HIV PrEP and PEP in Primary Care

Whitney Essex, APRN-CNP
Jorge Mera, MD, FACP

March 2024

Presentation prepared by: *Whitney Essex*
Date prepared: *Updated Feb 2024*

Outline

HIV PrEP

- Oral Options
- Finding those who need it

HIV PEP

HIV in Primary Care

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

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

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 l their cha

PrEP is not a substitution for other HIV prevention interventions!

PrEP does not protect against other STIs!

ble
ularly
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 and include HIV RNA test

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

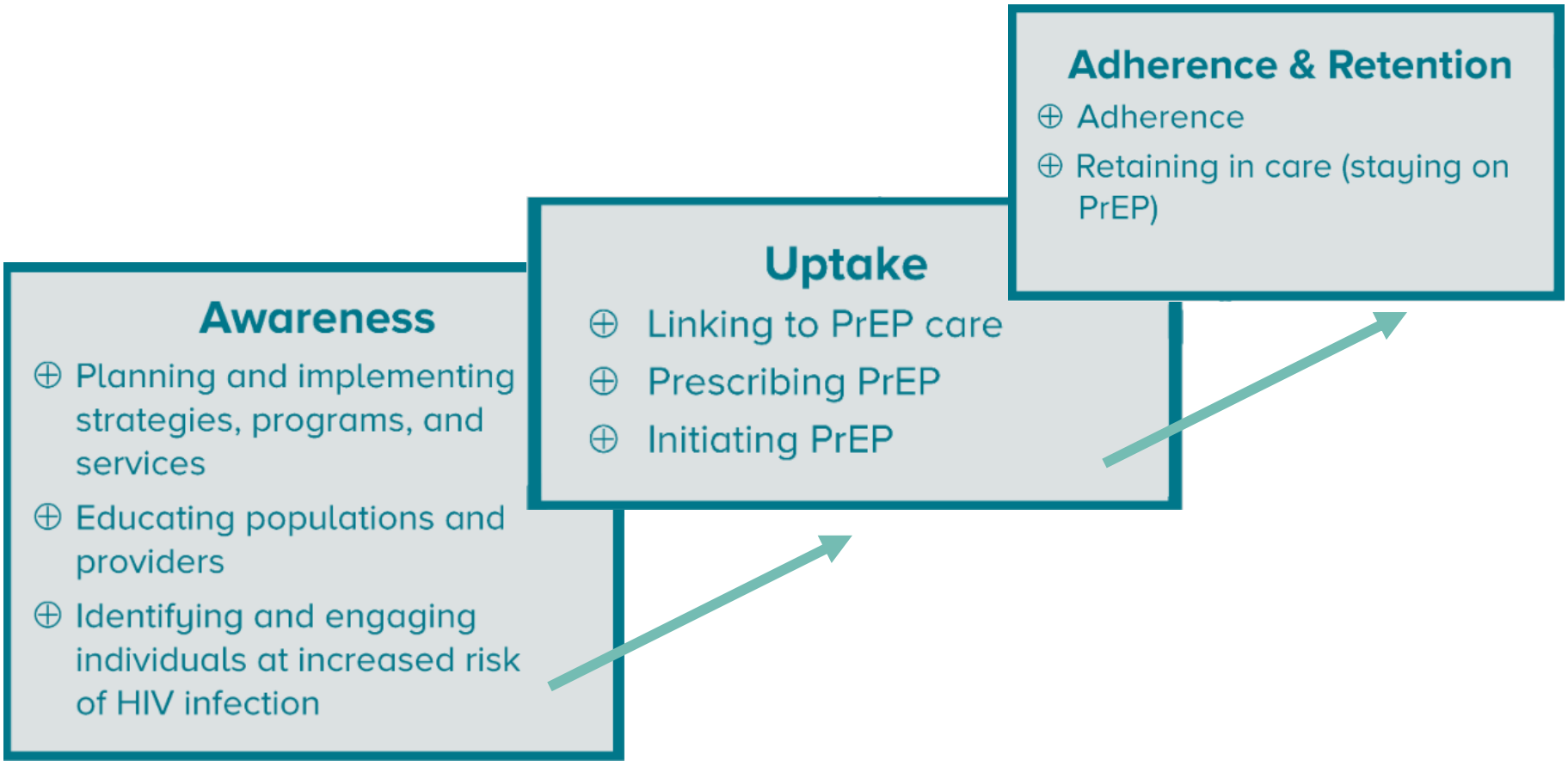
Restarting PrEP requires same initial evaluation, minus the Hep B serology

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

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?

