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STD/HIV
Prevention Training
Center

A Project of the Division of STD Prevention
Massachusetts Department of Public Health
Funded by the CDC



On-demand PrEP

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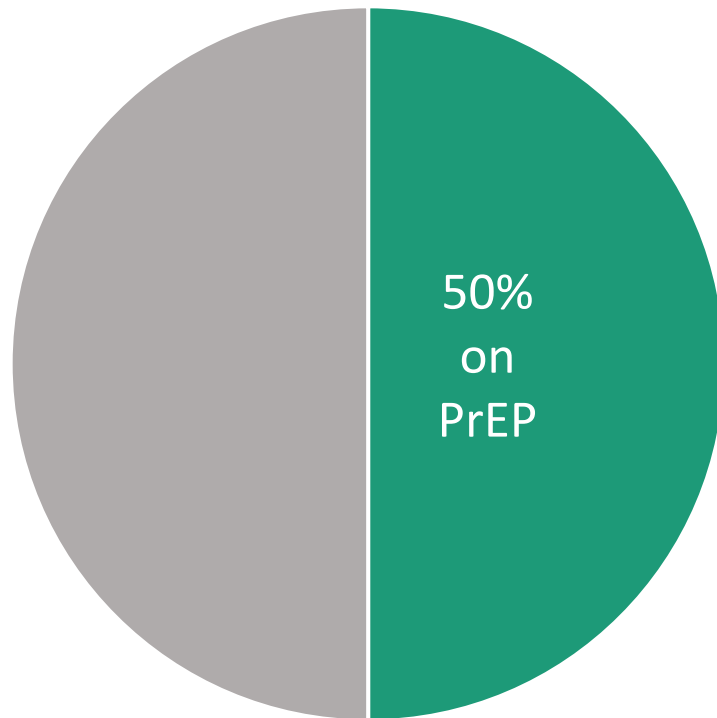
Lunch and Learn

