STEP INTO PREVENTION

Mastering the Power of PrEP in HIV Care

This program has been supported by an independent educational grant from Gilead Sciences, Inc.

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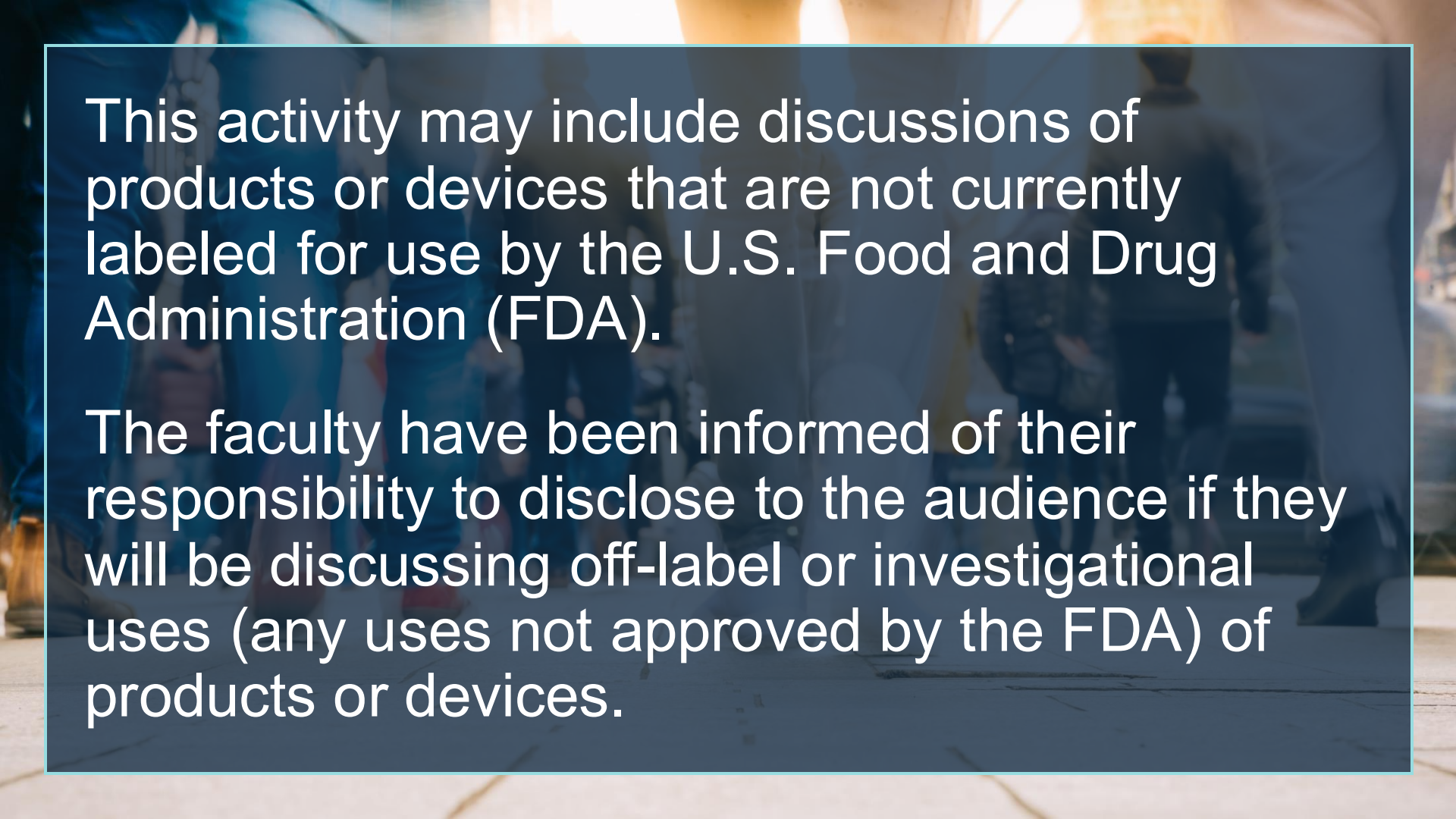

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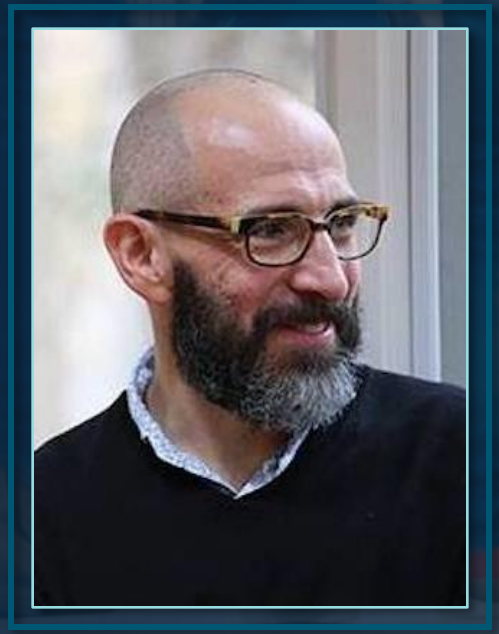

David Alain Wohl, MD (Moderator)

Professor
Division of Infectious Diseases
The University of North Carolina
Chapel Hill, NC

Christina M. Madison, PharmD, FCCP, AAHIVP

Founder and CEO
The Public Health Pharmacist, PLLC
Clinical Consultant, University of California, National Clinician Consultation Center
San Francisco, CA

Asia Sullivan, PA-C, MPH

Senior Physician Assistant
Suite 401 Medical Office
Patient Advocate and Social Media Influencer
Los Angeles, CA

Disclosures

FACULTY/PLANNERS

David Alain Wohl, MD, reports the following financial relationships:

Advisory Board—Gilead Sciences, Inc.; Merck & Co., Inc.; and ViiV Healthcare

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Christina M. Madison, PharmD, FCCP, AAHIVP, reports the following financial relationships:

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PEER REVIEWERS

Rebecca Vargas-Jackson, MD, reports no financial relationships to disclose.

Albert Eubanks, Jr., RN, reports no financial relationships to disclose.

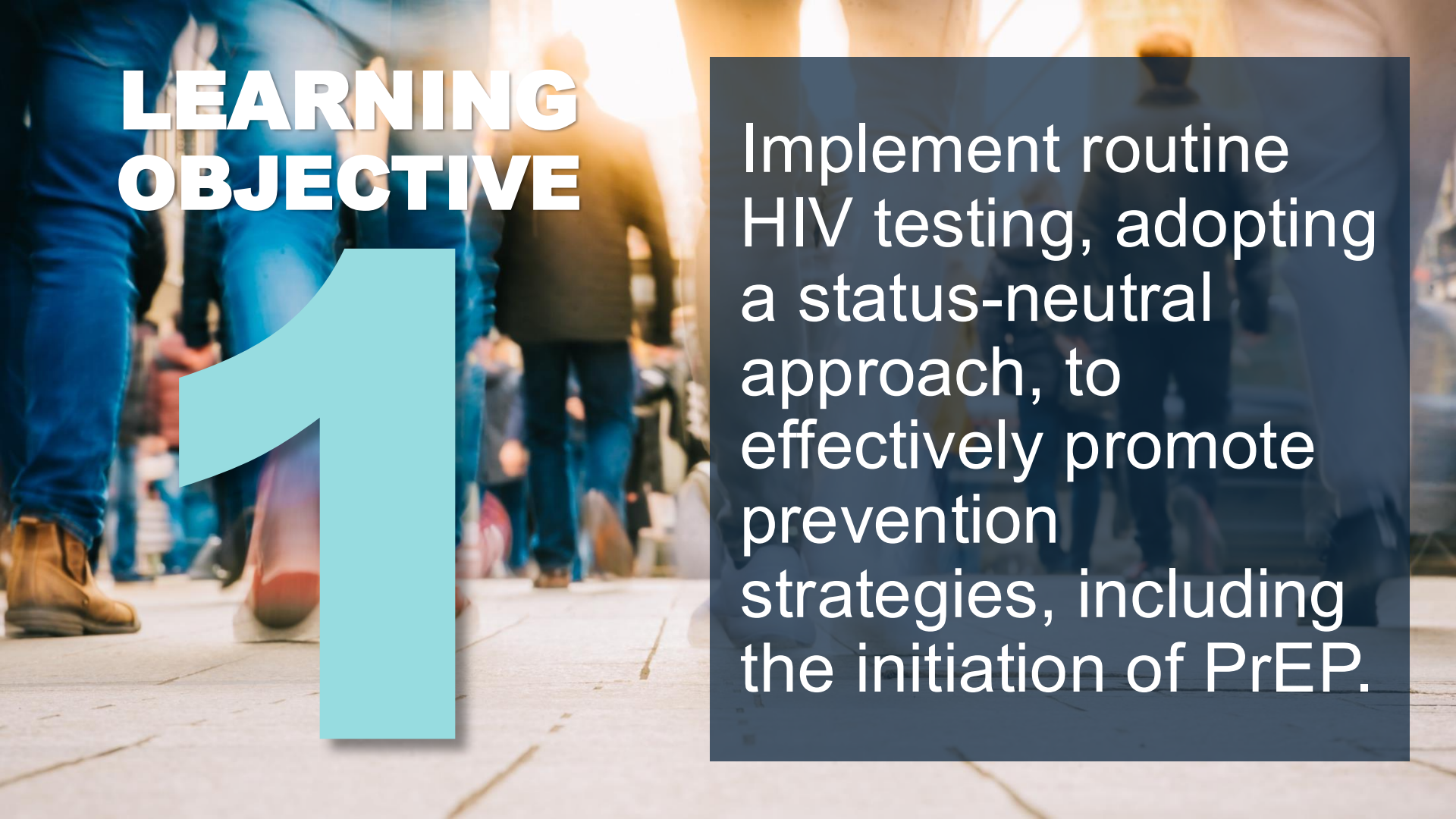
The following CMEO staff have no financial relationships to disclose:

- Keshia Pitt, PhD (Planning Committee)
- Leah Zadrozny, DVM, PhD (Planning Committee)
- Estelle Perera (Planning Committee)
- Scott J. Hershman, MD, FACEHP, CHCP (Planning Committee)
- Sandra Caballero, PharmD (Planning Committee)
- Sharon Tordoff (Planning Committee)

All identified conflicts of interest have been mitigated.

