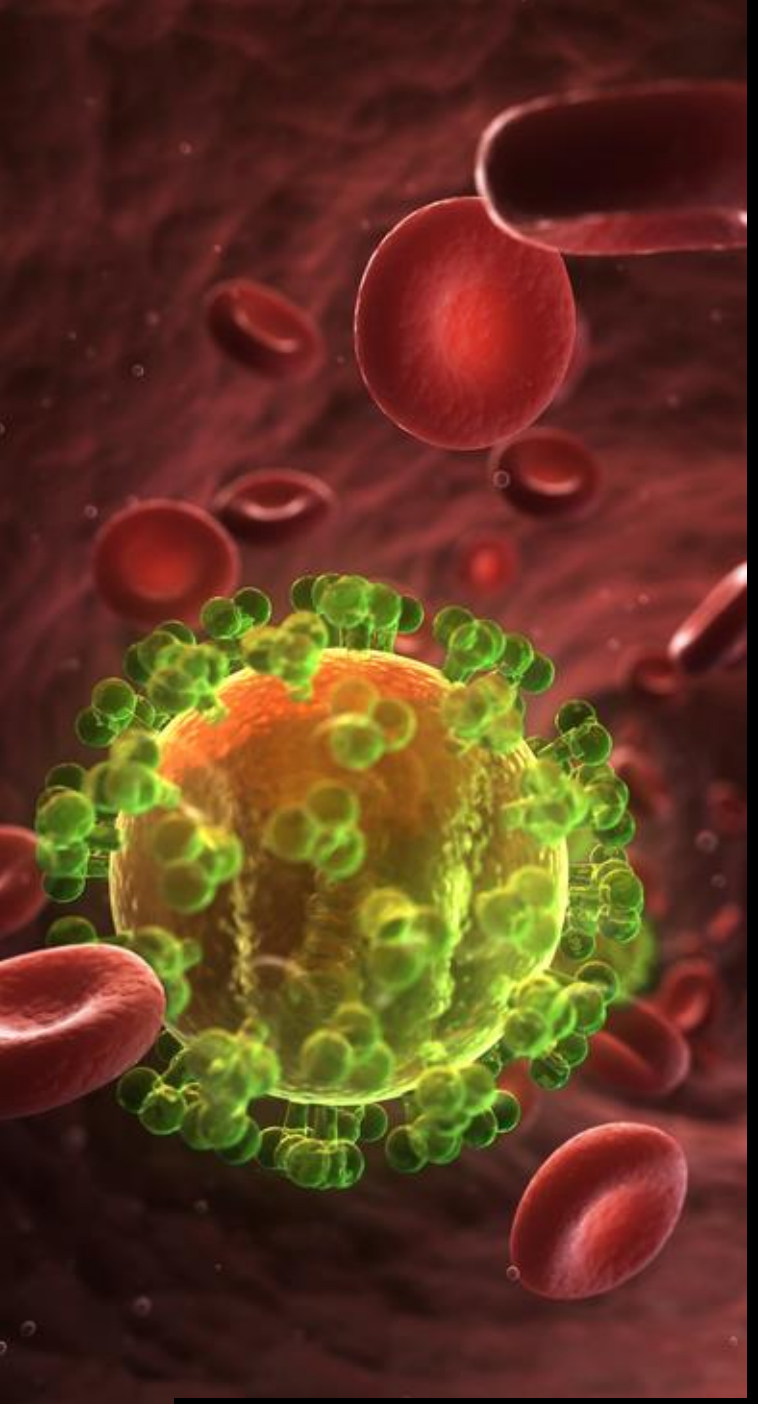

Prevention is the Best Treatment: Updates on Preexposure Prophylaxis of HIV Infection

Healthtrust Webinar
January 4, 2022

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Conflict of Interest Disclosure

- There are no financial interests to disclose for myself or the preceptor in the last 24 months.
- This presentation may include the mention of brand products or drugs. All content is for educational purposes only.

Learning Objectives

1

Identify factors that increase the risk of HIV exposure

2

Recall current guideline recommendations for utilizing antiretroviral medications for preexposure prophylaxis (PrEP)