PrEP Care

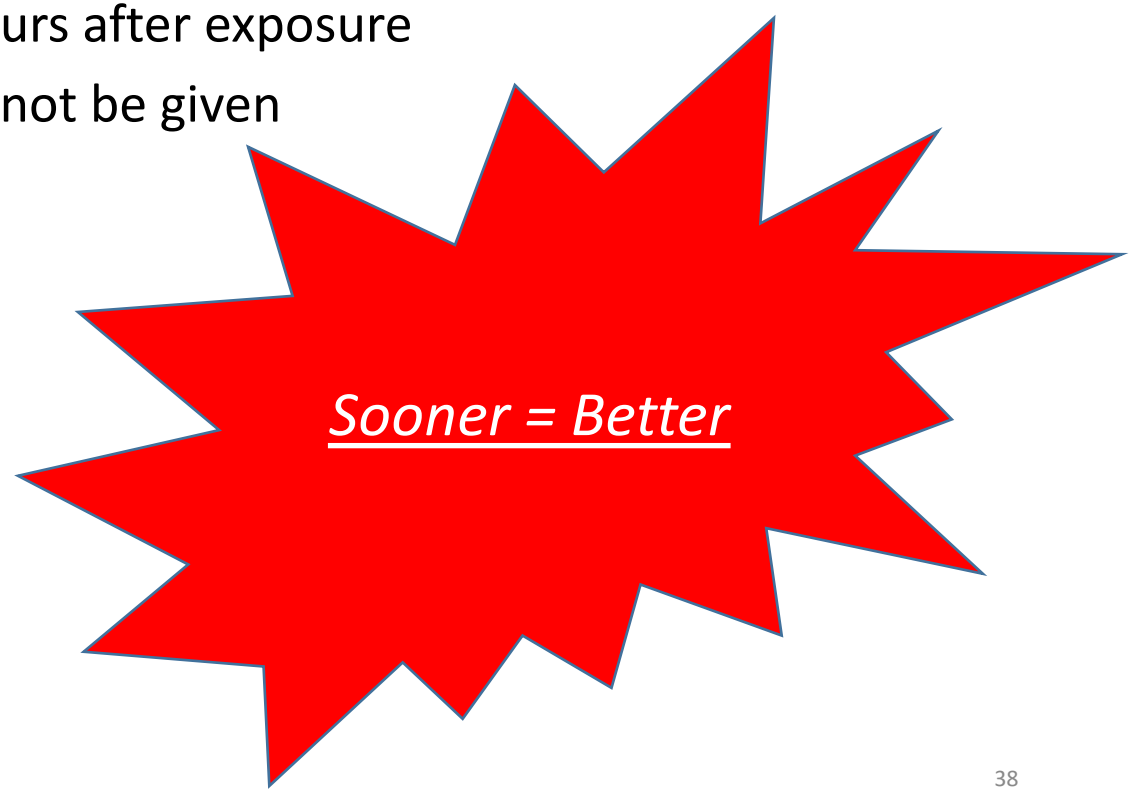


*Modified from Nunn, et al. Defining the HIV pre-exposure prophylaxis care continuum. *AIDS* 2017; 31(5):731-734.