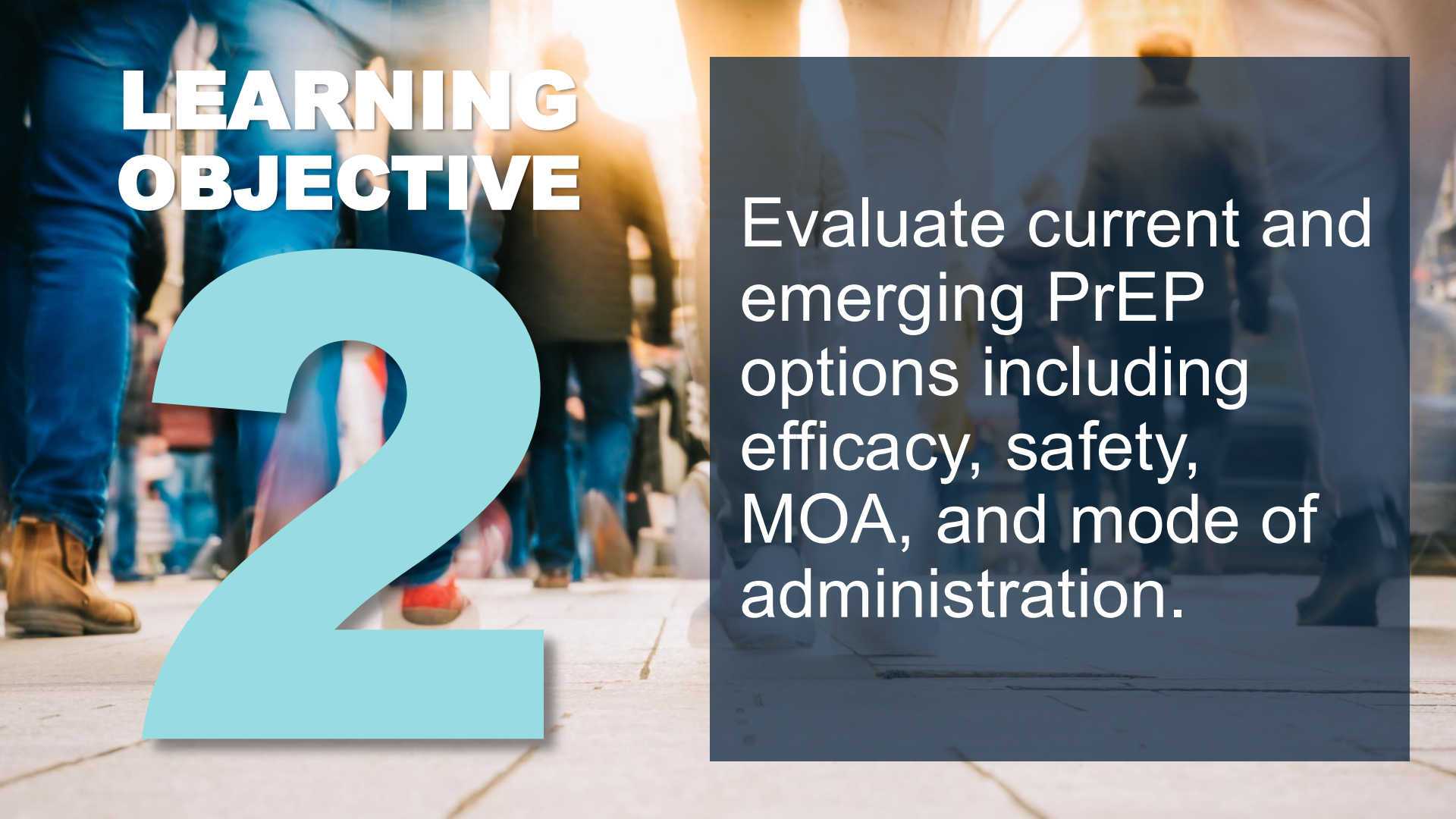
To Ask a Question

To submit a question, please go to the *Ask Question* tab at the bottom of the screen.



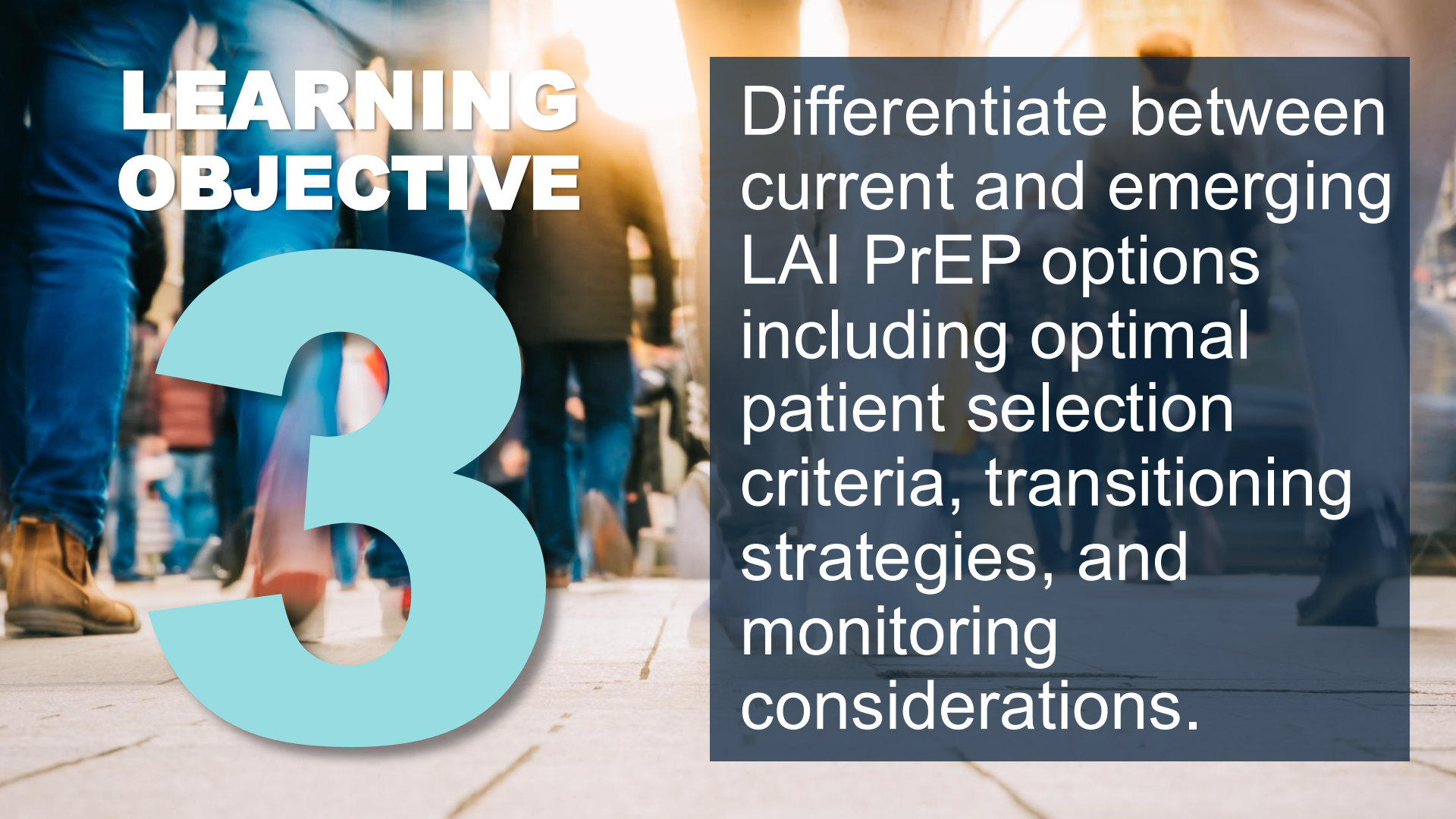
LEARNING OBJECTIVE 1

Implement routine HIV testing, adopting a status-neutral approach, to effectively promote prevention strategies, including the initiation of PrEP.



