

UPDATE FROM AIDS 2020

Health Commission

October 2020

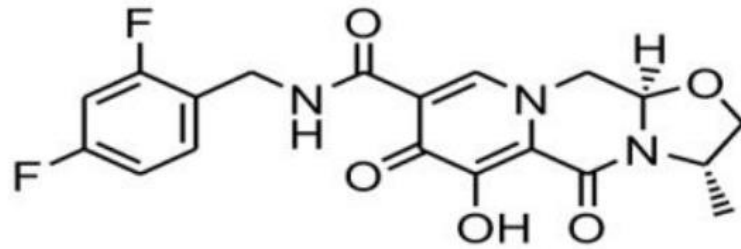
Susan Buchbinder, MD

Albert Liu, MD, MPH

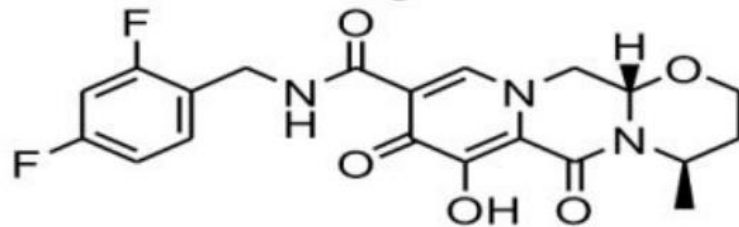
Hyman Scott, MD MPH

Cabotegravir Long Acting Injectable (CAB LA)

GSK1265744
(GSK744)



Dolutegravir



- Cabotegravir is an analog of dolutegravir, a very commonly used integrase inhibitor
- Very long half-life in its injectable form

Muller et al. European Journal of Pharmaceutics and Biopharmaceutics 2011

Spreen 7th IAS 2013; Min ICAAC 2009

Taoda International Congress on Drug Therapy in HIV Infection 2012

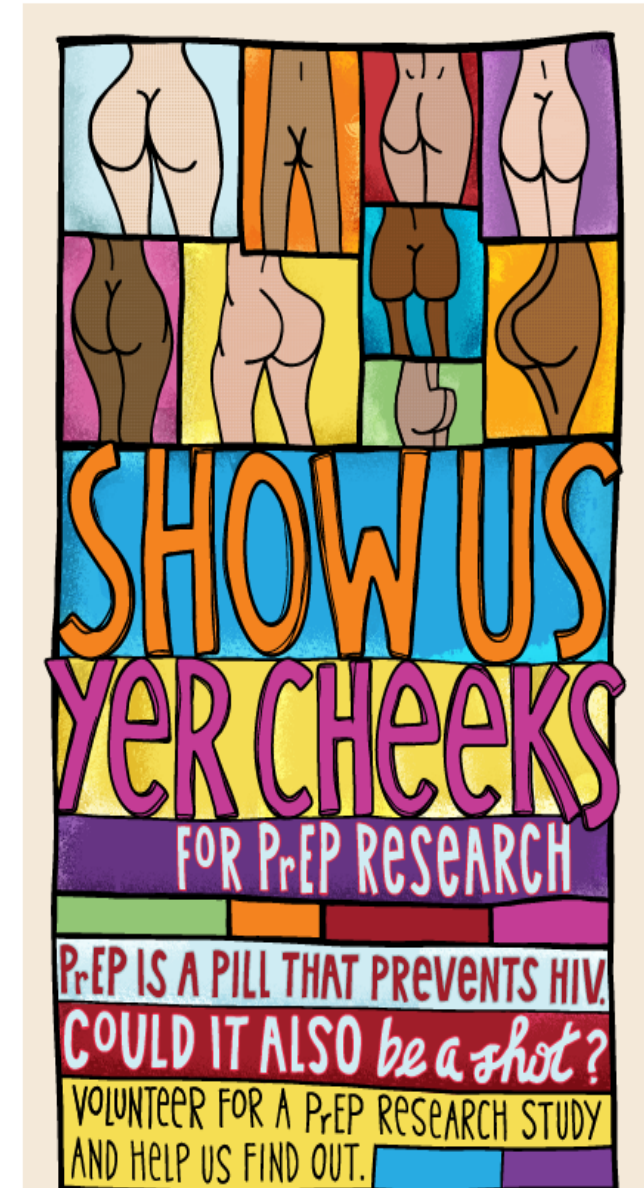
McPherson et al, Expert Opin on Investig Drugs 2018

Pros and Cons of Cabotegravir-LA

- Pros
 - Very potent, protects animals against IV, rectal, vaginal, penile challenge
 - Administered every 8 weeks; don't need to take a daily pill for PrEP
- Cons
 - Need to get an injection every 8 weeks (may be difficult to roll out)
 - Long “tail”: drug persists at very low levels for up to 3-4 yrs
 - If drug level is too low to protect, could it select for resistant virus, limiting treatment options