July 12, 2022

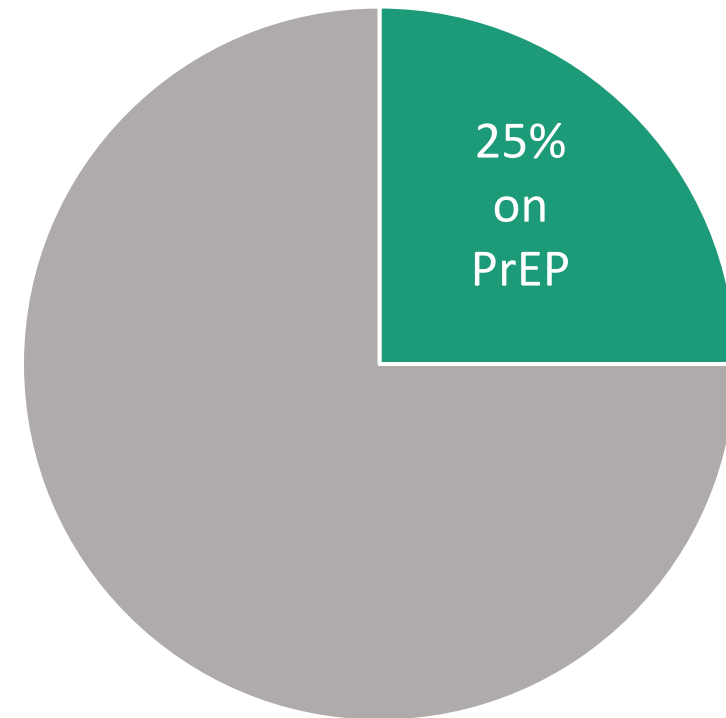
Current State of PrEP

Current prescribing for people who could benefit from PrEP

Ending the HIV Epidemic Goal for 2030



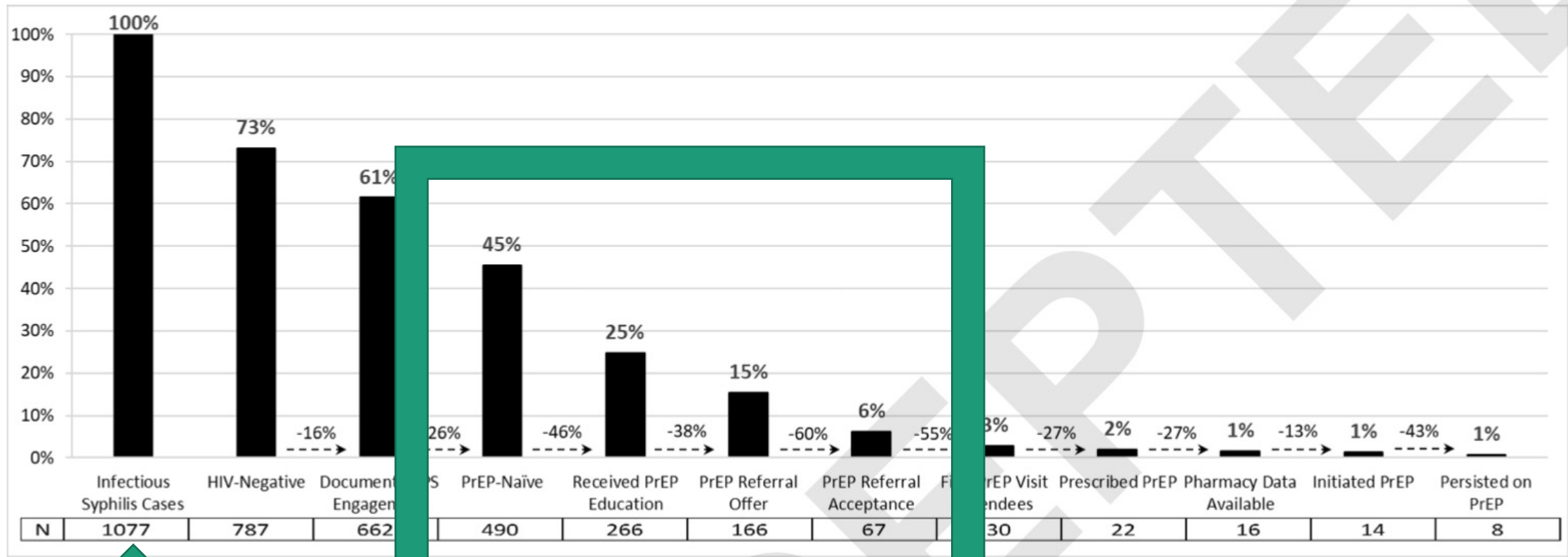
CDC estimates for 2020



PrEP Coverage for FL and MA

Area of residence	Persons prescribed PrEP ^a	Persons with PrEP indications ^b	PrEP coverage ^c
	No.	No.	%
		2020	
Florida			
Broward County	6,688	20,470	32.7
Duval County	745	8,970	8.3
Hillsborough County	1,519	12,910	11.8
Miami-Dade County	10,303	21,760	47.3
Orange County	3,876	15,310	25.3
Palm Beach County	3,023	9,170	33.0
Pinellas County	1,207	9,530	12.7
Massachusetts			
Suffolk County	2,806	6,520	43.0