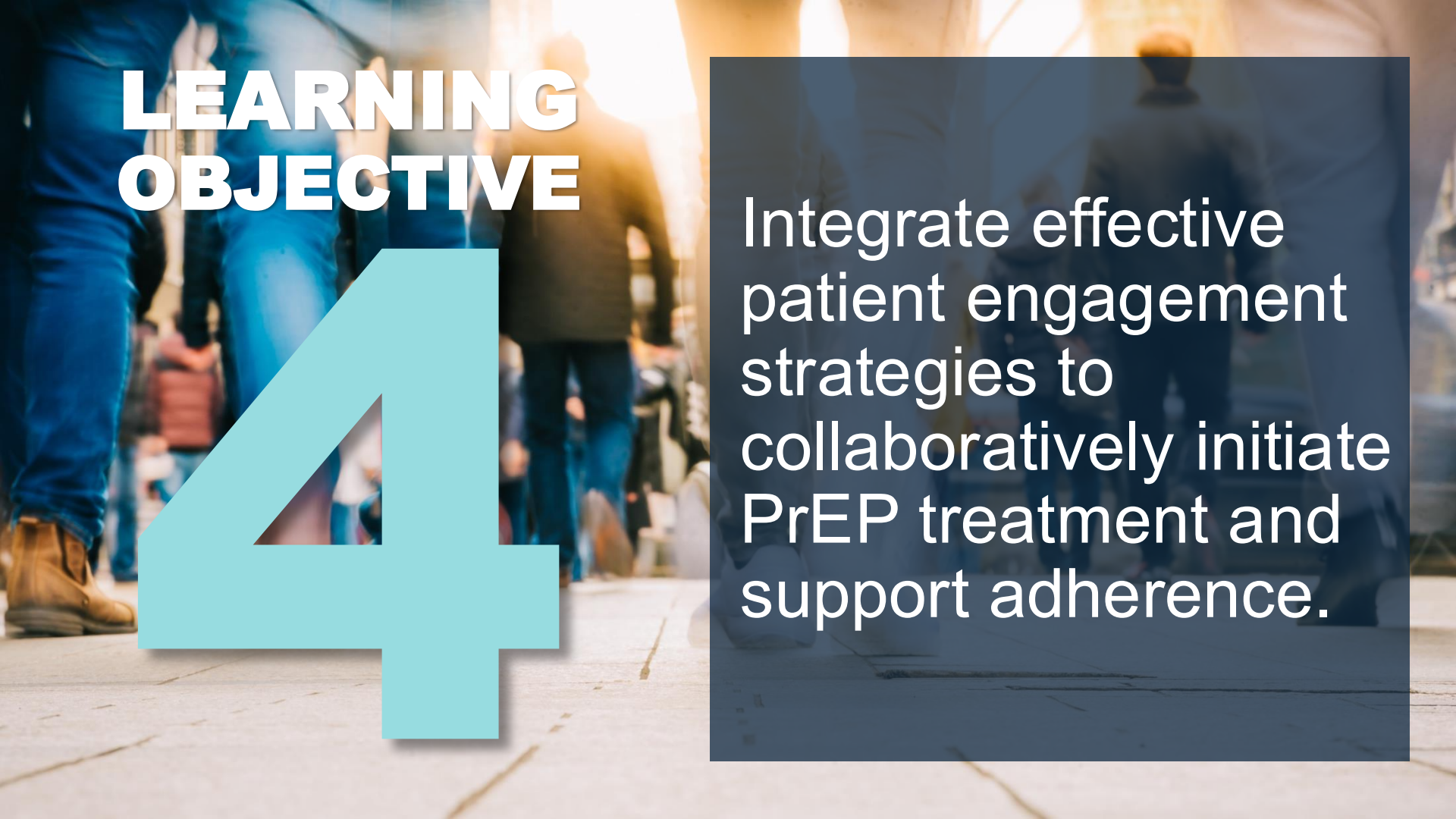
LEARNING OBJECTIVE 2

Evaluate current and emerging PrEP options including efficacy, safety, MOA, and mode of administration.



LEARNING OBJECTIVE 3

Differentiate between current and emerging LAI PrEP options including optimal patient selection criteria, transitioning strategies, and monitoring considerations.



LEARNING OBJECTIVE 4

Integrate effective patient engagement strategies to collaboratively initiate PrEP treatment and support adherence.

PrEP Impact on New HIV Diagnoses

Gains Made – But Progress is Plateauing

Progress Achieved	Ongoing Challenges
• States with highest PrEP coverage saw a **38% decline in new HIV diagnoses** (2012-2022) • Nationally, **new HIV infections declined 12%** (36,200 → 31,800; 2018-2022) • Success attributed to increased PrEP use, viral suppression, and expanded testing	• New HIV infections remain steady despite progress (> 37,000 in 2022) • Disparities persist: impact was greatest among White MSM, less consistent for Black and Hispanic populations • States with lowest PrEP coverage saw a 27% increase in new diagnoses • Diagnosis trends have stagnated in recent years

PrEP = pre-exposure prophylaxis; HIV = human immunodeficiency virus; MSM = men who have sex with men.
Sullivan PS, et al. *Lancet HIV*. 2025;12(6):e440-e448.

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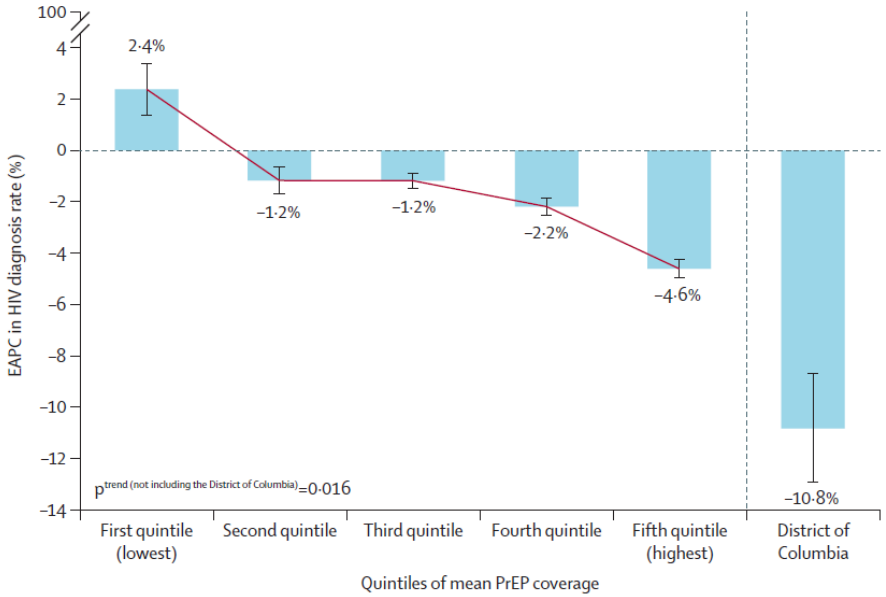
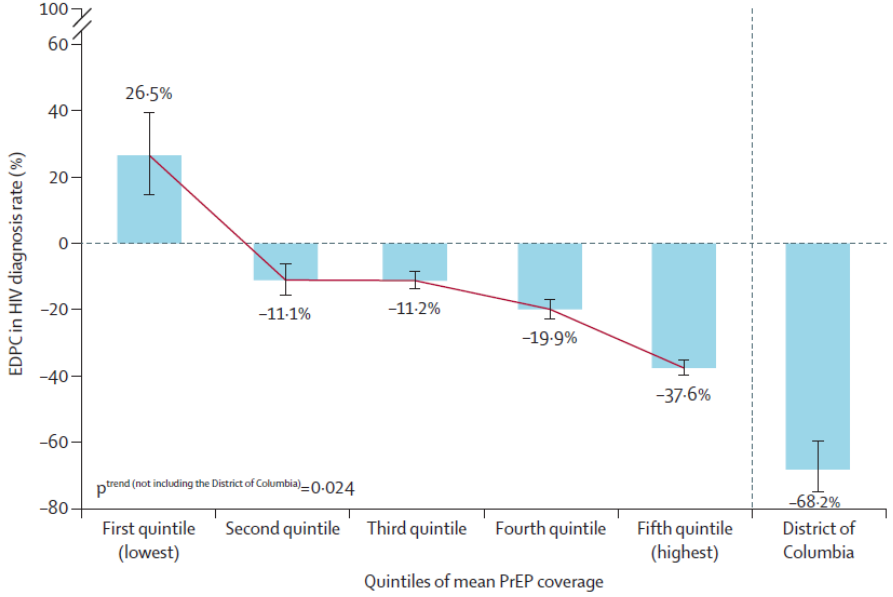
PrEP Impact on New HIV Diagnoses

Higher levels of PrEP use were associated with larger declines in HIV diagnosis rates





Quintile-specific **EAPC** (left) and **EDPC** (right) in HIV diagnosis rates, adjusted for jurisdiction-specific viral suppression, 50 US states and the District of Columbia, Jan 1, 2012, to Dec 31, 2022. Whiskers represent 95% CIs; the red line is the trend line connecting the EAPCs.

EAPC = estimated annual percentage change; EDPC = estimated decade percent change; CI = confidence interval.

Sullivan PS, et al. *Lancet HIV*. 2025;12(6):e440-e448.

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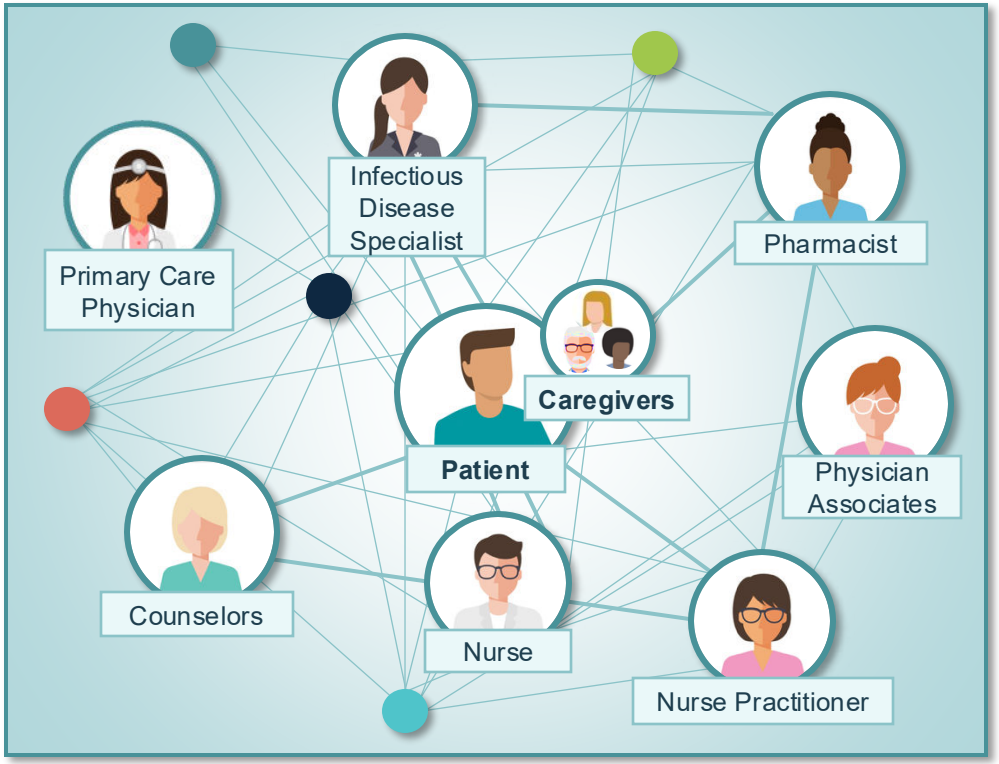
Multidisciplinary Approach for Individuals Considering PrEP



While a **comprehensive team approach** is ideal for PrEP communication, optimized patient-centered care, and improved outcomes, it is important to note that one **may not always be available** or necessary to ensure successful PrEP delivery.

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Part 1: Christina M. Madison PharmD, FCCP, AAHIVP

Implementing Routine HIV Testing with a Status-Neutral Approach

HIV Testing Guidelines

Guidelines vs Data: Concordance and Gaps

Guideline Emphasis

- Routine and frequent testing
- Normalization of HIV screening
- Adapting strategies to novel PrEP modalities

What the Data Shows

Despite increase in routine testing:

- Disparities in screening rates for high-risk populations persist
- Late diagnoses are still occurring

An estimated 13% of the 1.2 million individuals with HIV in the United States are **unaware of their status.** The **WHO** and **CDC** emphasize not just the frequency of testing, but the **quality of data collection** to inform program improvements and "diagnosis-to-linkage" timeframe.

