

PREVENTION OF SEXUALLY TRANSMITTED INFECTIONS WITH DOXY-PEP AND PREP

EMILY LEVY KAMUGISHA, MD, AAHIVS
ASSOCIATE PROFESSOR

DISCLOSURES

- None

LEARNING OBJECTIVES

- Describe the current evidence and clinical guidelines for the use of doxycycline post-exposure prophylaxis (Doxy-PEP) in reducing bacterial sexually transmitted infections (STIs)
- Explain the indications, efficacy, and safety considerations for HIV pre-exposure prophylaxis (PrEP) in those at high risk for HIV acquisition
- Identify appropriate patient selection criteria for implementing Doxy-PEP and HIV PrEP in primary care settings
- Discuss potential challenges, including antimicrobial resistance, adherence and equity considerations, when integrating Doxy-PEP and HIV PrEP into routine family medicine practice.

ABBREVIATIONS

- STI = sexually transmitted infections
- MSM = men who have sex with men
- TGW = transgender women
- TGM = transgender men
- AFAB = assigned female at birth
- MSW = Men who have sex with women
- WSM = Women who have sex with men
- PLWH = persons living with HIV infection
- PWID = people who inject drugs
- NRTI = nucleoside reverse transcriptase inhibitor
- NNT = number needed to treat

COMPREHENSIVE SEXUAL HEALTH

Prevention of Sexually Transmitted Infections

Risk reduction counseling

Condoms

PreP

Syringe services programs
(SPP): clean syringes

Avoid IVDU/Sex

Male circumcision

Vaccinations

Post-Exposure Prophylaxis (PEP)

Doxy-PEP

nPEP

oPEP

Treatment as Prevention (TasP)

U=U for HIV

Testing and treatment for STI

Expedited partner therapy
(EPT)

WHAT IS PrEP AND DOXY-PEP?

PrEP = Pre-Exposure Prophylaxis

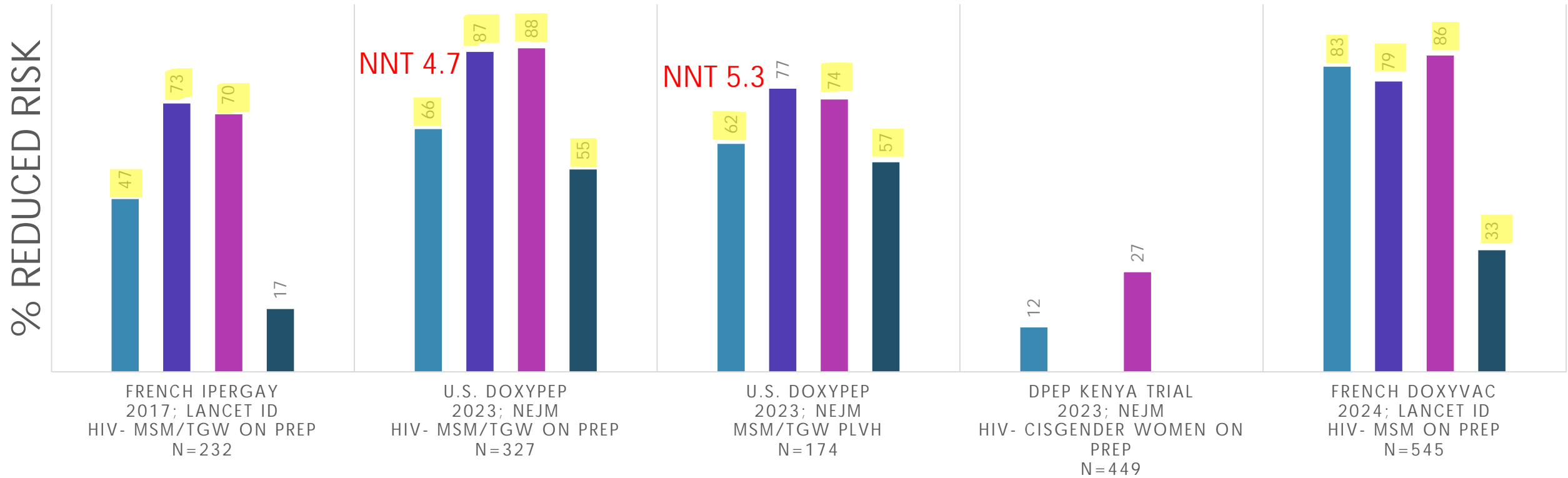
Use of antiretroviral medication to prevent acquisition of HIV infection

DOXY-PEP = Doxycycline Post-Exposure Prophylaxis

Use of Doxycycline medication as chemoprophylaxis to prevent bacterial sexually transmitted infections (STIs), including gonorrhea, chlamydia, and syphilis

EVIDENCE FOR DOXY-PEP

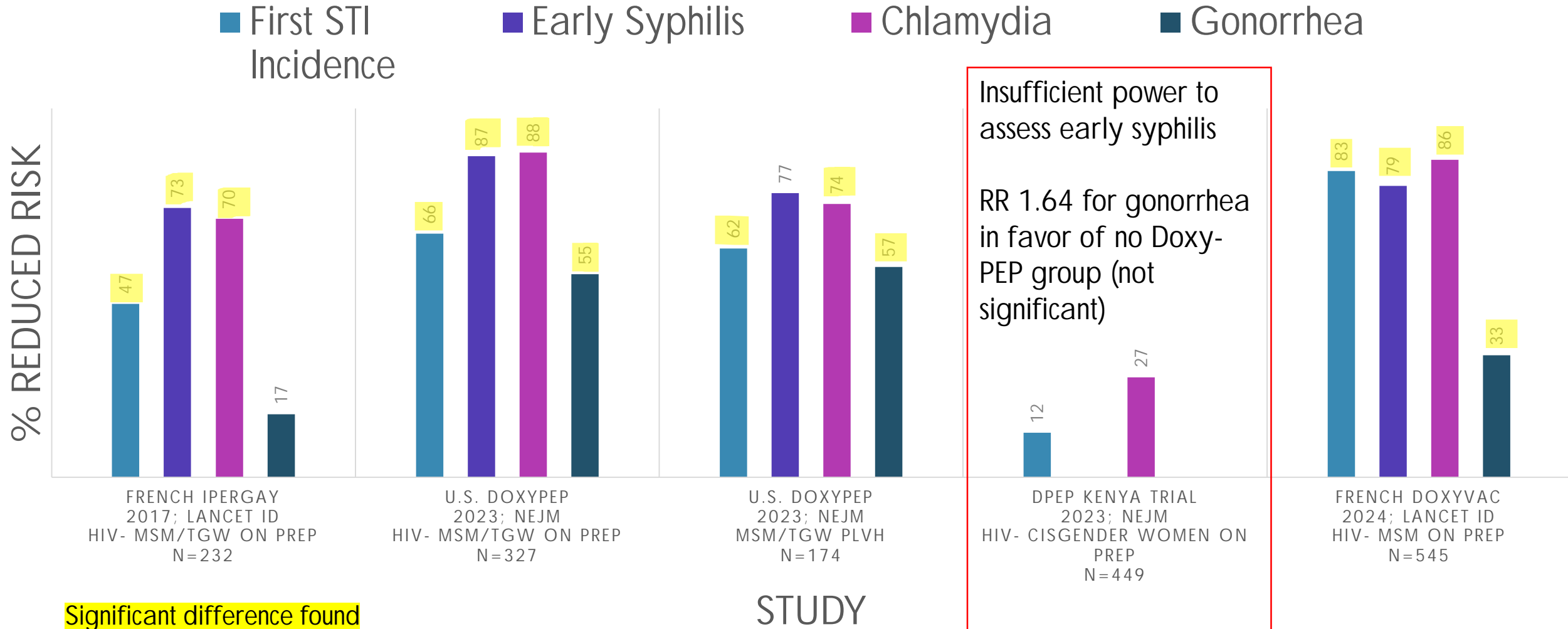
■ First STI Incidence ■ Early Syphilis ■ Chlamydia ■ Gonorrhea



