Human Immunodeficiency Virus: Prevention & Management

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NATIONAL LGBTQIA+ HEALTH EDUCATION CENTER
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HRSA Disclaimer

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Objectives

1. Review the history of HIV/AIDS in the US
2. Discuss HIV prevention and treatment modalities such as PrEP, nPEP, and Treatment as Prevention (TasP)
3. Explore options for clinic workflows to increase efficiency in prevention, testing, and treatment of HIV

Agenda

1. Poll Questions - Khan
2. HIV Pre-Exposure Prophylaxis (PrEP) – Khan
3. HIV Non-Occupational Post-Exposure Prophylaxis (nPEP) - Khan
4. HIV Testing – Ard
5. HIV Treatment as Prevention (TasP) - Ard
6. Rapid Anti-Retroviral Treatment (ART) - Ard

Question #1

In the past 3 months, how many patients **have you** actively started on PrEP?

- 0
- 1–2
- 3–5
- More than 5
- I don’t prescribe PrEP

Question #2

When **do you** typically think about PrEP for a patient?

- During routine sexual health screening
- Only if the patient asks
- After an STI diagnosis
- Rarely or never
- I refer patients elsewhere for PrEP

Question #3

Which of the following are current barriers at **your site** to initiating or maintaining patients on PrEP?
(Select all that apply)

- Insurance/medication access issues
- Provider discomfort or lack of training
- Patient hesitancy
- Time constraints in visits
- Lab capacity or follow-up challenges
- None of the above

Question #4

What support would be most helpful to improve HIV prevention and treatment delivery at **your site**?

- More provider/staff training
- Patient education materials
- EMR tools (e.g., alerts, templates)
- Dedicated navigator or PrEP coordinator
- Updated local protocols or guidelines
- Unsure / Other

Question #5

How is PrEP currently integrated into **your clinical** workflow?

- Fully integrated (e.g., standing orders, EMR prompts, standard screening questions)
- Partially integrated (some workflows or staff trained)
- Ad hoc (offered case by case with no set workflow)
- Not currently integrated
- Not applicable to my role/site

Question #6

What is **your level** of comfort discussing U=U (Undetectable = Untransmittable) with patients living with HIV?

- Very comfortable
- Somewhat comfortable
- Neutral
- Somewhat uncomfortable
- Very uncomfortable
- I do not usually have this discussion

Question #7

Have **you ever** prescribed or referred a patient for non-occupational PEP (nPEP)?

- Yes, I have prescribed it myself
- Yes, I've referred to another provider/site for it
- I've heard of it but never used it in practice
- I'm not familiar with nPEP
- Not applicable to my role

HIV/AIDS: A Brief History

1915 -1941

Chimpanzee simian immunodeficiency virus (SIV), likely transferred to humans West Africa

