

So you want to start a PrEP Clinic....

Pearls and pitfalls from a Southern
academic PrEP clinic experience

Mehri McKellar, MD
Duke PrEP Clinic

Learning Objectives

- To understand why we should be providing PrEP and who needs it most
- How to get ready to provide PrEP (with tips!)
- How to actually provide PrEP
- To hear about some real world PrEP clinic examples

Disclosures

- *Advisory boards (Merck, Theratechnologies)*

- *This program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535 as part of an award totaling \$4.2m. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit [HRSA.gov](https://www.hrsa.gov).*

- *“Funding for this presentation was made possible by cooperative agreement U1OHA30535 from the Health Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.”*

AETC Program National Centers and HIV Curriculum

- **National Coordinating Resource Center** – serves as the central web –based repository for AETC Program training and capacity building resources; its website includes a free virtual library with training and technical assistance materials, a program directory, and a calendar of trainings and other events. Learn more: <https://aidsetc.org/>
- **National Clinical Consultation Center** – provides free, peer-to-peer, expert advice for health professionals on HIV prevention, care, and treatment and related topics. Learn more: <https://nccc/ucsf.edu>
- **National HIV Curriculum** – provides ongoing, up –to-date HIV training and information for health professionals through a free, web –based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: www.hiv.uw.edu

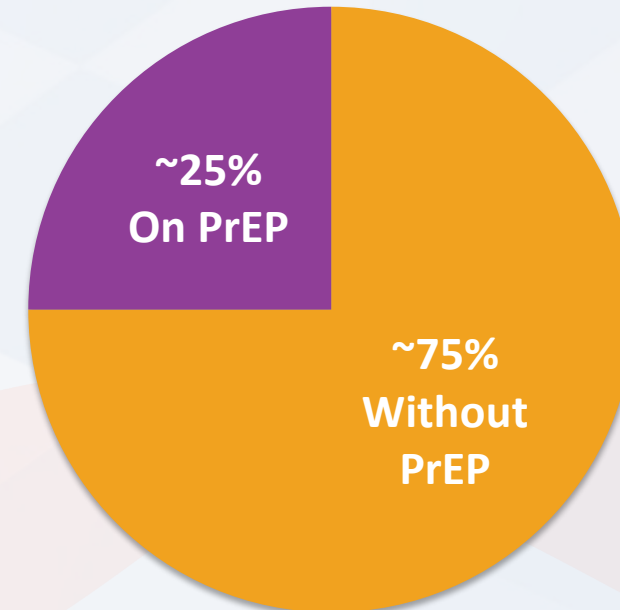
Objective 1

WHY SHOULD WE PROVIDE PREP AND WHO SHOULD BE ON IT

PrEP Coverage in the United States

- PrEP is ~99% effective at preventing HIV acquisition when taken as indicated.¹
- There are ~1.2 million Americans with an indication for PrEP.²

PrEP Use Among Those With an Indication (2020)²



1. [cdc.gov/hiv/basics/prep/prep-effectiveness.html](https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html) [cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf](https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf)

2. [cdc.gov/hiv/pdf/library/reports/surveillance-data-tables/vol-2-no-4/cdc-hiv-surveillance-tables-vol-2-no-4.pdf](https://www.cdc.gov/hiv/pdf/library/reports/surveillance-data-tables/vol-2-no-4/cdc-hiv-surveillance-tables-vol-2-no-4.pdf)

PrEP Coverage by Subgroups in the US

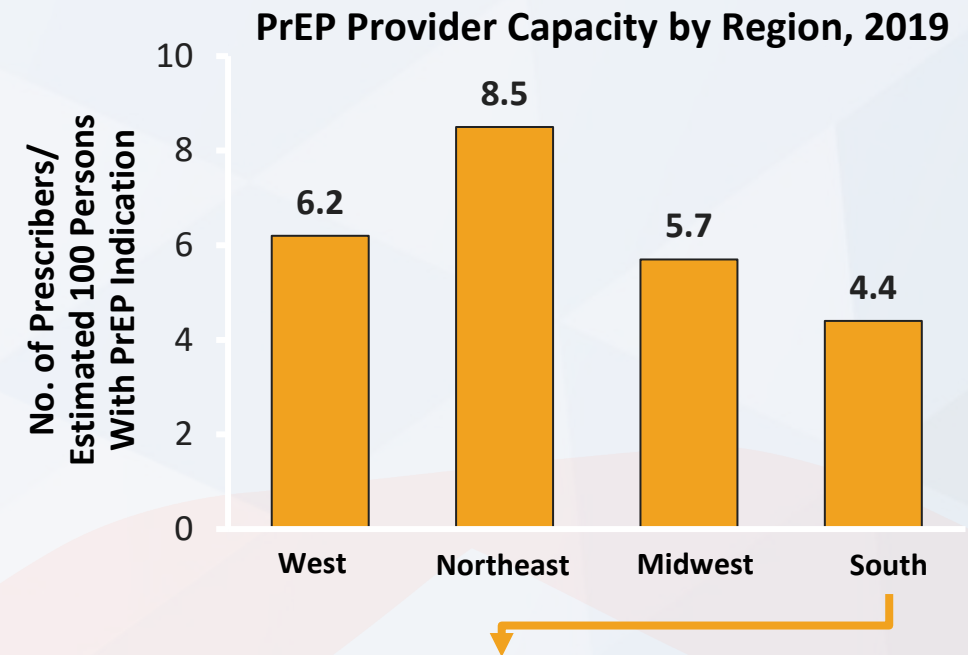
PrEP Coverage by Subgroup in US in 2020 Among Persons Aged ≥16 Yr	Persons Prescribed PrEP of Those With PrEP Indications, %
Sex at birth	
Male	28.0
Female	10.4
Age	
16-24 yr	15.6
25-34 yr	27.4
35-44 yr	30.3
45-54 yr	23.5
≥55 yr	24.6
Race/ethnicity	
Black/African American	9.0
Hispanic/Latinx	15.6
Other	9.4
White	65.7

Key populations with inequities in PrEP uptake

- Black and Hispanic/Latinx people¹
- Cisgender women²
- Transgender women¹
- Adolescents¹
- People who inject drugs¹

CDC: PrEP Prescribers in United States (2014-2019)

- Increases in those who prescribed PrEP from 2014-2019:
 - **All US providers:** 0.7% to 4.3%
 - **Primary care physicians:** 1.8% to 13.6%
 - **ID physicians:** 14.2% to 34.2%
- Number of PrEP providers increased from **9621** in 2014 to **65,822** in 2019
 - 2019: **physicians 68%, NPs 21%, PAs 9%**
 - 93% are in urban areas



- In 2019, the South accounted for:
 - 52% of new HIV infections
 - Largest proportion of people with PrEP indications (41%)

Zhu. *J Acquir Immune Defic Syndr.* 2021;88:282.

Objective 2

HOW TO GET READY TO PROVIDE PREP

Increase awareness of PrEP in your community

- Among providers
 - 76% of PCPs have heard of PrEP (vs 98% of HIV providers).¹
 - Fewer PCPs have felt familiar prescribing (28% vs 76% of HIV providers or have ever prescribed PrEP (17% vs 64%).
- Among patients
 - Patient awareness increasing overall but still lower among Hispanic and non-Hispanic Black MSM²⁻³.

1. Petroll. *AIDS Behav.* 2017 May;21(5):1256-1267. 2. Sullivan. *J Int AIDS Soc.* 2020;23:e25461. 3. Raifman. *AIDS Behav.* 2019;23(10):2706-2709.

How to increase awareness and willingness

- Educational campaign for providers and patients
- Advertising/social media

Duke PrEP Clinic for HIV Prevention



Call for an Appointment
919-385-0436

[Services](#)

[Our Providers](#)

[Insurance](#)

[Preparing For Your Visit](#)

Duke PrEP Clinic for HIV Prevention

Type: Duke University Hospital Outpatient Department

Hospital-based clinics are an extension of Duke Health hospitals and have additional facility charges. Some insurance companies process bills with a deductible and coinsurance rather than as a co-pay as for an office visit. This may impact the amount of the bill you are responsible for after payment from your insurance plan. Check with your insurance company before your visit to determine what your responsibility will be.

