

CDC's PrEP Clinical Practice Guideline and Strategies for Ending the HIV Epidemic in the U.S.

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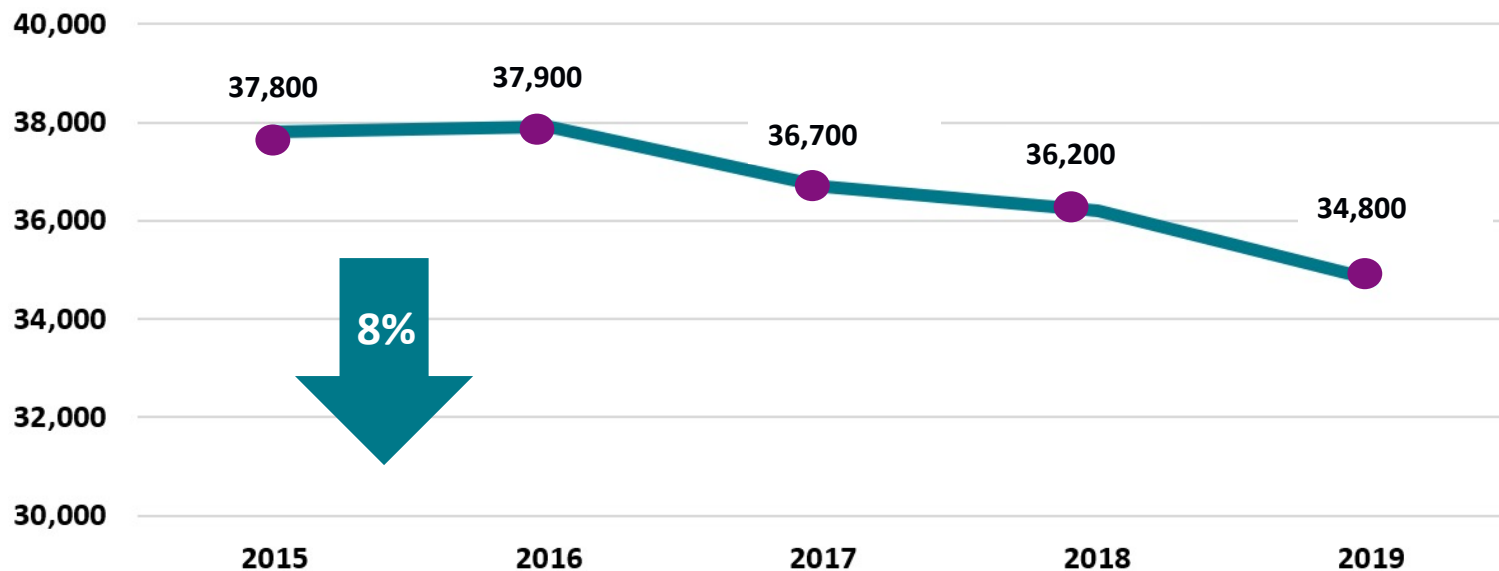




Status of HIV in the United States

National HIV Prevention and Care Efforts Have Reduced HIV Infections From a Peak of 130,000 in the Mid-1980s to Approximately 34,800 in 2019

Estimated Annual HIV Infections in the United States, 2015-2019



1.2 Million People in the United States Have HIV, and Health Disparities Persist

Snapshot of Disparities



Higher HIV Incidence

- Gay and Bisexual Men
- Black/African American Persons
- Hispanic/Latino Persons



