HIV PrEP and PEP

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August 24, 2023

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Date prepared: *August 2023*

Outline

HIV PrEP

- Oral
- Injectable

HIV PEP

- DoxyPEP

Which of the Following Best Describes your Experience with PrEP?

A. Never heard of PrEP

B. Familiar with PrEP but have never recommended it

C. Prescribed PrEP a few times before

D. Extensive experience prescribing PrEP to patients

HIV Prevention Strategies

- Sexual behavior modification
- Condom use
- Test and treat STIs
- HIV treatment as prevention (U=U)
- PrEP: Pre-Exposure Prophylaxis
- PEP: Post-Exposure Prophylaxis
- Offer sterile, personalized injection drug use equipment for people who inject drugs

https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/20/48/the-basics-of-hiv-prevention

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Which of the following patients would benefit from PrEP?

A. A person who injects drugs, shares needles and the last injection was 2 months ago
B. A man who has sex with men (MSM), has a stable HIV negative partner and uses condoms systematically
C. A heterosexual female recently diagnosed with syphilis
D. A 23 yo male who is asking for PrEP but denies any risk factors for HIV

Wha
PrEP?

- **Pre-ex ure pro s** (or PrEP) is when peop r HIV ta anti to h their cha

PrEP is not a substitution for other HIV prevention interventions!

PrEP does not protect against other STIs!

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administered e
ery two months

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

Why PrEP?

PrEP is highly effective

When taking oral PrEP daily or consistently (*at least 4 times per week*) the risk of acquiring HIV is reduced by:

about 99% among MSM (men who have sex with men)	an estimated 74 – 84% among PWID

https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html

Who should be offered PrEP?

- The federal guidelines recommend that PrEP be considered for people [illegible]HIV negative and:
  - Have **had anal or vaginal sex in the past 6 months and**:

[illegible]tectable

Anyone who is at risk for acquiring HIV

[illegible]).

[illegible]tional

post-exposure prophylaxis (PEP) and

- report continued risk behavior, or
- have used multiple courses of PEP

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

Oral PrEP

Oral PrEP

Recommended Oral PrEP Medications

Generic Name	Trade Name	Dose	Frequency	Most Common Side Effects[109,110]
F/TDF	Truvada	200 mg/300 mg	Once a day	Headache, abdominal pain, weight loss
F/TAF	Descovy	200 mg/25 mg	Once a day	Diarrhea

Adherence and F/TDF PrEP Efficacy in MSM

Weekly Medication Adherence Estimated by Drug Concentration	HIV Incidence per 100 person/years
None	4.2
≤2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	0.0

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

Baseline Labs for Oral PrEP

Plus other STI Screening

Renal function

Hepatitis B serology:

- Hep B Surface Ab
- Hep B Surface Ag
- Hep B Core Ab

Lipid profile (F/TAF)

HIV 1/2 Ab/Ag

- **Add on HIV RNA (Viral Load) for a**nyone who has taken oral PrEP in the last 3 months and/or has received a CAB injection in the last 12 months

HIV RNA (Viral Load)

- Anyone who has taken oral PrEP in the last 3 months and/or has received a CAB injection in the last 12 months

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

Oral PrEP Follow-up

- Every 3 months:
  - Repeat HIV testing
  - Assess for signs or symptoms of acute HIV infection
  - Provide RX for no more than 90 days (until the next HIV test)
  - Assess medication adherence and risk-reduction behaviors
  - Conduct STI testing if symptoms of infection
  - Conduct STI screening for asymptomatic MSM at high risk for syphilis, gonorrhea, or chlamydia

Features	Overall (n = 375) %
Fever	75
Fatigue	68
Myalgia	49
Skin rash	48
Headache	45
Pharyngitis	40
Cervical adenopathy	39
Arthralgia	30
Night sweats	28
Diarrhea	27

