

HIV Prevention and STI Screening and Prevention

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Financial Relationships With Ineligible Companies (Formerly Described as Commercial Interests by the ACCME) Within the Last 2 Years

Dr Landovitz has served on the scientific advisory board for Gilead Sciences, Inc. and Merck Inc (Updated 12/14/22)

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Learning Objectives

After attending this presentation, learners will be able to:

- Describe the recommended options for PrEP agent choice by risk-behavior category
- Describe the recommendations for which IAS-USA Guidelines diverge from CDC, FDA, and/or DHHS guidelines/recommendations
- List the resources for expert clinical assistance for complex PEP or PrEP cases

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Angeline

- Angeline is a 29 yo transfeminine patient who presents to discuss HIV prevention options
- 9 months ago, she was hospitalized for treatment of polytrauma resulting from an assault by a former partner
 - The assault occurred in the setting of the partner finding her oral PrEP medication in her purse
- She has a past medical history notable for poorly controlled hypertension, DM2, CKD with a baseline creatinine clearance of 65 mL/min, and dyslipidemia
 - She is not currently using GAHT
 - She is considering a number of gender-affirming surgical procedures, including gluteal fat transfers

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ARS 1: What are her PrEP options?

- A. Daily oral TDF/FTC is her only option
- B. Daily oral TDF/FTC or CAB-LA are her options
- C. Daily oral TDF/FTC or TAF/FTC, or CAB-LA are her options
- D. Daily oral or on-demand (2-1-1) TDF/FTC, daily oral TAF/FTC or CAB-LA are all options
- E. Daily oral or on-demand (2-1-1) TDF/FTC, daily oral TAF/FTC, CAB-LA and the DPV ring are all options

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What's New in 2022? PrEP Options by Population

PrEP Option	Daily oral		On-demand oral		Daily and TDF/FTC (understanding)	
	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Transgender men						
On-demand oral TDF/FTC	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral TDF/FTC	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral TAF/FTC	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral CAB-LA	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral DPV ring	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Transgender women						
On-demand oral TDF/FTC	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral TDF/FTC	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral TAF/FTC	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral CAB-LA	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)
Daily oral DPV ring	Yes (A)	No (B)	Yes (C)	No (D)	Yes (E)	No (F)

On-demand oral TDF/FTC now recommended for cisgender and TGM* and TGW**
*Rear-hole sex
**Caution with GAHT, particularly at inception

Daily oral TAF/FTC Recommended for transwomen*
*Excluding neovaginal sex

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As you review her PrEP options....

- Angeline discloses that recently she has met a new partner
- They have a sexual relationship but also share injection drug needles. She is not sure about the sterility of those needles before use
 - While she does not intend to have other sexual partners while seeing her current partner, she is unsure about whether he is having additional partners
 - She does not feel like she can ask him his HIV status, and is not sure she would believe his answer
- She asks if any of that information changes your thoughts on what is best for her for PrEP

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ARS 2: Now what are her PrEP options?

- Daily oral TDF/FTC is her only option
- Daily oral TDF/FTC or CAB-LA are her options
- Daily oral TDF/FTC or TAF/FTC, or CAB-LA are her options
- Daily oral or on-demand (2-1-1) TDF/FTC, daily oral TAF/FTC or CAB-LA are all options
- Daily oral TDF (alone) is her only option

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What's New in 2022? PrEP Options by Population

PrEP Option	MSM/MSM+PrEP*		Daily and TDF/FTC (on-demand only)	Injectable cabotegravir (on-demand only)
	MSM	MSM+PrEP		
Injectable cabotegravir	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)
Daily oral TDF/FTC	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)
Daily oral TAF/FTC	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)
Daily oral CAB-LA	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)
On-demand (2-1-1) TDF/FTC	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)
On-demand (2-1-1) TAF/FTC	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)
On-demand (2-1-1) CAB-LA	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)
On-demand (2-1-1) TDF (alone)	Yes (2022)	Yes (2022)	Yes (2022)	Yes (2022)

If PWID are sexually active, they should be considered with their risk group

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What tests should be used to screen for HIV?