Two Efficacy Trials of CAB-LA

- **HPTN 083** for MSM/TGW globally
- **HPTN 084** for women in sub-Saharan Africa
- Both have 3 steps:
 1. Oral lead-in
 2. Loading at 0 and 4 weeks, every 8 week injections
 3. Oral Truvada to cover the “tail” for 1 year
- Both trials are using F/TDF (Truvada) as comparator
- Bridging studies to adolescent MSM/TGW and cis-women



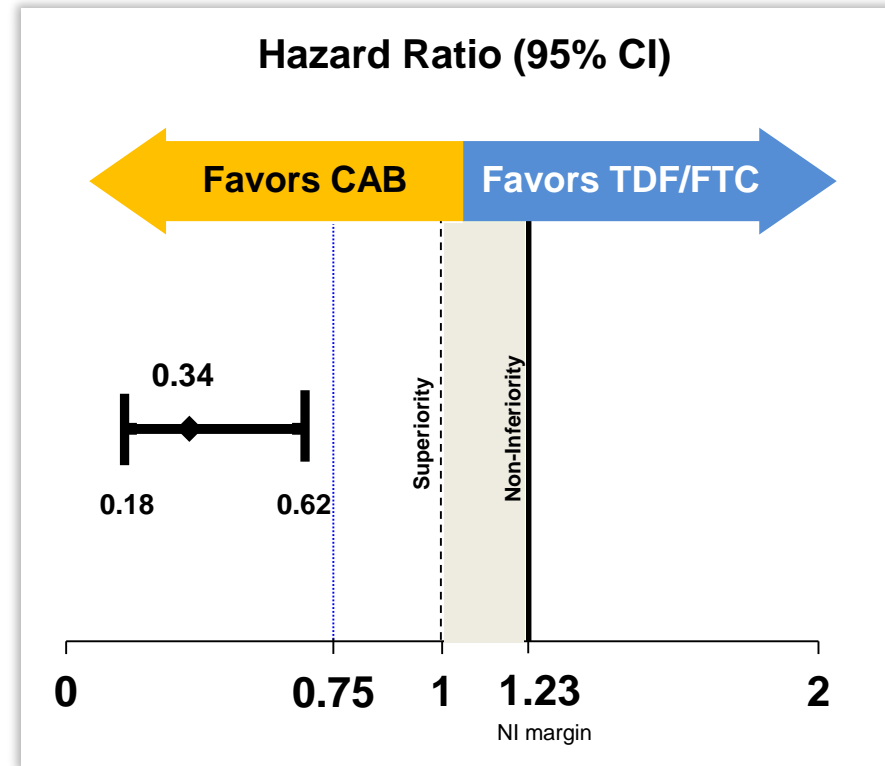
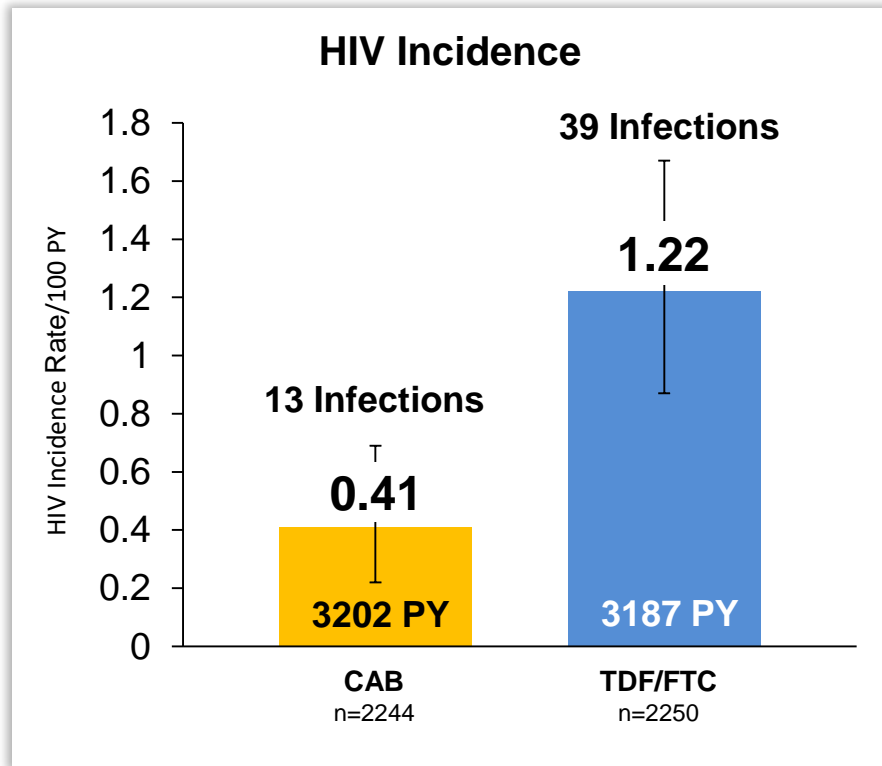
Enrollment

- Met or exceeded their enrollment targets.
- Of 4566 participants enrolled:
 - 12% transgender women (target 10%)
 - 67% < 30 years old (target 50%)
 - 50% of US participants Black/African American (target 50%)