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

Oral PrEP Follow-up

- Every 6 months:
  - Monitor eCrCl for persons age ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation
    - If other threats to renal safety are present (e.g., hypertension, diabetes), renal function may require more frequent monitoring or may need to include additional tests (e.g., urinalysis for proteinuria)
    - A rise in serum creatinine is not a reason to withhold treatment if eCrCl remains ≥60 ml/min for F/TDF or ≥30 for F/TAF
    - If eCrCl is declining steadily (but still ≥60 ml/min for F/TDF or ≥30 ml/min for F/TAF), ask if the patient is taking high doses of NSAID or using protein powders; consultation with a nephrologist or other evaluation of possible threats to renal health may be indicated
  - Conduct STI screening for sexually active persons (i.e., syphilis, gonorrhea, for all PrEP patients and chlamydia for MSM and TGW even if asymptomatic)
  - Assess need for continuing or discontinuing PrEP

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

Oral PrEP Follow-up

- At least every 12 months:
  - Monitor eCrCl for all patients continuing on PrEP medication
  - Monitor triglyceride, cholesterol levels, and weight for patients prescribed F/TAF for PrEP
  - Conduct chlamydia screening for heterosexual women and men even if asymptomatic

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

Timing of Oral PrEP-associated Lab Tests

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥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, and PWID only			MSM,TGW, and PWID only	

* Assess for acute HIV infection

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

Discontinuing Oral PrEP

Provider should document:

- HIV status at the time of discontinuation
- Reason for discontinuation
- Recent medication adherence and reported sexual risk behavior

Restarting PrEP requires same initial evaluation, minus the Hep B serology

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

Injectable PrEP

Injectable PrEP

- Cabotegravir (CAB) 600 mg (brand name Apretude®)
- Only for patients whose risk factors for HIV include sexual transmission only (not for PWID)
- Adults and adolescents who weigh at least 35 kg (77 lb)
- CAB injections may be a good option for PrEP for people who
  - Have problems taking oral PrEP as prescribed
  - Prefer getting a shot every 2 months instead of taking oral PrEP
  - Have serious kidney disease that prevents use of oral PrEP medications

https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-injectable-hiv-prep.pdf

How Is Injectable PrEP Administered?

