
# Antiretroviral Therapy (ART) for Special Populations

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## Disclosures of Financial Relationships with Relevant Commercial Interests

- None

## Special Populations

- Acute/recent HIV infection
- Acute opportunistic infection
- Tuberculosis
- HIV-HBV co-infection
- HIV-HCV co-infection
- Pregnancy
- Post-HIV exposure (PEP)
  - Occupational (oPEP)
  - Non-occupational (nPEP)
- Pre-HIV exposure (PrEP)

## Question #1

A 22-year-old man presents with fever, mouth pain, and skin rash. PE reveals 3 small oral ulcers and diffuse macular rash. Labs show WBC 3K, platelets 89K, monospot negative, RPR NR, HIV antibody negative, HIV RNA 1,876,000 cps/ml.

### Which statement is correct?

A. ART should not be offered
B. ART would decrease his symptoms
C. ART would not decrease ongoing transmission
D. ART has long-term clinical benefits in this setting

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## Acute or Recent HIV

- ART is RECOMMENDED.
- ART reduces symptoms and signs and reduces transmission.
- Long-term virologic, immunologic, and clinical data sparse.
- Goal is full virologic suppression.
- Obtain genotype prior to ART.
- If ART is started prior to genotype results, use bictegravir, dolutegravir, or boosted darunavir, together with tenofovir (TAF or TDF) + emtricitabine.
- If patient was on IM cabotegravir for PrEP, use **boosted darunavir-based** regimen (rather than integrase inhibitor-based).
- Can modify regimen, if needed, when genotype results return.

DHHS Guidelines 9/25/25

## Question #2

A 52-year-old woman is admitted for progressive SOB, is intubated, undergoes BAL and is found to have PCP. HIV Ab test is positive, CD4 103, HIV RNA 135,000 copies/ml. She is day 4 of IV trimethoprim-sulfa and corticosteroids and still intubated.

### When should she start ART?

A. Immediately
B. In the next 2 weeks
C. After completing 21 days of trimethoprim-sulfa
D. At her first outpatient clinic visit

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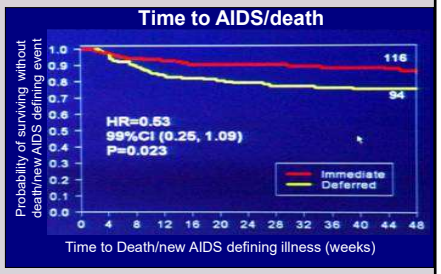
## ACTG 5164: Immediate vs Delayed ART with an Acute OI

- 282 patients with treatable OI diagnosed within 14 days randomized to start ART within 48 hours vs. after 4 weeks
  - Most common OI: PCP (63%)
- AIDS progression/death: **immediate rx (14%)** vs. **delayed rx (24%)**
- No differences in safety/toxicity, IRIS, or week 48 responses
- Caution with CNS OI (e.g., cryptococcus, TB)




SEE ENLARGED SLIDE FOLLOWING ENTIRE PRESENTATION

Zolopa PLoS One 2009;4:e5575

## HIV-TB Co-infection

- Treat active TB the same with or without HIV.
- All PWH with TB should start TB meds immediately.
- In PWH with TB, timing of starting ART depends on CD4 count:
  - For CD4 <50, start ART ASAP, within 2 weeks of TB rx
  - For CD4 >50, start ART within 8 weeks of TB rx
- Start pregnant women with HIV and TB on ART as early as feasible.
- For TB meningitis, after >2 weeks + monitor closely.

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## Question #3

A 39-year-old man with HIV, CD4 298, HIV RNA 23,000 cps/ml, never on ART is diagnosed with pulmonary TB. The plan is to start INH, RIF, PZA, and ETH while awaiting susceptibilities. He agrees to start ART and genotype is wild-type.

**Which of the following ART regimens do you recommend?**

A. TDF/emtricitabine/efavirenz
B. TDF/emtricitabine + atazanavir (unboosted)
C. TAF/emtricitabine + darunavir (boosted with cobicistat or ritonavir)
D. TAF/emtricitabine/bictegravir

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## HIV-TB Co-infection (2)

- Include a rifamycin in the regimen.
  - Rifampin
    - Significantly ↓ **TAF** – current FDA label: not recommended
    - Significantly ↓ ALL **PIs** – do not use
    - ↓ **Dolutegravir (DTG)** (need to ↑ DTG to 50 mg twice daily)
    - Significantly ↓ **bictegravir (BIC)** – do not use (*conflicting data)
    - ↓ NNRTI concentrations: **efavirenz (EFV)** 600 mg daily is recommended
  - Rifabutin: preferred; more manageable drug interactions with protease inhibitors
- For IRIS, continue both ART and TB meds while managing the syndrome.
- Treatment support, including directly observed therapy (DOT) of TB rx is strongly recommended.

