

PrEP for the PCP

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Learning Objectives

→ OUTLINE

National PrEP prescribing disparities

→ DISCUSS

PrEP as a risk reduction tool

→ IDENTIFY

Indications for PrEP

→ RECOGNIZE

Available formulations of PrEP

→ DISCUSS

Testing for patients on PrEP

→ UNDERSTAND

2-1-1 dosing

→ DISCUSS

QI at MMC & educational outcomes among residents

Disclosures



Why?

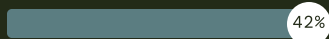


BLACK PEOPLE

PERCENT OF PREP USERS (2021)



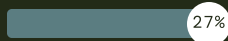
PERCENT OF NEW HIV DIAGNOSES (2020)

HISPANIC /
LATINX
PEOPLE

PERCENT OF PREP USERS (2021)



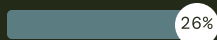
PERCENT OF NEW HIV DIAGNOSES (2020)

WHITE
PEOPLE

PERCENT OF PREP USERS (2021)



PERCENT OF NEW HIV DIAGNOSES (2020)

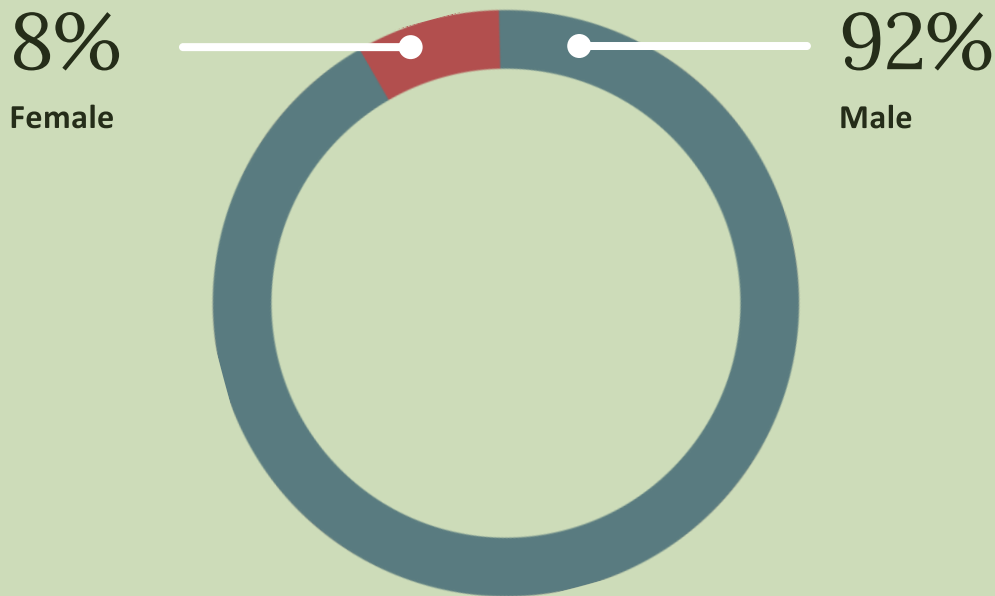


0 20 40 60 80 100

Black people represented only **14% of PrEP users (2021)** but accounted for **42% of new HIV diagnoses (2020)**, indicating a **significant unmet need for PrEP**.

There were **11 male PrEP users** for every new HIV diagnosis among men.

There were **4 female PrEP users** for every new HIV diagnosis among women.