Hahn et al. Science 2000; 287: 607-614

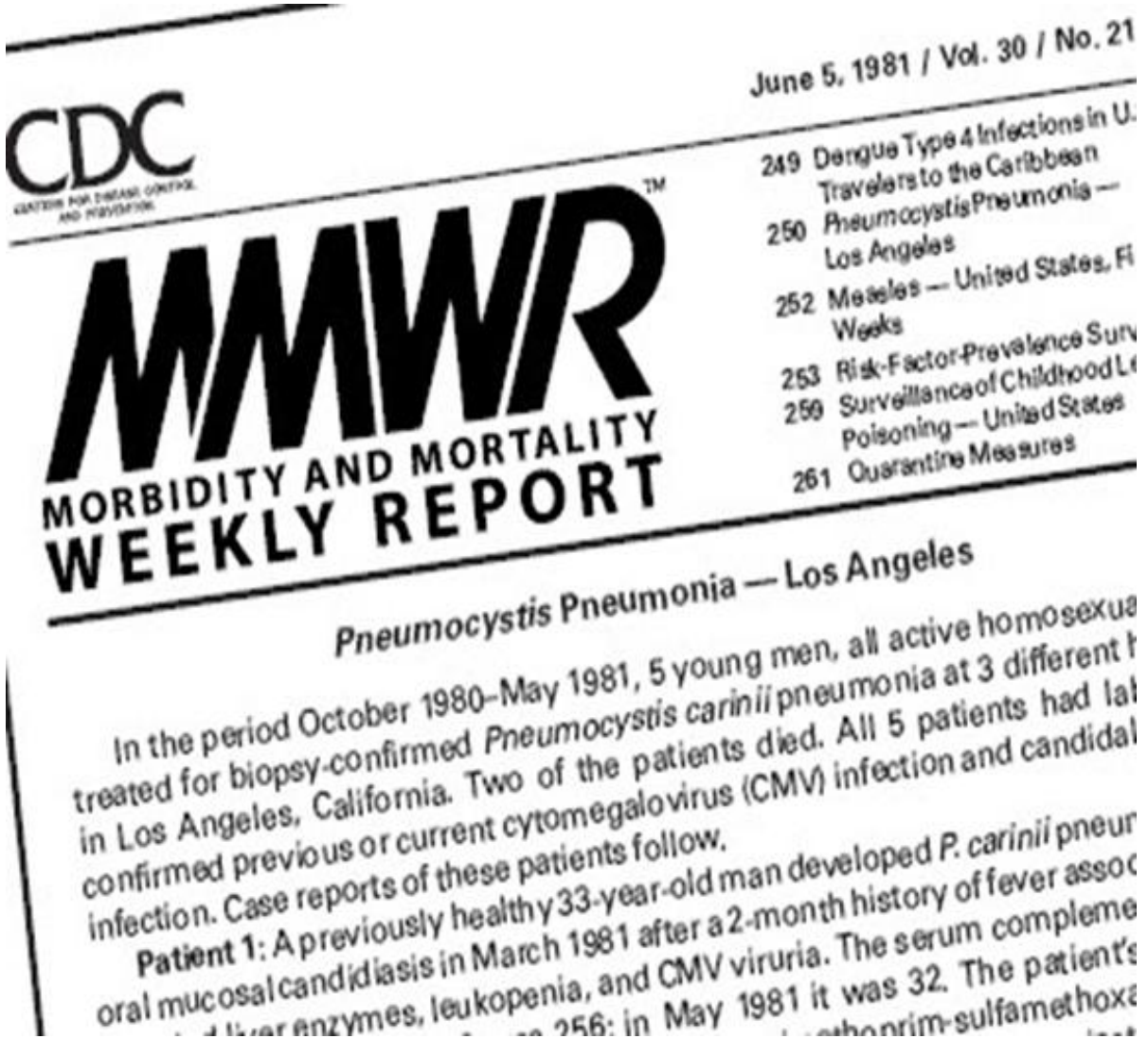
Source: Nature

https://www.nytimes.com/2016/10/27/health/hiv-patient-zero-genetic-

1915 -1941 — Chimpanzee simian immunodeficiency virus (SIV), likely transferred to humans West Africa

1967-1971 — The virus arrived to the United States via Haiti

Also in 1971, Northeastern University students opened a drop-in center in the basement of the Christian Science Church, named the Fenway Community Health Center.