Larger Gaps in PrEP Coverage

- Black/African American Persons
- Hispanic/Latino Persons



Lower Rates of Viral Suppression

- American Indian/Alaskan Native Persons
- Black/African American Persons



Higher HIV Prevalence

- Men who have sex with men (MSM)
- Transgender Women

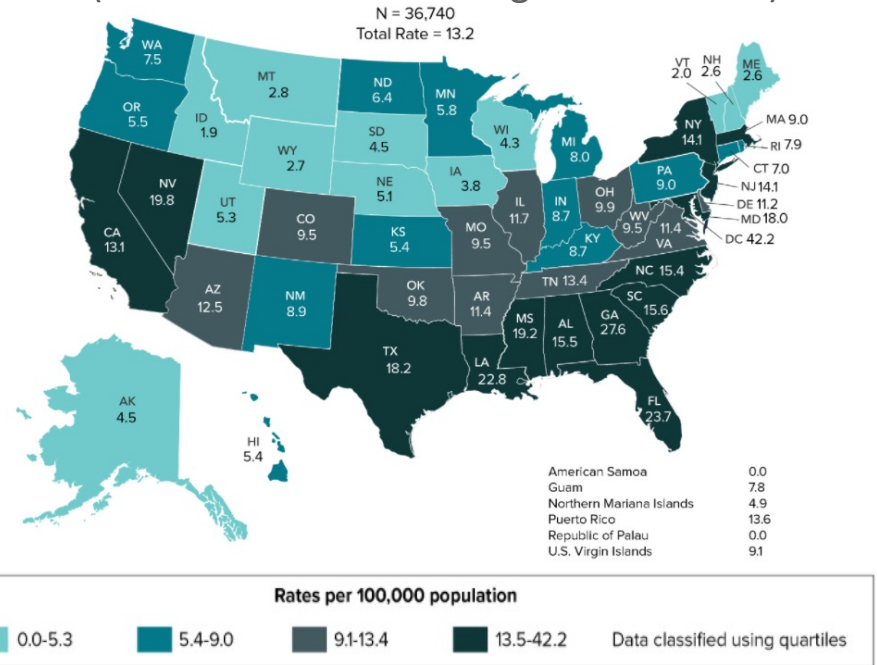


More HIV Outbreaks

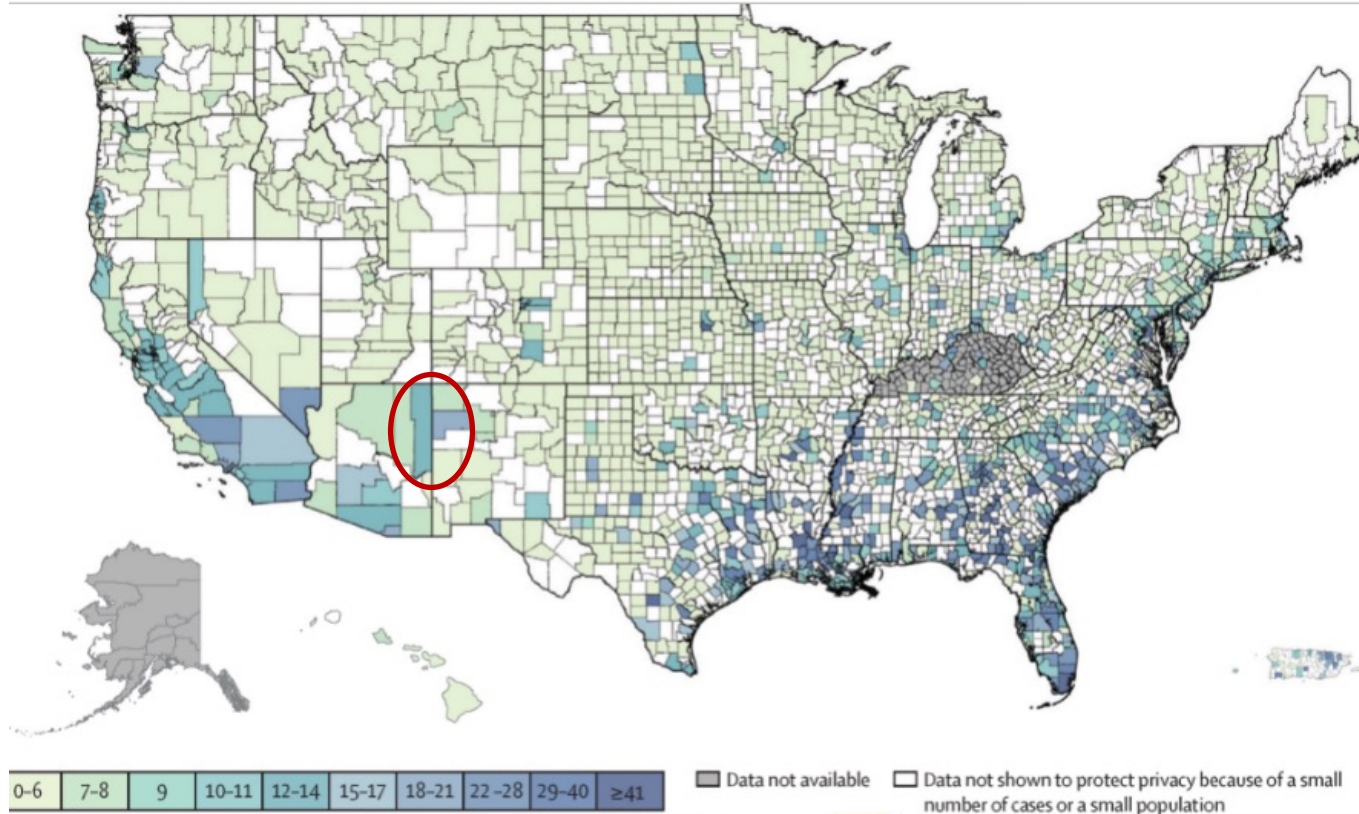
- People Who Inject Drugs

Rates of Diagnoses of HIV Infection Highest in the South

(>50% of all new HIV diagnoses in 2019)



Rates of New HIV Diagnoses in US Counties, 2018





Ending the HIV Epidemic (EHE) in the United States

Ending the HIV Epidemic in the United States



Diagnose all people with HIV as early as possible



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

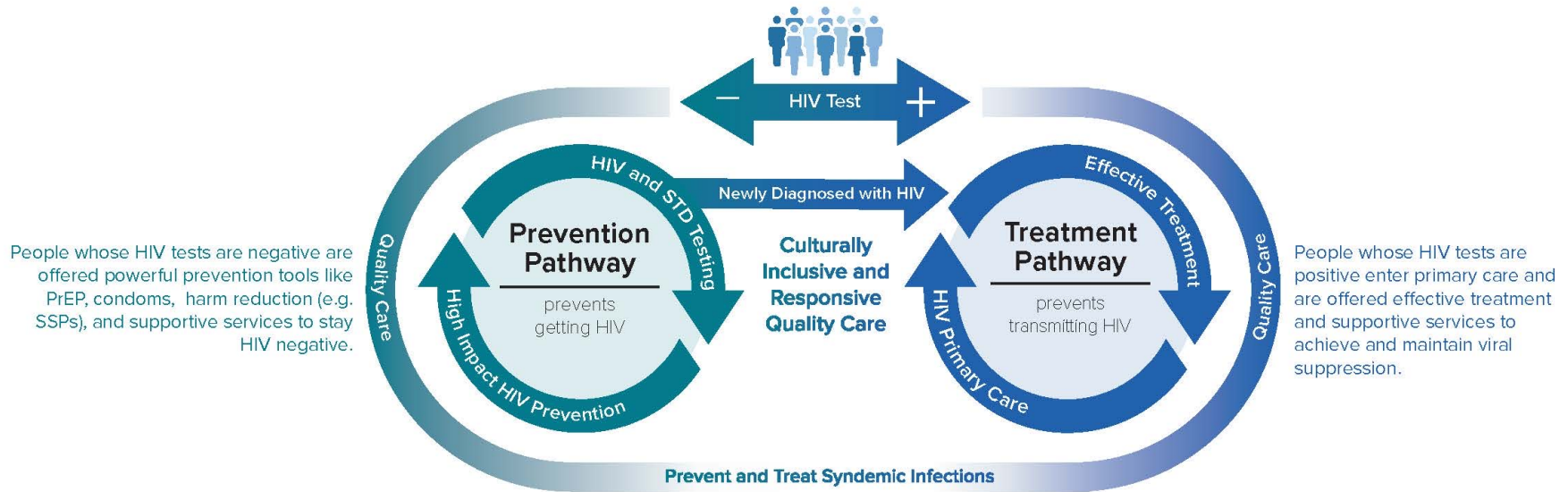


Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs)



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

Status Neutral HIV Prevention and Care



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 people with the tools they need to stay healthy and stop HIV.



