



# ***Building Skills in Sexual Health Series***

## ***Session #3:***

### ***HIV Prevention for Primary Care***

***Special Presentation from:***

***WA Department of Health PrEP DAP***

***WA AETC HIV Prevention Coaching***

***Friday, September 16, 2022***



# WELCOME!!!

Washington State Department of Health, the Washington Association for Community Health, and the Washington AIDS Education and Training Center are partnering to offer a monthly webinar series that will aid primary care health care professionals and organizations in Washington leverage the whole care team to address patients' sexual health.



# WELCOME!!!

Third Friday of each month

July 2022 through April 2023  
(No session in December)

Most sessions 90-minutes

Clinical information

Resources



# Logistics

- This session is being recorded.
- Zoom Meeting.
  - We encourage you to have your cameras on.
  - Be mindful of background noise.
  - Unmute to ask questions or use Q/A.
- CE certificates to all participants.
- Evaluation.
  - For data reporting purposes.



# Pre- and Post- Exposure Prophylaxis for HIV Prevention

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# Disclosures

Discussion of:

- 1) Commercial products
- 2) Off-label and investigational use of products



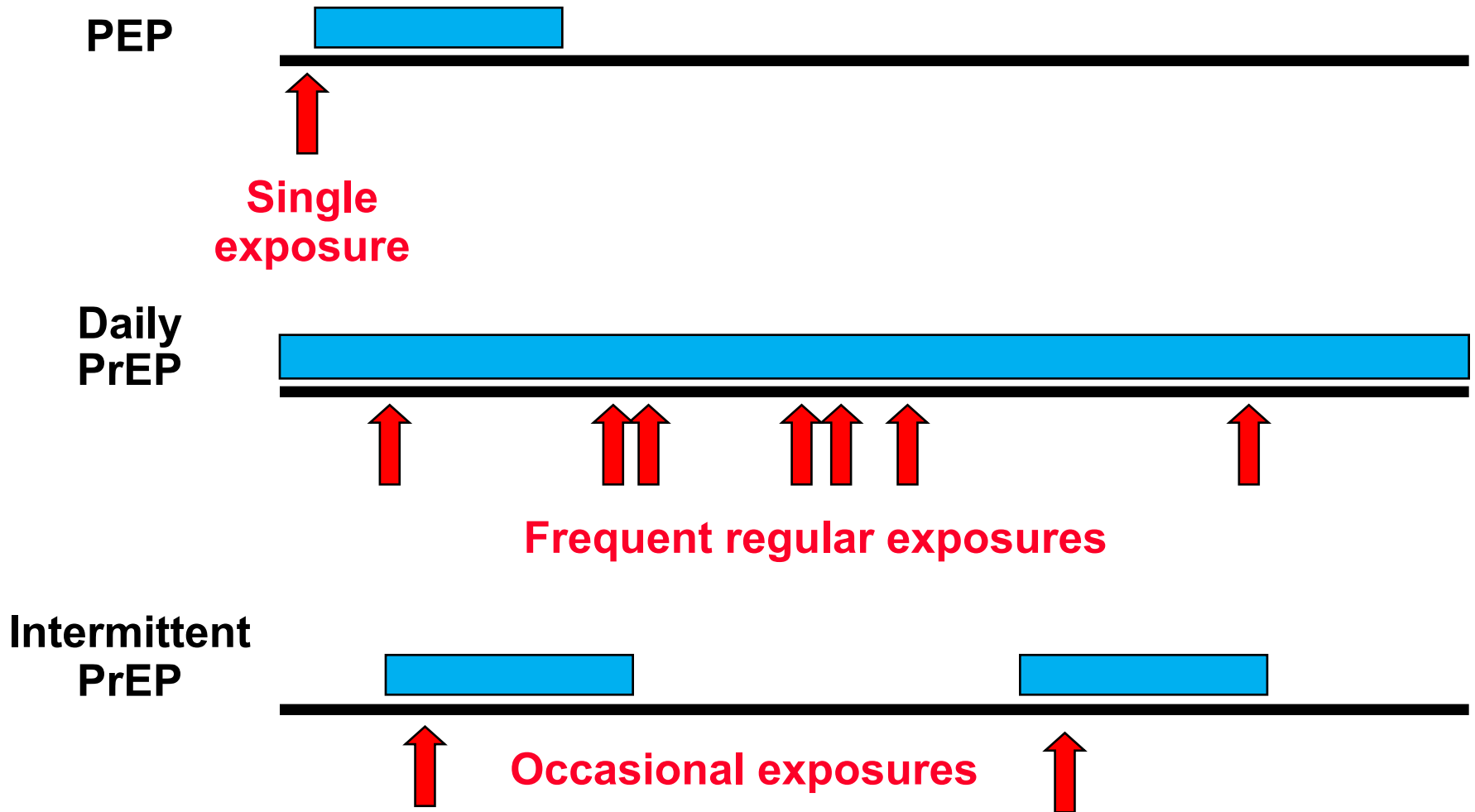
# OUTLINE

- PEP versus PrEP
- PrEP efficacy and medication adherence
- Concerns about PrEP
  - Sexual behavior and STIs
  - Drug resistance
- Prescribing, monitoring, and billing
- Questions



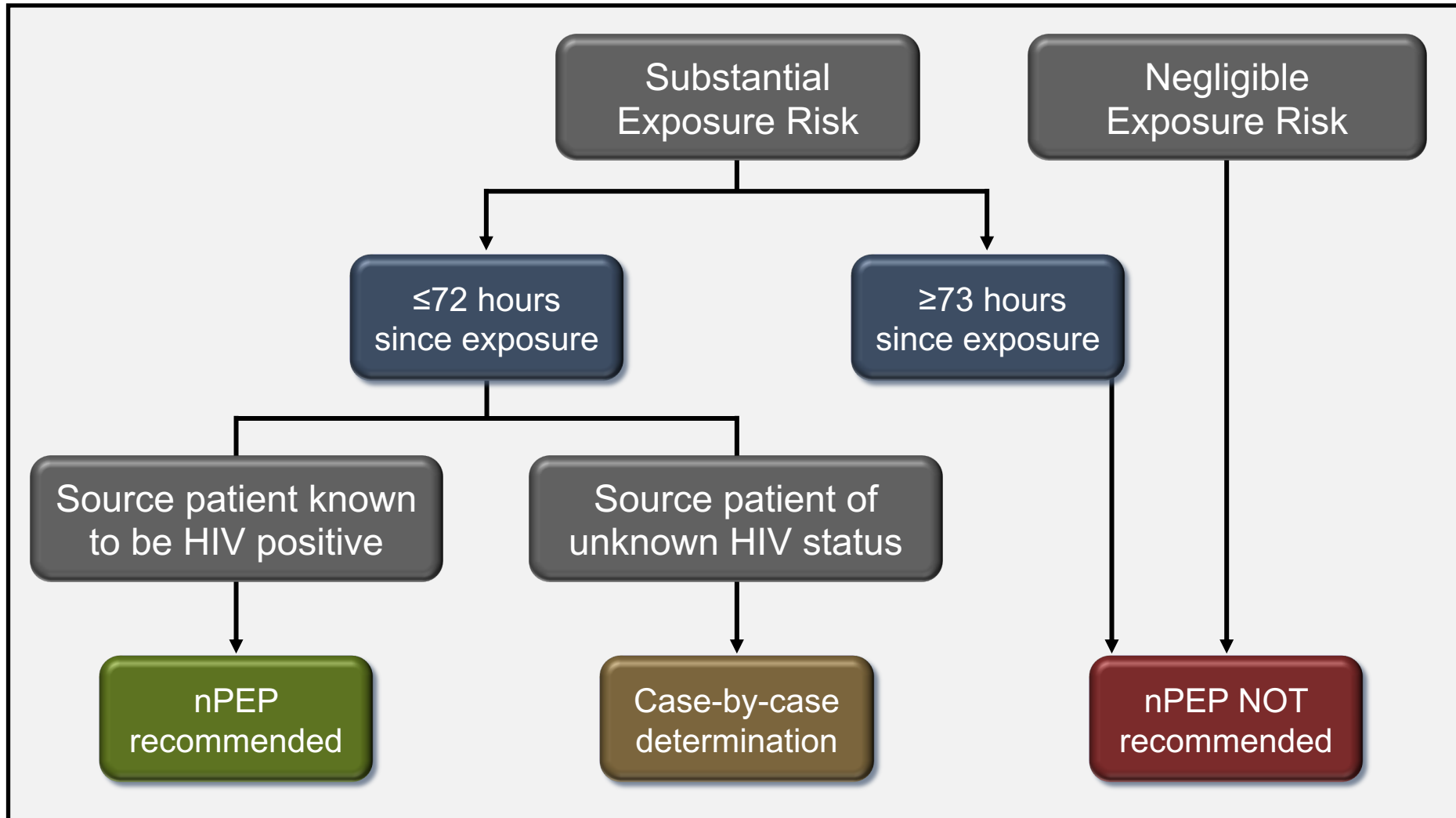
PEP=POST exposure

PrEP=PRE exposure



# 2016 Nonoccupational PEP Guidelines

## Evaluation for nPEP



# 2016 Nonoccupational PEP Guidelines

## Regimens for Nonoccupational PEP

### 2016 HHS Nonoccupational PEP Regimens for Adults and Adolescents

#### Preferred Regimen

Dolutegravir + Tenofovir DF-Emtricitabine

Raltegravir + Tenofovir DF-Emtricitabine

#### Alternative Regimen

Darunavir + Ritonavir + Tenofovir DF-Emtricitabine

Regimens for Patients with CrCl <60 ml/min

Replace Tenofovir DF-Emtricitabine with Zidovudine plus Lamivudine\*

\*Adjust doses for degree of renal impairment

# What is PrEP?

PrEP (Pre-Exposure Prophylaxis) = HIV-negative persons taking HIV medicine to prevent them from getting HIV infection.

## FDA-approved PrEP (September 2022)

Daily emtricitabine/tenofovir disoproxil fumarate (FTC/TDF: Truvada)  
Requires CrCl > 60 mL/min

Daily emtricitabine/tenofovir alafenamide (FTC/TAF: Descovy)  
For cisgender men and transgender women (sexual exposure)  
Requires CrCl > 30 mL/min

Injectable cabotegravir (Apretude)  
All adult populations (sexual exposure)

Dapivirine vaginal ring has been withdrawn.