CDC

June 5, 1981 / Vol. 30 / No. 21

MMWR™

MORBIDITY AND MORTALITY
WEEKLY REPORT

Pneumocystis Pneumonia — Los Angeles

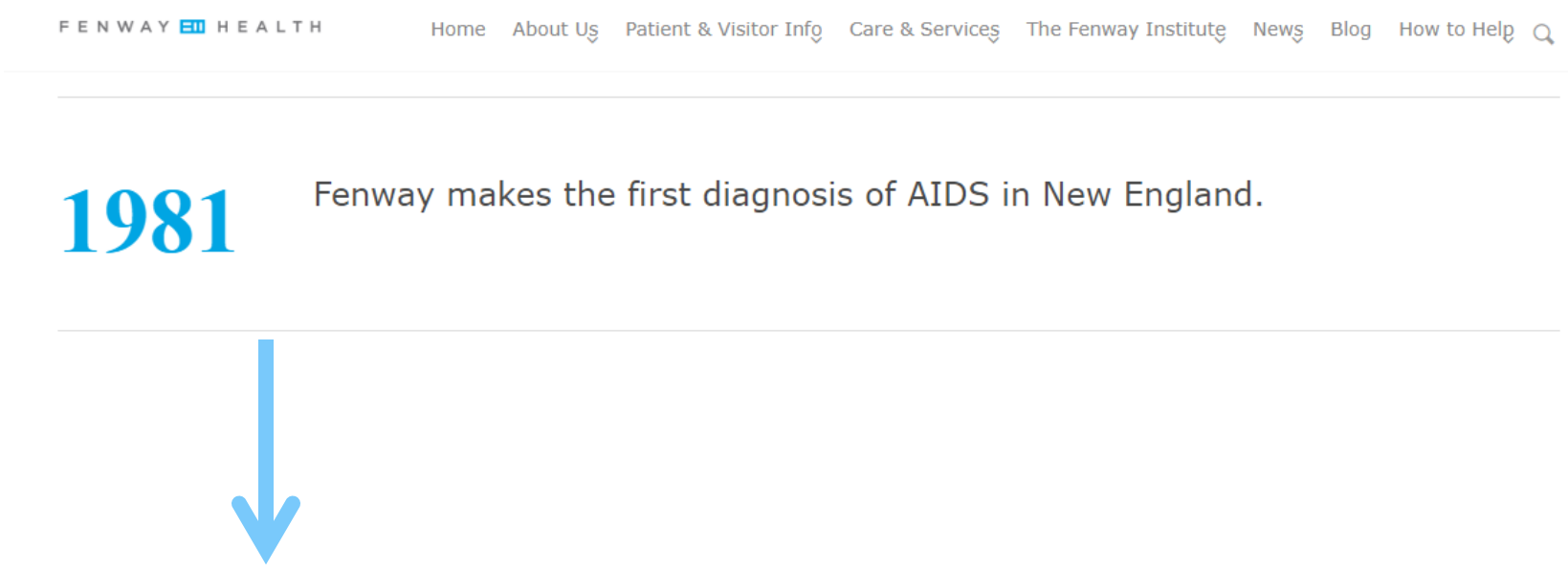
In the period October 1980–May 1981, 5 young men, all active homosexual, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory confirmed previous or current cytomegalovirus (CMV) infection and candidal infection. Case reports of these patients follow.

Patient 1: A previously healthy 33-year-old man developed *P. carinii* pneumonia and oral mucosal candidiasis in March 1981 after a 2-month history of fever associated with elevated liver enzymes, leukopenia, and CMV viruria. The serum complement [illegible] 256; in May 1981 it was 32. The patient's [illegible] thoprim-sulfamethoxa[illegible]

1915 -1941 — Chimpanzee simian immunodeficiency virus (SIV), likely transferred to humans West Africa

1967-1971 — The virus arrived to the United States via Haiti

1981 — First reporting of opportunistic infections and Kaposi's Sarcoma in men who have sex with men (MSM)



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1915 -1941	Chimpanzee simian immunodeficiency virus (SIV), likely transferred to humans West Africa
1967-1971	The virus arrived to the United States via Haiti
1981	First reporting of opportunistic infections and Kaposi's Sarcoma in MSM
1982	"GRID" → CDC coined "The 4H Disease" → AIDS
1983-1984	Two separate research groups led by American Robert Gallo and French investigators Françoise Barré-Sinoussi and Luc Montagnier independently declared that a novel retrovirus may have been infecting AIDS patients.

1985	First FDA approved antibody test developed
1986-1987	Zidovudine (AZT) shown to have antiviral activity
1994	First FDA approved non-blood test : Oral HIV Test
2002	First FDA approved rapid HIV test
2008	“Berlin Patient”: First person cured of HIV/AIDS
2010	iPrEX : Foundation for PrEP
2011	HPTN 052: Early initiation of AVRs
2012	PrEP FDA Approved
2017	U=U Campaign Launched

https://www.avert.org/professionals/history-hiv-aids/overview

Taking A Sexual History

- **Normalize**: "I ask these questions to all my patients to give the best care possible."

- Use the **5 Ps** approach:
  - **Partners** – number, sex, patterns
  - **Practices** – types of sex (oral, anal, vaginal)
  - **Protection** – condom use, PrEP use, U=U awareness
  - **Past STIs** – personal and partner history
  - **Pregnancy** – goals and contraception

- Use **open-ended, nonjudgmental** questions.

- Create a **safe, welcoming space** – avoid assumptions about identity or behavior.

Who is Eligible for PrEP?

Indications for PrEP include:

- Certain communities with recent **STI**, **multiple partners**, or **condomless sex**
- **Heterosexual individuals** with partners living with HIV or with sexual behaviors that increase their likelihood of acquiring HIV
- **People who inject drugs (PWID)** or share injection equipment
- Anyone with **ongoing sexual practice** that increases their likelihood of acquiring HIV and interest in PrEP, regardless of identity

FDA-approved for adolescents and adults

PrEP eligibility should be based on **behaviors, not identity alone**

What PrEP Options Exist?

