Pre-exposure prophylaxis with cabotegravir long-acting versus daily oral tablets: Increased frequency of testing for HIV and sexually transmitted infections

P016

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Background

- CAB LA PrEP is the first long-acting PrEP regimen approved for the prevention of HIV
  - Requires in-clinic injections every two months after two initiation injections in the first two months
- Regular testing for HIV and STIs is CDC-recommended for people taking PrEP, but timing varies by PrEP formulation:

Test	CAB LA PrEP	Oral PrEP
HIV	At each injection (± 14 days)	At initiation (± 14 days) and every 3 months after initiation
Syphilis	Every 4 months (MSM, trans women) or 6 months (everyone else)	Every 6 months
Gonorrhea		
Chlamydia		Every 6 months (MSM, trans women) or 12 months (everyone else)

- More frequent clinic visits for CAB LA PrEP injections than with oral PrEP use may provide opportunities for earlier detection and management of HIV and STIs

Objective

Describe the timing of HIV and STI testing during CAB LA PrEP versus daily oral PrEP use in the US-based OPERA Cohort

Methods

Study Population

- OPERA® observational cohort: Prospectively captured clinical data from electronic health records in the US
- Adults (≥ 18 years old) without HIV

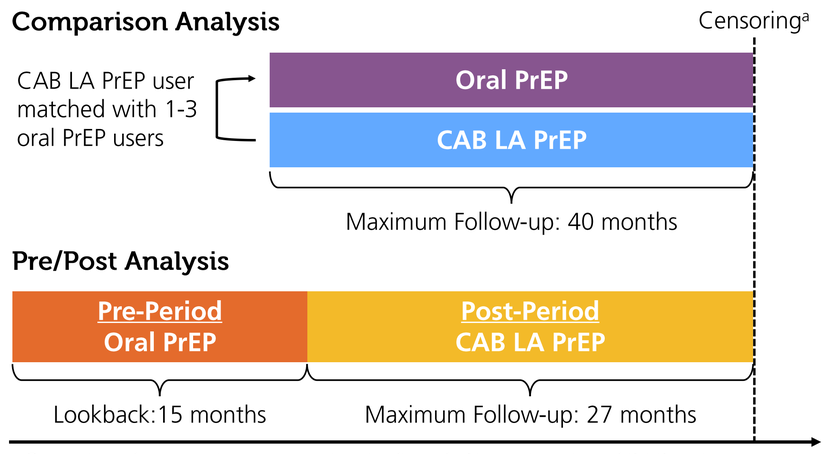
Comparison Analysis: Oral vs. CAB LA PrEP Users

- Prospective cohort study with matched groups
- Eligibility period: 01JAN2022 - 31OCT2023
- CAB LA PrEP group: Completed CAB LA PrEP initiation (i.e., two injections) during the eligibility period
  - Second CAB LA PrEP injection must have been ≤ 67 days after the first CAB LA PrEP injection (per the label)
- Each CAB LA PrEP user was matched with replacement on age (18-29, 30-39, 40-49, ≥ 50), sex (male, female), and location (healthcare system by state) with 1-3 individuals initiating a new oral PrEP regimen during the eligibility period

Pre/Post Analysis: Switch from oral to CAB LA PrEP

- Pre/Post study design
- Switched from oral PrEP (*pre*) and completed initiation of CAB LA PrEP 01FEB2023 – 31JAN2024 (*post*)
  - Maximum 90 days between end of prior oral PrEP regimen and the first CAB LA PrEP injection

Descriptive Analyses



[a] Censoring of person-time occurred at the first of: Discontinuation of PrEP regimen, loss to follow-up (12 months after last clinical contact), death, acquisition of HIV, or end of follow-up (30APR2025). Discontinuation of oral PrEP was defined as (a) > 45 days without an oral PrEP prescription or (b) switch to CAB LA PrEP injections. Discontinuation of CAB LA PrEP was defined as ≥ 128 days without injection; shorter delays were not considered a discontinuation.