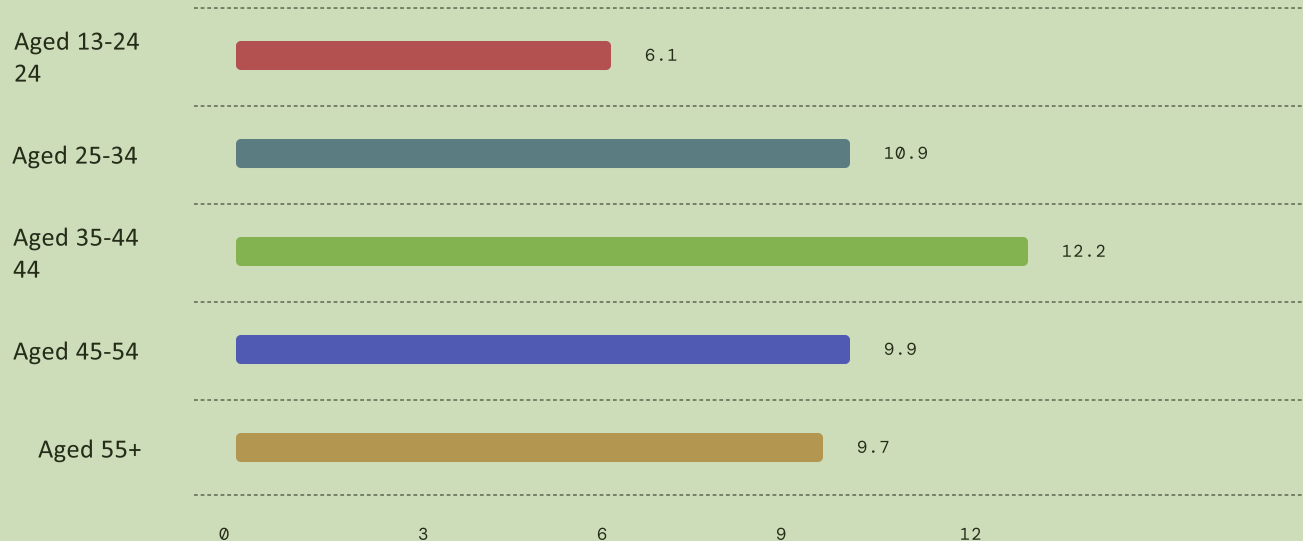


PrEP Users by Sex, 2021

In 2021, **92% of all PrEP users were male** and only **8% were female**, despite the fact that women represented 18% of new HIV diagnoses in 2020.

In 2021, **teenagers and young adults (aged 13-24 years)** had the the greatest unmet need for PrEP among all age groups, with a PnR of PnR of 6*. That means for every person in that age group diagnosed diagnosed with HIV, there were only 6 people using PrEP.

PrEP-to-Need Ratio by Age Group, 2021



*PREP-TO-NEED RATIO (PNR) IS THE RATIO OF THE NUMBER OF PREP USERS IN 2021 TO THE NUMBER OF PEOPLE NEWLY DIAGNOSED WITH HIV IN 2019. IT IS A MEASUREMENT FOR WHETHER PREP USE APPROPRIATELY REFLECTS THE NEED FOR HIV PREVENTION. A LOWER PNR INDICATED MORE UNMET NEED.

Why you should care

>99%

PrEP's effectiveness at preventing sexual transmission of HIV, when taken as prescribed

74%

PrEP's effectiveness at preventing transmission of HIV through IV drug use, when taken as prescribed

