AETC AIDS Education & Training Center Program Mountain West

IAS-USA Guidelines: Prevention of HIV Infection 2020 Update

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Disclosures

- I attended Gilead's 2018 U.S. Latinx/Hispanic PrEP Advisory Program.
- Only FTC/TDF and FTC/TAF are approved by the U.S. FDA and only for use as daily PrEP in some but not all populations. This talk will include discussion of other options for PrEP.

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Disclaimer

- This talk describes the new IAS recommendations
- This talk does not include CDC recommendations or specify where the IAS recommendations differ from the CDC's
- The most recent CDC recommendations can be found at

  https://www.cdc.gov/hiv/guidelines/persons.html

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Table 1. Strength of Recommendation and Quality of Evidence Rating Scale[a]

Evidence rating	Definition
Strength of recommendation	
A	Strong panel support
B	Moderate panel support
C	Limited or weak panel support
Quality of evidence	
Ia	Evidence from ≥1 RCTs published in the peer-reviewed literature
Ib	Evidence from ≥1 RCTs presented in abstract form at peer-reviewed scientific meetings
IIa	Evidence from cohort or case-control studies published in the peer-reviewed literature
IIb	Evidence from cohort or case-control studies presented in abstract form at peer-reviewed scientific meetings
III	Based on the panel's analysis of the available evidence

Who should be prescribed PrEP

- PrEP should be discussed with all sexually active adults and adolescents and individuals who inject drugs (AIII).
- FTC/TDF is recommended for at-risk individuals who are pregnant or breastfeeding (AIIa).

What to prescribe as PrEP

- FTC/TDF is the recommended oral PrEP regimen for all populations at risk (AIa).
- Daily FTC/TAF is recommended for the subset of MSM with eCrCl 30-60 mL/min, who have history of osteopenia or osteoporosis, or those at high risk for these (BIa).
- TDF or TAF alone are not recommended (BIIa).
- Long acting CAB (pending FDA approval) is recommended for MSM and transgender women (AIa/b*).
  - An oral lead in period is optional (BIb)

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HPTN 084: "NIH study finds long-acting injectable drug prevents HIV acquisition in cisgender women"

- 3223 CGW, 18-45 yo, 20 sites in Sub-Saharan Africa
- Planned interim review on 11/5/2020

	Infections	Incidence (95% CI)
CAB	4	0.21% (0.6% to 0.54%)
FTC/TDF	34	1.79% (1.24%-2.51%)

HR = 0.11% (0.04-0.32) = superiority of CAB

- Of subset w 362 participants, only 64% had detectable TFV
- No safety concerns, pain/tenderness at injection site
- Blinded phase stopped

https://www.hptn.org/research/studies/hptn084

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How to prescribe PrEP

- For MSM, 2 pills of FTC/TDF on day 1 reduces time to maximal protection (24 hours), and FTC/TDF should be continued for 2 days after the last at-risk exposure (AIIa).
- For others, maximum protection is likely achieved in ~7 days after initiation, and FTC/TDF should be continued for 7 days after the last at-risk exposure (BIIa).
- 2-1-1 dosing is recommended only for MSM (AIa). There are no data supporting 2-1-1 dosing using FTC/TAF.

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How to prescribe PrEP (2)

- PrEP should be started as soon as feasible (BIII).
- If there is a neg Ag-Ab test w/i 7d and no AHI symptoms, PrEP could be initiated same day (BIIa).
- For oral PrEP, the initial prescription should be 30d with 90d thereafter (BIII).