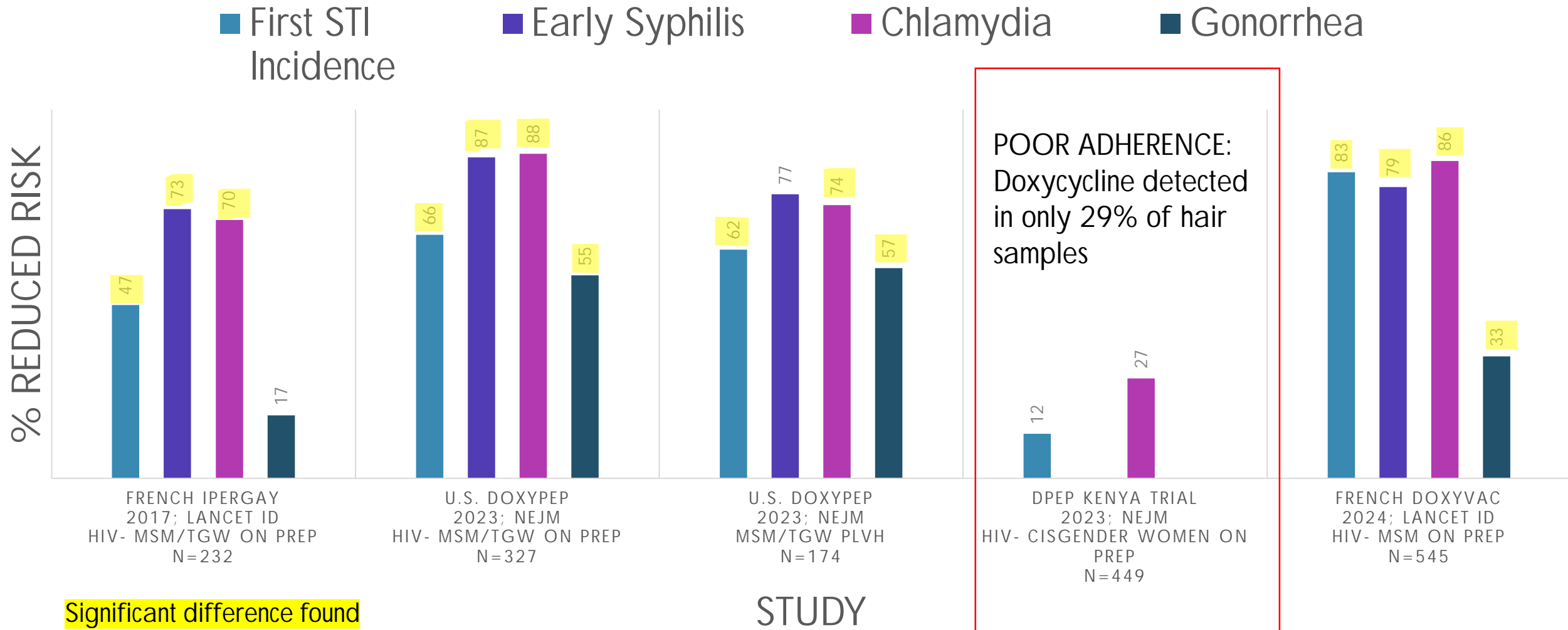
Significant difference found

STUDY

EVIDENCE FOR DOXY-PEP: CIS-WOMEN

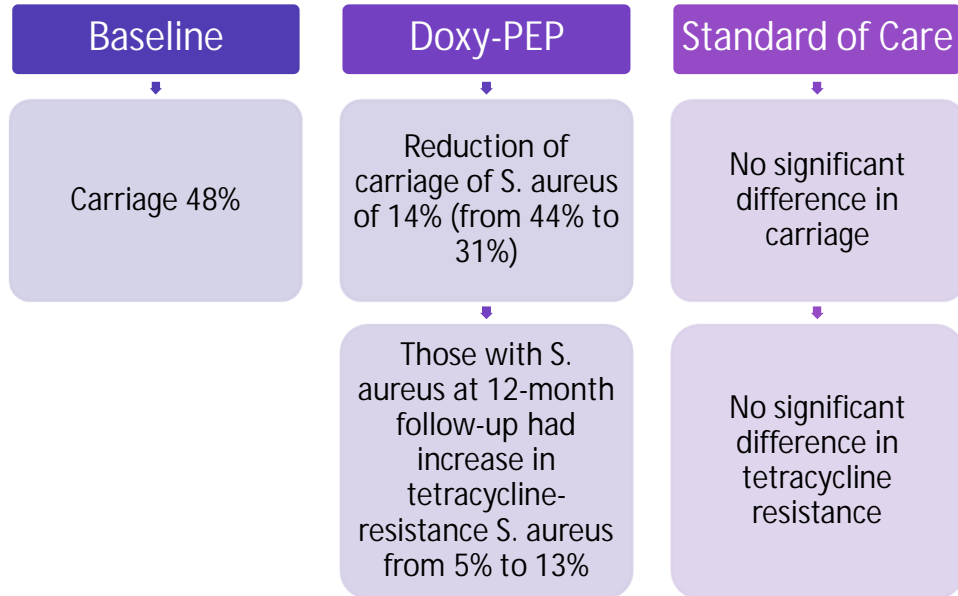


EVIDENCE FOR DOXY-PEP: ADHERENCE



ANTIMICROBIAL RESISTANCE

S. aureus



N. gonorrhoeae

USA

Group	Results
Baseline	• 24% gonorrhea isolates tetracycline resistant
Doxy-PEP	• 30% tetracycline resistant
Standard of Care	• 11% tetracycline resistant

France

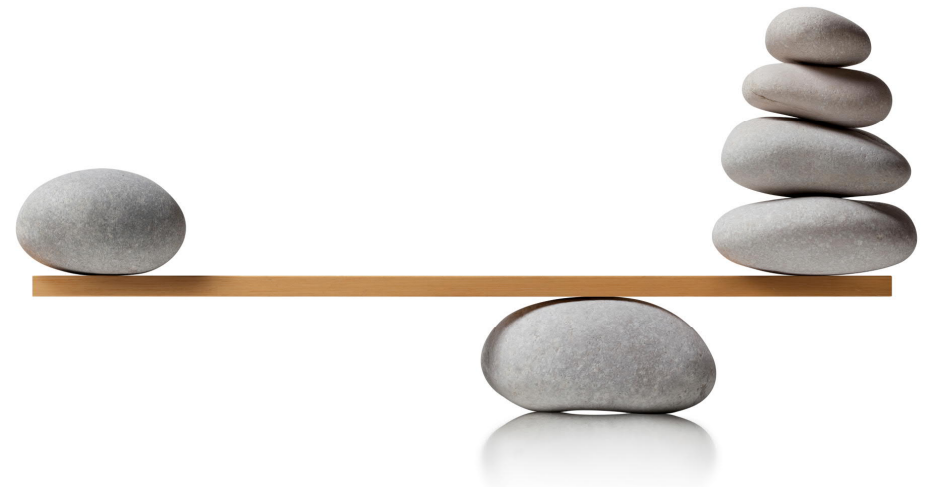
Group	Results
Baseline	• 100% tetracycline resistant
Doxy-PEP	• 67% tetracycline resistant
Standard of Care	• 81% tetracycline resistant

C. trachomatis; ESBL; MRSA

- No difference between study arms.

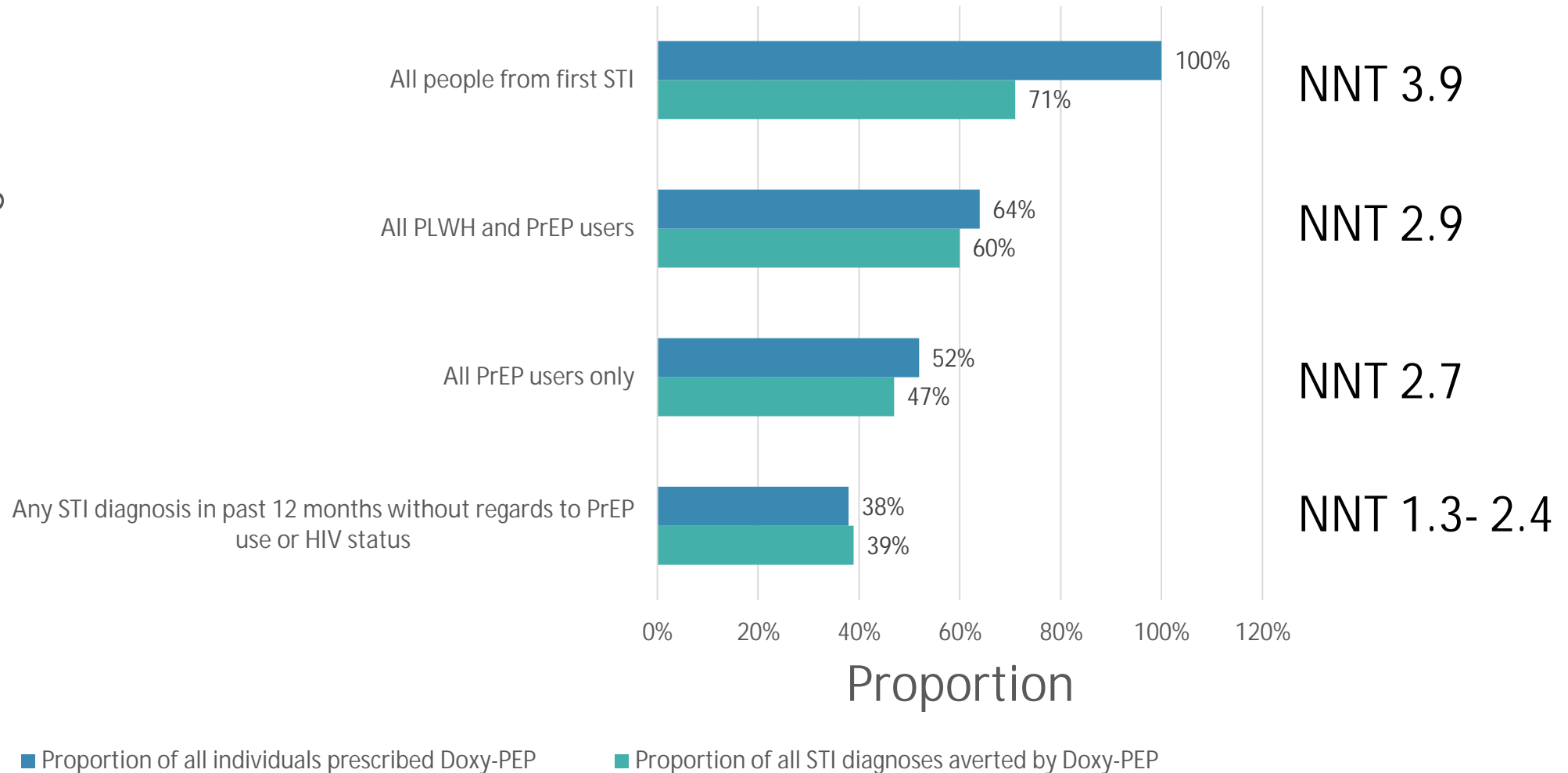
BALANCING IMPACT OF DOXY-PEP ON STI PREVENTION AND POTENTIAL FOR WIDESPREAD ANTIMICROBIAL RESISTANCE

- Across multiple studies, a subset of MSM taking HIV PrEP account for the majority of bacterial STIs
- Greatest population-level effect if focus on subpopulations at greatest risk for STI instead of broader MSM and TGW population



COUNTERFACTUAL DOXY-PEP PRESCRIBING STRATEGIES

Hypothetical Doxy-PEP
Prescribing



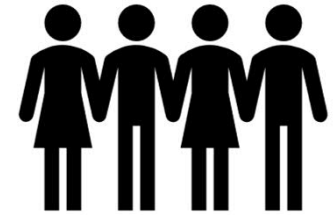
WHY DOES THIS MATTER?



