AETC AIDS Education & Training Center Program Southeast

HIV Pre-Exposure Prophylaxis

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Faculty Disclosure

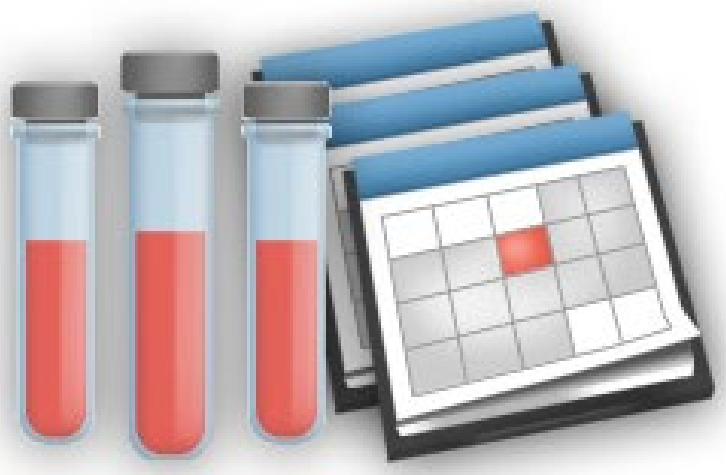
- I do not have financial or other relationships with the manufacture(s) of any commercial services discussed in this educational activity.

Objectives

- Identify patients at risk for HIV acquisition who may benefit from pre-exposure prophylaxis (PrEP)
- Describe steps for prescribing PrEP
- Discuss steps to counsel and provide PrEP to patients at high risk for HIV
- Discuss indications to stop PrEP

Pre-exposure Prophylaxis

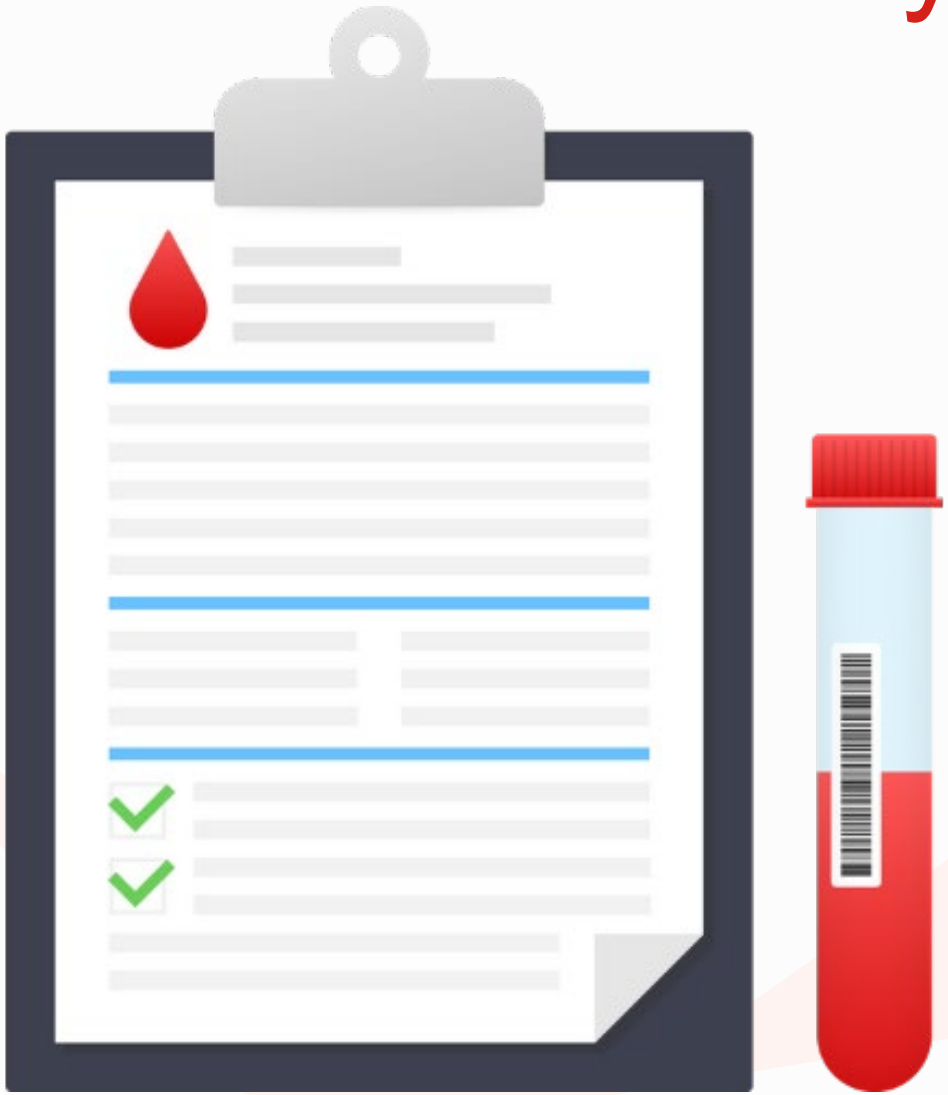
PrEP IS AN HIV PREVENTION METHOD IN WHICH PEOPLE WHO DO NOT HAVE HIV INFECTION TAKE A PILL DAILY TO REDUCE THEIR RISK OF BECOMING INFECTED



ONLY PEOPLE WHO ARE HIV-NEGATIVE SHOULD USE PrEP. AN HIV TEST IS REQUIRED BEFORE STARTING PrEP AND THEN EVERY 3 MONTHS WHILE TAKING PrEP.

http://aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/

Why PrEP?



50,000

estimated new HIV infections each year in the US

No Vaccine or Cure available

CDC.gov. PrEP FAQs. Available at https://www.cdc.gov/hiv/clinicians/prevention/prep.html. Accessed 12.15.2019.

Why PrEP?

Transmission Route	Effectiveness Estimate	Interpretation
Sexual	~99%	Very high levels of adherence to PrEP ensures maximum effectiveness.
Injection drug use	74% – 84%	These estimates are based on tenofovir alone and not necessarily when taken daily. The effectiveness may be greater for the two-drug oral therapy and if used daily.

CDC.gov. PrEP FAQs. Available at https://www.cdc.gov/hiv/clinicians/prevention/prep.html. Accessed 12.15.2019.

U.S. Preventive Services TASK FORCE

JAMA June 11, 2019 Volume 321, Number 22

Final Recommendation Statement

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

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 (What's This?)
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.	A

- The Centers for Disease Control and Prevention (CDC) recommends all sexually active adult and adolescent patients receive information about PrEP.

- "Any licensed prescriber can prescribe PrEP. Specialization in infectious diseases or HIV medicine is not required. In fact, primary care providers who routinely see people at risk for HIV acquisition should consider offering PrEP to all eligible patients."

Potential Benefits of PrEP

- Prevent HIV transmission
- Bring more attention to sexual health – proactive / taking control
- Can help resolve “discordance dilemma”
- Decreased anxiety, Increased communication,
- Increased disclosure
- Increased trust
- Increased self-efficacy
- Increased sexual pleasure
- Increased intimacy

Ware NC, et al., JAIDS, April 2012.

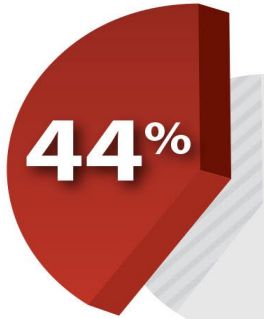
PrEP Use in in U.S.

Transmission risk group	% with PrEP indications	Estimated no.	(95% CI)
Men who have sex with men, aged 18–59 yrs	24.7	492,000	(212,000–772,000)
Adults who inject drugs, aged ≥18 yrs	18.5	115,000	(45,000–185,000)
Heterosexually active adults, aged 18–59 yrs	0.4	624,000	(404,000–846,000)
Men	0.2	157,000	(62,000–252,000)
Women	0.6	468,000	(274,000–662,000)
Total	—	**1,232,000**	**(661,000–1,803,000)**

CDC estimates 100,000 used PrEP in 2017

Smith DK, et al. MMWR 2015;64:1291-95. Sullivan PS, et al. Ann Epidemiol 2018; 28: 833-40.