WHO = World Health Organization; CDC = Centers for Disease Control and Prevention.

CDC. 2025. https://www.cdc.gov/hivnexus/hcp/guidelines/index.html. CDC. 2025. https://www.cdc.gov/hiv-data/nhss/national-hiv-prevention-and-care-objectives-2025.html.

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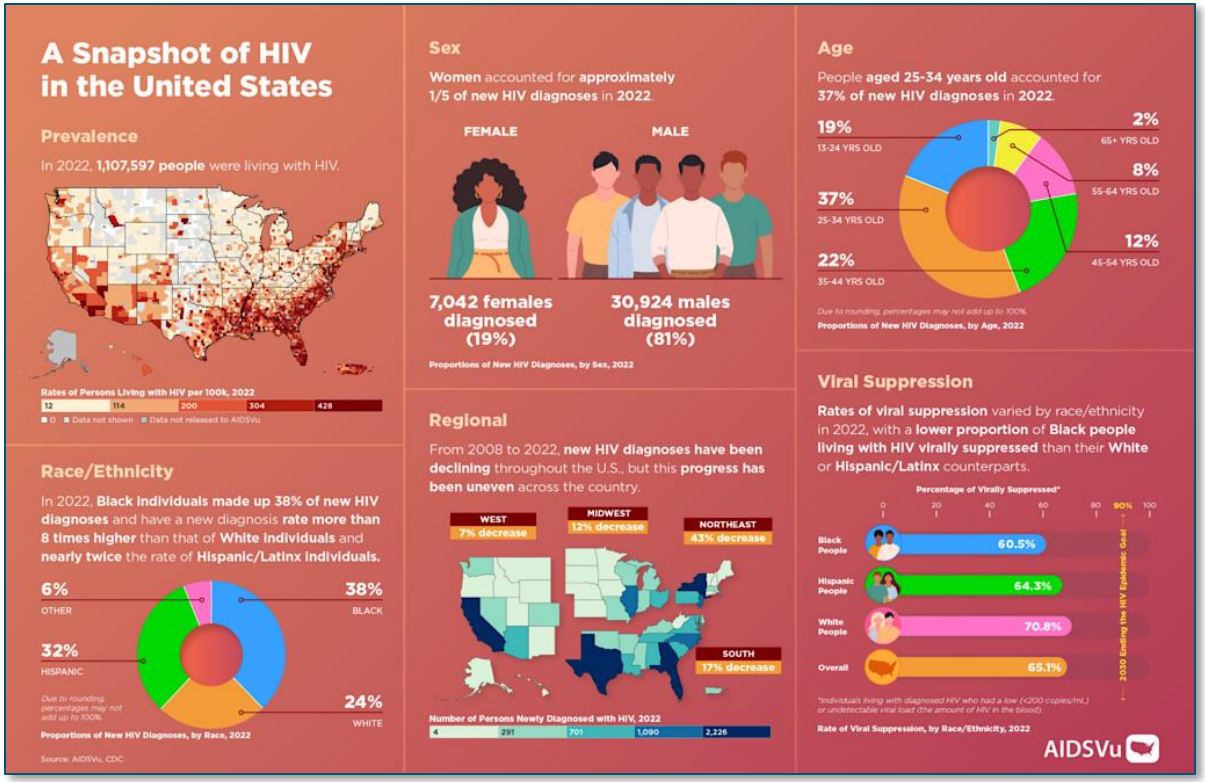
Where Are New HIV Diagnoses Being Made?

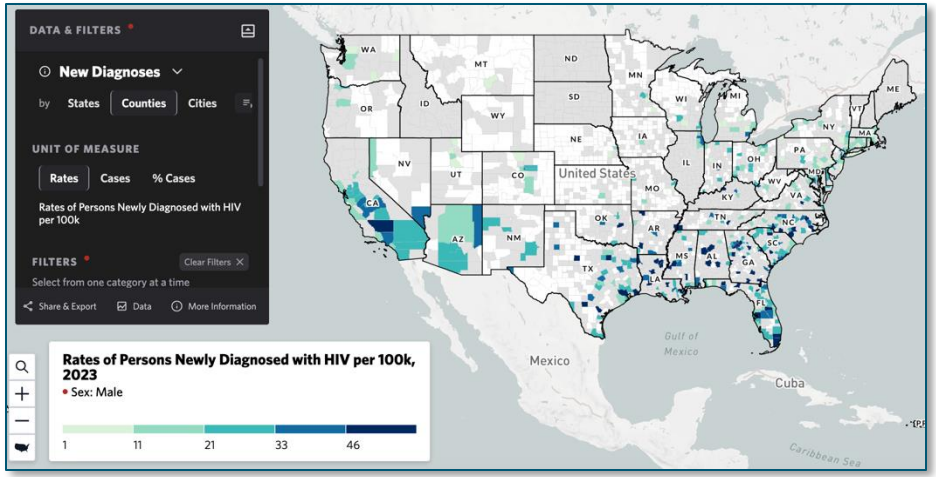


- **2022:** New diagnosis rate was 13 per 100,000 nationally
- Highest rates:
  - DC (~37/100K)
  - Georgia (~27/100K),
  - Florida and Louisiana (~22/100K)
- **Scale** testing and prevention in **hotspot regions** to maximize impact and interrupt transmission!

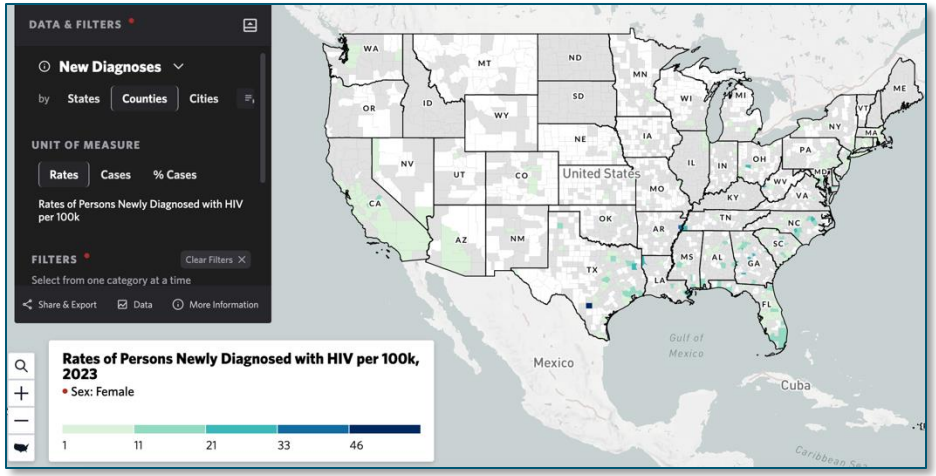
AIDSVu. 2024. https://aidsvu.org/news-updates/aidsvu-launches-2022-data-and-interactive-maps-places-emphasis-on-health-equitys-role-in-the-hiv-epidemic/.

Where Are New HIV Diagnoses Being Made?

2023: Men (rates per 100K)



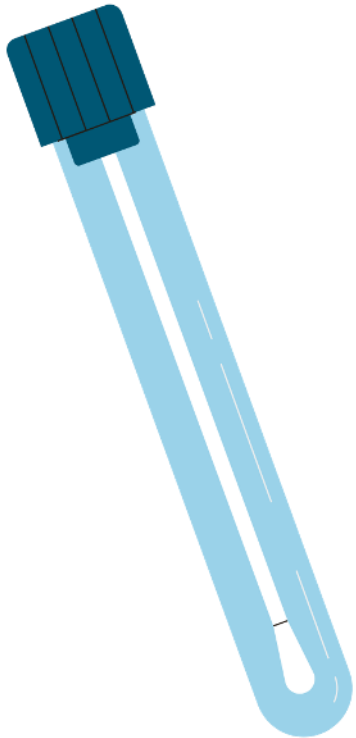
2023: Women (rates per 100K)



AIDSVu. 2023. https://map.aidsvu.org/nd/county/rate/sex_m/none/usa?geoContext=national. AIDSVu 2023. https://map.aidsvu.org/nd/county/rate/sex_f/none/usa?geoContext=national.

HIV Testing Strategies

- Routine, opt-out screening in clinical settings; repeat testing based on ongoing risk
- Expand access with HIV self-testing (including dual HIV/syphilis self-tests), social network-based testing, and non-clinical/community sites
- Choose blood-based rapid tests to better detect early infection; use NAAT for suspected acute infection or recent exposure
  - Oral tests to be avoided!
- Integrate HIV testing with STI services and partner services to increase uptake and case finding
  - Incorporate when individuals are being assessed for hormonal contraceptives for pregnancy prevention



NAAT = nucleic acid amplification testing; STI = sexually transmitted infection.
CDC. 2025. https://www.cdc.gov/hivnexus/hcp/diagnosis-testing/index.html.

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HIV Viral Load Testing

Guideline Recommendation	• CDC recommends combined HIV Ag/Ab testing and HIV NAAT/HIV-1 RNA (viral load) for quarterly monitoring in individuals taking daily oral PrEP
	  • Absence of NAAT, particularly in resource-limited settings, should not prevent PrEP use
	• Viral load testing not routinely recommended for all individuals on oral PrEP
	  • Regular Ag/Ab testing with prompt assessment of acute symptoms is sufficient

Rationale	• NAAT can pick up infections earlier than Ag/Ab tests • Low incidence of seroconversion for certain forms of PrEP plus high costs reserves testing for patients with suggestive symptoms or equivocal test results

Special Cases: Injectable PrEP	• CAB-LA
	  • Push for RNA or rapid molecular testing at each follow-up
	  • Slightly higher risk for “breakthrough” infection and delayed seroconversion
	• New lenacapavir PrEP guidance does not indicate need for RNA testing during follow-up

Ag/Ab = antigen/antibody; RNA = ribonucleic acid; CAB-LA = cabotegravir long-acting injection.

Patel RR, et al. *MMWR Morb Mortal Wkly Rep*. 2025;74(35):541-549. Meyerowitz EA, et al. *Open Forum Infect Dis*. 2022;9(7):ofac191. CDC. 2025. https://www.cdc.gov/hivnexus/hcp/guidelines/index.html.