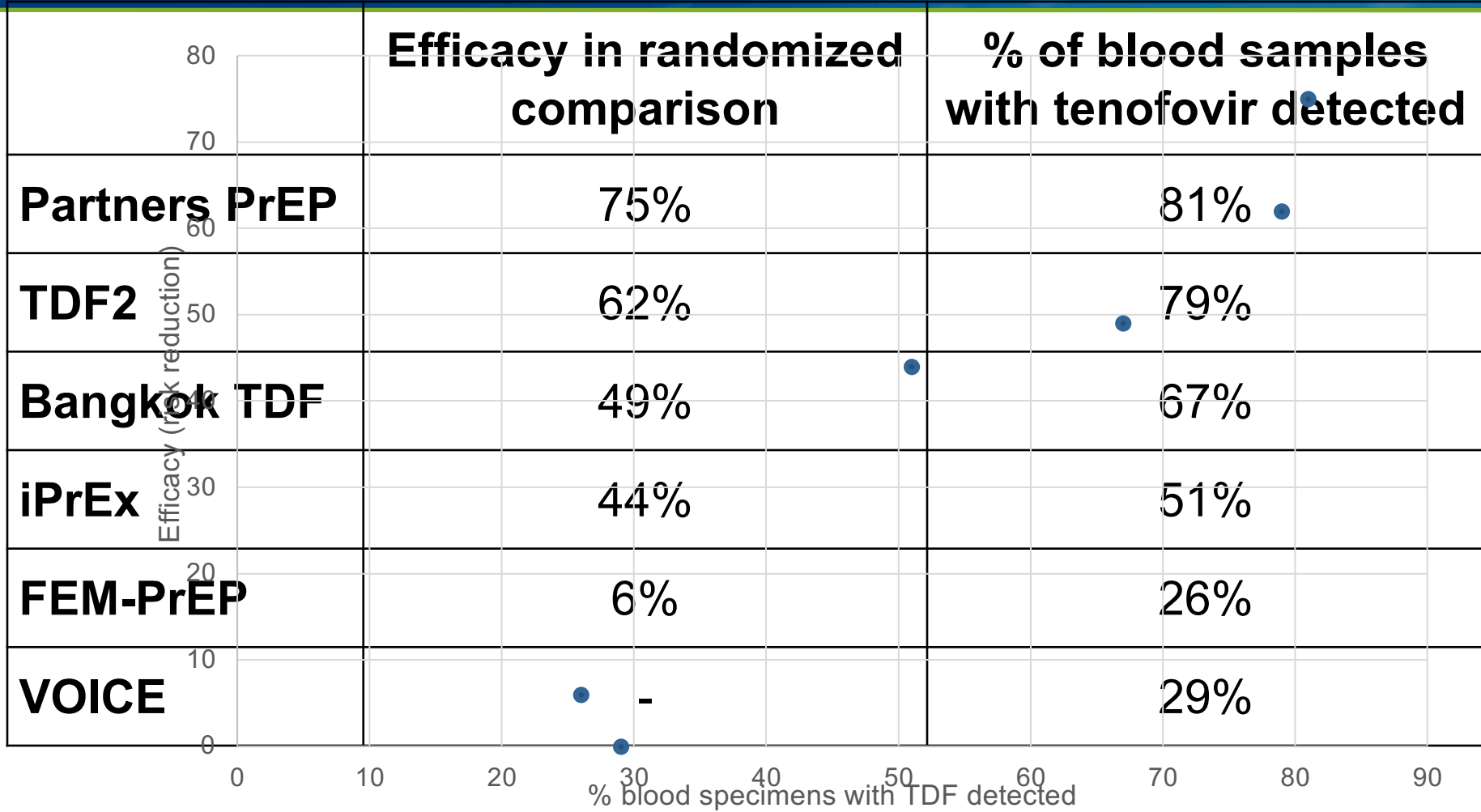
# Key HIV PrEP Trials Using Oral TDF, FTC/TDF, or FTC/TAF

Study	Study Population	Study Randomization	HIV Incidence Impact
<b>IPrEx</b> (Brazil, Ecuador, South Africa, Thailand, US)	2499 MSM and transgender women	Daily oral TDF-FTC or placebo	TDF-FTC: 44% ↓
<b>Partners PrEP Study</b> (Kenya, Uganda)	4147 heterosexual HIV discordant couples	Daily oral TDF, TDF-FTC, or placebo	TDF: 67% ↓ TDF-FTC: 75% ↓
<b>TDF2 Study</b> (Botswana)	1219 heterosexual men and women	Daily oral TDF-FTC or placebo	TDF-FTC: 63% ↓
<b>FEM-PrEP</b> (Kenya, South Africa, Tanzania)	2120 women	Daily oral TDF-FTC or placebo	TDF-FTC: no protection
<b>VOICE</b> (South Africa, Uganda, Zimbabwe)	5029 women	Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo	TDF: no protection TDF-FTC: no protection TDF gel: no protection
<b>Bangkok TDF Study</b> (Thailand)	2413 injection drug users	Randomized to daily oral TDF or placebo	TDF: 49% ↓
<b>IPERGAY</b> (France, Quebec)	400 MSM	Randomized to “on-demand” TDF-FTC or placebo	TDF-FTC: 86% ↓
<b>PROUD</b> (United Kingdom)	545 MSM and transgender women	Randomized to daily oral TDF-FTC immediately or delayed	Immediate TDF-FTC: 86% ↓
<b>DISCOVER</b> (Canada, Europe, US)	5387 MSM and transgender women	Daily oral FTC/TDF or FTC/TAF	F/TDF incidence: 0.3% F/TAF incidence: 0.16%



# Background: Does PrEP Work?

## The Relationship Between Adherence and Efficacy



Baeten et al N Engl J Med 2012  
 Grant et al N Engl J Med 2010  
 Choopanya et al Lancet 2013

Van Damme et al N Engl J Med 2012  
 Thigpen et al N Engl J Med 2012  
 Murrain et al N Engl J Med 2015

# Efficacy in Open-label Projects

## iPrEx OLE (open label extension)

Estimated adherence (TDF in DBS)	Incidence	Protection
Not detected	4.7/100 person-years	
<2 tab/week	2.3/100 person-years	51%
2-3 tab/week	0.6/100 person-years	87%
4-7 tab/week	0/100 person-years	100%

Source: Grant et al (iPrEx OLE), *Lancet*. 2014; 14; 819-829.

**There have been <10 well-documented cases of persons who became HIV-positive despite excellent adherence to PrEP. But there are probably others.**

Examples:

Knox et al *NEJM* 2017; 376: 501-502

Markowitz et al *JAIDS* 2017; 76(4): e104-106

Hoornenborg et al, *Lancet HIV* 2017; 4: e522-28

# FTC/TAF vs FTC/TDF for PrEP

## DISCOVER: Study Design

### Study Features

- Phase 3, multinational, double blind, active controlled trial designed to assess safety and efficacy of FTC/TAF for PrEP
- Enrolled high-risk\* cisgender MSM and transgender women (TGW)
- Exclusions: HIV, HBV, eGFR <60  
Prior PrEP was allowed
- All received counseling & condoms at entry and every 3 months
- Primary endpoint: HIV incidence/100 person-years of follow-up (PYFU)

1:1

**FTC/TDF daily**  
n = 2,694

**FTC/TAF daily**  
n = 2,694

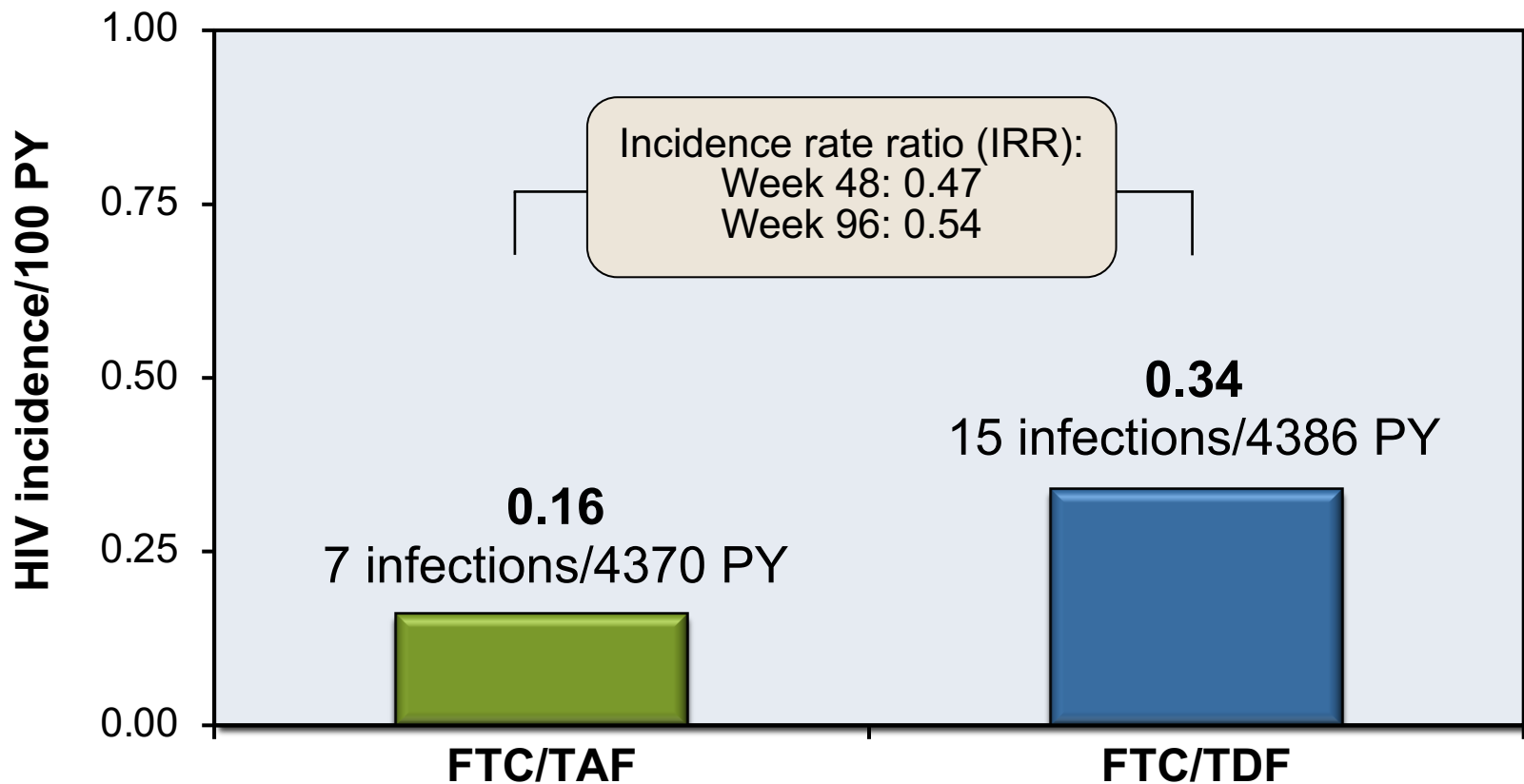
100% at 48 weeks  
50% at 96 weeks

\*  $\geq 2$  episodes condomless anal sex within past 3 months or bacterial STI within past 6 months

Source: Mayer et al Lancet 2020 Jul 25; 396: 239-254.