Oral Daily PrEP (Pills):

- **TDF/FTC (Truvada or generics)** – approved for all populations, including vaginal sex
- **TAF/FTC (Descovy)** – approved for people with penises; not studied for vaginal sex or for PWID

Long-Acting Injectable PrEP:

- **Cabotegravir (Apretude)** – every 2 months after oral lead-in or direct-to-injection option

Choice depends on **patient preference, adherence, side effect profile, insurance coverage**, and **renal health**

What PrEP Options Exist?

Table 4. Recommendations for Currently Approved Biomedical HIV Prevention by Type of Exposure[a]

Type of exposure	Daily TDF/FTC	On-demand ("2-1-1") TDF/FTC	Daily TAF/FTC	Every-other-month intramuscular long-acting cabotegravir[b]
Insertive anal/vaginal sex	✓	✓	✓	✓
Receptive anal sex	✓	✓	✓	✓
Receptive vaginal sex	✓			✓
Receptive neovaginal sex	✓			✓
Injection drug use[c]	✓			
Recommended for pregnant and breastfeeding women	✓			✓
Initiate with a double dose	✓	✓		
Recommended for individuals with reduced creatinine clearance (30-60 mL/min) or who have osteopenia or osteoporosis			✓	✓

Abbreviations: FTC, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

[a] Adapted from Gandhi et al.[2]

[b] Additional recommendations for long-acting cabotegravir: An optional 4- to 5-week oral lead-in is available before starting injections and is recommended for individuals with severe atopic histories or on request. The oral lead-in is not recommended for those who have difficulty adhering to daily oral dosing. Overlapping the first injection with 7 days of oral preexposure prophylaxis (PrEP) is recommended for maximal protection. Oral cabotegravir tablets are recommended for the overlap if an oral cabotegravir lead-in is used to initiate long-acting cabotegravir; otherwise tenofovir-containing oral PrEP can be used for the overlap. Providing a 1-month supply of tenofovir-based oral PrEP is recommended for injection delays exceeding 7 days. Administer gluteal injections at 600 mg, with the first 2 injections spaced 4 weeks apart and subsequent injections every 8 weeks. If injections are delayed by 8 weeks or more, resume with 2 injections 4 weeks apart before returning to the every-8-weeks schedule. If long-acting cabotegravir is discontinued but HIV protection is still required, transitioning to an alternative prevention method is recommended.

[c] Persons who inject drugs should also be assessed for sexual routes of exposure to HIV, and PrEP choice made considering that route of exposure as well (see text for the strength of the recommendations and quality of the data).

Gandhi RT, Landovitz RJ, Sax PE, et al. Antiretroviral Drugs for Treatment and Prevention of HIV in Adults: 2024 Recommendations of the International Antiviral Society–USA Panel. *JAMA.* 2025;333(7):609–628. doi:10.1001/jama.2024.24543

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What Are the Future PrEP Options?

- **Lenacapavir (LEN)** – under investigation as a **6-month subcutaneous injection**
- **Implantable PrEP** – slow-release drug implants similar to contraceptive implants
- **New Oral Options** – new classes of drugs, include those that require weekly dosing
- **Multipurpose prevention products** – combined **HIV + contraception** or **HIV + STI** prevention tools in development, Behavioral Congruent options: **rectal TDF douche**

What is nPEP (Non-Occupational PEP)?

nPEP is a **28-day course of antiretroviral medications** taken after a potential HIV exposure

Should be **started within 72 hours** of the exposure — the **sooner, the better**

Indications include:

