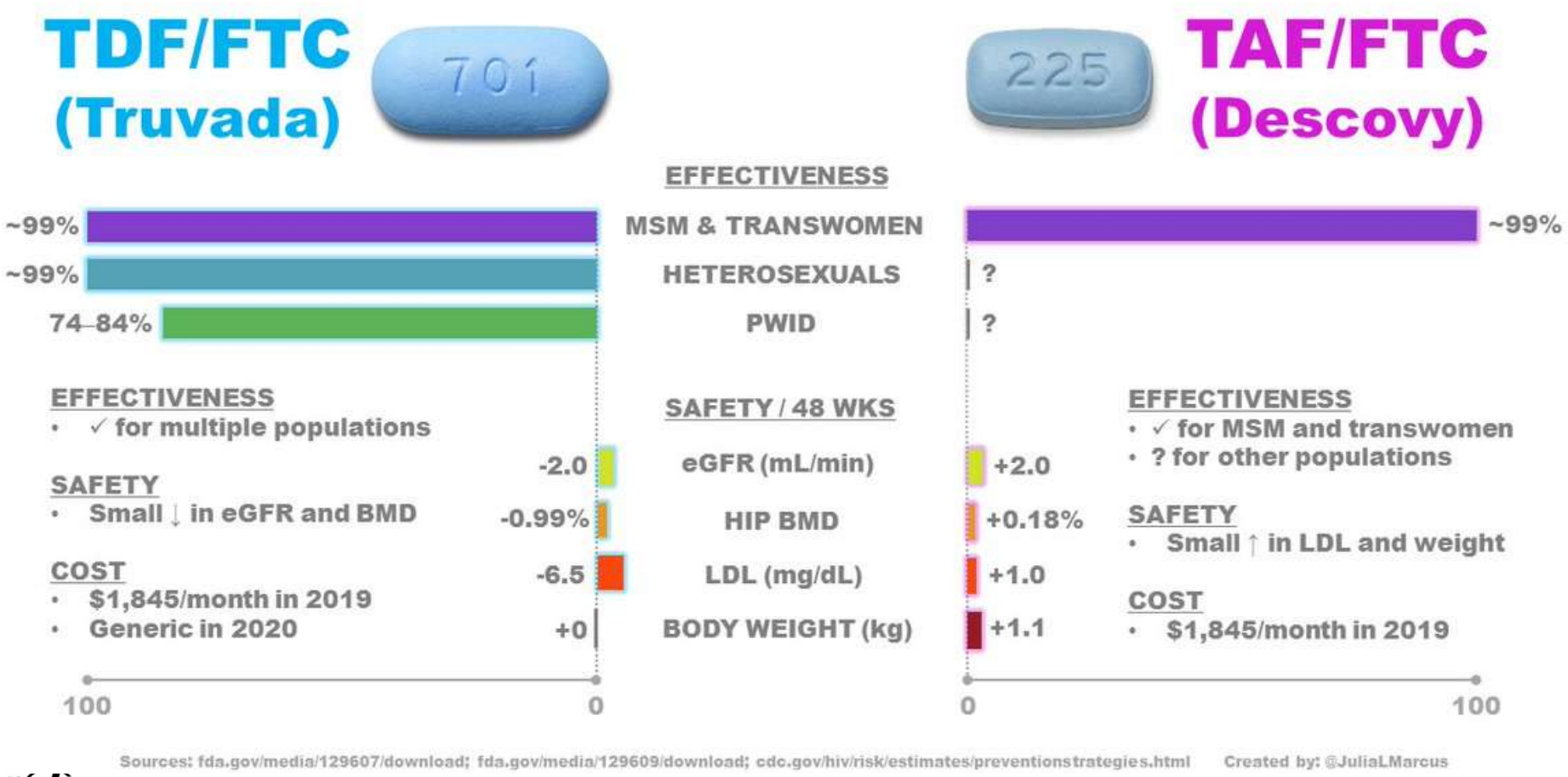
Slide 21

DR1 Should this slide include a source?
Drew Register, 2025-06-18T05:10:27.537

ED1 0 Reference slide included at the end of presentation
Elise Damman, 2025-06-27T13:53:08.995

Which medication should I prescribe for PrEP?



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- http://paetc.org/resource-item/which-medication-should-i-prescribe-for-prep-truvada-vs-descovy-infographic/; Hare, C. The Phase 3 DISCOVER Study: Daily F/TAF or F/TDF for HIV Pre-exposure Prophylaxis. CROI 2019, Abstract 104.