# FTC/TAF vs FTC/TDF for PrEP

## DISCOVER: Primary Endpoint Result (week 48)



Pre-specific criteria for non-inferiority: IRR <1.62  
Excluding baseline HIV infections (1 FTC/TAF, 4 FTC/TDF), IRR: 0.55  
1 new infection in each arm occurred with adequate drug levels

# Truvada v Descovy: short-term side effects

## Short-term side effects in the DISCOVER TRIAL

	<b>Descovy N=2694</b>	<b>Truvada N=2693</b>
Diarrhea	5%	6%
Nausea	4%	5%
Headache	2%	2%
Fatigue	2%	3%
Abdominal pain	2%	3%

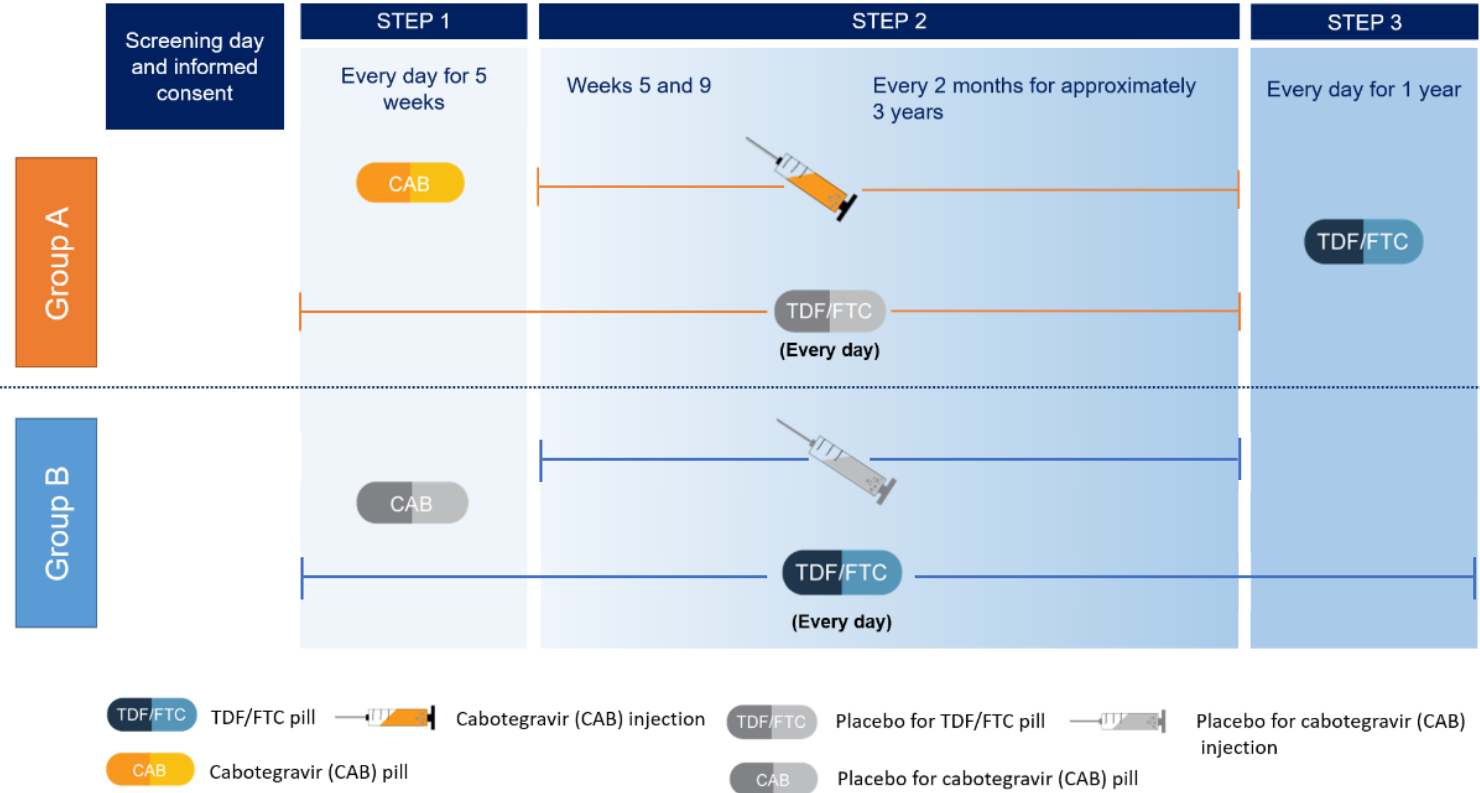
Neither needs to be taken with food

## FTC/TAF vs FTC/TDF for PrEP

# DISCOVER: Secondary Endpoint Results (Week 96)

	FTC/TAF	FTC/TDF
Drug-related AE's		
Mean change (%), spine BMD	1.0	-1.4
Mean change (%), hip BMD	0.6	-1.0
Mean change (mL/min), eGFR	-0.6	-4.1
Weight and lipids		
Mean change (kg)	1.7	0.5
Mean change total cholesterol (mg/dL)	-3	-14
Mean change LDL (mg/dL)	-2	-7

# HPTN 083 and 084 Study



Slide courtesy of Dr. Landovitz

# Injectable cabotegravir (CAB)

## **Superior** to oral FTC/TDF

HPTN 083 (4570 cisgender men and transgender women)

13 infections in the CAB arm (incidence rate 0.41%)

39 infections in the FTC/TDF arm (incidence rate 1.22%).

Hazard ratio for CAB versus FTC/TDF was **0.34 (95% CI 0.18-0.62)**

HPTN 084 (3223 cisgender women).

4 infections in the CAB arm (incidence rate 0.21%)

34 infections in the FTC/TDF arm (incidence rate 1.79%)

Hazard ratio for CAB versus FTC/TDF was **0.11 (95% CI 0.04-0.32)**





**ANOTHER BLUE PILL FOR SEX**

# Sexual behavior: what PrEP offers to patients

- Decreased anxiety
- Increased communication and disclosure
- Increased self-efficacy
- Increased sexual pleasure and intimacy
- Reframing of sexual health in a positive framework

# PrEP and STI incidence

- STI incidence among MSM PrEP users is high  
Liu AY. *JAMA Int Med* 2016;176:75; McCormick S. *Lancet* 2016;387:53
- PROUD - No difference in STI incidence  
McCormick S. *Lancet* 2016;387:53
- Kaiser Permanente - 44% men ↓ condom use with PrEP  
Volk JE. *CID* 2015;61:1601
- Meta-analysis suggested ↑ STI risk in MSM using PrEP  
Kojima et al. *AIDS*. 2016 Sep 10;30(14):2251-2.
- Modeling study found potential for decreased population risk of STI's over time because of frequent screening  
Jeness SM et al. *Clin Infect Dis*. 2017 Sep 1;65(5):712-718

# Drug resistance in PrEP Trials

## Proportions of seroconverters with drug resistance

	Acute HIV at enrollment		HIV infection post-enrollment	
	PrEP	Placebo	PrEP	Placebo
BTS	0/0	0/2	0/17	0/33
FEM-PrEP	0/1	0/1	4/33	1/35
iPrEx	2/2	1/8	0/48	0/83
Partners	2/8	0/6	0/27	0/51
TDF2	1/1	0/2	0/9	0/24
VOICE	2/14	0/1	1/113	0/60
<b>Total</b>	<b>7/26 (27%)</b>	<b>1/20 (5%)</b>	<b>5/247 (2%)</b>	<b>1/286 (0.3%)</b>

Excluding acute infections when PrEP was started:

10 (39/4) infections averted per drug resistant infection.

US Public Health Service

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

A CLINICAL PRACTICE GUIDELINE



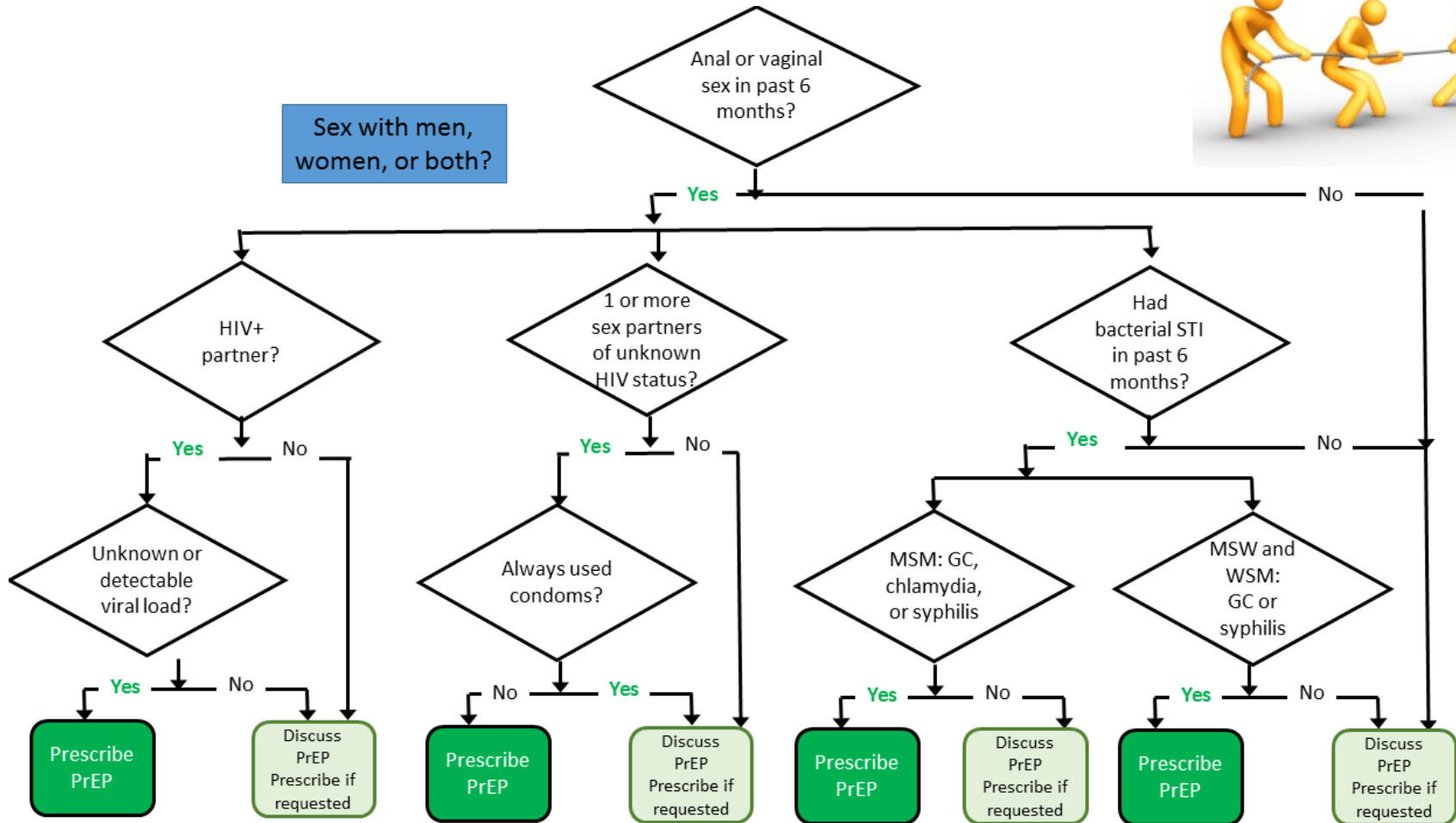
Source: US Public Health Service. Clinical practice guidelines for PrEP.