HIV Incidence

CAB vs. TDF/FTC

52 HIV infections; 1.4 years median per-participant follow-up
Pooled infection rate 0.81 (95%CI 0.61-1.07) per 100 PY
66% reduction in infections in the CAB arm

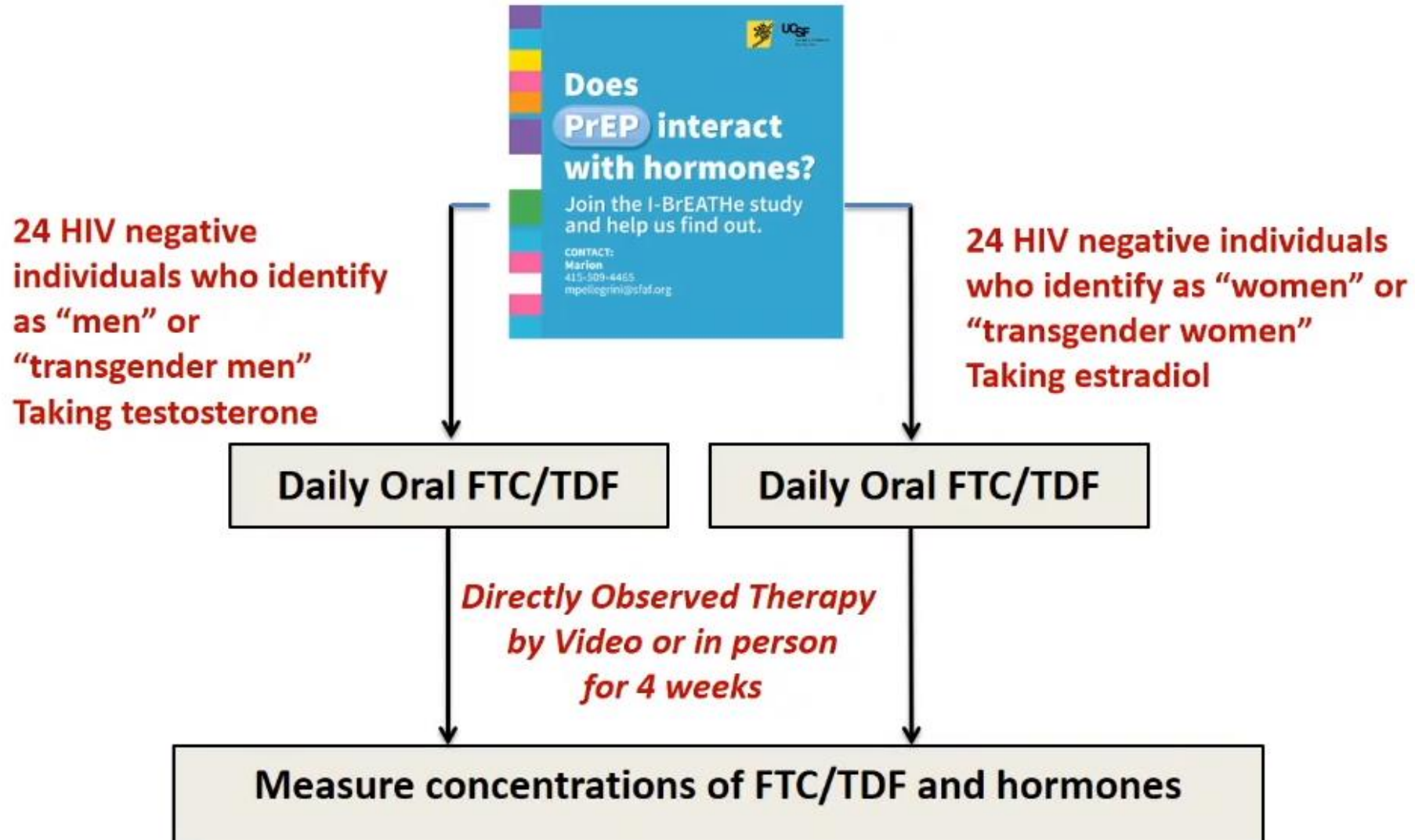


CI, confidence interval

Unanswered Questions

- Why did some people on CAB-LA still become infected?
 - Some occurred during early oral period – adherence or not high enough drug levels?
 - Some occurred after regular injections – was this because drug levels weren't high enough or infected with resistant virus?
- Why did some people on Truvada still become infected?
 - Adherence? Resistance?
- Did people who became infected on CAB-LA develop drug resistance?

I-BrEATHe Study Design



Conclusions

- Daily oral TDF/FTC PrEP did not affect feminizing or masculinizing hormone concentrations
- There were no symptoms of hormone withdrawal after starting PrEP
- All TGW and TGM were projected to achieve highly protective concentrations of PrEP drugs
- SFAF extended 2-1-1 dosing strategies to TGW and TGM on hormone therapy after these results.