Efficacy

- Most effective when taken consistently each day (or every 2 months if on Apretude)
- CDC reports that studies have shown that consistent use of PrEP reduces the risk of getting HIV
  - From sex by about 99%
  - From injection drug use by at least 74% - 84%
- Adding other prevention methods, such as condom use, along with PrEP can reduce a person's risk of getting HIV even further

• https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/20/85/pre-exposure-prophylaxis--prep-/, accessed 1/18/20

Steps to Setting up a PEP/PrEP Clinic

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Step-by-Step Setup Plan

1. Assess community need
2. Understand state laws (CPA, standing orders)
3. Build protocol
4. Train staff
   - National HIV Curriculum - https://www.hiv.uw.edu
5. Set up documentation & billing
6. Market the service

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Collaborative Prescribing & Legal Setup

- CPA vs standing orders
  - Examples from NM, CA, OR, WA
- May need additional credentialing based on state laws or restrictions

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Slide 26

ED1 Just an FYI that there will be a session on CPAs on Friday
Elise Damman, 2025-06-27T13:34:21.278

Lab Access & Results

- Partnerships with local clinics/labs
- In-house CLIA waiver options
  - Need dedicated space and policies for quality and competency

Positive or Reactive Results

- Preliminary positive HIV tests need to be referred for further evaluation
  - Linkage to same day care and same day start for treatment
- STIs – are you going to test at pharmacy or refer?
- Hepatitis B, renal function, and pregnancy tests

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Prescribing & Dispensing

Pharmacist conducts appointment (can be appointment based)

- Patient interview/Review of intake form
- Makes assessment and plan
- Orders and collects labs (POC or referral to lab or lab review if patient has current labs available)
- Issues/prescribes prescription if appropriate
- Medication and behavioral risk reduction counseling
- Administers vaccines
- Documents visit SOAP note in EHR
- Complete billing and dispensing

- Support for uninsured (Ready, Set, PrEP; manufacturer coupons)

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Billing & Sustainability

- CPT codes for PrEP counseling (if allowed)
- Public health or grant support
- Documenting interventions
- Is it a medical benefit or pharmacy benefit?

CPT Code	Description	Notes
99401	Preventive medicine counseling, individual, approx. 15 min	Can be used for HIV risk reduction or PrEP initiation discussion
99402	Preventive counseling, approx. 30 min	For longer sessions, especially initial PrEP consult
99403–99404	45–60 minutes of counseling	For more complex or initial multi-topic visits
99406	Smoking and tobacco use cessation counseling, 3–10 min	Not PrEP-specific, but useful for co-counseling
99407	Smoking cessation, >10 min	Same as above, if applicable in patient case
96160	Administration of health risk assessment	Can be used for HIV risk screening tool or questionnaire (e.g., PrEP eligibility)
G0445(Medicare)	Annual HIV screening (15–65 years or at increased risk)	Medicare-specific code for HIV testing (once annually or up to 3x/year for high-risk individuals)
S9445(HCPCS)	Patient education, non-physician provider, individual, per session	Often used in pharmacy-led services (payer-dependent)

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Slide 29

ED1 There is also a medical billing session on Friday if people are interested in learning more about medical billing and how to get credentialed.

Elise Damman, 2025-06-27T13:42:26.279

Does this fit for your pharmacy?

- Generic Compliance Ratio
  - Currently there is only one generic PrEP medication – tenofovir disoproxil fumarate/emtricitabine (TDF/FTC)
- Taxes
- Carrying costs of the medications
- PBM DIR fees
- Medical billing vs. pharmacy benefit billing

Patient Education & Communication

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PATIENT CASE

VA is a 32-yo cismale whose husband is living with HIV but has been in and out of care

He comes to your pharmacy asking if there's a good way to prevent HIV infection

Broken condom 3 weeks ago: HIV testing was negative

Consent for husband's medical info, request he speak with pharmacist

- He missed his last 2 clinic appointments
- Condom broken or removed more frequently

What's next?

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Monitoring: Before Starting PrEP

- Negative HIV test immediately before starting PrEP
- HIV Ab/Ag
  - Usually detects 18-45 days after exposure
- Viral load (HIV RNA, or NAT) if symptoms of acute HIV or if patient had at-risk sexual exposure with HIV+ person in last 30 days
  - Usually detects 10-30 days after exposure
- Pregnancy *if applicable
  - The safety of PrEP medication exposure to infants during pregnancy has not been fully assessed but no harm reported to date
- Assess creatinine clearance, assure > 60 mL/min (>30 mL/min for TAF/FTC)
- Screen for hepatitis B infection
  - Vaccinate if appropriate
  - Treat if active infection identified
- STI screening and treatment (if needed)