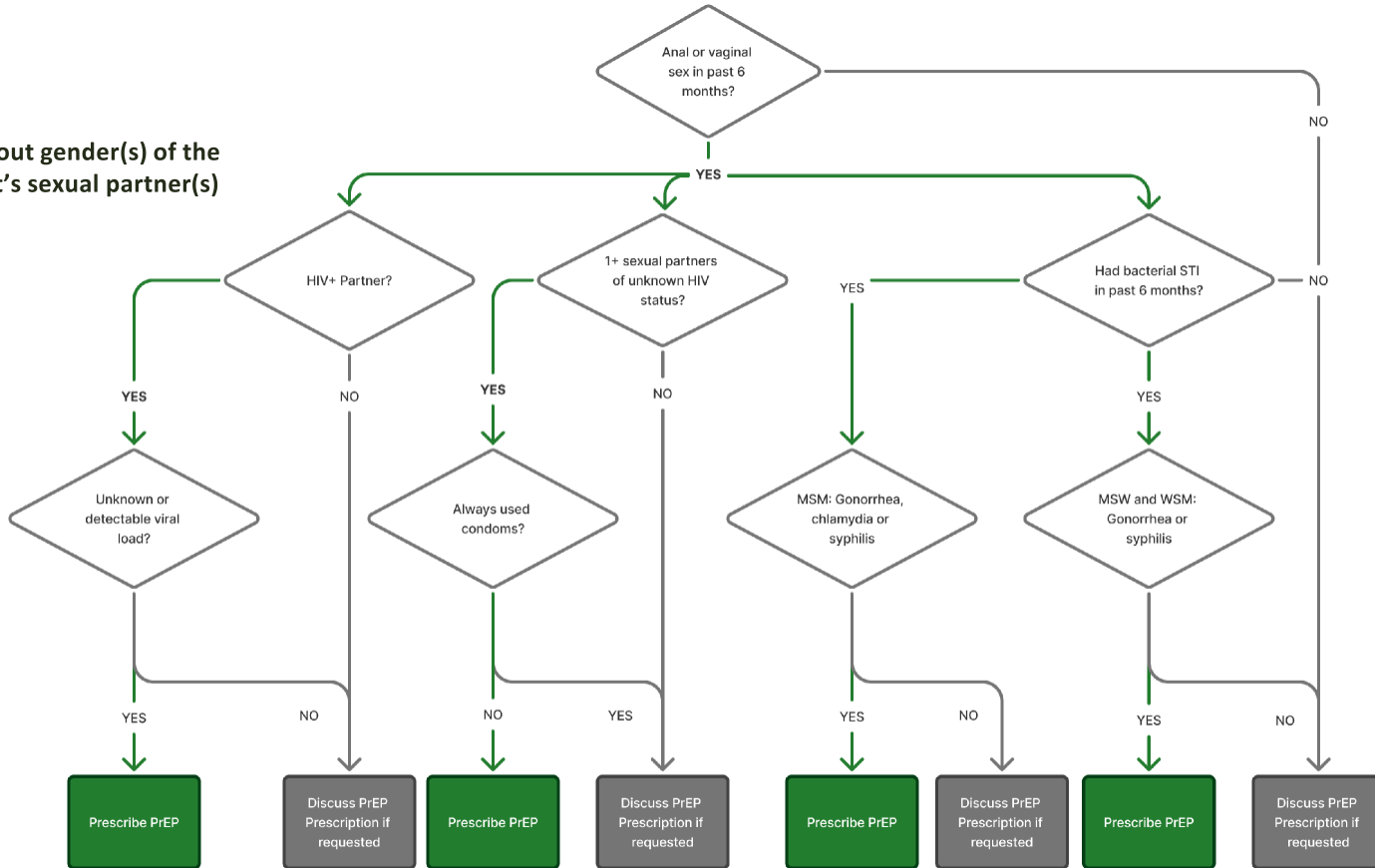
Who gets PrEP?