A person with HIV who takes HIV medicine as prescribed and gets and stays virally suppressed or undetectable can stay healthy and has effectively no risk of sexually transmitting HIV to HIV-negative partners.

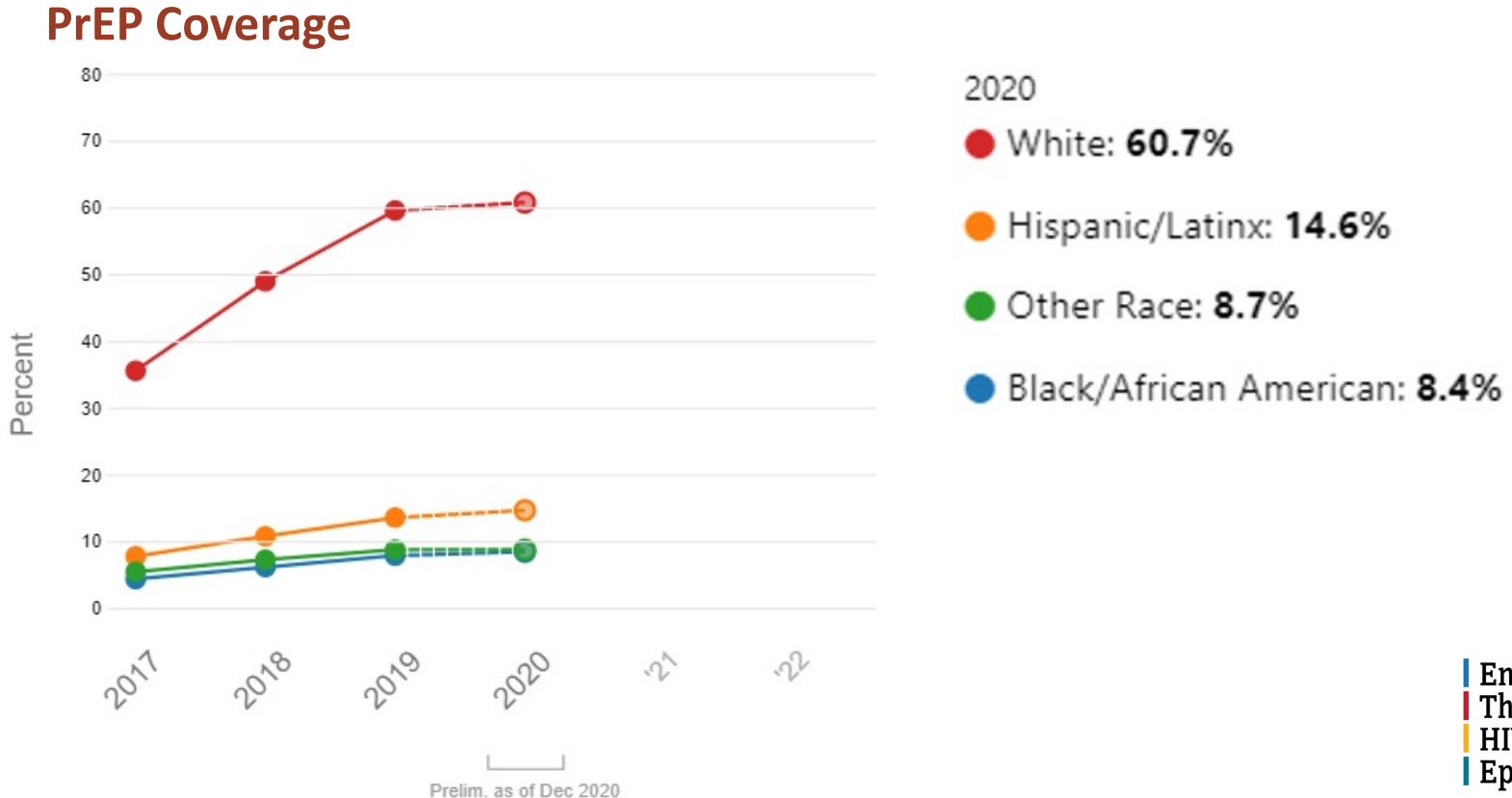
www.cdc.gov/hiv/risk/art/index.html



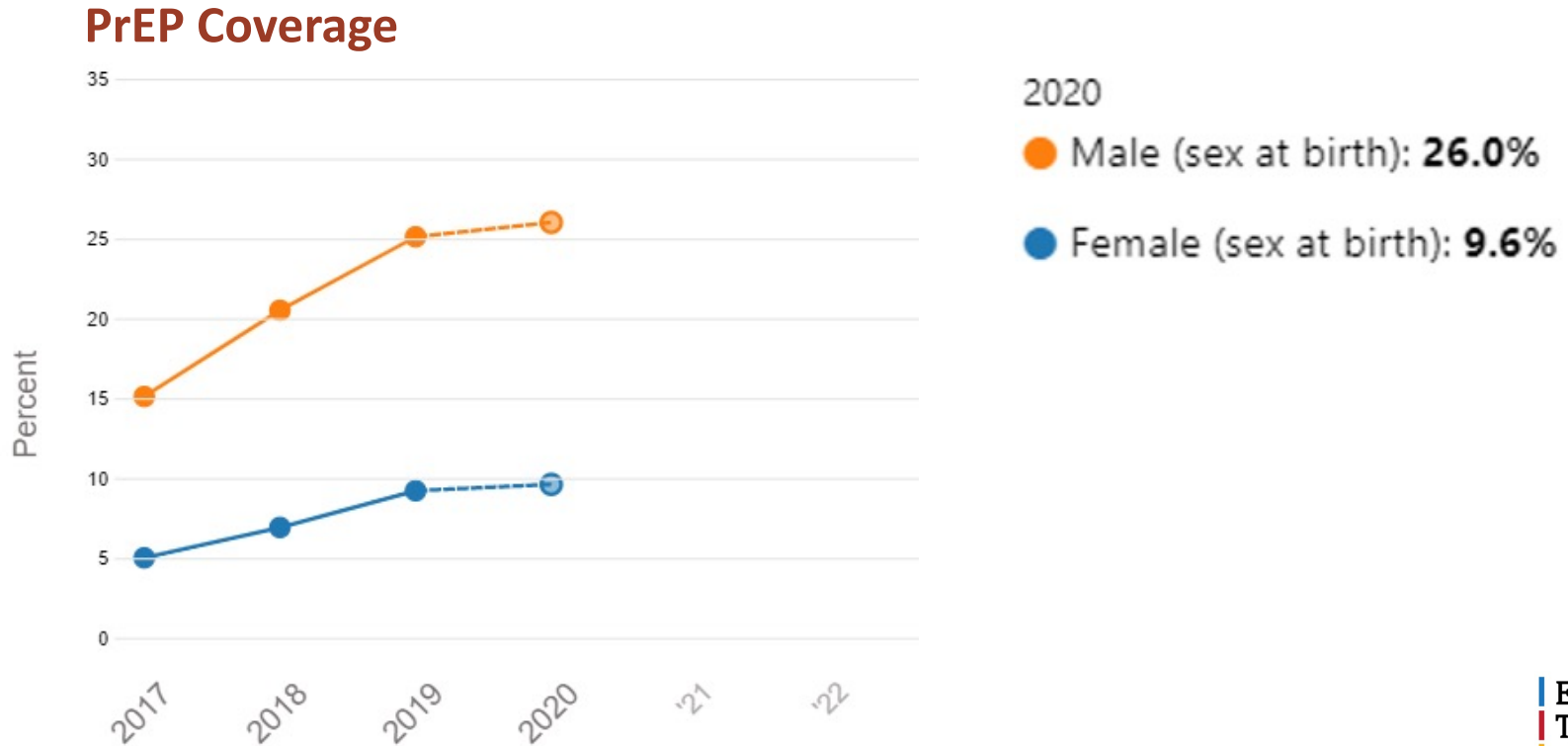


Increasing PrEP Coverage and Providers

PrEP Coverage by Race/Ethnicity 2017-2020



PrEP Coverage by Gender 2017-2020



Increasing PrEP Providers

- **Now is the time to incorporate PrEP deeper into primary care**
 - The U.S. Preventive Services Task Force (USPSTF) assigns a grade A recommendation for primary care preventive care
 - CMS FAQ supports that both the medications and the clinical services that support PrEP should be covered by insurers without out-of-pocket cost to the patient