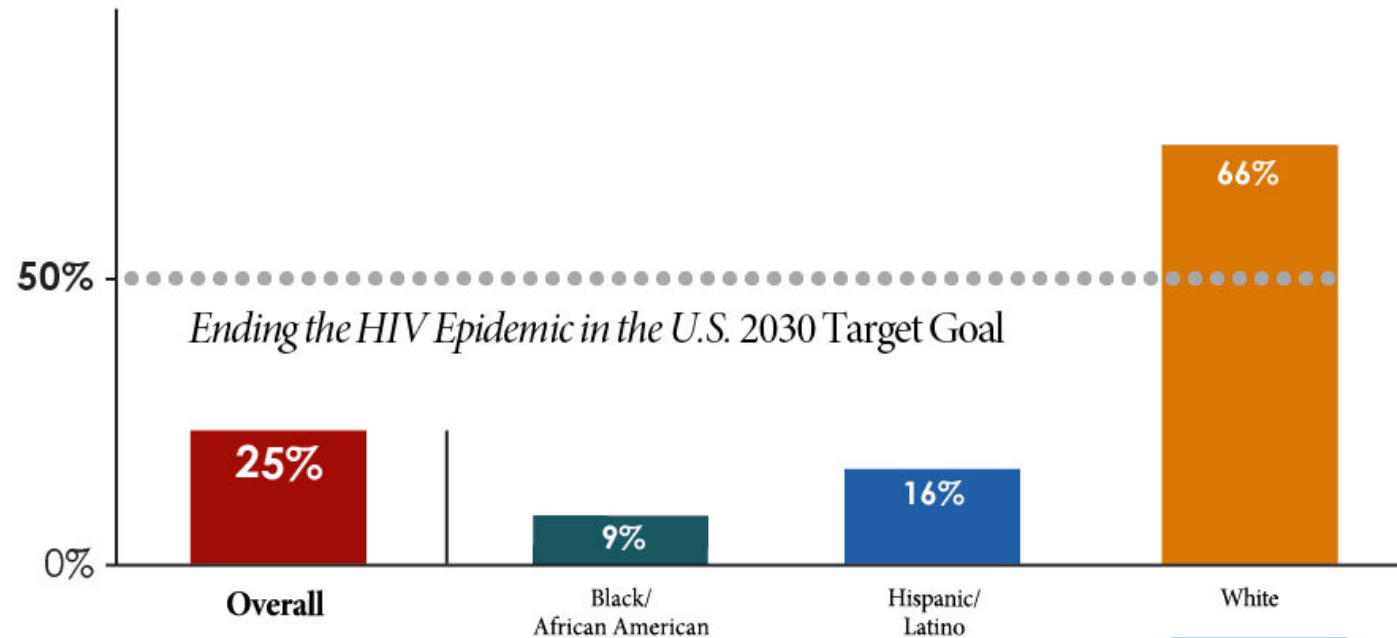
Provider impact on PrEP prescribing



Disparities in PrEP Prescribing

WHILE 25% OF PEOPLE ELIGIBLE FOR PREP WERE PRESCRIBED IT IN 2020, COVERAGE IS NOT EQUAL

PREP COVERAGE IN THE U.S. BY RACE/ETHNICITY, 2020



- Also disparities for:
- Women
 - Young people 18-24y

For more information, visit
[cdc.gov/nchhstp/newsroom](https://www.cdc.gov/nchhstp/newsroom)

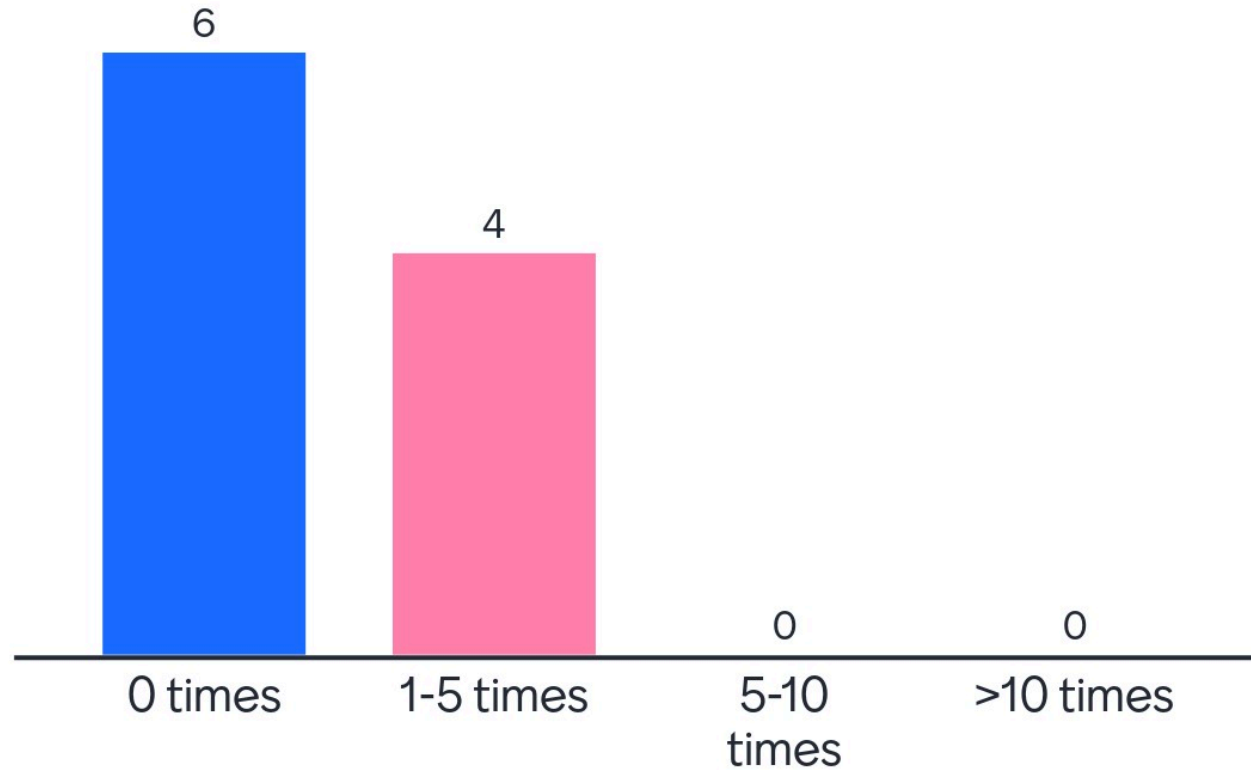


U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

On-demand PrEP

Taking PrEP only when at risk for getting HIV

In the past three months, how often have you prescribed on demand PrEP?



On Demand PrEP

“2-1-1”

“intermittent”

“non-daily”

“event-driven”

“off-label”

“vacation”

“episodic”