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Baseline testing

- Ag/Ab testing (AIa)
  - Point-of-care HIV tests can be used and PrEP started, but a lab-based Ag/Ab test should also be performed.
- If clinical suspicion of AHI, order HIV RNA testing (AIa) and withhold PrEP. If suspicion extremely high, start ART (AIII)

- Serum creatinine (AIIa)
- HAV Ab for MSM/PWID if not known to be immune (AIIa)
- HBV sAg (AIIa)
- HCV Ab (AIIa) or HCV RNA if not recently known
- Genital and nongenital GC/CT (AIIa)
- Syphilis (AIIa)

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Monitoring

- HIV testing
  - 1 month (AIII/BIII)
  - Quarterly (AIa)
- eCrCl
  - At month 3, then annually (AIIa)
  - Q3-6 months for pts with/risk for kidney injury (BIIa)
    - >50 years, eCrCl<90 at baseline, comorbidities (DM, HTN)
- STD testing: Quarterly (AIIa)
- Pregnancy testing: Quarterly (AIIa)

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Monitoring (2)

- Patients who have stable visits with on time refills can substitute telemedicine for in-person visits, assuming laboratory testing results will be available for the visit.

- Extending refills to 6 months is reasonable and should be individualized if visits/laboratory assessments are not available (AIII).

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Persistence and retention

- Patients who discontinue PrEP because they no longer consider themselves at risk should have those assumptions reviewed and discussed (BIII).
- Patients who discontinue due to economic or structural barriers should have individualized assistance.
- Individuals at high risk who discontinue PrEP have high rates of HIV acquisition (BI).
- Patients who have stopped daily PrEP for ≥7 days should be retested for PrEP using a lab-based Ag/Ab test prior to restarting PrEP (BIII).

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Adherence support

- Individuals with adherence challenges should be provided individualized counseling.
- Those who are willing should be considered for alarms, pill boxes, electronic reminders, or SMS services (BIIa).

PEP and PrEP

- If a PrEP candidate reports a high risk, condomless exposure in <72 hours, a 3 agent course of PEP for 1 month is recommended, followed by seamless 2 agent PrEP (AIII).
- In setting of non-adherence, a 28 day course of PEP is recommended (CIII).
- Nonadherence is defined as <4 dose/wk average for MSM/TGW and <6 doses in last week for CGW, PWID, heterosexual men (CIIa).

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Transgender women

- Measures to support maximal adherence to daily dosing is recommended (BIII).

PrEP failure

- Most PrEP “failure” is due to poor medication adherence, and, therefore most infection is with wild-type HIV.
- Even if M184V or K65R/M184V variants are present, DTG-based, BIC-based, DRV-based regimens boosted with RTV or cobicistat in combination with TDF/TAF plus FTC/3TC would still be expected to achieve high rates of viral suppression (AIIb).
- The treatment regimen should be adjusted based on the genotype results prior to ART initiation.

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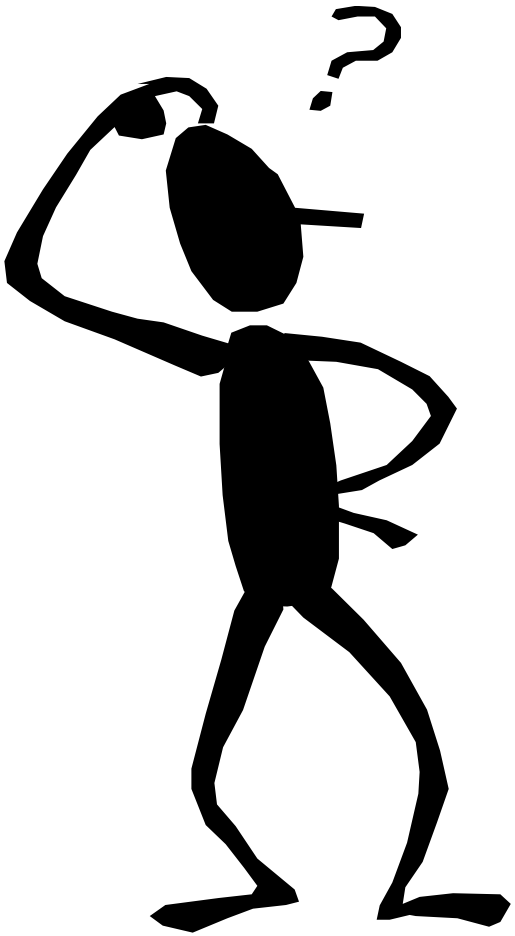
Questions?



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