Efficient strategy to prescribe Doxy-PEP



May improve access to Doxy-PEP in those that may have otherwise been excluded (e.g. those not on PrEP or not living with HIV)



May reduce racial and ethnic inequities in Doxy-PEP prescribing seen in PrEP prescribing

STRENGTH OF CDC RECOMMENDATION

A.I.

- Counsel MSM and TGW with a history of at least one bacterial STI during the past 12 months about Doxy-PEP

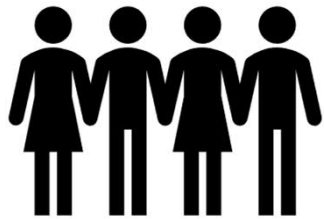
Shared Decision-making

- MSM and TGW without bacterial STI in the past 1 year but has upcoming sexual activities that are known to increase their risk of STI

Insufficient evidence to recommend

- Use clinical judgement and shared decision-making to inform use of Doxy-PEP in other populations (cisgender women, MSW, AFAB, TGM)

HOW TO PRESCRIBE DOXY-PEP



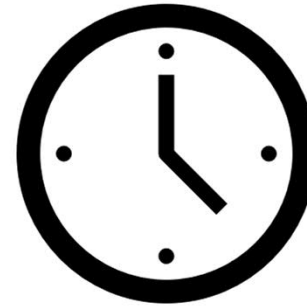
Population

MSM and TGW with STI in the past 12 months regardless of PrEP use or HIV status



Dose

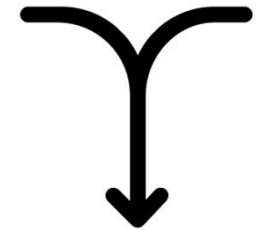
Single oral dose of Doxycycline 200mg (two tablets) by mouth



Timing

Ideally within 24-hours and no later than 72-hours after condomless oral, vaginal, or anal sex

Maximum dose of 200mg every 24 hours



Quantity

Dispense enough to account for anticipated sexual activity

Reassess need for ongoing Doxy-PEP every 3-6 months

HOW TO TAKE DOXY-PEP

Two 100mg pills of doxycycline ideally within 24 hours but no later than 72 hours after condomless oral, anal, or vaginal sex



Take Doxy up to 72 hours after sex



Take Doxy up to 72 hours after sex

Friday

Saturday

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

Sunday



Doxy



Doxy



Doxy



Take Doxy up to 72 hours after sex

Friday

Saturday

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

Sunday

CLINIC VISITS FOR DOXY-PEP

Initial visit

STI screening/ treatment
Risk reduction counseling
Risks and benefits of Doxycycline

Follow-up visit (q3-6 months)

STI screening/ treatment
Risk reduction counseling
Assess for side effects
Reassess need for continued Doxy-PEP

Additional Prevention Services

Screen for HBV and HCV
Vaccinations (HBV, HPV, Mpox, HAV)
Linkage to care: HIV, primary care, mental health, substance use treatment

PATIENT COUNSELING FOR DOXY-PEP

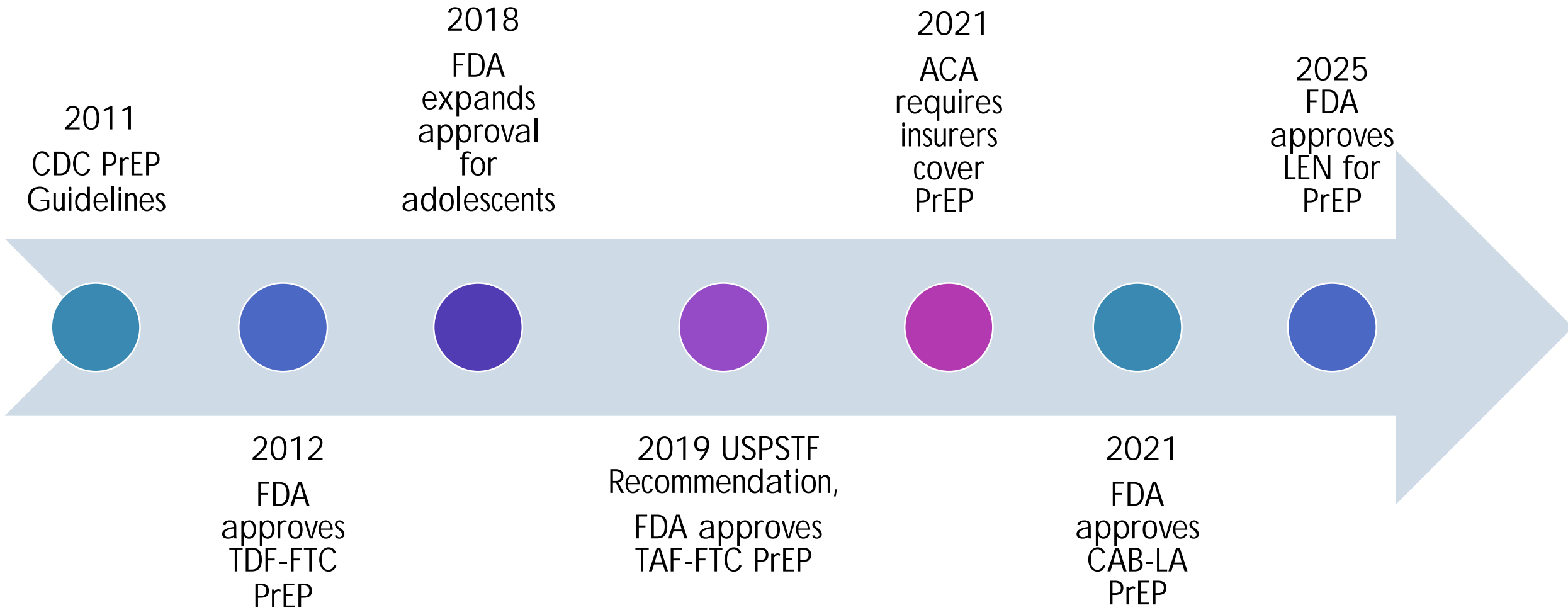
Side effects

- Photosensitivity
- Esophagitis
- Gastrointestinal intolerance (nausea, vomiting, diarrhea)
- Potential for antimicrobial resistance and changes to microbiome with unclear long-term effects

Administration

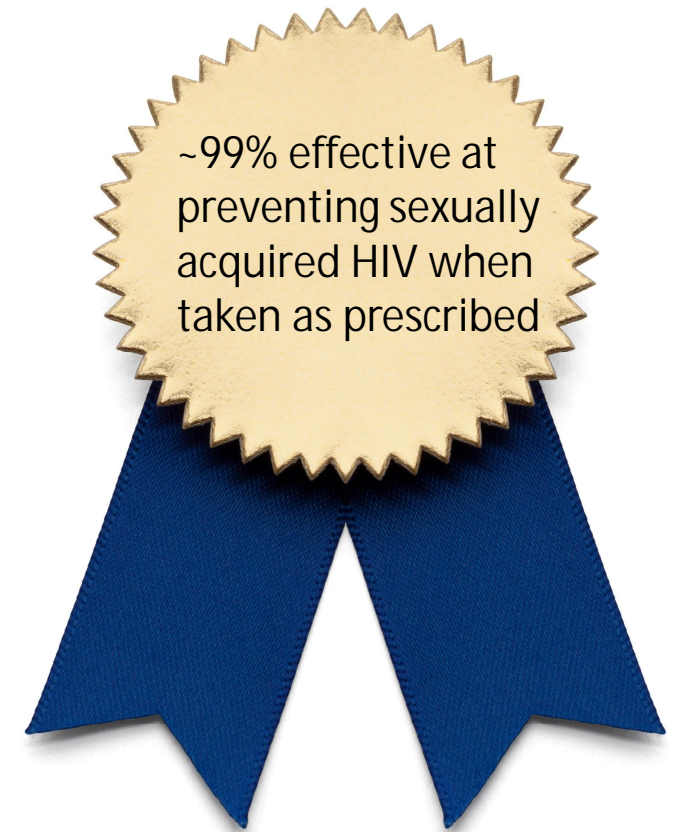
- Timing within 72 hours of sex
- Take with meal with full glass of water, avoid laying down for 1 hour to minimize GI side effects
- Separate dose by at least 2 hours from antacids, dairy products, and supplements containing Ca^{2+} , Mg^{2+} , Fe^{2+} , or NaHCO_3
- Review drug-drug interactions