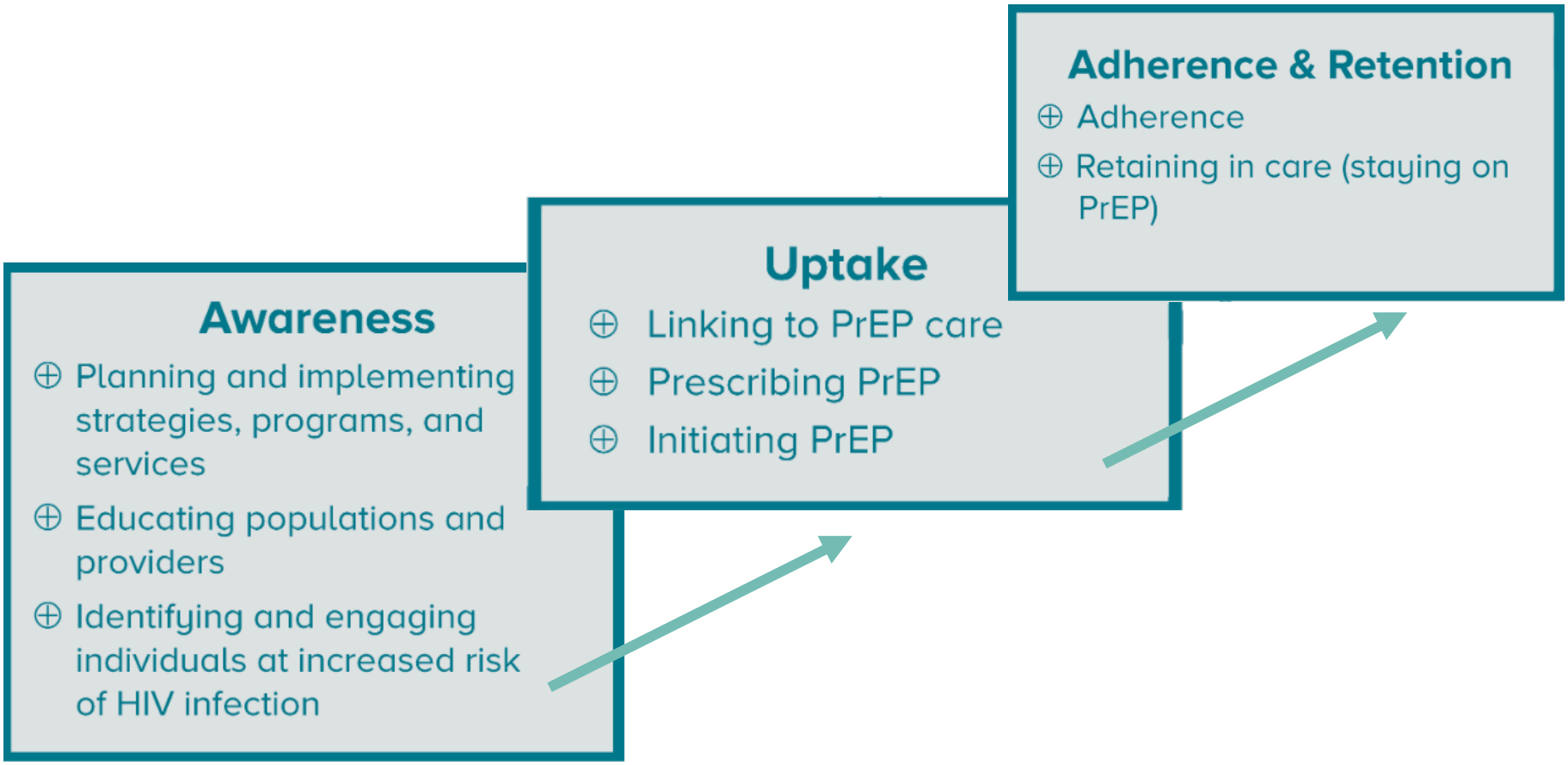
- IM – ventro- (preferred) or dorso- gluteal – 3mL at room temp – must be given within 2 hours of drawing it up in syringe – use long enough needle based on body habitus – 1.5-2”

- First dose – IM injection of CAB 600mg
- 1 month later – IM injection of CAB 600mg
- Every 2 months after - IM injection of CAB 600mg

- If concern for side effects:
  - A 4-week lead-in period of 30 mg daily oral CAB prior to the first injection is optional

https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-injectable-hiv-prep.pdf;
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215499s002lbl.pdf

Continuum of PrEP Care



*Modified from Nunn, et al. Defining the HIV pre-exposure prophylaxis care continuum. *AIDS* 2017; 31(5):731-734.