Short Answer – Anyone who wants it

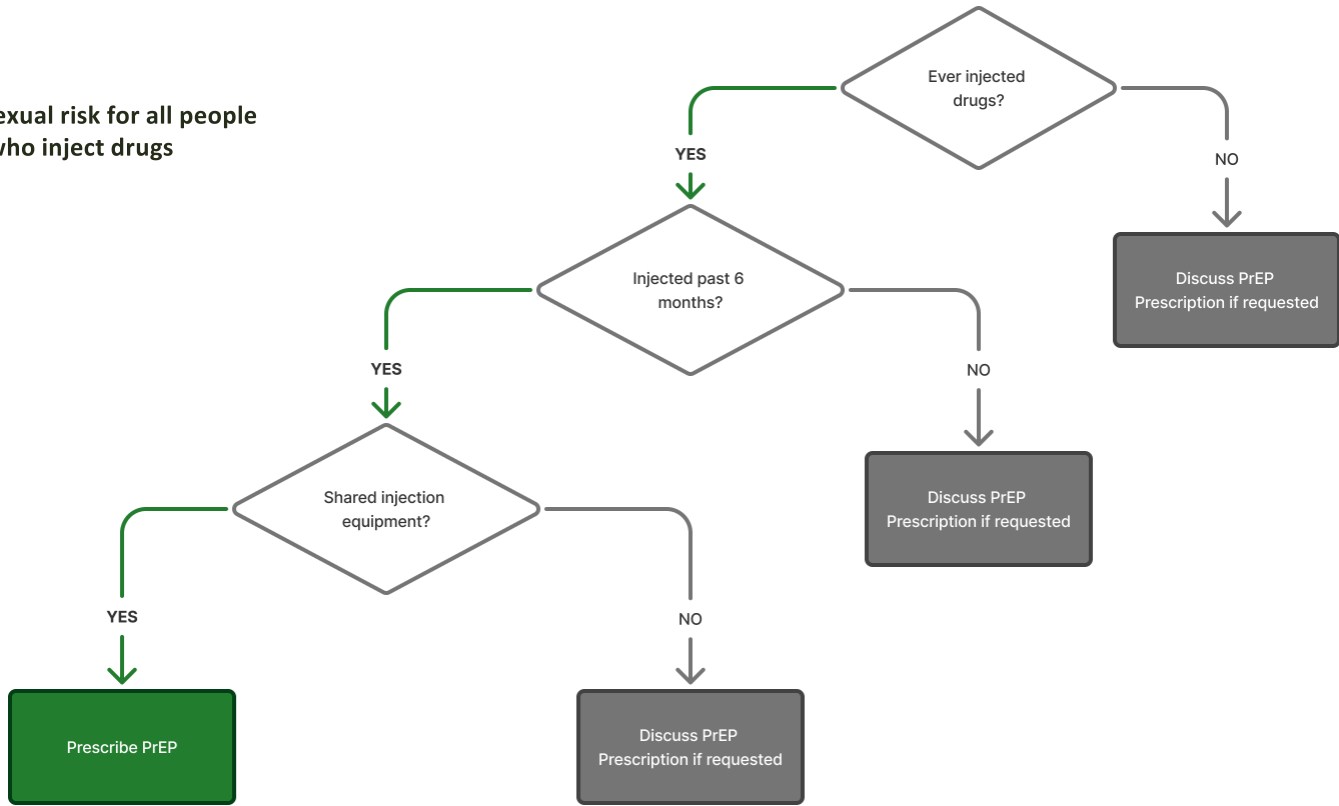
- Approved for individuals >35 kg (77 lbs)
- Must be HIV Negative



Ask about gender(s) of the patient's sexual partner(s)



Assess sexual risk for all people
people who inject drugs



What should I prescribe?

There are four FDA approved options for PrEP

Two options in a single daily oral tablet



Emtricitabine (F) + TDF

Emtricitabine (F) 200mg with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – Truvada or generic).



Emtricitabine (F) + TAF

Emtricitabine (F) 200 mg with tenofovir alafenamide (TAF) 25 mg (F/TAG – Descovy).

Bi-monthly injection option



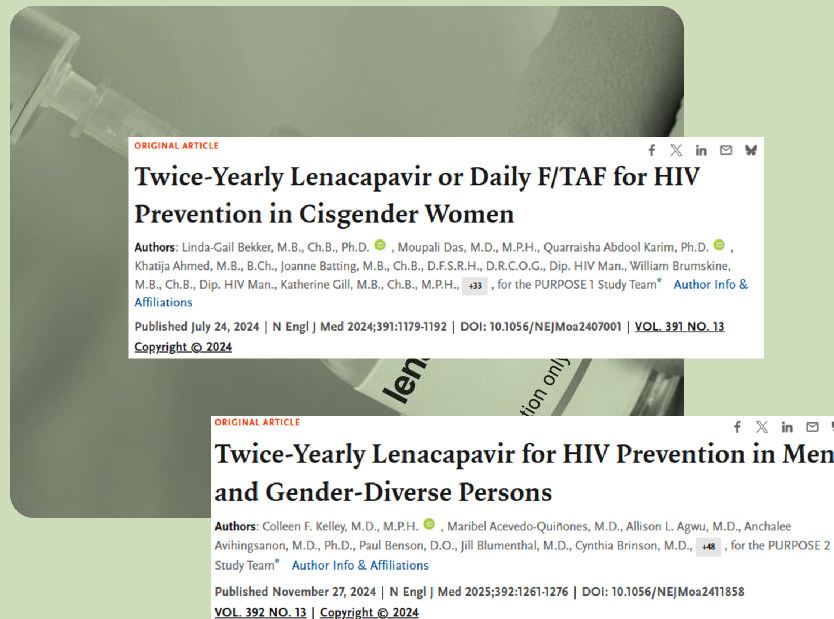
Cabotegravir (CAB)