PrEP IS THE STANDARD OF CARE



THE EVIDENCE IS CLEAR

In August 2023, the USPSTF reaffirmed a Grade A recommendation for PrEP

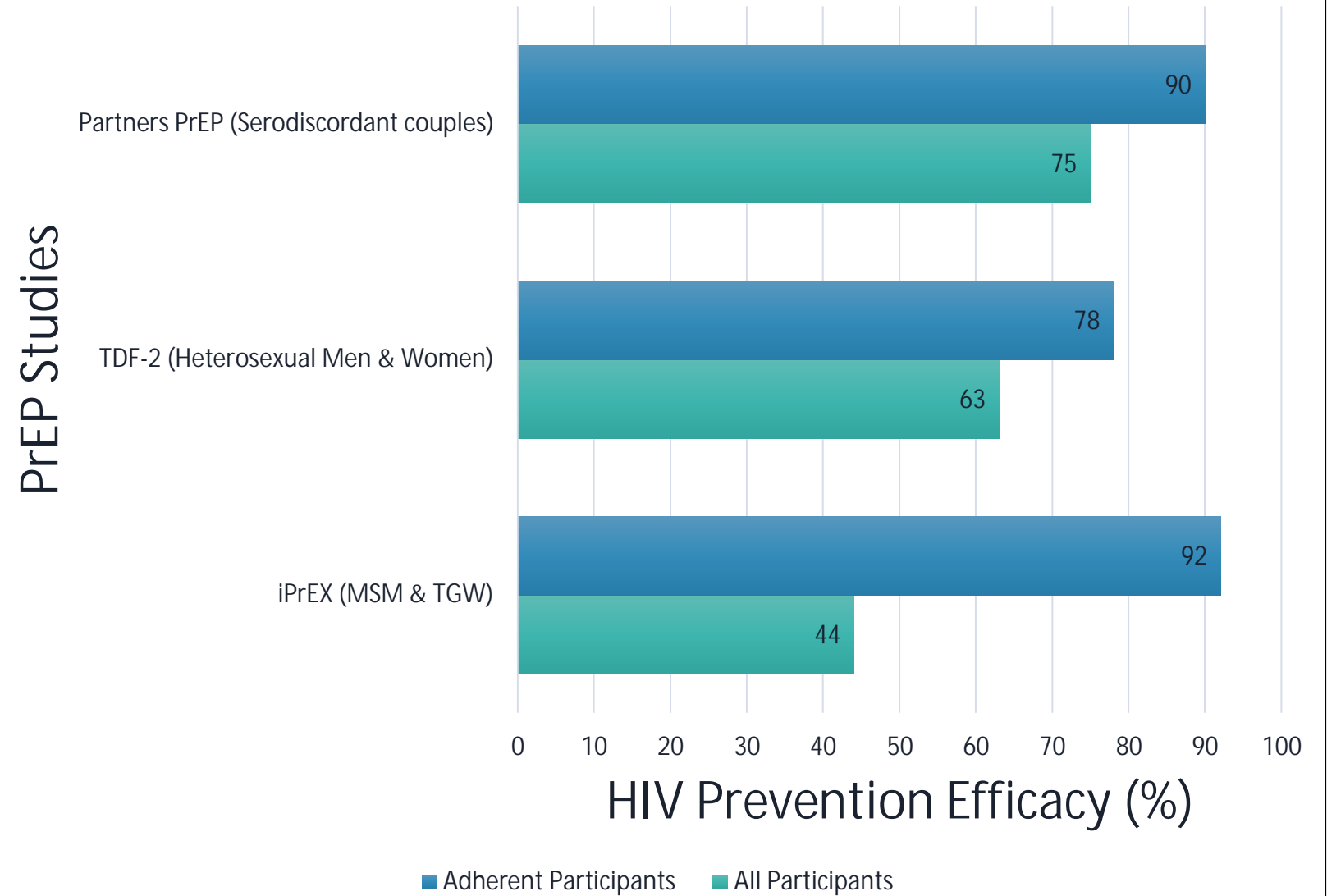


Under the ACA, PrEP related services and medications must be covered without cost-sharing

Population	Recommendation	Grade
Adolescents and adults at increased risk of HIV	<p>The USPSTF recommends that clinicians prescribe preexposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV.</p> <p>See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy.</p>	A

EFFICACY TIED TO ADHERENCE

Estimates of PrEP Efficacy Adjusted for Adherence



EFFICACY +
ADHERENCE:
ORAL PrEP
IN MSM

99%
Effective

7 doses per
week (taken
daily as
prescribed)

96%
Effective

4 doses per
week

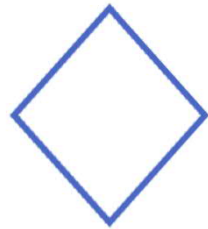
76%
Effective

2 doses per
week

EFFICACY +
ADHERENCE:

VAGINAL
AND
COLORECTAL
TISSUE

Significant Protection Against HIV



Lower vaginal tract tissue

- 6-7 doses per week (> 85% adherence)



Colorectal tissue

- 2 doses per week (28% adherence)

High levels of adherence maximizes PrEP effectiveness.

EFFICACY +
ADHERENCE:

PWID

74%-84%
Effective

Based on
tenofovir alone
and not
necessarily when
taken daily

Likely higher levels of effectiveness when taking
TDF/FTC together AND when taking it daily

PrEP
INEQUITY:

GENDER
AND RACE

Gender
most utilizing
PrEP

Male

Race most
utilizing
PrEP

White

PrEP
INEQUITY:
GEOGRAPHIC
REGIONS IN
THE U.S.

Region with
least unmet
need for PrEP

Northeast

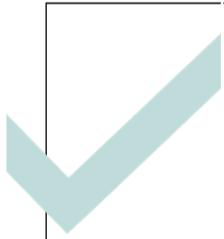
Region with
most unmet
need for PrEP

South

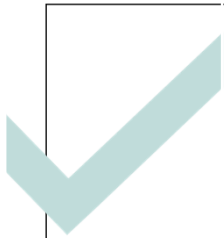
INDICATIONS FOR PrEP

- Adult or adolescent
- Weight \geq 35kg (77 lbs.)
- At increased risk for HIV acquisition

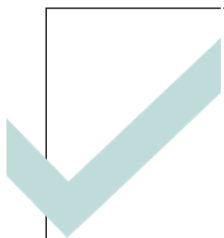
WHO IS AT RISK FOR HIV?



Anal or vaginal sex in past 6 months
----with HIV positive partner or
----inconsistent condom use or
----bacterial STI in the past 6 months



Person who injects drugs (PWID) and
shares injection equipment



Transactional sex workers

Golden Rule: Prescribe
PrEP to anyone who asks
for it – including those
who do not report
specific HIV risk factors

FRAMEWORK FOR PREP PRESCRIBING



Documented negative HIV test within 1 week

No signs or symptoms of acute HIV infection

No contraindications

Prescribe PrEP

PrEP prescription should extend until the appropriately scheduled follow-up

Every 3 months for oral PrEP

Every 2-6 months for injectable PrEP

ABSOLUTE CONTRAINDICATIONS

Unknown or positive HIV-1 status

Weight < 35kg (77 lbs.)

Prior hypersensitivity reaction to the medication

HOW DO YOU KNOW IF SOMEONE IS HIV NEGATIVE?

Patient reports NO high-risk HIV exposure or s/s of acute HIV infection in the prior 4 weeks

4th generation
Ab/Ag HIV
Test

4th Generation Ab/Ag test
result

Negative

Positive

HIV Negative

HIV Positive

CAVEAT: This is only for those who have not taken PrEP recently

- Oral PrEP: More than 3 months ago
- Injectable PrEP: More than 12 months ago

HOW DO YOU KNOW IF SOMEONE WITH ILLNESS IS HIV NEGATIVE?

Patient reports high-risk HIV exposure and s/s of acute HIV infection in the prior 4 weeks

4th generation Ab/Ag HIV Test = negative

Check HIV-1 RNA assay (HIV Viral Load)

HIV-1 RNA \geq 200 copies/mL

HIV Positive

HIV-1 RNA detectable but < 200 copies/mL

Draw new plasma specimen. Defer PrEP until false positive ruled out

HIV-1 RNA < level of detection AND **no** s/s of acute HIV on day of blood draw

HIV Negative

HIV-1 RNA < level of detection AND **yes** s/s of acute HIV on day of blood draw

Retest in 2-4 weeks. Defer PrEP. Consider nPEP

HOW DO YOU KNOW IF SOMEONE WHO WAS RECENTLY ON PrEP IS HIV NEGATIVE?

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

4th generation
Ab/Ag HIV Test
AND HIV-1 RNA
Assay

Ab/Ag testing AND HIV-1 RNA
Assay Results

REACTIVE Ab/Ag
test and HIV-1
RNA detected

NON-reactive
Ab/Ag test AND
HIV-1 RNA not
detected

Discordant Ab/Ag
and HIV-RNA
Assay results

HIV Positive

HIV Negative

Draw new plasma
specimen. Defer
PrEP until false
positive ruled out

HIV-1 RNA
detected = HIV
Positive

HIV-1 RNA not
detected = HIV
Negative

Rationale:

PrEP may suppress early viral replication of HIV, which can affect timing of antibody development

Allows for earlier detection of HIV

FOUR APPROVED PrEP OPTIONS

TDF/FTC

- 300 mg tenofovir disoproxil fumarate (TDF) + 200 mg emtricitabine (FTC)
- 1 tablet daily
- FDA approved for PrEP 2012

TAF/FTC

- 25 mg tenofovir alafenamide (TAF) + 200 mg emtricitabine (FTC)
- 1 tablet daily
- FDA approved for PrEP 2019

Oral PrEP

FOUR APPROVED PrEP OPTIONS CONT.

Cabotegravir

- 600 mg IM injection
- Q2 months
- Long acting
- FDA approved for PrEP 2021

Lenacapavir

- 927 mg SQ injection
- Q6 months
- Long acting
- FDA approved for PrEP 2025

Injectable PrEP

PrEP SAFETY

All FDA approved options are safe!