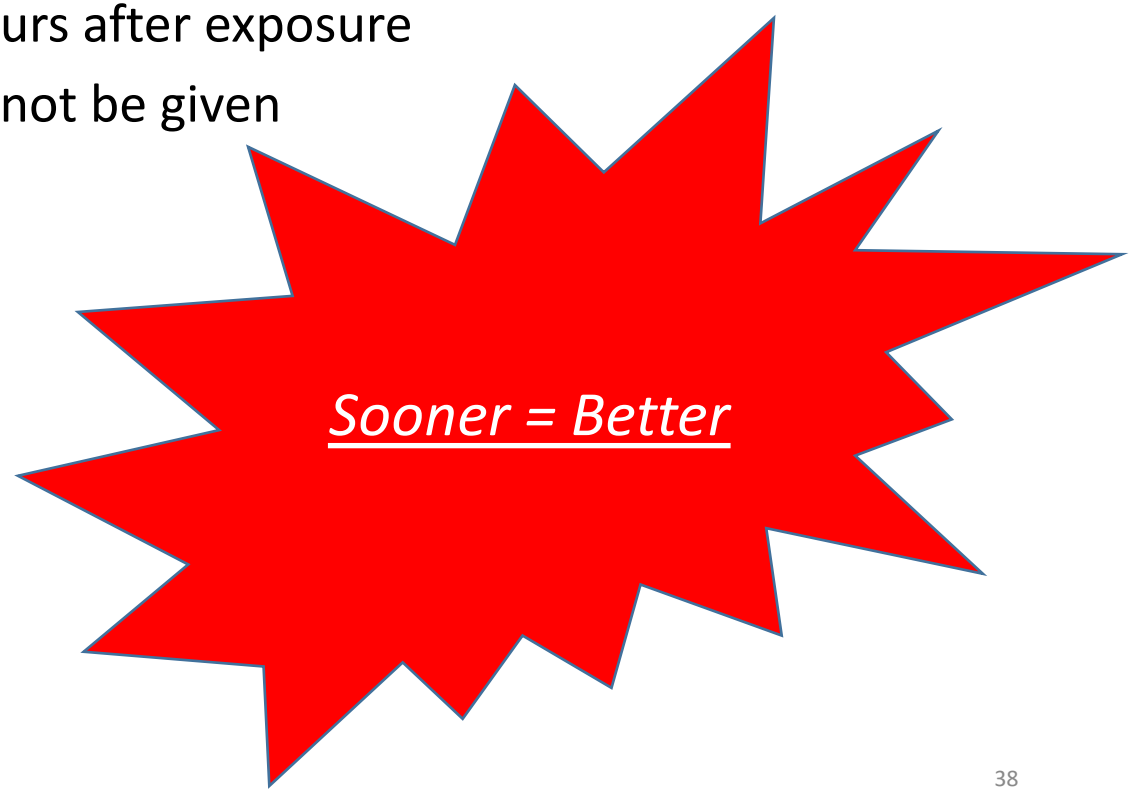
Role of the PCP in PrEP

- Consider PrEP for at-risk individuals
  - Take a good sexual health history to find at-risk individuals
  - Ask about injection drug use
- Discuss with the patient the principles of PrEP
- Offer brochures for PrEP in your office
- Decide:
  - Is this something I will offer my patient?
  - If not me, who? If not now, when?

Post-exposure Prophylaxis (PEP)

Exposure to HIV is an Emergency!

- The ideal time to administer PEP – within 2 hours of exposure!
  - Consider giving the first dose, aka emergency dose, immediately upon presentation
- Can be given up to 72 hours after exposure
- After 72 hours, it should not be given



Who should be offered PEP?

Individuals who are HIV negative or unknown HIV status who:

- May have been exposed to HIV during sex
- Shared needles or other equipment (works) to inject drugs
- Were sexually assaulted
- May have been exposed to HIV at work

Determining Exposure Risk

Negligible Risk for HIV Acquisition

Exposure of
Vagina, rectum, eye, mouth or other mucous membrane, intact or nonintact skin, or percutaneous contact

With
Urine, nasal secretions, saliva, sweat, or tears if not visibility contaminated with blood