The Duke PrEP Clinic specializes in offering pre-exposure prophylaxis (PrEP) to HIV-negative individuals at risk for HIV infection who are interested in PrEP as a means to prevent HIV.

Clinic Hours

Mon

Tues

Wed

Thur

Fri

Sat

Sun



Duke Clinic
40 Duke Medicine Cir
Clinic 1K, Room 5
Durham, NC 27710-4000

 [Get Directions](#)



Appointments
919-385-0436

Office

919-668-3197



Fax

919-613-6430

Be Prepared

PrEP to prevent
HIV infection



DukeHealth



To schedule an appointment, call: 919-620-5300

Protect Yourself With PrEP

PrEP

(pre-exposure prophylaxis)

- for anyone concerned about becoming infected with HIV
- one pill, once each day
- taking it daily gives **very strong** protection against HIV
- covered by insurance
- assistance is available if you don't have health insurance

PrEP might be right for you if

- you use condoms sometimes or not at all
- you are a man who has sex with men
- you have a sexual partner(s) who is HIV-positive or multiple partners with unknown status
- you have been treated recently for an STD, such as syphilis or gonorrhea
- you inject drugs intravenously

Advertising PrEP services

- When ready, list your services on locator pages
 - PrEPlocator.org
 - HIV.gov
 - CDC's NPIN PrEP locator widget
 - Pleaseprepme.org

US PrEP Provider Directory: X
 https://prelocator.org

PrEP Locator Find Your Provider

About Us | Locator Data | FAQ | Add Provider | Add Locator To Your Site | Contact

Zip code or city & state, or full address

PrEP for uninsured
 PrEP access assistance

Duke Infectious Diseases Clinic
 40 Duke Medicine Circle
 Clinic 1K
 Durham, NC 27710
 919-620-5300
 Distance from your location: 0.1 miles

Lincoln Community Health Center
 1301 Fayetteville St.
 Durham, NC 27707
 919-956-4000
 Distance from your location: 2.8 miles

Chapel Hill CHC
 1828 Martin Luther King Jr. Blvd.
 Chapel Hill, NC 27514
 919-951-7600
 Distance from your location: 7.3 miles

Orange County HD - Chapel Hill
 2501 Homestead Rd
 Chapel Hill, NC 27516
 919-968-2022
 Distance from your location: 8.1 miles

UNC Family Medicine
 590 Manning Drive
 Chapel Hill, NC 27599
 919-966-0210

[Add PrEP Locator to Your Site](#)
[Suggest a provider for the directory](#)

please PrEP me .org

Stay HIV Negative | Paying for PrEP | Where Can I get PrEP/PEP? | About

Enter your city or ZIP code

Filters | Select...

Search tips

Sort: Distance: nearest first

View Online Providers

WakeMed Health and Hospitals - Primary Care Downtown Raleigh

- 150 E Davis St, Two Progress Plaza, Raleigh, NC 27601 | 0.29 mi
- (919) 834-5299 (main) | Directions
- Website

Advance Community Health - Southeast Raleigh

- 1011 Rock Quarry Rd, Raleigh, NC 27610 | 1.54 mi
- (919) 833-3111 (main) | Directions
- Website

Avance Care

- 815 Oberlin Rd, Suite 200, Raleigh, NC 27605 | 1.70 mi
- (919) 322-4722 (main) | Directions
- Website

Wake County Human Services - Public Health Center

- 10 Sunnybrook Rd, Clinic A, Raleigh, NC 27610 | 2.93 mi

Map | Satellite

Keyboard shortcuts | Map data ©2022 | Terms of Use | Report a map error

Duke PrEP Clinic posters

ONE PILL A Una Píldora al dia



TO PREVENT Previene el VIH

DON'T WAIT, GET PrEP No esperes, adquiere **PrEP** hoy!

ASK YOUR PROVIDER, OR CALL (919) 385-0436 Habla con tu doctor o llama al 919-385-0436



DUKE PrEP CLINIC
 for HIV PREVENTION
 40 Duke Medicine Circle
 Clinic 1K
 Durham, NC 27710

ONE PILL A DAY TO PREVENT HIV
DON'T WAIT, GET PrEP TODAY

(919) 385-0436
DukeHealth
DUKE PrEP CLINIC
 for HIV PREVENTION
 40 Duke Medicine Circle
 Clinic 1K
 Durham, NC 27710

(919) 385-0436
DukeHealth
DUKE PrEP CLINIC
 for HIV PREVENTION
 40 Duke Medicine Circle
 Clinic 1K
 Durham, NC 27710



**JUST ONE PILL
CAN PROTECT YOU FROM
HIV**



**DON'T WAIT
GET PrEP
TODAY.**

ASK YOUR PROVIDER, OR CALL

**JUST ONE PILL
CAN PROTECT YOU FROM
HIV**



**DON'T WAIT
GET PrEP
TODAY.**



DukeHealth

DUKE PREP CLINIC
for HIV PREVENTION
40 DUKE MEDICINE CIRCLE
CLINIC 1K
DURHAM, NC 27710

ASK YOUR PROVIDER, OR CALL (919) 385-0436

**JUST ONE PILL
CAN PROTECT YOU FROM
HIV**



**DON'T WAIT
GET PrEP
TODAY.**



DukeHealth

DUKE PREP CLINIC
for HIV PREVENTION
40 DUKE MEDICINE CIRCLE
CLINIC 1K
DURHAM, NC 27710

ASK YOUR PROVIDER, OR CALL (919) 385-0436

Community Events

TEC & COMMUNITY PARTNERS PRESENTS
PREP NAKED RAINBOW AFFAIR
 Triangle Empowerment Center Presents
Dinner, Cocktails and Conversation
 Join TEC for an evening of fellowship and conversation, health and community engagement.

Free! 21+ Only
 Limited Seating | RSVP (800) 806-3555
 August 19 6-10 PM @ ReCity
 112 Broadway St. Durham, NC



DukeHealth

El Centro Hispano

AGOSTO 25
 7PM

25 @ El Centro Hispano
 Celebrando 25 años de fundación - Celebrando a la Comunidad Latina

FREE Activities:
 Health Screenings
 Dental Services
 Health Information
 Cooking Demos
 Prizes and Giveaways
 Live Entertainment and more!

Latino Community Center
WELLS FARGO

Miss HISPANIDAD 2017



AGOSTO 25
 7PM

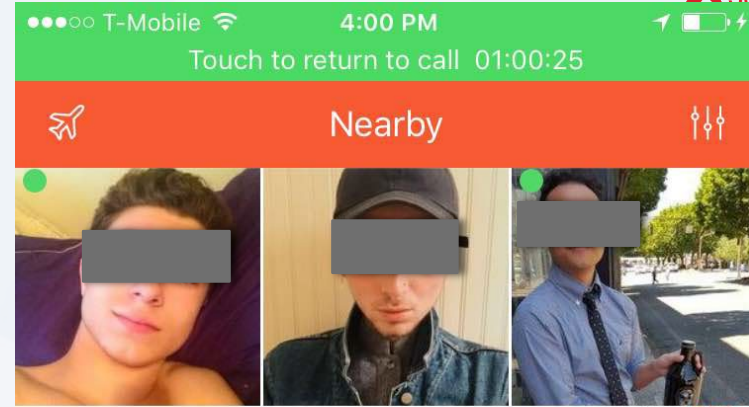
25 @ El Centro Hispano
 Celebrando 25 años de fundación - Celebrando a la Comunidad Latina

ENTRADA: \$10.00
 TICKETS A LA VENTA EN EL CENTRO HISPANO INC. (919) 687-4635

DURHAM ARTS COUNCIL
 120 MORRIS ST DURHAM, NC 27701

LATINO COMMUNITY CENTER
Latino Community Center
WELLS FARGO

Dating Apps



					
Campaign: Duke University Flight Dates: 4/1/17-6/27.17 Market: Durham, NC					
Campaign Creative	Start	End	Impressions	Clicks	CTR
300x50 Mobile Banner	4/1	6/27	1,047,465	9,020	0.86%
320x480 Full Screen Interstitial	4/1	6/27	20,328	915	4.50%
Total			1,067,793	9,935	2.58%

Durham County Bus Ads



**ONE PILL,
ONCE A DAY,
CAN DECREASE
YOUR RISK OF HIV.**

Call (919) 560-8819 at the Durham County
Department of Health, or (919) 620-5300
at Duke Health to schedule an appointment.