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Barriers to HIV Testing

Stigma and Discrimination

- Fear of judgment
- Breach of privacy
- Discrimination if diagnosed
- Lack of perceived risk due to being cisgender and/or heterosexual

Fear

- Fear of a positive diagnosis or its consequences leads to testing avoidance
- Anxiety about confidentiality and mistrust of health systems may exacerbate continued avoidance

Misinformation

- Persistent myths and lack of knowledge surrounding current effective therapies may delay/deter testing

Low Health Literacy

- Misunderstanding of information
- Difficulty navigating the healthcare system

CDC. 2025. https://www.cdc.gov/hivnexus/hcp/index.html?CDC_AAref_Val=https://www.cdc.gov/hiv/clinicians/testing. Foley EE. *AIDS Care.* 2025;17(8):1030-1043. Owusu MW, et al. *IJID REG.* 2023;7:206-215. Gerwen OT, et al. *Nat Microbiol.* 2022;7(8):1116-1126.

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Barriers to HIV Testing

Perception of Low Risk

- Underestimation of personal risk leading to decreased motivation to test
- Knowledge gap between guideline recommendations and perceived personal vulnerability

Cultural Barriers

- Cultural norms may prevent open discussions about HIV, sexuality, and/or drug use, thus discouraging individuals from seeking tests
- Language barriers

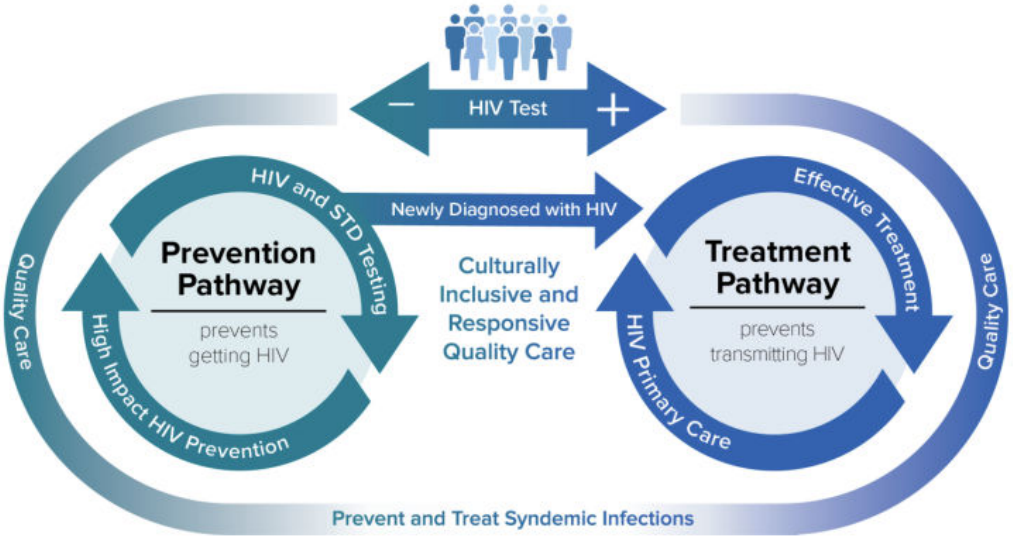
Lack of Cultural Humility and Competencies

- Fosters mistrust and impedes communication
- Disregards lived experiences

CDC. 2025. https://www.cdc.gov/hivnexus/hcp/index.html?CDC_AAref_Val=https://www.cdc.gov/hiv/clinicians/testing. Hussen SA, et al. *J Infect Dis.* 2020;222(Suppl 6):S535-S542.

Status-Neutral HIV Prevention and Care

People whose HIV tests are negative are offered powerful prevention tools like PrEP, condoms, harm reduction (e.g. SSPs), and supportive services to stay HIV negative.



People whose HIV tests are positive enter primary care and are offered effective treatment and supportive services to achieve and maintain viral suppression.

Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide individuals with the tools they need to stay healthy and stop HIV.

SSPs = syringe service programs.

Daskalakis DC. *The Status Neutral Approach: A Whole-Person Approach to Ending the HIV Epidemic in the US.* National Association of County & City Health Officials [NACCHO] Website. 2025. https://www.naccho.org/uploads/body-images/NACCHO-Status-Neutral-Approach-Daskalakis.pdf. Myers JE, et al. *Open Forum Infect Dis.* 2018;5(6):ofy097. Bond KT, et al. *J Assoc Nurses Aids Care.* 2021;32(3):283-305.

Status-Neutral HIV Prevention and Care

HIV-Negative Tests

Individuals are offered powerful prevention tools such as PrEP, condoms, harm reduction (e.g., SSPs), and supportive services to stay HIV-negative

HIV-Positive Tests

Individuals enter primary care and are offered effective treatment and supportive services to achieve and maintain viral suppression

Benefits

Reduced stigma, improved health equity, dramatic decreases in new HIV infections, and streamlined workflows

Daskalakis DC. *The Status Neutral Approach: A Whole-Person Approach to Ending the HIV Epidemic in the US.* National Association of County & City Health Officials [NACCHO] Website. 2025. https://www.naccho.org/uploads/body-images/NACCHO-Status-Neutral-Approach-Daskalakis.pdf. Myers JE, et al. *Open Forum Infect Dis.* 2018;5(6):ofy097. Bond KT, et al. *J Assoc Nurses Aids Care.* 2021;32(3):283-305.

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Audience Response

Which of the following best reflects a status-neutral approach to HIV testing?

A. Offering HIV testing to individuals for whom transmission may be a concern
B. Conducting HIV testing only when individuals request it
C. Integrating routine, opt-out HIV testing at all clinical visits, linking all patients to prevention or treatment services based on results
D. Testing individuals annually that are ≤ 40 years old
E. I don't know

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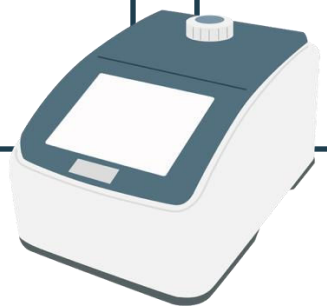
Key Considerations for PrEP

Before Initiation → HIV-Negative Required

- Confirm HIV-negative with 4th-gen Ag/Ab test
  - Offering same day PrEP service increases uptake and retention
- If recent high-risk exposure or acute symptoms → add HIV NAAT or RNA PCR
- Prevents resistance



Testing Cadence by PrEP Type

- Daily oral PrEP (F/TDF, F/TAF) → q3M
- CAB-LA (q2M injection) → before each injection
- Lenacapavir (q6M injection) → before each injection (guidance more flexible than with CAB-LA)

PCR = polymerase chain reaction; F/TDF = emtricitabine-tenofovir disoproxil fumarate; F/TAF = emtricitabine-tenofovir alafenamide; q = every; M = month.

CDC. 2025. https://www.cdc.gov/hivnexus/hcp/prep/index.html. Wiser AL. *Cleve Clin J Med.* 2024;91(6):361-371.

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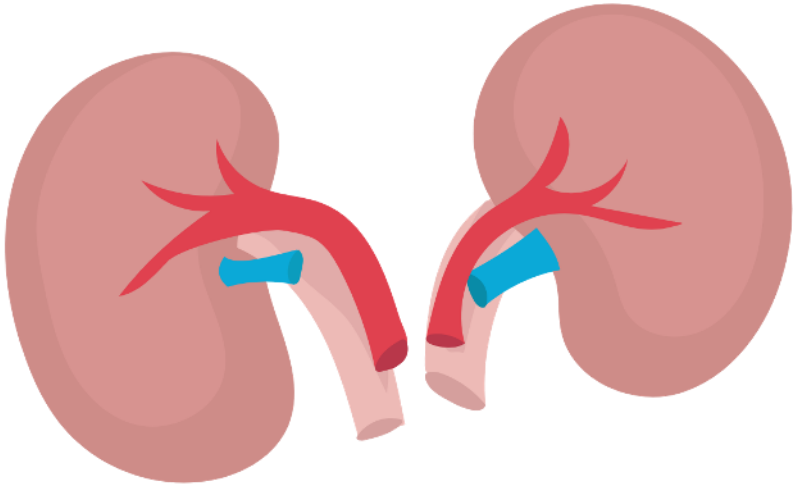
Ongoing Monitoring with PrEP

- **STI screening:** every 3-6 months; based on risk and exposure site(s)
- **Renal function:**
  - Needed for oral tenofovir-based PrEP (baseline eGFR; repeat q6-12M in healthy individuals)
  - Not required for CAB-LA or lenacapavir beyond routine clinical assessment
- **If HIV-positive:** stop PrEP → immediate ART initiation



eGFR = estimated glomerular filtration rate; ART = antiretroviral therapy.

CDC. 2025. https://www.cdc.gov/hivnexus/hcp/prep/index.html. Wiser AL. *Cleve Clin J Med.* 2024;91(6):361-371.

CME OUTFITTERS

Post-Exposure Prophylaxis (PEP): May 2025 Public Health Service Guideline Updates

What's New

- Incorporates prior PrEP history into decision-making
- Considers source viral suppression (U = U): may not be required if undetectable
- Updated risk stratification for sexual and occupational exposures
  - For nPEP: de-emphasis when source partner is on PrEP

Core Principles

- Initiate ASAP, ≤ 72 hours after exposure
- 28-day, 3-drug regimen: integrase inhibitor + 2 NRTIs
- Perform baseline and follow-up HIV Ag/Ab + RNA testing
- Transition to PrEP if ongoing risk persists

U = U: undetectable = untransmittable; nPEP = non-occupational post-exposure prophylaxis; NRTI = nucleoside reverse transcriptase inhibitor; ASAP = as soon as possible.

Patel RR, et al. *MMWR Morb Mortal Wkly Rep*. 2025;74(35):541-549.

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PEP Summary

Timing

- Start ASAP, ideally within hours
- Do not start > 72h post-exposure
- Duration: 28 days

Regimen

- Preferred: Bictegravir + FTC + TAF ***or***
- Dolutegravir + TAF/TDF + FTC/3TC
- Alternatives: Darunavir + booster + (TAF/TDF + FTC/3TC)
- Pregnancy/renal: expert input

Monitoring

- Baseline: HIV Ag/Ab (4th-gen), renal/liver panel
- Follow-up HIV test at 12 weeks
- Routine labs if symptomatic

Undetectable source = shared decision | On PrEP = case by case | Pregnancy/breastfeeding = expert consult

FTC = emtricitabine; 3TC = lamivudine.

