

What will PrEP Implementation Look Like Post-COVID?

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Disclosures



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.

Case:

- 25yo MSM who has been on PrEP for three years. Prior to the COVID-19 pandemic, he came in for appointments every three months. During the COVID-19 pandemic, you have seen him for one in-person visit. His last HIV/STI testing and eCrCl were 6 months ago.
- PMH: h/o secondary syphilis in 2018
- Social and Family history: In open relationship with HIV-negative main partner and 20 condomless anal sex partners in the last year. No substance use.
- He asks you “Do I really have to come in to the clinic to see you every three months?”

What is your recommendation to him for in-person visits and HIV/STI/eCrCI testing?

- A. He should come to the clinic every 3 months for visits and testing.
- B. He can come into the clinic only every 6 months for visits and testing.
- C. He needs to come to the clinic at least once a year, but he should get his testing done in the outpatient laboratory every 3 months.
- D. He should come to the clinic once a year, but he needs to buy home test kits every 3 months and call to discuss the results.

Summary of Recommended Laboratory Evaluation Baseline and Routine Monitoring for Patients taking PrEP

Recommended Laboratory Testing and Frequency for Patients Taking PrEP				
Laboratory test	Baseline	Every 3 months	At least every 6 months	Notes
HIV screening assay	✓	✓		Consider need for HIV RNA PCR
HBV antibody panel and HCV antibody	✓			Offer HBV vaccination if not immune
Serum creatinine	✓		✓	Avoid PrEP if CrCl <60 mL/min
General STI screen	✓	✓	✓	Include oral/rectal screen for MSM if risk
Pregnancy test for women	✓	✓		

Barriers to PrEP Engagement During the COVID-19 Pandemic



Patients wish to avoid in-person visits



Staff unease with working in office and seeing patients



Need for more space in clinic for social distancing



Patients may not be having as much sex



Mandated shutdowns and travel restrictions



Potential lack or shortage of personal protective equipment

Adaptations in PrEP implementation due to the COVID-19 pandemic

- Changes in how visits were conducted
 - Telemedicine
 - Pharmacy only consultations
 - Reduced frequency of visits
- Changes in laboratory monitoring
 - Reduced frequency of testing
 - Laboratory only visits
 - Home collection and home self-testing
- Changes in PrEP dosing and prescribing
 - Provision of 90 day supply to reduce in-person pharmacy contact
 - Courier delivery or shipment of meds
 - 2-1-1 or event-based dosing

Potential advantages and disadvantages of PrEP by telemedicine

↓ Risk for COVID transmission

? Legal issues

↓ Patient time and costs

? Insurance coverage

↓ Provider time and costs

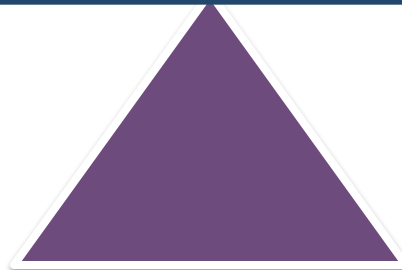
? Technology availability

↑ Access

? Digital literacy

? ↓ Stigma

? Laboratory evaluations



“Dear Colleague” Guidance PrEP During COVID-19 (5/15/2020)

“Quarterly testing should be continued for patient safety... Lab-only visits... are preferred. When these are not available or feasible, CDC recommends considering two additional options.”

- A home specimen collection kit ... which is covered by most insurance plans and can be ordered by clinicians. Some laboratories (such as Molecular Testing Labs) have validated protocols...
- An oral swab-based test. Although this type of self-test is usually not recommended for PrEP patients due to its lower sensitivity in detecting recent infection, clinicians should consider use of these tests when other options are not available.

CDC guidelines for HIV testing in PrEP (2017)

- Clinicians should document a negative antibody test result within the week before initiating (or reinitiating) PrEP medications, ideally with an antigen/antibody test conducted by a laboratory.
- The required HIV testing can be accomplished by
 - (1) drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test or and antibody-only test or
 - (2) performing a rapid, point-of-care, FDA-approved, fingerstick blood test.
- Rapid tests that use oral fluid should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests .
- Clinicians should not accept patient-reported test results or documented anonymous test results.

Characteristics of HIV tests and home testing options

	Sample	Time to result	“Window period” (Time from exposure to detection of infection)
Nucleic acid tests (NAT)	Venipuncture (Fingerstick tests in development)	Hours to days (point-of-care tests in development)	As early as 10 days, up to 33 days
Antigen/antibody combo tests	Venipuncture	Hours to days	As early as 18 days, up to 45 days
Antigen/antibody combo tests	Fingerstick	20-30 minutes	As early as 18 days, up to 90 days
Home collection	Fingerstick	Days to weeks	As early as 18 days, up to 90 days
Home self-testing	Oral fluid	20-40 minutes	90 days (package insert)

Is self-collection adequate?