Find out more at durhamknows.org

 Partnership for a Healthy Durham

DURHAM KNOWS
GET TESTED. STAY SAFE.



Tip 2: Make sure you have financial assistance help for patients

- Patients will need help for navigating financial aid options
- Thinking about costs
 - Medication, lab tests, clinic visits

USPSTF recommends PrEP, June 2019



Final Recommendation Statement

Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis

June 11, 2019

Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.



Recommendation Summary

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. See the Clinical Considerations section for information about identification of persons at high risk and selection of effective antiretroviral therapy.	A

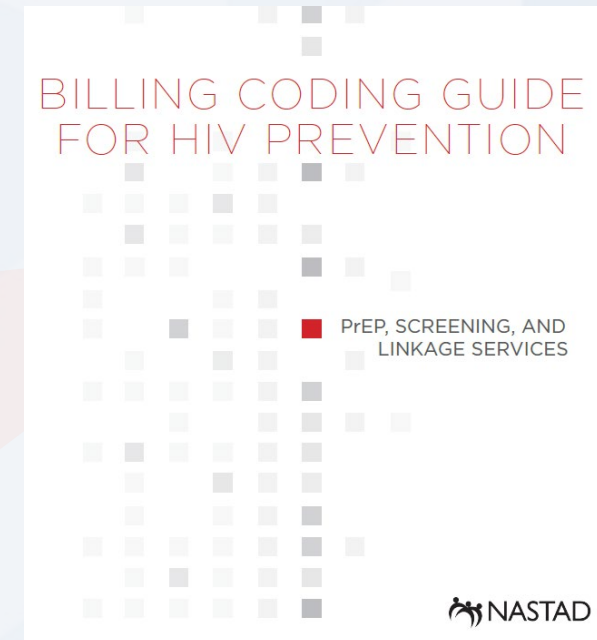
PrEP and cost sharing

- Jan 2021: oral PrEP coverage without cost sharing was mandated following 2019 grade A recommendation by USPS Task Force.
- July 2021: CMS issued clarification that PrEP clinical services include the laboratory testing and behavioral services.



For insured patients – no cost sharing as of Sept 2021

- Non-grandfathered health plans are required to cover **PrEP services** without cost sharing (before deductible and without coinsurance or copayment) due to the USPTF Grade A recommendation
 - Marketplace plans
 - Employer sponsored plans
 - Medicaid expansion programs
 - Medicare provider & lab services
- 23 million people in grandfathered plans
 - Insurances slow to follow these requirements
- Work with your billing office
 - Dedicated CPT codes
 - Modifier 33
 - NASTAD = excellent resource



PrEP is a service, not just a drug...

<https://www.nastad.org/resource/nastad-prep-coverage-brief-prep-services-covered-no-cost-sharing>



NASTAD PrEP Coverage Brief: PrEP Services Covered with No Cost-Sharing July 2021

Pre-exposure prophylaxis (PrEP) – a once daily antiretroviral medication taken to prevent HIV – is an incredibly effective HIV prevention tool. In light of its effectiveness and safety, in June, 2019, the US Preventive Services Task Force (USPSTF) gave PrEP an “A” grade recommendation, noting that “the USPSTF concludes with high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial.” This fact sheet will walk through the coverage and cost-sharing requirements for public and private payers that come with this USPSTF Grade A recommendation.

What Does a USPSTF Grade A Recommendation Mean for Coverage and Cost Sharing?

The Affordable Care Act (ACA) requires commercial health plans and Medicaid expansion programs to cover select preventive services – including any service with a Grade A or B from the USPSTF – without cost-sharing, which means that these services must be covered before any deductible and without coinsurance or a copayment.¹ Now that PrEP has a Grade A recommendation from USPSTF, most commercial health plans and Medicaid expansion programs must cover PrEP without cost sharing as of January 1, 2021.

Preventive Services

The list of preventive services that must be covered without cost-sharing is based on the recommendations of several expert bodies, including the USPSTF, which is an independent, volunteer panel of national experts in prevention and evidence-based medicine. The USPSTF works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. In addition to PrEP, there are other sexual health services that have a USPSTF A or B grade, including screening for HIV, chlamydia, gonorrhea, HBV, HCV, and Syphilis. A list of preventive services is available at [healthcare.gov/preventive-care-benefits](https://www.healthcare.gov/preventive-care-benefits)

What Plans Must Cover PrEP without Cost Sharing?

All non-grandfathered commercial health plans are required to cover PrEP services without cost sharing. This includes individual marketplace plans, and small and large group employer-sponsored plans. In addition, state Medicaid expansion coverage programs, including Basic Health Plans, must also cover PrEP without cost sharing.

By 17 September 2021, non-grandfathered health plans were required to cover PrEP services without cost-sharing (before deductible and without coinsurance or copayment).

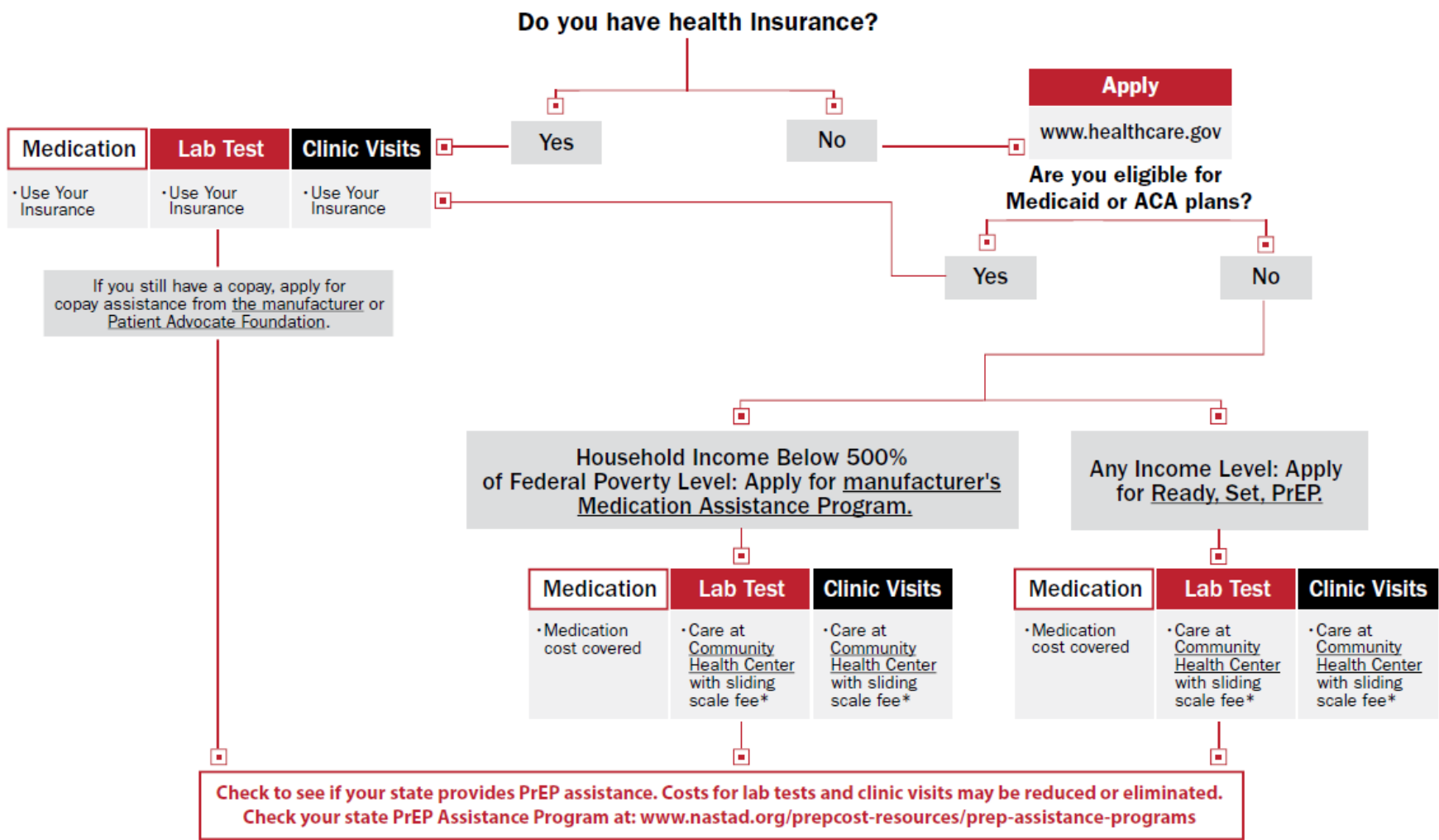
- Marketplace plans
- Employer-sponsored plans
- Medicaid expansion programs
- Medicare provider & lab services