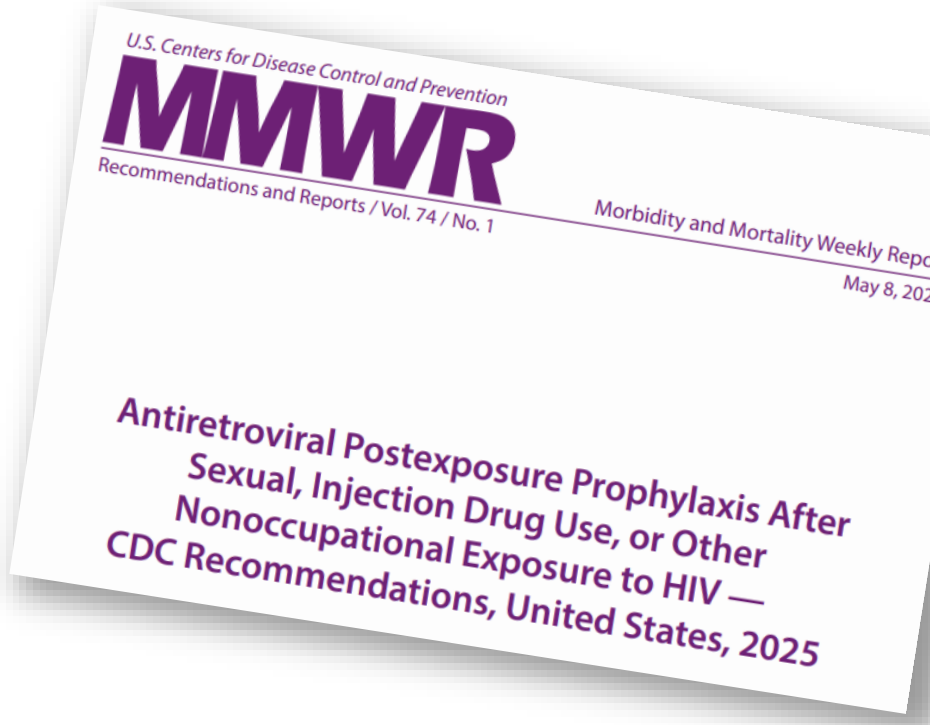
- Condomless sex or condom failure with a partner of unknown or positive HIV status
- Sexual assault
- Shared needles or injection equipment

What is nPEP (Non-Occupational PEP)?

Recommended regimens (as of CDC 2025):
• bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF)
• dolutegravir (DTG) plus (tenofovir alafenamide [TAF]) or tenofovir disoproxil fumarate [TDF]) plus (emtricitabine [FTC] OR lamivudine [3TC])

Follow-up care includes:

- Baseline and repeat HIV testing (at 4–6 weeks, 3 months, and sometimes 6 months)
- STI testing, pregnancy testing, hepatitis B/C screening
- Transition to **PrEP** if ongoing risk exists



Who Gets Tested for HIV?

CDC Recommendation:
- Everyone aged 13–64 should be tested for HIV at least once.

Annual testing is recommended for:
- Sexually active men who have sex with men (MSM)
- People who have multiple partners, STIs, or exchange sex for money/drugs
- People who inject drugs and share needles

Opt-out testing is the preferred model in most clinical settings.

Pregnant individuals should be tested early in pregnancy and again in the third trimester (optional).

Testing should be offered more frequently (e.g., every 3–6 months) tailored to individual sexual practices.