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## Question #4

A 55-year-old with HIV not previously on rx, CD4 320 and HIV RNA 67,000 cps/ml
Lab testing reveals: toxoplasma Ab+; CMV Ab+; HAV total Ab+; HBV surface Ag+, core Ab+, surface Ab-; HCV Ab-; RPR NR

**Of the following, which ART regimen would you recommend?**

A. Abacavir/lamivudine/dolutegravir
B. Cabotegravir + rilpivirine IM
C. Dolutegravir/lamivudine
D. Tenofovir (TAF or TDF)/emtricitabine + darunavir (boosted)

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**D. Tenofovir (TAF or TDF)/emtricitabine + darunavir (boosted)***

## HIV-HBV Co-infection

- Some ART has activity against HBV
  - Lamivudine (3TC), emtricitabine (FTC), tenofovir (TDF and TAF)
- Some HBV drugs have activity against HIV
  - Entecavir (can select M184V) McMahon NEJM 2007;356:2614
- If treatment started, treat both optimally
  - 2 active agents for HBV (TAF or TDF) + (3TC or FTC)
  - + 3rd drug for HIV (preferred = BIC or DTG)
  - If tenofovir cannot be used, start a fully suppressive regimen and add entecavir

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## HIV-HCV Co-Infection

- Anyone with HCV should be screened for HIV.
- High-risk HIV+ patients should be screened for HCV annually.
- ART should be started in those with concomitant HCV.
  - Same initial regimens recommended, but caution with drug-drug interactions and overlapping toxicities.
- Patients with HIV and HCV should be evaluated for HCV therapy (including assessing liver fibrosis stage).
  - Also evaluate for HBV co-infection.
- HCV direct-acting antiviral regimens → high cure rates

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## Question #5

A 26-year-old woman with HIV on TAF/emtricitabine + efavirenz with CD4 630 and VL suppressed below detection becomes pregnant.

**What do you recommend regarding ART?**

A. Discontinue ART until 2nd trimester
B. Change TAF to zidovudine
C. Change efavirenz to bictegravir
D. Continue current regimen

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## Antiretrovirals in Pregnancy

- ART recommended for all pregnant people, as early as possible, regardless of CD4 or VL level (rx and prevention of MTCT: mother to child transmission)
  - Perform drug-resistance testing if VL >500-1000 cps/ml
  - Start (or continue if safe/tolerated) standard 3-drug ART as early as possible (while awaiting drug resistance testing):
    - 2-drug regimens can be continued, if virologically suppressed
    - Modify regimen when drug resistance testing results available
  - ART does NOT increase the risk of birth defects
- Near delivery, if HIV RNA >1000 (or unknown), use intravenous zidovudine, and recommend Cesarean section at 38 weeks

DHHS Perinatal Guidelines 3/31/26 <www.clinicalinfo.hiv.gov>

## ART in Pregnancy: NRTI

- Preferred:
  - Tenofovir (TAF or TDF)/(emtricitabine or lamivudine)
- Alternative:
  - Abacavir
  - Zidovudine/lamivudine
- IV zidovudine recommended close to delivery if VL >1000

DHHS Perinatal Guidelines 3/31/26 <www.clinicalinfo.hiv.gov>

## ART in Pregnancy: NNRTI

- Alternative:
  - Efavirenz (birth defects reported in primate studies, NO evidence in human studies and extensive experience; screen for depression)
  - Rilpivirine (NOT with baseline VL >100K or CD4 <200 or PPIs)
- Insufficient data: doravirine
- Not recommended (could continue if already taking):
  - Etravirine (not for treatment-naïve pts)
  - Nevirapine (toxicity, need for lead-in dosing, low barrier to resistance)

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## ART in Pregnancy: PI

- Preferred:
  - Darunavir/ritonavir (when previously on cabotegravir PrEP; need to use bid)
- Alternative:
  - Atzanavir/ritonavir
  - Darunavir/ritonavir (need to use bid)
- Not recommended:
  - Cobicistat (↓ drug concentrations, limited experience)
  - Lopinavir/ritonavir (side effects)

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## ART in Pregnancy: INSTI

- Preferred (with TAF or TDF / 3TC or FTC):
  - Bictegravir
  - Dolutegravir (neural tube defects NOT significantly ↑ vs. other ART)
- Alternative:
  - Dolutegravir/lamivudine (2-drug regimen)
  - Raltegravir (need to use bid)
- Not recommended:
  - Elvitegravir/cobicistat (↓ drug concentrations)
  - IM cabotegravir + rilpivirine (could continue if already taking)

DHHS Perinatal Guidelines 3/31/26 <www.clinicalinfo.hiv.gov>

## ART in Pregnancy: Other

- Not recommended:
  - Cobicistat as a booster (for EVG or PIs)
- Only recommended for treatment-experienced:
  - Etravirine, fostemsavir, ibalizumab, lenacapavir, maraviroc

DHHS Perinatal Guidelines 3/31/26 <www.clinicalinfo.hiv.gov>

## Question #6

A 34-year-old nurse without HIV sustains a needlestick from a patient with HIV who has not taken ART for 2 years.