# Who should be prescribed PrEP?

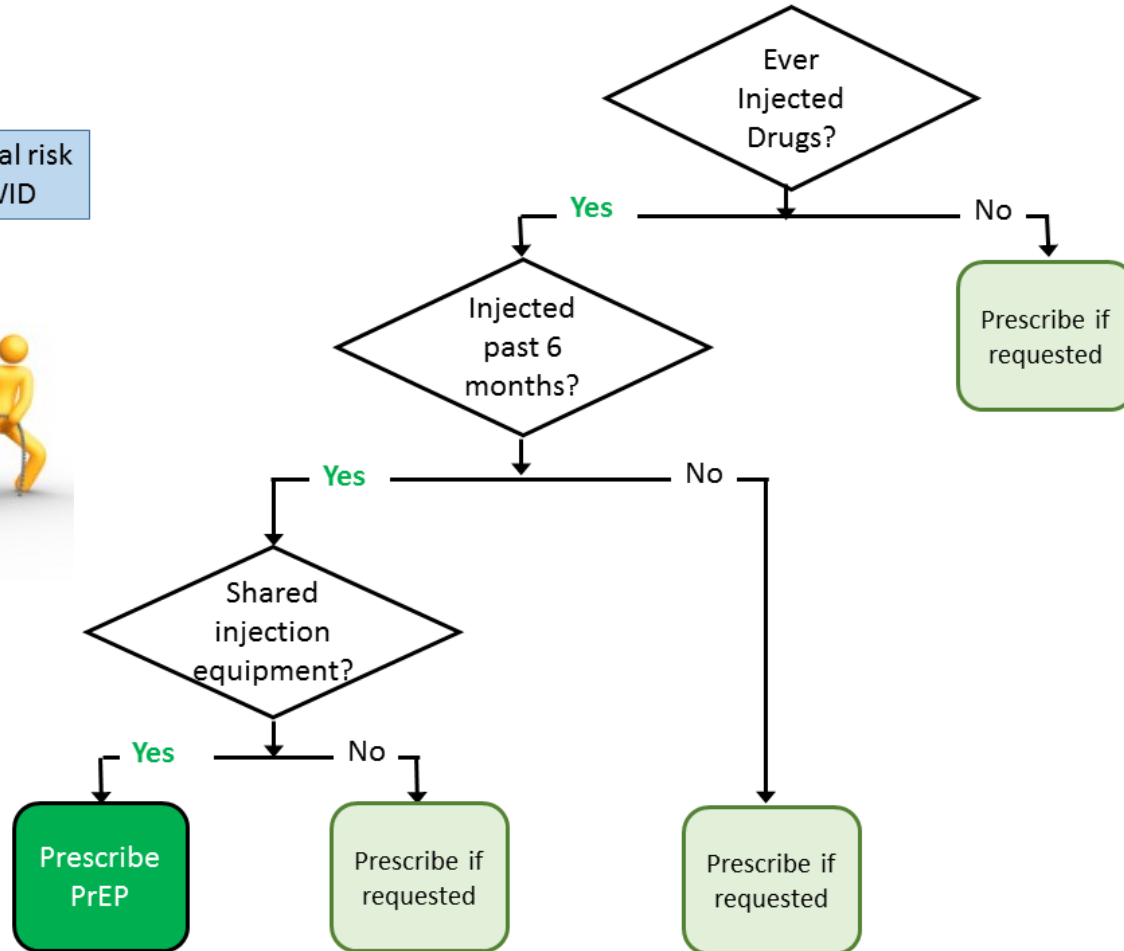
- All sexually active adult and adolescent patients should receive information about PrEP **(III B)**
- For both men and women, PrEP with daily F/TDF is recommended for sexually-active adults and adolescents (>35 kg) who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition **(IA)**
- For both men and women, PrEP with daily F/TDF is recommended for persons who inject drugs (PWID) and report injection practices that place them at substantial ongoing risk of HIV exposure and acquisition **(IA)**
- PrEP should be prescribed in discordant couples
  - If the sexual partner with HIV has been inconsistently virally suppressed
  - If their VL is unknown
  - If the HIV-negative partner has other sexual partners
  - If the HIV-negative partner wants the additional reassurance of protection

# Assessing Indications for PrEP in Sexually Active Persons



# Assessing Indications for PrEP in Persons Who Inject Drugs

Assess sexual risk for all PWID





# HIV testing and PrEP

## My guiding principles...

- Use tests w shortest window period to avoid starting PrEP during AHI → resistance.
- Do not ask people to remain abstinent/use condoms while waiting out the window period.
- Screen for symptoms of AHI
  - If symptoms and recent exposure → delay PrEP start
- PrEP may lead to delayed seroconversion and false-negative tests, particularly with oral fluid tests

Curlin et al CID 2017; 64(12): 1663-69

Donnell et al AIDS 2017; 31(14): 2007-16

- PrEP programs will have new problem of lots of false positive test results because of lower HIV incidence plus frequent HIV testing.

# Baseline HIV testing with oral PrEP

## CDC guidelines

- Document an HIV test within one week before PrEP.
- Ideally lab-based antigen/antibody (Ag/Ab) test.
- Point-of-care (POC) Ag/Ab testing is acceptable. When PrEP is prescribed based on POC results, a laboratory Ag/Ab test should always be ordered when baseline labs are drawn.
- Oral fluid tests should not be used.

# Screening to determine PrEP eligibility

## STI testing (new section in 2017)



- Screen for syphilis and gonorrhea at baseline + semi-annual
- Chlamydia
  - MSM – screen baseline and semi-annually
  - Women – not recommended as part of PrEP, refer to 2015 guidelines
- What tests
  - MSM: 3-site NAAT (pharyngeal, rectal, urine)
    - self-collected specimens ok
  - Women – self-collected vaginal swabs
    - Rectal specimens if report anal sex
- Quarterly STI testing for
  - symptomatic, sexually active persons
  - asymptomatic MSM “at high risk for recurrent bacterial STI”
    - e.g. past STI or multiple sex partners

# Screening to determine PrEP eligibility

## HBV and HCV testing

- “HBV infection is not a contraindication to PrEP use”
- “Those patients found to be HBsAg positive should be evaluated for possible treatment either by the clinician providing PrEP care or by linkage to an experienced HBV care provider.”
- HCV testing is recommended for:
  - persons who have ever injected drugs
  - MSM starting PrEP
  - anyone born 1945-1965
- Annual HCV testing is recommended for PWID.

# What to prescribe as PrEP

## Cost considerations

- Fall 2020, Truvada has been available as a generic
  - In some states, the company will no longer be able to offer Truvada through the MAP but will be thru Ready Set PrEP!
- As of August 2021
  - No cost differences in TAF/FTC, generic or brand TDF/FTC
  - Equal coverage by company medication assistance program
  - AppleHealth requires TDF/FTC except in certain conditions
  - Private healthcare plans vary
  - Expect PAs, even with USPSTF grade A rec
- Analysis by Walensky et al suggests that TAF associated with incremental cost effectiveness ratio: \$7 million/QALY

# What to prescribe as PrEP?

- F/TAF is a recommended option for men. F/TAF has not yet been studied in persons at risk through receptive vaginal sex. **(IA)**
- For transgender women who have sex with men, F/TAF is a recommended option. **(IIB)**
- For most patients, there is no need to switch from F/TDF to F/TAF.
- F/TAF is indicated for patients with eCrCl 30-60.
- Clinicians may prefer F/TAF for patients with previously documented osteoporosis or related bone disease.
- Other daily oral antiretroviral medications for PrEP have not been studied extensively and are not recommended. **(IIIA)**
- Conditioned on a PrEP indication approved by FDA, PrEP with intramuscular cabotegravir (CAB) injections is recommended for HIV prevention in adults and adolescents who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. **(IA)**

# How to prescribe oral PrEP?

## Same day PrEP

Same-day PrEP initiation **is not appropriate** for:

- Patients who express ambivalence about starting PrEP (e.g., need more time to think)
- Patients for whom blood cannot be drawn for laboratory testing
- Patients with signs/symptoms and sexual history indicating possible acute HIV infection
- Patients with history of renal disease or associated conditions (e.g., hypertension, diabetes)
- Patients without insurance or a means to pay when picking up the prescribed medication that day
- Patients who do not have a **confirmed** means of contact should laboratory test indicate a need to discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction)

Same-day PrEP initiation **may not be appropriate** for:

- Patients with a very recent possible HIV exposure but no signs and symptoms of acute infection (should be evaluated for nPEP before PrEP)
- Patients who may not be easily contacted for return appointments
- Patients with mental health conditions that are severe enough to interfere with understanding of PrEP requirements (adherence, follow-up visits)

2-1-1 dosing – clinicians may choose to prescribe **F/TDF** off label for **adult MSM** who have **sex less than once/week** and can **anticipate sex**.