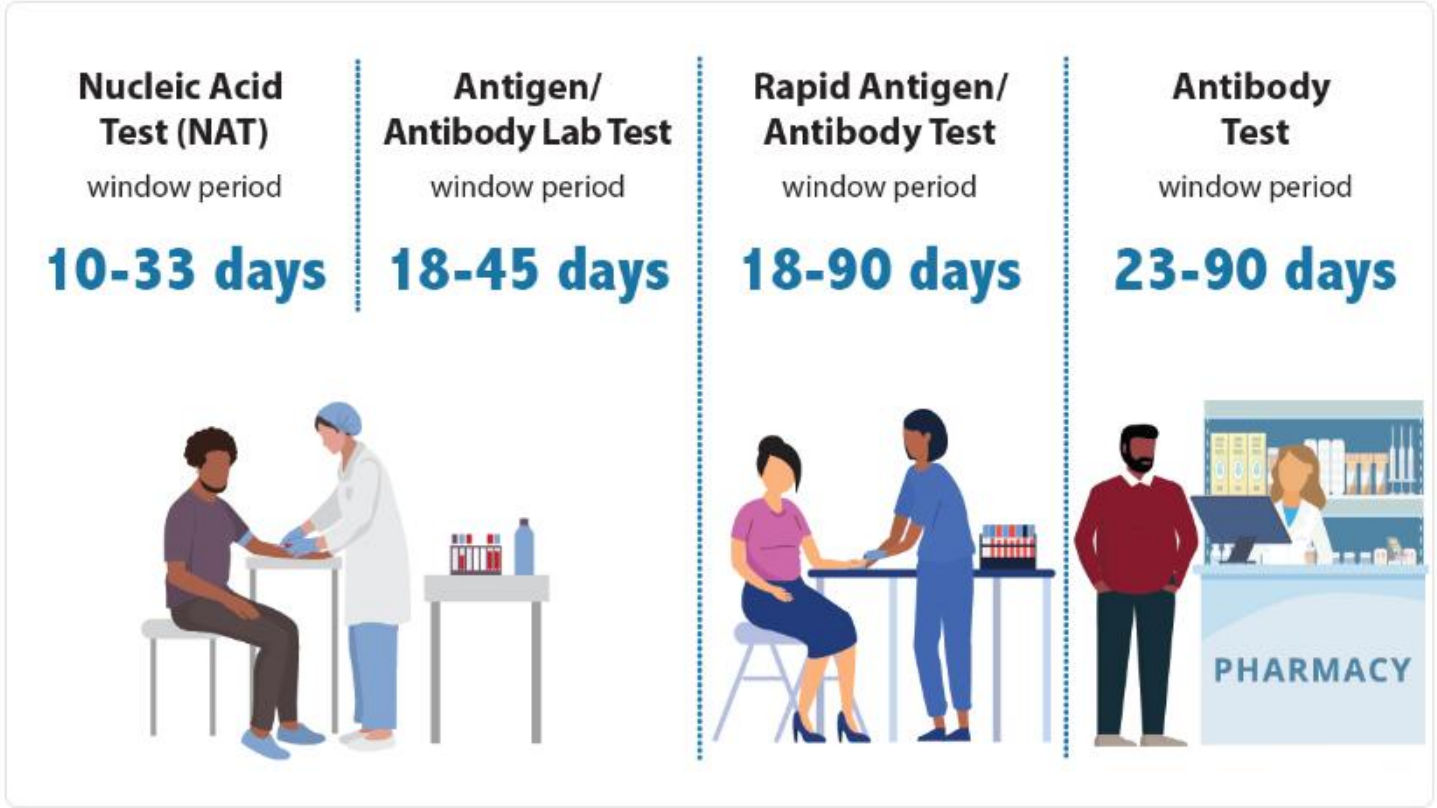
HIV testing and treatment

Learning objectives

1. Describe evidence-based approaches to HIV testing for people taking PrEP.
2. Summarize the evidence for and implications of Undetectable=Untransmittable (U=U).
3. Outline how to provide rapid initiation of antiretroviral therapy for people diagnosed with HIV.

HIV testing for people taking PrEP

Types of HIV tests



CDC: HIV monitoring for PrEP

PrEP formulation	Recommended testing
Oral	At baseline, every 3 months, and at cessation
Injectable	At baseline, at every injection visit, and at cessation

- The baseline test should occur within a week before initiating PrEP
- For monitoring, both an HIV RNA and an antibody/antibody test are recommended

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. 2021. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

Laboratory monitoring for injectable PrEP

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X	[redacted]	[redacted]	MSM^/[redacted] only	Heterosexually active women and men only	X	MSM/[redacted] only
Gonorrhea	X	[redacted]	[redacted]	MSM/[redacted] only	Heterosexually active women and men only	X	MSM/[redacted] only
Chlamydia	X	[redacted]	[redacted]	MSM/[redacted] only	MSM/[redacted] only	Heterosexually active women and men only	MSM/[redacted] only

* HIV-1 RNA assay

X all PrEP patients

^ men who have sex with men

[redacted]

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. 2021. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

Acute HIV versus the LEVI syndrome

Feature	Acute HIV	LEVI syndrome
Viral replication	Explosive	Smoldering
Symptoms	Fever, chills, malaise, lymphadenopathy	Minimal, often absent
Detection	HIV RNA assays, antigen/antibody tests	Often low/undetectable RNA, diminished/delayed antibody production
Assay reversion	Rare	Common
Duration	1-2 weeks	Months
Transmission	Likely	Unlikely
Drug resistance	No, unless transmitted	Yes, even when the viral load is low

LEVI = Long acting early viral inhibition syndrome

Differentiating breakthrough HIV infection from false-positive results

- CDC guidelines recommend HIV RNA assays for PrEP monitoring, but how to adjudicate ambiguous results is not clear
- In rare cases of breakthrough infection on cabotegravir, assay reversion was common
- Some quantitative HIV RNA assays are not FDA-approved for diagnosis, but a qualitative assay is
- If the HIV RNA assay is 99% specific, one would expect one false positive result per year among 17 people on cabotegravir

