High Suppression and Rare Virologic Failure with Long-Acting Cabotegravir + Rilpivirine: Real World Evidence Over Five Years from the OPERA Cohort

Ricky K. Hsu

AIDS Healthcare Foundation , New York, NY, USA

NYU Langone Medical Center, New York, NY, USA

OPERA® the longitudinal cohort

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Disclosures

- Research grants: Gilead Sciences, ViiV Healthcare
- Speaker honoraria: ViiV Healthcare, Merck, Gilead Sciences
- Advisory board participation: ViiV Healthcare, Gilead Sciences, Epividian

This study was supported by ViiV Healthcare

Learning Objectives

1. Describe the uptake of CAB+RPV LA over the first five years of availability in the United States (21Jan2021 - 31Dec2025)

2. Demonstrate real-world CAB+RPV LA patterns of use, virologic outcomes and persistence after a suppressed switch

3. Define provider-reported reasons for CAB+RPV LA discontinuation

Cabotegravir + Rilpivirine Long-Acting (CAB+RPV LA) Injectable



1st and only complete long-acting ART regimen approved for HIV treatment in the US (January 2021)



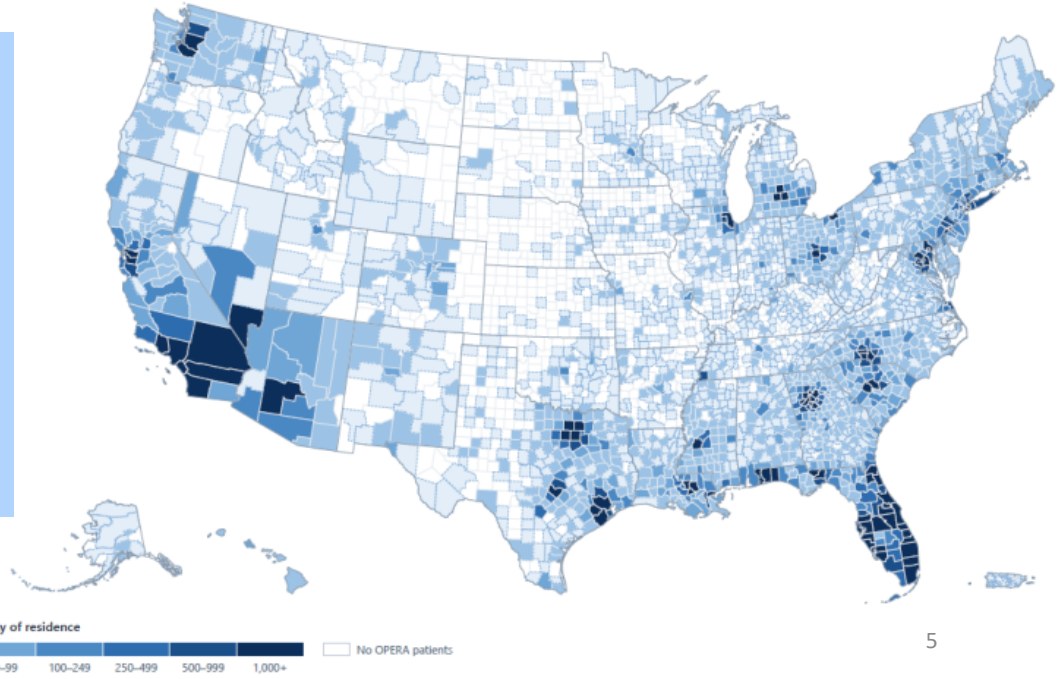
Injections monthly (Q1M) or every 2 months (Q2M)



Indicated for ART-experienced individuals with VL < 50 copies/mL

The Observational Pharmaco-Epidemiology Research & Analysis Cohort

- Collaboration between Epividian and providers since 2013
- Cohort of electronic health records from routine care in primary care clinics and wellness centers throughout the US
- 101 clinics in 23 US states & territories
- > 172,000 people with HIV