Ad Examples: Facebook left/right; Youtube center

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Victims who qualify may be entitled to compensation..

Gilead drugs such as Viread, Truvada, Atripla, Complera and Stribild used for HIV treatment cou...
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TRUVADA linked to **KIDNEY DAMAGE**
BONE LOSS

GET COMPENSATED
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HIV/HIV PrEP Drug Lawsuit [LEARN MORE](#)

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Approved to treat HIV-1, but it is now also being used as a PrEP drug to prevent HIV infections.


TRUVADA LEGAL HELPLINE
CALL US NOW! **1-800-914-0188**



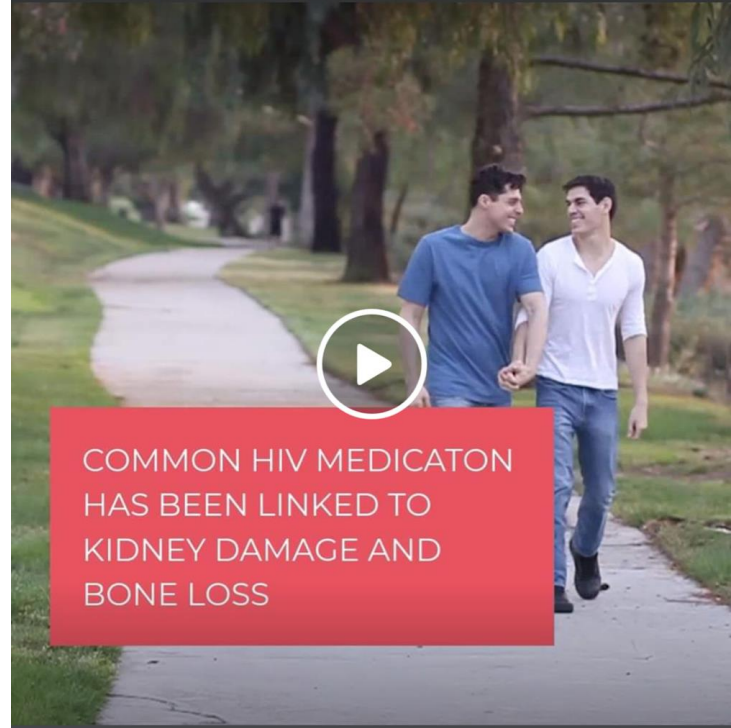
THE LOVELY LAW FIRM
JUSTICE IS LOVELY

TRUVADA: WHAT YOU SHOULD KNOW

Justin M. Lovely 1053 Lonsden St. Mt. SC 29677

 **Truvada Alert**
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Cash settlements for victims who qualify.... [See More](#)



COMMON HIV MEDICATION HAS BEEN LINKED TO KIDNEY DAMAGE AND BONE LOSS

TDF-DRUGS.QUALIFIED-CASE.COM
HIV/HIV PrEP Drug Lawsuit
Time is Limited - Act Now [LEARN MORE](#)

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Quantitative Analyses

	n=722 (48.61% of sample)
Q. Where have you seen the lawsuit ads? A. Social media.	86.3%
Q. Did the lawsuit ads change your decision to not start Truvada PrEP or stop taking Truvada PrEP? A. Yes.	18.7%
Q. Did the lawsuit ads change your opinion about Truvada-based PrEP? A. Yes.	32.1%

Participants with higher education (less than college vs some college or more) were significantly less likely to quit or to decide against initiating PrEP use (OR = 0.29, 99% CI 0.14-0.61).

