

Pre-Exposure Prophylaxis with Cabotegravir Long-Acting Injectable in the OPERA Cohort

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Background

- Cabotegravir long-acting (CAB LA) was approved as pre-exposure prophylaxis (PrEP) for the prevention of HIV by the FDA on 20DEC2021.
- CAB LA PrEP may be especially appropriate in the context of sub-optimal oral PrEP adherence.¹
 - In the HPTN 083 trial, adherence was achieved by 92% of CAB LA and 72% of oral PrEP users.²
- Real-world evidence on use of CAB LA PrEP is limited.

Objective

To describe uptake and injection patterns of CAB LA for PrEP in routine clinical care in the US.

Methods

Study population

- OPERA cohort:
 - Prospectively captured, routine clinical data from electronic health records in the US
 - 101 clinics in 23 US states/territories
 - >879K HIV-negative individuals; 40,697 PrEP users
- Inclusion criteria:
 - HIV-negative
 - Aged ≥12 years old
 - ≥1 CAB LA injection between 21Dec2021 and 31Mar2023
- Censoring criteria: study end (30Jun2023), incomplete initiation, CAB LA discontinuation, loss to follow-up, death, or HIV acquisition.

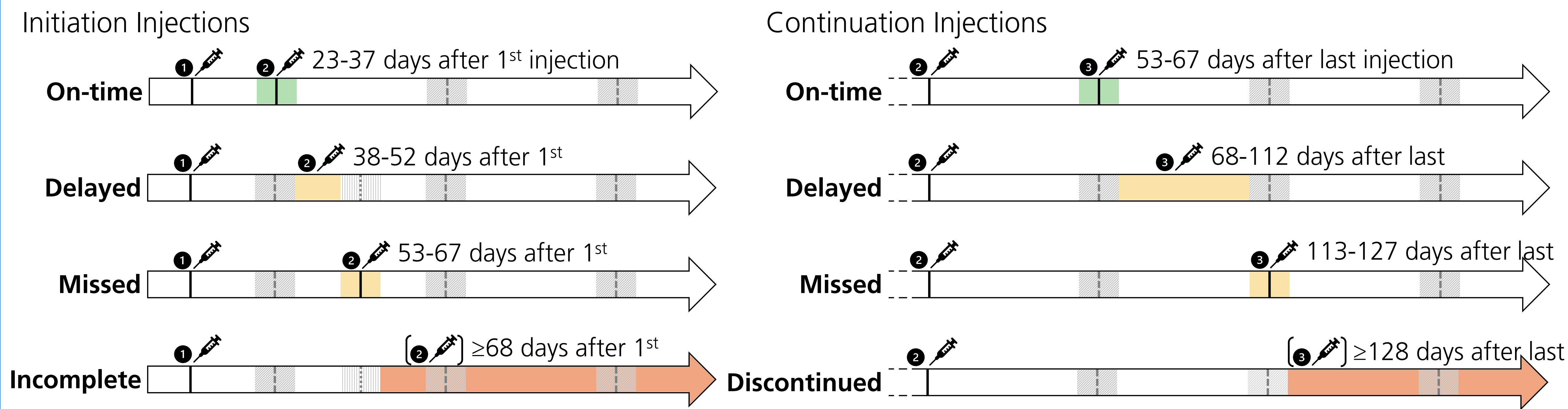
Definition of injection patterns

- Among all CAB LA users:
 - Incomplete initiation: receipt of the first injection, with no additional injection ≤68 days after the 1st
- Among complete initiators:
 - Discontinuation: ≥128 days without injection
 - Non-adherence: ≥1 delayed or missed injection
- See **Figure 1** for more details