Included in CDC PrEP guidelines as an option for selected patients

HOW TO TAKE: PREP 2-1-1 FOR ANAL SEX

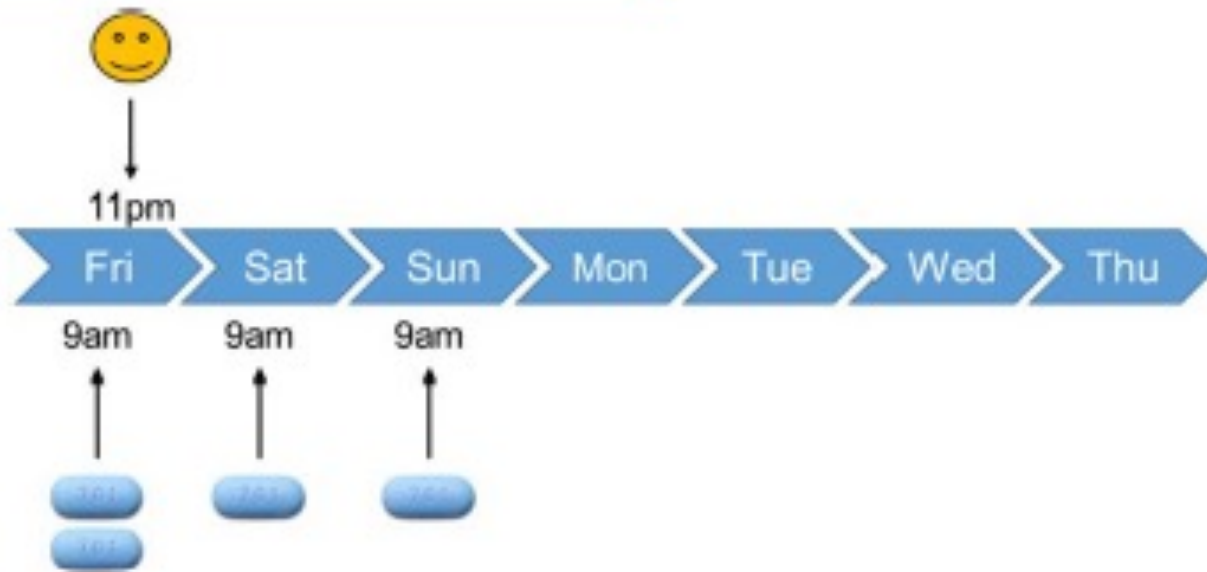
Before Sex

- Take 2 PrEP tablets at least 2 hours and not more than 24 hours before sex

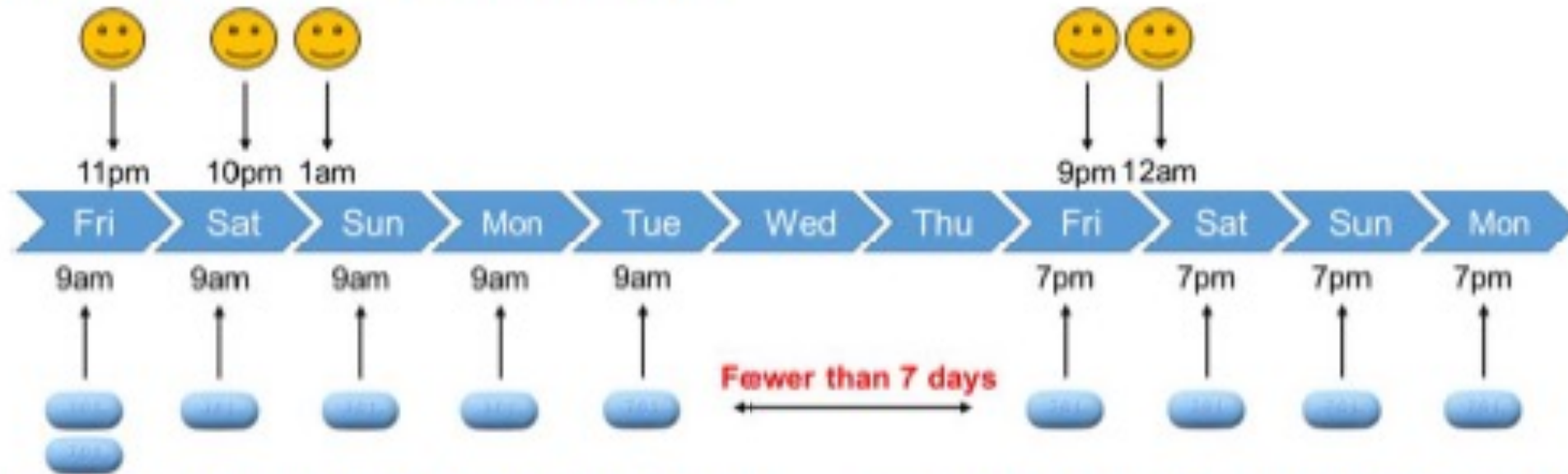
After Sex

- Take 1 PrEP tablet 24 hours after the 1st 2 tablets, then 1 PrEP tablet 48 hours after 1st 2 tablets
- Continue taking 1 PrEP tablet every 24 hours until 2 days after your last “sex day.” (In Example 2 below, Sunday is the last “sex day,” so PrEP should be taken until Tuesday)

Example 1: One Sex Encounter



Example 2: Multiple Sex Encounters



- If there are fewer than 7 days between the end of one 211 dosing period and the beginning of another, you only need to take 1 single PrEP tablet when you restart.
- If there are 7 or more days since your last PrEP 211 dose, start again with 2 PrEP tablets.