# Drug Interactions

## Oral PrEP (Table 4, p39)


	TDF	TAF
Feminizing hormones	Lower TDF levels (unclear impact on effectiveness). No impact on hormone levels.	No data
ACV, ValACV ... NSAIDs (drugs that decrease kidney function)	Serum concentrations may be increased. Monitor for renal toxicity.	No data
Adefovir	<b>Do not co-administer.</b>	No data
Hepatitis C treatments	TDF may be increased. Monitor for toxicity.	No significant effect
St John's Wort	No significant effect.	<b>Possible decreased TAF. Do not co-administer.</b>
Rifampin	No significant effect	<b>Do not co-administer unless benefits &gt; risks.</b>
Rifabutin, Rifapentine	No significant effect.	<b>Do not co-administer.</b>



# Monitoring

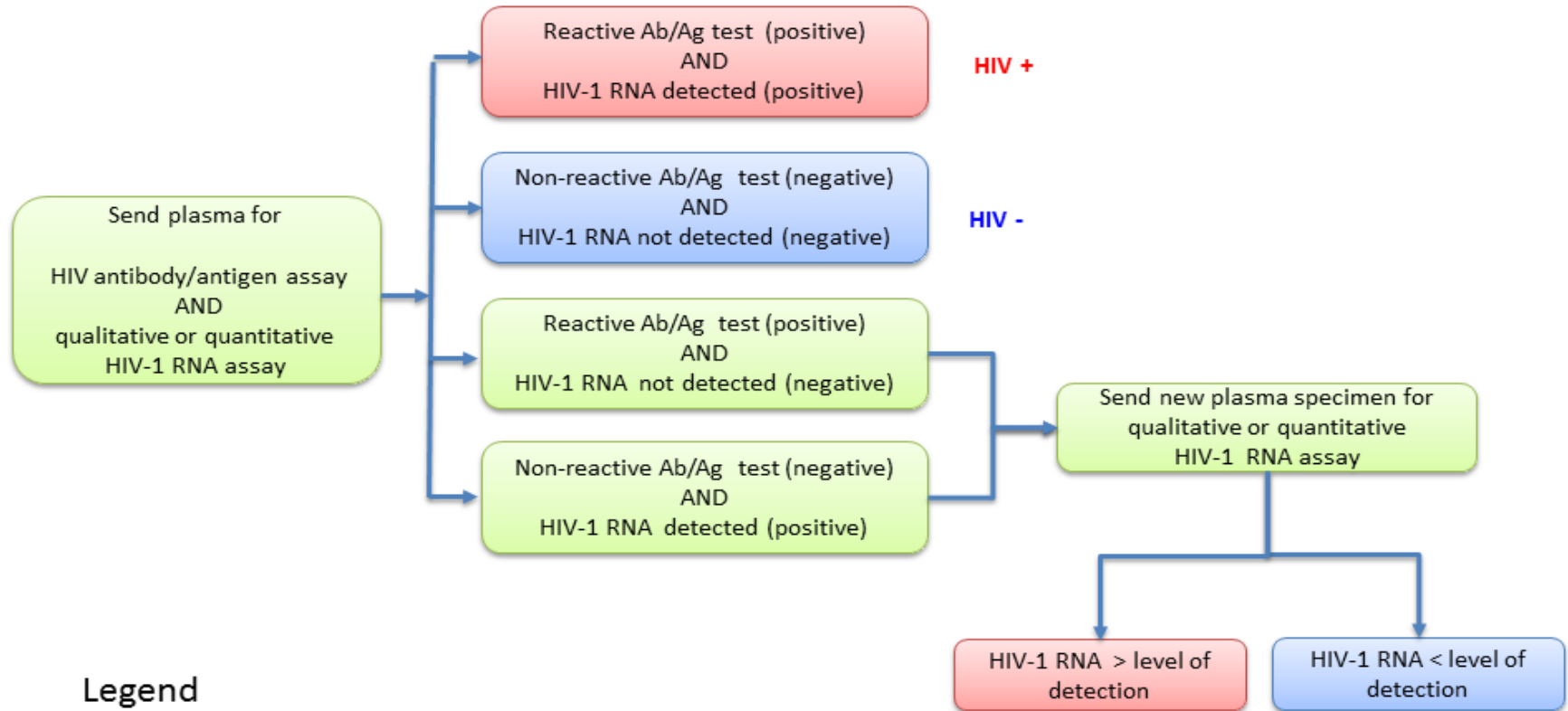
- HIV infection should be assessed at least every 3 months for patients taking daily oral PrEP and every 2 months for patients receiving CAB injections for PrEP. **(IA)**
- Estimated creatinine clearance (eCrCl) should be assessed every 6 months for patients over age 50 OR those who have an eCrCl <90 ml/min at initiation. **(IIA)**
- For all other daily oral PrEP patients, eCrCl should be assessed at least every 12 months. **(IIA)**
- Triglycerides and cholesterol levels should be checked annually for all persons on F/TAF.
- Tests NOT indicated
  - Oral PrEP – DEXA, LFTs, CBC, UA
  - CAB – eCrCl, HBV\*, lipids, LFTs

# Summary of guidance for daily oral PrEP

	Sexually-Active Adults and Adolescents <sup>1</sup>	Persons Who Inject Drug <sup>2</sup>
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> <li>• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>• Bacterial STI in past 6 months<sup>3</sup></li> <li>• History of inconsistent or no condom use with sexual partner(s)</li> </ul>	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<p style="text-align: center;"><b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b></p> <ul style="list-style-type: none"> <li>• Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP</li> <li>• No signs/symptoms of acute HIV infection</li> <li>• Estimated creatinine clearance <math>\geq 30</math> ml/min<sup>4</sup></li> <li>• No contraindicated medications</li> </ul>	
Dosage	<ul style="list-style-type: none"> <li>• Daily, continuing, oral doses of F/TDF (Truvada®), <math>\leq 90</math>-day supply                              OR</li> <li>• For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), <math>\leq 90</math>-day supply</li> </ul>	
Follow-up care 	<p><b><u>Follow-up visits at least every 3 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay medication adherence and behavioral risk reduction support</li> <li>• Bacterial STI screening for MSM and transgender women who have sex with men<sup>3</sup> – oral, rectal, urine, blood</li> <li>• Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <p><b><u>Follow-up visits every 6 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for patients aged <math>\geq 50</math> years or who have an eCrCl <math>&lt; 90</math> ml/min at PrEP initiation</li> <li>• Bacterial STI screening for all sexually-active patients<sup>3</sup> – [vaginal, oral, rectal, urine- as indicated], blood</li> </ul> <p><b><u>Follow-up visits every 12 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for all patients</li> <li>• Chlamydia screening for heterosexually active women and men – vaginal, urine</li> <li>• For patients on F/TAF, assess weight, triglyceride and cholesterol levels</li> </ul>	

# Follow-up HIV testing

If the patient has taken oral PrEP or PEP medication in the past 3 months  
OR  
has received a cabotegravir injection in the past 12 months



## Legend

- HIV – assay result
- HIV + assay result
- HIV Status Unclear

# Adherence support

## Box B: Key Components of Oral Medication Adherence Counseling

### Establish trust and bidirectional communication

### Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

### Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses

## A Brief Medication Adherence Question

### Monitor

- “Many people find it difficult to take a medicine every day.
- 
- 

Thinking about the last week – on how many days have you not taken your medicine?”

# Options in cases of suspected PrEP failure

*Open Forum Infectious Diseases*

MAJOR ARTICLE



## A Strategy for PrEP Clinicians to Manage Ambiguous HIV Test Results During Follow-up Visits

Dawn K. Smith<sup>□</sup>, William M. Switzer, Philip Peters, Kevin P. Delaney, Timothy C. Granade, Silvina Masciotra, Luke Shouse, and John T. Brooks

Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

- 1) Continue PrEP while conducting additional tests
- 2) Initiate ART while conducting additional tests
- 3) Discontinue PrEP to reassess status/conduct additional tests after a brief medication-free interval

PrEPline consultation: 855-448-7737 (11a-6p EST)



# Paying for PrEP

## U.S. Preventative Services Task Force (2019)

### 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.	<b>A</b>

- All non-grandfathered private health plans must cover PrEP without cost-sharing (such as a copay or coinsurance) beginning no later than the 2021 plan year.
- However, prior authorizations are allowed, as is placing generics on zero cost-sharing tiers with cost sharing for brand equivalents.
- Sept 2022: Braidwood Management Inc v Becerra struck down this requirement in TX. Appeal pending.

# ICD-10 codes to consider using for PrEP prescribing

Visit and HIV/STD testing	
Z20	
Z20.6	Contact with and (suspected) exposure to HIV
Z72.5	High risk behavior (main category not billable)
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior
Z11	Encounter for screening infectious and parasitic diseases (not billable)
Z11.3	Encounter for screening for infectious with a predominantly sexual mode of transmission
Z11.4	Encounter for screening for HIV
Laboratory monitoring	
Z51.81	Encounter for therapeutic drug level monitoring
Z79.899	Other long-term (current) use of drug/prophylactic therapy

**Source: US Public Health Service. Clinical practice guidelines for PrEP. May 2014**

Family Planning ▼

Food Safety ▼

Healthy Aging ▼

Healthy Home ▼

**Illness and Disease ▲**

Animal Transmitted Diseases

Antibiotic Resistance ▼

Asthma ▼

Autism ▼

Avian Influenza

Birth Defects ▼

Brucellosis

Campylobacter

Cancer ▼

Chickenpox (Varicella)

Cryptococcosis

Cryptosporidium

Death with Dignity Act ▼

Diabetes ▼

Diphtheria

Ebola ▼

E. coli

**Enterovirus D68**

Epilepsy

Flu ▼

# Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)

## What is PrEP?

Pre-Exposure Prophylaxis (PrEP) is an HIV prevention method in which HIV-negative people take a daily pill to reduce their risk of becoming infected.

When used consistently, PrEP has been shown to reduce the risk of HIV-1 infection among adult men and women at very high risk for HIV infection through sex or injection drug use. TRUVADA® has been approved by the Federal Drug Administration for use in PrEP.

If you are interested, your prescribing medical provider can answer your questions.