 - PrEP is a highly effective primary care intervention, but we need more providers to educate their patients about PrEP and prescribe it

Who Are PrEP Providers?

Primary Care
Providers

Sexually Transmitted Disease
Clinic Providers

HIV-Negative
Individuals

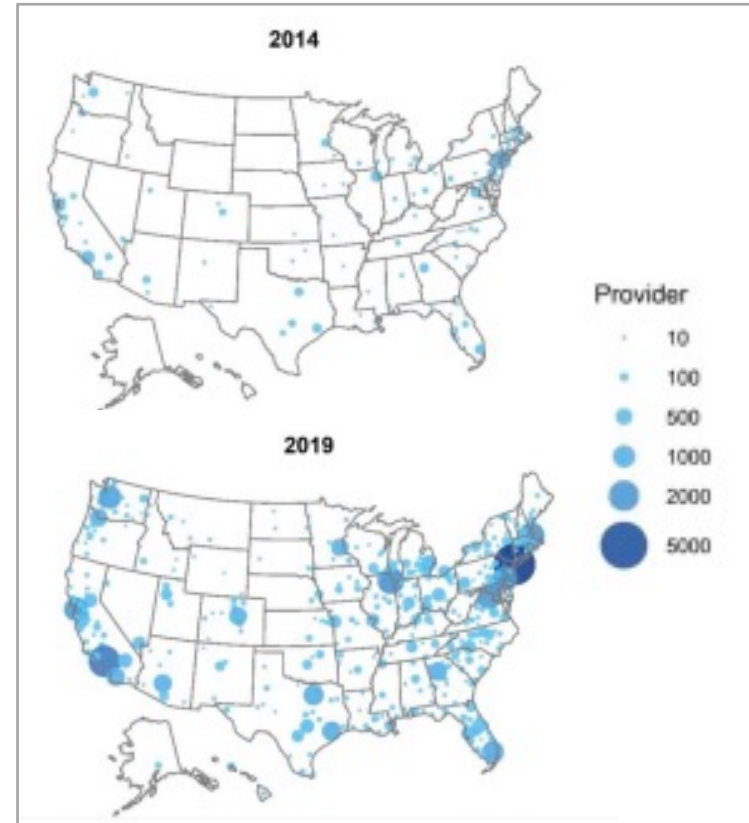
HIV Care
Providers

Drug Treatment
Providers

Increasing Number of PrEP Prescribers in U.S.

In 2019:

- **There were 66,000 PrEP prescribers**
 - Compared to 9,600 in 2014
 - 68% were physicians
 - 30% were NPs or PAs
- **4% of all active providers had prescribed PrEP**
 - 13% of family practitioners
 - 34% of ID physicians
- **50% of PrEP patients prescribed by 3% of PrEP providers**