Denominators for Comparison and Pre/Post Analyses

Testing	CAB LA PrEP	Oral PrEP	
	Comparison* & *Pre/Post	***Comparison***	***Pre/Post*[a]**
HIV (**Fig 1**)	PrEP users (At initiation) Injections (During PrEP)	PrEP users	Initiations (At initiation) Episodes (During PrEP)
STI (**Fig 2**)	PrEP users	PrEP users	Episodes

[a] Some individuals had multiple oral PrEP episodes during the pre-period

Results

Table 1. Population characteristics at oral PrEP start (*comparison* analysis) or at CAB LA PrEP start (*comparison* & *pre/post* analyses)

	***Comparison* Analysis**		***Pre/Post* Analysis**
	Oral PrEP Users N = 2,613	**CAB LA PrEP Users[a] N = 874**	**At Switch from Oral to CAB LA PrEP N = 544**
Age in years, median (IQR)	32 (26, 40)	32 (26, 40)	34 (28, 41)
Female, n (%)	297 (11)	102 (12)	45 (8)
Black race, n (%)	631 (24)	248 (28)	153 (28)
Hispanic ethnicity, n (%)	716 (27)	264 (30)	161 (30)
MSM, n (%)	1,174 (45)	546 (62)	343 (63)
Medicaid recipient, n (%)	363 (14)	255 (29)	113 (21)
Medicare recipient, n (%)	96 (4)	51 (6)	26 (5)
≥ 1 clinical visit within 12 months prior to initiation of new PrEP regimen, n (%)	2,288 (88)	872 (> 99)	543 (> 99)

[a] Six additional CAB LA PrEP users had no matches on oral PrEP and were excluded from the *comparison* analysis

Table 2. History of infections[a] at oral PrEP start (*comparison* analysis) or at CAB LA PrEP start (*comparison* & *pre/post* analyses)

	***Comparison* Analysis**		***Pre/Post* Analysis**
	Oral PrEP Users N = 2,613	**CAB LA PrEP Users N = 874**	**At Switch from Oral to CAB LA PrEP N = 544**
Syphilis	369 (14)	209 (24)	134 (25)
Gonorrhea	447 (17)	251 (29)	162 (30)
Chlamydia	424 (16)	250 (29)	162 (30)
Hepatitis B	117 (4)	52 (6)	34 (6)
Hepatitis C	44 (2)	16 (2)	8 (1)
HSV-2	30 (1)	30 (3)	17 (3)
HPV and/or genital warts	74 (3)	53 (6)	37 (7)

[a] Diagnosis or positive lab result in OPERA, on or anytime prior to initiation of new PrEP regimen

Figure 1. Proportion of on-schedule HIV testing among oral PrEP and CAB LA PrEP users in the *comparison* (purple, blue) and *pre/post* analyses (orange, yellow)