## Where can I find additional information on PrEP?

- [What is PrEP?](#)
- [PrEP Facts](#)

## What is PrEP DAP?

PrEP DAP is a drug assistance program for HIV-negative people who have risk factors that expose them to HIV. PrEP DAP will pay for TRUVADA® for people who want to be on PrEP.

[Learn about PrEP DAP in our brochure - English \(PDF\)](#)

[PrEP DAP brochure - Spanish version \(PDF\)](#)



# Questions without answers

- How long does it take to achieve protection on PrEP?
- When discontinuing PrEP, how long does someone need to continue PrEP after their exposure?
- How will injectable PrEP be implemented?
- Will healthcare insurance cover injectable PrEP?

# The PrEP Pipeline

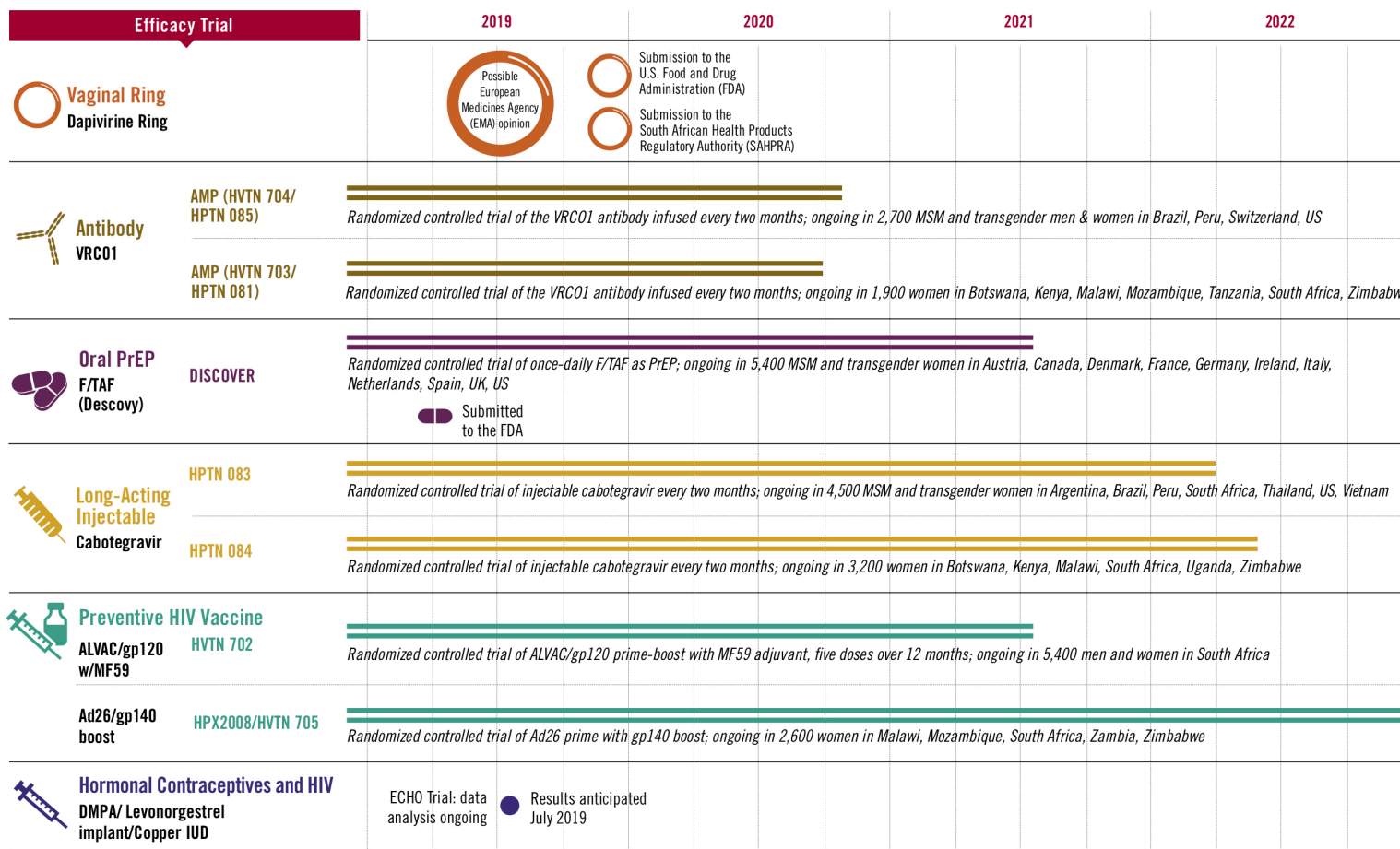
www.avac.org

**AVAC**

Global Advocacy for HIV Prevention

## The Years Ahead in Biomedical HIV Prevention Research

Status of select biomedical HIV prevention clinical trials



 Randomized Controlled 
  Open-label and Randomized 
  Regulatory Submission

 AVAC  
[www.avac.org](http://www.avac.org)  
 May 2019



# Resources

## CDC/HHS

[www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf](http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf)

[www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf](http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf)

## IAS-USA

[www.iasusa.org/resources/guidelines/](http://www.iasusa.org/resources/guidelines/)

## Consultation and assistance

MWAETC Prevention Detailing Program

[mwaetc.org/washington-state-hiv-prevention-detailing-program](http://mwaetc.org/washington-state-hiv-prevention-detailing-program)

Consultation PrEPLine (855-448-7737)

For urgent questions or ambiguous test results

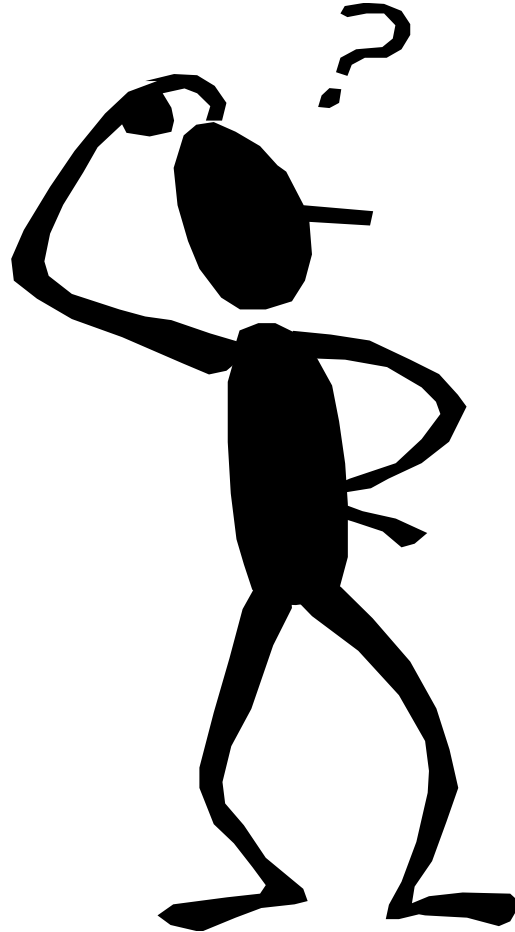
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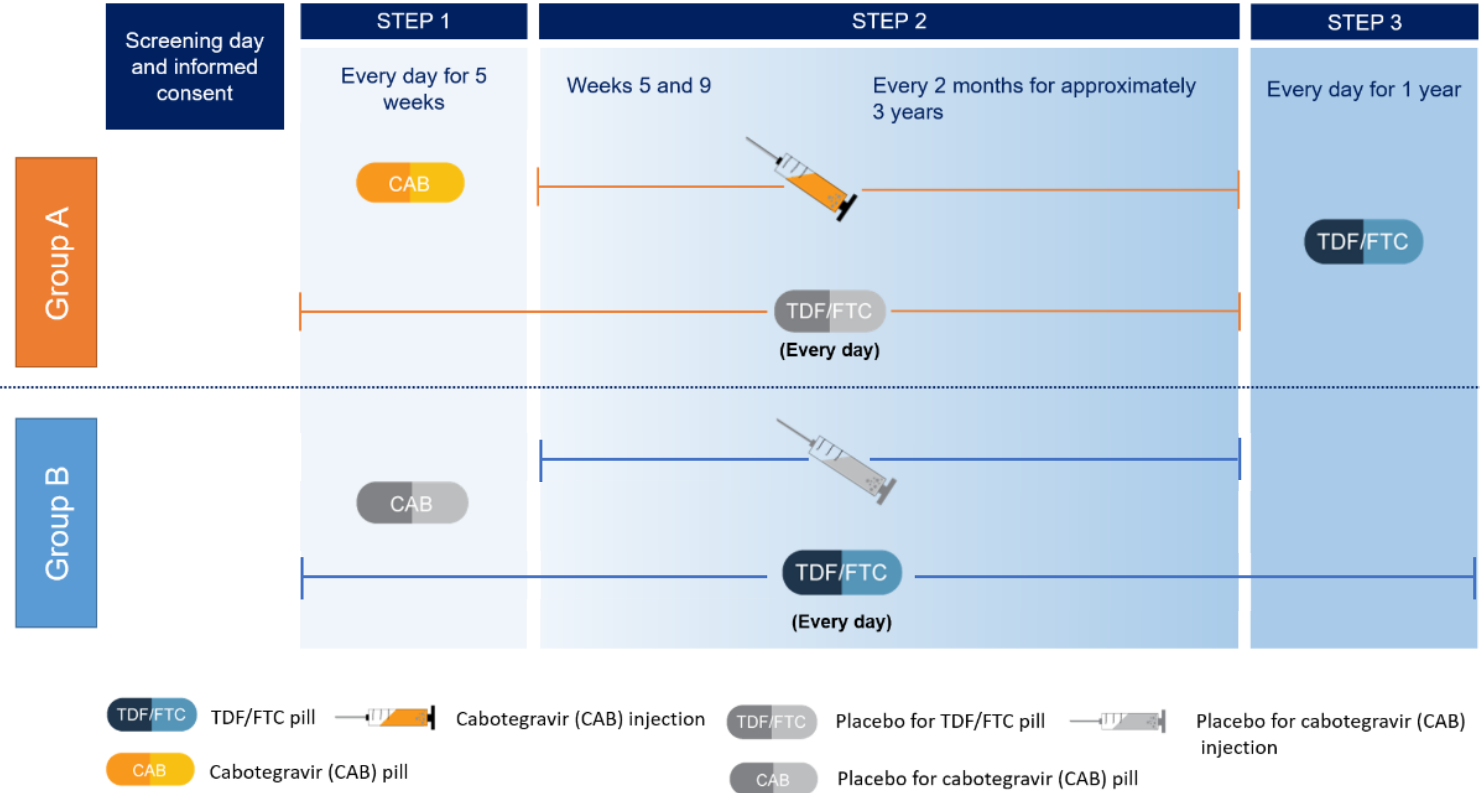
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# Questions?