TDF/FTC

- Rare renal toxicity
- Decreases BMD
- Lipid lowering

TAF/FTC

- Weight gain
- Even rarer renal toxicity
- Increased triglycerides

CAB-LA

- Injection site reactions

LEN

- Injection site reactions
- Headache
- Nausea

MEDICATION INTERACTIONS

TDF/FTC

Nephrotoxic or impact renal tubular secretion

- Acyclovir
- Valacyclovir
- Aminoglycosides
- High-dose or multiple NSAIDS

TAF/FTC

CYP3A Inducer

- Rifampin
- St. John's Wort
- Anticonvulsants
- Corticosteroids
- Barbituates

Cabotegravir

UGT1A1 Inducers

- Anticonvulsants
 - Carbamazepine
 - Oxcarbazepine
 - Phenobarbital
 - Phenytoin
- Rifampin

Lenacapavir

Moderate – Strong CYP3A Inducer

- May require supplemental Lenacapavir dosing (injections)

CHOOSING A PrEP AGENT

	TDF/FTC	TAF/FTC	Cabotegravir	Lenacapavir
Type of sex				
Insertive Anal sex	X	X	X	X
Receptive Anal sex	X	X	X	X
Insertive vaginal sex	X	X	X	X
Receptive vaginal sex	X		X	X
Receptive neovaginal sex	X		X	X
Renal Function				
CrCl ≥ 60 mL/min	X	X	X	X
CrCl ≥ 30 mL/min		X	X	X
CrCl < 30 mL/min			X	X
ESRD		If on HD	X*	Insufficient evidence*
Liver				
Treats Hepatitis B	X	X		
Does NOT treat Hep B			X	X
Cirrhosis	X	X	X	Avoid in decompensated cirrhosis

*high protein binding – not expected to dialyze for those patients on dialysis.

CHOOSING A PrEP AGENT CONT.

	TDF/FTC	TAF/FTC	Cabotegravir	Lenacapavir
Population				
Adolescent	X	X	X	X
Adult	X	X	X	X
Pregnant	X			X
Lactating	X			X
PWID	X			
Cisgender Women	X		X	X
Dosing				
2-1-1	X			
Bone Health				
Normal	X	X	X	X
Osteopenia or Osteoporosis		X	X	X

ORAL PrEP OPTIONS

TDF/FTC

TAF/FTC

Combination tablets with two NRTIs

Dosing: 1 tablet daily, without regard to food

Can be used to treat hepatitis B

Approved for Men & Trans Women who have anal sex or insertive vaginal sex

Oral PrEP

APPROVED ORAL PrEP OPTIONS

TDF/FTC

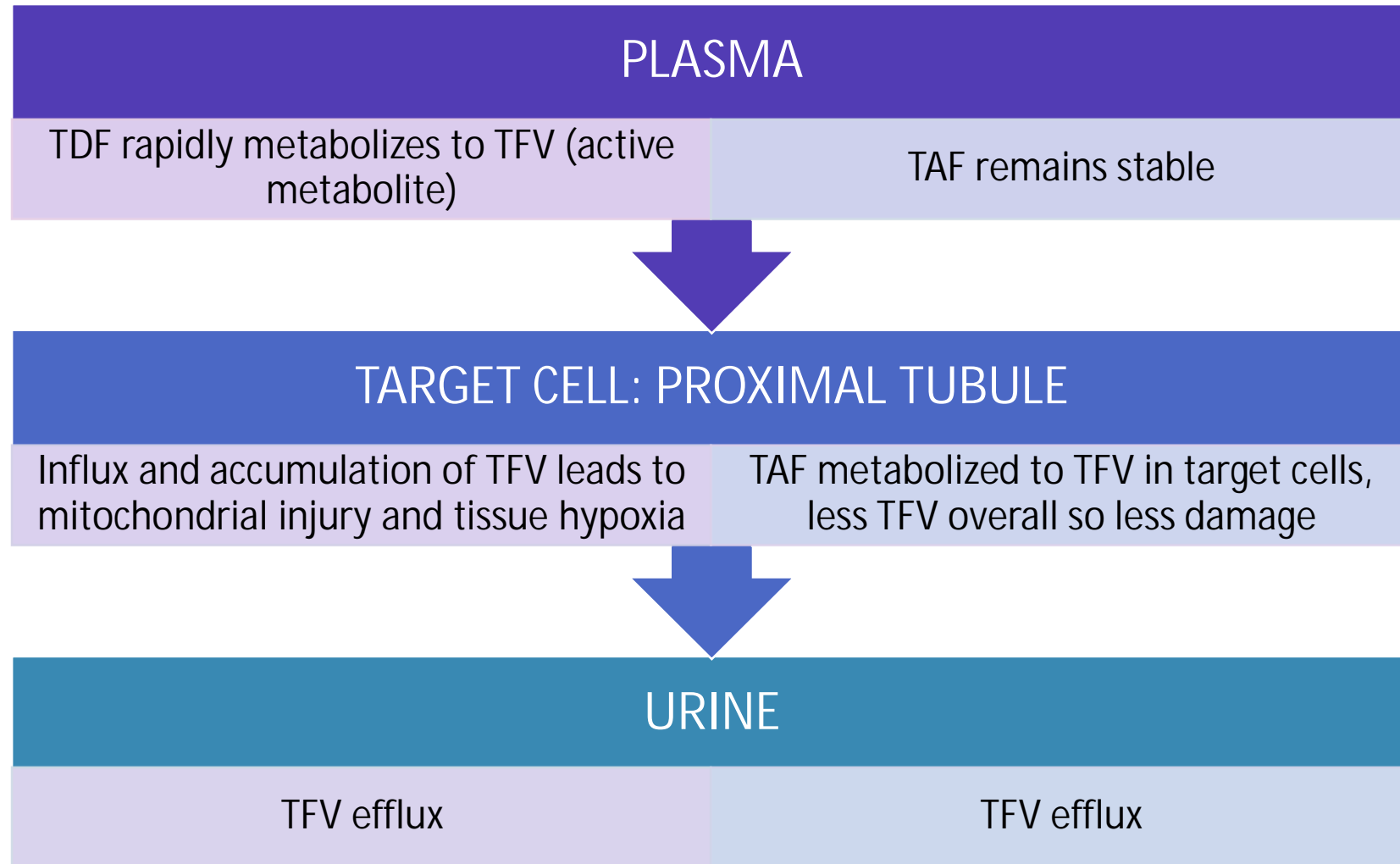
- 300 mg **tenofovir disoproxil fumarate (TDF)** + 200 mg emtricitabine (FTC)
- **eCrCl \geq 60**
- **PWID** (w/ no sex hx risk factors)
- **Receptive vaginal sex**

TAF/FTC

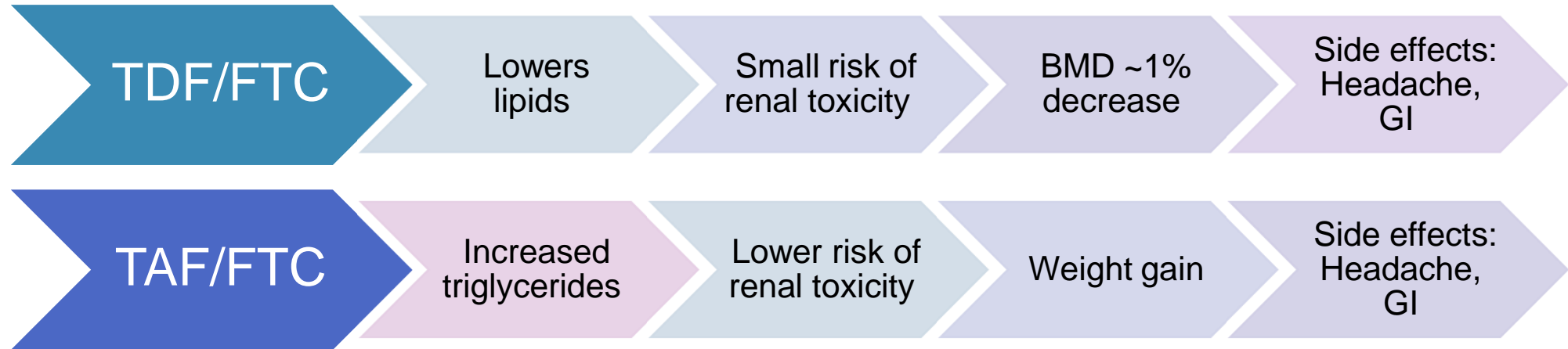
- 25 mg **tenofovir alafenamide (TAF)** + 200 mg emtricitabine (FTC)
- **eCrCl \geq 30**