HIV prevention pill is not reaching most who could potentially benefit – especially African Americans and Latinos



of people who could potentially benefit from PrEP are **African American – approximately 500,000 people**…

…but only **1%** of those – **7,000 African Americans** – were prescribed PrEP*

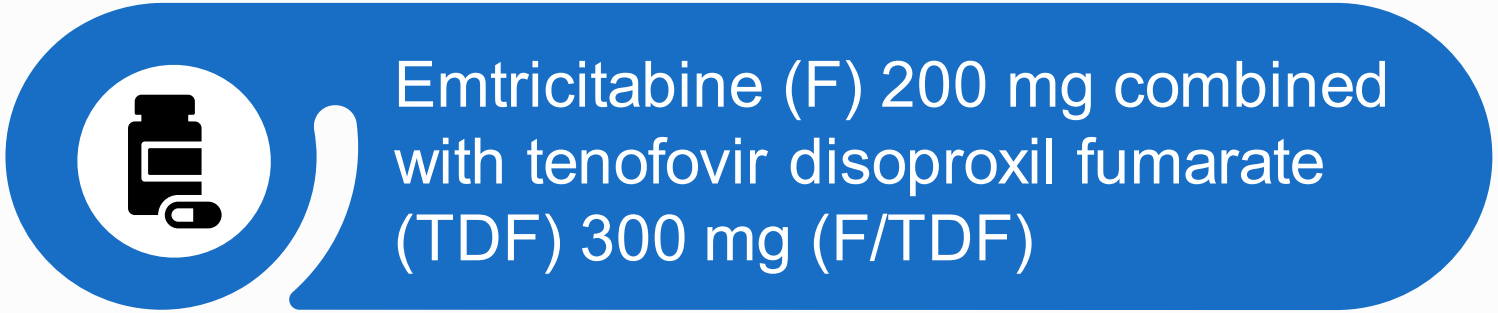
of people who could potentially benefit from PrEP are **Latino – nearly 300,000 people**…

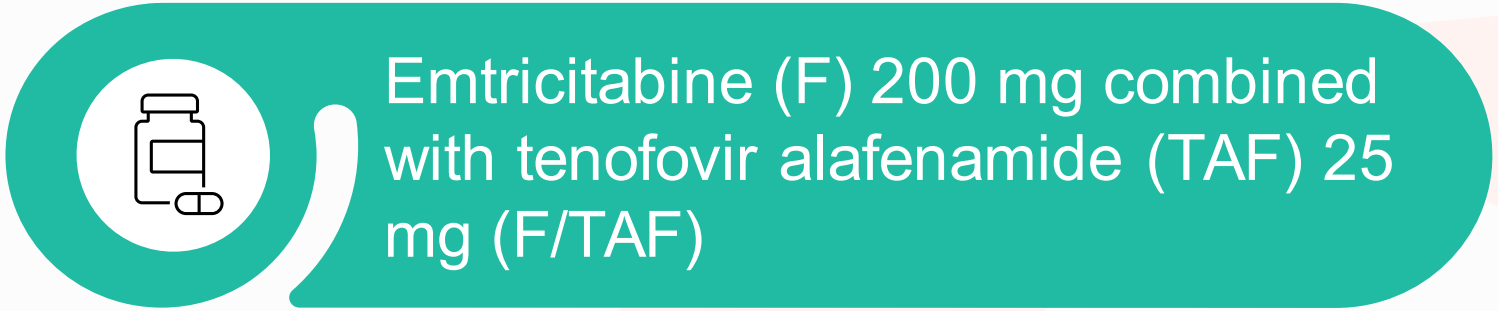
…but only **3%** of those – **7,600 Latinos** – were prescribed PrEP*

*Prescription data in this analysis limited to those filled at retail pharmacies or mail order services from September 2015 – August 2016; racial and ethnic information not available for one-third of the prescription data

Smith, DK., et al. CROI 2018; March 4-7, Boston, MA, USA

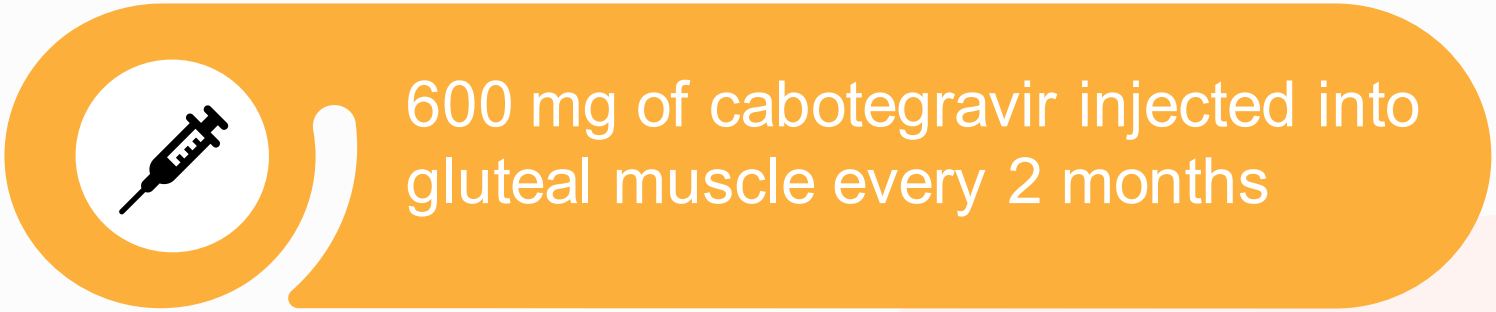
FDA approved Oral Medications for PrEP- One pill once a day





All preparations are approved to prevent HIV in adults and adolescents who weigh at least 77 pounds

FDA approved Intramuscular Preparation for PrEP



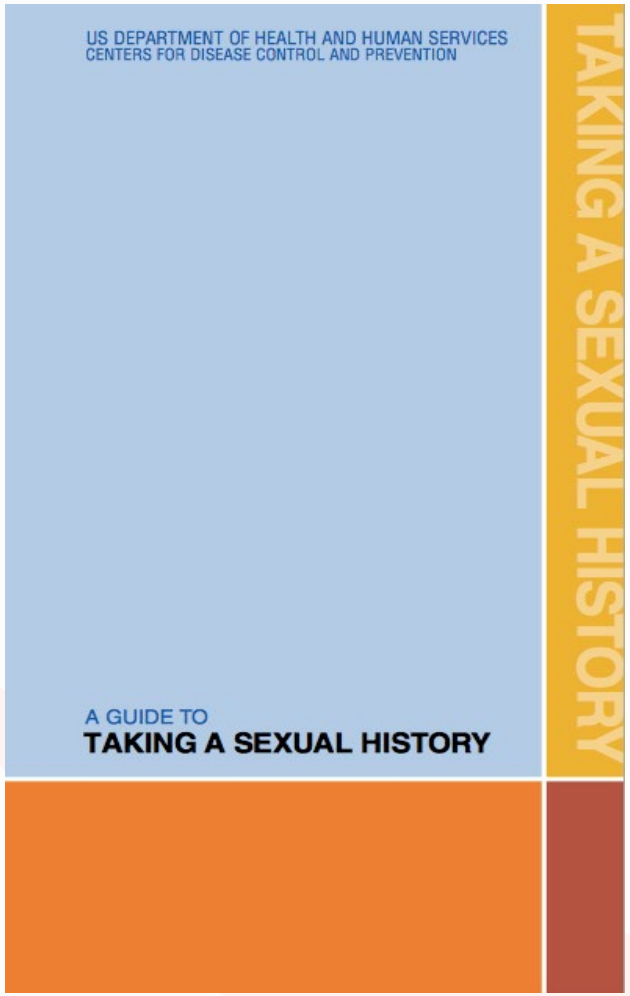
All preparations are approved to prevent HIV in adults and adolescents who weigh at least 77 pounds

Comprehensive HIV Prevention

PrEP is always part of a comprehensive HIV prevention package

- Condoms
- Counseling
- Frequent STD testing and treatment
- Frequent HIV testing

Taking a Sexual History



- Make it a normal part of each visit
- The Five “P”s
  - Partners
  - Practices
  - Protection from STDs
  - Past history of STDs
  - Prevention of pregnancy

CDC.gov. Available at https://www.cdc.gov/std/treatment/sexualhistory.pdf

STEP 1

Identify indications for PrEP

STEP 2

Assess risk for HIV acquisition

STEP 3

Laboratory evaluation

STEP 4

Prescribe PrEP

STEP 5

Clinical follow-up and monitoring

Step 1:Who Should be Offered PrEP?