USE E/M MODIFIER 33

For non-insured patients

- Medication
 - Apply for manufacturer's medication assistance program (if household income <500% of FPL) OR
 - Apply for the Ready, Set, PrEP Program (any income level)
- Labs/services
 - Sliding fee scale or charity care plan at your facility?
 - Health department or community health center providing PrEP may be better option
- Are they eligible for Medicaid or ACA plan?

How do I Pay for Pre-Exposure Prophylaxis (PrEP)?



* To find a Community Health Center: findahealthcenter.hrsa.gov



Ending
the
HIV
Epidemic

Objective 3

HOW TO PRESCRIBE PREP

New PrEP Guidelines Dec 2021

HIV uninfected, plus:

Any condomless anal or vaginal sex in past 6m

Any partner(s) with HIV or unknown HIV status in past 6m

Any bacterial STI in past 6m

Shared injection equipment in past 6m

Injecting partner(s) with HIV

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline
Page 1 of 108

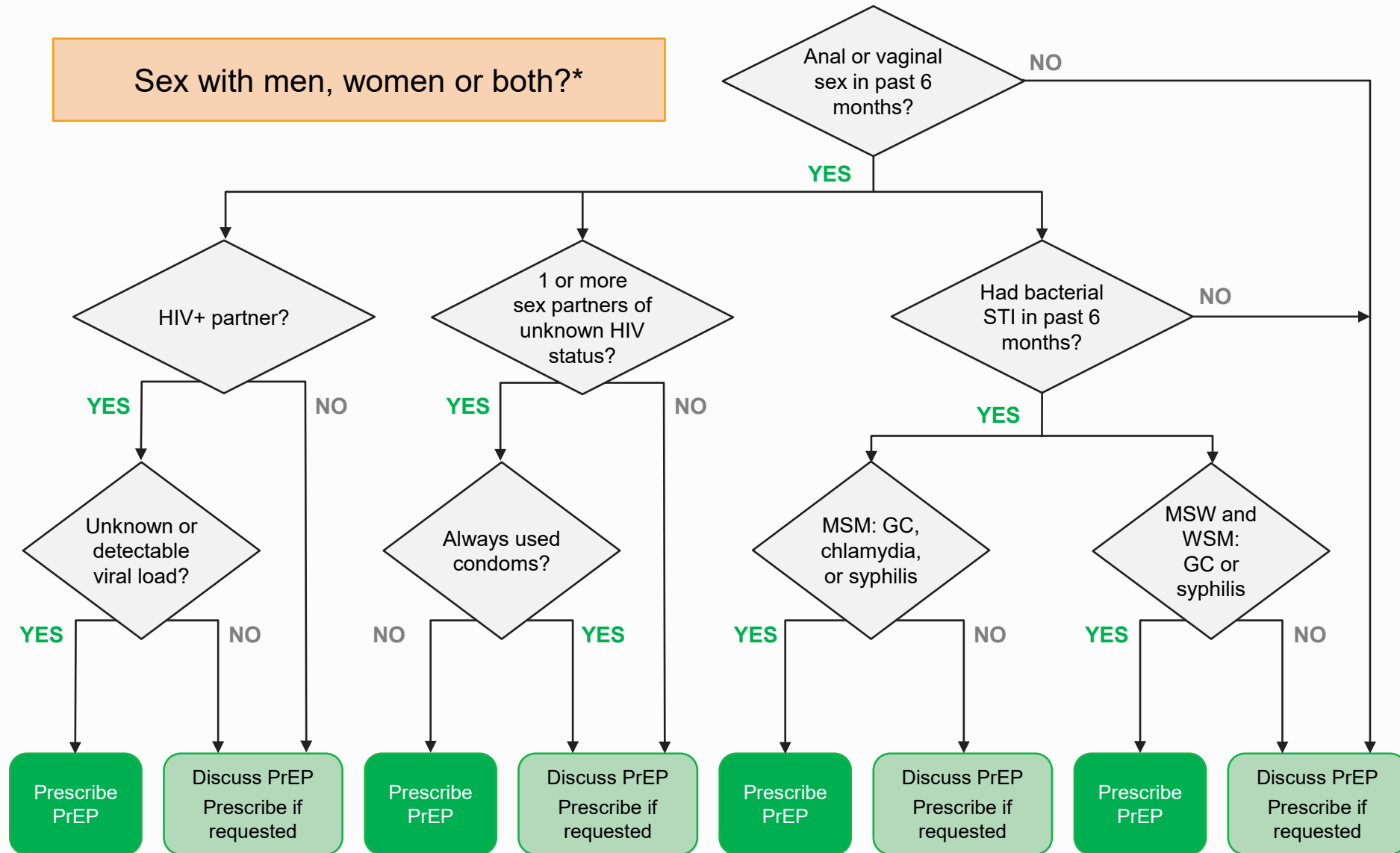
Updated supplement as well

- Patient/provider checklist which includes Descovy, 2-1-1 Truvada for MSM, and cabotegravir
- Patient information sheets
- Risk reduction counseling
- MSM Risk Index
- PWID (IDU) Risk Index
- Transition from PEP to PrEP
- ICD/CPT codes

What's new in 2021 PrEP guidelines

- All sexually active adults and adolescent patients should receive information about PrEP
- Core primary care service
- Increase knowledge among potential users
- Increase knowledge in the community

Assessing eligibility based on sexual risk(s)