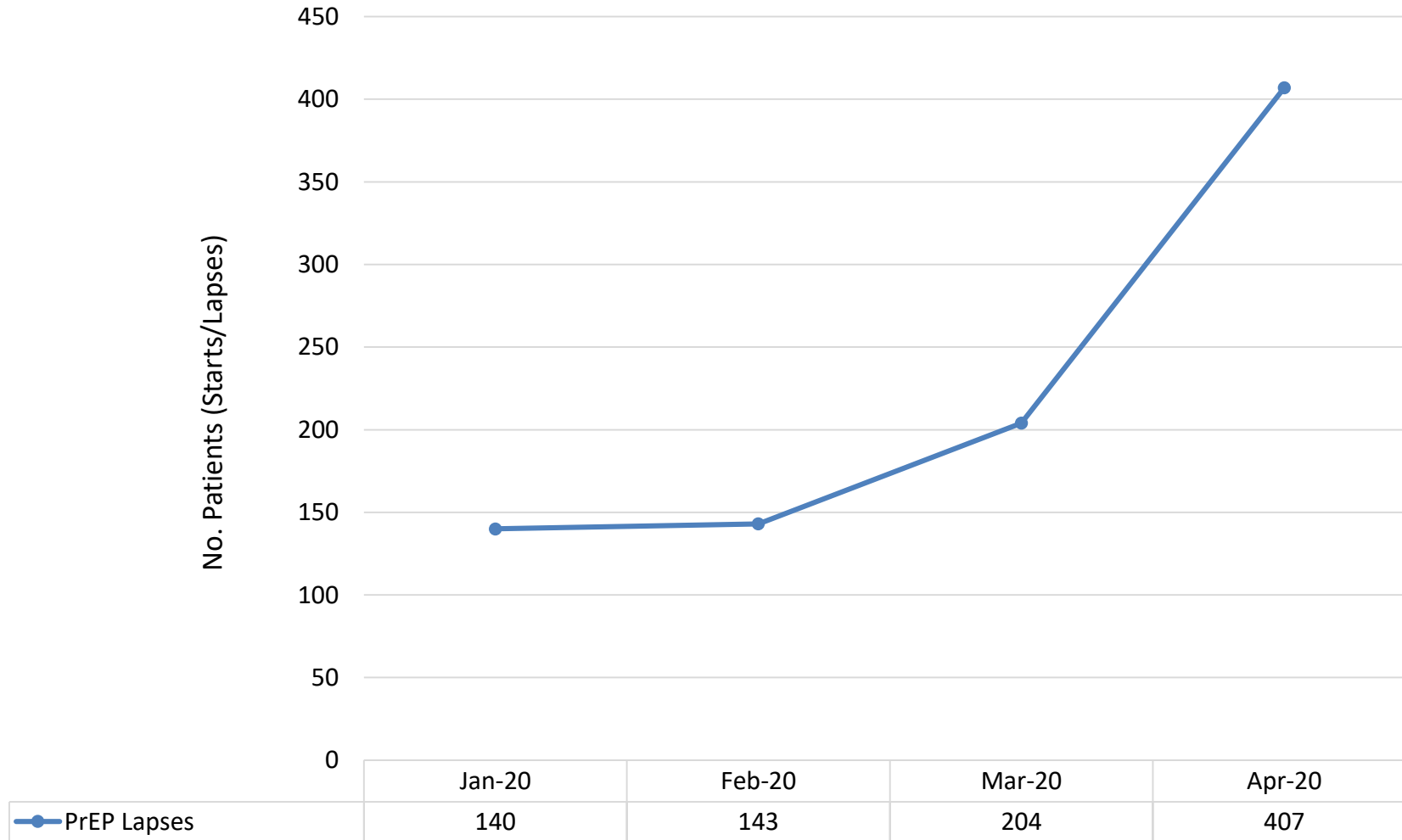


Methods

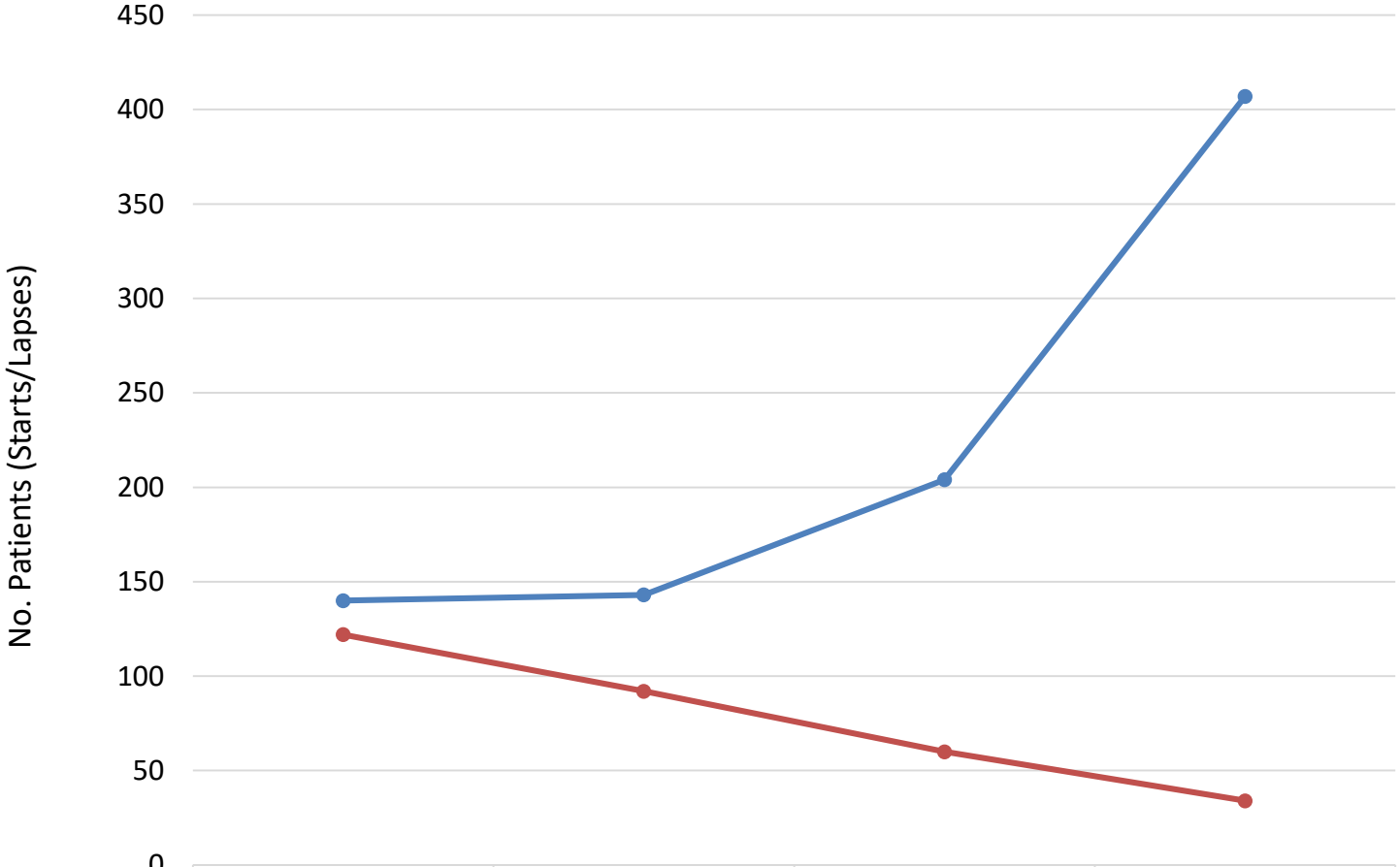
- Fenway Health: community health center, LGBTQIA+
- Electronic health records data
 - PrEP refill lapses (i.e., no refill before end of prior Rx)
 - New PrEP starts
 - HIV/STI testing
 - Telehealth
- Jan 1, 2020 to April 30, 2020
- Assess patient factors associated with PrEP refill lapses in April 2020 (Chi-square tests)