Oral PrEP

TENOFOVIR AND THE KIDNEYS



ADDITIONAL CONSIDERATIONS FOR ORAL PrEP



Avoid use if
eGFR < 60
mL/min

Proximal Tubular Injury
Fanconi Syndrome
Progression of CKD

TDF/FTC

Lowers lipids

Small risk of renal toxicity

BMD ~1% decrease

Side effects:
Headache,
GI

TAF/FTC

Increased triglycerides

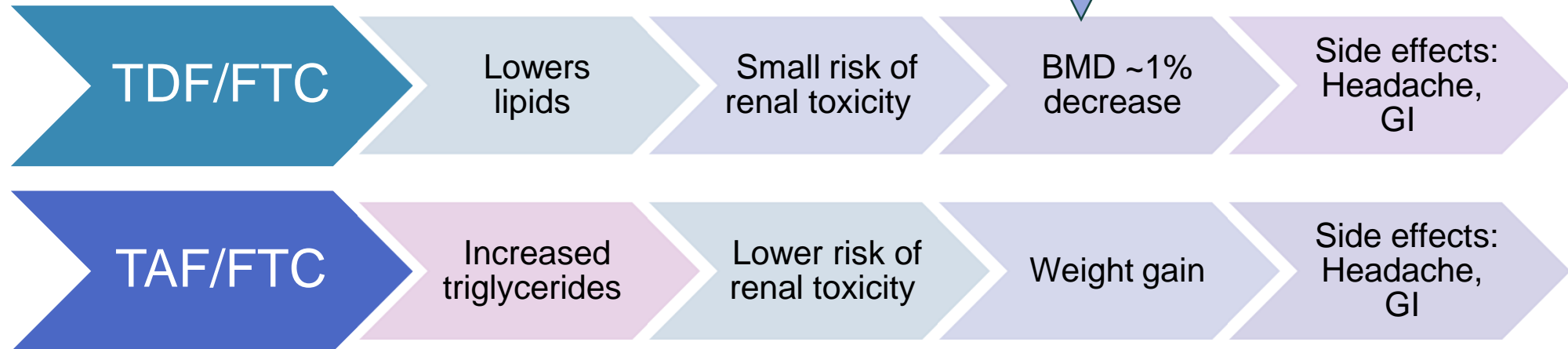
Lower risk of renal toxicity

Weight gain

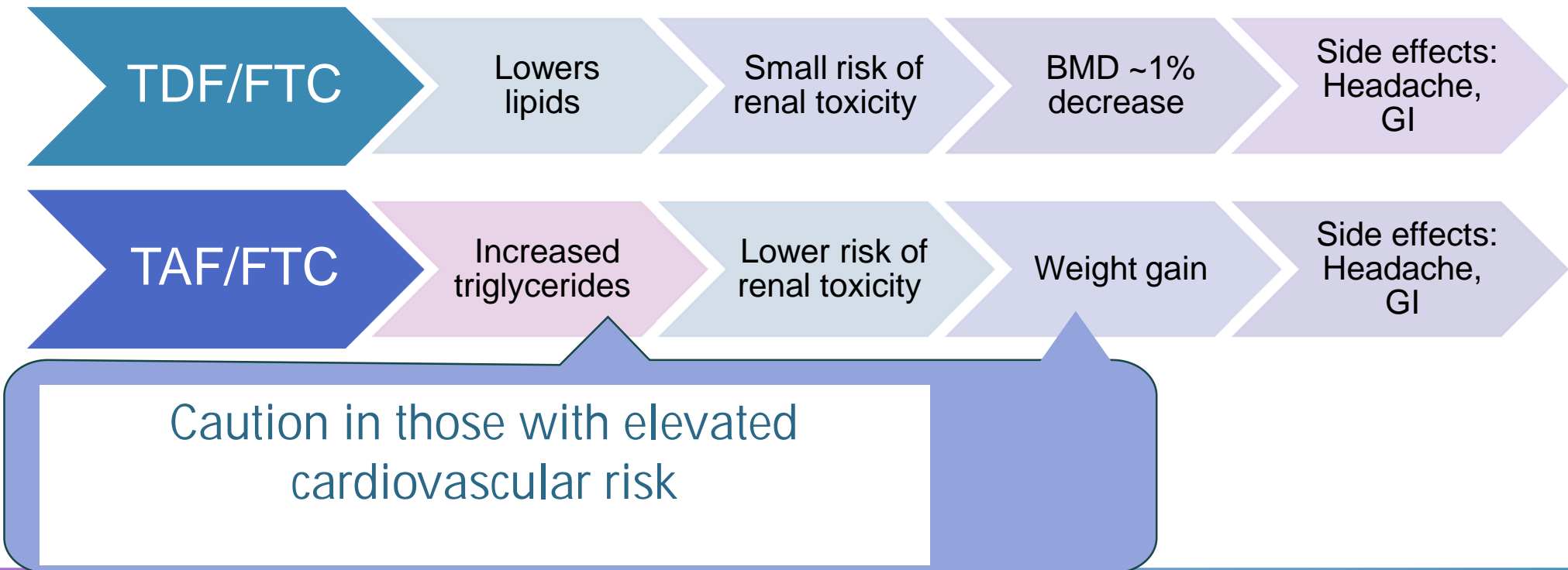
Side effects:
Headache,
GI

Occurs during first few months of PrEP and then stabilizes or returns to normal (iPrEx trial).

Routine DEXA scan not indicated*



*may consider further evaluation for those with a history of pathologic or fragility bone fracture or those with significant risk factors for osteoporosis.



CHRONIC HEP B AND ORAL PrEP

- Oral PrEP (TAF/FTC and TDF/FTC) treats Hepatitis B.
- If patient with active Hep B goes on PrEP and then stops, they can have acute Hep B flare. Counsel those patients!
- If a patient with chronic Hep B decides to discontinue PrEP
 - Regular monitoring LFTs, HBsAg, and HBV viral load.

WHAT IF MY
PATIENT'S
SERUM
CREATININE
INCREASES
ON ORAL
PrEP?

- PrEP does not need to be stopped for a rise in creatinine IF eCrCl remains ≥ 60 ml/min for TDF/FTC or ≥ 30 for TAF/FDC.
- If eCrCl is steadily declining, assess for other factors, e.g. NSAID usage, HTN, DM2 prior to stopping PrEP.

HOW LONG
DO YOU
NEED TO
TAKE DAILY
ORAL PrEP
TO BE
PROTECTED?

Cervicovaginal
Tissue

20 days

Rectal tissue

7 days

ORAL PrEP BASELINE LABS

Required labs prior to PrEP start

- HIV Antigen/Antibody (negative)
- Estimated Creatinine Clearance (eCrCl)

Other Testing (results not required to start PrEP)

- Hepatitis B surface Ab
- Hepatitis B surface Ag
- STI screening:
 - Gonorrhea/Chlamydia (site-specific “3-site” testing)
 - Syphilis
- Hepatitis C Ab
- Lipid panel (TAF/FTC)

STI SCREENING: GONORRHEA AND CHLAMYDIA

3 site testing

- Pharyngeal
- Rectal
- Urine

Self-collected samples

- Equivalent performance as clinician-obtained samples

Treatment

- Chlamydia: Doxycycline 100mg PO BID x 7 days
- Gonorrhea: high dose ceftriaxone 500mg IM x1. Need TOC at day 14 for any pharyngeal infection since harder to clear infection
- Expedited Partner therapy

MONITORING ON ORAL PrEP

TEST	Baseline Visit	Every 3 Months	Every 6 months	Every 12 months	When Stopping PrEP
HIV	X*	X			X*
eCrCl	X		If age \geq 50 or eCrCl $<$ 90 mL/min at PrEP initiation	If age $<$ 50 and eCrCl \geq 90 mL/min at PrEP initiation	X
Syphilis	X	MSM/TGW	X		MSM/TGW
Gonorrhea	X	MSM/TGW	X		MSM/TGW
Chlamydia	X	MSM/TGW	X		MSM/TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, PWID only			MSM, TGW, PWID only	
Pregnancy test**	X	X			

Guideline Update:
HIV Viral Load (NAAT) + HIV Ag/Ab
 q3 months on PrEP

Guideline Update:
 Decreased frequency of eCrCl monitoring.

Guideline Update:
 Lipid panel monitoring yearly on TAF/FTC

*assess for acute HIV infection; **for those with capacity for pregnancy

MITIGATING SIDE EFFECTS

TDF/FTC

TAF/FTC

“Start-Up Syndrome” (<10%)

HA, nausea, abdominal discomfort

Resolves within 1 month

Treatment: OTC medications

Preempt adverse reaction with a prescription for an antiemetic and recommendations for an anti-diarrheal with the first PrEP prescription

Oral PrEP

Monitor patients with HBV infection who discontinue taking oral PrEP medication closely for flare of hepatitis

*theoretical risk, seen more so in those with HIV on tenofovir-based regimens

DISCONTINUING ORAL PrEP



ORAL PrEP PATIENT COUNSELING

- It takes up to 3 weeks for PrEP to be effective.
 - Condoms are important during that time!
- PrEP only works if you take it!
- Side effects can include GI symptoms, headache
 - most resolve after 3-4 weeks.
- PrEP does not prevent other STIs; condom use
- Alert your healthcare provider if you develop signs or symptoms of acute HIV (fever, malaise, rash, enlarge lymph nodes)
- Alert your healthcare provider if you intend to stop PrEP.

INJECTABLE PrEP OPTIONS

Cabotegravir

- 600 mg **IM** injection
- Baseline, 1 month, Q2 months thereafter
- ESRD, Cirrhosis

Lenacapavir

- 927 mg **SQ** injection
- 2-day initiation, then Q6 months thereafter
- Pregnancy; lactation

Injectable PrEP

EFFICACY:
INJECTABLE
CAB-LA PrEP

66% reduction in
risk of HIV
compared to
TDF/FTC in MSM
and TGW

HPTN
083 Trial

Landovitz et al. HPTN083, NEJM August 2021

88% reduction in
risk of HIV
compared to
TDF/FTC in
cisgender women

HPTN
084 trial

Delaney-Moretlwe S, et al., Lancet 2022; 399: 1779–89

CAB-LA is SUPERIOR to TDF/FTC in MSM, TGW, and
cisgender women

ADMINISTERING CAB-LA PrEP

Optional: Oral lead-in

- Cabotegravir 30 mg PO daily x 4 weeks
- Not required since the trials showed no major safety concerns

Initial Dose:

- Cabotegravir 600 mg (3 ml) IM injection in the gluteal muscle (in clinic)

Second dose:

- 4 weeks after first dose

Maintenance:

- Every 8 weeks thereafter +/- 7 days

Note: Gluteal IM injection
2-inch needle for BMI \geq 30
1.5-inch needle for BMI $<$ 30

ADMINISTERING CAB-LA PrEP CONT.