600 mg injection (Apretude) for PrEP. Initial dose followed by a second dose after 1 month, then injections every 2 months.

Bi-annual injection option

Lenacapavir

Lenacapavir 927mg injection (brand name Yeztugo). Lenacapavir is given as a once once every 6 months injection. An oral loading dose of Lenacapavir PO 600 mg is administered on the day of injection and the day after.





Approved indications by medication

Approved medications for HIV prevention in adults and adolescents weighing at least 77 lb (35 kg) include:

- Daily oral PrEP with F/TDF for all individuals at risk of HIV through sex or injection drug use.
- Daily oral PrEP with F/TAF for preventing HIV transmission through sex, except for those at risk via receptive vaginal sex.
- Injectable PrEP with cabotegravir and lenacapavir for preventing sexual HIV transmission in all individuals, with consideration for those at risk from injection drug use.

Time to protection

7 days

F/TDF drug levels peak in rectal tissue and blood after daily dosing

- The data on the time to protection with cabotegravir is currently insufficient. However, it is generally believed to be achieved within 7 days post days post initial injection.
- Limited information is available on the protection timeline for lenacapavir. Nonetheless, it appears to reach adequate serum levels after 2 days when administered with the initial PO loading dose.

20 days

F/TDF drug levels peak in cervicovaginal tissue

Known side effects

Oral PrEP

- May lead to nausea, diarrhea, or headache when starting the medication, typically mild and resolves within 1 month. It can also result in reversible renal dysfunction, especially with TDF.
- There is a slight (1%) decrease in bone mineral density over a year, with no increased fracture risk (mainly a concern for TDF).

Injection PrEP (cabotegravir, lenacapavir)

- May cause injection site reactions.

Oral PrEP (Truvada*, Descovy)



Diarrhea



Nausea



Headache



Renal Dysfunction*



↓ Bone Density*
Density*

Injection PrEP (cabotegravir, lenacapavir)



Pain, swelling, redness

Baseline Labs

HIV testing

Point-of-care HIV tests are acceptable to reduce barriers
barriers to prescribing.

HIV RNA

Testing is not routinely indicated unless there is concern
concern for acute infection.

STI testing

Tests for chlamydia, gonorrhea, syphilis, and hepatitis
hepatitis

It is important to test patients at ALL points of contact for gonorrhea and
chlamydia (ie oral, anal, vaginal swabs and/or urine PCR)

For oral PrEP

Additional Labs

Kidney function

- F/TDF is approved for administration in individuals with an estimated creatinine clearance (eCrCl) greater than 60 mL/min.
- F/TAF is approved for administration in individuals with an eCrCl of 30 mL/min or greater.

Hepatitis B testing

Lipid profile (F/TAF only)

	Monitoring labs & frequency	Harm reduction considerations	Discontinuation considerations
<p>F/TDF (Truvada) F/TAF (Descovy)</p>	<ul style="list-style-type: none"> • HIV Ab/Ag q3m (ideally within 7 within 7 days of new Rx) • CrCl q6-12m • STI testing q3-6m • HCV q6-12m 	<ul style="list-style-type: none"> • Reasonable to accept POC HIV HIV testing if venous draw is not is not possible before start • F/TDF comes as generic, F/TAF does not re: cost to patient • PrEP does not impact gender affirming hormone levels 	<p>For patients with HBV, should monitor AST/ALT after discontinuation of TDF or TAF for HBV HBV reactivation</p>