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment

All AI recommendations

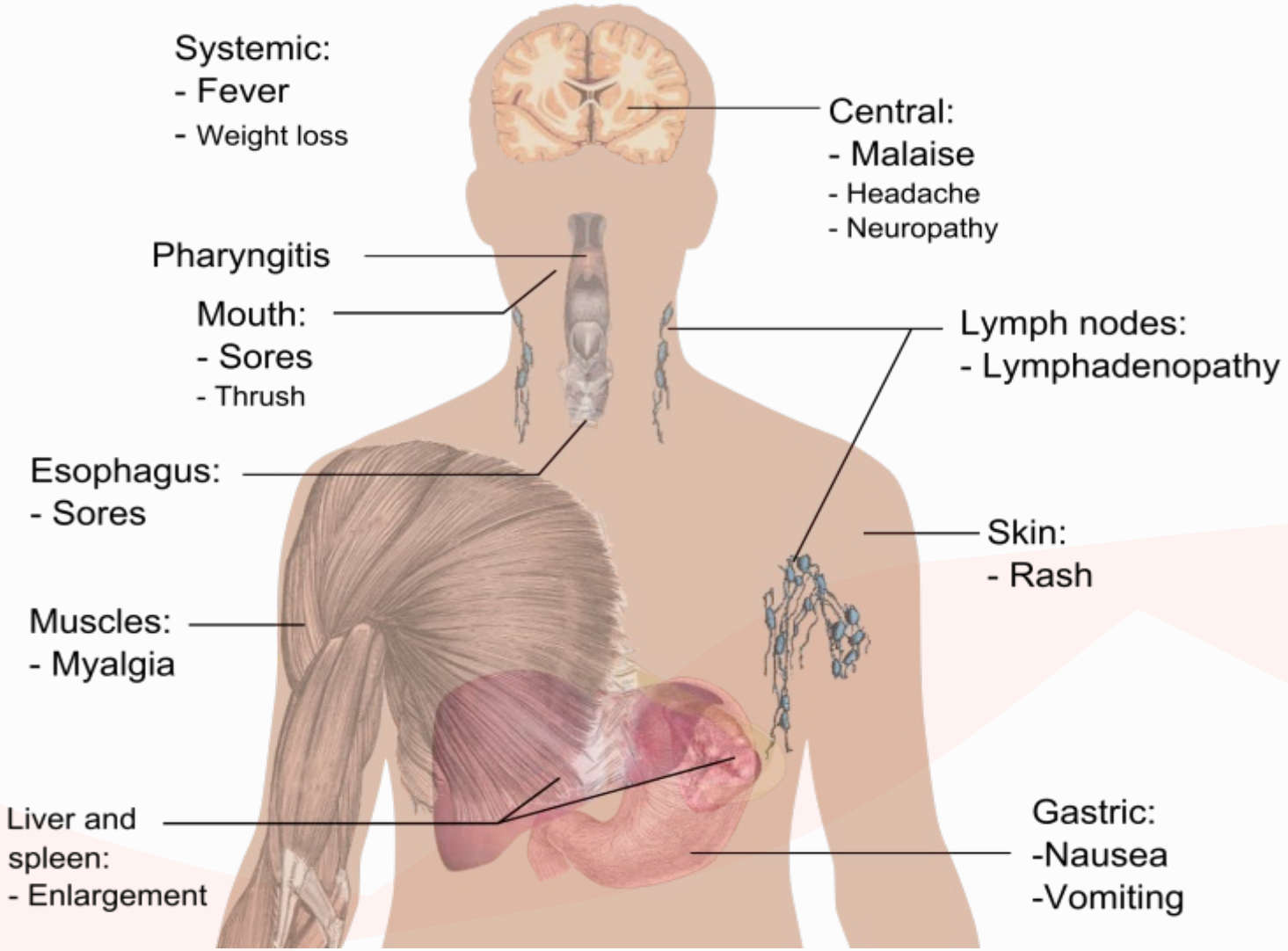
. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Step 2: Assess risk for HIV acquisition

- Acute or Chronic HIV infection needs to be ruled out prior to initiating PrEP
- Screen for signs of acute HIV or suspect acute HIV infection in persons who have engaged in exposure-prone behaviors in the 4 weeks prior to evaluation for PrEP
- Should have a documented negative HIV test result prior to starting PrEP.
- If anticipating doing long acting IM cabotegravir obtain HIV RNA prior to starting PrEP
- Clinicians should not accept patient-reported test results or documented anonymous test results.
- Rapid tests that use oral fluid should not be used to screen for HIV infection

Main symptoms of

Acute HIV infection



http://upload.wikimedia.org/wikipedia/commons/4/4a/Symptoms_of_acute_HIV_infection.png

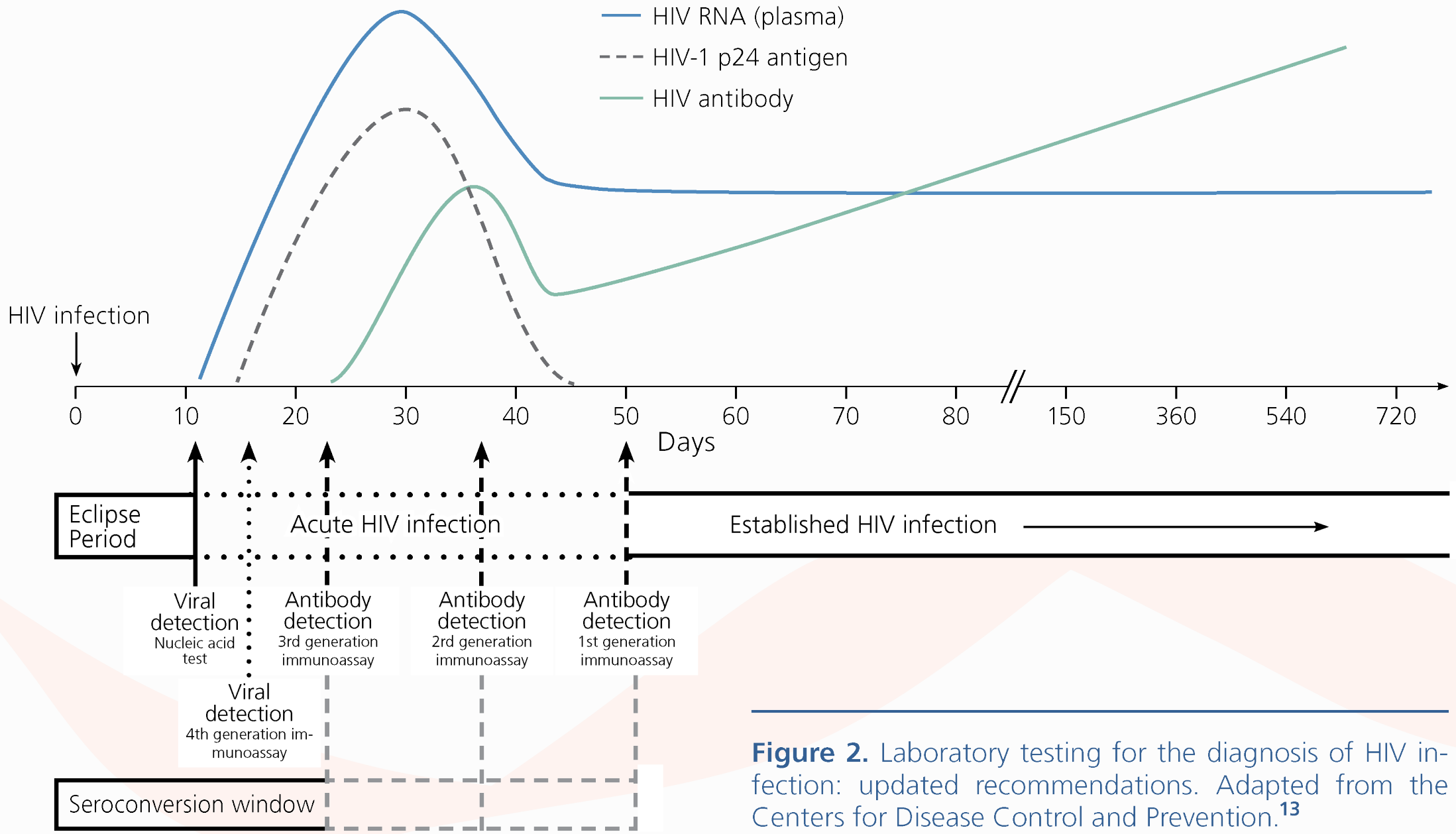
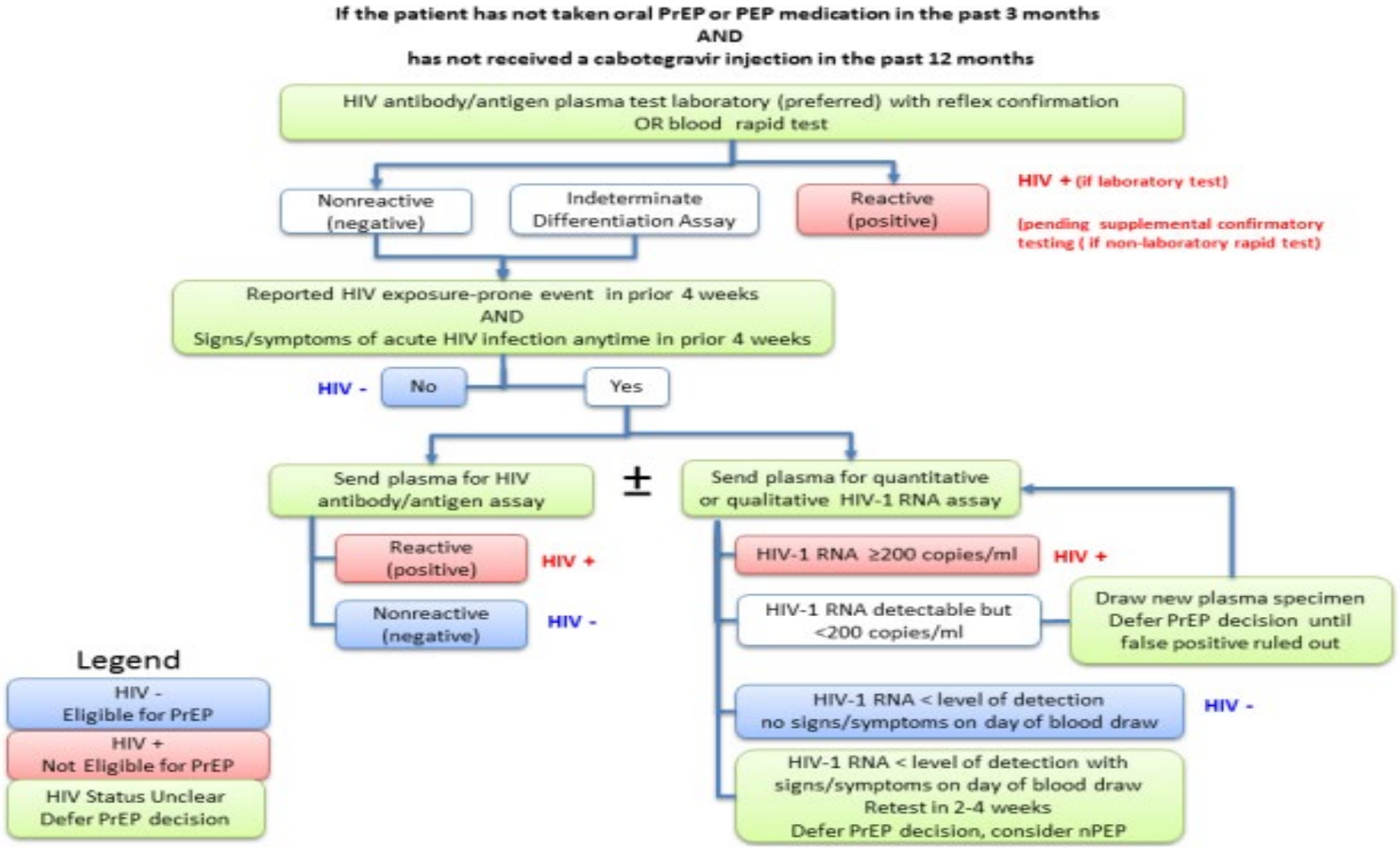