Assay Reversion

	Days since 1st HIV pos visit	Rapid test	Ag/Ab test	Qualitative RNA test LLOD 30 c/mL	Confirmatory Ab test	Viral load LLOQ 40 c/mL or single copy	DNA test LLOD 4.09 c/10^6 cells
11 months	0	NR	NR	R		6.1	
	42	NR	NR	NR			
	55	NR	NR	R		ND	
	98	NR	NR	NR			
	105	R	R	NR	NEG		Detect <LLOD
	112	NR	R	NR	NEG		
	119	NR	NR	NR			
	132	NR	R	NR	INDET		ND
	195	R	NR	NR			Detect <LLOD
	235	NR	R	NR	INDET		
	280	NR	R	R	NEG	<40	Detect 5.8
	333	R	R	R	INDET	<40	

Eshleman, CROI 2023, Abstract 160

The IAS-USA no longer recommends HIV RNA assays for PrEP monitoring

"Follow up testing for cabotegravir PrEP breakthrough infections should not routinely include HIV RNA testing but should include a point-of-care rapid HIV antibody test and a laboratory-based antigen/antibody test. RNA testing as part of routine monitoring for PrEP failure is not recommended because such testing has a low positive predictive value and false-positive results have significant negative sequelae."

Gandhi RT, JAMA, 2024

U=U

Undetectable = Untransmittable

CDC: “A person living with HIV who is on treatment and maintains an undetectable viral load has zero risk of transmitting HIV to their sexual partners.”

www.cdc.gov/global-hiv-tb/php/our-approach/undetectable-untransmittable.html#cdc_report_pub_study_section_1-overview

Rapid initiation of antiretroviral therapy

In general, how quickly do people newly diagnosed with HIV at your site start ART?