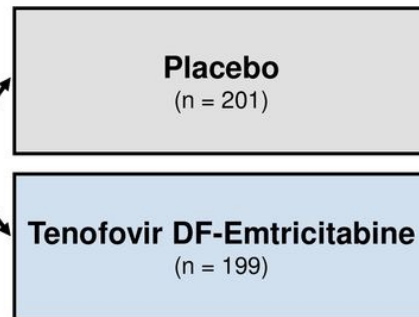
Clinical Trials for On-demand PrEP

Ipergay RCT

On Demand PrEP for Men at High Risk for HIV IPERGAY: Study Design

Study Design: IPERGAY Study

- **Background:** Randomized, phase 3, double-blind, placebo-controlled trial conducted in France and Canada that investigated tenofovir DF-emtricitabine as on-demand preexposure prophylaxis for men who sex with men or transgender women
- **Inclusion Criteria** (400 enrolled)
 - 18 years of age or older and HIV seronegative
 - Men or TG women who have sex with men
 - Unprotected anal sex ≥ 2 partners in prior 6 months
 - Excluded if chronic HCV or HBsAg-positive
 - Excluded: CrCl < 60 mL/min, glycosuria, proteinuria
- **Treatment Arms:**
 - Placebo: (on demand schedule*)
 - Tenofovir DF-emtricitabine: (on demand schedule*)

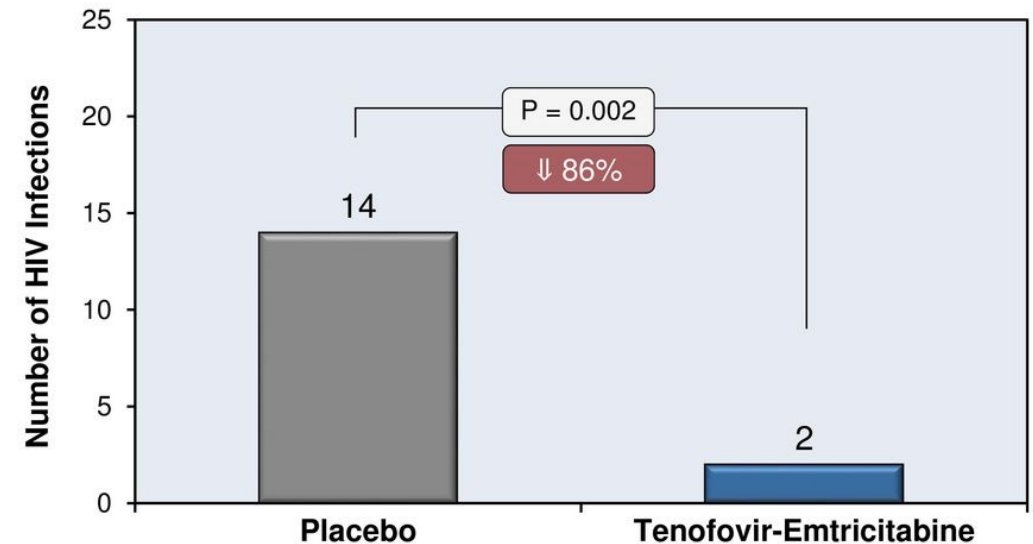


On demand Schedule: take loading dose of two pills of TDF-FTC or placebo with food 2 to 24 hours before sex, followed by a third pill 24 hours after the first pill and a fourth pill 24 hours later. With multiple consecutive episodes of sex, take one pill per day until until 48 hours after last sex.

Source: Molina JM, et al. N Engl J Med. 2015;373:2237-46.



On-Demand Preexposure Prophylaxis Event-Driven Strategy IPERGAY: Results



Due to high effectiveness of PrEP, participants unrandomized and all offered PrEP

Source: Molina JM, et al. N Engl J Med. 2015;373:2237-46.