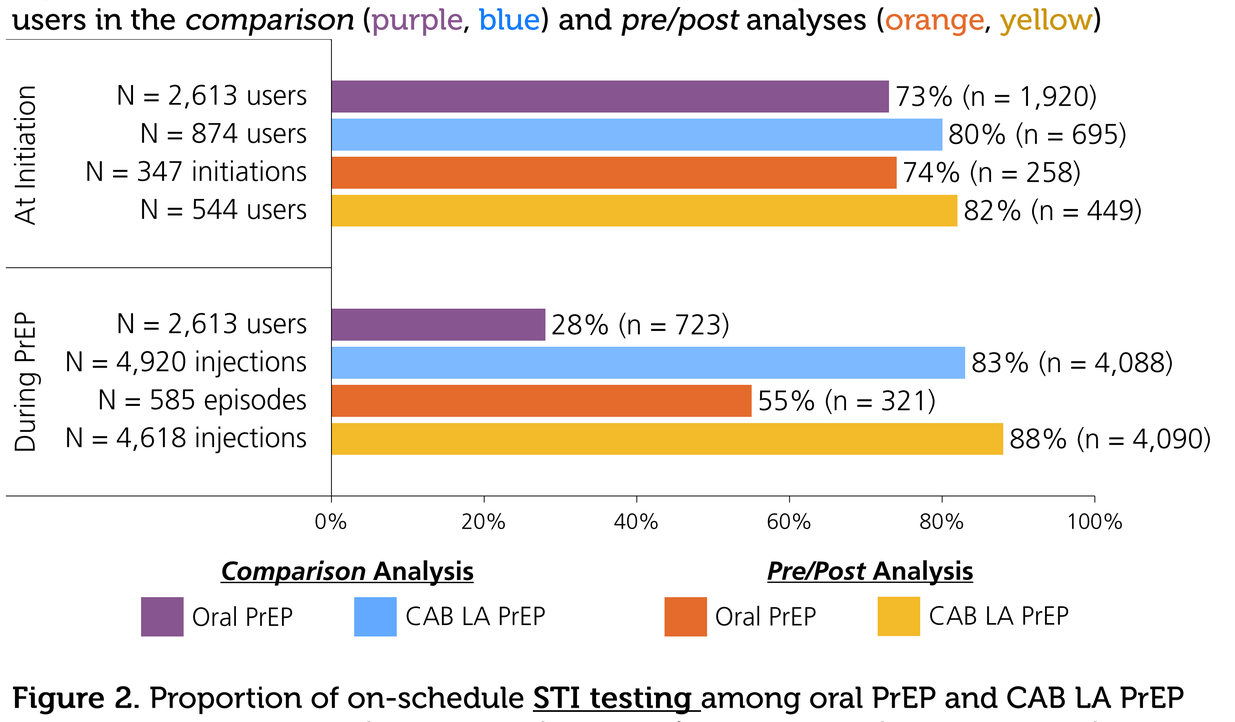
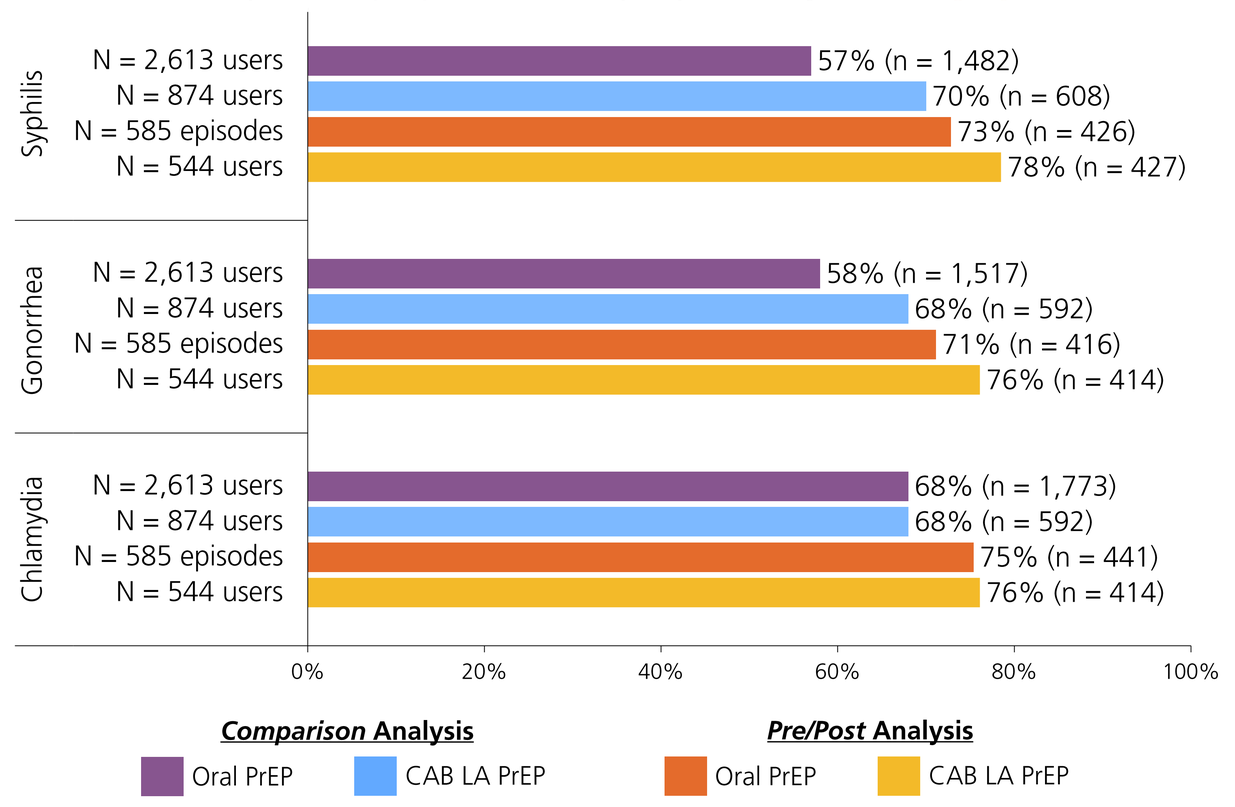