Figure 2. Laboratory testing for the diagnosis of HIV infection: updated recommendations. Adapted from the Centers for Disease Control and Prevention.[13]

Branson BM, et al. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. CDC.gov. June 27, 2014. Available at http://stacks.cdc.gov/view/cdc/23446

Figure 4a Clinician Determination of HIV Status for PrEP Provision to Persons without Recent Antiretroviral Prophylaxis Use

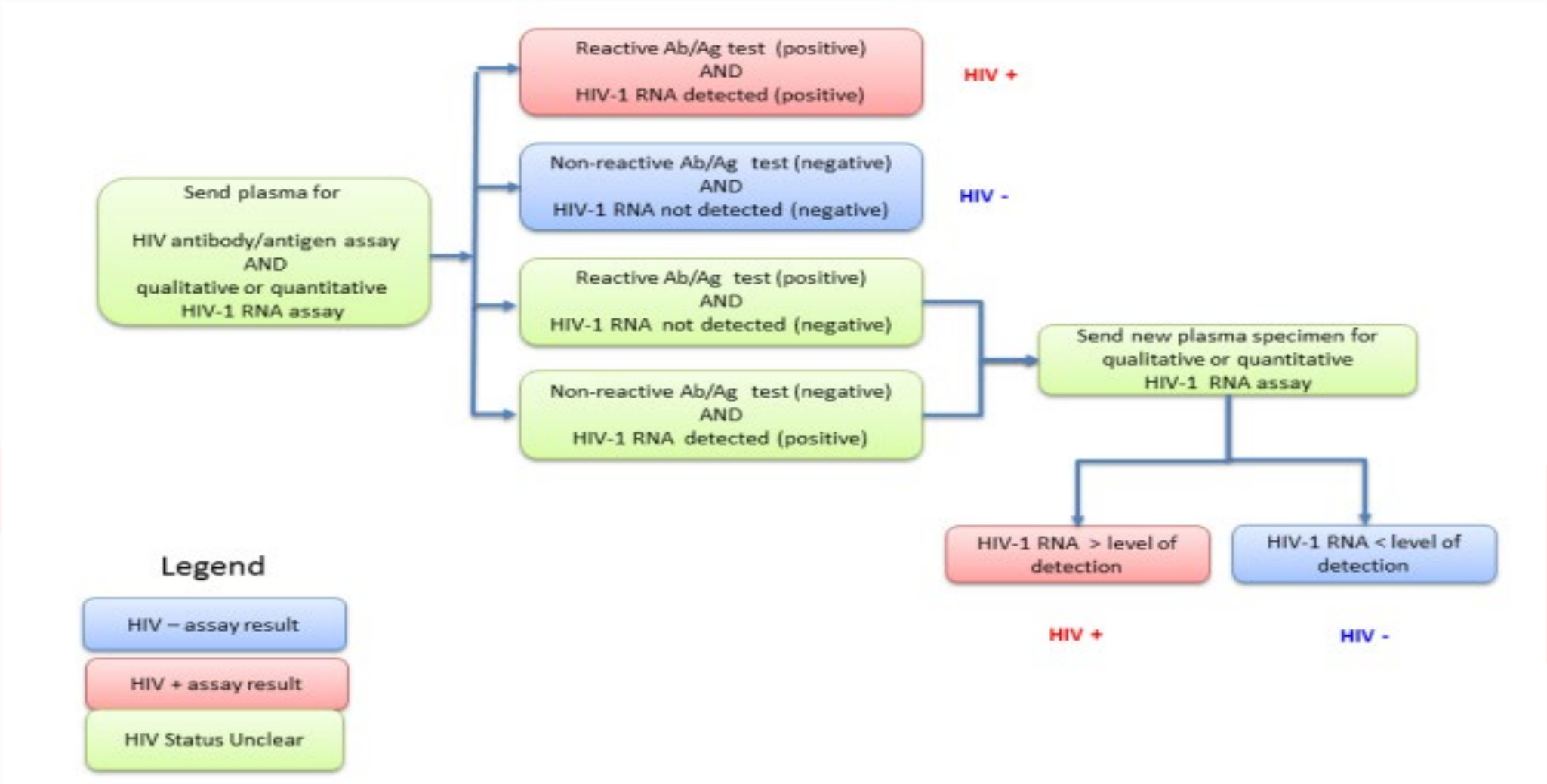


https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

HIV Testing in Patients on Oral or Intramuscular PrEP

- Testing may be more unreliable in patients who acquire HIV while on PrEP
- The antiretrovirals used for PrEP can suppress early viral replication which can affect the timing of antibody development.
- In HPTN 083, detection of HIV, in the cabotegravir group with Ag/Ab testing was delayed by a mean of 62 days compared to detection by qualitative HIV-1 RNA assay for infections determined to have been present at baseline; the delay was 98 days for incident infections.
- Among participants in the F/TDF group, detection by Ag/Ab testing was delayed by a mean of 34 days from qualitative HIV-1 RNA detection for baseline infections and 31 days for incident infections
- Given this the traditional method of using 4th generation test is insufficient to rule out HIV while on PrEP

Monitoring HIV status while on PrEP



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

HIV testing for PrEP- Summary

- For patients who are starting or restarting Oral PrEP after a long stop, test using an HIV antigen/antibody test (laboratory-based is preferred).
- If Patient starting long acting Cabotegravir – HIV RNA in addition to Ag/AB test is prefffered
- For patients who are taking or have recently taken PrEP (including patients who have taken oral PrEP in the last 3 months or patients who had a CAB injection in the last 12 months), test using an HIV antibody/antigen assay **AND** a qualitative or quantitative HIV-1 RNA assay.

FDA Indications for F/TDF vs F/TAF

- F/TDF (Truvada)
  - Prevention of HIV infection among **all people at risk through sex or injection drug use**
  - **Renal function: eGFR > 60 mL/min**
- F/TAF (Descovy)
  - Prevention of HIV infection among people **at risk through sex, excluding people at risk through receptive vaginal sex**
  - **Renal function: eGFR > 30 mL/min**

Truvada (F/TDF)

- Approved for HIV PrEP in 2012
- One pill by mouth daily with or without food
- **Do not use for PrEP if estimated eGFR < 60 mL/min**
- Potential side effects
  - Headache, abdominal pain and weight loss – usually resolves in 2-4 weeks
  - Decreased bone mineral density (no fracture risk)
  - Renal dysfunction including Fanconi syndrome

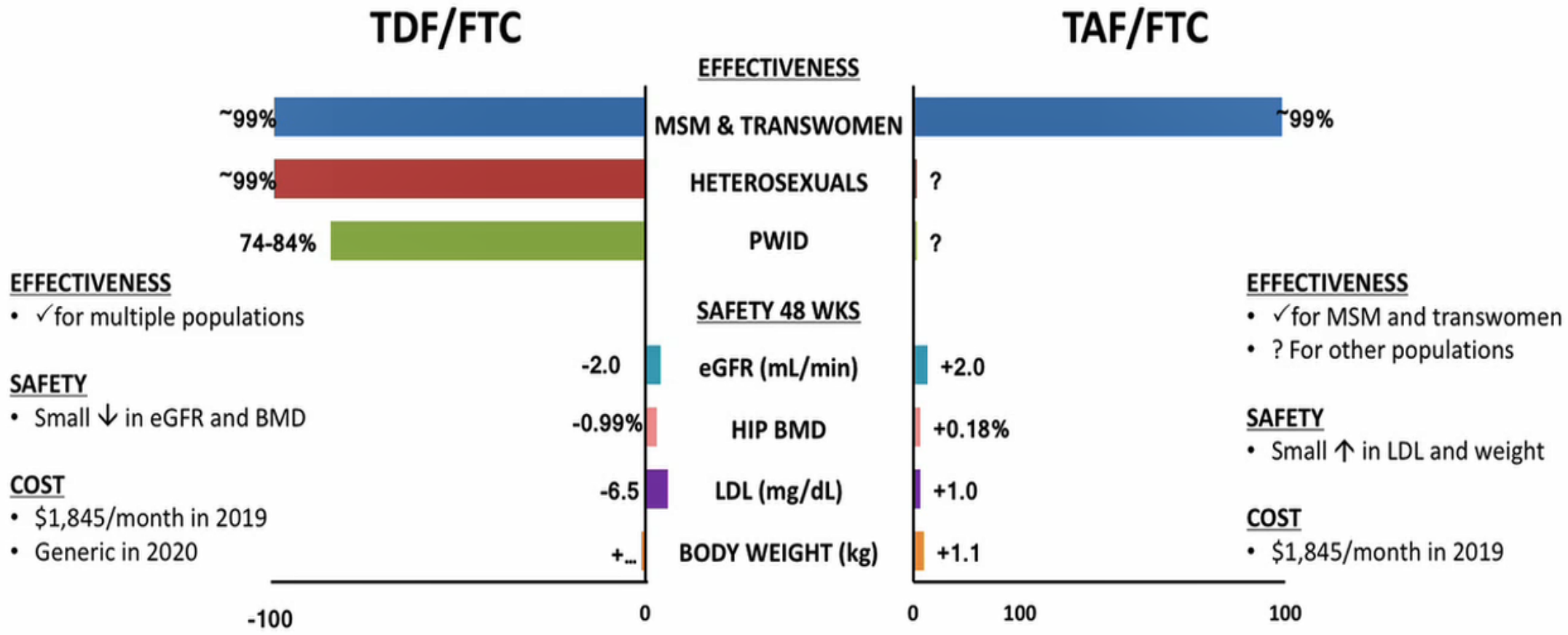
Typically reversible with stopping Truvada