Study Population

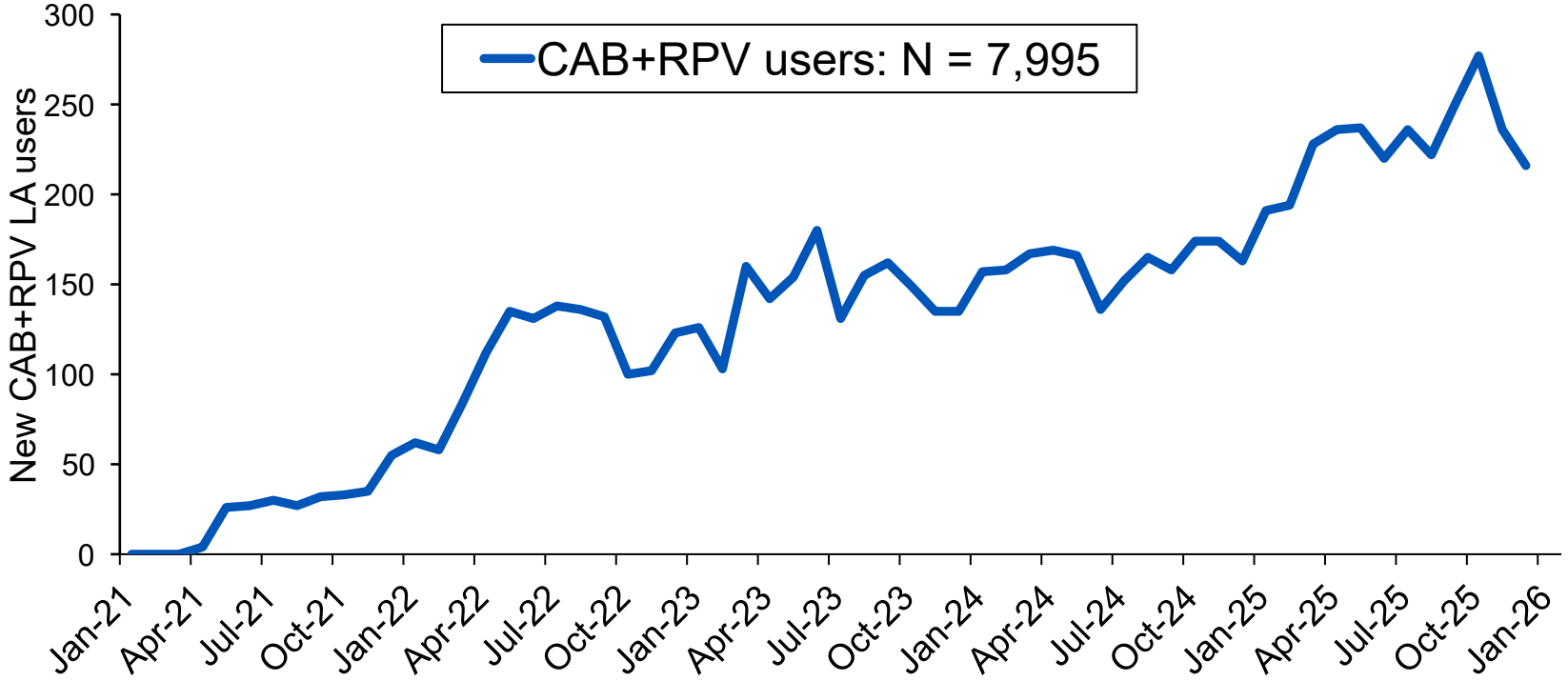
Inclusion Criteria	Censoring Criteria
◆ ≥18 years old ◆ ART-experienced ◆ 1st CAB+RPV LA injection between January 21, 2021 and December 31, 2025 ◆ Did not participate in CAB+RPV LA clinical trials	◆ CAB+RPV LA discontinuation ◆ Lost to follow-up ◆ Death ◆ Analysis end (February 28, 2026)