# HPTN 083 and 084 Study



Slide courtesy of Dr. Landovitz

# Injectable cabotegravir (CAB)

## **Superior** to oral FTC/TDF

HPTN 083 (4570 cisgender men and transgender women)

13 infections in the CAB arm (incidence rate 0.41%)

39 infections in the FTC/TDF arm (incidence rate 1.22%).

Hazard ratio for CAB versus FTC/TDF was **0.34 (95% CI 0.18-0.62)**

HPTN 084 (3223 cisgender women).

4 infections in the CAB arm (incidence rate 0.21%)

34 infections in the FTC/TDF arm (incidence rate 1.79%)

Hazard ratio for CAB versus FTC/TDF was **0.11 (95% CI 0.04-0.32)**

# HIV Testing Plan: HPTN 083

- Real time:
  - Screening visit (within 14d of enrollment)
    - HIV RNA test
  - Entry and follow-up
    - Point-of-care test
    - Laboratory-based Ag/Ab combo test
- Confirmation
  - Supplemental antibody testing
  - Quantitative HIV RNA
  - Ultrasensitive DNA testing (performed at Johns Hopkins U)
- Retrospective (for incident HIV-positive cases) until negative
  - Ag/Ab combo test
  - Qualitative HIV RNA → quantitative HIV RNA (“viral load”)
  - Single copy viral load test as needed (U Pittsburgh)



# Delayed detection of HIV infection in CAB-LA PrEP (n=11)

	Group A (baseline)	Groups C + D
Median delay 1 <sup>st</sup> pos (range)	62 (28-72) days	98 (35-185 days)
Median log VL at 1 <sup>st</sup> pos visit	4.4 (3.1-4.7)	2.1 (ND-2.9)
		5 of 7 detectable
Received CAB p infection	4/4	6/7

5 of these participants acquired INSTI resistance.

These 11 are 0.2% of the 4570 participants in the study.

# Delayed detection of HIV infection in oral PrEP

PrEP may lead to delayed seroconversion and false-negative tests, particularly with oral fluid tests

## **Curlin et al CID 2017; 64(12): 1663-69**

- Delayed diagnosis occurred in 80/287 seroconverting persons
- OFOQ conversion delay: median 98.5, range 14.5-547.5 days
- Delay was associated with low plasma RNA level

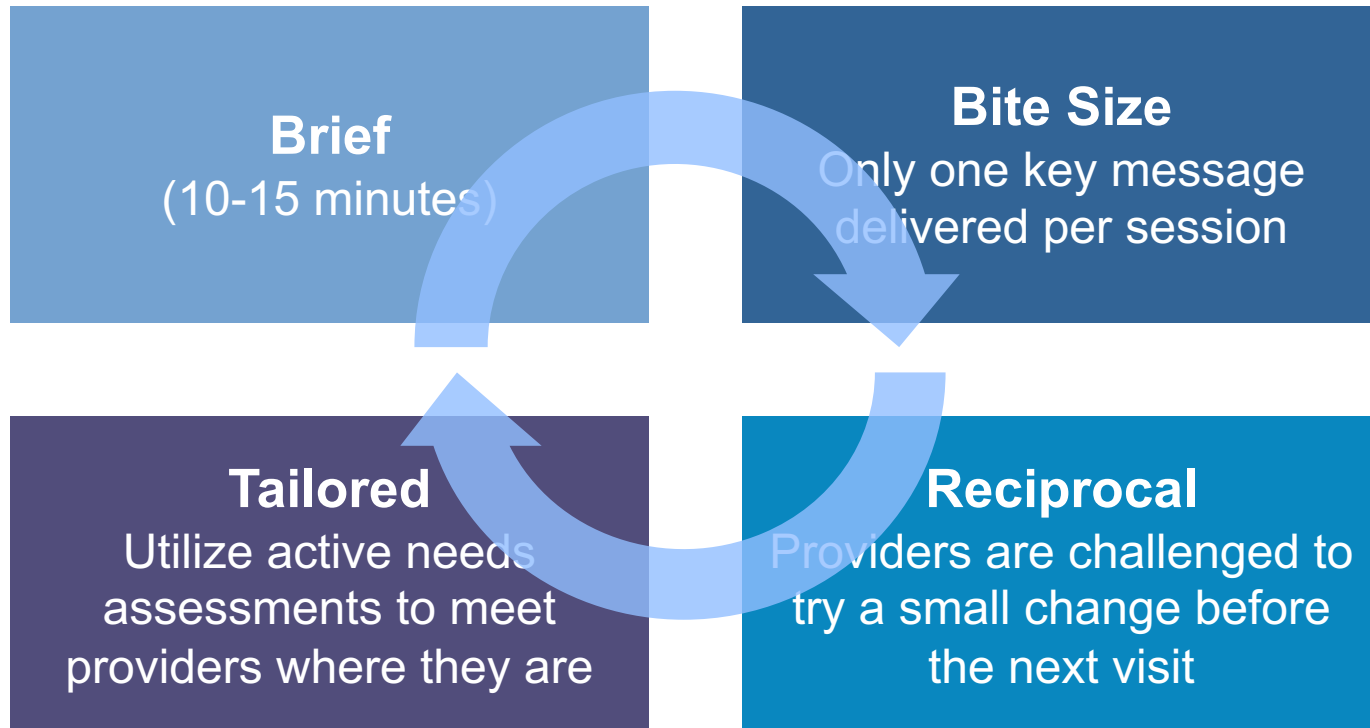
## **Donnell et al AIDS 2017; 31(14): 2007-16**

- PrEP was associated with more frequent delayed diagnosis >100 days by POC Ab testing (17% v 6%)

# **Mountain West AETC Washington State HIV Prevention Detailing Program**

# One-on-One Provider Education

*This just sounds like a group training, but for one person...*



# WA State HIV Prevention Detailing Focus

- Take a thorough sexual history to identify patients who might benefit from PrEP.
- Offer PrEP to patients at risk for HIV infection.
- In particular, offer PrEP to BIPOC patients, patients with a recent bacterial STI or methamphetamine use, and transgender patients.
- Prescribe PrEP for 90 days at a time and screen for HIV/STIs quarterly, including three-site STI screening as appropriate.
- Use neutral language that is person first, culturally appropriate, and non-stigmatizing.

# WA State HIV Prevention Detailing

[ABOUT US](#)[PARTNERS](#)[PROGRAMS](#)[RESOURCES](#)[CALENDAR](#)[CONTACT US](#)

## WASHINGTON STATE HIV PREVENTION DETAILING PROGRAM

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Supporting Washington State goals to *End AIDS Washington*, and the U.S. Department of Health and Human Services strategy to *End the HIV Epidemic* by 2030, the **MWAETC Washington State HIV Prevention Detailing Program** provides focused education, technical assistance, and resources for primary care providers to support their efforts to reduce newly acquired HIV infections across Washington.

**The goal of our program is to reduce HIV disparities and increase PrEP uptake among members of underserved and at-risk populations.** This is achieved by supporting providers via personalized one-on-one education, tools, and resources to help increase their knowledge and comfort with HIV risk assessment and screening, sexual history taking, and PrEP prescribing.

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- PrEP guidelines and decision-making
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- Incorporating PrEP into your primary care practice
- Latest guidelines for STI screening and treatment

#### Visits are:

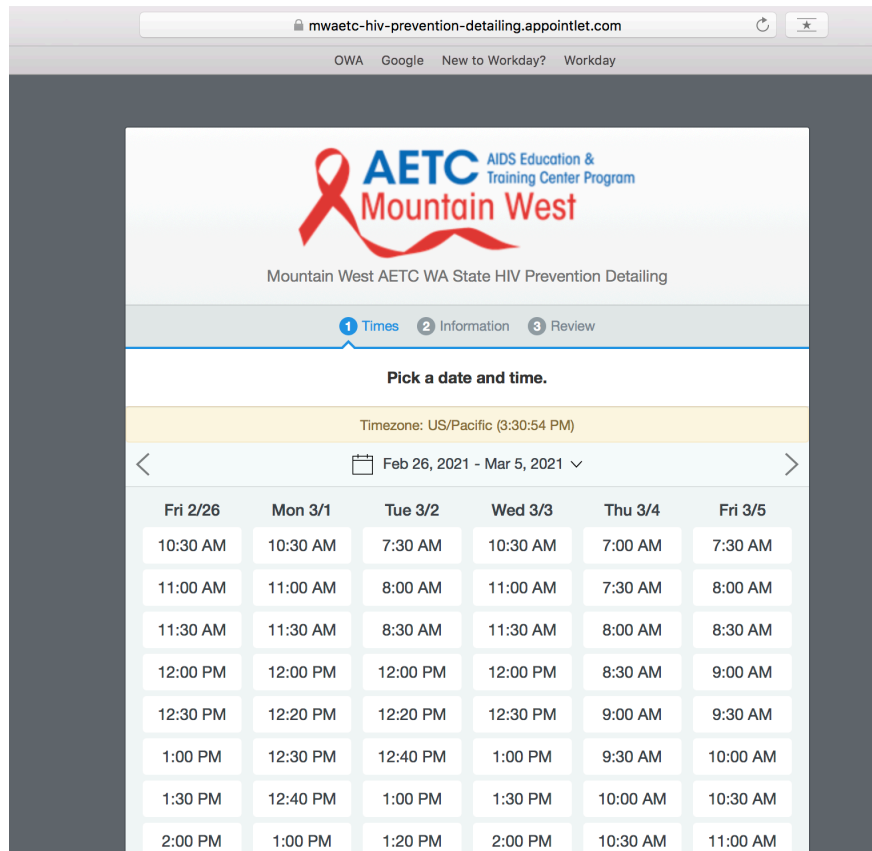
- FREE
- 15 minutes or less
- Easy to schedule, with multiple times to choose from
- One-on-One
- Individualized, with customized information
- Virtual