3

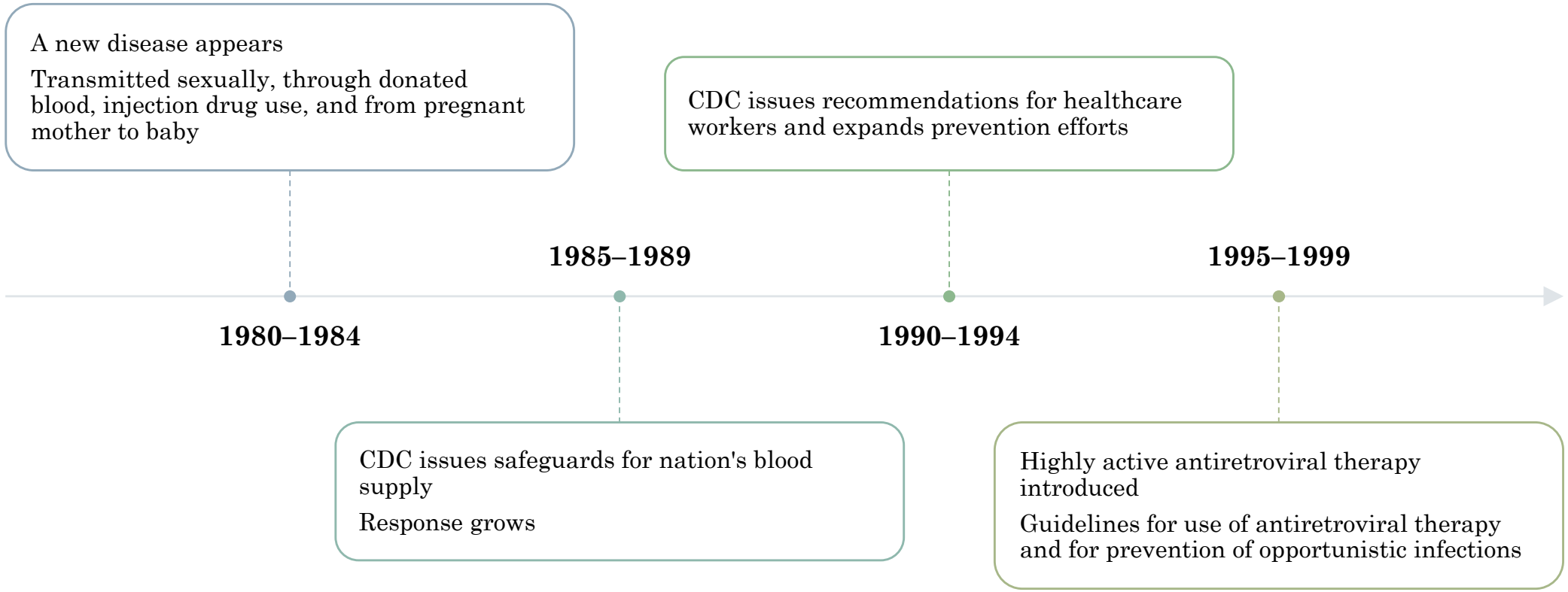
Recognize the roles of the pharmacist in HIV prevention

The Basics of HIV

- HIV: Human immunodeficiency virus
- Single-stranded RNA virus
- Attacks the CD4 cells of the immune system
- Inhibits the body's ability to fight infections

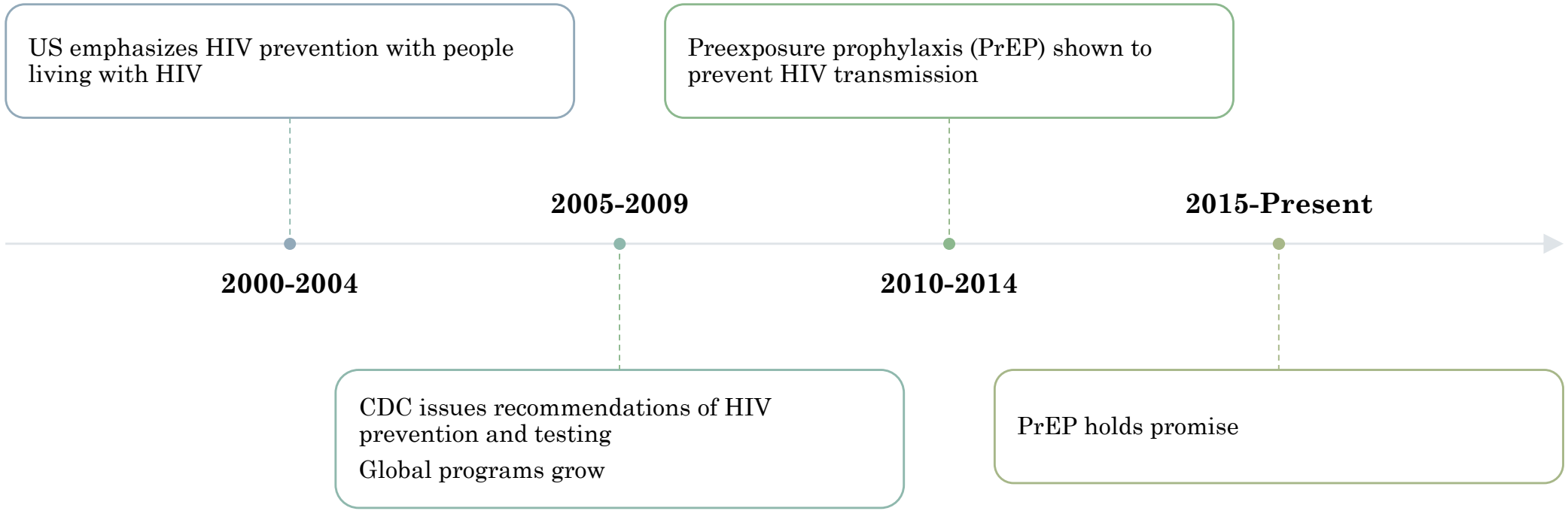
Source: HIV/AIDS. World Health Organization; [2022]

HIV Epidemic Through the Years



Source: CDC-National Prevention Information Network-HIV and AIDs Timeline. https://npin.cdc.gov/pages/hiv-and-aids-timeline November 21, 2022

HIV Epidemic Through the Years



Source: CDC-National Prevention Information Network-HIV and AIDs Timeline. https://npin.cdc.gov/pages/hiv-and-aids-timeline November 21, 2022

Learning Objectives

1

Identify factors that increase the risk of HIV exposure

2

Recall current guideline recommendations for utilizing antiretroviral medications for PrEP