CAB+RPV LA Uptake

From January 21, 2021 to December 31, 2025

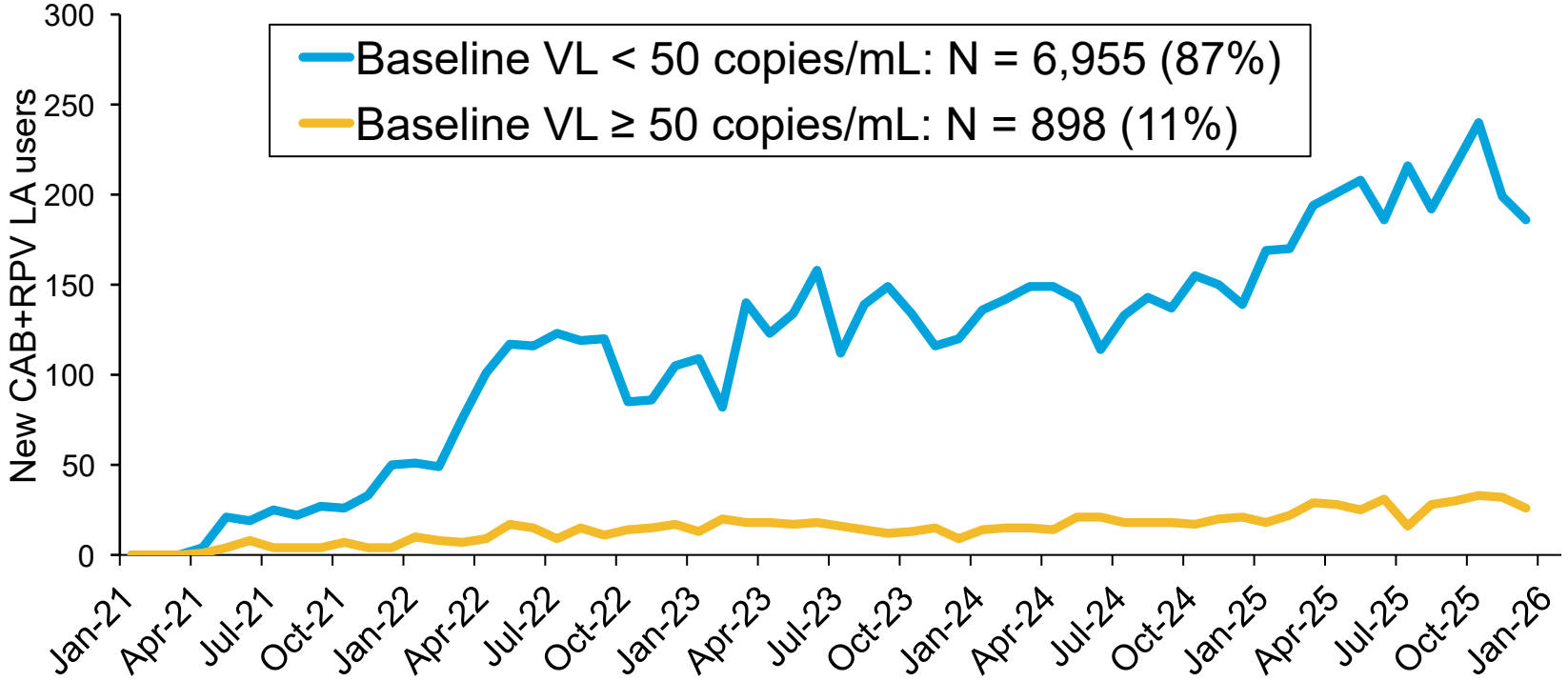
CAB+RPV LA Uptake

Overall



CAB+RPV LA Uptake

By Baseline VL*



* 142 individuals without a baseline VL ≤ 12 months before/at CAB+RPV LA start

Characteristics & Treatment Outcomes

Among CAB+RPV LA Users With a VL < 50 copies/mL

Baseline Demographic Characteristics

Among 6,955 People with Baseline VL < 50 copies/mL

	People with baseline VL < 50 N = 6,955
Age, median years (IQR)	38 (32, 49)
Age ≥50 years, n (%)	1,603 (23)
Male sex, n (%)	5,991 (86)
Black race, n (%)	3,002 (43)
Hispanic ethnicity, n (%)	2,215 (32)
Injection drug use (ever), n (%)	374 (5)
Care in Southern US, n (%)	3,959 (57)

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Baseline Clinical Characteristics