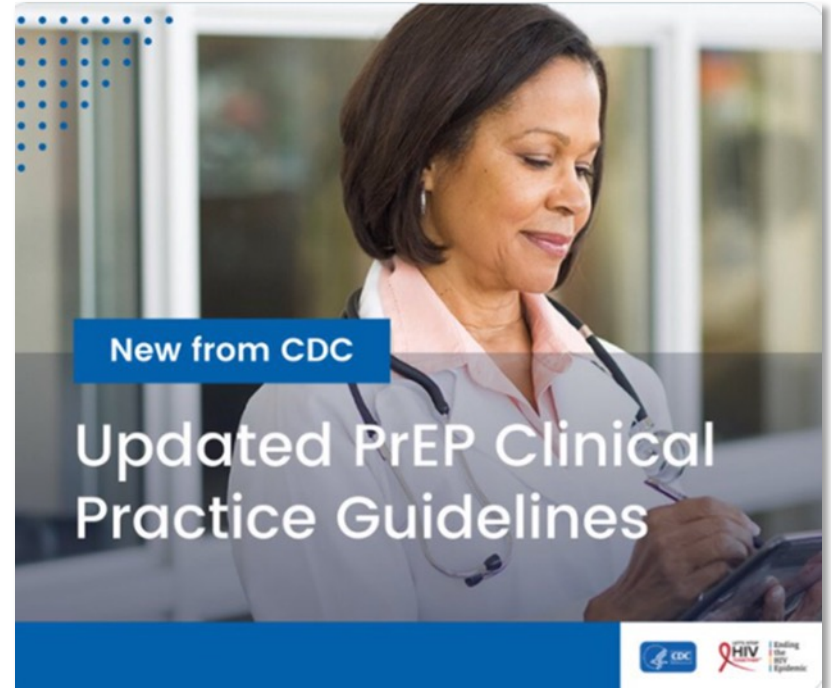




2021 PrEP Clinical Practice Guideline

What's Unchanged From the 2017 Guideline

- No changes to:
 - Indications for PrEP use
 - Frequency of follow-up visits for oral PrEP
 - Schedule for HIV and STI testing for oral PrEP

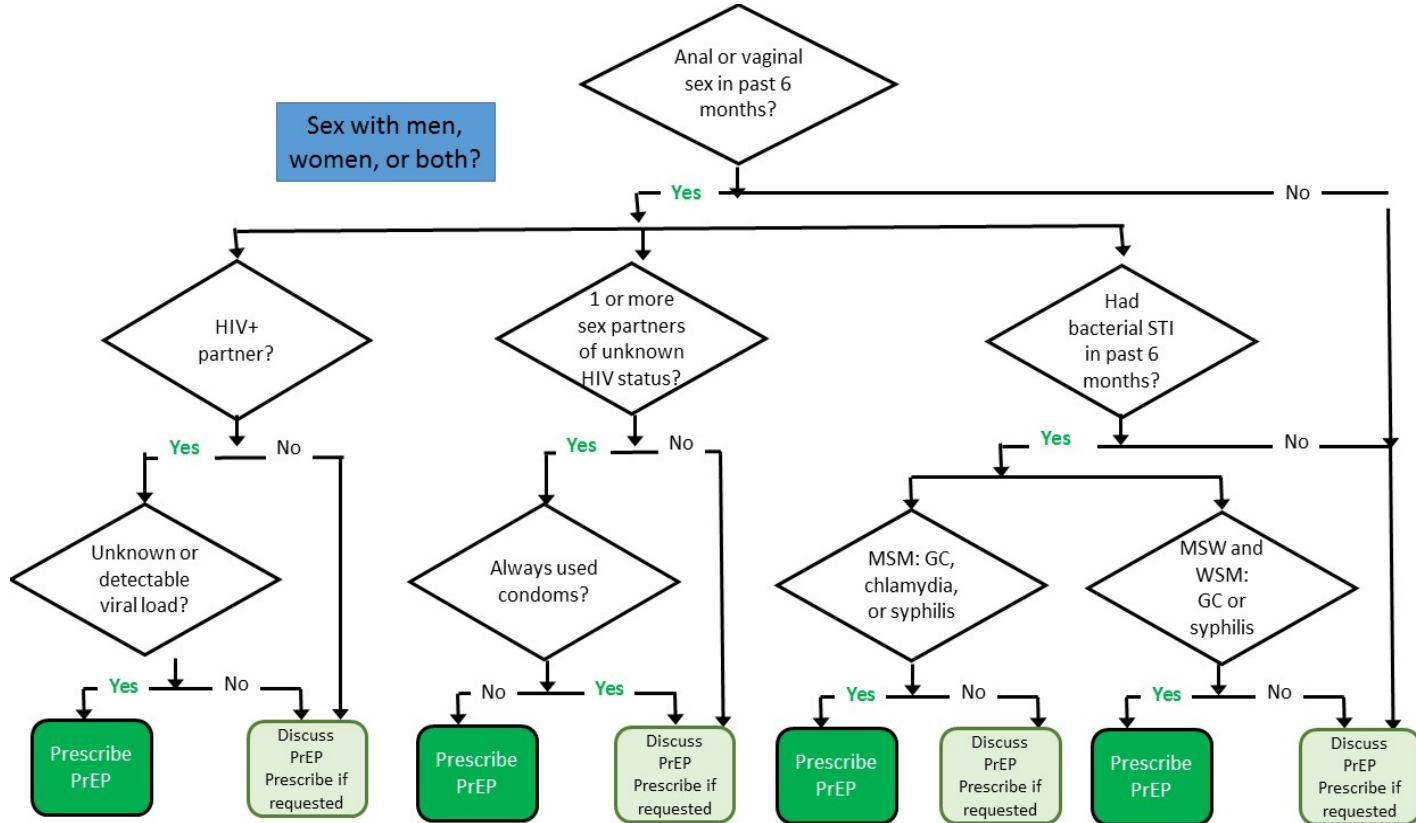


Increase Awareness of PrEP as an Option

NEW RECOMMENDATION: All sexually active adult and adolescent patients should receive information about PrEP