CDC. 2025. https://www.cdc.gov/hivnexus/hcp/prep/index.html. Kofman AD, et al. Cambridge University Press Website. 2025. https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/2025-us-public-health-service-guidelines-for-the-management-of-occupational-exposures-to-human-immunodeficiency-virus-and-recommendations-for-postexposure-prophylaxis-in-healthcare-settings/A410E90C8C13C8B9FB417C7F42051D2A.

CME OUTFITTERS

PrEP Summary

PrEP		Occupational
Before HIV exposure: • Before sex, drug use, or other HIV exposure	**When is it taken?**	After HIV exposure: • In emergency situations, is started within 72 hours after possible exposure and taken for a month thereafter
For individuals without HIV for whom transmission may be a concern	**Who is it for?**	For individuals without HIV who may have been exposed
Consistent use of PrEP reduces the risk of HIV transmission by up to 99%	**How effective is it?**	It can prevent HIV when taken correctly, but is not always effective and is dependent upon several factors (e.g., how soon after exposure it is initiated, adherence, type and severity of exposure)*
Rx from an HCP	**How do you get it?**	ASAP, within **72 hours** after potential exposure, get an Rx from an HCP, urgent care, or an emergency department

*Based on both animal models and human observational data (no randomized controlled trials in humans).
Rx = prescription; HCP = health care professional.
HIV Info.NIH.gov. 2025. https://hivinfo.nih.gov/understanding-hiv/infographics/prep-vs-. Sagaon-Teyssier L, et al. *AIDS Care.* 2016;28(Suppl 1):48-55.

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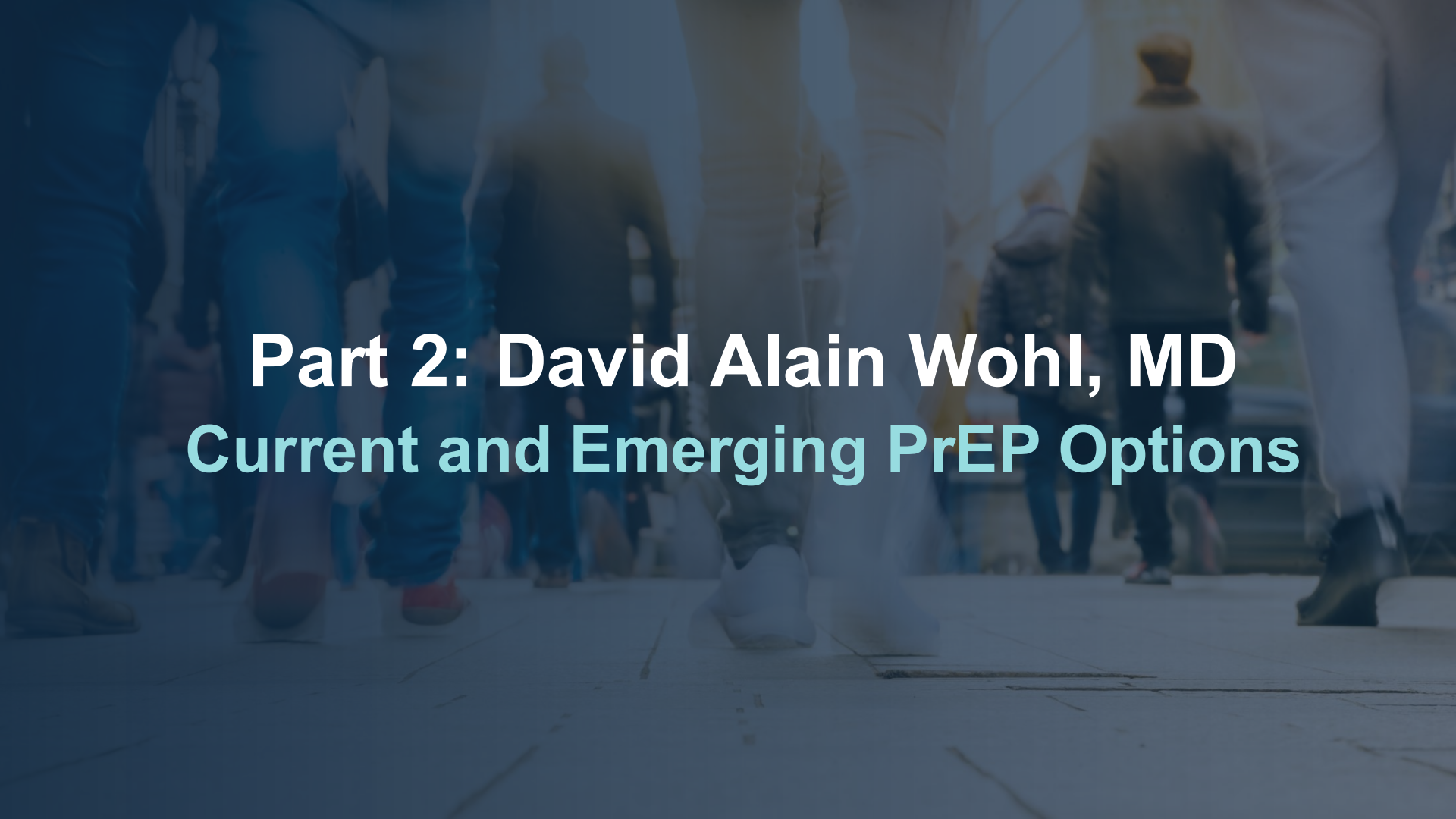


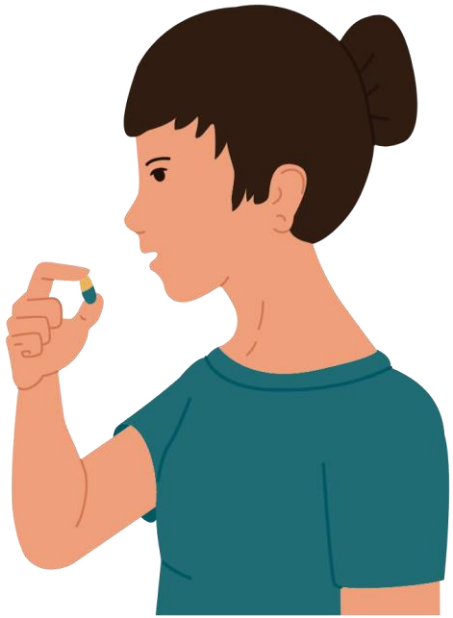
Part 2: David Alain Wohl, MD

Current and Emerging PrEP Options

FDA-Approved Oral PrEP

Oral PrEP

- **F/TDF (1 tablet daily):**
  - FDA-approved July 2012 for all men and women
  - NRTI/NtRTI: terminates viral DNA chain replication
  - ~99% efficacy with high adherence
  - Bone/renal safety: greater BMD loss; higher systemic tenofovir → increased risk of tubular toxicity
- **F/TAF (1 tablet daily):**
  - FDA-approved October 2019 for MSM, MSW, and transgender women
  - NRTI/NtRTI: terminates viral DNA chain replication
  - ~99% efficacy with high adherence
  - Bone/renal safety: smaller decreases in BMD; lower plasma tenofovir → reduced renal toxicity



NRTI/NtRTI = nucleoside/nucleotide reverse transcriptase inhibitor; DNA = deoxyribonucleic acid; MSW = men who have sex with women; BMD = bone marrow density.

CDC. *MMWR Morb Mortal Wkly Rep.* 2012;61(31):586-589. Wu L, et al. *Front Reprod Health.* 2024;6:1325257. Mayer KH, et al. *Lancet*. 2020;396(10246):239-254. Emtricitabine and tenofovir disoproxil fumarate [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021356s058%2C022577s014lbl.pdf. Emtricitabine and tenofovir alafenamide [package insert]. https://rsc.niaid.nih.gov/sites/default/files/emtricitabine-tenofovir-alafenamide-descovy-pi_june-2025.pdf.

CME OUTFITTERS

FDA-Approved Long-Acting Injectable (LAI) PrEP

LAI PrEP

- **CAB-LA:**
  - FDA-approved December 2021 for all men and women
  - INSTI: blocks HIV DNA integration
  - IM injection: 600 mg at month 1, month 2, then every 2 months (with optional oral lead-in)
  - **Opera** and **Trio Health** cohorts demonstrated > 99% efficacy (n = 1,300); 85% initiation, 69% on-time injection adherence; safe during pregnancy; stigma reduction reported (PILLAR implementation study)
  - **HPTN 083** (MSM and transgender women)
    - Additional follow-up confirms lower HIV incidence with CAB-LA vs daily oral F/TDF PrEP
  - **HPTN 084** (cisgender women)
    - lower HIV incidence with CAB-LA vs daily oral F/TDF PrEP
  - **HPTN 084-01** (adolescents, three African countries)
    - Safe, tolerable, and acceptable, supporting scale-up in younger populations (< 18 years old)

INSTI = integrase strand transfer inhibitor; IM = intramuscular.

Cairns G. aidsmap Website. 2022. https://www.aidsmap.com/news/feb-2022/injected-prep-cabotegravir-maintains-its-advantage-over-four-years. National Institutes of Health [NIH]. 2024. https://www.nih.gov/news-events/news-releases/long-acting-injectable-cabotegravir-hiv-prevention-safe-pregnancy. Stranix-Chibanda L, et al. *Lancet HIV.* 2025;12(4):e252-e260. Landovitz R, et al. *Lancet HIV.* 2023;10(12):e767-e778. Fonner V, et al. *AIDS.* 2023;37(6):957-966.