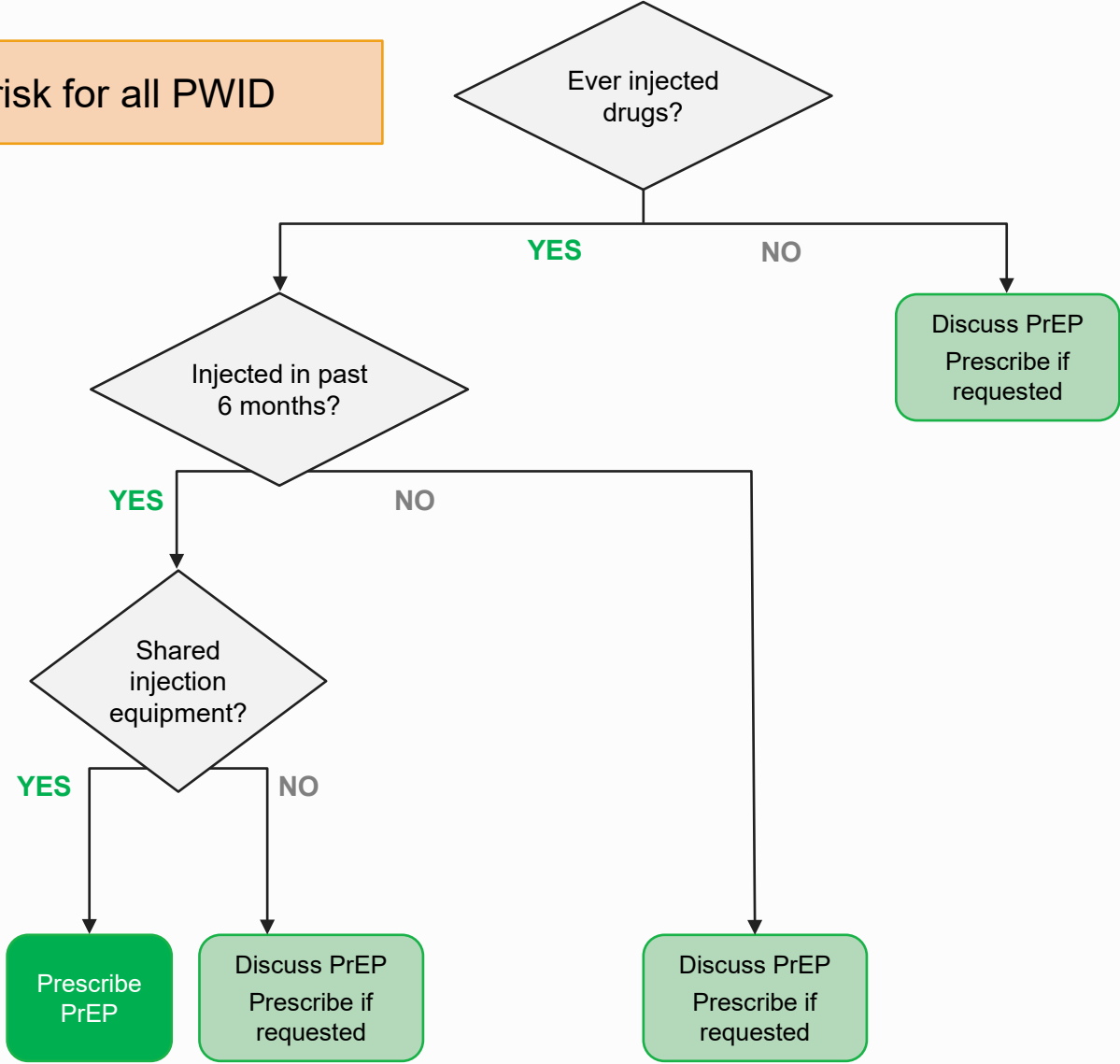


*consider modernizing how you ask this

Adapted from Fig 2 – <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

Assessing eligibility based on injection risk(s)

Assess sexual risk for all PWID



Adapted from Fig 3 – <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

Laboratory test schedule for oral PrEP

	Baseline	Month 3	Month 6	Month 9	Month 12	Stopping PrEP
HIV *	✓	✓	✓	✓	✓	✓
Creatinine & eCrCl †	✓		if ≥ 50 years old or < 90 mL/min at baseline		✓	✓
Syphilis		MSM & TGW (others if sxs)	✓	MSM & TGW (others if sxs)	✓	MSM & TGW (others if sxs)
Gonorrhea	✓	MSM & TGW (others if sxs)	✓	MSM & TGW (others if sxs)	✓	MSM & TGW (others if sxs)
Chlamydia	✓	MSM & TGW (others if sxs)	✓	MSM & TGW (others if sxs)	✓	MSM & TGW (others if sxs)
Lipid panel	If starting F/TAF				If using F/TAF	
Hepatitis B §	✓					
HCV Ab ‡	MSM, TGW and PWID (others per USPSTF)				MSM, TGW and PWID (others per USPSTF)	

* Follow Figures 4a or 4b (or strategies suggested in this presentation) for testing – depends on recency of ARV use, HIV exposure history, and acute HIV symptom screening

† Per the 2021 CDC PrEP Guidelines: “If other threats to renal safety are present (e.g., hypertension, diabetes), renal function may require more frequent monitoring or may need to include additional tests (e.g., urinalysis for proteinuria).”

§ **NOTE:** The 2021 CDC PrEP Guidelines do not specify what to check, but serologies usually include surface antibody (HBsAb), surface antigen (HBsAg), and core total Ab (HBcTAbs).

‡ **NOTE:** Oral PrEP has no effect on hepatitis C virus (HCV). Persons at risk include anyone who injects drugs, anabolic steroids, or body fillers OR anyone who has sex that could result in bleeding, such as fisting or sex under the influence of drugs like cocaine or methamphetamine that alter pain perception. USPSTF (2020) recommends screening all persons 18-79 years old for HCV infection, at least once in their lifetime. Optimal frequency for rescreening is largely based on ongoing risks for HCV acquisition (or lack thereof).

Comparing the oral options



Truvada^{TDF}

emtricitabine / tenofovir disoproxil fumarate

Approved in 2012

Proven to protect people during:

- Injection drug use
- Insertive vaginal sex
- Insertive anal sex (topping)
- Receptive vaginal sex
- Receptive anal sex (bottoming)

Descovy^{TAF}

emtricitabine / tenofovir alafenamide fumarate

Approved in 2019

Proven to protect people during:

- ~~Injection drug use~~
- ~~Insertive vaginal sex~~
- Insertive anal sex (topping)
- ~~Receptive vaginal sex~~
- Receptive anal sex (bottoming)

Comparing the oral options



Truvada^{TDF}

emtricitabine / tenofovir disoproxil fumarate

Generics available

Negligible weight loss within first 6m of use, then return to baseline

Asymptomatic, reversible renal dysfunction in ~2 of 100 users

Descovy^{TAF}

emtricitabine / tenofovir alafenamide fumarate

No generics available

Significant weight gain (1.1 kg = 2.5 lbs.) after 2Y

No significant adverse effects on renal function

Comparing the oral options



Truvada^{TDF}

emtricitabine / tenofovir disoproxil fumarate

Can be used “on demand”

Bone density loss of ~1.5% within 3-6 months of initiation among persons who have achieved peak bone mass

Lowers HDL and LDL
 (“good” and “bad” cholesterol levels)

Descovy^{TAF}

emtricitabine / tenofovir alafenamide fumarate

CANNOT be used “on demand”

No significant adverse effects on bone density / health

Elevated triglycerides observed
 in DISCOVER trial

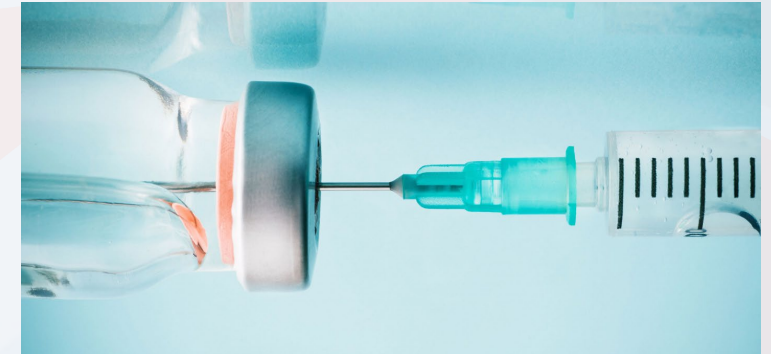
Injectable cabotegravir approved 12/2021

Apretude, IM injection Q 2 mo

Proved superior to oral FTC/TDF among cisgender MSM, cisgender WSM and trans women¹⁻²

Tolerability very high, with few participants in clinical trials stopping injections

No data for IDU



1. Landovitz, et al. "Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women". *N Engl J Med* 2021.

2. Delany-Moretlwe, et al. Cabotegravir for the prevention of HIV-1 in women: Results from HPTN 084, a phase 3, randomised clinical trial. *Lancet* 2022.