Descovy (F/TAF)

- Approved for HIV PrEP for prevention of sexual transmission, **excluding** individuals at risk from receptive vaginal sex on October 3, 2019
- One pill by mouth daily with or without food
- **Do not use if estimated eGFR < 30 mL/min**
- Potential side effects
  - Headache, diarrhea and abdominal pain – usually resolves in 2-4 weeks
  - Decreased bone mineral density (no fracture risk)
  - Renal dysfunction including Fanconi syndrome

Typically reversible with stopping Descovy

Which medication should you prescribe for daily PrEP



Fda.gov.media/129607/dow nload-cdc.gov/hiv/risk/estimates/prevention stratergies.html

Eligibility for Oral PrEP

1. Negative HIV test within 1 week before of prescribing PrEP
2. No signs/symptoms of acute HIV infection
3. Normal renal function
4. No contraindicated medications

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

Baseline Lab Evaluation for Oral PrEP

- HIV test
- STI screen
  - Gonorrhea & chlamydia at all mucosal sites of exposure
  - Syphilis testing
- Serologic testing for Hepatitis B & C
- Creatinine clearance
- Lipid panel if TAF/FTC (Descovy) to be used

Hepatitis B and Oral PrEP

- Check hepatitis B serology before initiating oral PrEP
- Severe acute exacerbations of hepatitis B can occur in patients infected with hepatitis B who discontinue current PrEP medications
- Vaccinate if nonimmune

Test	Result	Interpretation
HBsAg anti-HBc anti-HBs	negative negative negative	Susceptible (vaccinate)
HBsAg anti-HBc anti-HBs	negative positive positive	Resolved HBV infection
HBsAg anti-HBc anti-HBs	negative negative positive	Vaccinated
HBsAg anti-HBc anti-HBs	positive positive negative	Active HBV infection (usually chronic) *If anti-HBc IgM present, may represent acute infection.
HBsAg HBcAb HBsAb	negative positive negative	Various possibilities: distant resolved infection (most common) recovering from acute infection false positive occult hepatitis B

Clinically significant Oral PrEP Medication Drug Interaction

	TDF	TAF
Ledipasvir, sofosbuvir, velpatasvir, voxilaprevir	Serum concentrations of TDF may be increased. Monitor for toxicities	No significant effect
St John's Wort	No significant effect	Do not co-administer with TAF Decrease in TAF concentration possible
Rifampin	No significant effect	Do not co-administer with TAF unless benefits outweigh risks
Rifabutin, Rifapentine	No significant effect	Do not co-administer with TAF

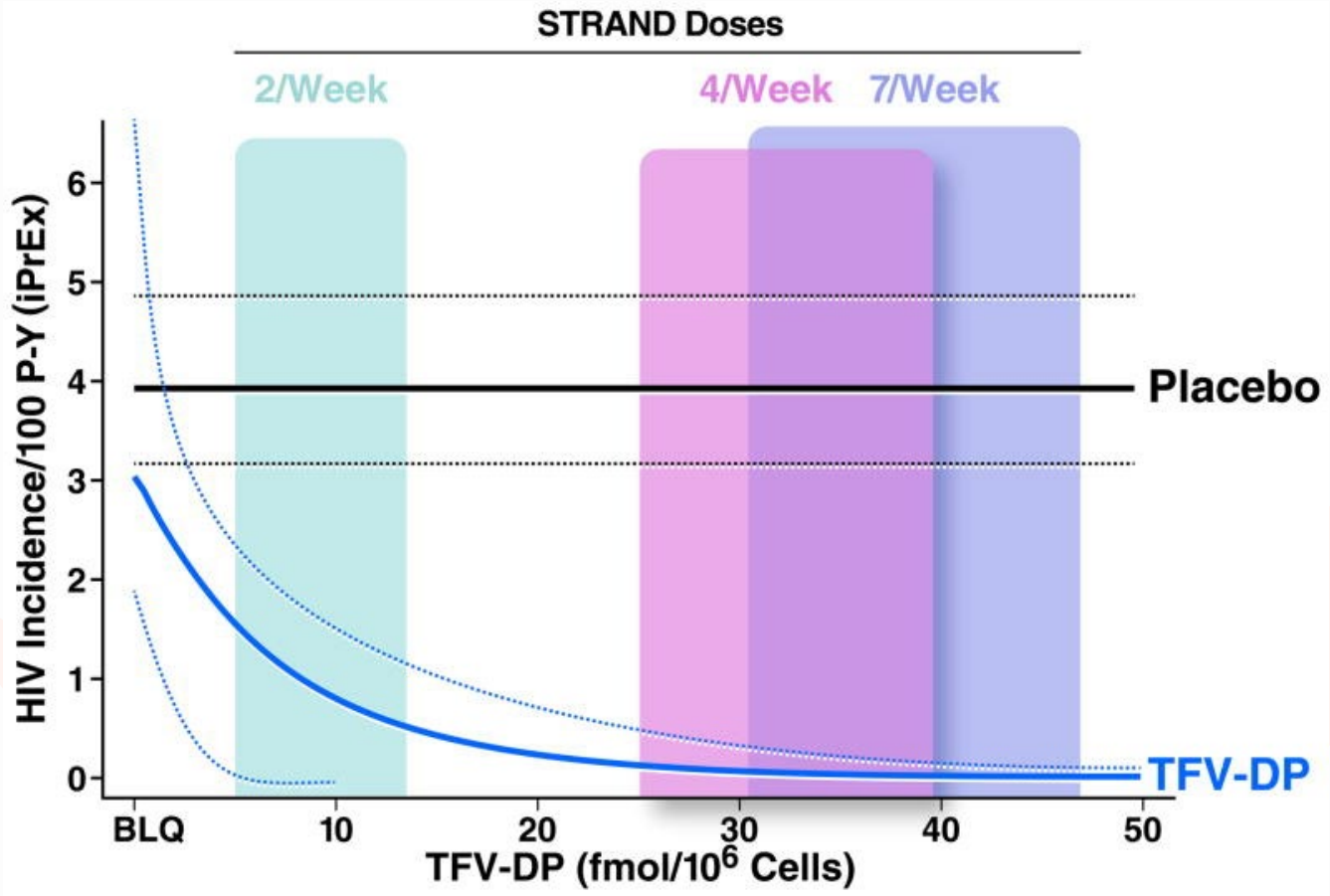
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Prescribing and Monitoring

- Truvada or Descovy with or without food
  - No more than 90 day supply
- How long does it take for protection from HIV after starting oral PrEP?
  - TDF/FTC (Truvada) estimates –
    - 20 days for cervicovaginal tissue
    - 7 days for blood mononuclear cells and rectal tissue
  - Data for TAF/FTC (Descovy) not available

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

Adherence Is Critical



Dosing	Estimated PrEP Efficacy
2x/week	76%
4x/week	90%
Daily	99%

Anderson PL. Sci Transl Med 2012;4:1-8

Timing of Oral PrEP-Associated Laboratory Tests

Lab Test	Every 3 months	At least every 6 months	Every 12 months	When stopping
HIV Ab/Ag and HIV RNA	X			X
CrCL		If age ≥50 or CrCL < 90 at PrEP initiation	If age <50 or CrCL> 90 at PrEP initiation	X
Syphilis	MSM/TGW	X		MSM/TGW
Gonorrhea/Chlamydia	MSM/TGW	X		MSM/TGW
Lipid Panel/weight (F/TAF)			X	X