A. The same day they are diagnosed

B. Within 2 days

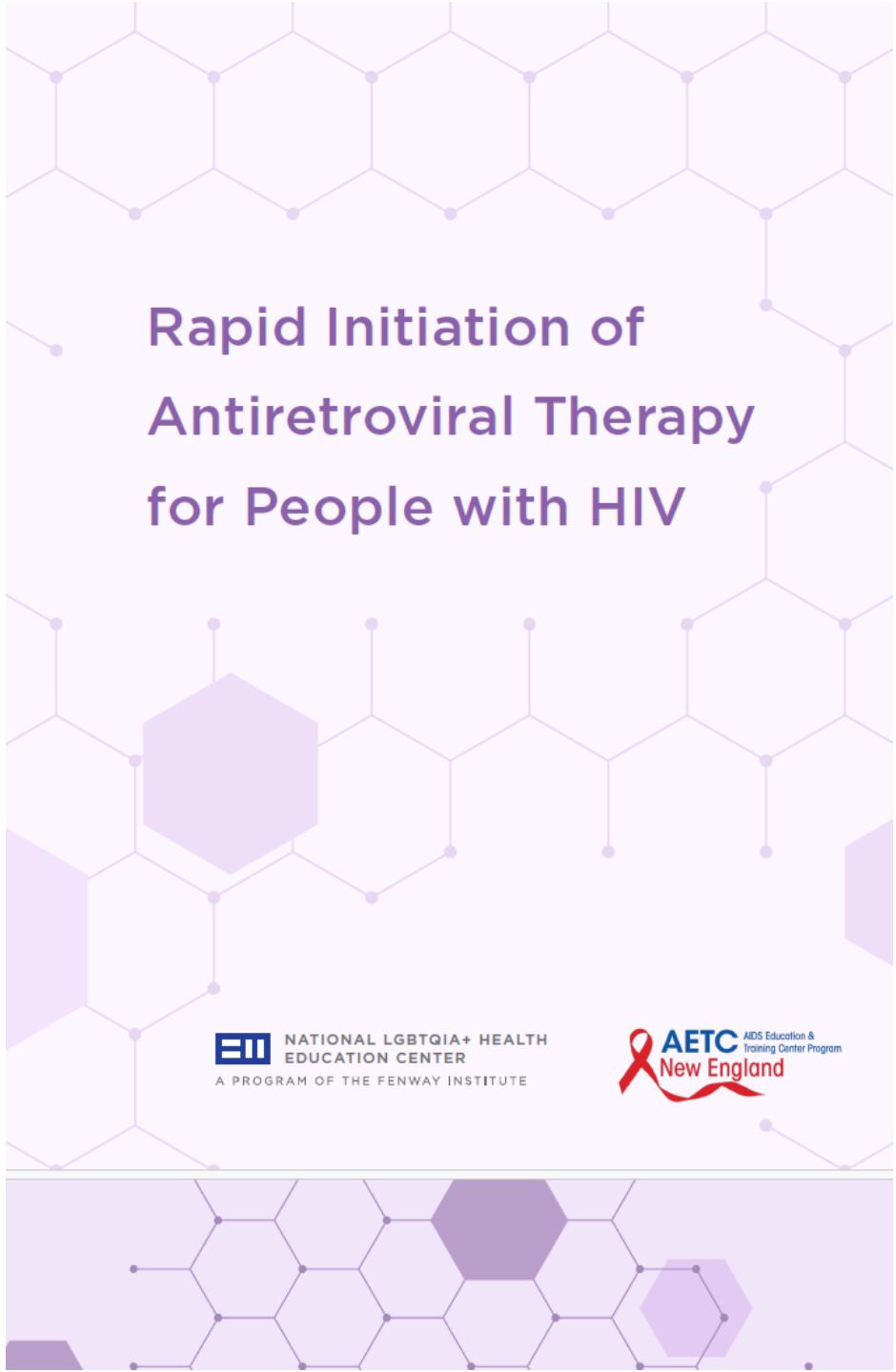
C. Within 1 week

D. Within 1 month

E. More than 1 month after diagnosis

A resource for health centers

www.lgbtqiahealtheducation.org



Definitions of “rapid start” vary

- Department of Health and Human Services guidelines recommend starting antiretroviral therapy (ART) as soon as possible after HIV diagnosis
- The most stringent is “immediate ART,” in which ART is prescribed the same day the HIV diagnosis is made

Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. DHHS. 2019. Available at: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/initiation-antiretroviral-therapy?view=full.

Why initiate ART in a rapid fashion?

- **Improved** linkage to care in randomized trials and observational studies
- **Reduced** mortality in a randomized trial performed in Haiti
- **High levels** of viral suppression at one year, including among people with substance use disorders, mental health conditions, and homelessness

Rosen S, PLoS Med, 2016; Koenig S, PLoS Med, 2017; Labhardt ND, JAMA, 2018; Coffey S, AIDS, 2019

Steps to rapidly initiate ART

1. Counsel patients about the rationale for ART, its expected benefits, and side effects

- ✓ Explore barriers to ART adherence and help overcome those barriers
- ✓ Extensive or numerous counseling sessions are generally unnecessary
- ✓ Many team members – including nurses and case managers – can play a role in counseling

2. Send baseline laboratory tests

- ✓ HIV viral load, CD4 count, drug resistance genotype, hepatitis B and C serologies, liver enzymes, renal function
- ✓ ART will be prescribed before some or all of the above results have returned; this affects medication selection

Steps to rapidly initiate ART, continued

3. Consider contraindications to rapid ART initiation

✓ Diagnosis or concern for some central nervous system opportunistic infections, namely cryptococcal and tuberculous meningitis

4. Select an ART regimen

✓ Avoid regimens with viral load or CD4 count cut-offs for use (e.g., two-drug regimens, rilpivirine-containing regimens)

✓ Avoid regimens more likely to be affected by transmitted drug resistance, those which do not treat hepatitis B, and those which contain abacavir

✓ Common choices: tenofovir alafenamide/emtricitabine/bictegravir OR dolutegravir with either tenofovir alafenamide/emtricitabine or tenofovir disoproxil fumarate/emtricitabine

Steps to rapidly initiate ART, continued

5. Ensure access to medication

- ✓ On-demand access to benefits navigation
- ✓ Starter packs of medication

Summary

- HIV RNA assays are no longer recommended for routinely monitoring people receiving PrEP
- People with HIV who are virologically suppressed on antiretroviral therapy do not transmit HIV to others through sex
- Antiretroviral therapy should be initiated as rapidly as possible after HIV diagnosis; this can often be done the same day the diagnosis is made

Thank You!

Questions/Comments?

Request for Panel Questions

- Session 4 will include a panel discussion on ***A Whole Person Approach to STI Care***
- Panelists
  - **Victor Luna** – Founder & CEO of ProTech Care and previous manager of HIV prevention initiatives
  - **Dr. Taimur Khan** – Interim Co-Director of The Fenway Institute and Primary Care Provider at Fenway Health
  - **Dr. Kevin Ard** – Medical Director of the National LGBTQIA+ Health Education Center and Assistant Professor of Medicine at Harvard Medical School
- Please **submit questions** to Gavin Granitto at **ggranitto@fenwayhealth.org** by **Monday 6/23**
  - Questions can be theoretical or practical, be specific to Victor's work, be around specific barriers you are facing at your site, or anything else you can think of