Laboratory test schedule for injectable PrEP

	Baseline	Month of Follow-Up							Stopping PrEP	
		1	2	4	6	8	10	12		
HIV	Ag/Ab* (± RNA)	Ag/Ab AND RNA	Ag/Ab AND RNA	Ag/Ab AND RNA	Ag/Ab AND RNA	Ag/Ab AND RNA	Ag/Ab AND RNA	Ag/Ab AND RNA	Ag/Ab AND RNA	
Creatinine & eCrCl ††	???									
Syphilis	✓	only if symptoms	only if symptoms	MSM & TGW (others if sxs)	Hetero men & women (others if sxs)	MSM & TGW (others if sxs)	only if symptoms	✓	MSM & TGW (others if sxs)	
Gonorrhea	✓	only if symptoms	only if symptoms	MSM & TGW (others if sxs)	Hetero men & women (others if sxs)	MSM & TGW (others if sxs)	only if symptoms	✓	MSM & TGW (others if sxs)	
Chlamydia	✓	only if symptoms	only if symptoms	MSM & TGW (others if sxs)	Hetero men & women (others if sxs)	MSM & TGW (others if sxs)	only if symptoms	✓	MSM & TGW (others if sxs)	
Lipid panel										
Hepatitis B §	???									
HCV Ab ‡	???								???	

* Follow Figures 4a or 4b for baseline testing – depends on recency of ARV use, HIV exposure history, and acute HIV symptom screening

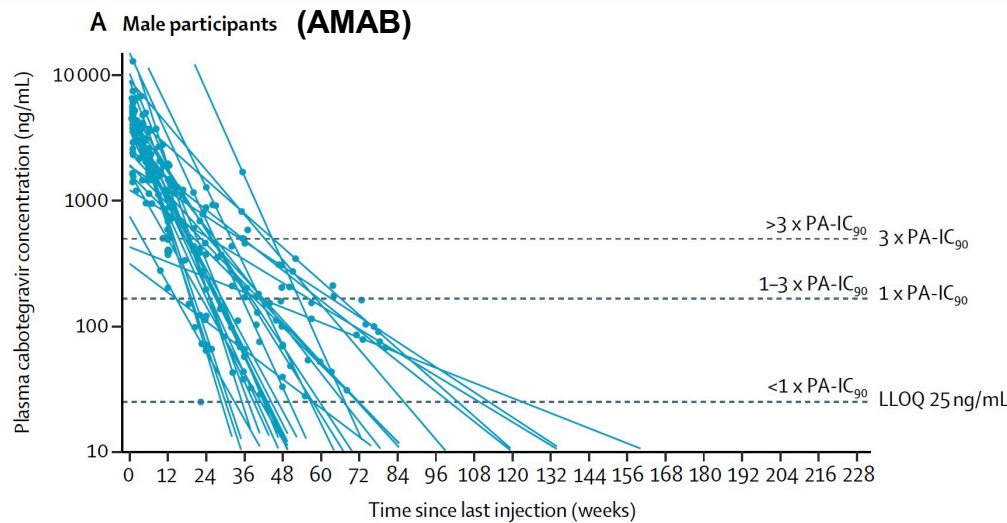
†† **DR. HURT'S OPINION:** Knowing baseline creatinine and eCrCl could be clinically useful even though CAB has no effect on renal function. Patients who stop CAB injections must switch to oral PrEP to “cover the tail” as CAB levels fall. One could wait to check creatinine prior to initiating oral PrEP... or also check it at baseline (thinking/planning ahead).

§ **DR. HURT'S OPINION:** Checking baseline hepatitis B serologies is clinically reasonable, even though CAB has no effect on HBV replication. Patients who stop CAB injections must switch to F/TAF or F/TDF to “cover the tail” of falling CAB levels, and both forms of oral PrEP affect HBV. One could wait to check prior to initiating oral PrEP, or check at baseline. In Table 8 of the 2021 CDC PrEP Guidelines, providers are encouraged to administer HBV vaccine to susceptible, at-risk persons.

‡ **NOTE:** The 2021 CDC PrEP Guidelines recommend HCV screening for persons starting oral PrEP but do not comment on screening for persons starting CAB. CAB has no effect on hepatitis C replication, but it's reasonable to check for HCV if the patient is at risk. This includes persons who inject drugs, anabolic steroids, or body fillers OR anyone who has sex that could result in bleeding, such as fisting or sex under the influence of drugs like cocaine or methamphetamine that alter pain perception. USPSTF (2020) recommends screening all persons 18-79 years old for HCV infection, at least once in their lifetime. Optimal frequency for rescreening is largely based on ongoing risks for HCV acquisition (or lack thereof).

Cabotegravir takes months to “wash out”

CAB’s pharmacokinetic “tail” is a VERY important consideration



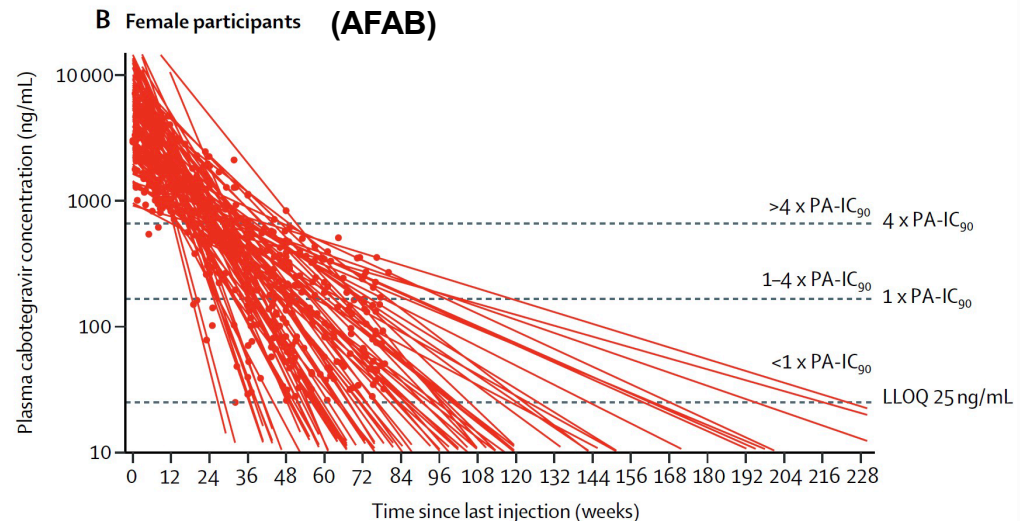
CAB dropped below LLOQ after a median of

10 months

among participants assigned male at birth (IQR 7-15; range 5-35)

15.5 months

among participants assigned female at birth (IQR 7-21; range 4-52)