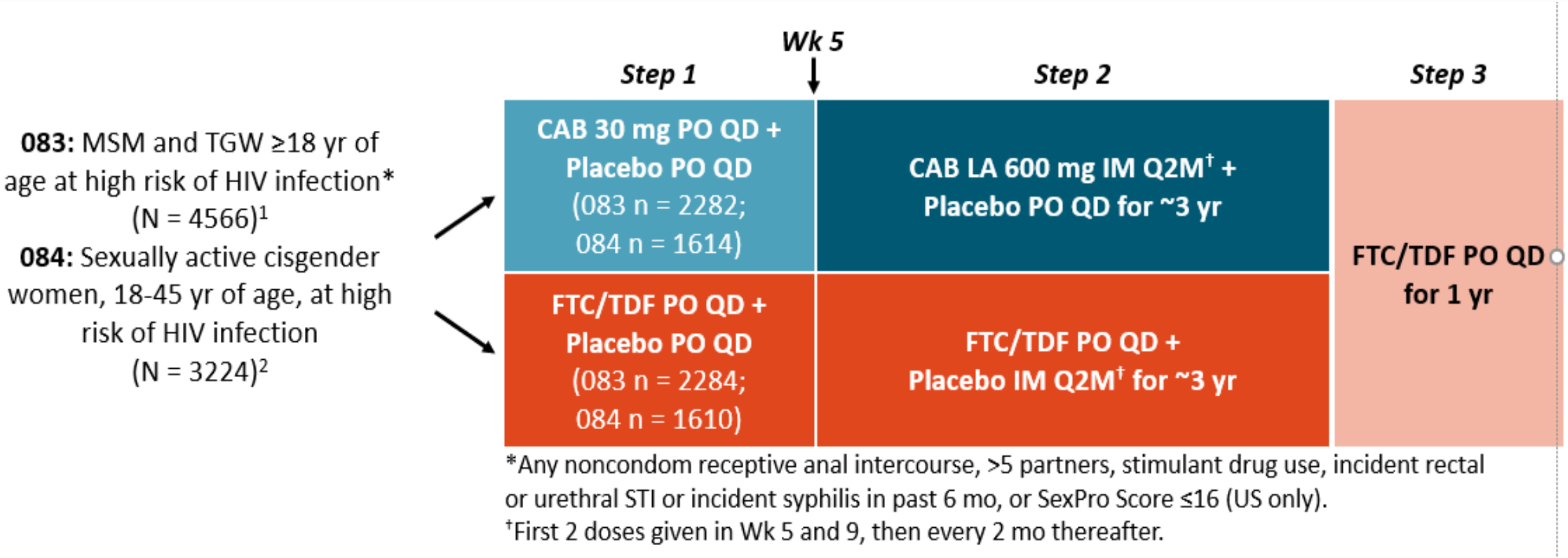
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Long Acting Intra-Muscular PrEP

- 600 mg of cabotegravir injected into gluteal muscle every 2 months is recommended for PrEP in adults at risk of acquiring HIV.
- Can delay Identification of baseline HIV – so ideally should do HIV RNA + HIV Ag?AB prior to starting long acting cabotegravir
- 30 mg daily oral cabotegravir is optional for a 4-week lead-in prior to injections.(Do not prescribe ongoing daily oral CAB other than for 4 week lead in)
- Cannot be self administered at home – so patient will need bi-monthly clinic visits for administration – has to be given in the gluteal muscle
- This may be especially appropriate for patients with significant renal disease, those who have had difficulty with adherent use of daily oral PrEP but can be compliant with clinic visits

Efficacy/Safety of LA Injectable CAB vs Daily Oral FTC/TDF

- HPTN 083 and 084:International, randomized, double-blind phase IIb/III (083) and phase III (084) trials



Landovitz. AIDS 2020. Abstr OAXLB0101. 2. Delany-Moretlwe. HIVR4P 2021. Abstr HY01.02

Efficacy/Safety of LA Injectable CAB vs Daily Oral FTC/TDF

- HPTN 083 and 084: HIV Incidence:
- LA CAB met criteria for superiority vs FTC/TDF in both 083 and 084

Primary Efficacy Endpoint	HPTN 083[1]		HPTN 084[2]	
	CAB (n = 2244)	FTC/TDF (n = 2247)	CAB (n = 1614)	FTC/TDF (n = 1610)
HIV infections, n	13*	39	3†	36
PYFU	3205	3187	1956	1942
HIV incidence per 100 PY	0.41	1.22	0.15	1.85
HR for CAB vs FTC/TDF (95% CI)	0.34 (0.18-0.62)		0.08 (0.03-0.27)	

*Includes 1 case readjudicated post hoc as a baseline infection; revised HIV incidence based on readjudication: 0.37 (95% CI: 0.19-0.65), revised HR: 0.32 (95% CI: 0.16-0.58).
†Includes 1 baseline infection.

Landovitz. NEJM. 2021;385:595. 2. Marzinke. IAS 2021. Abstr PECLB25.

CAB PrEP Initiation Visit

- Negative HIV Ag/Ab test + HIV RNA test + no concern for acute HIV
- STI screen
  - Gonorrhea & chlamydia at all mucosal sites of exposure
  - Syphilis testing
- Testing NOT needed for CAB PrEP patients :

creatinine, CrCl, hepatitis B serology, lipid panels, liver function tests

- Oral lead in not required-may be optionally used for patients who are especially worried about side effects to relieve anxiety about using the long-acting CAB injection.

Cabotegravir (CAB) PrEP Drug Interactions

Rifampicin, rifapentin	**Do not co-administer with CAB** Rifampicin and rifapentine increase metabolism of CAB and may result in significantly reduced exposure to protective levels of CAB
Rifabutin	**Co-administer with caution** Rifabutin moderately increases metabolism of CAB and may result in somewhat reduced exposure to protective levels of CAB
Carbamazepine, oxcarbazepine, phenytoin, phenobarbital	Do not co-administer with CAB Concern that these anticonvulsants may result in significantly reduced exposure to protective levels of CAB but strength of evidence is weak

CAB Administration

- Dosing:3 ml suspension of CAB 600 mg IM in gluteal muscle
  - 3 ml suspension of CAB 600 mg IM in gluteal muscle
  - Second dose 4 weeks after first dose (month 1 follow-up visit)
  - Every 8 weeks thereafter

- Managing Injection Site reactions
  - In the clinical trials, injection site reactions (pain, tenderness, induration) were frequent following CAB injections
  - These reactions were generally mild or moderate, lasted only a few days, and occurred most frequently after the first 2-3 injections
  - Patients should be informed that these reactions are common and transient
  - Take an over-the-counter pain medication soon after the injection
  - apply a warm compress or heating pad to the injection site for 15-20 minutes after the injection

Timing of CAB PrEP-Associated Laboratory Tests

Lab Test	Every 2 months	Every 4 months	Every 6 months	When stopping
HIV Ab/Ag and HIV RNA	X			X
Syphilis		MSM/TGW	X	MSM/TGW
Gonorrhea/Chlamydia		MSM/TGW	X	MSM/TGW

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

Implementation Considerations to Facilitate Uptake/Use of Long-Acting Injectable HIV Prevention

- Shot clinics (in and out) in clinical programs
- Pharmacies administer shots
- Constant supply of oral formulations at home for “bridges” when shot dose missed
- Incentives
- Mobile vans
- Good staff communication, teamwork
- Effective appointment reminder systems, designated staff for appointment tracking

What if the HIV test is positive?

- Do confirmatory test if rapid test positive
- Convert the PrEP regimen to an HIV treatment regimen recommended by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents
- Order an HIV-1 RNA PCR, HIV-1 Genotype, CD4 count and other baseline labs
- Reinforce need for adherence to medications
- Discuss the importance of condom use to protect sex partners and provide condoms
- Offer HIV testing for sex and drug injection partners, nPEP and assistance with disclosure
- Ask if they have a family member they would like to be contacted for support and provide support and counselling

Managing PrEP Patients with Ambiguous HIV test Results

- Given that you are doing both a HIV ag/ab test and a HIV RNA test when assessing for acquisition off HIV while on PrEP – you may get discordant results:
- Either a positive HIV ag/ab with a negative HIV RNA or a negative HIV ag/ab with a positive HIV RNA
- In this situation you should assess adherence and draw a new blood specimen after a few days for repeat laboratory HIV including Ag/Ab and HIV RNA.
- You can consult the National Clinician Consultation line for further guidance about continuing/ discontinuing PrEP

Development of Resistance- Oral PrEP

- Risk is low despite 2 drug therapy with PrEP
- IPrEX
  - 48 people with HIV – none with significant resistance
- Partner's PrEP
  - 5 of 63 seroconverters developed resistance
  - M184V

Table 1. Results of Genotypic and Phenotypic Drug-Resistance Testing of the Patient's Plasma Sample on Day 7.*

Drug Class and Drug	Drug Resistance on Genotypic Testing	Relative Drug Susceptibility on Phenotypic Testing
Nucleoside or nucleotide reverse-transcriptase inhibitors		
Abacavir	Intermediate	Susceptible (3.9 × IC_{50})
Lamivudine	High	Resistant (more than maximum IC_{50})
Emtricitabine	High	Resistant (more than maximum IC_{50})
Tenofovir	Low	Sensitive (0.6 × IC_{50})
Nonnucleoside reverse-transcriptase inhibitors		
Efavirenz	Intermediate	Sensitive (0.56 × IC_{50})
Etravirine	Intermediate	Sensitive (0.19 × IC_{50})
Nevirapine	High	Resistant (19 × IC_{50})
Rilpivirine	Intermediate	Sensitive (0.53 × IC_{50})
Protease inhibitors: all agents	Susceptible	Susceptible
Integrase strand-transfer inhibitors		
Raltegravir	Intermediate	Reduced response (9.6 × IC_{50})
Elvitegravir	High	Resistant (>100 × IC_{50})
Dolutegravir	Low	Reduced response (2.7 × IC_{50})

Knox DC, Et al. N Engl J Med. 2017 Feb 2;376(5):501-502..