On-Demand PrEP: “2-1-1” for MSM

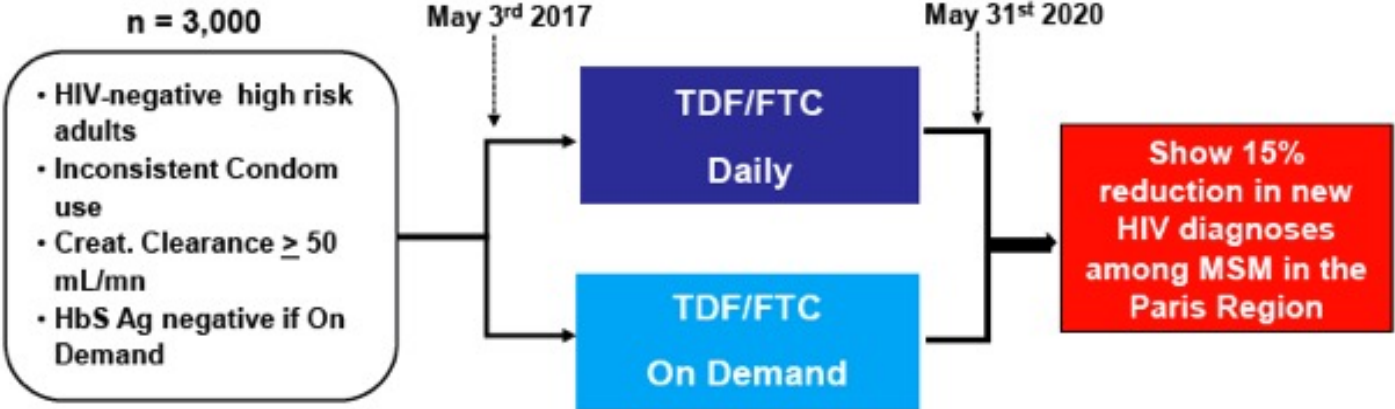
PREVENIR Open Label



<http://prevenir.anrs.fr/>

Study Design

Open-Label Prospective Cohort Study in the Paris Region

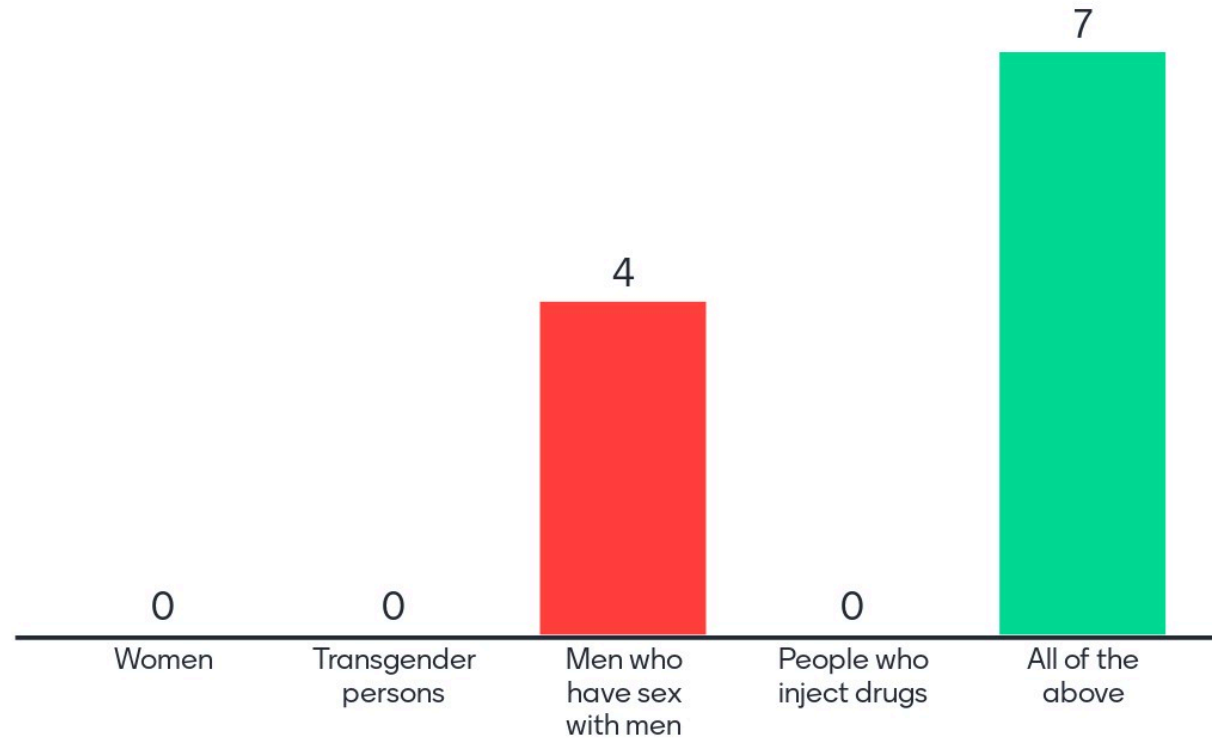


- 3067 pts, half 2-1-1 regimen
- 3 HIV infections in daily, 3 HIV infections in 2-1-1, all off PrEP
- More GI effects 2-1-1, more lab abnormal w/daily
- Estimated 361 infections averted

Slide courtesy of Doug Krakower

On-Demand PrEP in the Clinic

Which groups of patients are eligible for on demand PrEP?