Optional: Oral lead-in

- Cabotegravir 30 mg PO daily x 4 weeks
- Not required since the trials showed no major safety concerns

Initial Dose:

- Cabotegravir 600 mg (3 ml) IM injection in the gluteal muscle (in clinic)

Second dose:

- 4 weeks after first dose

Maintenance:

- Every 8 weeks thereafter +/- 7 days

Oral Lead-in: May be good for patients with anxiety about side effects

Can confirm they tolerate the oral medication prior to starting the long-acting injectable form

PLANNED MISSED INJECTIONS: CAB-LA



≤ 1 month since missed target injection date

Resume continuation injections as soon as possible

> 1 month since missed target injection date

Restart with initiation injections

Oral Bridging

- Prescribe oral cabotegravir 30mg daily for up to 2 months as replacement for missed injection
- Take first oral dose 2 months after the last CAB-LA injection
- Restart injection within 3 days of last oral dose
- Clinically reassess those who miss target injection date to determine if CAB-LA remains appropriate for them

UNPLANNED MISSED INJECTION: CAB-LA



≤ 2 months since 1st injection

Administer missed injection ASAP, then continue Q2 month injections

> 2 months since 1st injection

Restart with initiation injections

≤ 3 months since last maintenance injection

- Administer missed injection ASAP, then continue Q2 month injections

> 3 months since last maintenance injection

- Restart initiation injections
- Clinically reassess those who miss target injection date to determine if CAB-LA remains appropriate for them

EFFICACY:
INJECTABLE
LEN PrEP

100% reduction in
HIV incidence
compared to
TDF/FTC in
cisgender women

PURPOSE-
1 Trial

Bekker et al., NEJM October 2024

89% reduction in HIV
incidence compared
to TDF/FTC in
cisgender men and
gender diverse
persons

PURPOSE-
2 Trial

Kelley et al., NEJM April 2025

LENCAPAVIR is SUPERIOR to TDF/FTC in cisgender men,
gender diverse, and cisgender women

ADMINISTERING LENACAPAVIR PrEP

Dosage forms:

- Oral tablets: 300 mg PO taken with or without food
- Injection 463.5 mg/1.5 mL (309 mg/mL) in single-dose vials

2-Day Initiation dosing:

- Day 1 (in clinic): Lenacapavir 927mg (3mL) SQ injection dose (2x 1.5mL injections) PLUS Lenacapavir 600mg orally (2 x 300mg tablets)
- Day 2 (at home): Lenacapavir 600mg orally (2 x 300mg tablets)

Maintenance dosing:

- Lenacapavir 927mg (3mL) SQ injection dose (2x 1.5mL injections) every 6 months (26 weeks) from date of last injection (+/- 2 weeks)

ADMINISTERING LENACAPAVIR PrEP

Injection technique:

- Subcutaneous injection
- Choose two injection sites (Abdomen (at least 2 inches from umbilicus) or thigh)
- Inject medication slowly (over 30-60 seconds) while pinching the skin.
- Apply ice pack for 10 minutes to injection site after the injection

Management of injection site reactions:

- Immediate reaction (pain, redness, swelling, itching): Ice packs 10-15 min q3 hours for 24 hours; topical steroid for pruritis, acetaminophen/NSAIDS for analgesia if no contraindication
- Persistent/delayed reaction (nodule, induration): warm compress, gentle massage to area.
- Assess for cellulitis or abscess (rare)

Note: Require two vials to get 927mg dose. Use separate syringes/needles. Two injections must be given at distinct sites, at least 4 inches apart. Needle is 22g, 0.5in.

PLANNED MISSED INJECTIONS: LEN



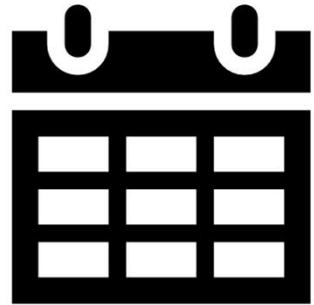
2 -4 weeks since missed target injection date
(26-28 weeks since last injection)

Oral Lenacapavir 300mg every 7 days until injections resume

Oral Bridging

- Oral Lenacapavir 300mg PO every 7 days (up to 6 months)
- Restart injection within 7 days of last oral dose
- Clinically reassess those who miss target injection date to determine if LEN remains appropriate for them

UNPLANNED MISSED INJECTION: LEN



> 28 weeks since last injection and no oral bridge

Restart with
initiation
dosing

HOW LONG
AFTER THE
FIRST
INJECTION
TO BE
PROTECTED?

~7 days

Note: International Antiviral Society-USA Panel recommends oral PrEP bridge for 7 days with either CAB-LA or Tenofovir-based PrEP, OR barrier protection for 7 days

INJECTABLE PrEP: BASELINE LABS

Required labs prior to PrEP start

- HIV Antigen/Antibody (negative)
- **HIV viral load (NAAT)**

Other Testing (results not required to start PrEP)

- STI screening:
 - Gonorrhea/Chlamydia (site-specific “3-site” testing)
 - Syphilis

MONITORING ON CAB-LA PrEP

TEST	Baseline Visit	1 month visit	Every 2 months	Every 4 months	Every 6 months	Every 12 months	When stopping PrEP
HIV	X	X	X				X
eCrCl							
Syphilis	X			MSM/TGW	MSW/WSM		MSM/TGW
Gonorrhea	X			MSM/TGW	MSW/WSM		MSM/TGW
Chlamydia	X			MSM/TGW	MSW/WSM		MSM/TGW
Lipid panel (F/TAF)							
Hep B serology*	X						
Hep C serology*	X			MSM, TGW, PWID only		MSM, TGW, PWID only	
Pregnancy test**	X			X			

Guideline Update:
HIV Viral Load (NAAT)
 Baseline, 1 mo F/U, q2 months onwards

Guideline Update:
 No eCrCl monitoring.
 Risk based hepatitis monitoring
 No Lipid monitoring

Guideline Update:
 STI testing q4mo for MSM/TGW
 STI testing q6mo for MSW/WSM

*Screening in adults if not done previously. If Hep B non-immune, vaccinate;

**for those with capacity for pregnancy

MONITORING ON LEN PrEP

TEST	Baseline Visit	Optional 1 month visit check-in	Optional Every 3 months based on STI risk	Every 6 months	Every 12 months	When stopping PrEP
HIV	X			X		X
eCrCl						
Syphilis	X		MSM/TGW	X	X	X
Gonorrhea	X		MSM/TGW	X	X	X
Chlamydia	X		MSM/TGW	X	X	X
Lipid panel (F/TAF)						
Hep B serology*	X					
Hep C serology*	X				MSM, TGW, PWID only	
Pregnancy test**	X			X	X	

Guideline Update:
HIV Viral Load (NAAT)
 Baseline, q6 months onwards

Guideline Update:
 No eCrCl monitoring.
 Risk based hepatitis monitoring
 No Lipid monitoring

Guideline Update:
 STI testing q3-6mo for MSM/TGW
 STI testing q6mo for MSW/WSM

*Screening in adults if not done previously. If Hep B non-immune, vaccinate;

**for those with capacity for pregnancy

MITIGATING SIDE EFFECTS: INJECTION SITE REACTION

Cabotegravir

- Mild-moderate; resolves within a few days AND after first 2-3 doses
- Treatment: OTC analgesics 2-hours prior to injection; warm compress, heating pad following injection

Lenacapavir

- Longer-lasting palpable nodule (MONTHS) that represents SQ drug depot
- Treatment: Ice site before/after injection, consider topical numbing medicine

Injectable PrEP

DISCONTINUING CAB-LA OR LEN FOR PrEP

Delayed HIV seroconversion; INSTI resistance.
Long-Acting Early Viral Inhibition (LEVI) Syndrome: Viral suppression and diminished Ab response can persist for months after last injection. INSTI resistance can occur if HIV is acquired in the months following CAB-LA injection. More common if infection within 6 months of last injection

HPTN 083.

Conduct HIV-1 RNA test at each quarterly follow-up visit after stopping

Re-educate about 'tail period'