Among 6,955 People with Baseline VL < 50 copies/mL

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Years since HIV diagnosis, median (IQR)	5 (1, 12)
CD4 cell count, median cells/μL (IQR)	712 (528, 918)
BMI, median kg/m^2 (IQR)	27 (24, 31)
BMI ≥ 30 kg/m^2, n (%)	2,100 (30)
Months on prior regimen, median (IQR)	21 (8, 43)
Core class in prior regimen, n (%)	
INSTI	5,486 (79)
PI	254 (4)
NNRTI	364 (5)
≥2 core agents	400 (6)
Other/Missing	451 (6)

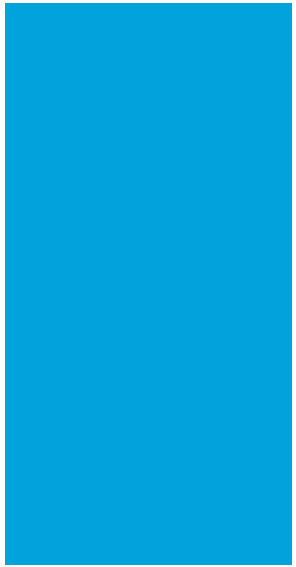
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CAB+RPV LA Initiation

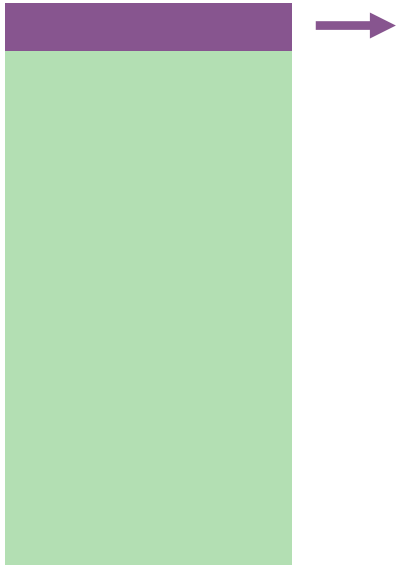
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N = 6,955
CAB+RPV LA users

CAB+RPV LA Initiation

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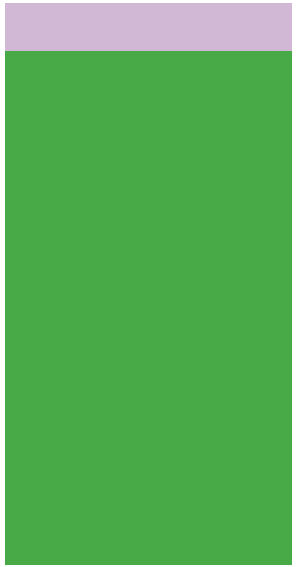


N = 6,955
CAB+RPV LA users

Incomplete initiation
(only 1 injection, or 2nd injection > 67days after the 1st)
n = 593 (8%)

CAB+RPV LA Initiation

Among 6,955 People with Baseline VL < 50 copies/mL



N = 6,955
CAB+RPV LA users

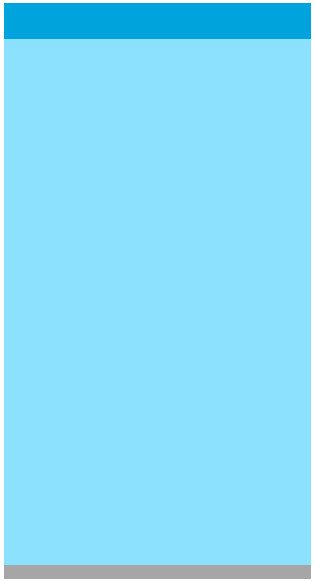
Complete initiation
(first 2 injections ≤67 days apart)
n = 6,362 (92%)