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

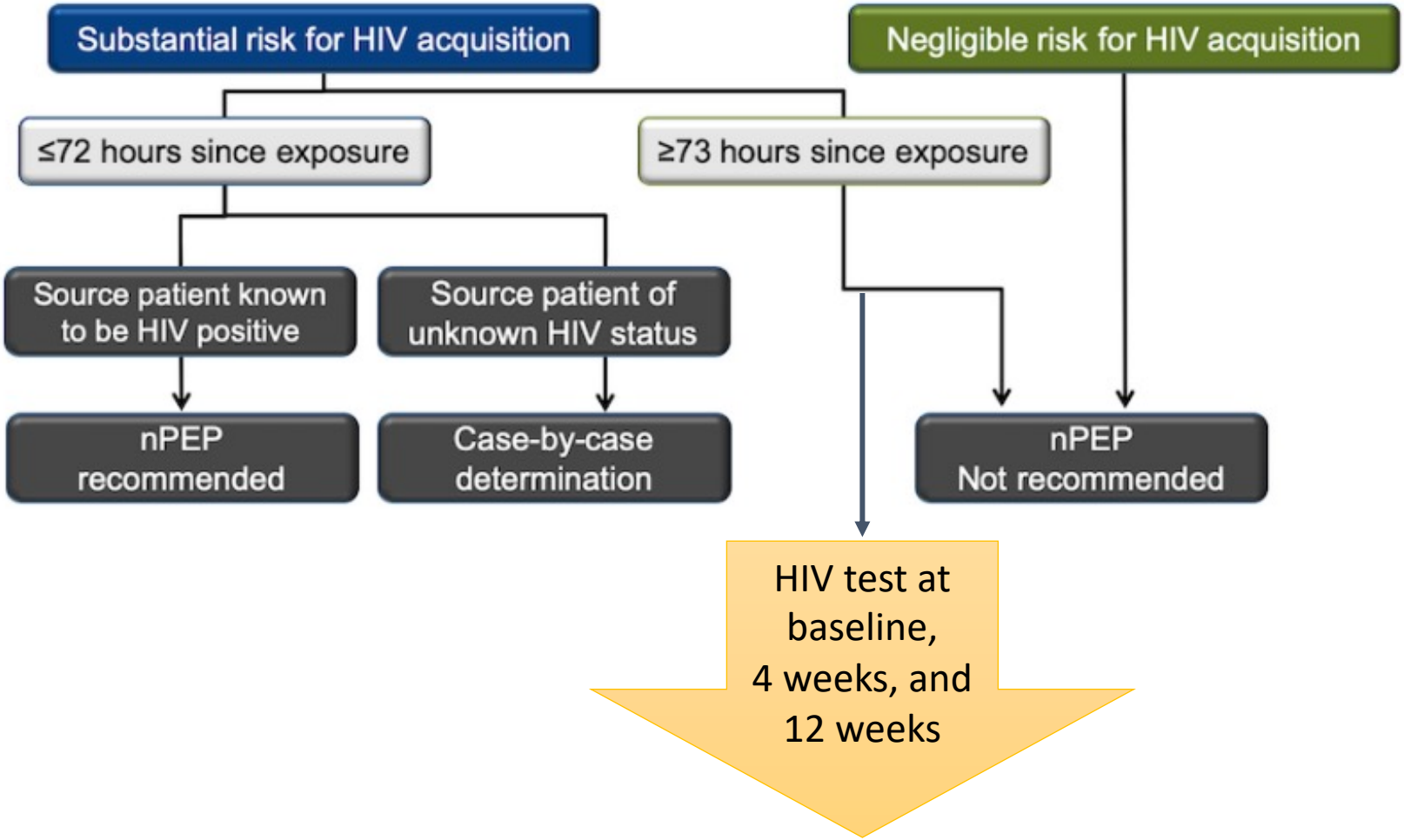
Exposure of
Vagina, rectum, eye, mouth or other mucous membrane, nonintact skin, or percutaneous contact

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]

Barriers to PrEP/PEP

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

What do I do if a patient tests positive for HIV (confirmed)?

- Get to know the patient
- Destigmatize HIV and normalize HIV care
- Explain the basics
- Focus on the effectiveness of HIV treatment
- Get labs
- Start medication on the same day

Initial HIV+ Evaluation - Labs

CD4 cell count	At baseline Every 3 to 6 months (may be extended to ≥12 months in clinically stable patients on ART*)
HIV viral load	At baseline •After ART initiation: At 4 to 8 weeks •Every 4 to 8 weeks until the viral load is suppressed •Every 3 to 4 months thereafter (may be extended to every 6 months in patients who have suppressed viral loads for ≥1 year)
Genotypic resistance testing	At baseline