Statistical analyses

- Predictors of non-adherence: multivariable logistic regression

Figure 1. Definitions of CAB LA injection patterns



Results

Figure 2. CAB LA injection patterns

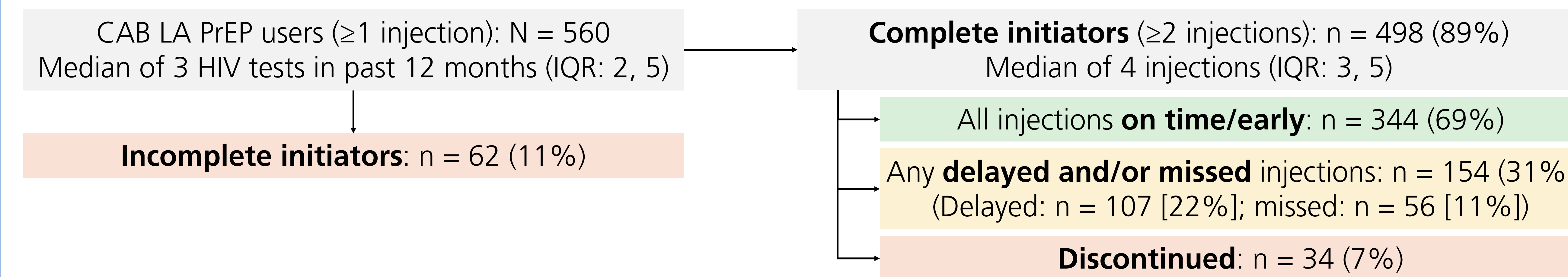
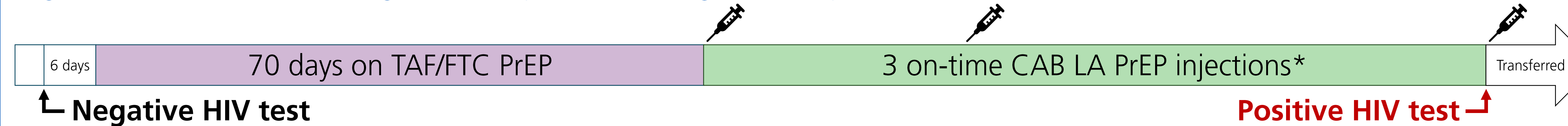


Figure 3. Timeline of the single HIV acquisition during follow-up



* No HIV tests were administered prior to switching from oral PrEP to CAB LA PrEP

Table 1. Baseline characteristics and likelihood of non-adherence to injection schedule among complete initiators

	No delayed or missed injection	Any delayed and/or missed injection	aOR (95% CI)
N	344	154	NA
Age	Median: 32 (IQR: 27, 40)	Median: 31 (IQR: 26, 40)	0.97 (0.78, 1.20) ^a
Female	43 (13%)	20 (13%)	0.61 (0.26, 1.39)
Black race ^b	109 (32%)	52 (34%)	1.03 (0.62, 1.70)
Hispanic ethnicity	103 (30%)	40 (26%)	0.75 (0.44, 1.30)
Southern US	106 (31%)	54 (35%)	1.28 (0.80, 2.06)
Married or in a domestic partnership ^c	41 (12%)	16 (10%)	0.87 (0.44, 1.71)
Any STI within 12 months prior to 1 st injection	145 (42%)	66 (43%)	0.98 (0.62, 1.56)
Any history of PrEP use	299 (87%)	142 (92%)	1.72 (0.78, 3.77)

^a Per 10-year increase.

^b Missing race: n=29.

^c Missing marital status: n=98.

Abbreviations: aOR, adjusted odds ratio; CAB, cabotegravir; CI, confidence interval; FTC, emtricitabine; IQR, interquartile range; LA, long-acting; N, number; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TAF, tenofovir alafenamide.

Discussion

- 560 HIV-negative individuals received ≥1 CAB LA PrEP injection through routine clinical care in OPERA; most (89%) completed the 2 initiation injections (**Figure 2**).
- Oral PrEP use and diagnoses of sexually transmitted infections were common prior to CAB LA PrEP initiation (**Table 1**).
- Among complete initiators:
 - 69% complied with the injection schedule and received all injections on-time (**Figure 2**).
 - 11% missed an injection (**Figure 2**), although oral bridging to cover missed injections could not be ascertained for all individuals.
 - No statistically significant predictor of non-adherence could be identified (**Table 1**).
- Only 1 person tested positive for HIV during CAB LA PrEP use (**Figure 3**).
 - The timing of HIV acquisition is uncertain due to the absence of HIV testing immediately prior to the first CAB LA injection.

Key Findings

- Over two thirds (69%) of CAB LA PrEP users adhered to the injection schedule.
- While 11% missed an injection, this may be an overestimate of true gaps in therapy if oral bridging was used.
- Continued counseling on the importance of adhering to the CAB LA PrEP injection schedule is needed.

References

1. Department of Health & Human Services, Centers for Disease Control and Prevention. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2021 Update Clinical Practice Guideline.
2. Landovitz et al. Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. *N Engl J Med* 2021; 385: 595-608.

Acknowledgements

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