Dried blood spots

A few examples

- eSTAMP: 27% (6/22) of DBS cards were of “bad” quality
- Hirshfield : 554 MSM enrolled in DBS feasibility study of home HIV VL monitoring
 - 439 attempted to collect blood
 - 418 mailed a DBS specimen
 - 337 (337/439 = 77%) had an adequate DBS
- Kromdijk: Netherlands feasibility study of home TDM
 - 50 subjects collected 200 DBS
 - 87.5% suitable for analysis
 - 68% of participants reported success with first DBS attempt

eSTAMP: MacGowan et al; AIDS Behav, 2018 Jan 22(1): 117-26.

Hirshfield et al; JMIR Public Health Surveillance 2018 Nov 1; 4(4) e10847

Kromdijk et a; Antivir Ther 2013; 18(6) 821-5

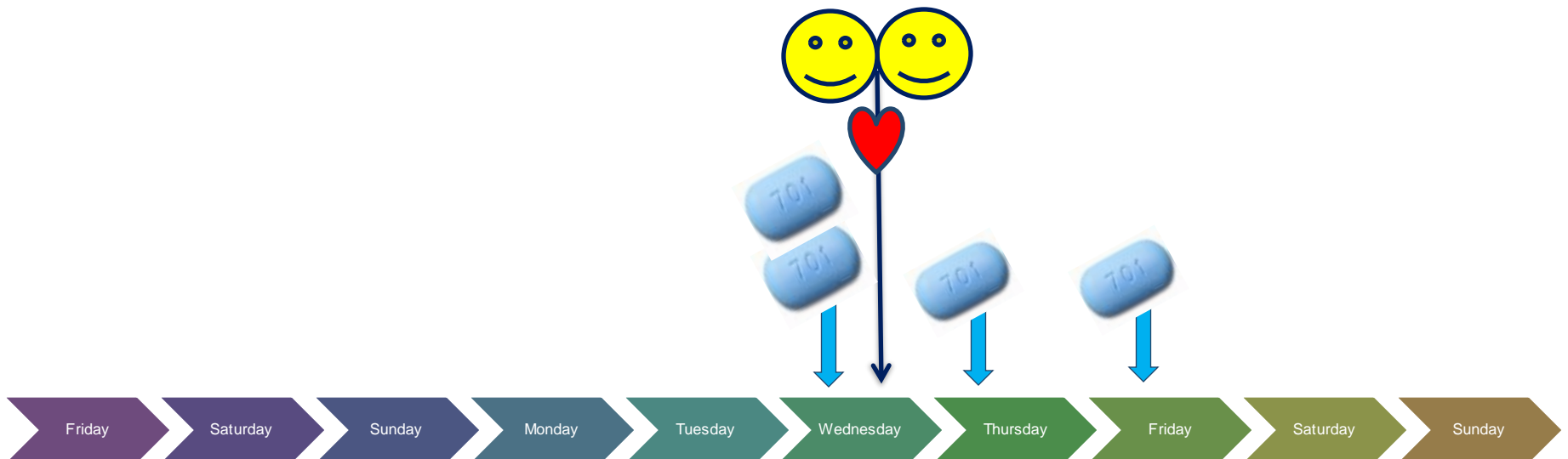


2-1-1 or “event-based” dosing

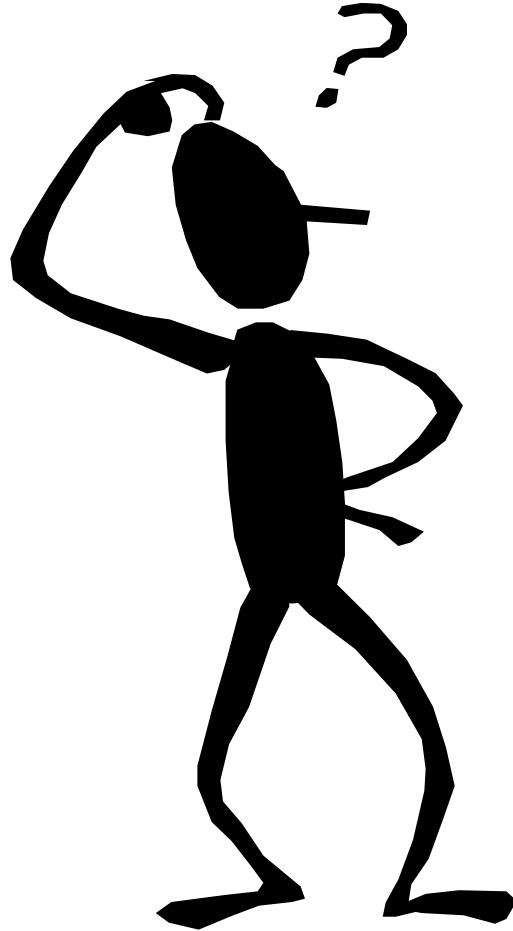
Intermittent dosing strategy

- ✓ 2 tablets 2-24 hours before sex
- ✓ 1 tablet 24 hours later
- ✓ 1 tablet 48 hours after first intake

Recommended by WHO and IAS-USA but not (yet) by CDC/HHS



Questions?



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