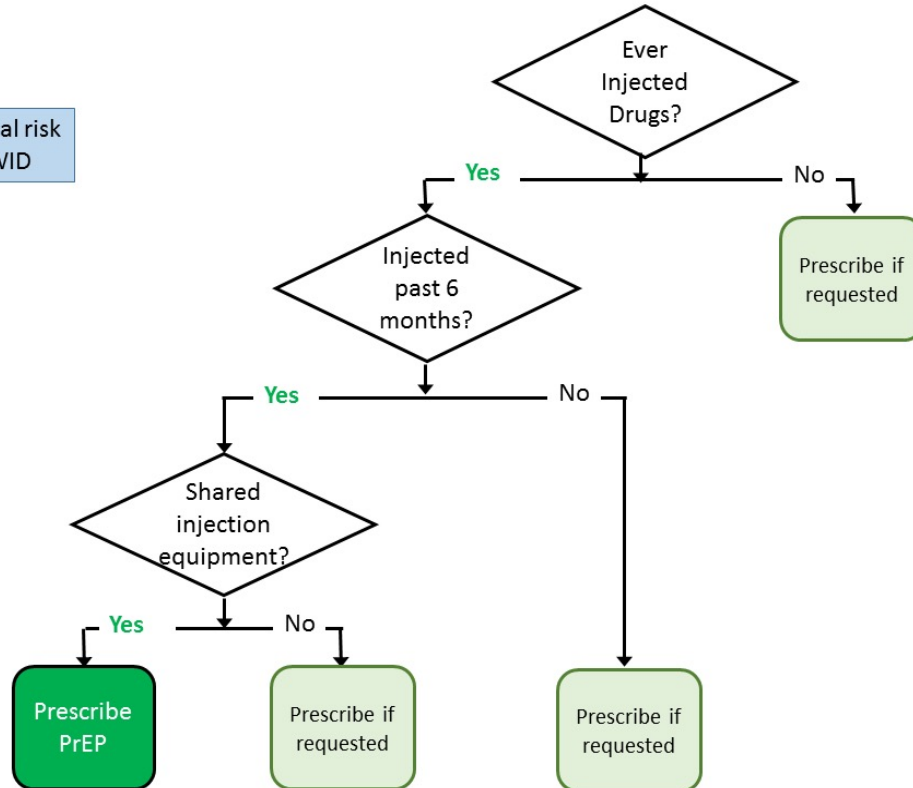
- Encourage providers to offer PrEP as a core primary care service
 - Reduce missed opportunities for PrEP provision
- Increase knowledge of PrEP among potential users
 - Allow consideration of immediate or future use and PrEP requests
- Increase knowledge of PrEP in the community
 - Those who can recommend to others or support use by family or friends

PrEP Indications for Sexually Active Persons



PrEP Indications for Persons Who Inject Drugs

Assess sexual risk
for all PWID

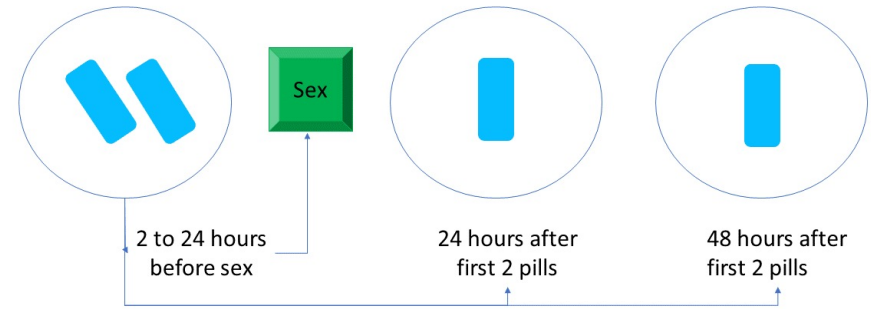


Daily Oral PrEP Protocol

	PrEP Initiation Visit	Follow-Up Visits (q 3 months)
HIV Status	<ul style="list-style-type: none"> HIV Ag/Ab test (lab preferred) 	<ul style="list-style-type: none"> HIV-1 qualitative RNA + Ag/Ab
Renal Status	<ul style="list-style-type: none"> eCrCl <ul style="list-style-type: none"> >60 mL/min (F/TDF or F/TAF) >30 mL/min (F/TAF) 	<ul style="list-style-type: none"> Assess q 6 months if baseline <ul style="list-style-type: none"> Age ≥50 years or eCrCl <90 mL/min Otherwise assess q 12 months
STI Infection Status	<ul style="list-style-type: none"> Syphilis serology for all <i>Neisseria gonorrhoeae</i> (GC) and <i>Chlamydia trachomatis</i> (CT) nucleic acid amplification testing (NAAT) at sites of exposure for MSM and transgender women (TGW) GC for women 	<ul style="list-style-type: none"> Repeat STI screen for MSM/TGW q 3 months Repeat STI screen for heterosexually active men and women q 6 months CT screen for heterosexually active men and women q 12 months
Lipid Screen	<ul style="list-style-type: none"> Only for persons prescribed F/TAF 	<ul style="list-style-type: none"> Repeat q 12 months for persons prescribed F/TAF
Screen for Active HBV	Hepatitis B serology	If not done at initiation visit
Prescription	90-day supply	90-day refill if HIV test is negative

Prescribing 2-1-1 Event-Driven PrEP

- **Only for adult MSM/TGW who:**
 - Request non-daily dosing
 - Have sex infrequently (e.g., less often than once a week) and
 - Can anticipate sex (or delay sex) to permit the doses at least 2 hours prior to sex
- **Prescribe F/TDF with 30-day supply before next HIV test**
- **Anticipate and advise how to safely switch between daily and 2-1-1- dosing**



Note that 2-1-1 dosing is not approved by the FDA and is not recommended by CDC.

Cabotegravir Injection PrEP Protocol

	PrEP Initiation Visit	Follow-Up Visits (q 2 months)
HIV Status	<ul style="list-style-type: none">• HIV-1 qualitative (or quant) RNA + Ag/Ab	<ul style="list-style-type: none">• HIV-1 qualitative (or quant) RNA + Ag/Ab
STI Infection Status	<ul style="list-style-type: none">• Syphilis serology for all• GC and CT NAAT at sites of exposure for MSM and TGW• GC for women	<ul style="list-style-type: none">• Repeat STI screen for MSM/TGW q 4 months• Repeat STI screen for heterosexually active men and women q 6 months• CT screen for heterosexually active men and women q 12 months
Prescription	<ul style="list-style-type: none">• Provide cabotegravir injection at initiation visit and again 1 month later	<ul style="list-style-type: none">• Provide cabotegravir injection q 2 months if HIV test is negative

