Adherence and Persistence in US Real-World New PrEP Users: Cabotegravir (CAB-LA) vs Oral PrEP

Aimee A. Metzner,[1] Catherine Nguyen,[2] Farbod Alinezhad,[3] Azeem Banatwala,[2] Leili Young-Xu,[3] Gabrielle Herman,[1] Dora Martinez,[1] Shana Walko,[1] Maral DerSarkissian[2]

[1]ViiV Healthcare, Durham, NC, USA; [2]Analysis Group, Inc, Los Angeles, CA, USA; [3]Analysis Group, Inc, Boston, MA, USA

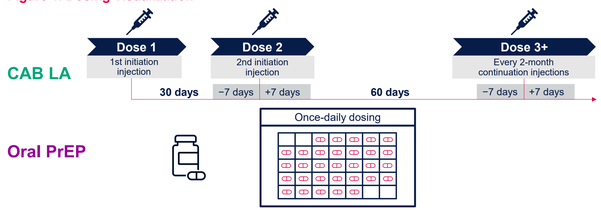
Plain Language Summary

- In real-world US settings, people who started long-acting cabotegravir stayed on HIV prevention longer and were more likely to use it as recommended than people who started daily oral pre-exposure prophylaxis (PrEP)
- These findings suggest that long-acting cabotegravir may help more people maintain effective use of PrEP over time, which is important for preventing HIV

Introduction

- The United States Food and Drug Administration approved long-acting cabotegravir (CAB LA) for HIV pre-exposure prophylaxis (PrEP) in 2021[1]; however, real-world data show that oral PrEP adherence does not align with labeled daily dosing requirements[2]
  - In a national retrospective cohort study, 82% of individuals newly using oral PrEP achieved a proportion of days covered (PDC) ≥0.80 from initiation to the first day of a 60-day gap; the Pharmacy Quality Alliance utilizes a threshold of 90% (0.9) PDC for antiretroviral medications[2,3]
- There is a need to understand how adherence and persistence compare between CAB LA and daily oral PrEP in real-world settings
- CAB LA is an intramuscular gluteal injection given every 2 months after initiation is complete, whereas oral PrEP is taken daily (Figure 1)

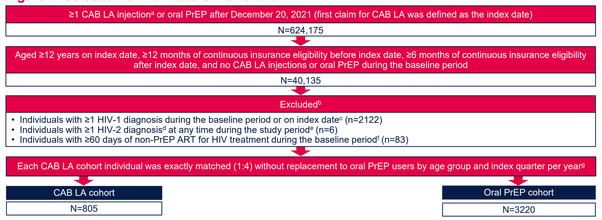
Figure 1. Dosing Visualization



Methods

- PrEPFACTS was a retrospective US cohort study using data from the Komodo Research Database (December 1, 2020, to September 30, 2024)
- Inclusion criteria
  - Individuals aged ≥12 years who received ≥1 CAB LA injection or oral PrEP fill (first claim defined as the index date)
  - Individuals who had ≥12 months of continuous insurance eligibility before the index date (defined as baseline period)
  - Individuals who had ≥6 months of continuous insurance eligibility after the index date
- Key exclusion criteria are summarized in Figure 2

Figure 2. Selection of Individuals Flowchart



ART, antiretroviral therapy; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, national drug code. [a]NDCs 49702-238-03, 49702-238-61, 49702-264-23, and 49702-280-63 were utilized to identify individuals using CAB LA. [b]Exclusion criteria was applied sequentially rather than simultaneously. [c]ICD-10-CM diagnosis codes Z21 and B20 were utilized to identify HIV-1. [d]ICD-10-CM diagnosis code B97.35 was utilized to identify HIV-2. [e]The study period was December 1, 2020, to September 30, 2024. [f]Non-PrEP ART was identified utilizing NDC codes; 24 people with claims for both CAB LA and oral PrEP on the same date were excluded. [g]A total of 37,117 individuals met the oral PrEP cohort selection criteria and 807 people met the CAB LA cohort selection criteria before matching. Two people using CAB LA were excluded due to insufficient matches based on their index date in the 2nd quarter of 2024.

PrEPFACTS was a retrospective US cohort study that reported real-world adherence and persistence among individuals newly using long-acting cabotegravir (CAB LA) compared with individuals newly using oral pre-exposure prophylaxis (PrEP).