3

Recognize the roles of the pharmacist in HIV prevention

HIV Statistics in the United States

New HIV diagnoses in 2020: **30,635**

Prevalence in 2019: **1,189,700** (87% were aware of their HIV status)

Source: CDC-HIV: HIV Statistics Center. https://www.cdc.gov/hiv/statistics/overview/in-us/prep-coverage.html. November 15, 2022

HIV Statistics in the United States

2020 New Diagnoses by Transmission Category

- Male-to-Male Sexual Contact: **68%**
- Heterosexual Contact: **22%**
- Injection Drug Use: **7%**
- Male-to-Male Sexual Contact and Injection Drug Use: **4%**

2020 New Diagnoses by Race /Ethnicity

- Black/African American: **42%**
- Hispanic/Latino: **27%**
- White: **26%**
- Multiracial: **3%**
- Asian: **2%**
- American Indian/Alaska Native: **1%**
- Native Hawaiian and other Pacific Islander: **<1%**

Source: CDC-HIV Basics: Basic Statistics. https://www.cdc.gov/hiv/basics/statistics.html#:~:text=In%202020%2C%20male%2Dto%2D,22%25%20of%20all%20HIV%20diagnoses. November 15, 2022.

Preexposure Prophylaxis of HIV

PrEP

Taking a medication to prevent/reduce the risk of HIV

Used in individuals who are HIV-negative but at risk of acquiring HIV

Transmission Route	Estimated Effectiveness
Sexual	~99%
Injection drug use	74-84%

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.
CDC-HIV: HIV Nexus Clinician Resources. https://www.cdc.gov/hiv/clinicians/prevention/prep.html. November 15, 2022

Assessment Question #1

Preexposure prophylaxis is using antiretroviral medications to:

A. Treat HIV infection in a newly diagnosed patient before resistance testing

B. Prevent infection after an accidental needle stick involving an HIV-positive patient

C. Prevent infection in a person who does not have HIV but participates in high exposure risk activities

D. Prevent infection after sharing intravenous drug use supplies with an HIV-positive person

Correct Response

Preexposure prophylaxis is using antiretroviral medications to:

A. Treat HIV infection in a newly diagnosed patient before resistance testing

B. Prevent infection after an accidental needle stick involving an HIV-positive patient

C. **Prevent infection in a person who does not have HIV but participates in high exposure risk activities**

D. Prevent infection after sharing intravenous drug use supplies with an HIV-positive person

HIV Risk Factors

- Unprotected sexual intercourse
- HIV-positive sexual partners
- Sexual partners with unknown HIV status
- Bacterial sexually transmitted infection in past 6 months
- History of inconsistent or no condom use
- Injection drug use
- HIV-positive injecting partner
- Sharing needles/equipment
- Alcohol use disorder

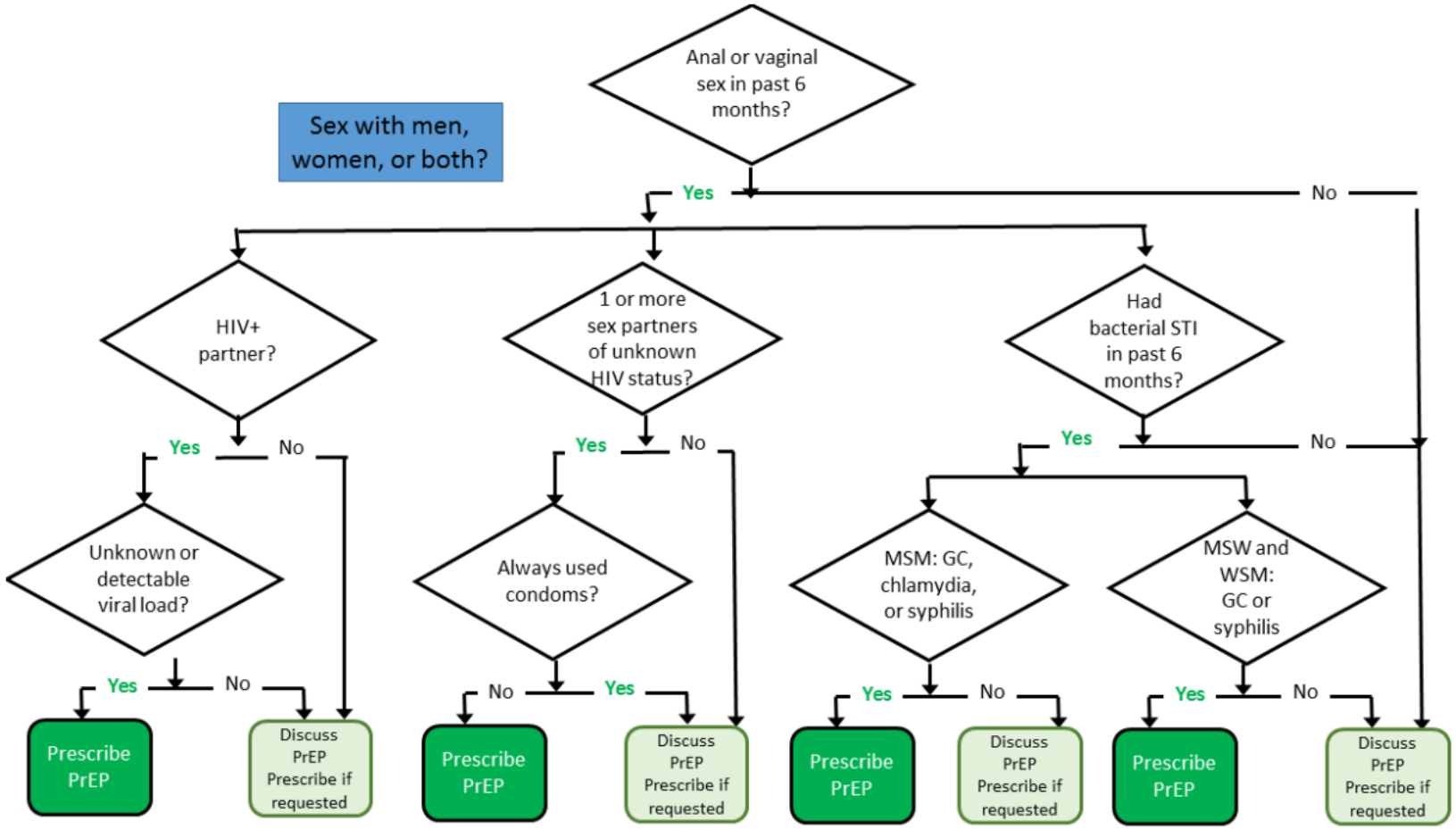
Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