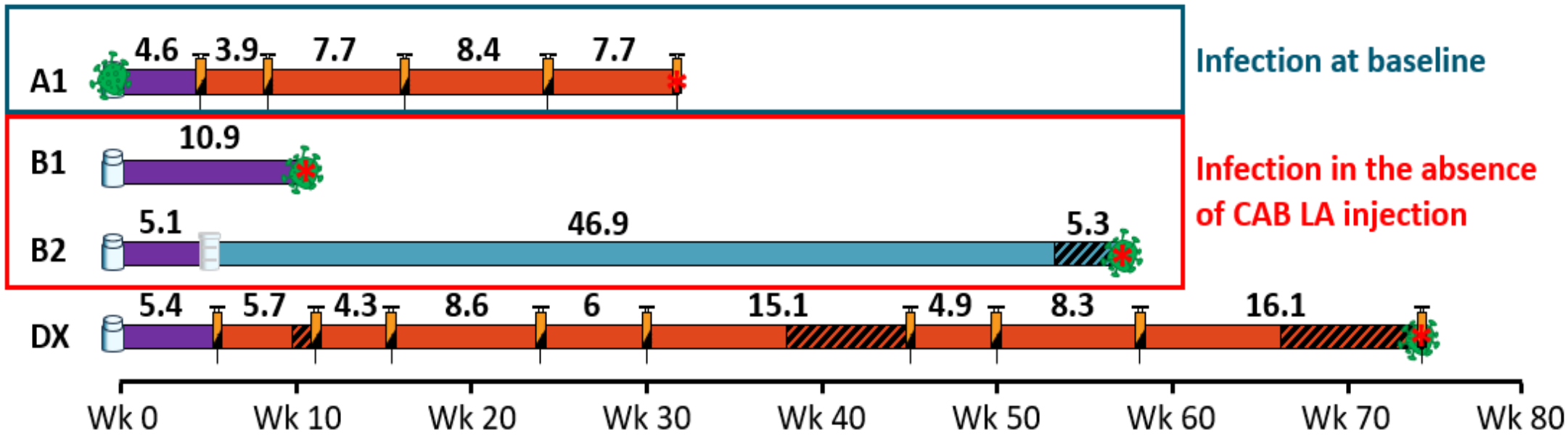
HPTN 083: Incident HIV Infections With Cabotegravir

- INSTI resistance observed upon viremic "escape" at higher CAB concentrations; not observed in 3 tail-phase infections or 1 tail "escape" case

HIV Infection Timing	Number of Infections	Resistance Information
Baseline (Group A)	4	NA
With no recent CAB exposure (ie, after long delay in scheduled dosing; Group B)	5	▪ WT: n = 3 ▪ Y181C, H221Y: n = 1 ▪ GT result not available: n = 1
During oral lead-in (before CAB injections; Group C)	3	▪ WT: n = 1 ▪ L74I, E138E/K, G140G/S, Q148R: n = 1 ▪ E138A, Q148R: n = 1
With appropriately timed CAB LA doses and expected plasma CAB levels (Group D)	4	▪ K103N, R263K: n = 1 ▪ G140A, Q148R: n = 1 ▪ GT result not available: n = 2

Landovitz. NEJM. 2021;385:595

HPTN 084: Incident HIV Infections With Cabotegravir



- Step 1: Oral CAB lead-in
- Step 2: CAB LA 600 mg IM
- Step 2: CAB LA injection >2 wk overdue
- Step 3: Open-label FTC/TDF for pregnancy
- Step 3: Overdue FTC/TDF dispensation
- Annual follow-up

- Blinded CAB dispensed
- CAB LA 600 mg IM
- Open-label FTC/TDF dispensed
- First positive visit
- First site positive visit

- No major INSTI mutations in CAB arm
- HIV detection via routine diagnostic assays delayed in patients receiving CAB LA; HIV-1 RNA testing as primary HIV screen will be evaluated in open-label extension

Marzinke. IAS 2021. Abstr PECLB25.

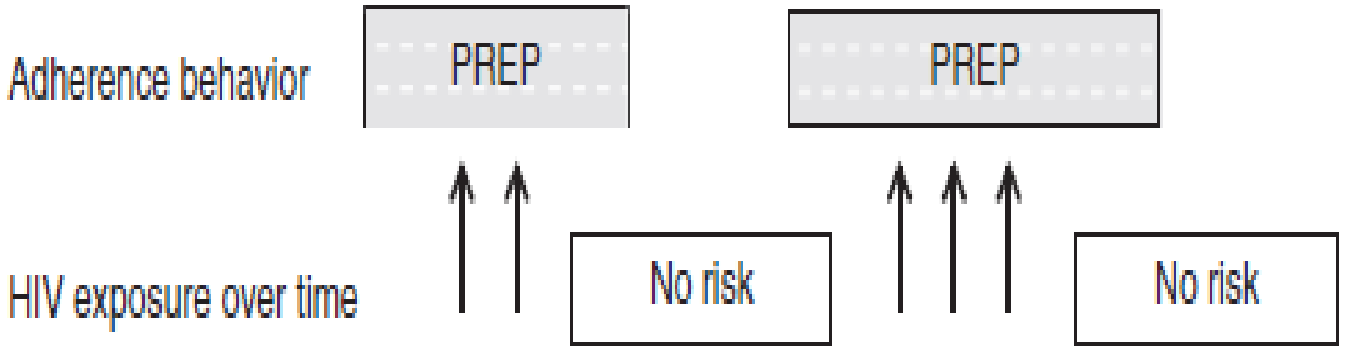
Discontinuing PrEP

- Positive HIV result /Acute HIV signs or symptoms
- Chronic nonadherence to prescribed dosing regimen or scheduled follow up visits
- Patient choice/changed life situation resulting in lower risk of HIV acquisition
- Document HIV status at time of discontinuation, reason for discontinuation
- Advise risk of developing drug resistant HIV during the period of waning drug levels (the “tail period”)
- CAB levels slowly wane over many months after injections are discontinued. In the HPTN 077 trial, the median time to undetectable CAB plasma levels was 44 weeks for men and 67 weeks for women with a wide range for both sexes

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

PrEP May Be Periodic

(b) Prevention-effective adherence paradigm: Success is achieved because PrEP is used during all episodes of HIV exposure. Adherence to PrEP may be periodic and mapped to periods of risk.



Haberer, Jessica, Bangsberg David et al. Defining success with HIV pre-exposure prophylaxis: a prevention-effective adherence paradigm. AIDS 2015. 29: 1277-1285.

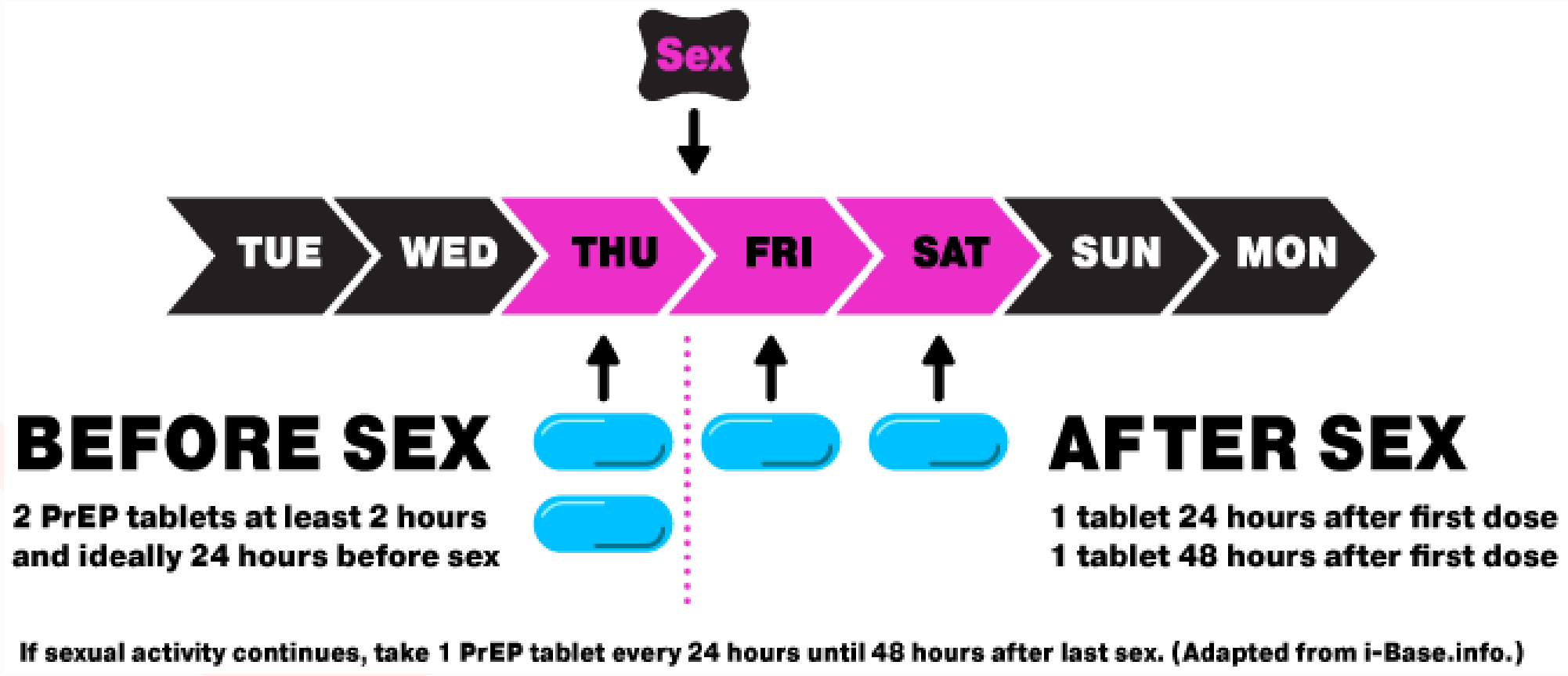
PrEP in Pregnancy

- F/TDF as PrEP is considered generally safe for pregnant and breastfeeding women
- F/TDF has been widely used for treatment of HIV and continued during pregnancy
- The data on pregnancy outcomes in the Antiretroviral Pregnancy Registry provide no evidence of adverse effects among fetuses exposed to these medications
- Both the FDA documentation and the perinatal antiretroviral treatment guidelines permit off-label use in pregnancy.
- Providers should discuss available information about potential risks and benefits of beginning or continuing PrEP during pregnancy so that an informed decision can be made.