- Each individual in the CAB LA cohort was exact matched to 4 individuals using oral PrEP by age group and index quarter per year
- Standardized mortality ratio (SMR) weighting was applied after matching to ensure comparability between cohorts
  - The SMR weights were generated using propensity scores to balance baseline characteristics between cohorts
- Adherence was described using PDC from index date to discontinuation, with PDC ≥90% considered adherent[3]
  - Discontinuation was defined as ≥60 days since exhaustion of previous supply of oral PrEP, a gap of ≥91 days after the first CAB LA injection or ≥121 days after subsequent injections
- Logistic and Cox proportional hazards regression models were used to determine the odds of adherence and risk of discontinuation, respectively
- An SMR-weighted Kaplan–Meier analysis was used to estimate days until discontinuation (hereafter referred to as persistence)

Results

Demographic Characteristics

- The CAB LA cohort (N=805) had a median (IQR) age of 33 (27-44), with primarily commercial (48%) and Medicaid (48%) insurances (Table)
  - 67% were male, 31% White, and 26% Black

Table. Baseline Demographics and Characteristics

Parameter, n (%)[b]	Original sample		SMR-weighted sample[a]	
	CAB LA cohort (N=805)	Oral PrEP cohort (N=3220)	CAB LA cohort (N=805)	Oral PrEP cohort (N=795)
Age at index, median (IQR), y	33 (27-44)	33 (26-43)	33 (27-44)	33 (26-42)
Sex recorded by payer				
Male	539 (67)	2904 (90)	539 (67)	542 (68)
Female	255 (32)	268 (8)	255 (32)	242 (31)
Other/Unknown	11 (1)	48 (2)	11 (1)	12 (1)
Transgender identity[c]				
Transgender men	78 (10)	61 (2)	78 (10)	76 (10)
Transgender women	48 (6)	142 (4)	48 (6)	46 (6)
Race and ethnicity[d]				
White	253 (31)	1094 (34)	253 (31)	246 (31)
Black or African American	206 (26)	430 (13)	206 (26)	203 (26)
Hispanic or Latin American	139 (17)	480 (15)	139 (17)	136 (17)
Asian or Pacific Islander	28 (4)	123 (4)	28 (4)	26 (3)
Race not listed or unknown	179 (22)	1093 (34)	179 (22)	185 (23)
Insurance plan type				
Commercial	389 (48)	2444 (76)	389 (48)	395 (50)
Medicaid	385 (48)	670 (21)	385 (48)	372 (47)
Medicare	30 (4)	96 (3)	30 (4)	27 (3)
Insurance plan not listed/unknown	1 (<1)	10 (<1)	1 (<1)	1 (<1)

DSM, Diagnostic and Statistical Manual of Mental Disorders; IQR, interquartile range. [a]Covariates included in the propensity score used to generate SMR weights were sex recorded by payer, race/ethnicity, US census bureau region, insurance plan type, baseline comorbidities of interest, Elixhauser comorbidities, DSM-V psychiatric comorbidities, concomitant medications, and all-cause healthcare resource utilization. [b]Unless indicated otherwise. [c]An algorithm was used to identify individuals likely to identify as a gender different than their sex assigned at birth based on medical claims data. [d]Race and ethnicity could not be reported as mutually exclusive categories due to categories being defined as such in the Komodo Research Database.

- The oral PrEP cohort (N=3220) had a median (IQR) age of 33 (26-43) and were primarily commercially insured (76%), White (34%), and males (90%)
- After SMR-weighting, the characteristics of individuals using PrEP were similar between cohorts

Adherence

- A significantly larger proportion of the CAB LA cohort was adherent compared with that of the oral PrEP cohort (Figures 3 and 4)
  - CAB LA users had 2.2 times higher odds of being adherent compared with oral PrEP users in the SMR-weighted cohort (OR [95% CI] 2.20 [1.71, 2.85]; *P*<0.001)
    - Similar results were observed in the unadjusted sample (OR [95% CI] 2.12 [1.71, 2.85]; *P*<0.001)

Figure 3. Descriptive Adherence Analysis

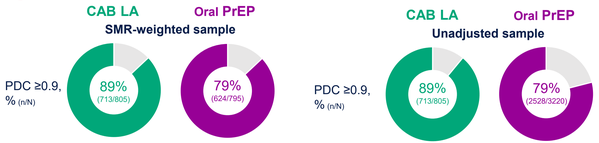
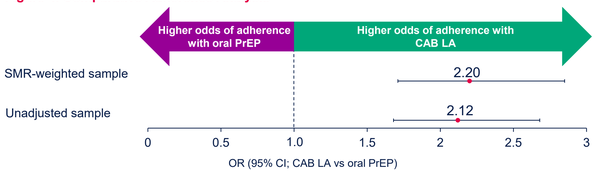