Regardless
Of the known or suspected HIV status of the source

Substantial Risk for HIV Acquisition

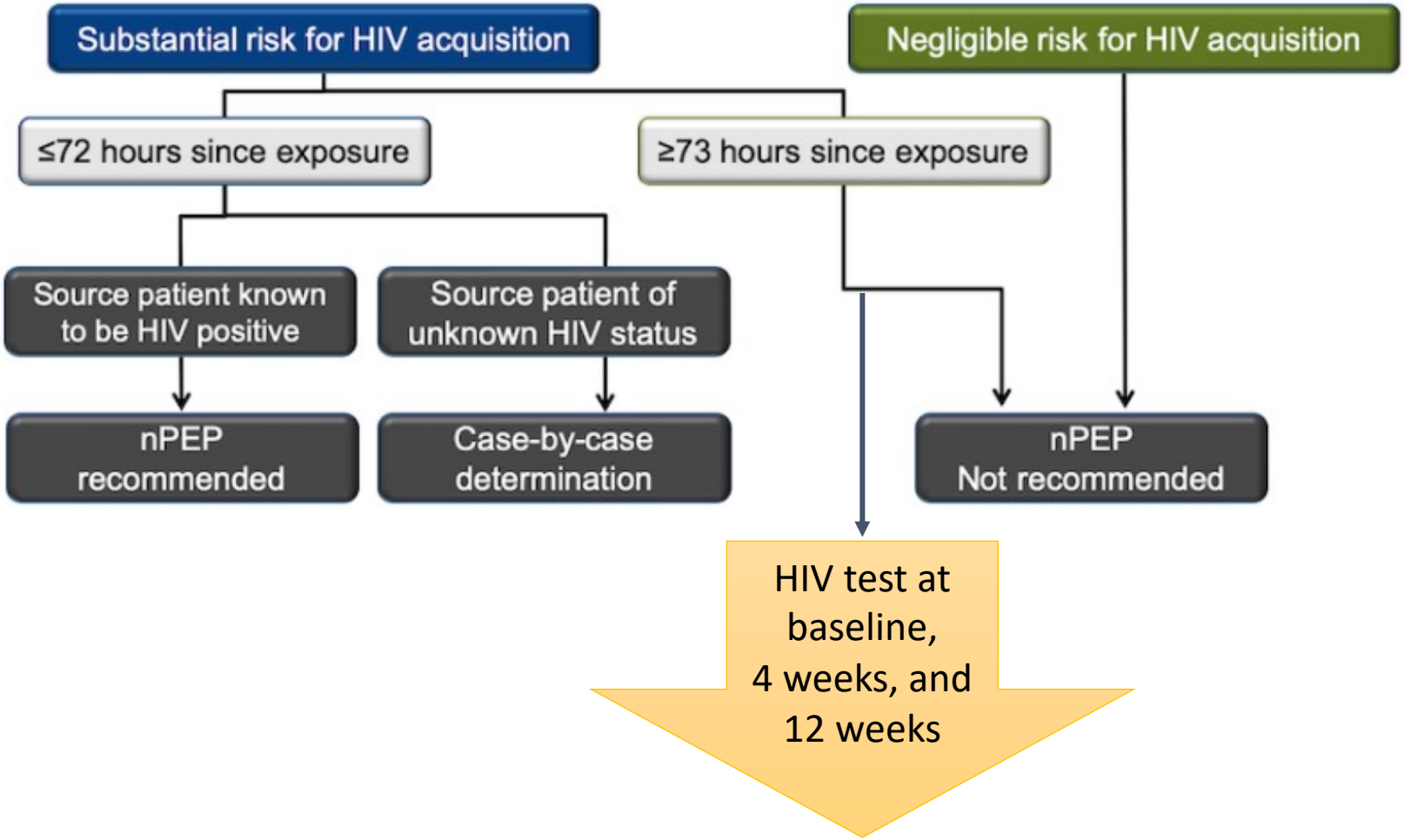
Exposure of
Vagina, rectum, eye, mouth or other mucous membrane, nonintact skin, or percutaneous contact

With
Blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood

When
The source is known to be HIV-positive

https://www.hiv.uw.edu/pdf/prevention/nonoccupational-postexposure-prophylaxis/core-concept/all

Algorithm for Evaluation and Treatment of possible nonoccupational HIV exposures



https://www.hiv.uw.edu/pdf/prevention/nonoccupational-postexposure-prophylaxis/core-concept/all

