1110

Real-World Use of Cabotegravir Long-Acting for Pre-Exposure Prophylaxis: Trio Health Cohort

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BACKGROUND

- Cabotegravir (CAB) long-acting (LA) for pre-exposure prophylaxis (PrEP) was approved in the United States in December 2021 to reduce the risk of sexually acquired HIV-1 infection.
- The Centers for Disease Control and Prevention (CDC) guidelines state that both HIV antigen (Ag)/antibody (Ab) and HIV RNA testing should be conducted at every injection.
- Real-world testing, effectiveness, and adherence were assessed among individuals initiating CAB LA for PrEP in the US.

METHODS

- Individuals without HIV initiating CAB LA for PrEP were identified from electronic health record data from a subset of sites in Trio Health cohort with adjudicated CAB LA PrEP injection dates between December 2021-May 2023.
- HIV testing and incidence were assessed among individuals with at least one injection of CAB LA. HIV testing was assessed at baseline within 90 days prior to the first injection and during follow-up within ±14 days of injection.
- Incident HIV was defined as either a positive HIV Ag/Ab lab result with confirmatory HIV RNA test or one detectable HIV RNA.
- Adherence was assessed among individuals with ≥2 injections of CAB LA for PrEP. On-time injections were defined as occurring within the target window (±7 days of target date) and missed injections were defined as receiving no injections for a full injection cycle.
- Potential hypersensitivity reactions were identified through ICD-10 codes for rash and reviewed by independent adjudication committee.

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Cabotegravir long-acting for pre-exposure prophylaxis is effective at preventing HIV acquisition and well tolerated.

Table 1. Study Population Characteristics

Study Population Characteristics, n (%)		Individuals with ≥1 Documented Injection N=85	Individuals with ≥2 Documented Injections N=64	Individuals with ≥3 Documented Injections N=43
Age	Age, median (IQR)	41 (33,48)	41 (34,48)	43 (38,52)
Gender	Female	5 (5.9%)	5 (7.8%)	2 (4.7%)
	Male	79 (92.9%)	58 (90.6%)	40 (93.0%)
	Unknown gender	1 (1.2%)	1 (1.6%)	1 (2.3%)
Race	White	51 (60.0%)	42 (65.6%)	30 (69.8%)
	Black or African American	8 (9.4%)	6 (9.4%)	3 (7.0%)
	Hispanic or Latino	16 (18.8%)	11 (17.2%)	7 (16.3%)
	Other Race	2 (2.4%)	1 (1.6%)	0 (0.0%)
	Unknown Race	8 (9.4%)	4 (6.2%)	3 (7.0%)
Payer Type	Commercial	55 (64.7%)	45 (70.3%)	33 (76.7%)
	Medicaid/Medicare	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Other/Self Pay	7 (8.2%)	7 (10.9%)	5 (11.6%)
	Unknown Payer	23 (27.1%)	12 (18.8%)	5 (11.6%)
Region	East	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Northeast	0 (0.0%)	0 (0.0%)	0 (0.0%)
	South	70 (82.4%)	59 (92.2%)	43 (100.0%)
	West	15 (17.6%)	5 (7.8%)	0 (0.0%)
PrEP History	Prior FTC/TAF	62 (72.9%)	47 (73.4%)	33 (76.7%)
	Prior FTC/TDF	46 (54.1%)	35 (54.7%)	25 (58.1%)
	Prior both FTC/TAF & FTC/TDF	35 (41.2%)	26 (40.6%)	22 (51.2%)
HIV Testing within 90 days prior to 1st injection	HIV Ag/Ab-	85 (100.0%)	64 (100.0%)	43 (100.0%)
	HIV Ag/Ab+	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Unknown HIV Ag/Ab	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Undetectable HIV RNA	65 (76.5%)	52 (81.2%)	37 (86.0%)
	Unknown HIV RNA	20 (23.5%)	12 (18.8%)	6 (14.0%)

Figure 1. Proportion of CAB LA PrEP Initiators with all on time injections by Injection Period

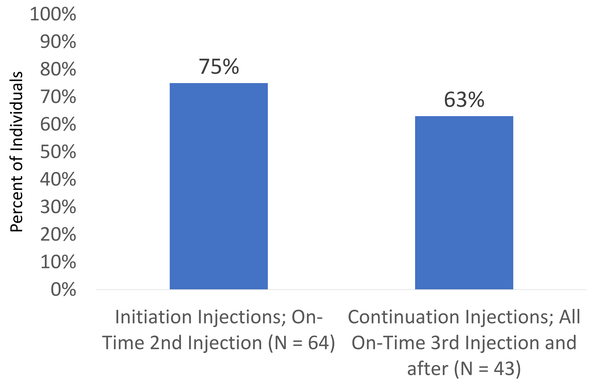
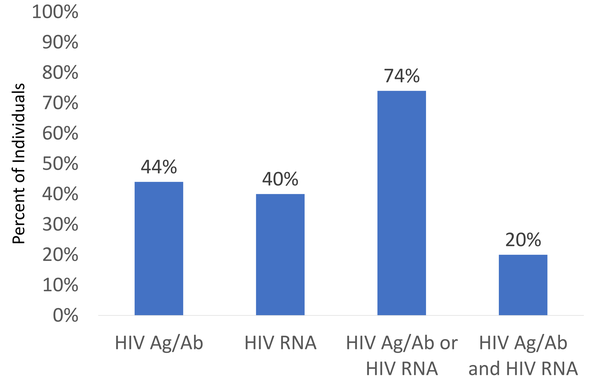


Figure 2. Proportion of CAB LA PrEP Initiators with HIV screening at all follow-up injections (N=64)



RESULTS

- Among 85 individuals with ≥1 documented injection of CAB LA for PrEP, the majority were male (93%), White (60%), from the Southern region of US (82%), with median age 41 years [Table 1].
- Of 64 individuals with ≥2 injections of CAB LA, 48 (75%) had on-time 2nd injection [Figure 1].
- Among 43 individuals with ≥3 injections, 27 (63%) had all continuation injections on-time, and no missed injections were observed.
- Within 90 days prior to initiation, all individuals had ≥1 documented HIV Ag/Ab or HIV RNA, and 77% had both tests.
- During follow-up, 74% of individuals had either HIV Ag/Ab or HIV RNA results at all injections, while 44% had HIV Ag/Ab results, 40% had HIV RNA results, and 20% of individuals had both HIV RNA and HIV Ag/Ab results [Figure 2].
- No incident HIV diagnoses were identified, and no hypersensitivity reactions were observed.
- Of the 85 individuals, 94% continued on CAB LA PrEP at analysis date.

CONCLUSIONS

- Initial data from Trio cohort suggest CAB LA for PrEP is effective at preventing HIV acquisition.
- Injections were administered on-time among most individuals.
- HIV testing practices in this real-world setting during the early period of CAB LA for PrEP did not align with the CDC testing guidelines among a significant proportion of CAB LA for PrEP users.

ACKNOWLEDGEMENTS

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