Testing Procedure for Determining HIV Status

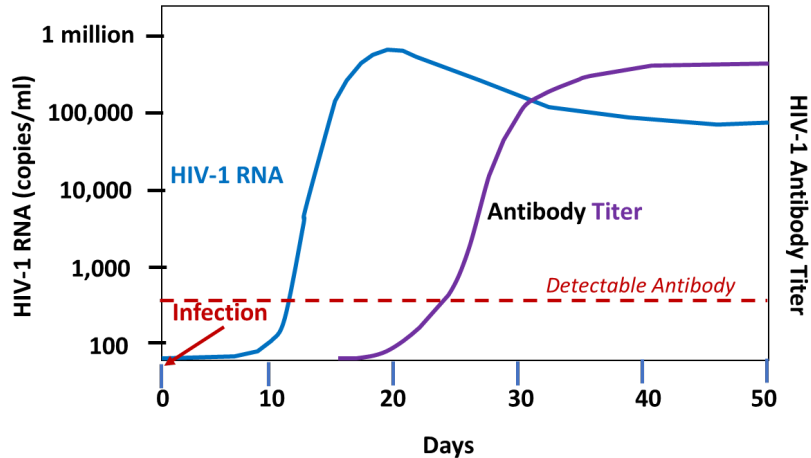
- **Starting/restarting PrEP for persons with no recent antiretroviral use**
 - Lowered HIV-1 RNA threshold for retesting for possible false positive result
- **Restarting/continuing PrEP for persons with recent antiretroviral use**
 - New algorithm using qualitative (or quantitative) HIV-1 RNA assays

Delay between 1st reactive qualitative HIV-1 RNA test and 1st reactive Ag/Ab test (HPTN 083)

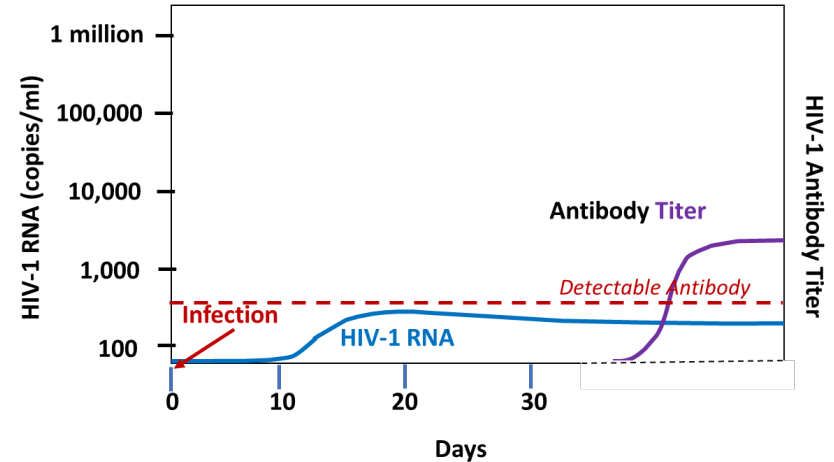
	Cabotegravir Arm			F/TDF Arm	
	Baseline n=4	Incident No CAB n=5	Incident On CAB n=7	Baseline n=3	Incident n=30
Participant number (%)	3 (75)	0	7 (100)	3 (100)	8 (21)
Duration of delay, median, (range), days (among those with delayed Ag/Ab test result)	62 (28-72)	NA	98 (35-185)	34 (14-36)	31 (7-68)

Diagnosing Acute HIV Infection

No Antiretrovirals



On PrEP



HIV RNA “spike” precedes production of HIV antibody



PrEP: Opportunities for Primary Care

PrEP Is Appropriate for Primary Care



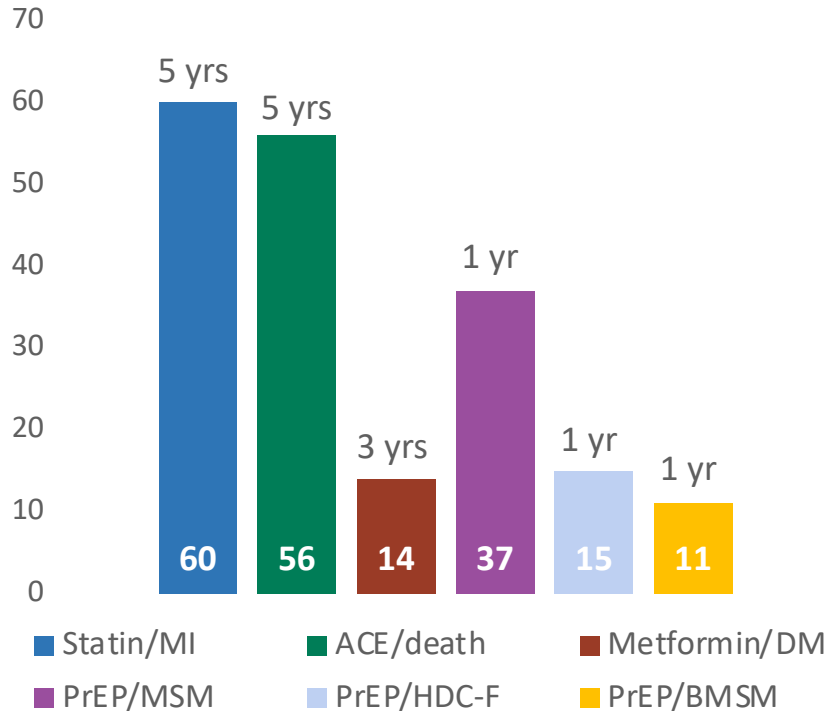
PrEP can be easily integrated into primary care practice, similar to other preventive measures regularly prescribed:

- Metformin for prediabetes
- Statins for cardiovascular disease
- Oral contraceptives for pregnancy
- Antimalarial medication for travelers

If patients test HIV positive, or as appropriate based on clinical judgment, refer to an HIV treatment specialist

Is It Worth It?

