



Steven Barnett,¹ Laurence Brunet,² Jennifer S. Fusco,² Karam Mounzer,³ Kevin R Frost,⁴ Supriya Sarkar,⁵ Kimberley Brown,⁵ Harmony P. Garges,⁵ Vani Vannappagari,⁵ Gregory P. Fusco²
¹ CAN Community Health, Tampa, FL, USA; ² EpiVidian, Raleigh, NC, USA; ³ Philadelphia FIGHT, Philadelphia, PA, USA; ⁴ Foundation for AIDS Research (amfAR), New York, NY, USA; ⁵ ViiV Healthcare, Durham, NC, USA



Background

- CAB LA was approved for HIV prevention by the FDA on 20DEC2021
 - 2 initiation injections administered one month apart, followed by 1 maintenance injection every 2 months
- Oral PrEP (TDF/FTC, TAF/FTC) is approved as a single daily tablet
- Trials have demonstrated the superior efficacy of CAB LA PrEP over daily oral PrEP with TDF/FTC
- Adherence to the injection schedule or daily oral intake impacts PrEP effectiveness; lower PrEP coverage may increase the risk of HIV acquisition and may differ for CAB LA vs. oral PrEP

Objective

To compare PrEP coverage, HIV testing and HIV acquisition between individuals on CAB LA vs. oral PrEP in the OPERA cohort

Methods

Study population

- OPERA cohort: prospectively captured, routine clinical data from electronic health records in the US (101 clinics, 23 US states/territories)
- Inclusion criteria
 - ≥18 years old
 - Start a new PrEP formulation (TDF/FTC, TAF/FTC, CAB LA) between 21DEC2021 and 30JUN2024
 - First-time PrEP use, direct switch from one formulation to another, or return to PrEP (same or different formulation) after a pause ≥61 days without PrEP
 - No evidence of HIV prior to start of PrEP formulation
- PrEP episodes: continuous use of either CAB LA or oral PrEP; all PrEP episodes during the study period were included
- PrEP episode censoring criteria
 - PrEP type switch
 - 12 months after PrEP episode start
 - Death
 - Study end (30JUN2025)
 - HIV acquisition (HIV acquisition analyses only)

PrEP coverage

- Oral PrEP coverage = $\frac{\sum \text{Number of pills in each Rx}}{\text{Follow up days}}$
 - Number of pills: based on Rx duration and refills
- CAB LA coverage = $\frac{\sum \min(\text{window, days between injections})}{\text{Follow up days}}$
 - Injection windows: 37 days for initiation, 67 days for maintenance injections

HIV acquisition and testing

- Univariate Poisson regression (IR, IRR)
- HIV acquisition confirmed through chart review
- HIV testing event: multiple HIV tests on the same day count as one testing event

Results

Figure 1. CAB LA and oral PrEP use in OPERA between 21DEC2021 and 30JUN2024, with follow-up through 30JUN2025

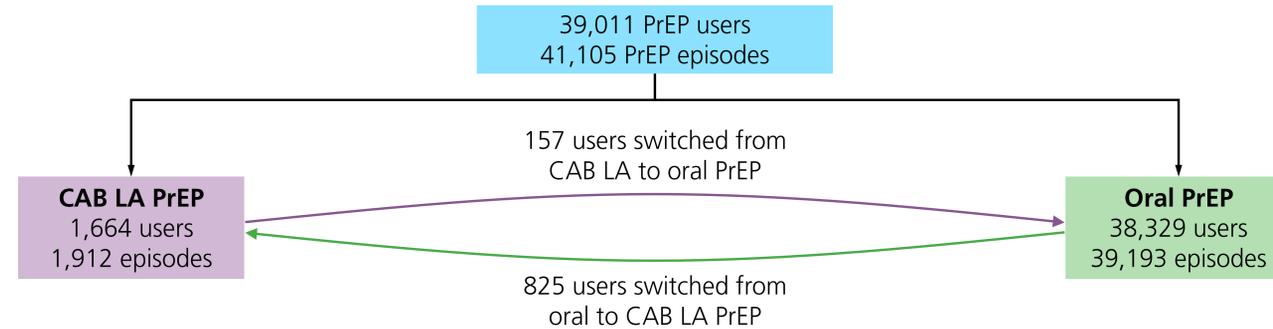


Table 1. Characteristics at the start of the PrEP episode

	CAB LA PrEP episodes N = 1,912	Oral PrEP Episodes N = 39,193
Age, median (IQR)	33 (27, 41)	31 (26, 38)
Women, n (%)	221 (12)	3,702 (9)
Transgender, n (%)	167 (9)	922 (2)
Black race, n (%)	542 (28)	9,465 (24)
Hispanic ethnicity, n (%)	541 (28)	13,439 (34)
Medicaid, n (%)	497 (26)	2,353 (6)
Medicare, n (%)	97 (5)	598 (2)
Syphilis (past 3 months), n (%)	269 (14)	4,508 (12)
Gonorrhea (past 3 months), n (%)	169 (9)	3,971 (12)
Chlamydia (past 3 months), n (%)	158 (8)	3,409 (9)

Table 2. HIV acquisition within the first 12 months since PrEP episode start

	CAB LA PrEP episodes N = 1,912	Oral PrEP Episodes N = 39,193
HIV acquisitions, n (%)	1 (<1)	180 (<1)
Person-years of follow-up	1,088	36,488
IR per 1,000 person-years (95% CI)	0.9 (0.1, 6.5)	4.9 (4.3, 5.7)
Months from start of PrEP episode to HIV diagnosis, median (IQR)	3 (NA)	7 (4, 10)