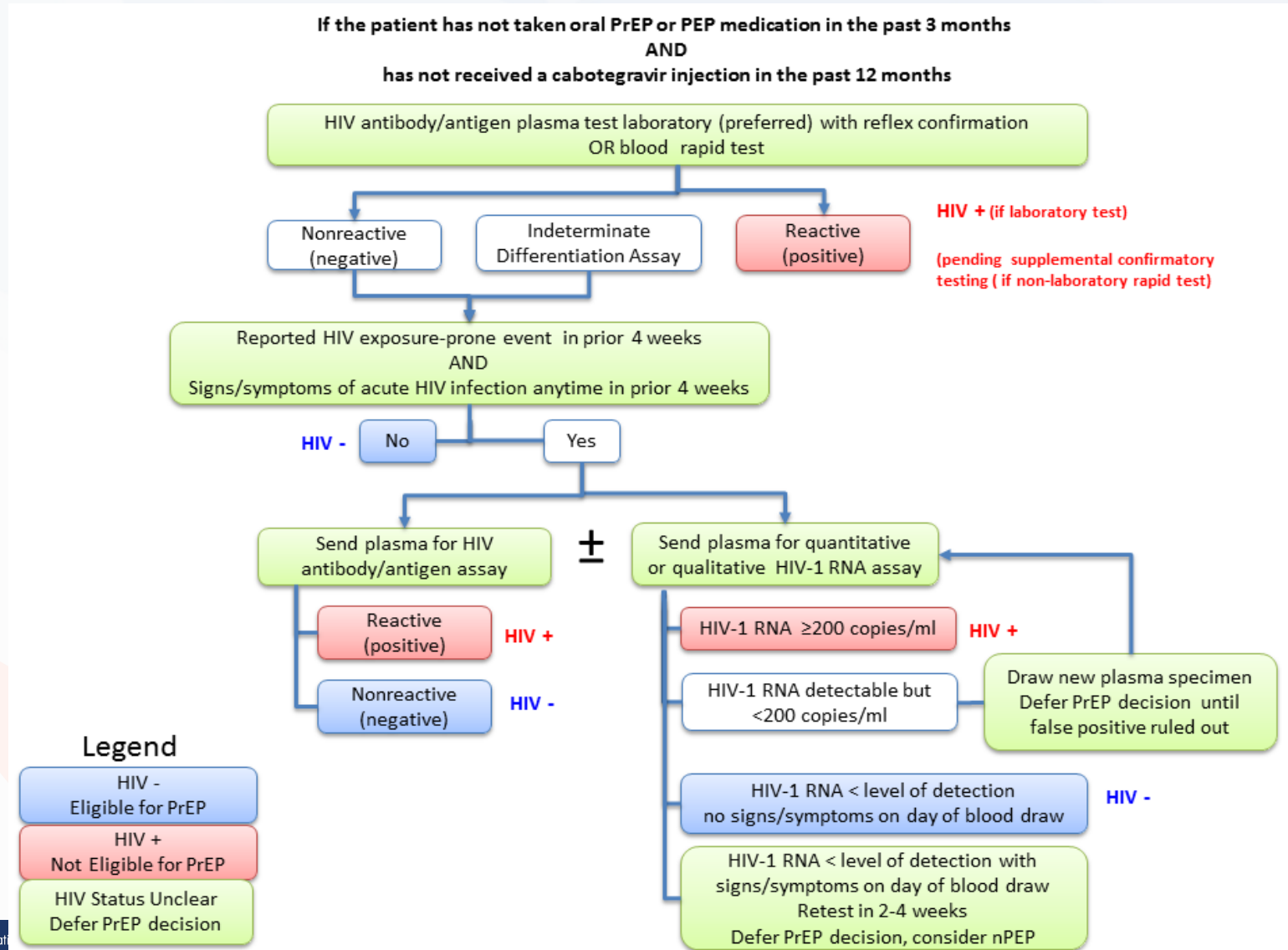


Revised HIV testing algorithms

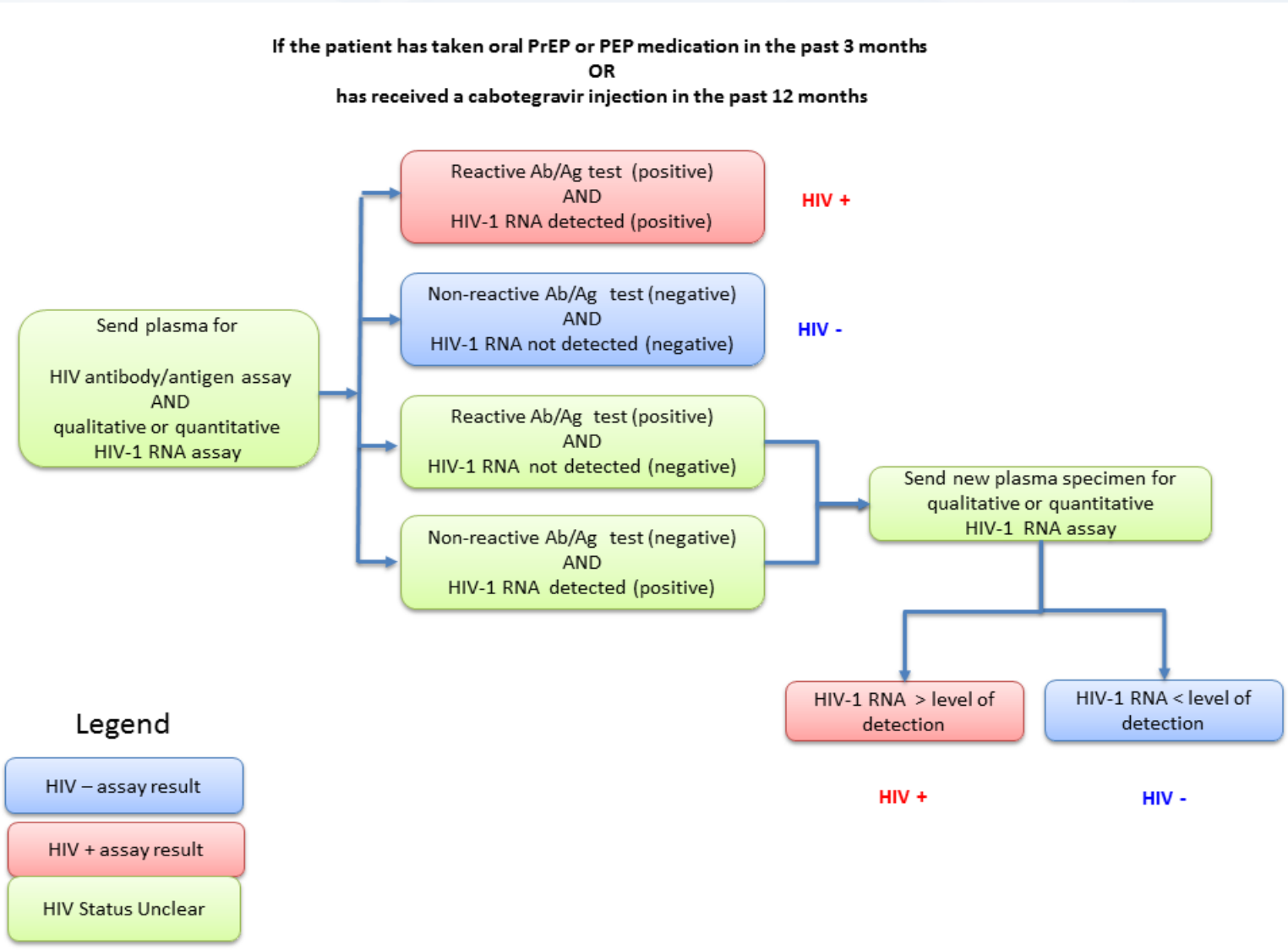
#1 - No recent ARV exposure who are starting/restarting PrEP

#2 - Follow up visits in persons who are taking or recently taking PrEP

New testing algorithm



New testing algorithm #2

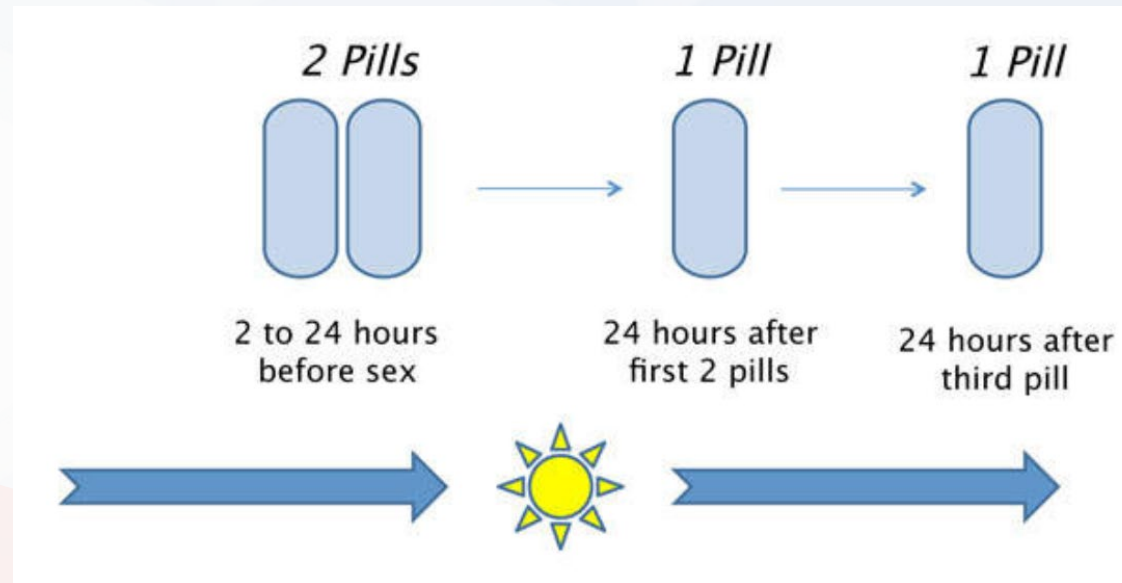


On-demand PrEP (in CDC guidelines)