- In speaking with colleagues, you have heard that the CDC's updated PrEP guidelines recommend both HIV Antigen/Antibody and HIV RNA testing before initiating:
 - Oral TXF/XTC based PrEP
 - CAB-LA PrEP
- AND
- Both HIV Antigen/Antibody and HIV RNA testing before each PrEP dispensation
 - At 3-monthly oral PrEP dispensations
 - At the time of every CAB-LA injection (and when oral CAB is dispensed if used)

Agree to Disagree

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What's New in 2022?

Laboratory Testing at Initiation

For oral TXF-based PrEP, When using oral-based PrEP regimens, RNA testing is **ONLY** recommended if high-risk exposure in last 4 weeks or signs and symptoms of HIV infection

When using cabotegravir, HIV RNA testing is recommended in all HIV testing algorithms
If HIV RNA not available, use the most sensitive assay that is implementable and feasible

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What tests should be used to screen for HIV?

- Angeline decides to initiate CAB-LA
- A rapid phlebotomized blood rapid test in the office is negative and she has no signs or symptoms consistent with acute HIV
- She decides to skip the oral lead-in and go "direct to inject"
- She is on-time for her 2nd injection 4 weeks later, at which time Ag/Ab and HIV RNA testing is again negative
- She then is out of touch (phone is disconnected) and misses her 3rd injection
 - She calls the clinic 15 weeks after her 2nd injection (7 weeks late), and is able to come in that day

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ARS 3: In addition to strategizing about barriers to on-time injections....

- A. You tell her CAB-LA is clearly not working for her
- B. You proceed with injection, having sent HIV Ag/Ab and RNA testing (which are pending), and plan to "reload her" 4 weeks later
- C. You proceed with injection, having sent HIV Ag/Ab and RNA testing (which are pending), and plan to continue with the next injection 8 weeks later
- D. You send HIV Ag/Ab and RNA testing, but you hold the injection until the results have returned, holding all PrEP
- E. You send HIV Ag/Ab and RNA testing, but you hold the injection until the results have returned, "bridging" with oral PrEP in the meantime

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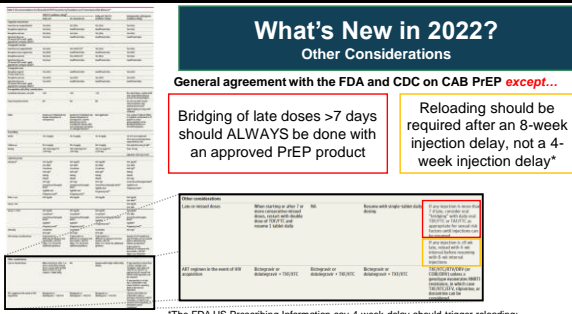
What's New in 2022?

Other Considerations

General agreement with the FDA and CDC on CAB PrEP *except...*

Bridging of late doses >7 days should ALWAYS be done with an approved PrEP product

Reloading should be required after an 8-week injection delay, not a 4-week injection delay*



*The FDA US Prescribing Information say 4-week delay should trigger reloading; HPTN 083 and 084 used an 8-week delay to trigger reloading.

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The HIV testing you sent has now resulted

- The HIV Ag/Ab test is negative
- The HIV RNA returns DETECTED 1200 c/mL
- She is generally asymptomatic but had been diagnosed with SARS-CoV-2 since you last saw her, and although recovered, has some lingering protean symptoms
- She last had sexual contact with her partner ~3 weeks ago

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ARS 4: Your interpretation of these results is:

- A. It's a false positive, 100%
- B. It's probably a false positive, but what if it isn't?
- C. It could really be the first manifestation of CAB PrEP breakthrough, but let's test again, holding any further CAB PrEP
- D. This is 100% clearly a breakthrough infection, start fully suppressive ART immediately
- E. I'd like to phone a friend

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Sorry, wrong number

1-800-232-4636 is the general CDC public facing number

The correct number to call for discordant and difficult-to-interpret test results is the NCCC number, **(855) 448-7737**

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Question-and-Answer Session

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