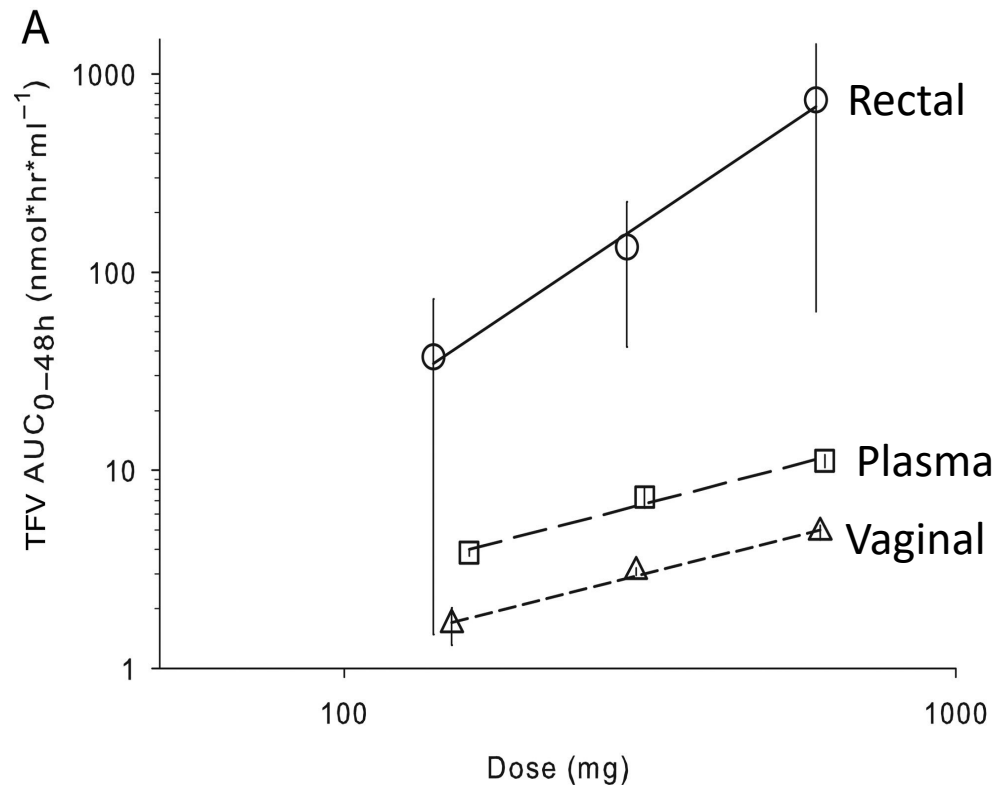


On-demand PrEP Key Points

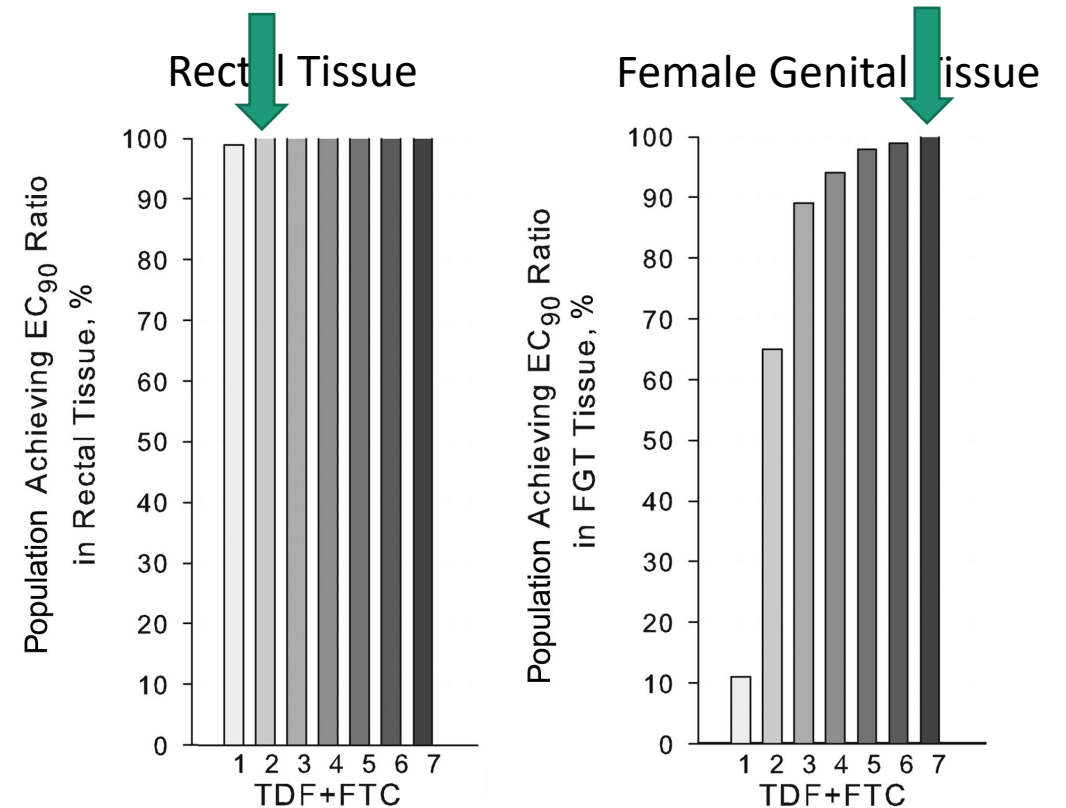
- ONLY recommended in MSM at this time
 - Not recommended for women, transgender persons, or for injection drug use
 - No studies in these populations AND concerns about drug levels in different tissues

Truvada reaches appropriate levels in rectal tissue more quickly than in vaginal tissue

Concentrations in tissue after tenofovir dose



Percent of people with effective drug levels in rectal/vaginal tissue based on doses per week



On demand PrEP Key Points

- ONLY recommended in MSM at this time.
- ONLY Truvada has been studied. Descovy has not been studied.
- Cannot use in patients with chronic Hepatitis B.