HIV Risk Behaviors

Type of Exposure	Risk per 10,000 Exposures
Blood transfusion	9,250
Needle-Sharing during Injection drug use	63
Percutaneous (Needle-Stick)	23
Receptive Anal Intercourse	138
Insertive Anal Intercourse	11
Receptive Penile-Vaginal Intercourse	8
Insertive Penile-Vaginal Intercourse	4
Receptive Oral Intercourse	Low
Insertive Oral Intercourse	Low
Biting, Spitting, Sharing Sex Toys	Negligible

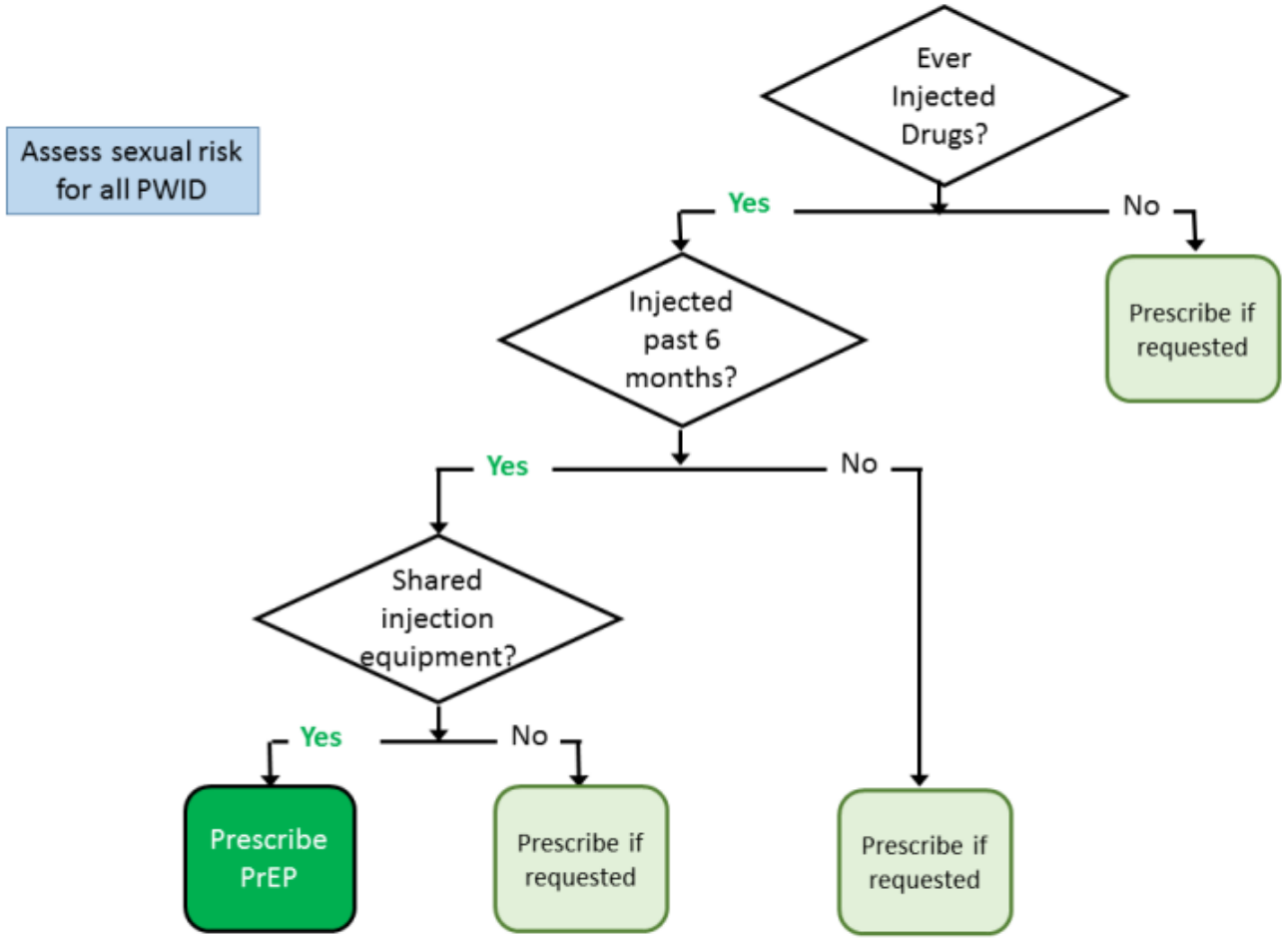
Source: CDC-HIV: HIV Risk and Prevention. https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html. November 15, 2022.