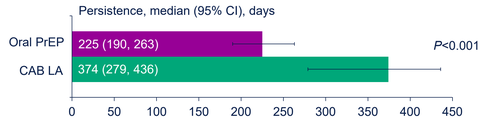
Figure 4. Comparative Adherence Analysis



Persistence

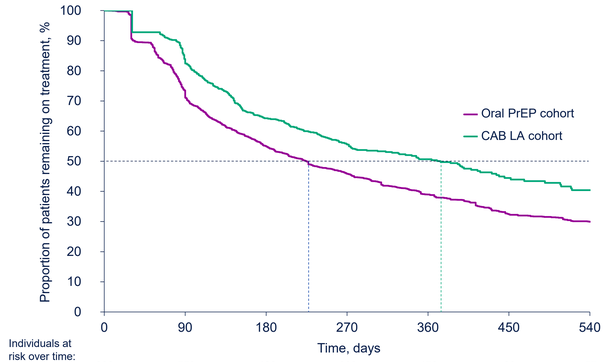
- Among individuals newly initiating PrEP with ≥2 CAB LA injections or oral PrEP fills, median (95% CI) persistence on CAB LA and oral PrEP in the SMR-weighted sample was 374 (279, 436) and 225 (190, 263) days, respectively (Figure 5) and 374 (279, 436) and 267 (245, 286) for the unadjusted sample, respectively

Figure 5. Persistence Among the SMR-Weighted Sample



- The risk of discontinuation was significantly lower in the CAB LA cohort vs the oral PrEP cohort in both unadjusted and SMR-weighted oral PrEP cohorts (hazard ratio [95% CI]: 0.79 [0.70, 0.90] and 0.71 [0.62, 0.82], respectively; both *P*<0.001; Figure 6)
  - Note, as the proportional-hazards assumption was not met for this analysis, the hazards ratios should be interpreted as weighted average effects over the follow-up period, consistent with the literature supporting that Cox model estimates retain meaningful interpretation even under non-proportional hazards[4]

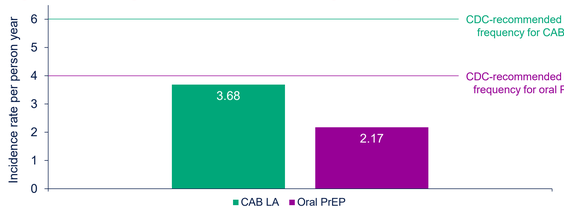
Figure 6. SMR-Weighted Kaplan–Meier Analysis of Persistence Among Individuals Newly Using PrEP Receiving CAB LA or Oral PrEP (At Least 2 Injections or Oral PrEP Fills)



Individuals at risk over time:							
CAB LA	666	559	428	283	170	89	57
Oral PrEP cohort	622	506	347	206	121	68	40

- Individuals in the CAB LA cohort had a higher rate of HIV testing while on PrEP compared with individuals in both the unadjusted and SMR-weighted oral PrEP cohorts (unadjusted incidence rate ratio [95% CI] 1.97 [1.81, 2.15]; adjusted IRR 1.90 [1.77, 2.04]; both *P*<0.001; Figure 7)

Figure 7. HIV Testing While on PrEP in the SMR-Weighted Sample[a]



CDC, Centers for Disease Control; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System. [a]HIV testing was identified using CPT codes 86689, 86701–86703, and 87389–87391, 87534–87539 and HCPCS codes G0432-G0435 over the "time on PrEP," defined as the time period between the index date (the date of the first claim for CAB LA or oral PrEP) and earliest of the date of PrEP discontinuation, end of continuous enrollment, death, or end of data availability. Average (standard deviation) time on PrEP was 226 (187) days for the CAB LA cohort and 214 (181) days for the oral PrEP cohort. [b]CDC guidelines recommend that HIV testing should be repeated at least every 3 months after oral PrEP initiation and every 2 months when CAB LA injections are given.[5] [c]Unadjusted oral PrEP cohort incidence rate was 1.82.

Conclusions

- As adherence and persistence are critical for HIV PrEP effectiveness,[5] individuals newly using PrEP on CAB LA exhibited statistically significant improved adherence and persistence relative to individuals who chose oral PrEP
- Individuals using CAB LA were tested for HIV at nearly twice the rate of individuals using oral PrEP, while neither group met their respective testing frequencies recommended by the CDC[5]

Acknowledgments: This study was funded by ViiV Healthcare. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by Fingerpaint Medical and funded by ViiV Healthcare.

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Presenting author: Aimee A. Metzner; aimee.a.metzner@viivhealthcare.com