ORIGINAL ARTICLE

On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

Jean-Michel Molina, M.D., Catherine Capitant, M.D., Bruno Spire, M.D., Ph.D., Gilles Pialoux, M.D., Laurent Cotte, M.D., Isabelle Charreau, M.D., Cecile Tremblay, M.D., Jean-Marie Le Gall, Ph.D., Eric Cua, M.D., Armelle Pasquet, M.D., François Raffi, M.D., Claire Pintado, M.D., *et al.* for the ANRS IPERGAY Study Group*



Take-home points: on-demand (2-1-1)

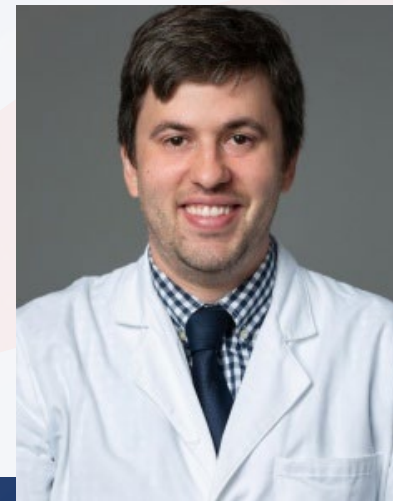
- The **only** option for on-demand PrEP is F/TDF.
- On-demand is an off-label use of F/TDF for PrEP.
- On-demand is only for persons whose exposure to HIV is from anal sex. (CDC says MSM only.)
- Generally speaking, 2-1-1 is probably best for patients who have sex infrequently. (Daily = default.)
- Patients opting for 2-1-1 need to accurately track sexual encounters and reliably take follow-up doses.

Objective 4

REAL WORLD EXAMPLES

Duke PrEP Clinic

- Initiated 12/2015
- 1 primary provider – Justin Frye, PA
- 3 other providers seeing PrEP regularly
- Wed PM – new starts
- F/u throughout week
- To date >500 patients at risk for HIV seen for PrEP
- No HIV seroconversions



Duke PrEP Clinic (2015-19)

TABLE 1. PRE-EXPOSURE PROPHYLAXIS CLINIC PATIENT DEMOGRAPHICS

Demographic	N (%) (N=255)
Age at initial PrEP visit	
17-25	63 (24)
26-35	90 (36)
36-45	51 (20)
46-55	37 (15)
≥56	14 (5)
Gender	
Male	224 (88)
Female	25 (10)
Transgender female	6 (2)
Race/ethnicity	
Black	95 (37)
White	122 (48)
Multiracial/other	21 (8)
Hispanic/Latino	14 (5)
Declined	17 (7)
Sexual practice	
MSM	186 (73)
HIV+ partner ever	76 (30)
Insurance status	
Uninsured	52 (20)
Referral source	
Medical provider	91 (36)
Self	62 (24)
Community organization	30 (12)
Dating apps	27 (11)
Peers	20 (8)
Health department	9 (4)
Insurance	3 (1)
Unknown	13 (5)

MSM, men who have sex with men; PrEP, pre-exposure prophylaxis.

TABLE 2. ADJUSTED ODDS RATIOS FOR SHORT- AND LONG-TERM RETENTION IN CARE AT 3 AND 8-12 MONTHS, RESPECTIVELY

Variable	Completion of 3-month appointment OR (95% CI)	Completion of 8-12 month appointment OR (95% CI)
Female	2.81 (0.73-10.8)	0.17 (0.01-1.48)
Black	0.81 (0.45-1.46)	0.83 (0.39-1.79)
Hispanic	1.42 (0.42-4.76)	0.96 (0.22-4.11)
MSM	5.22 (1.57-17.32)	1.46 (0.39-5.37)
Uninsured	0.50 (0.25-1.02)	0.32 (0.11-0.91)
Self-referred	1.18 (0.67-2.07)	2.18 (1.12-4.23)
HIV+ partner and under	0.89 (0.44-1.78)	1.66 (0.72-3.85)
35 years old and under	0.87 (0.50-1.52)	0.59 (0.30-1.13)
Baseline STI	0.81 (0.35-1.86)	1.95 (0.73-5.18)

Bold values are statistically significant.
 CI, confidence interval; OR, odds ratio; STI, sexually transmitted infection.

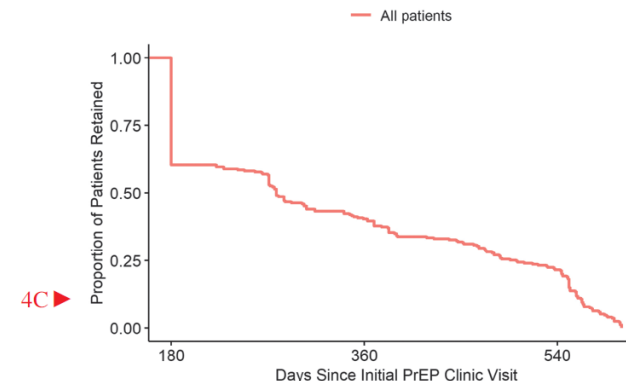


FIG. 1. Overall retention in PrEP care for all patients. PrEP, pre-exposure prophylaxis.

Duke PrEP Clinic Findings

- 55% patients retained at 3 months and 37% at 8-12 months respectively.
 - Similar to other reports in Southeast with 56% and 30% of patients retained at 3 and 12 months
- MSM and self-referred patients were more likely to remain in care, both in the short and long term.
- Uninsured patients were less likely to remain in care in the long term.
- Patients with STI diagnoses on PrEP seemed to remain in care longer.

Duke PrEP Clinic further questions

- Why are people dropping out of PrEP Care?
 - Do they no longer need it? Getting elsewhere? Moved? Or no longer interested? Not interested.
 - Is a 3 month follow up visit too frequent?
 - Why are some patients returning to PrEP (aka 'Seasons of Care')?
- Is the PrEP Clinic the best place for PrEP?
- How do we provide equitable access to PrEP?

Providing PrEP by telehealth

PrEP screening, initiation, or follow-up visits can be conducted by phone or web-based consult with HCPs²

Obtain specimens for HIV, STI, or other PrEP-related laboratory tests by:

- Laboratory visits for specimen collection only

- Order home specimen collection kits for specified tests

Progressive decline in PrEP initiation observed from Feb 2020 - April 2020 at start of COVID-19 pandemic¹

Immediate PrEP initiation at NYC sexual health clinic

- Medical record–based cohort study of PrEP candidates >18 yr of age (n = 1437 cisgender men and women) in NYC sexual health clinics from 2017-2018¹
 - Eligible for immediate PrEP if they had a negative rapid HIV test and no reported kidney disease, HBV infection, or symptoms of acute HIV (BL sample drawn)
- 97% of candidates qualified for immediate PrEP
 - <1% stopped for eGFR <60 mL/min or a positive HIV NAAT result
- Only 3% of candidates had delayed PrEP; of those, only 35% started PrEP
- 2021 CDC PrEP Guidelines outline procedures for providing PrEP on the same day as initial evaluation for select patients²

1. Mikati. CROI 2019. Abstr 962. 2. [cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf](https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf).

Thank you!

- Happy to take any questions
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