Figure 2. PrEP coverage within the first 12 months since PrEP episode start

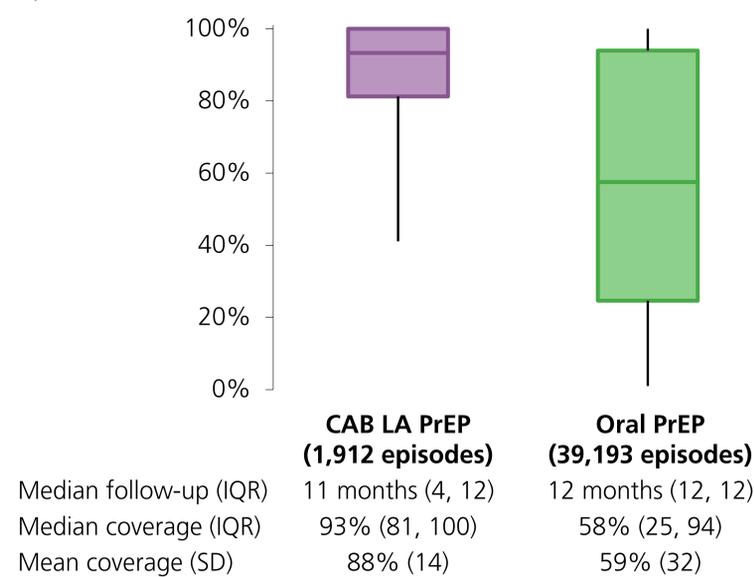


Figure 3. Incidence rate ratio of HIV acquisition within first 12 months of PrEP episode start with oral PrEP compared to CAB LA PrEP

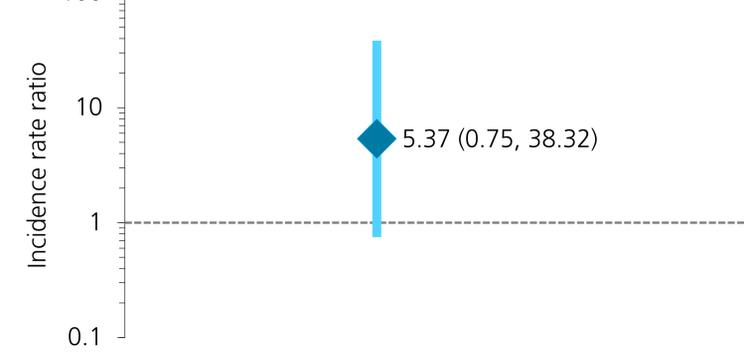


Table 3. HIV testing within the first 12 months since PrEP episode start^a

	CAB LA PrEP episodes N = 1,912	Oral PrEP Episodes N = 39,193
Total HIV testing events, N	9,276	111,003
Person-years of follow-up	1,424	38,221
IR per person-years (95% CI)	6.51 (6.38, 6.65)	2.90 (2.89, 2.92)

^a Testing performed ≤14 days before, up to ≤12 months after PrEP episode start

Abbreviations: CAB LA, cabotegravir long-acting; CI, confidence interval; FDA, Food and Drug Administration; FTC, emtricitabine; IQR, interquartile range; IR, incidence rate; IRR, incidence rate ratio; N, number; NA, not applicable; PrEP, preexposure prophylaxis; SD, standard deviation; STI, sexually transmitted infection; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate, Rx, prescription

Discussion

- A total of 39,011 PrEP users contributed 1,912 CAB LA PrEP and 39,193 oral PrEP episodes (Fig 1)
- Medicare/Medicaid enrolment and transgender identity were more common with CAB LA PrEP (Table 1)
- PrEP coverage was higher with CAB LA than oral PrEP (Fig 2)
 - CAB LA PrEP: median 93% coverage (IQR: 81, 100) over a median 11 months of follow-up
 - Oral PrEP: median 58% coverage (IQR: 25, 94) over a median 12 months of follow-up
- Within 12 months of start, HIV acquisition was less frequent on CAB LA than oral PrEP (Table 2, Fig 3)
 - 1 HIV acquisition after 3 months on CAB LA PrEP, no HIV test performed before start [see poster 979]
 - 181 HIV acquisitions after a median of 7 months on oral PrEP (IQR: 4, 10)
 - HIV acquisition rates were >5 times higher on oral PrEP than on CAB LA PrEP (not statistically significant): IRR = 5.40 (95% CI: 0.76, 38.51)
- HIV testing was performed more than twice as frequently during CAB LA than oral PrEP (Table 3)
- Limitations
 - Unlike CAB LA PrEP (directly observed injections), Rx-based oral PrEP may lead to measurement error
 - Unknown timing of pharmacy dispensing
 - Unknown PrEP on-demand use
 - Unknown planned pauses vs. suboptimal adherence
 - Oral bridging during CAB LA PrEP injection gaps could not be assessed due to inconsistent recording
 - HIV acquisition rates may be underestimated when testing is infrequent

Key Findings

In this real-world US cohort of PrEP users:

- PrEP coverage with CAB LA was very high, and considerably higher than with oral PrEP
- HIV acquisition while on PrEP was rare
- Despite more frequent testing, HIV acquisition was numerically lower on CAB LA than oral PrEP

These findings confirm the importance of PrEP access and formulation options to end the HIV epidemic

Acknowledgements

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