	Monitoring labs & frequency	Harm reduction considerations	Discontinuation considerations
Cabotegravir (Apretude)	<ul style="list-style-type: none"> HIV Ab/Ag q2m (ideally within 7 days of or of or at time of injection) STI testing q2-4m HCV q6-12m HIV RNA not routinely recommended 	<ul style="list-style-type: none"> Consider for people who inject drugs Reasonable to accept POC HIV testing if venous draw is not possible before start +/- 7 days timing for subsequent injections without recommending reloading with q1m injection x2 Cannot be used in patients with gluteal fillers PrEP does not impact gender affirming hormone levels 	Tail period: offer oral PrEP starting at 2 months after last injection if ongoing HIV exposure risk
Lenacapvir (Yeztugo)	<ul style="list-style-type: none"> HIV Ab/Ag q6m (ideally within 7 days of or of or at time of injection) STI testing q3-6m HCV q6-12m HIV RNA not routinely recommended 	<ul style="list-style-type: none"> Reasonable to accept POC HIV testing if testing if venous draw is not possible before start +/- 2 weeks timing for subsequent injections without recommending additional oral doses PrEP does not impact gender affirming hormone levels 	Tail period: offer oral PrEP starting at 6 months after last injection if ongoing HIV exposure risk

2-1-1 Dosing for Oral PrEP

When used correctly, studies indicate that this form of PrEP is approximately **85% effective** in preventing HIV transmission.



This dosing regimen may be suitable for individuals who engage in infrequent sexual activity and/or prefer not to take daily doses.

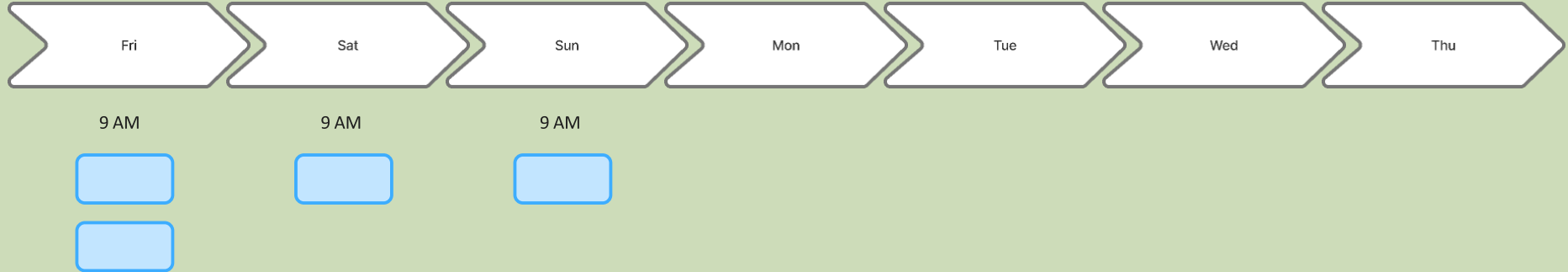
In general, if the patient can adhere to daily oral PrEP or injection PrEP, injection PrEP, it is the preferred option due to its higher efficacy compared to the 2-1-1 dosing. Nonetheless, the harm reduction provided by 2-1-1 dosing is still significantly better than no PrEP at all. It is important to have a personalized discussion with the patient to determine the most suitable approach.

Ex. 1: One sex episode.

