Consistently high cabotegravir + rilpivirine long-acting persistence and effectiveness across ages and race/ethnicity in the US OPERA Cohort

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Background

- CAB+RPV LA is the only complete LA ART regimen
  - Approved in January 2021 for the treatment of HIV
  - Indicated for ART-experienced individuals with VL < 50 copies/mL at CAB+RPV LA initiation
  - Injections monthly or every two months
- High efficacy and effectiveness demonstrated in clinical trials and observational studies
- CAB+RPV LA is increasingly used among diverse groups of people
  - Limited literature on CAB+RPV LA treatment outcomes by age and race/ethnicity

Objective

Describe persistence and virologic outcomes by age and race/ethnicity among CAB+RPV LA users in routine clinical care in the US

Methods

OPERA Cohort

- Prospectively captured, routine clinical data from electronic health records in the US (101 clinics, 23 US states/territories)

Inclusion Criteria

- Aged ≥18 years
- Treatment-experienced
- Switched to CAB+RPV LA between 21 January 2021 and 31 December 2025
- VL < 50 copies/mL at CAB+RPV LA initiation

Censoring Criteria

- CAB+RPV LA discontinuation (> 67 and > 127 days without injections for the monthly and every 2 months dosing, respectively)
- End of study period (28 February 2026)
- Loss to follow-up (i.e., no clinic contact for 12 months)
- Death

Stratification

- Age at first CAB+RPV LA injection: 18-49 vs. 50-64 vs. ≥ 65
- Race/ethnicity: Hispanic vs. non-Hispanic Black vs. non-Hispanic White

Outcomes

- Among complete initiators (first 2 injections ≤ 67 days apart)
  - **Persistence**: on CAB+RPV LA at study end
- Among complete initiators with ≥1 follow-up VL
  - **Maintenance of virologic suppression**
    - Last follow-up VL < 50 c/mL
    - All follow-up VL < 50 c/mL
  - **Confirmed Virologic Failure**
    - Two consecutive VLs ≥200 c/mL or
    - VL ≥ 200 c/mL followed by CAB+RPV LA discontinuation within 2 months (monthly dosing) or within 4 months (every 2 months dosing)

Abbreviations

ART, antiretroviral therapy; **CAB+RPV**, cabotegravir + rilpivirine; **INSTI**, integrase strand transfer inhibitor; **IQR**, interquartile range; **LA**, long-acting; **N**, number; **VL**, viral load

Results

Table 1. Demographic and clinical characteristics at the first CAB+RPV LA injection, stratified by age

	Aged 18-49 (N=5,352)	Aged 50-64 (N=1,352)	Aged ≥ 65 (N=251)
Female, n (%)	626 (12)	276 (20)	62 (25)
Years since HIV diagnosis, median (IQR)	4 (1, 9)	12 (3, 23)	17 (5, 29)
VACS, median (IQR)[a]	19 (13, 26)	31 (26, 37)	43 (35, 52)
Months on prior regimen, median (IQR)	19 (8, 40)	28 (11, 52)	25 (9, 54)
Switched from an INSTI-based regimen, n (%)	4,400 (82)	939 (70)	147 (59)

[a] VACS mortality index estimates the risk of 5-year all-cause mortality in individuals with HIV, with higher scores indicating a higher risk of death within 5 years (range: 0 to 129)

Table 2. Demographic and clinical characteristics at the first CAB+RPV LA injection, stratified by race/ethnicity[a]

	Hispanic (N=2,215)	Non-Hispanic Black (N=2,686)	Non-Hispanic White (N=1,346)
Female, n (%)	183 (8.3%)	574 (21.4%)	137 (10.2%)
Years since HIV diagnosis, median (IQR)	4 (1, 10)	6 (2, 12)	6 (2, 14)
VACS, median (IQR)[b]	21 (14, 29)	21 (14, 30)	25 (18, 34)
Months on prior regimen, median (IQR)	19 (8, 40)	23 (9, 46)	20 (7, 43)
Switched from an INSTI-based regimen, n (%)	1,837 (83)	2,095 (78)	996 (74)

[a] Missing race/ethnicity (N=708)
[b] VACS mortality index estimates the risk of 5-year all-cause mortality in individuals with HIV , with higher scores indicating a higher risk of death within 5 years (range: 0 to 129)