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

“On-Demand” PrEP

- IPERGAY trial found that taking PrEP on a 2-1-1 schedule reduced risk of HIV infection by 86% in MSM- only F/TDF



Same Day PrEP Prescribing

- For all patients, safely initiating PrEP requires determination of HIV status and assessment of renal function if they are on oral PrEP
- Some patients may have time or work constraints that impose a significant burden to return to the clinic a week or two after evaluation for a prescription visit.
- Other patients report risk behaviors that put them at substantial risk of acquiring HIV infection in the time between visits for evaluation and PrEP prescription

To use a same-day PrEP initiation protocol, the clinic must be able to:

- Conduct point-of-care HIV testing, ideally with an ag/ab fingerstick or other blood test.
- Draw blood for laboratory creatinine and HIV testing when same day HIV and creatinine test results are not available
- Provide assistance for eligible patients to enroll in health insurance, or medication assistance programs
- Provide rapid follow-up contact for patients whose laboratory test results indicate HIV infection or renal dysfunction • Provide scheduled follow-up care appointments
- Have clinicians available to dispense or prescribe oral PrEP medication, to administer a gluteal intramuscular injection of CAB,

PrEP in Clinical Practice: What Are the Barriers to PrEP Uptake?

- Users
  - Unaware of HIV risk, PrEP availability, or how to access it
  - No or delayed access to clinical preventive care
  - Lack of knowledge about insurance coverage
  - Adherence challenges
  - Concern about disclosure and stigma
- Providers
  - Unaware of intervention
  - Wary of complexity and time involved
  - Discomfort with assessing risk
    - Uncertain how to bill for intervention

Ready, Set, PrEP

- Launched by the US Department of Health and Human Services on 12/3/19

- To qualify, patients must:
  -test negative for HIV
  -have a valid prescription from a healthcare provider
  -not have prescription drug coverage

- Beginning no later than March 30, 2020, patients may obtain PrEP through CVS, Walgreens, Rite Aid or mail order all at no cost

- https://www.getyourprep.com/ or 855-447-8410

- HIV.gov Locator

Original Investigation

Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy

Alison J. Rodger, MD; Valentina Cambiano, PhD; Tina Bruun, RN; Pietro Vernazza, MD; Simon Collins; Jan van Lunzen, PhD; Giulio Maria Corbelli; Vicente Estrada, MD; Anna Maria Geretti, MD; Apostolos Beloukas, PhD; David Asboe, FRCP; Pompeyo Viciana, MD; Félix Gutiérrez, MD; Bonaventura Clotet, PhD; Christian Pradier, MD; Jan Gerstoft, MD; Rainer Weber, MD; Katarina Westling, MD; Gilles Wandeler, MD; Jan M. Prins, PhD; Armin Rieger, MD; Marcel Stoeckle, MD; Tim Kümmerle, PhD; Teresa Bini, MD; Adriana Ammassari, MD; Richard Gilson, MD; Ivanka Krznaric, PhD; Matti Ristola, PhD; Robert Zangerle, MD; Pia Handberg, RN; Antonio Antela, PhD; Sris Allan, FRCP; Andrew N. Phillips, PhD; Jens Lundgren, MD; for the PARTNER Study Group

- The PARTNER1 study looked at 888 couples where one was HIV positive and on antiretroviral treatment (ART) and who were already having sex without condoms:

-548 heterosexual couples

-340 MSM

- They found that in more than 58,000 acts of condomless sex there were no HIV transmissions from the HIV positive partner among those on treatment with an undetectable viral load
- Couples were followed for a median of 1.3 years

JAMA. 2016;316(2):171-181. doi:10.1001/jama.2016.5148

Partner 2 Study:

- Prospective observational study in 14 European countries
- Enrolled 927 homosexual serodiscordant couples between September 2010 and July 2017
- Positive partner was on suppressive ART
- A total of 74568 condomless-sex acts were reported, with 0 cases of within couple HIV transmission

http://programme.aids2018.org/Abstract/Abstract/13470

Conclusions/Recommendations

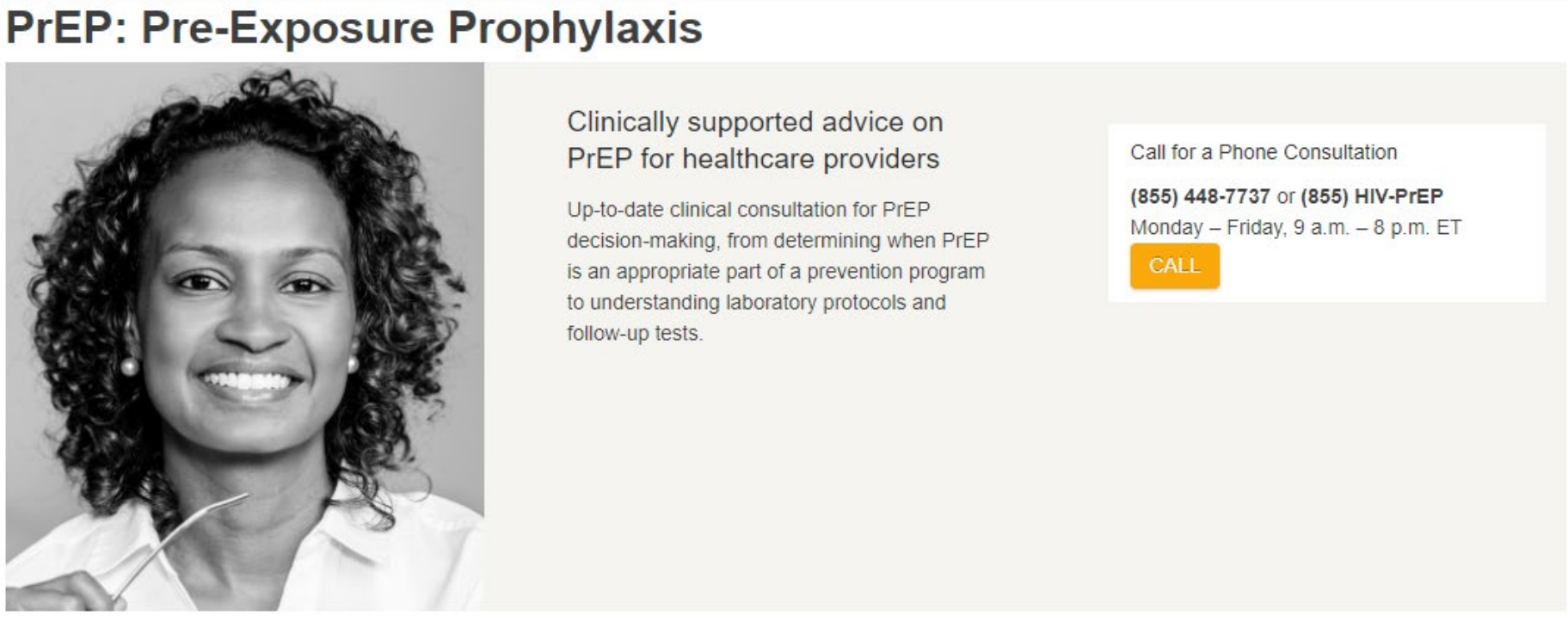
- PrEP Works!
- Easy to prescribe and monitor – with minimal side effects

- Don't forget other pillars of prevention:
  - HIV Testing that adheres to CDC/USPTF guidelines
  - Treatment as Prevention
  - PEP
- Raise awareness in the community to increase uptake and reduce stigma

PrEP Resources

NATIONAL CLINICIAN CONSULTATION CENTER

CLINICIANS CAN CALL THE NATIONAL CLINICIANS CONSULTATION CENTER PREPLINE AT 855-448-7737 FOR ADVICE ABOUT INTERPRETATION OF HIV TEST RESULTS AND MANAGEMENT OF PATIENTS WHO ACQUIRE HIV INFECTION WHILE TAKING PREP MEDICATION.



http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/

AETC AIDS Education & Training Center Program Southeast

THANK YOU!