Assessing Indications for PrEP in Sexually Active Persons



Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Assessing Indications for PrEP in Persons Who Inject Drugs



Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Of the **1.2 million** people who could benefit from PrEP in the United States and Puerto Rico, only **25%** were prescribed PrEP in 2020

Population	% of New Diagnosis	% of persons with an indication who received PrEP
African Americans	42%	6%
Hispanic/Latino	27%	10%
Women	19%	7%

*Data from 2018

Populations at the highest risk for HIV acquisition are not receiving prescriptions for PrEP

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021. CDC-HIV: HIV Statistics Center. https://www.cdc.gov/hiv/statistics/overview/in-us/prep-coverage.html. November 15, 2022

Assessment Question #2

Which behavior(s) would help identify people who are at an increased risk of acquiring HIV infection? (Select all that apply)

A. No history of sexually transmitted infections

B. Sharing needles for intravenous drugs

C. Consistent and proper condom use

D. Vaginal sex with an HIV-positive partner

E. Using clean needles each time to inject intravenous drugs

F. Anal sex with an HIV-positive partner

Correct Response

Which behavior(s) would help identify people who are at an increased risk of acquiring HIV infection? (Select all that apply)

A. No history of sexually transmitted infections

B. **Sharing needles for intravenous drugs**

C. Consistent and proper condom use

D. **Vaginal sex with an HIV-positive partner**

E. Using clean needles each time to inject intravenous drugs

F. **Anal sex with an HIV-positive partner**

Learning Objectives

1

Identify factors that increase the risk of HIV exposure

2

Recall current guideline recommendations for utilizing antiretroviral medications for PrEP

3

Recognize the roles of the pharmacist in HIV prevention

Highlights of CDC Guideline Updates

- Recommendation to inform all sexually active adults and adolescence about PrEP
- PrEP indication determination was simplified with flowcharts
- Emtricitabine/tenofovir alafenamide was added as an FDA-approved choice for at-risk sexually active men and transgender women
- Recommendations on the use of cabotegravir intramuscular injection for PrEP were added
- Frequency for assessing estimated creatinine clearance (eCrCl) was updated to every 12 months for individuals <50 years old or with eCrCl ≥90 ml/min at PrEP initiation
- Drug interactions with tenofovir alafenamide were added

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Prior to PrEP

- All sexually active adults and adolescents should receive information about PrEP
- Acute and chronic HIV infection must be excluded
  - Symptom history
  - HIV testing
- Assess renal function
  - eCrCl ≥30 ml/min
- Assess for medication contraindications
- No more than a 90-day supply is prescribed

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Assessment Question #3

What is the maximum day supply of a PrEP regimen can be given at a time?

A. 15 days

B. 30 days

C. 60 days

D. 90 days

Correct Response

What is the maximum day supply of a PrEP regimen can be given at a time?

A. 15 days

B. 30 days

C. 60 days

D. **90 days**

Antiretroviral Agents for PrEP

Emtricitabine/tenofovir disoproxil fumarate (Truvada™)

- Approved for PrEP on July 16, 2012
- Combination of two nucleoside reverse transcriptase inhibitors
- Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada™)

Guideline recommended for HIV prevention

- **Men and women**
- Weighing at least 35 kg
- Reporting sexual behaviors or injection practices that put them at substantial ongoing risk for HIV exposure and acquisition

Renal function should be assessed using eCrCl

- Every 12 months for individuals <50 years old or with eCrCl ≥90 ml/min at PrEP initiation
- Every 6 months for patients over age 50 or those who have an eCrCl <90 ml/min at initiation

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada™)

- **Box warnings**
  - **Posttreatment acute exacerbation of hepatitis B**
  - **Risk of drug resistance**
- Dosing
  - One tablet daily
  - With or without food
  - Not recommended for eCrCl <60 mL/minute
- Side effects and adverse events
  - Nausea, diarrhea, trouble sleeping, dizziness, headache, nightmares, weight loss, loss of strength or energy
  - Decreased bone mineral density, kidney injury

Source: Truvada (emtricitabine and tenofovir disoproxil fumarate) package insert. Foster City, CA: Gilead Sciences, Inc.; Revised 2020 Jun.