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Slide 33

DR1 Should this slide include a reference to the guidelines (mentions viral load, lab thresholds)?
Drew Register, 2025-06-18T05:06:35.381

ED1 0 Reference slide included at the end of presentation
Elise Damman, 2025-06-27T13:53:39.271

PATIENT CASE

- Labs were drawn
  - HIV Ab/Ag negative
  - GFR 83 mL/min
  - Gonorrhea, chlamydia, syphilis, hepatitis C, and pregnancy negative
  - Immune to hepatitis B
- You decide to prescribe tenofovir disoproxil fumarate/emtricitabine X 30 doses with 2 refills
- Plan: ideally pharmacist will call to check-in 2 weeks after starting PrEP; provider or pharmacist will reassess every 3 months with labs and PrEP clinic visit

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	Screening Assessment (Pre-prescription)	Within 1st month of starting PrEP	At least every 3 months	At least every 6 months	At least every 12 months
Sexual history, risk for HIV	√		√[1]		
HIV test/assess for acute infection[2,3]	√		√		
Hepatitis B serology[4]	√				√
Hepatitis C	√				√[5]
Serum creatinine & creatinine clearance[6]	√[6]		√[7]	√	
STI testing[8]	√		√[8]	√	
Pregnancy test[9]	√		√		
Medication adherence		√	√		
Medication adverse events		√	√		

See Next Slide for footnotes; √ = guideline recommendation; √ = optional, based on individual risk

Collaborative practice agreement, University of Iowa HealthCare; updated November 2019. Center for Disease Control and Prevention: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2017 Update: a clinical practice guideline. https//www.cdc.gov/hivpdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.

ED1

Slide 35

ED1 Updated to reference next slide
Elise Damman, 2025-06-27T13:49:43.242

ED1

Table Footnotes

1. Risk behaviors and ongoing risk.
2. Acute and chronic HIV infection must be excluded by symptom history and HIV testing immediately before PrEP is prescribed.
    1. -Symptoms of acute HIV infection: fever, fatigue, myalgia, skin rash, headache, pharyngitis, lymphadenopathy, arthralgia, night sweats, and diarrhea.
    2. -Clinicians should document a negative antibody HIV test result within 1 week of initiating medication
    3. -HIV testing
        1. Blood draw (serum) and lab testing for antigen/antibody or antibody only OR
        2. 4th generation rapid/POC test
        3. DO NOT use oral fluid rapid tests – less sensitive than blood tests
3. HIV infection should be assessed at least every 3 months so that those with incident HIV infection are treated appropriately. Truvada® or Descovy® alone is inadequate therapy for established HIV infection.
4. HBsAg at minimum prior to starting Truvada® or Descovy®. Preferred serology: HBsAg, HBsAb, HBcoreAb (total IgM and IgG). HBsAg should be monitored annually in people without documented HBV immunity. HBV vaccination recommended, especially for MSM.
5. Annual HCV retesting for people with injection drug use. Consider annual retesting for others with ongoing risk of HCV exposure.
6. Do not initiate or continue Truvada®, as PrEP, in individuals with a creatinine clearance < 60 mL/minute, based on Cockcroft-Gault formulas. Do not initiate or continue Descovy®, as PrEP, in individuals with a creatinine clearance < 30 mL/minute.
7. Consider for patients with borderline renal function or risk factors for renal disease (e.g. HTN, Diabetes)
8. Syphilis, chlamydia, gonorrhea – genital, rectal, and oropharyngeal testing as indicated. Every 3 month testing recommended for persons with signs/symptoms of infection and for asymptomatic MSM at high risk for bacterial STIs (e.g. condom use < 100%, receptive anal sex without condom use)
9. Repeat pregnancy testing for women who may become pregnant. If a patient takes PrEP while pregnant or becomes pregnant during utilization of PrEP, providers are encouraged to prospectively and anonymously submit information about the pregnancy to the *Antiretroviral Use in Pregnancy Registry*. Pregnancy test can be waived for women with documented hysterectomy or tubal ligation.

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Slide 36

ED1 Attendees won’t have access to the speaker notes in their handout so added this just as a reference for them to refer back to later; Wasn’t sure exactly what to title, feel free to edit

Elise Damman, 2025-06-27T13:48:45.588

Counseling Points

- Adherence is key
  - Ask how many doses have been missed within the past week
  - Refill history
  - Significant reduction in risk of acquisition has been reported with 4 doses/week **IN MSM**, but this is not a recommendation
  - Tools
    - Alarms on phones
    - Placing medication where they can see it daily
    - Integrating into daily routine
    - Pillboxes
    - Keychain med holders
    - Adherence apps
- Educate on what to do in case of missed doses
- Side effects (mild GI, headache, injection site reactions if applicable)
- Address myths and stigma