2 PrEP tablets 2-24 hours before sex; 1 PrEP tablet 24 hours after and another 48 hours after the double dose.

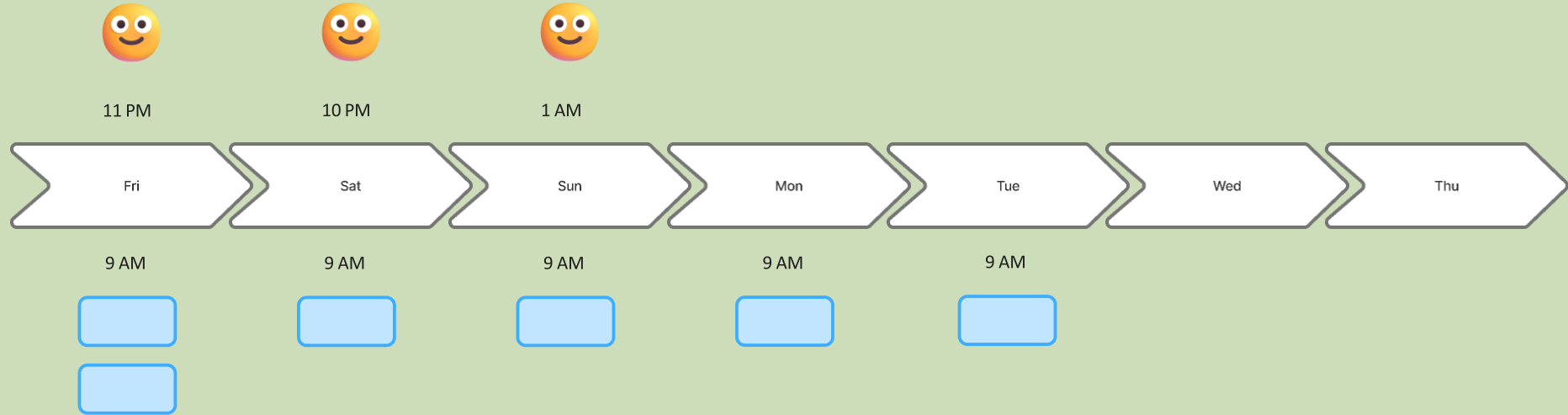


11 PM



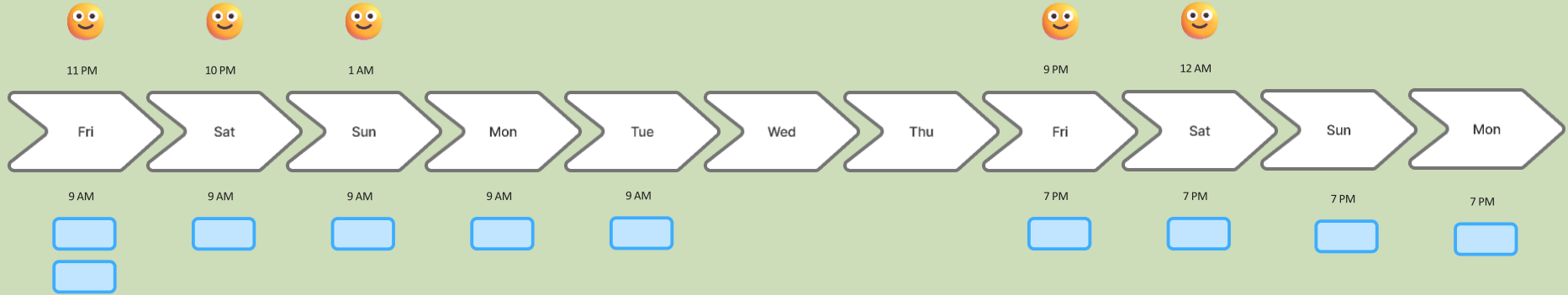
Ex. 2: Multiple sex episodes.

Continue 1 PrEP tablet every 24 hours until 2 days after last "sex day."



Ex. 3: Multiple sex episodes in one week.

If there are <7 days between end of one on-demand dosing period and beginning of another, take one single PrEP tablet to restart. If there are ≥ 7 since last PrEP dose, start again with 2 PrEP tablets.





QI at Maine Medical Center

- Issue: Residents lack comfort in indications, prescribing, or monitoring of PrEP.
- Interventions: Development of an educational module for use in the resident clinic and conducting a didactic session on PrEP.
- Results: Improvement in residents' reported knowledge and comfort levels in PrEP prescribing and monitoring.
- Continuous assessment to determine if this results in an increase in PrEP prescriptions.

Questions?