Antiretroviral Agents for PrEP

Emtricitabine/tenofovir alafenaminde (Descovy™)

- Approved for PrEP on October 3, 2019
- Combination of two nucleoside reverse transcriptase inhibitors
- Emtricitabine 200 mg and tenofovir alafenamide 25 mg

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Emtricitabine 200 mg/tenofovir alafenamide 25 mg (Descovy™)

Guideline recommended for HIV prevention

- **Men and transgender women** who have sex with men
- Weighing at least 35 kg
- Reporting sexual behaviors that put them at substantial ongoing risk for HIV exposure and acquisition

Renal function should be assessed using eCrCl

- Every 12 months for individuals <50 years old or with eCrCl ≥90 ml/min at PrEP initiation
- Every 6 months for patients over age 50 or those who have an eCrCl <90 ml/min at initiation

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Emtricitabine 200 mg/tenofovir alafenamide 25 mg (Descovy™)

- **Box warnings**
  - **Severe, acute exacerbation of hepatitis B**
  - **Risk of drug resistance**
- Dosing
  - One tablet daily
  - With or without food
  - Not recommended for eCrCl <30 mL/minute
- Side effects and adverse events
  - Nausea, diarrhea
  - Infection, kidney problems, liver problems

Source: Descovy (emtricitabine and tenofovir alafenamide) package insert. Foster City, CA: Gilead Sciences, Inc.; Revised 2021 Sep.

Oral PrEP Agents

HIV status should be assessed at least every 3 months

- 2-drug regimens are not effective treatment for established HIV infection and increases risk of resistance to other treatment options

Support for medication adherence, follow-up care, and other risk-reduction strategies should be provided

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Assessment Question #4

Which of the following oral medications is approved for PrEP in both men and women?

A. Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy™)

B. Emtricitabine/tenofovir alafenamide (Descovy™)

C. Emtricitabine/ tenofovir disoproxil fumarate (Truvada™)

D. Dolutegravir/lamivudine (Dovato™)

Correct Response

Which of the following oral medications is approved for PrEP in both men and women?

A. Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy™)

B. Emtricitabine/tenofovir alafenamide (Descovy™)

C. **Emtricitabine/ tenofovir disoproxil fumarate (Truvada™)**

D. Dolutegravir/lamivudine (Dovato™)

Antiretroviral Agents for PrEP

Cabotegravir (Apretude™)

- Approved for PrEP in 2021
- Integrase inhibitor
- Cabotegravir 600mg/3mL intramuscular (IM) injection

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Cabotegravir Injection (Apretude™)

Approved for HIV prevention

- **Adults and adolescents**
- Weighing at least 35 kg
- Reporting sexual behaviors that place them at substantial ongoing risk for HIV exposure and acquisition

Administered by a healthcare professional to the gluteal muscle

- 4-week oral lead-in with cabotegravir 30 mg is optional

Appropriate for:

- Significant renal disease
- Poor adherence to daily oral regimens
- Individuals who prefer injections every two months

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Cabotegravir Injection (Apretude™)

- **Box warnings**
  - **Risk of drug resistance**
- Dosing
  - Cabotegravir 30 mg oral lead in for 4 weeks is optional
  - 600 mg intramuscular injection monthly for 2 doses then 600 mg intramuscular injection every two months
  - No renal dose adjustment recommendations
- Side effects and adverse events
  - Headache, upset stomach, trouble sleeping, strange or odd dreams, dizziness, irritation at injection site, gas, vomiting, back pain, decreased appetite
  - Depression, liver problems, muscle or joint pain, eye irritation

Source: Apretude (cabotegravir extended-release injectable suspension) package insert. Reseach Triangle Park, NC: ViiV Healthcare; Revised 2021 Dec.

Cabotegravir Injection (Apretude™)

Injection Schedule After Missed Injection		
Dose missed	Time since previous dose	Recommendation
Second injection	≤2 months	Administer dose as soon as possible, then continue every 2-month schedule
	>2 months	Restart initiation dosing
Third or subsequent injection	≤3 months	Administer dose as soon as possible, then continue every 2-month schedule
	>3 months	Restart initiation dosing

Source: Apretude (cabotegravir extended-release injectable suspension) package insert. Reseach Triangle Park, NC: ViiV Healthcare; Revised 2021 Dec.

Assessment Question #5

What is the dosage form of cabotegravir for PrEP?

A. Oral tablet

B. Intramuscular injection in the deltoid muscle

C. Oral capsule

D. Intramuscular injection in the gluteal muscle

Correct Response

What is the dosage form of cabotegravir for PrEP?

A. Oral tablet

B. Intramuscular injection in the deltoid muscle

C. Oral capsule

D. **Intramuscular injection in the gluteal muscle**

PrEP Pipeline: Lenacapavir

Investigational drug

Mechanism:

- Interferes with HIV capsid that protects HIV genetic material and enzymes needed for replication
- Prevents HIV from multiplying and can reduce the amount of HIV in the body

Side effects:

- Injection site reactions, headache, nausea, diarrhea, COVID-19

Source: Lenacapavir-NIH: Clinical Info HIV.gov. https://clinicalinfo.hiv.gov/en/drugs/lenacapavir. Accessed November 20,2022

Lenacapavir PrEP Trials

Purpose 1: Phase 3 Trial

- Evaluating the efficacy of twice yearly subcutaneous lenacapavir and daily emtricitabine/tenofovir alafenamide for PrEP in adolescent girls and young women at risk for HIV
- Recruiting participants in South Africa

Purpose 2: Phase 3 Trial

- Evaluating the efficacy of twice yearly subcutaneous lenacapavir for PrEP in cisgender men, transgender women, transgender men, and gender nonbinary individuals who have sex with partners assigned male at birth and are at risk for HIV
- Recruiting participants in United States, Puerto Rico, and South Africa

Source: Lenacapavir-NIH: Clinical Info HIV.gov. https://clinicalinfo.hiv.gov/en/drugs/lenacapavir. Accessed November 20,2022