CME OUTFITTERS

FDA-Approved LAI PrEP

LAI PrEP

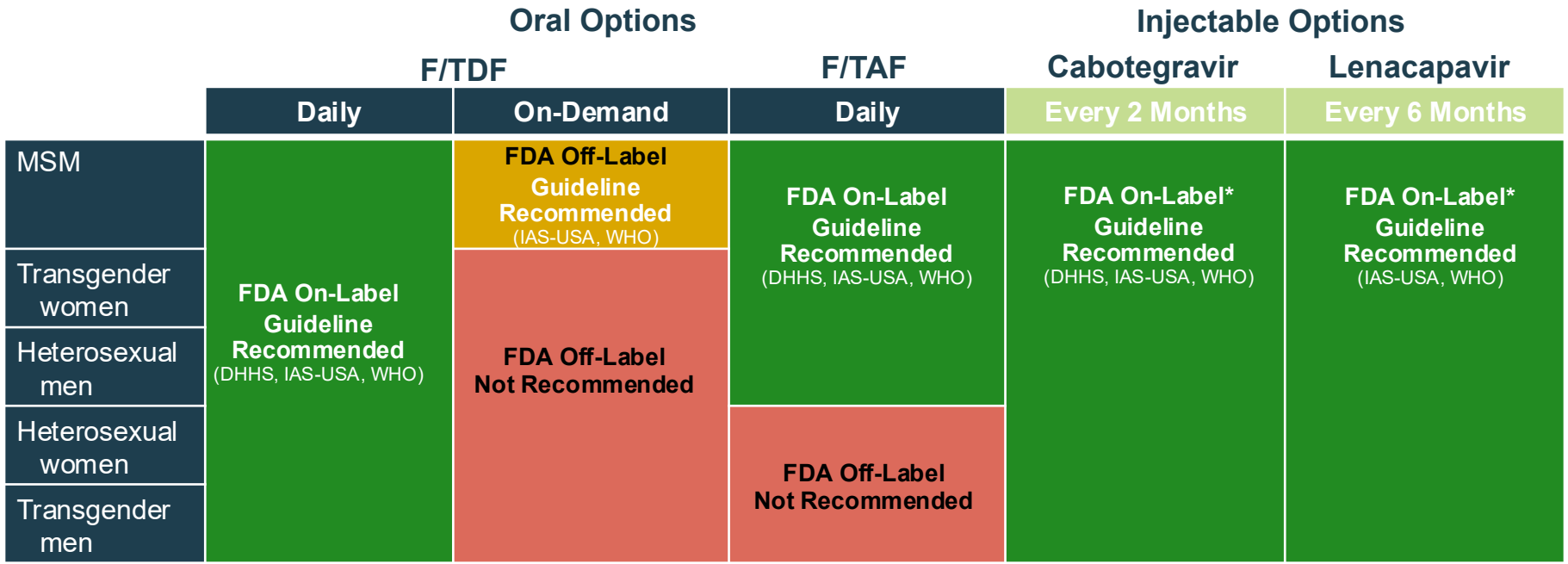
- **Lenacapavir**
  - FDA-approved June 2025 for all men and women
  - HIV capsid inhibitor: disrupts uncoating and assembly
  - SC injection every 6 months (after oral + injection initiation phase)
    - **PURPOSE 1** (cisgender women, Africa): 100% efficacy, superior to oral TDF/FTC, safe during pregnancy
    - **PURPOSE 2** (MSM & transgender populations): met primary endpoint, superior to oral PrEP
  - Cisgender Patient Preferences (**PURPOSE 1, CROI 2025**)
    - Week 52 questionnaire (n = 2,561):
      - Two-thirds preferred twice-yearly SC injections over daily pills
      - 61% felt more protected with injections (↑ from 59% baseline)
      - 61% reported more confidence avoiding missed doses with injections vs pills

SC = subcutaneous.

Jogiraju V, et al. *Lancet*. 2025;405(10485):1147-1154. Bekker LG, et al. *N Engl J Med*. 2024;391(13):1179-1192. Kelley CF, et al. *N Engl J Med*. 2025;392(13):1261-1276. Mansoor LE, et al. Conference on Retroviruses and Opportunistic Infections [CROI]; 2025. Abstract No. 1230. https://www.croiconference.org/abstract/1160-2025/.

CME OUTFITTERS

PrEP Options: Consensus and Different Perspectives on Eligibility



People who inject drugs: assess and consider sexual risk.
CDC indicates that people who inject drugs are likely to benefit from any FDA-approved PrEP option with or without a sexual risk indication.
*Except pregnancy: insufficient human data to adequately assess a drug-associated risk of birth defects and miscarriage.

DHHS = Department of Health and Human Services; IAS-USA = International Antiviral Society-United States of America.

Gandhi RT, et al. *JAMA*. 2025;333(7):609-628. WHO. 2025. https://www.who.int/publications/i/item/9789240111608. CDC. 2025. https://www.cdc.gov/hivnexus/hcp/prep/index.html.

CME OUTFITTERS

Investigational PrEP Formulations

- **Lenacapavir* (once-yearly IM injection, LAI)**
  - Phase I data (CROI 2025): safe, well-tolerated, higher plasma levels vs twice-yearly SC lenacapavir
  - Potential for improved adherence and prevention impact with a once-yearly IM injection
- **MK-8527****
  - Capsid inhibitor being studied as a long-acting PrEP agent
    - Developed in oral and potential LAI formulations
  - May offer potent protection with more forgiving adherence profiles
  - Capsid inhibitors complement existing classes and may reduce resistance overlap
  - Could fill gaps for individuals who can't (or won't) use integrase inhibitors
  - Preclinical/early clinical trials are ongoing

*Lenacapavir is not FDA-approved for IM injection of HIV PrEP.
**MK-8527 is not FDA-approved as an oral or injectable PrEP option.

Jogiraju V, et al. *Lancet*. 2025;405(10485):1147-1154. Kelley CF, et al. *N Engl J Med*. 2025;392(13):1261-1276. Bekker LG, et al. *N Engl J Med*. 2024;391(13):1179-1192. Raheem IT, et al. CROI; 2024. Abstract No. 638. https://www.croiconference.org/wp-content/uploads/sites/2/posters/2024/638.pdf.

CME OUTFITTERS

Patient Eligibility Considerations for LAI PrEP

- **Baseline testing:**
  - HIV-negative status confirmed via 4th-gen Ag/Ab (plus NAAT if acute infection suspected)
  - RNA testing is highly recommended
- **Renal and bone health:**
  - F/TAF preferred for individuals with renal impairment or bone density concerns
- **Age and pregnancy:**
  - F/TAF and CAB-LA safe in adolescents and during pregnancy
  - Lenacapavir permitted during pregnancy per recent MMWR guidance
- **Barriers:**
  - Access, stigma, patient-advocated adherence support
  - Clinician awareness and comfort prescribing, administering, and managing
  - Cost and insurance coverage

MMWR = morbidity and mortality weekly report.

Saidi F, et al. *Curr HIV/AIDS Rep.* 2025;22(1):44. Patel RR, et al. *MMWR Morb Mortal Wkly Rep.* 2025;74(35):541-549. Spinelli MA, et al. *JAMA.* 2024;332(18):1574-1575.

CME OUTFITTERS

Audience Response

What is the mechanism of action of cabotegravir long-acting injection (CAB-LA)?

A. Integrase strand transfer inhibitor: blocks HIV DNA integration
B. Capsid inhibitor: disrupts uncoating and assembly
C. Reverse transcriptase inhibitor: terminates viral DNA chain
D. Fusion inhibitor: prevents viral entry
E. I don’t know

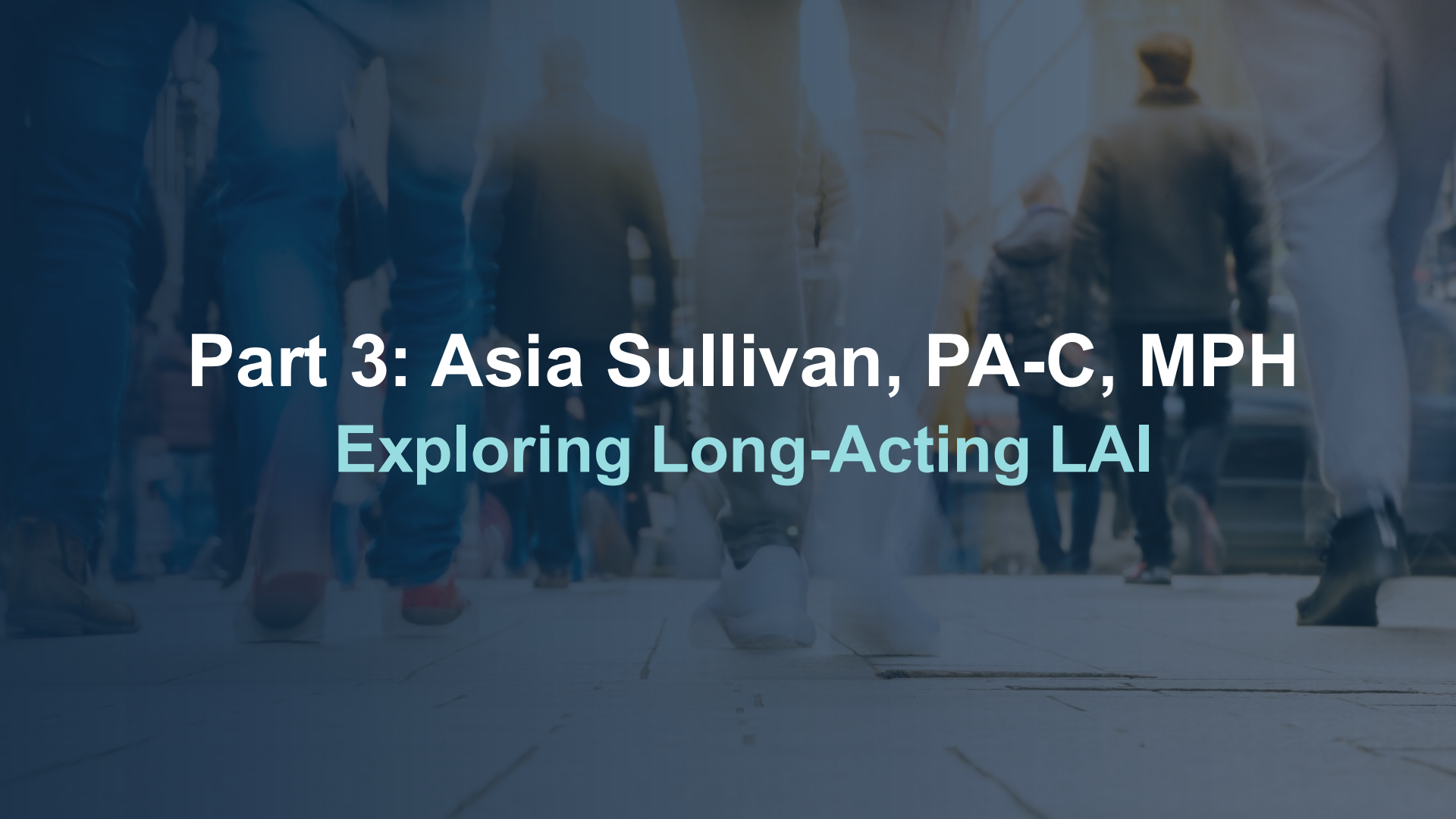
CME OUTFITTERS

Clinical Clues Escape Room

INSERT INFOGRAPH-ED

- Testing knowledge on current and emerging PrEP options (safety, efficacy, eligibility)
- Faculty discussion
- Polling questions

CME OUTFITTERS



Part 3: Asia Sullivan, PA-C, MPH

Exploring Long-Acting LAI

FDA-Approved LAI PrEP Options

Cabotegravir LA

- **Who:** Adults & adolescents ≥ 35 kg, HIV-negative
- **Dosing:** IM injection every 2 months (after 2 loading doses)
- **Best for:** individuals struggling with daily pills; prefer clinic visits
- **Evidence:** HPTN 083/084 → FDA-approved Dec 2021

Lenacapavir

- **Who:** Adults & adolescents ≥ 35 kg, HIV-negative
- **Dosing:** SC injection every 6 months (after oral lead-in)
- **Best for:** twice-yearly dosing; strong data in women, MSM, transgender, and nonbinary populations
- **Evidence:** PURPOSE 1 & 2 → FDA-approved June 2025

Cabotegravir [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215499Orig1s004lbl.pdf.
Lenacapavir [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/220020s000lbl.pdf.