Median **14 months (IQR: 8, 27)**
on 1st CAB+RPV LA

CAB+RPV LA Dosing

Among 6,362 Complete Initiators with Baseline VL < 50 copies/mL

At regimen initiation

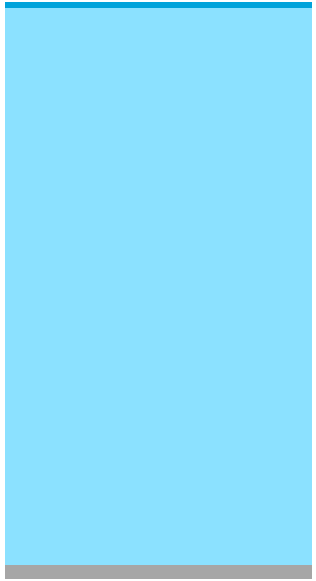


Q1M: 6% (n = 397)

Q2M: 91% (n = 5,816)

Unknown: 2% (n = 149)

At study end



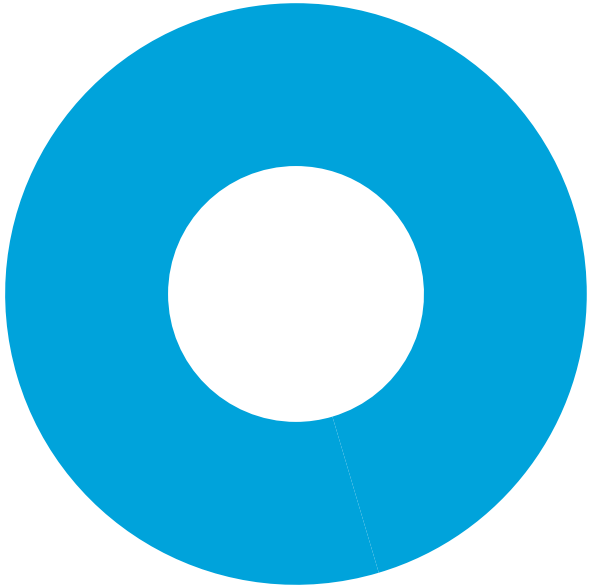
Q1M: 1% (n = 62)

Q2M: 97% (n = 6,151)

Unknown: 2% (n = 149)

Adherence

Among 5,713 Complete Initiators with Baseline VL < 50 copies/mL and ≥ 1 Maintenance Injection



Adherence

Among 5,713 Complete Initiators with Baseline VL < 50 copies/mL and ≥ 1 Maintenance Injection

**All injections on time*
n = 3,119 (55%)**

*Q1M: ≤37 days apart;
Q2M: ≤67 days apart



Adherence

Among 5,713 Complete Initiators with Baseline VL < 50 copies/mL and ≥ 1 Maintenance Injection