Learning Objectives

1

Identify factors that increase the risk of HIV exposure

2

Recall current guideline recommendations for utilizing antiretroviral medications for PrEP

3

Recognize the roles of the pharmacist in HIV prevention

Barriers to PrEP Uptake

- Awareness of PrEP
- HIV risk perception
- Stigma
- Provider bias
- Distrust of healthcare system
- Lack of access to medical care
- Lack of access to financial assistance
- Side effects

Source: Mayer KH, et al. *Adv Ther*. 2020;37(5):1778-1811

Potential Approaches to Removing Barriers

- Patient and provider education
- Better communication between providers
- Improved cultural humility
- Development of patient-provider relationship
- Addressing systemic bias
- Extending access to PrEP
- Financial aid options

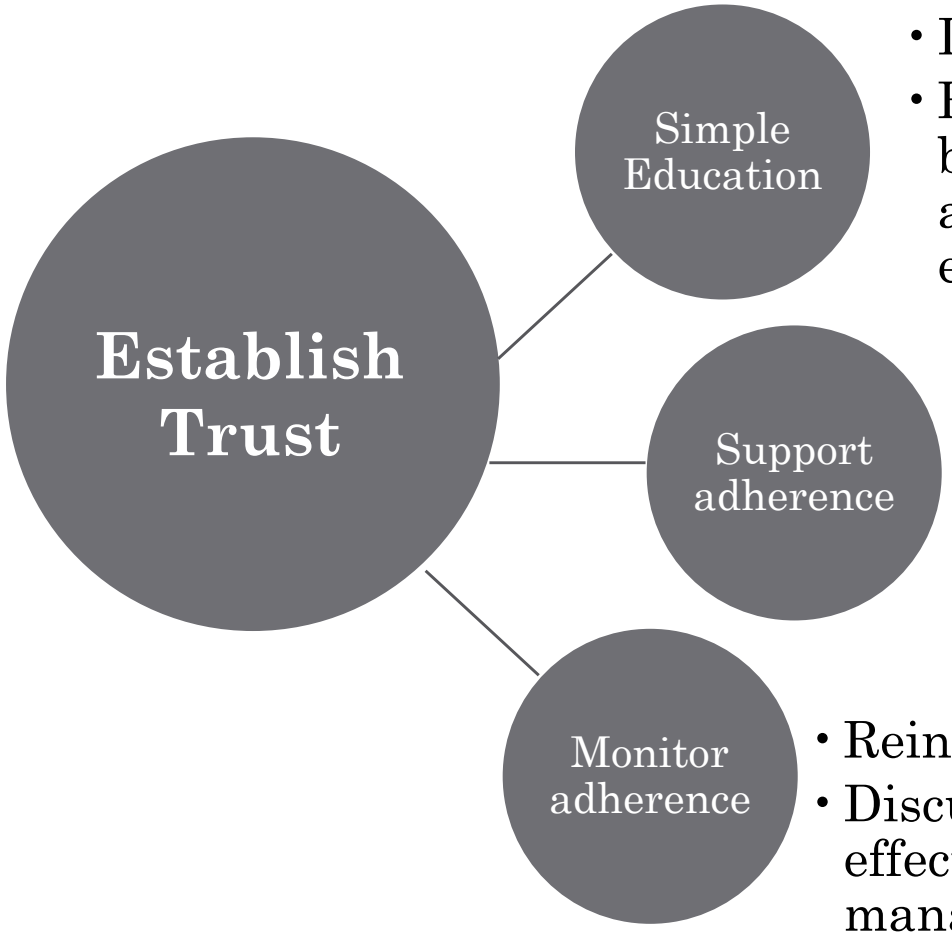
Source: Mayer KH, et al. *Adv Ther*. 2020;37(5):1778-1811

Pharmacist's Role in PrEP

- Act as educational liaisons for patients
- Assist individuals to overcome adherence issues
- Ensure optimal pharmacotherapy
- Identify medication-related adverse effects and interactions
- Provide medication education to healthcare providers
- Increase access to PrEP information
- Enroll patients in medication assistance programs
- Facilitate conversations about PrEP with interested individuals

Source: American Society of Health-System Pharmacists. ASHP guidelines on pharmacist involvement in HIV care. *Am J Health-Syst Pharm*. 2016; 73:468–94
Mayer KH, et al. *Adv Ther*. 2020;37(5):1778-1811

Key Points for Adherence Counseling



- Dosing schedules
- Relationship between adherence and efficacy

- Tailor regimen to daily routine
- Overcome adherance barriers

- Reinforce success
- Discuss side effect management

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published 2021.

Pharmacist's Role in PrEP

Certain states have passed legislation that allow pharmacists to initiate PrEP/PEP in the pharmacy setting

California, Colorado, Oregon, Nevada, Washington, Maine, Virginia, New Mexico

California law allows pharmacists to initiate and furnish a 30 or a 60-day supply of a drug combination that follows CDC guidelines

Prior to initiating PrEP, pharmacists must:

Complete an approved training program	Obtain HIV test results within the previous seven days	Use a self-reported checklist to ensure patient does not have signs and symptoms of an acute HIV infection	Ensure no contraindications	Provide counseling on the use of PrEP to prevent HIV	Record and maintain records of services provided	Not furnish more than a 60-day supply to a single patient more than once every 2 years	Notify the patient's primary care provider

Source: California State Board of Pharmacy, 2022 Law Book for Pharmacy, Section 4052.02 and 4052.03.