Treatment (DHHS recommendation)

- Tenofovir/Emtricitabine/Bictegravir 1 po daily

Or

- Tenofovir + (Emtricitabine or Lamivudine) + Dolutegravir

Or

- Abacavir/Lamivudine/Dolutegravir 1 po daily
  - (only if HLA B*5701 negative and HBV negative)

Or

- Dolutegravir/Lamivudine 1 po daily
  - Only (if HIV VL< 500K, HBV negative, sensitive on GART)

DHHS Adult and Adolescent Antiretroviral HIV Guidelines: https://clinicalinfo.hiv.gov/en/guidelines/adultand-adolescent-arv/hhs-adults-and-adolescents-antiretroviral-guidelines-panel

Screen for other infections

Syphilis serology	At baseline Annually for sexually active persons (or more frequently if at high risk)
Chlamydia and gonorrhea testing (at all sites of potential exposure)	At baseline Annually for sexually active persons (or more frequently if at high risk)
Trichomonas	At baseline for all women Annually for sexually active women
TB testing (TST or IGRA)	At baseline unless there is a history of a prior positive test Annually in patients at ongoing risk for TB unless there is a history of a prior positive test
HAV and HBV serologies	At baseline, with vaccination(s) in persons not immune
HCV serology, with reflex viral level for positive result	At baseline Annually in patients at risk (eg, persons who inject drugs, men who have sex with men, transgender women)

Up to Date: Initial Evaluation of Adults with HIV: https://www.uptodate.com/contents/initial-evaluation-of-adults-with-hiv?search=new%20hiv%20diagnosis&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#

Screen for past infections

Test	Frequency	Comment
Toxoplasma Ab	Once	Prophylaxis if CD4<100
CMV Ab	Once	Test only if low risk (nonMSM/transgender/PWID)
Varicella Ab	Once if no h/o Chickenpox or Shingles	Consider vaccination if negative and CD4>200

Assess CV risk

Blood pressure check	At baseline and annually (or more frequently as indicated)
Random or fasting glucose and/or hemoglobin A1c	At baseline 1 to 3 months following ART initiation or modification and then annually[¶]
Fasting lipid profile	At baseline 1 to 3 months following ART initiation or modification and then every 12 months
Weight assessment	At baseline and follow-up visits
Tobacco use assessment	At baseline and annually
Aortic aneurysm screening (abdominal ultrasonography)	Once in men 65 to 75 years old who have ever smoked

Other assessments/screenings

Assessing other risks	
Bone densitometry	At baseline in postmenopausal women and men ≥50 years old Subsequent testing frequency depends on findings on baseline exam
Screening for neuropsychiatric disorders	
Depression screening	At baseline and annually
Screening for cognitive deficits	At baseline and annually

Follow-up tests for monitoring ART toxicity

Complete blood count with differential	At baseline Complete blood count with differential every 3 to 6 months when monitoring CD4 count and every year once the CD4 count is no longer monitored
CMP	At baseline 4 to 8 weeks after ART initiation and every 6 months thereafter
Urinalysis	At baseline After ART initiation or change Every 12 months on ART (every 6 months while on tenofovir disoproxil fumarate or tenofovir alafenamide-containing regimens)

Screening for cancer

Colonoscopy	At 45 years old in asymptomatic patients at average risk Earlier screening may be warranted for those with strong family history of colon cancer Subsequent testing frequency depends on findings on baseline exam
Mammography	Every other year or annually in women 50 to 74 years old[Δ]
Cervical Pap smear (with or without HPV testing in women ≥30 years)	At baseline; interval for repeat testing depends on results and whether HPV co-testing was performed[◊] Additional testing may be warranted for those with abnormal results
Anal Pap smear	Consider at baseline and annually More frequent or additional testing may be warranted for those with abnormal results
Prostate-specific antigen	For men aged 55 to 69 years, the decision to undergo periodic prostate-specific antigen (PSA)-based screening for prostate cancer should be individualized[§]
Low-dose helical chest CT	Adults age 50 to 80 years old who are at risk of lung cancer due to smoking (at least a 20 pack-year smoking history and are either current smokers or former smokers having quit within the past 15 years)

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?