Figure 2. Proportion of on-schedule STI testing among oral PrEP and CAB LA PrEP users in the *comparison* (purple, blue) and *pre/post* analyses (orange, yellow)



Abbreviations

CAB LA, cabotegravir long-acting; **CDC**, Centers for Disease Control and Prevention; **HIV**, human immunodeficiency virus; **HPV**, human papilloma virus; **HSV-2**, herpes simplex-2; **IQR**, interquartile range; **MSM**, men who have sex with men; **N**, number; **OPERA**, Observational Pharmaco-Epidemiology Research & Analysis; **n**, number; **PrEP**, pre-exposure prophylaxis; **STI**, sexually transmitted infection; **US**, United States

Discussion

- In the *comparison* analysis, CAB LA PrEP users were more likely than oral PrEP users to be non-White, Medicaid recipients, and MSM (**Table 1**)
- CAB LA PrEP users were also more likely to have had a visit in the prior 12 months (>99% vs. 88%) and to have a documented history of syphilis, gonorrhea, and chlamydia in OPERA (**Table 2**)
- CAB LA PrEP users were similar between the *comparison* and *pre/post* analyses (**Tables 1 & 2**)
  - Limitation: There was some overlap in eligibility periods between the two analyses
- On-schedule **HIV testing** at initiation of a new PrEP regimen was high overall, but higher for CAB LA PrEP users in the *comparison* (80%) and *pre/post* (82%) analyses than oral PrEP users (73% & 74%, respectively) (**Fig 1**)
- On-schedule **HIV testing** during PrEP use was higher among CAB LA users in the *comparison* (83%) and *pre/post* (88%) analyses than oral PrEP users (28% & 55%, respectively) (**Fig 1**)
- CAB LA users had a higher proportion of on-schedule **syphilis** and **gonorrhea** testing than oral PrEP users, though differences were attenuated in the *pre/post* analysis (**Fig 2**)
- No difference was observed in the frequency of on-schedule **chlamydia** testing between CAB LA PrEP and oral PrEP users in either analysis (**Fig 2**)
- Potential bias: Differences in the characteristics of PrEP users at initiation of a new PrEP regimen may be suggestive of a channeling bias toward prescribing LA PrEP to people with a greater history of STIs or individuals more active in care

Key Findings

- In this large real-world study, use of CAB LA PrEP was associated with an overall increase in on-schedule HIV and STI testing, compared to oral PrEP
- The higher testing frequency observed among CAB LA PrEP users has the potential to result in faster detection and lower transmission rates of HIV and STIs

Acknowledgements

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