Pharmacist's Role in PrEP

Pharmacist-managed HIV PrEP clinic in a community pharmacy in Washington State

Collaborative practice agreement allows pharmacists to initiate and manage tenofovir disoproxil fumarate/emtricitabine

Over 3-year Study Period

- 714 patients were evaluated
- 695 (97.3%) patients were initiated on PrEP
- 513 patients began medication on the same day as their initial appointment
- 90% of patients had a mean proportion of days covered greater than 80%
- 19% of patients were lost to follow up
- 207 sexually transmitted infections were diagnosed but there were zero HIV seroconversions

PrEP in the pharmacy setting has the ability to increase access to PrEP resources

Source: Tung EL, et al. *Sex Health*. 2018;15: 556–61.

Assessment Question #6

What are potential pharmacist roles in PrEP?

A. Assist individuals to overcome adherence issues
B. Identify medication-related adverse effects and interactions
C. Increase access to PrEP information
D. Facilitate conversations about PrEP with interested individuals
E. All the above

Correct Response

What are potential pharmacist roles in PrEP?

A. Assist individuals to overcome adherence issues
B. Identify medication-related adverse effects and interactions
C. Increase access to PrEP information
D. Facilitate conversations about PrEP with interested individuals
E. **All the above**

Wrap Up

- Pharmacist should understand the social and clinical aspects of preexposure prophylaxis
- Pharmacists must be up to date on the most recent guideline recommendations for PrEP
- PrEP is **highly effective** but **underutilized**

Goal = Increase pharmacist knowledge on HIV transmission and prevention to decrease new HIV diagnoses

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13. California State Board of Pharmacy, 2022 Law Book for Pharmacy, Section 4052.02 and 4052.03.
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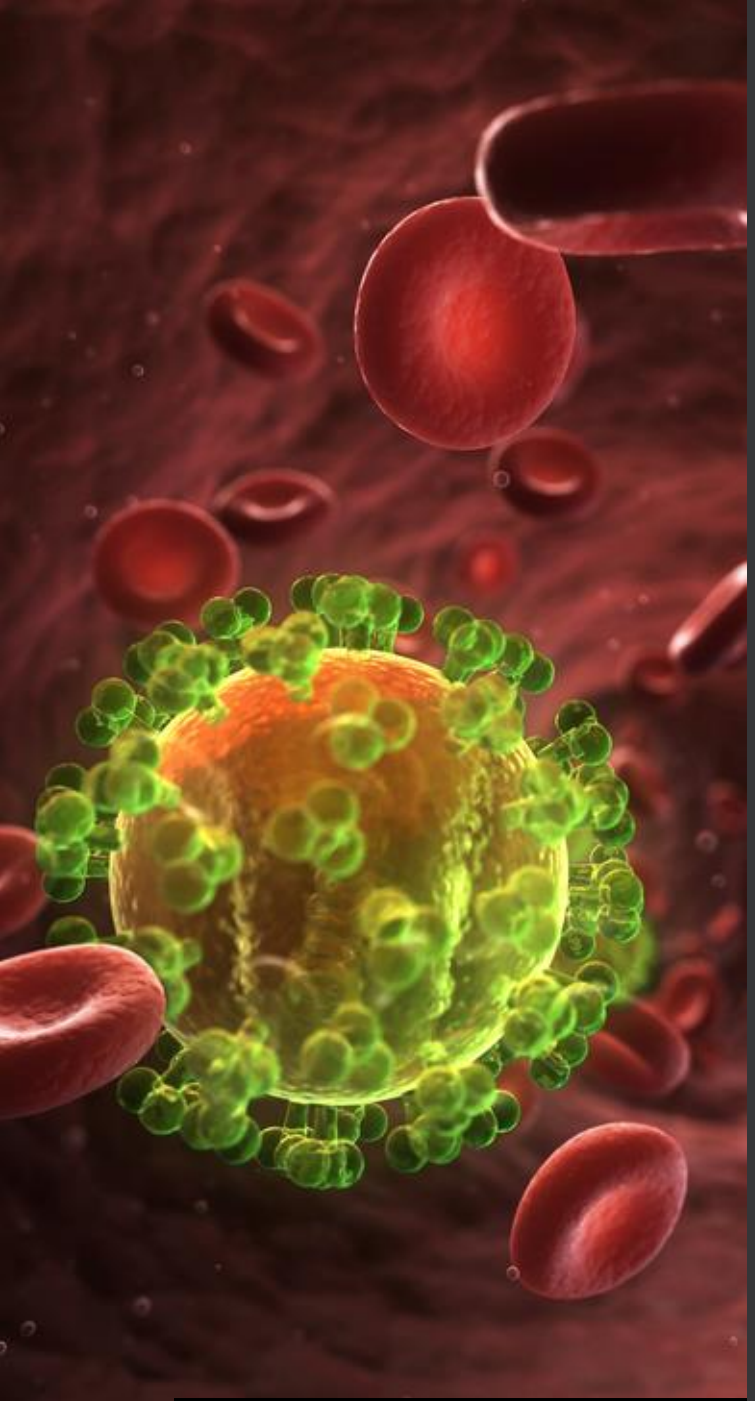

Thank you!

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