PrEP refill lapses increased by 191%



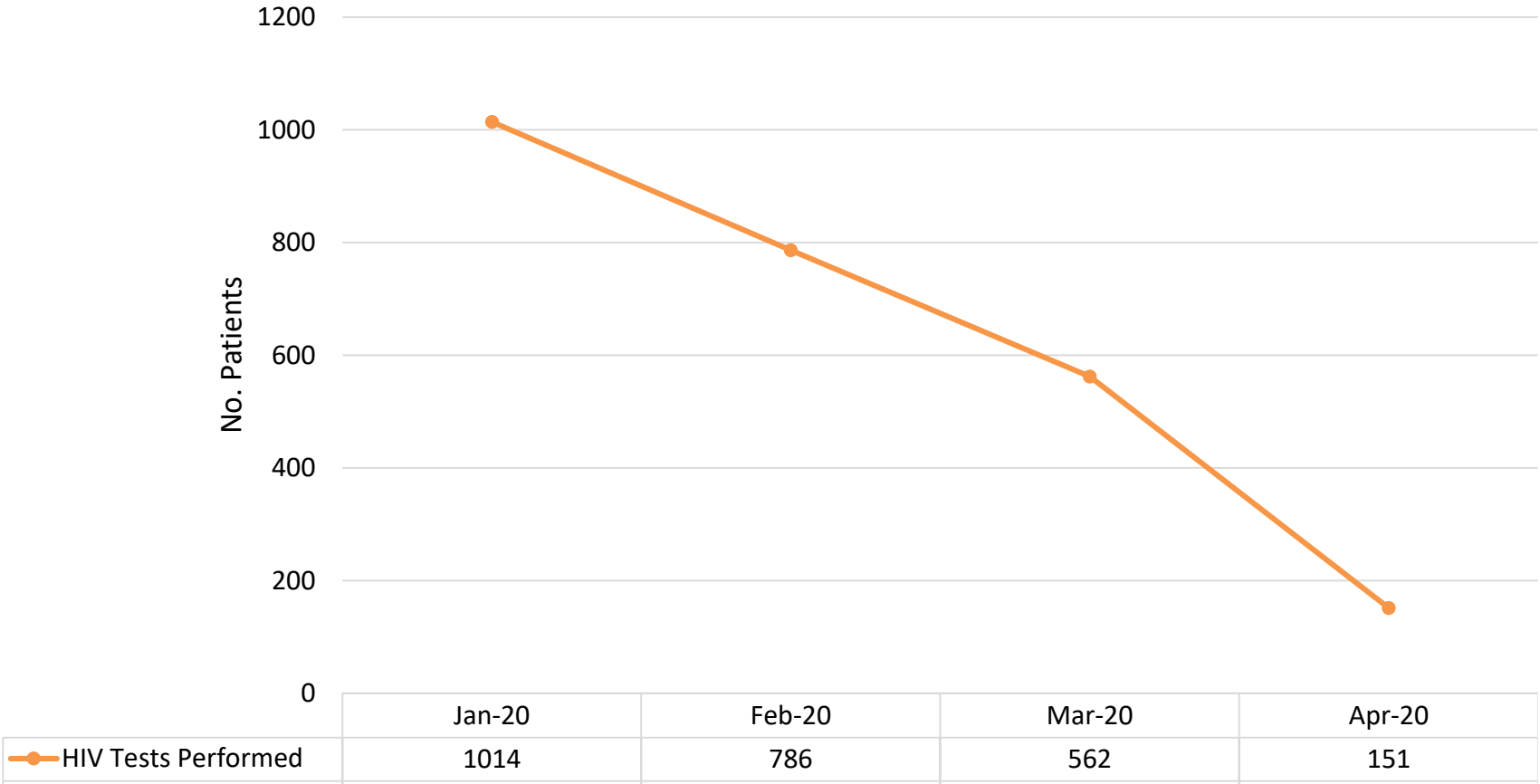
New PrEP starts decreased by 72.1%



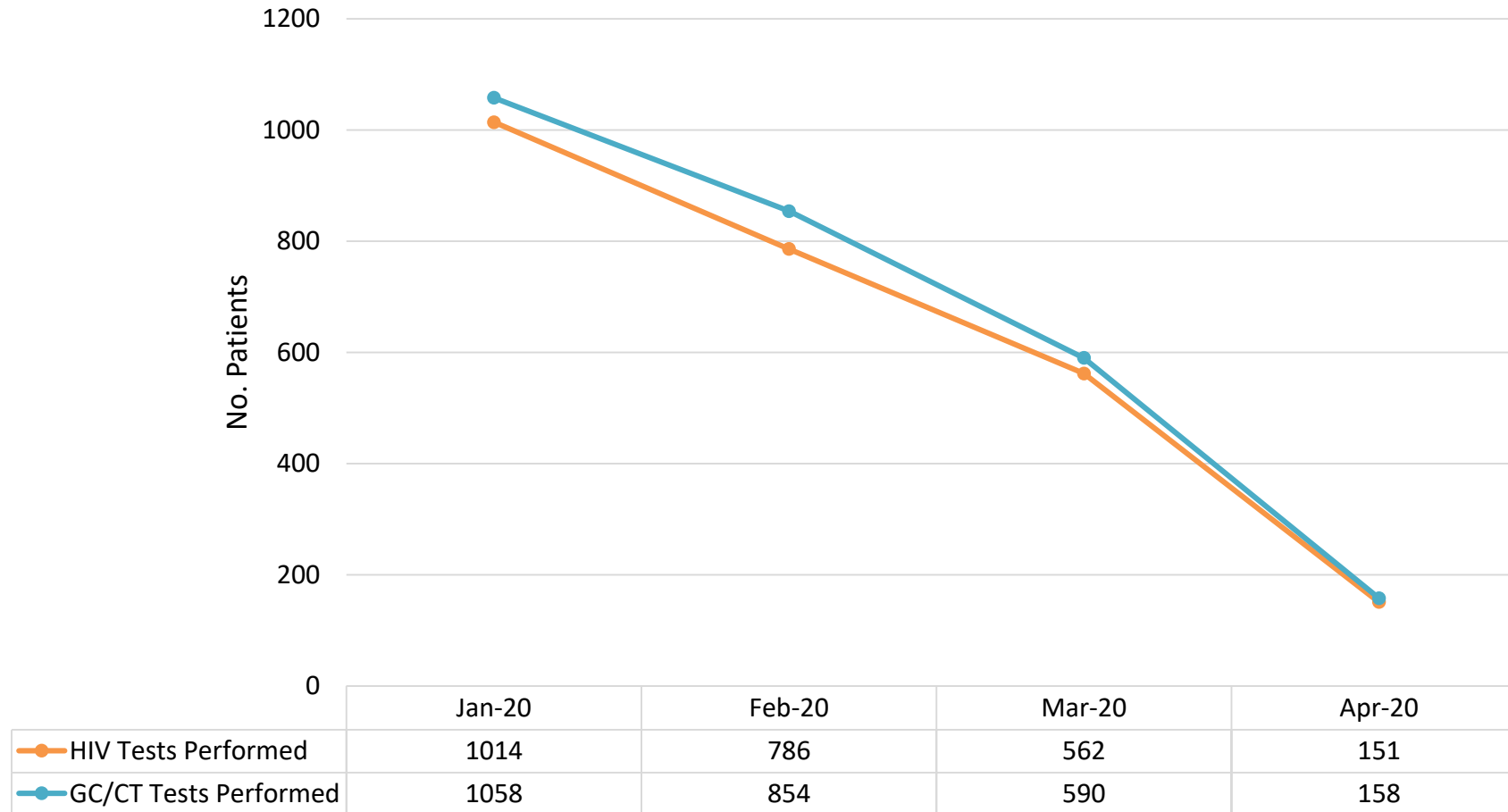
	Jan-20	Feb-20	Mar-20	Apr-20
PrEP Lapses	140	143	204	407
New Starts	122	92	60	34