Table 3. CAB+RPV LA complete initiation, dosing, persistence and confirmed virologic failure, stratified by age

	Aged 18-49 (N=5,352)	Aged 50-64 (N=1,352)	Aged ≥ 65 (N=251)
Number of viral loads per person, median (IQR)	13 (7, 21)	20 (11, 33)	23 (11, 39)
Completed initiation, n (%)	4,908 (92)	1,223 (90)	231 (92)
Q2M dosing schedule at initiation, n (%)	4,519 (92)	1,102 (90)	195 (84)
Q2M dosing schedule at study end, n (%)	4,749 (97)	1,181 (97)	221 (96)
Months on CAB+RPV LA until first censoring event, median (IQR)	14 (7, 25)	15 (8, 30)	18 (10, 34)
On CAB+RPV LA at study end, regardless of previous discontinuation(s), n (%)	3,788 (77)	905 (74)	186 (80)
Cumulative months on CAB+RPV LA at study end, median (IQR)	17 (8, 30)	20 (9, 35)	23 (11, 37)
Confirmed virologic failure, n (%)	53 (1)	14 (1)	1 (<1)

Table 4. CAB+RPV LA complete initiation, dosing, persistence and confirmed virologic failure, stratified by race/ethnicity[a]

	Hispanic (N=2,215)	Non-Hispanic Black (N=2,686)	Non-Hispanic White (N=1,346)
Number of viral loads per person, median (IQR)	13 (8, 22)	15 (9, 25)	16 (8, 27)
Completed initiation, n (%)	2,066 (93)	2,436 (91)	1,223 (91)
Q2M dosing schedule at initiation, n (%)	1,929 (93)	2,226 (91)	1,074 (88)
Q2M dosing schedule at study end, n (%)	2,009 (97)	2,351 (96)	1,179 (96)
Months on CAB+RPV LA until first censoring event, median (IQR)	14 (8, 25)	14 (8, 26)	15 (8, 29)
On CAB+RPV LA at study end, regardless of previous discontinuation(s), n (%)	1,600 (77)	1,910 (78)	870 (71)
Cumulative months on CAB+RPV LA at study end, median (IQR)	17 (8, 30)	17 (9, 31)	20 (10, 34)
Confirmed virologic failure, n (%)	16 (1)	35 (2)	12 (1)

[a] Missing race/ethnicity (N=708)