Number Needed to Treat



Missed Opportunities

- **In NYC, among seroconverters 2012-2017,**
 - **42%** had a prior negative HIV test visit without provision of PrEP
- **In SC, among seroconverters 2013-2016,**
 - **25%** had a diagnosis of gonorrhea or syphilis at a prior healthcare visit without provision of PrEP
- **In VA, among patients with indications for PrEP,**
 - **35%** experienced delays receiving PrEP ranging from 6 weeks to 16 months
- **In AL, among adolescents at a primary care center,**
 - **44%** had a PrEP indication. None were offered/prescribed PrEP

Opportunity for Primary Health Care Provision

Regular visits for PrEP care are an opportunity to provide a range of primary care services

		MSM	MSW*	Women	PWID
Vaccine# (if not previously vaccinated)	Hepatitis A vaccine	Yes	Yes	Yes	Yes
	Hepatitis B vaccine	Yes	Yes	Yes	Yes
	HPV vaccine	Through age 26	Through age 26	Through age 26	Through age 26
	Meningococcal B vaccine	Ages 16-18	Ages 16-18	Ages 16-18	Ages 16-18
	Influenza vaccine	Yes	Yes	Yes	Yes
General Health	Hepatitis C infection^	Ages 18-79	Ages 18-79	Ages 18-79	Ages 18-79
	Screen for depression^	Yes	Yes	Yes	Yes
	Screen for unhealthy alcohol use^	Ages 18 and older	Ages 18 and older	Ages 18 and older	Ages 18 and older
	Screen for smoking^	Yes	Yes	Yes	Yes
	Screen for Intimate Partner Violence^	Yes		Yes	If female, yes
Women's Health	Mammography^			Ages 50-74 q 2 years	If female, ages 50-74 q 2 years
	Screen for cervical cancer^~			Ages 21-65 q 3 years	If female, ages 21-65 q 3 years
Men's Health	Screen for prostate cancer^	Ages 55-69	Ages 55-69		If male, ages 55-69

*Men who have sex w/ Women

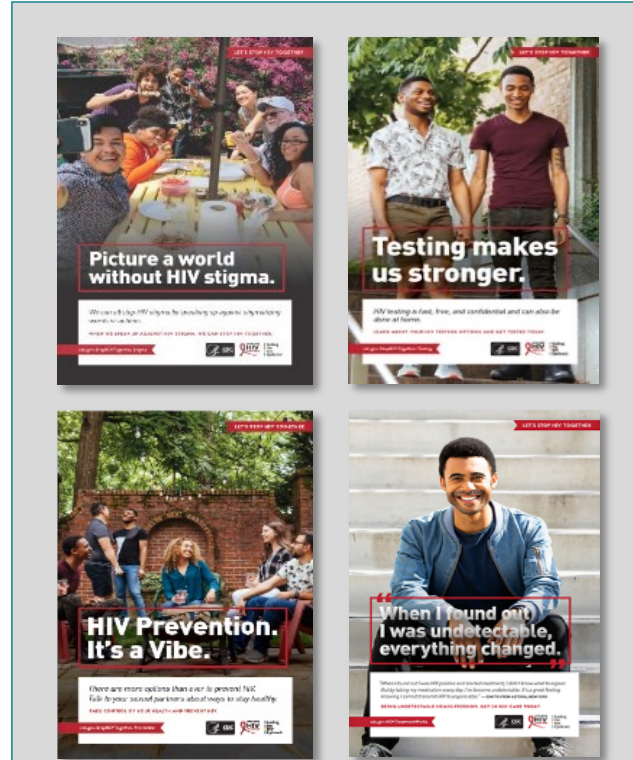


Resources

The CDC HIV Campaign: *Let's Stop HIV Together*™

Content Areas:

- Stigma/Patient-Centered Care
- Testing
- Prevention
- Treatment and Care



Picture a world without HIV stigma.
We can't stop HIV stigma by ourselves. We can stop it together.

Testing makes us stronger.
HIV testing is fast, free, and confidential and can allow you to live all forms.

HIV Prevention. It's a Vibe.
There are more options than ever to prevent HIV. Talk to your sex partners about ways to stay healthy.

When I found out I was undetectable, everything changed.
When I found out I was undetectable, I didn't have to stop sex. I didn't have to stop living. I didn't have to stop being who I am. I just had to keep taking my medicine every day. And I was undetectable. It's great feeling strong. I'm proud of my health. I'm proud of my life. I'm proud of my future.

Consumers



A GUIDE FOR HEALTH CARE PROVIDERS
Integrating Routine HIV Screening Into Your Practice
We consider the likelihood of gender, sexual orientation, age, and ethnicity when choosing who can help make HIV screening and routine health practices for patients in your practice.

Combat stigma
and address barriers to care for those disproportionately affected by HIV.

RESOURCES FOR HEALTH CARE PROVIDERS
HIV Care is Prevention: A Toolkit for Health Care Providers
This toolkit provides resources for health care providers to help patients understand the importance of HIV prevention, including PrEP and PEP, and how to access these services.

RESOURCES FOR HEALTH CARE PROVIDERS
PrEP and PEP for HIV Prevention: A Toolkit for Health Care Providers
This toolkit provides resources for health care providers to help patients understand the importance of HIV prevention, including PrEP and PEP, and how to access these services.

Clinicians

Resources for Clinicians

■ PrEPline

855-448-7737 (855-HIV-PrEP) toll-free

- Clinical care questions
- Access to advanced diagnostics for
 - Ambiguous test results
 - Person who acquire HIV while prescribed PrEP

■ NASTAD

- Billing and coding guide
 - <https://www.nastad.org/resource/billing-coding-guide-hiv-prevention>
- PrEP healthcare coverage calculator
 - [NASTAD \(checkbookhealth.org\)](http://NASTAD.checkbookhealth.org)

■ HIV Nexus

- <https://www.cdc.gov/hiv/clinicians/index.html>



HIV Nexus: A Clinical Resource

- Serves as a one-stop hub for resources designed to support clinicians
- Contains latest research and information on HIV prevention, screening, and treatment
- Provides access to free continuing medical education programs
- Highlights CDC guidelines and recommendations
- Includes patient education materials



www.cdc.gov/HIVNexus



Helping Patients Pay for PrEP Care

- **Commercially insured patients have no out-of-pocket cost for medication, clinical care, and lab tests**
 - USPSTF Grade A recommendation
 - CMS rule
- **Uninsured persons**
 - Healthcare.gov
 - [Get 2022 health coverage. Health Insurance Marketplace® | HealthCare.gov](#)
 - Free medication from
 - [Ready, Set, PrEP \(hiv.gov\)](#) (oral PrEP medication)
 - Gilead Medication Assistance Program (oral PrEP medication)
 - ViiV Medication Assistance Program (cabotegravir injections)



Today, we have an
unprecedented
opportunity to **end**
America's HIV epidemic.

Questions?