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Culturally Responsive Communication

- Avoid assumptions
- Use inclusive language
- Understand barriers in LGBTQ+ communities

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Motivational Interviewing Tips

- Open-ended questions
- Reflective listening
- Avoid judgmental tone

Example:

Pharmacist: *"PrEP is a great option for people who want to take control of their health and reduce their HIV risk. It's over 99% effective when taken daily. May I ask a few quick questions to learn more about your risk and medical history?*

(Screening): [Ask about recent sexual activity, use of condoms, injection drug use, HIV status of partners]

Pharmacist: *Based on what you've shared, you may be a good candidate for PrEP. We'll need to do some labs first-mostly to make sure you're HIV-negative and that your kidneys are functioning well. From there, we can talk about options: either a daily pill or a shot every two months. Which sounds better for your lifestyle?*

Adherence Support

- Text or app reminders
- Long-acting injectable appointments
- Monthly check-ins or sync with other meds
  - Patient's may use a 2-1-1 method (a double dose of TDF/FTC before sex, then if sex happens a single dose 24 hours after the first dose, and another 48 hours later)
    - Now emerging limited data on event-based dosing for women(vaginal receptive sex) would include taking an extra pill 72 hours after sex, or '2-1-1-1' dosing

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Workflow Integration & Sustainability

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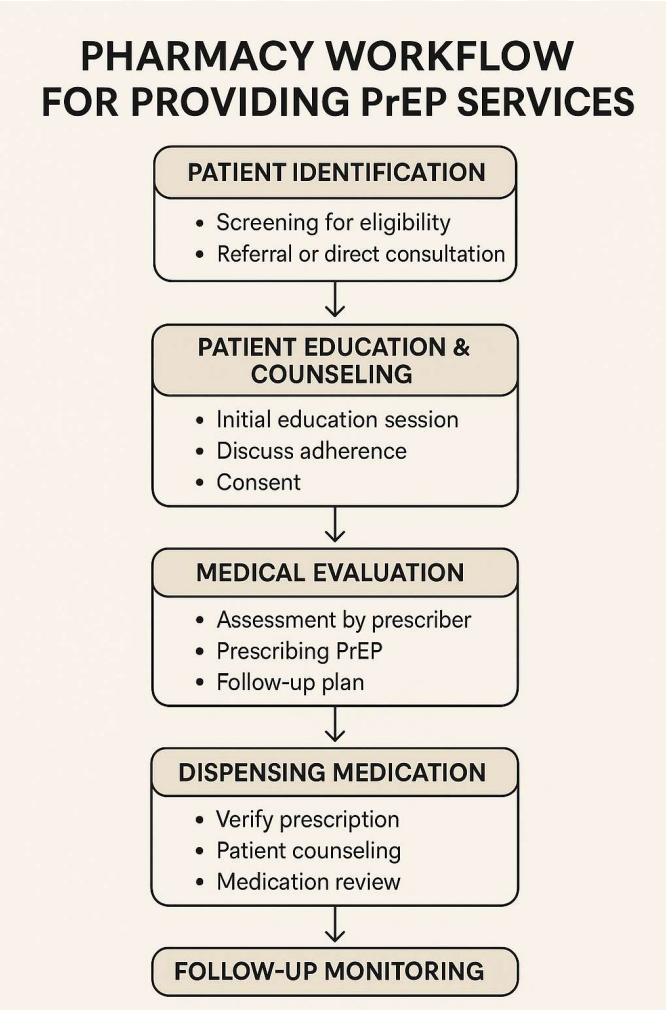
Sample Pharmacy Workflow

- Intake form → Baseline tests → Prescribe → Dispense → Follow-up

Potential Team Roles	
Team Member	**Role**
Technician	Intake, reminders, refill coordination, patient assistance programs, scheduling, document scanning, prior authorizations, medical billing management
Intern	Counseling, follow-up check-ins, other roles as able
Pharmacist	Clinical review, prescribing, education, documentation, billing, calling on reactive or positive results, refill authorizations, answering patient clinical questions, lab compliance, reporting to county on positive results



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Measuring & Growing the Program

- Track # patients initiated
- % retained at 3 and 6 months
- Referral partnerships for STIs, Hep C, behavioral health, positive results

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Wrap-Up & Q&A

Key Takeaways

- Pharmacies are critical access points for HIV prevention
- PEP/PrEP clinics are achievable with the right framework
- Patient-centered communication is vital to success

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Questions?

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References

Section 1: HIV Prevention Overview & Guidelines (Slides 4–8)

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Section 2: Clinic Setup Process (Slides 9–13)

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