Figure 1. Last VL < 50 copies/mL among complete initiators with ≥ 1 follow-up VL

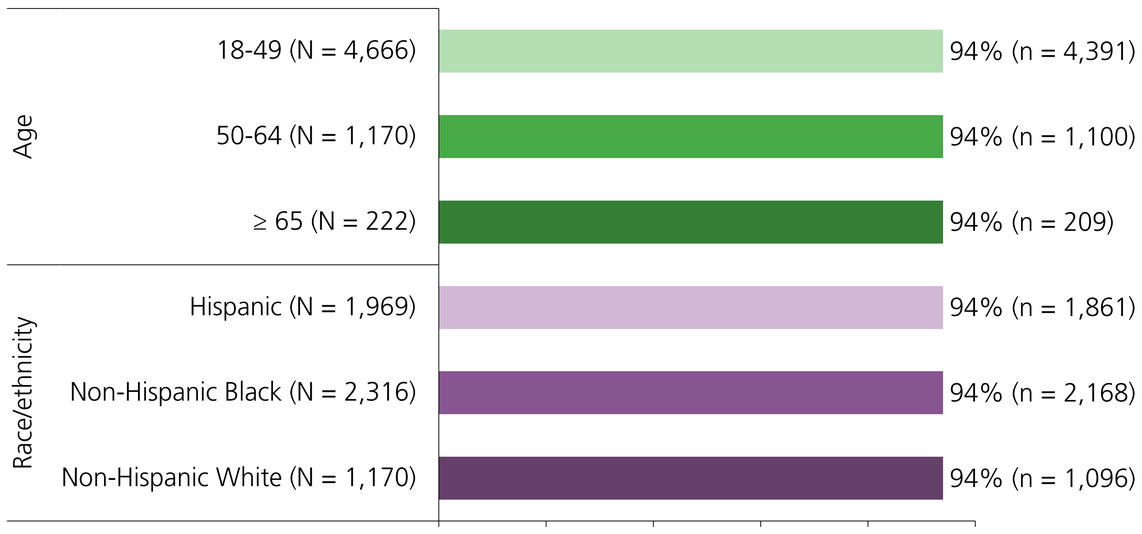
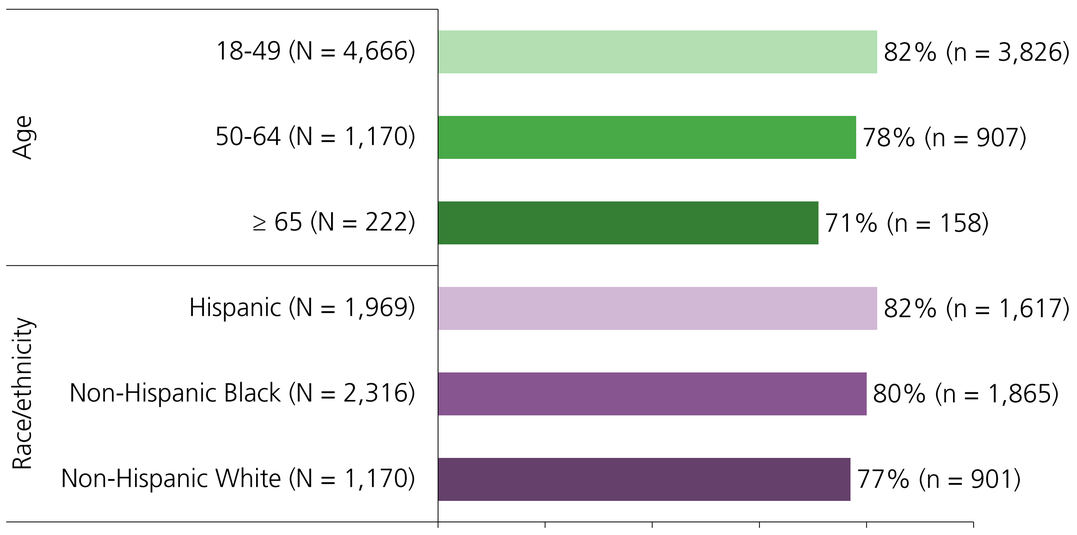


Figure 2. All VL < 50 copies/mL among complete initiators with ≥ 1 follow-up VL



Discussion

Summary of findings

- Out of 6,955 adults starting CAB+RPV LA while virologically suppressed in OPERA, most (76%) were aged 18-49 and were either Hispanic (32%) or non-Hispanic Black (39%)
- Older individuals had been on the previous regimen for longer, but were less likely to switch from an INSTI-based regimen than younger individuals (**Table 1**); they also had more VL testing during follow-up (**Table 3**)
- Non-Hispanic Black individuals were more likely to be women, but other characteristics were somewhat balanced across race/ethnicity groups (**Table 2**)
- Most (90-93%) completed the initiation sequence, with no variation across age and race/ethnicity (**Tables 3-4**)
- At study end, 74-80% of complete initiators alive and in care remained on CAB+RPV LA for a median of 17-23 months, with minimal variation across age and race/ethnicity (**Tables 3-4**)
- Virologic effectiveness was high
  - Confirmed virologic failure was rare across all groups (**Tables 3-4**)
  - 94% were suppressed at last follow-up in all age and race/ethnicity groups (**Figure 1**)
  - A lower proportion of individuals aged ≥ 65 years maintained continuous suppression without any VL ≥ 50 copies/mL (71%) compared with those aged 18–49 years (82%); variation was minimal across race/ethnicity (**Figure 2**)

Strengths

- Real-world experience with CAB+RPV LA among virologically suppressed individuals
- OPERA cohort is representative of routine clinical care in the US
- Large population with variety of ages and races/ethnicities

Limitations

- Electronic health records data quality may vary across practices and providers; measurement error is possible
- Oral bridging is not well documented; this may result in overestimation of discontinuation and underestimation of cumulative time on CAB+RPV LA
- The number of individuals aged ≥ 65 was small, leading to some uncertainty around outcomes estimates in this group

Key Findings

- CAB+RPV LA showed high persistence and consistently high effectiveness across age and race/ethnicity groups
- Continuous virologic suppression was maintained by the majority of individuals across all groups
  - Although the proportion was somewhat lower among adults aged ≥ 65 years, this was not associated with a higher risk of virologic failure and may be attributable to increased VL monitoring frequency

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