For which patients do you discuss on demand PrEP as an option?

date night
male
individuals w male anat
vacation
many sexual partners
msm 😊
young msm
infrequent sex acts
those who plan sex
getting drunk

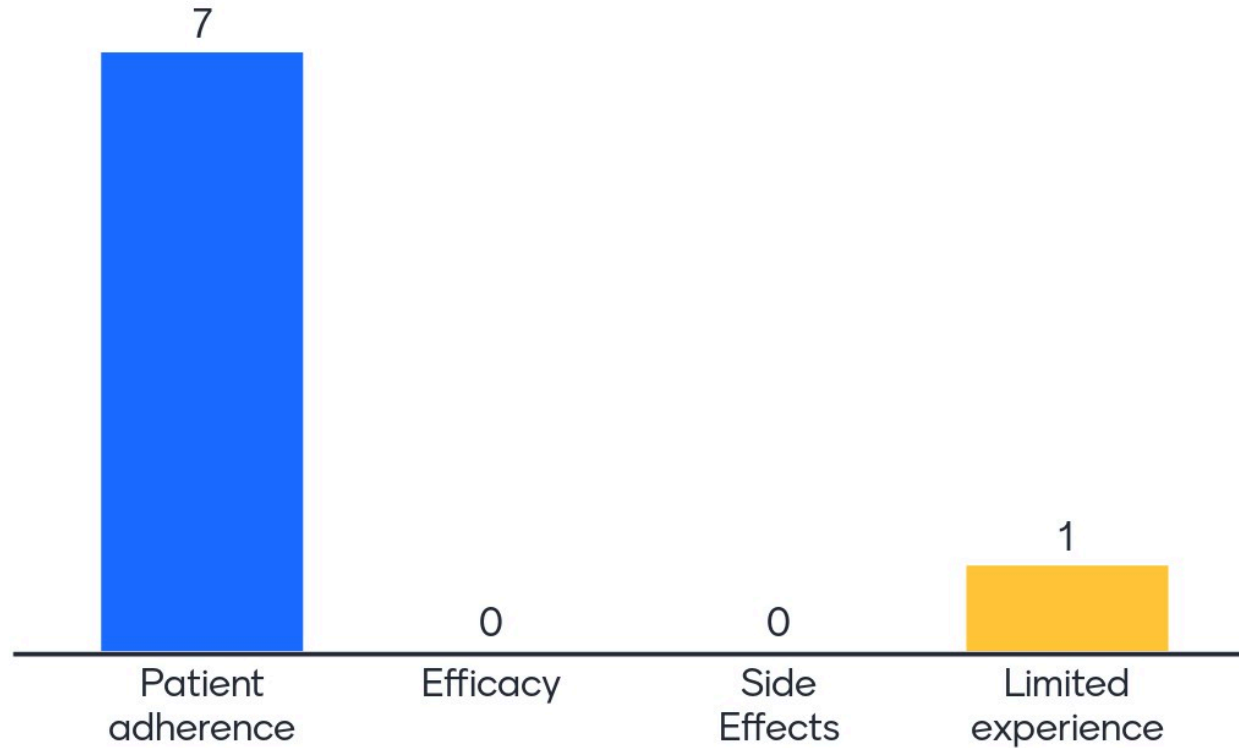
Patients who may benefit from PrEP

- When sexual encounters can be anticipated
- Those who experience periods of sexual inactivity
- Do not want to commit to daily medication
- Cannot afford daily PrEP

Patient reasons for switching from daily to on-demand PrEP

Reason	Percent
Having sex less frequently	64%
Wanting to take fewer pills	46%
Need to reduce costs	22%
Desire to reduce side effects	19%

What are your biggest concerns about on demand PrEP?



Patient reported challenges for on-demand PrEP dosing

Challenge	Percent
Unplanned sexual encounters leading to missing the first double dose	44%
Trouble remembering doses post-sex	29%

Logistics of On Demand PrEP

Prescribing

- No more than 30 pills
- If once weekly sex, this will last 7+ weeks

Counseling

- Dosing
- Adherence
- Use with every sexual encounter
- Possible "start-up" symptoms

Follow-up

- Negative HIV test before providing refill
- Ongoing STI testing

Questions and Discussion