<https://mwaetc.org/washington-state-hiv-prevention-detailing-program>



# WA State Program – Make appointments online

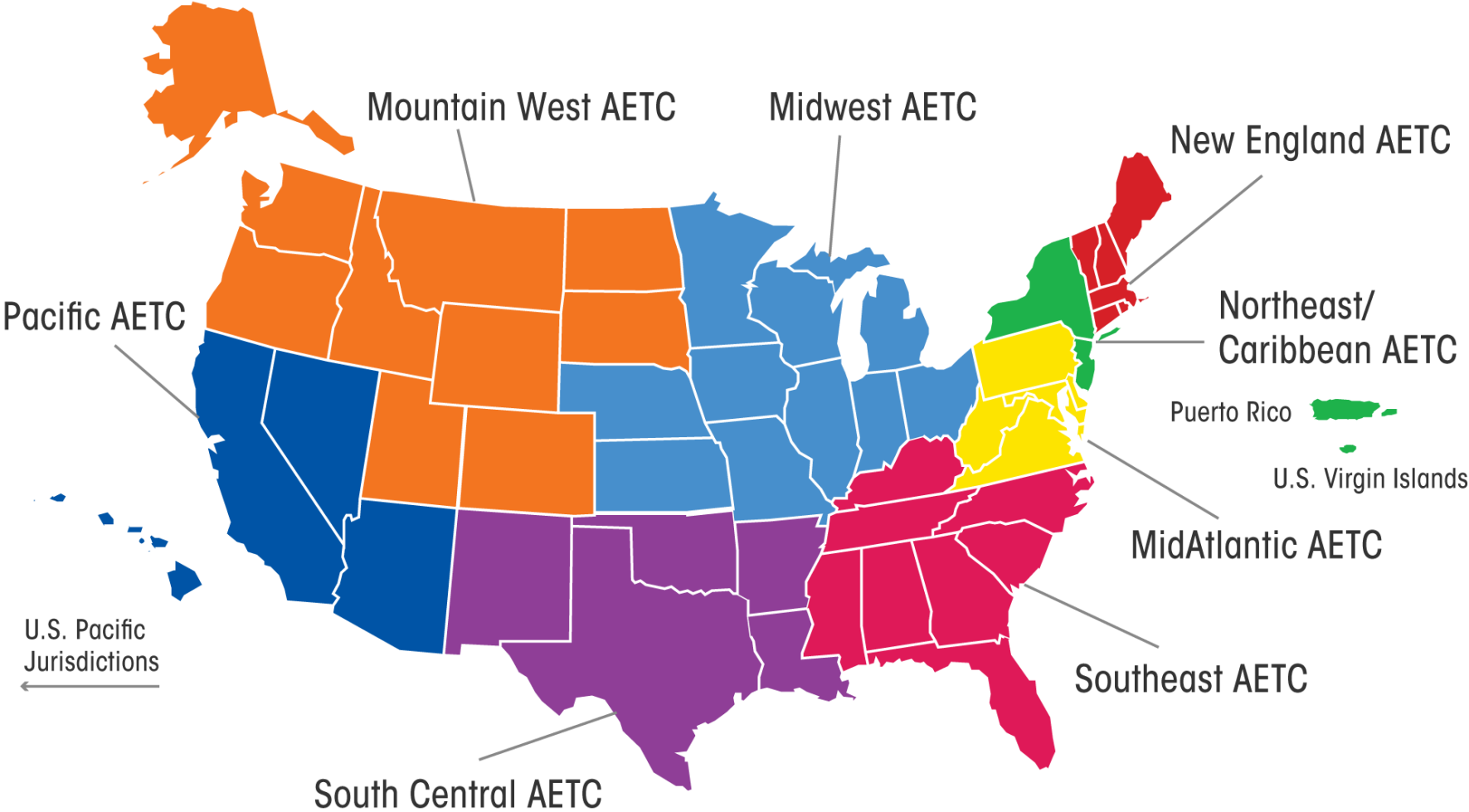
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12:00 PM	12:00 PM	12:00 PM	12:00 PM	8:30 AM	9:00 AM
12:30 PM	12:20 PM	12:20 PM	12:30 PM	9:00 AM	9:30 AM
1:00 PM	12:30 PM	12:40 PM	1:00 PM	9:30 AM	10:00 AM
1:30 PM	12:40 PM	1:00 PM	1:30 PM	10:00 AM	10:30 AM
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# AETC Regional Training Centers



[mwaetc.org/](http://mwaetc.org/)

[aidsetc.org/about](http://aidsetc.org/about)





# MWAETC: Types of Training

- AIDS Clinical Conference
- Capacity Building Assistance
- Clinical Consultation
- Dental Program
- HIV in Corrections Program
- Inter-Professional Education (IPE)
- MWAETC HIV ECHO
- Practice Transformation Program
- Preceptorship Programs

Victor Ramirez  
WA State Training Coordinator  
[vmrg1@uw.edu](mailto:vmrg1@uw.edu)  
206-543-3319

# Mountain West AETC Web Site (mwaetc.org)

ABOUT US

MWAETC OFFICES

TRAINING

RESOURCES

CALENDAR

CONTACT US

mwaetc.org



- Trainings calendar
- Regional program information
- AIDS Clinical Conference presentations
- Resources

## FIND A TRAINING CENTER IN YOUR AREA

Select your state to learn more about the HIV services and educational products these regional offices offer.



AK



CO



ID



MT



ND & SD



OR



UT



WA



WY

## The Mountain West AIDS Education and Training Center (MWAETC)

In 2015, the Northwest AETC and some of the Mountain Plains AETC states merged to form the Mountain West AIDS Education and Training Center. Through state based and regional programs, the new region now serves ten states: Alaska, Colorado, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah and Wyoming. Our name has changed but our mission is the same: increase health care providers' capacity to provide high quality HIV/AIDS care within the region's health care systems by providing HIV treatment education, clinical consultation, capacity building, and technical assistance. Please check out our calendar pages for upcoming events and our training and resources page for your clinical or continuing education needs or just email or call one of the offices.

ABOUT US



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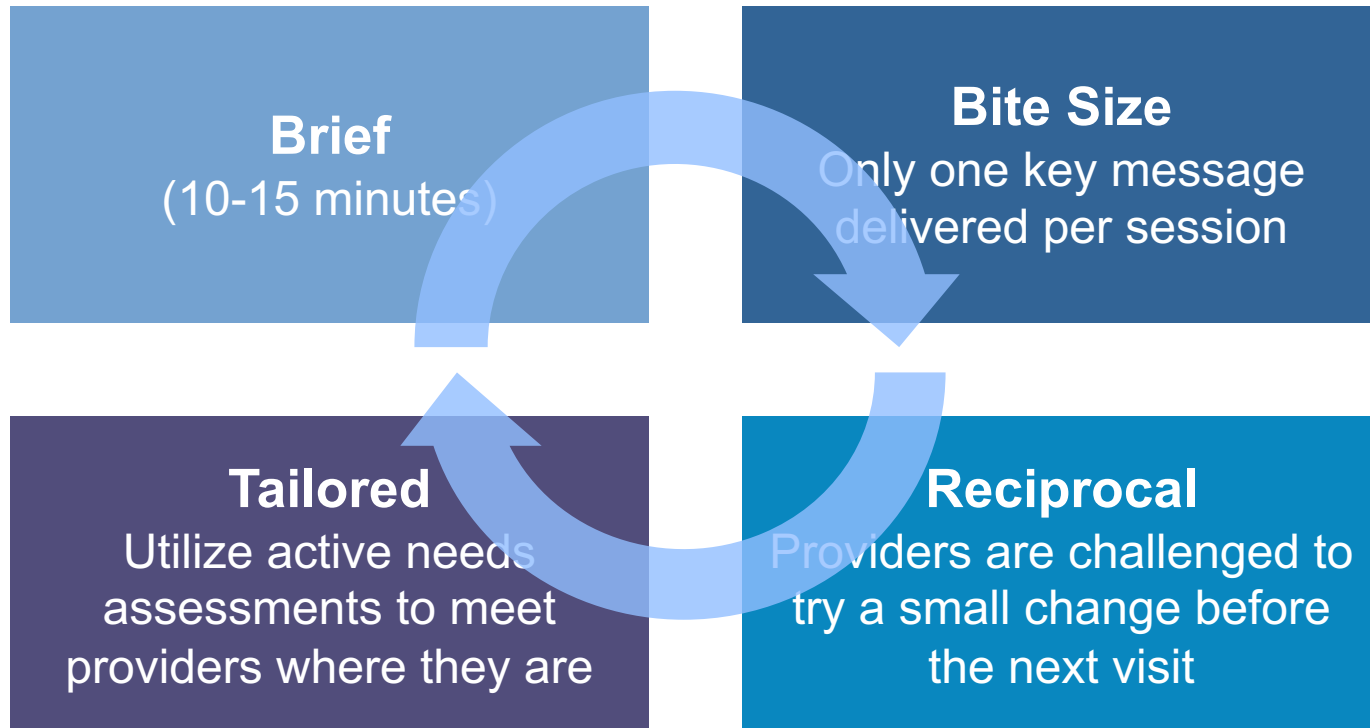
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# WA State HIV Prevention Coaching (Detailing)

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1:30 PM	12:40 PM	1:00 PM	1:30 PM	10:00 AM	10:30 AM
2:00 PM	1:00 PM	1:20 PM	2:00 PM	10:30 AM	11:00 AM



# Next Session

**Friday, October 16**

**9:00 – 10:30 AM PT**

**HIV Testing in Primary Care**

**Neil Barg, MD**

Health Officer

Yakima Health District

Medical Director

New Hope Clinic

Yakima Valley Farm Workers Clinic

Director of Hospital Epidemiology and Director of Antibiotic Stewardship Program

Yakima Valley Memorial Hospital

Clinical Professor of Medicine

Division of Infectious Diseases

University of Washington



# HIV Outbreak Response Plan – Community Engagement Sessions

The Washington State Department of Health (DOH) is developing a statewide HIV Outbreak Response Plan. DOH and partners aren't currently responding to any outbreaks of HIV in Washington but having a plan in place will help us respond effectively if any outbreaks occur.

**Community input is an essential part of this planning process.**

DOH hopes to engage individuals living in Washington state who are outside King County, and who are impacted by HIV. PHSKC will organize community listening session for King County.

Ten listening sessions from Sept 21 to Dec 1.

<https://doh.wa.gov/about-us/programs-and-services/disease-control-and-health-statistics/infectious-disease/hiv-outbreak-response-plan-community-engagement-sessions>

# Questions

Victor Ramirez  
WA State Training Coordinator  
WA AETC  
[vmrg1@uw.edu](mailto:vmrg1@uw.edu)

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