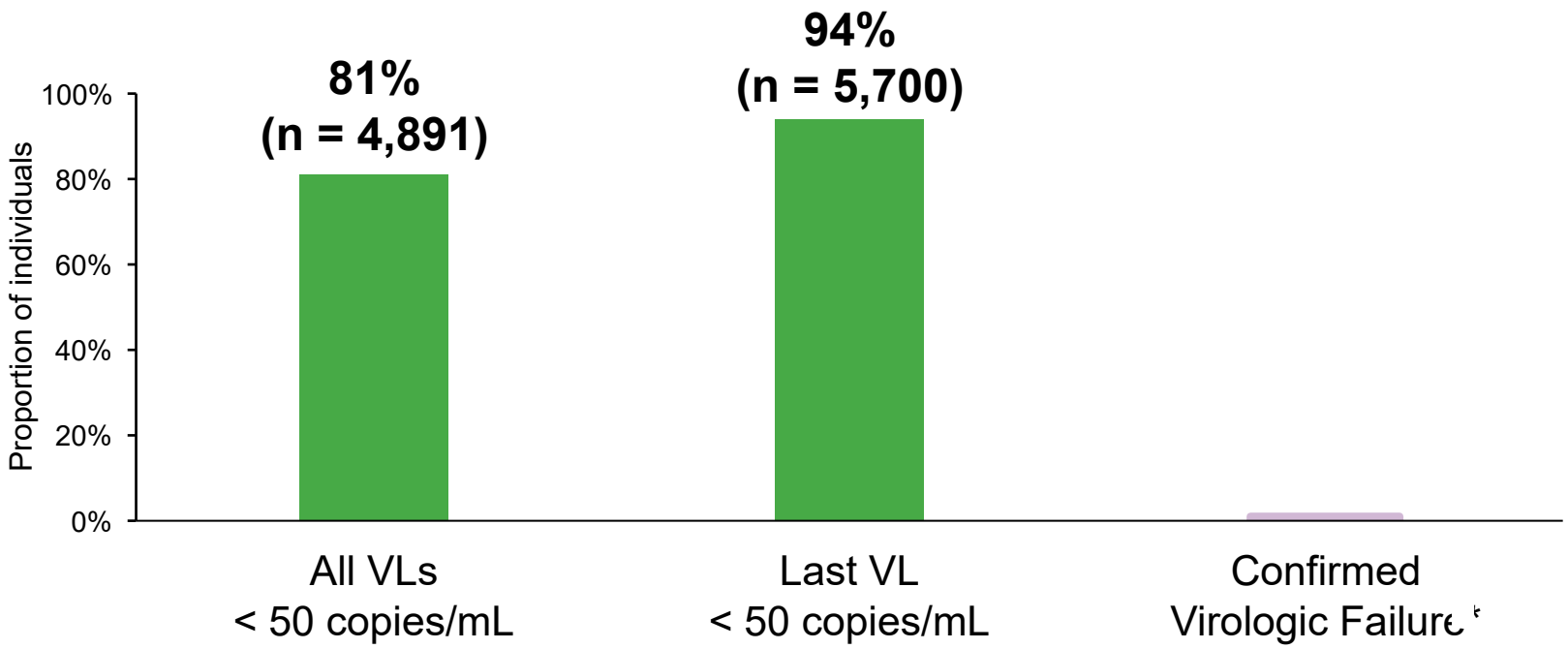
≥ 1 late injection*
n = 2,594 (45%)
Median 1 delay/person
(IQR: 1, 2)

4,590 delays /28,584 injections
Median 5 days late
(IQR: 3, 19)