Recommended Labs for nPEP evaluation

Baseline	4-6 weeks	3 months	6 months
☐ HIV Ab/Ag test	☐ HIV Ab/Ag test	☐ HIV Ab/Ag test	☐ Syphilis serology*
☐ Hep B Surface Ab	☐ Cr/AST/ALT**		☐ HIV Ab/Ag test if acquired HCV from the exposure
☐ Hep B Surface Ag	☐ Syphilis serology*		☐ Hep B serologies if not immune
☐ Hep B core Ab	☐ Gonorrhea*^		☐ Hep C Ab
☐ Hep C Ab	☐ Chlamydia*^		
☐ Cr/AST/ALT	☐ Pregnancy*		
☐ Syphilis serology*			
☐ Gonorrhea*^			
☐ Chlamydia*^			
☐ Pregnancy*			

*Sexual exposure only; ^Screen all sites of contact; **Only if taking oral PEP

Recommended Regimens for PEP

Adults and adolescents aged ≥13 years with normal renal function (creatinine clearance ≥60 mL/min), including pregnant women

Preferred Regimens:

- Raltegravir (400 mg twice daily) plus tenofovir DF-emtricitabine (300-200 mg once daily)
- Dolutegravir (50 mg once daily) plus tenofovir DF-emtricitabine (300-200 mg once daily)

Alternative Regimen:

- Darunavir (800 mg once daily) plus ritonavir (100 mg once daily) plus tenofovir DF-emtricitabine (300-200 mg once daily)

Adults and adolescents aged ≥13 years with renal dysfunction (creatinine clearance ≤59 mL/min)[+]

Preferred Regimens:

- Raltegravir (400 mg twice daily) plus zidovudine (dose adjusted) plus lamivudine (dose adjusted)
- Dolutegravir (50 mg once daily) plus zidovudine (dose adjusted) plus lamivudine (dose adjusted)

Alternative Regimen:

- Darunavir (800 mg once daily) plus ritonavir (100 mg once daily) plus zidovudine (dose adjusted) plus lamivudine (dose adjusted)

[a]These recommendations do not reflect current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table.

[b]Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors. Ritonavir is not counted as a drug directly active against HIV in the above "3-drug" regimens.

[+]The dose adjustments for zidovudine and lamivudine are made based on degree of renal function

Centers for Disease Control and Prevention: U.S. Department of Health and Human Services. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, and Other Nonoccupational Exposure to HIV—United States, 2016. [CDC]

DoxyPEP (Post-Exposure Prophylaxis)

Take 1 dose, **Doxycycline 200mg within 72 hours** of having condomless sex

Repeat as needed, but no more than 1 dose within 24 hours

DoxyPEP

- Open-label DoxyPEP study (2022): 501 MSM and TGW living with HIV (N=174) or on HIV PrEP (N=327) in San Francisco and Seattle
- Randomized to either take DoxyPEP up to once daily (intervention group) vs no medication prophylaxis (control group).
- Primary endpoint was incidence of at least 1 STI per follow-up quarter
- Study ended early after the data safety monitoring board found a **66% reduction in STIs overall** for the intervention group
- In the intervention arm, 86% reported taking doxycycline always/often and 71% reported never missing doxycycline

DoxyPEP is Off-Label

- CDC has acknowledged that providers and patients have started to use DoxyPEP off-label and provided considerations for its use:
  - Reminder that current studies with promising results are only inclusive of MSM and transgender women
  - Only Doxycycline has been studied, no other antibiotics
- IHS acknowledges that any current use of DoxyPEP or DoxyPrEP is considered off-label
  - IHS does not yet officially endorse use of DoxyPEP or DoxyPrEP as the standard of care. Any use of DoxyPEP or DoxyPrEP will be made at the individual provider level
  - Currently awaiting CDC to publish guidelines

Barriers to PrEP/PEP

- What barriers do you have or foresee to starting PrEP at your site?

Resources

- **HIV/PrEP Warm Line: (800) 933-3413**
  - HIV/AIDS Management | National Clinician Consultation Center (ucsf.edu)
  - Clinicians are available Monday through Friday, 9:00 a.m. to 8:00 p.m. EST. Voice mail is available 24 hours a day.
- **Indian Country ECHO**
  - http://www.indiancountryecho.org
  - HIV ECHO, 2nd Wednesday of every month 2-3 pm ET

Questions?