CME OUTFITTERS

Expanding the HIV Prevention Toolkit

PrEP

is a cornerstone of HIV prevention

- LAI PrEP vs oral PrEP offers:
  - Improved adherence
  - Reduced transmission risk
- Clinician familiarity
  - Benefits, risks, and individual monitoring considerations?

Don’t let knowledge gaps result in missed opportunities to optimize patient care!

CME OUTFITTERS

Benefits and Differences in LAI PrEP

Distinct differences among current FDA-approved LAI formulations

CAB-LA

IM injection: 1 dose → 1 month → every 2 months

Twice-Yearly Lenacapavir*

SC injection every 6 months: initiation requires oral tablets + injection

Dosing and administration routes affect initiation, patient education, and preferences

*Lenacapavir is not FDA-approved for IM injection of HIV PrEP.

Cabotegravir [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215499Orig1s004lbl.pdf.
Lenacapavir [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/220020s000lbl.pdf.

Monitoring and SDoH Considerations

Monitoring for LAI differs from oral PrEP

- LAI requires visits every 2-6 months
  - More visits necessary with CAB-LA vs lenacapavir
  - Re: CAB-LA, instead of the q3M visits for oral PrEP, patients would come in q2M
  - Opportunity to ↓ clinic burden and ↑ access through providing sites for injection administration
- Timely injections are crucial
  - Missed doses may compromise protection
  - Infections with on-time injections are rare, but can happen
- Clinics need to incorporate organizational systems:
  - Track injection schedules and follow up on missed visits
- Patient-centered SDoH must be considered (e.g., work leave, transportation, housing, insurance, and socioeconomic barriers)

Emerging LAI options may mitigate these barriers with fewer required visits

SDoH = social drivers of health.

PrEPWatch. *The Lens on LEN: The Basics on Injectable Lenacapavir as PrEP.* 2024. https://www.prepwatch.org/wp-content/uploads/2024/07/The-Lens-on-LEN.AVAC-primer.July-2024.pdf. Parikh UM, et al. *Open Forum Infect Dis.* 2025;12(6):ofaf285. Miller AS, et al. *J Urban Health.* 2023;100(1):212-214.

CME OUTFITTERS

Clinical Considerations for LAI PrEP

- **Optimal patient selection:**
  - Individual preference, adherence challenges, stigma concerns, high-risk populations
- **Transitioning patients from oral → LAI PrEP:**
  - Requires careful timing and overlap
- **Monitoring:**
  - Confirm HIV-negative status at each injection, track injection adherence
- **Implementation challenges:**
  - Staffing for injection visits and follow-up
  - Prior authorizations, insurance approvals, and billing workflows
  - Logistics: storage, ordering, and drug availability on site

Dedicated personnel or teams improve success of LAI PrEP programs

Baker D, et al. *J Gen Intern Med.* 2025 Feb 11. [Epub ahead of print]. Khan T, et al. 5th HIV Research for Prevention Conference. 2024. Abstract No. OA0502. https://www.natap.org/2024/HIVR4P/HIVR4P_29.htm.

CME OUTFITTERS

Audience Response

What is the primary monitoring requirement for individuals on LAI PrEP?

A. Monthly viral load testing
B. Confirm HIV-negative status at each injection and assess for acute infection
C. Bone density scans at every visit
D. Quarterly re-check chemistry panel and complete blood count (CBC)
E. I don’t know

CME OUTFITTERS

Implications for LAI PrEP

- **For patients:**
  - Expands choices for HIV prevention tailored to lifestyle, preferences, and barriers
  - Potential for improved adherence and satisfaction with less frequent dosing
- **For clinicians:**
  - Must stay updated on evolving LAI PrEP evidence (e.g., once-yearly lenacapavir)
  - Need training on initiation protocols, monitoring, and resistance prevention
- **For health systems:**
  - Opportunity to improve HIV prevention outcomes and reduce new infections
  - Requires investment in workflows, insurance navigation, and dedicated staff
- **For public health:**
  - LAI PrEP may help close gaps in PrEP uptake in populations with adherence challenges
  - Could play a key role in achieving UNAIDS and national HIV prevention goals

UNAIDS = The Joint United Nations Programme on HIV/AIDS.

WHO. 2025. https://www.who.int/publications/i/item/9789240111608. Jogiraju V, et al. *Lancet.* 2025;405(10485):1147-1154. Suarez E Jr, et al. *AIDS Behav.* 2025;29(4):1235-1246. Haberer JE, et al. *Lancet HIV.* 2023;10(6):e404-e411.

CME OUTFITTERS

Clinical Clues Escape Room

INSERT INFOGRAPH-ED

- Matching appropriate patients with LAI PrEP, transition strategies, and patient monitoring
- Faculty discussion
- Polling questions

Part 4: Panel

Patient Engagement Strategies for PrEP Initiation and Adherence

Why Patient Engagement in PrEP Matters

Progress!

- ↓ **new HIV infections** by 12% (2018-2022)
- Expanding PrEP coverage in **diverse populations**
- In 2022, for the first time, **more than one-third** (36%) of individuals in the U.S. who could benefit from PrEP were prescribed it – up from ~23% in 2019

But…

Persistent Gaps

- **Racial disparities:** Black individuals made up 38% of diagnoses (2022)
- **PrEP access:** 13% Black, 24% Latine vs 94% White (2022)
- **Youth:** Ages 13-24 = ~19% of new infections (2021 and 2022); lowest PrEP uptake
- Limited impact of oral PrEP → need **better marketing** and appeal for stronger LAI PrEP uptake
- Require **culturally tailored** and **youth-focused strategies** to reduce new infections

CDC. *HIV Surveill Suppl Rep*. 2024;29(1). Yusuf H, et al. *JAMA Pediatr*. 2020;174(11):1102-1108. CDC. 2023. https://www.cdc.gov/nchhstp/director-letters/expanding-prep-coverage.html. CDC. 2024. https://www.cdc.gov/nchhstp/director-letters/cdc-publishes-new-hiv-surveillance-reports.html. CDC. 2025. https://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-prevalence.html#:~:text=At%20a%20glance,52%25)%20of%20all%20diagnoses.

CME OUTFITTERS

Overcoming Barriers & Building Trust

Address Stigma Directly

- Barriers include homophobia, transphobia, racism, sexism, and PrEP-shaming
- Frame PrEP as a wellness and empowerment tool, not a “high-risk” burden

Inclusive Patient Communication

- Normalize sexual health discussions for all sexually active individuals
- Avoid siloed “risk-only” messaging; promote protection, health, and self-efficacy

Strategies for Adherence

- Reassure about side effect management and safety data
- Offer options (oral vs LAI PrEP) tailored to lifestyle and preferences
- Address SDoH (transport, insurance, clinic hours)

Antonini M, et al. *Rev Bras Enferm.* 2023;76(3):e20210963. Mayer KH, et al. *Adv Ther.* 2020;37(5):1778-1811. Cahill S, et al. *AIDS Care.* 2017;29(11):1351-1358. Calabrese SK, et al. *J Acquir Immune Defic Syndr.* 2018;79(1):46-53.

CME OUTFITTERS

Best Practices for Patient Engagement

- **For clinicians and teams:**
  - Take a nonjudgmental, open sexual history; avoid assumptions
  - Integrate PrEP into routine preventive care discussions
  - Use multidisciplinary support (pharmacists, nurses, counselors)
  - Addressing low health literacy
    - Incorporate plain language, visual aids, and cultural sensitivity
- **For programs and systems:**
  - Train HCPs on culturally sensitive, inclusive communication
  - Develop systems to track adherence and follow up proactively
  - Dedicate staff for navigation (prior authorizations, billing, medication access)
- **Key principle:** Promote PrEP as an empowering, individualized wellness choice, not just a medication

Rivet Amico K, et al. *Lancet HIV.* 2019;6(2):e137-e140.

CME OUTFITTERS

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

Put information into action! Consider the following goals, then *set a time frame* that fits with your work environment and *a reasonable improvement target* that aligns with your patient population.

- **Increase** the percentage of patients who are offered routine HIV testing using a status-neutral approach at primary care and specialty visits
- **Increase** the percentage of patients who are counseled on the full range of current and emerging PrEP options, including oral and LAI formulations
- **Improve** the percentage of patients engaged in shared decision-making conversations about PrEP, addressing stigma, side effect concerns, and wellness framing
- **Increase** the percentage of adolescent and underserved patient populations who are assessed for PrEP eligibility and counseled in a culturally sensitive manner

CME OUTFITTERS


QUESTIONS
&
ANSWERS
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3. Enter your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so credit can be submitted to ABIM

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How to Claim This Activity as a CME for MIPS Improvement Activity

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STEP INTO PREVENTION

Mastering the Power of PrEP in HIV Care

This program has been supported by an independent educational grant from Gilead Sciences, Inc.

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