*Q1M: 38-67 days apart;
Q2M: 68-127 days apart

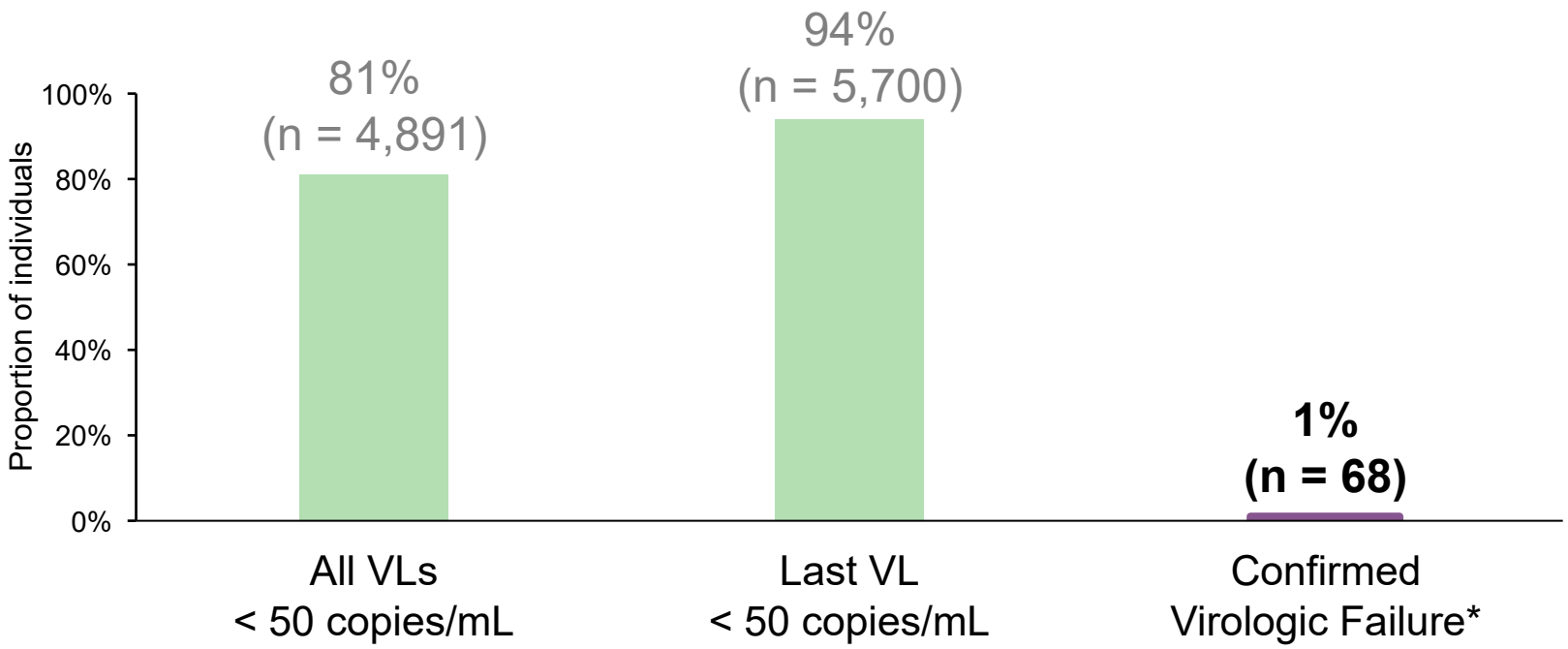
Virologic Outcomes

Among 6,058 Complete Initiators with Baseline VL < 50 copies/mL and Follow-Up VL(s)



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*2 VL ≥200 or 1 VL ≥200 discontinuation within 4 months

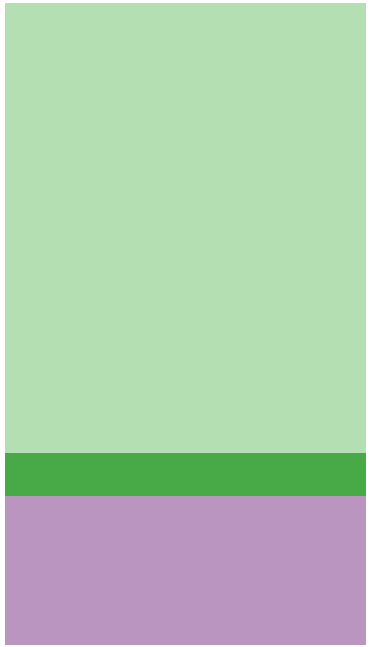
Persistence and Discontinuation

Among 6,362 Complete Initiators with Baseline VL < 50 copies/mL

70% (n = 4,458)
Never discontinued*

7% (n = 421)
Discontinued* & resumed

23% (n = 1,483)
Discontinued



* Discontinuation: >127 days without CAB+RPV LA injections

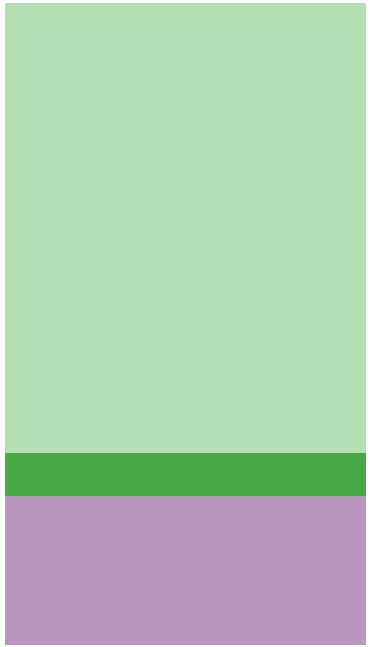
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23% (n = 1,483)
Discontinued