**Which of these post-exposure (PEP) regimens do you recommend?**

A. Tenofovir (TDF or TAF)/emtricitabine
B. Tenofovir (TDF or TAF)/emtricitabine + non-nucleoside RT inhibitor (NNRTI)
C. Tenofovir (TDF or TAF)/emtricitabine + integrase inhibitor
D. Tenofovir (TDF or TAF)/emtricitabine + protease inhibitor

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D. Tenofovir (TDF or TAF)/emtricitabine + protease inhibitor

## Antiretrovirals for PEP (Post-Exposure Prophylaxis)

- Assess exposure: source fluid, volume of fluid, type of exposure, timing
- Assess exposure source: HIV and hepatitis testing
- Testing
  - Baseline: HIV Ag/Ab test, HBV, pregnancy, + creatinine and AST/ALT (f/up only for abnormal results or clinical indications)
  - Follow-up (4-6 weeks; only if PEP started >24 hours after exposure or missed PEP doses): HIV Ag/Ab and HIV RNA
  - Follow-up (12 weeks): HIV Ag/Ab and HIV RNA
- Offer 4 weeks of PEP for recognized transmission risk
  - Start ASAP (within 72 hours; adjust regimen for possibility of drug resistance)
    - **Preferred: BIC**/TAF/FTC or **DTG** + (TAF or TDF)/(FTC or 3TC)
    - **Alternative: DRV/r or /c** + (TAF or TDF)/(FTC or 3TC)
  - F/u within 72 hours

CDC Kofman ICHE 2025:1-11 (occupational); CDC Tanner MMWR 2025;74:1-56 (non-occupational)

## Question #7

23-year-old man without HIV with a partner with HIV on ART with HIV RNA suppressed below detection asks you about starting pre-exposure prophylaxis (PrEP).

### Which of these PrEP regimens do you recommend?

A. Nothing – PrEP is not indicated
B. PrEP with tenofovir (TDF)/emtricitabine daily
C. PrEP with tenofovir (TAF)/emtricitabine "on demand"
D. PrEP with bictegravir/tenofovir (TAF)/emtricitabine daily

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D. PrEP with bictegravir/tenofovir (TAF)/emtricitabine daily

## CDC Guidance for PrEP:

- Inform all sexually active adults and adolescents about PrEP
- Before starting:
  - Exclude acute and chronic HIV infection (by HIV testing and symptoms)
  - Assess baseline CrCl, screen for STIs and HBV infection
- Prescribe PrEP for people with ongoing risk from sex or injecting drugs:
  - Tenofovir (TDF)/FTC for ♂ and ♀ (daily; some guidelines recommend "on-demand")
  - Tenofovir (TAF)/emtricitabine for ♂ ONLY (daily)
  - IM cabotegravir for ♂ and ♀ (every 2 months)
  - SC lenacapavir every 6 months for ♂ and ♀ (as of 6/25)
  - Provide risk reduction, adherence counseling, condoms
- On PrEP:
  - HIV testing every 3-4 months, monitor CrCl every 6 (age >50 or CrCl <90) or 12 months
  - Risk reduction, condoms, STI assessments/treatment + evaluate need to continue PrEP

SEE ENLARGED SLIDE FOLLOWING ENTIRE PRESENTATION

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

## Conclusions

- Acute (and recent) HIV – ART recommended
- Acute OI – ART within 2 weeks of diagnosis reduces mortality; caution with CNS opportunistic infections
- TB – Early ART prolongs survival; caution with rifamycin drug interactions
- Hepatitis B and C co-infection – Consider antiviral activity, drug-drug interactions, drug toxicities
- Pregnancy – Treat and reduce MTCT; modify ART recommendations based on safety and experience
- Post-exposure prophylaxis (PEP) – ART within 72 hours; give for 4 weeks; adjust for known drug resistance
- Pre-exposure prophylaxis (PrEP) – TDF/FTC (♂+♀), TAF/FTC (♂+ possibly ♀), IM CAB (♂+♀), SC lenacapavir (♂+♀)

## Acknowledgments


- **Cornell HIV Clinical Trials Unit (CCTU)**
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- HIV Prevention Trials Network
- Division of AIDS/NIAID/NIH
- The patient volunteers!


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