Assess for ongoing risk for HIV

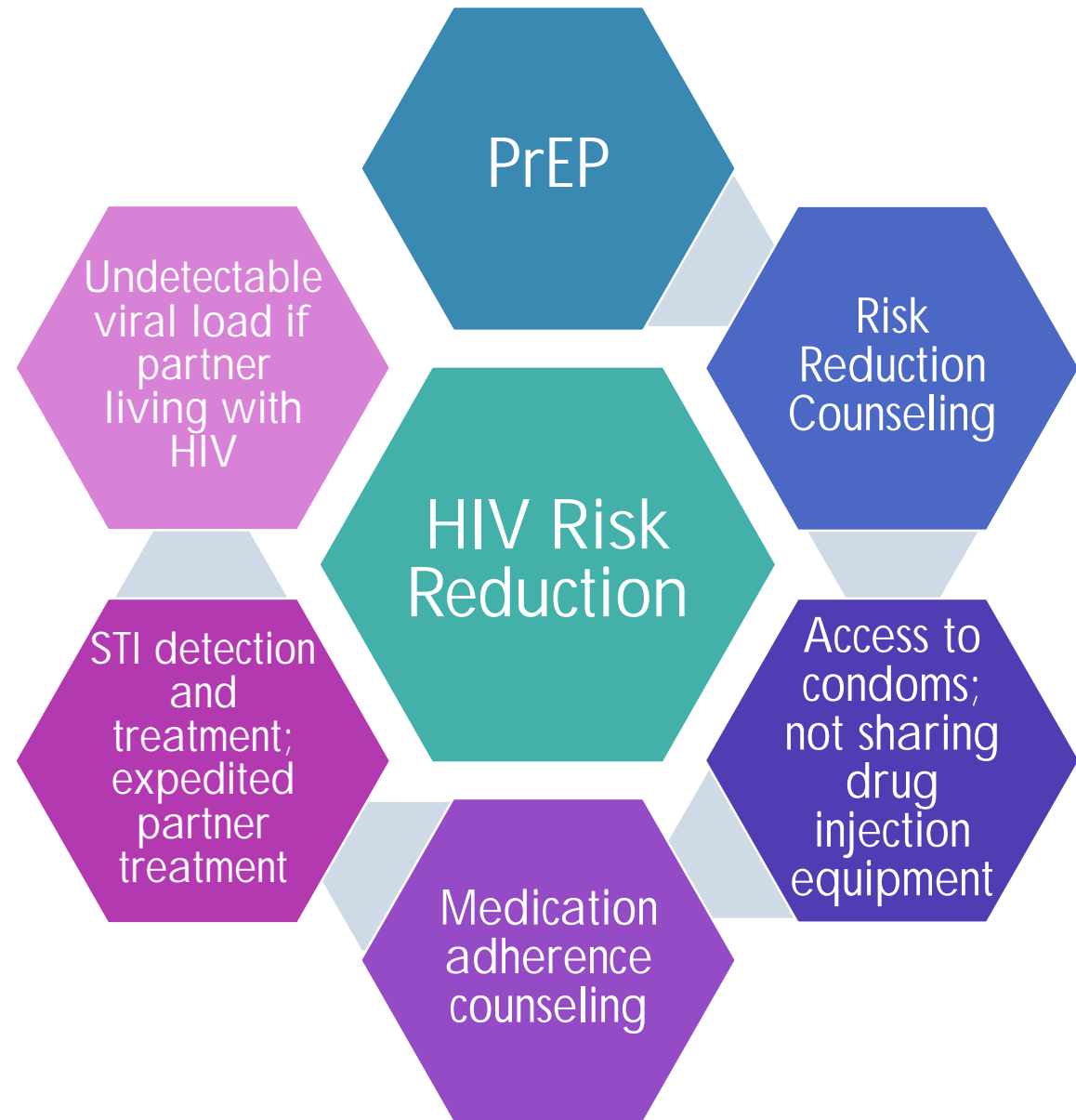
STOPPING
INJECTABLE
PrEP

Continue follow-up visits quarterly for 12 months

If PrEP indicated, prescribe oral PrEP beginning within 8 weeks of last CAB-LA or 28 weeks of last LEN injection

Educate about nPEP

PrEP IS
ONLY ONE
PART OF
HIV RISK
REDUCTION
STRATEGIES



Risk reduction counseling should be performed at every PrEP visit

WHAT IF MY PATIENT DEVELOPS ACUTE HIV WHILE ON PrEP?

- Confirm HIV diagnosis
- Counsel and quick referral/linkage to HIV care
- CDC recommendation: convert from PrEP regimen to an HIV treatment regimen without waiting for additional laboratory test results
- Call CDC PrEP line: 1-855-448-7737 (1-855 HIV-PREP)

TDF/FTC	TAF/FTC	CAB-LA	LEN
<ul style="list-style-type: none">• TDF/FTC + Dolutegravir• TAF/FTC/Bictegravir	<ul style="list-style-type: none">• TAF/FTC + Dolutegravir• TAF/FTC/Bictegravir	<ul style="list-style-type: none">• TAF/FTC/ Darunavir/cobicistat• (Until resistance testing returns. If no INSTI resistance, can switch to standard recommended first-line treatment)	<ul style="list-style-type: none">• TDF/FTC + Dolutegravir• TAF/FTC/Bictegravir

PrEP ACCESSIBILITY

- ACA requires insurers to cover PrEP
- TDF/FTC is generic
- Insurers *may* require prior auth for TAF/FTC
- Insurers may NOT cover CAB-LA on LEN
- If unfunded, there are options:
 - Patient assistance program (income-based)
 - Ready, Set, PrEP <https://readyssetprep.hiv.gov/>
 - If funded but high copays, can apply for copay assistance

BILLING AND COVERAGE FOR PrEP

No Part B Cost-Sharing Obligations

- No longer subject to deductible, coinsurance or co-pay

CMS covers furnishing HIV PrEP

- Supplying and dispensing PrEP
- Administration of injectable PrEP
- Preventive Services – visits, HIV testing

PrEP Diagnosis Codes

- Z29.81: Encounter for HIV pre-exposure prophylaxis

Physician Billing Code

- G0011
- Individual counseling for preexposure prophylaxis (PrEP) by physician or QHP [qualified health professional] to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minute

CONCLUSIONS

- Doxy-PEP is effective for reducing risk of bacterial STI, predominantly in MSM and TGW with STI in the prior 12 months
- PrEP is highly effective at preventing HIV
- PrEP has an increasing number of options including injectable!
- PrEP is standard of care for prevention of HIV (thank you USPSTF!)

REFERENCES

1. Molina J-M, Charreau I, Chidiac C, et al. Post-exposure prophylaxis with doxycycline to prevent sexually transmitted infections in men who have sex with men: an open-label randomised substudy of the ANRS IPERGAY trial. *The Lancet Infectious Diseases*. 2018;18(3):308–317.
2. Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. *N Engl J Med*. Apr 6 2023;388(14):1296–1306. doi:10.1056/NEJMoa2211934
3. Stewart J, Oware K, Donnell D, et al. Doxycycline prophylaxis to prevent sexually transmitted infections in women. *New England Journal of Medicine*. 2023;389(25):2331–2340.
4. Molina J-M, Bercot B, Assoumou L, et al. Doxycycline prophylaxis and meningococcal group B vaccine to prevent bacterial sexually transmitted infections in France (ANRS 174 DOXYVAC): a multicentre, open-label, randomised trial with a 2× 2 factorial design. *The Lancet Infectious Diseases*. 2024;24(10):1093–1104.
5. Bachmann LH, Barbee LA, Chan P, et al. CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024. *MMWR Recomm Rep*. Jun 6 2024;73(2):1–8. doi:10.15585/mmwr.rr7302a1
6. Traeger MW, Mayer KH, Krakower DS, Gitin S, Jenness SM, Marcus JL. Potential impact of doxycycline post-exposure prophylaxis prescribing strategies on incidence of bacterial sexually transmitted infections. *Clin Infect Dis*. Aug 18 2023;82(2):304–11. doi:10.1093/cid/ciad488
7. US Preventive Services Task Force. Preexposure prophylaxis for the prevention of HIV infection: US Preventive Services Task Force recommendation statement. *JAMA*. 2019;321(22):2203-2213.
8. Chou R, Spencer H, Bougatsos C, Blazina I, Ahmed A, Selph S. Preexposure Prophylaxis for the Prevention of HIV: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA*. 2023;330(8):746–763. doi:10.1001/jama.2023.9865
9. Marrazzo JM, Del Rio C, Holtgrave DR, et al. HIV prevention in clinical care settings: 2014 recommendations of the International Antiviral Society–USA Panel. *Jama*. 2014;312(4):390–409.
10. [HIV Nexus: CDC Resources for Clinicians | HIV Nexus | CDC](#)

REFERENCES

11. Huang YA, Zhu W, Smith DK, Harris N, Hoover KW. HIV Preexposure Prophylaxis, by Race and Ethnicity — United States, 2014–2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1147–1150. DOI: http://dx.doi.org/10.15585/mmwr.mm6741a3external_icon
12. Sullivan PS, DuBose SN, Castel AD, et al. Equity of PrEP uptake by race, ethnicity, sex and region in the United States in the first decade of PrEP: a population-based analysis. *The Lancet Regional Health–Americas*. 2024;33
13. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline. 12/01 2021;
14. Jotwani, Vasantha*, †; Atta, Mohamed G. ‡; Estrella, Michelle M. *, †. Kidney Disease in HIV: Moving beyond HIV-Associated Nephropathy. *Journal of the American Society of Nephrology* 28(11):p 3142-3154, November 2017. | DOI: 10.1681/ASN.2017040468
15. Gandhi RT, Landovitz RJ, Sax PE, et al. Antiretroviral drugs for treatment and prevention of HIV in adults: 2024 recommendations of the international antiviral society–USA panel. *Jama*. 2025;333(7):609–628.
16. Patel RR, Hoover KW, Lale A, Cabrales J, Byrd KM, Kourtis AP. Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis - United States, 2025. *MMWR Morb Mortal Wkly Rep*. Sep 18 2025;74(35):541–549. doi:10.15585/mmwr.mm7435a1
17. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med*. Oct 3 2024;391(13):1179–1192. doi:10.1056/NEJMoa2407001
18. Delany-Moretlwe S, Hughes JP, Bock P, et al. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. *Lancet*. 2022;399(10337):1779-1789. doi:[10.1016/S0140-6736\(22\)00538-4](https://doi.org/10.1016/S0140-6736(22)00538-4)
19. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *N Engl J Med*. Apr 3 2025;392(13):1261–1276. doi:10.1056/NEJMoa2411858
20. Landovitz RJ, Delany-Moretlwe S, Fogel JM, et al; HPTN 083 and 084 Study Teams. Features of HIV infection in the context of long-acting cabotegravir preexposure prophylaxis. *N Engl J Med*. Published online July 24, 2024. doi:[10.1056/NEJMc2402088](https://doi.org/10.1056/NEJMc2402088)
21. [Core Concepts - Follow-Up Care and Monitoring on HIV PrEP - HIV PrEP Fundamentals - Core Concepts - Follow-Up Care and Monitoring on HIV PrEP - HIV PrEP Fundamentals - National HIV PrEP Curriculum](#)

THANK YOU

Questions