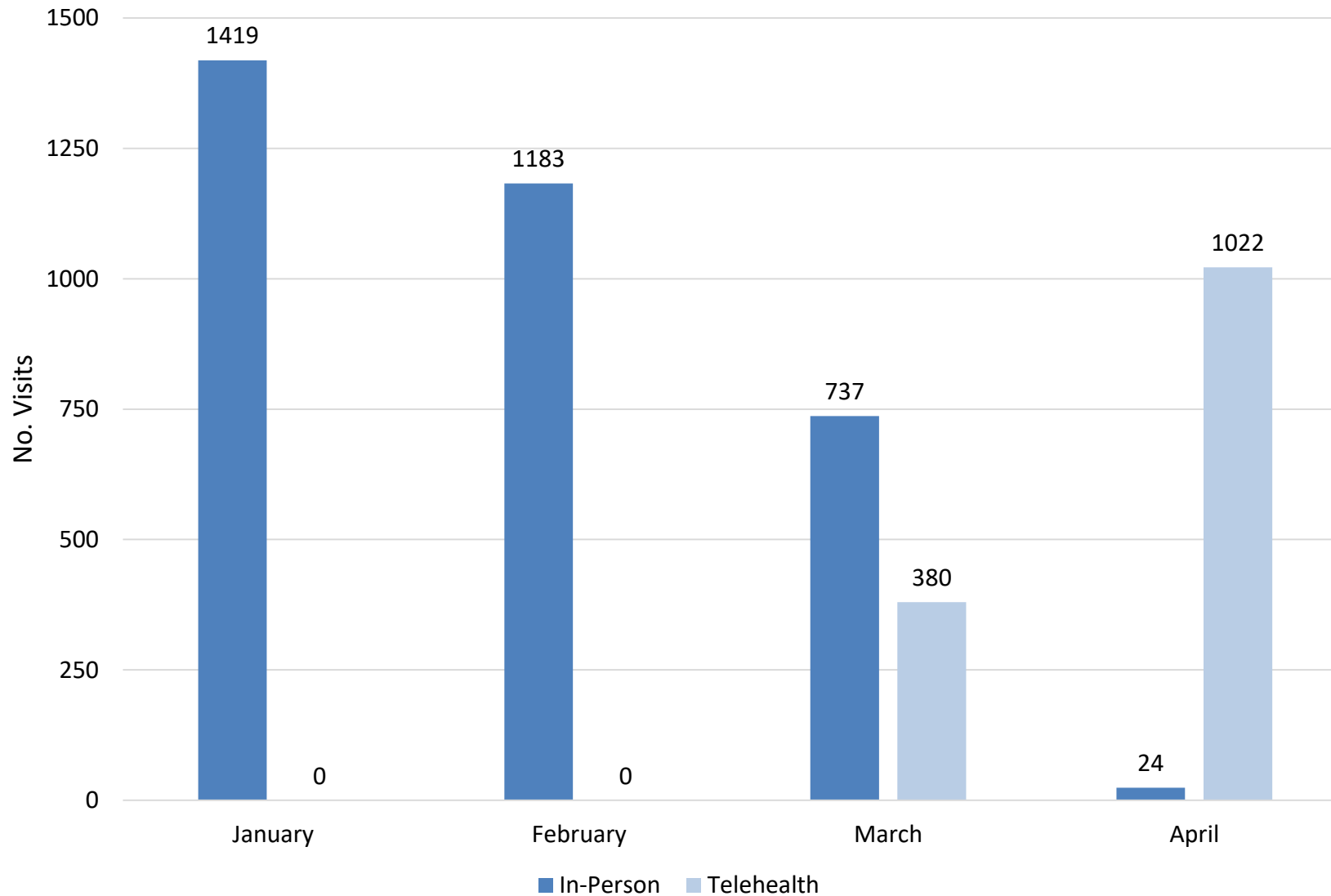
HIV tests decreased by 85.1%



Gonorrhea/chlamydia tests decreased by 85.1%



A major shift from in-person visits to telehealth occurred



Conclusions

- COVID-19 was associated with major disruptions in PrEP refills, new starts, and HIV/STI testing, despite near-complete shift to telehealth
- PrEP refill lapses associated with younger age, Latinx or multi-race, public insurance
- Limitation: cannot ascertain sexual and pill-taking behaviors
- Future directions: Assess for changes in prevention-effective adherence, in particular among vulnerable subpopulations

SEARCH Study Results

- 16 communities in rural Kenya and Uganda
- Women and men at risk of HIV infection were offered PrEP
- Of 74,000 people ≥ 15 years
 - 21% were at increased risk of HIV infection (n=15,632)
 - 35% of those started PrEP (n-5447)
 - 78% of those returned for at least one HIV test (n-4260)
- Saw a 74% reduction in HIV infection rates in women and men
- PrEP works when taken at scale

The “Sao Paulo Patient”

- Previously, only 2 people cured from HIV
 - Both had bone marrow transplants with receptor for HIV deleted
- 36 year old man in Brazil, enrolled into a treatment trial
- Given DTG, Maraviroc, Nicotinamide (Vit B3) for 1 year, then regular antiretroviral regimen, then stopped drugs
- Drugs stopped in March 2019, still no virus detectable
- Cure??
- Haven't sampled lymph nodes, GI tract to see if virus can be recovered from these locations