77% (n = 4,879)
On CAB+RPV at study end

Median **18 cumulative months (IQR: 9, 31)** on CAB+RPV LA

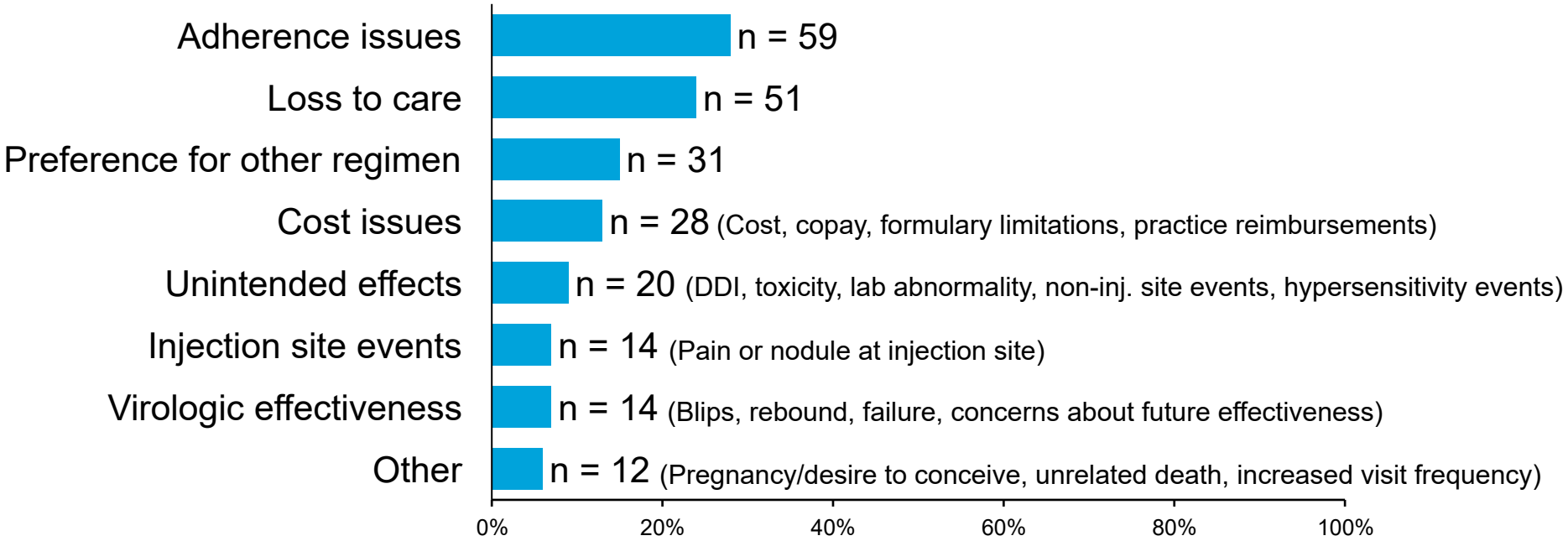
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Reasons for CAB+RPV LA Discontinuation

As Reported in a Survey of Providers

Reasons for discontinuation*

From a Sample of Providers Surveyed about 213 Discontinuers**



* Reasons were not mutually exclusive

** Surveys sent between 03JUL2024 and 06JUL2026; data updated since abstract

Key Findings

Wide Reach of CAB+RPV LA in the US

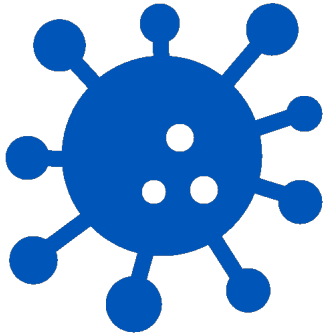


7,995 CAB+RPV LA initiators in the first five years since FDA approval

87% started CAB+RPV LA while virologically suppressed, per the label

CAB+RPV LA reached a diverse population (23% aged 50+, 43% Black, 32% Hispanic, 5% injection drug users, 30% obese)

CAB+RPV LA was highly effective among virologically suppressed individuals



Virologic suppression was consistently maintained on CAB+RPV LA (81% with all VL <50; 94% with last VL <50)

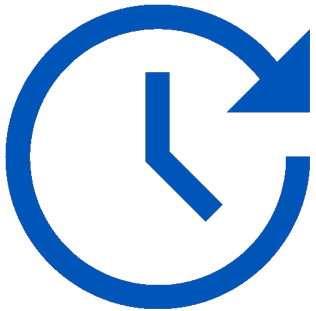
Confirmed virologic failure was rare on CAB+RPV LA (1%)

More than half (55%) received all injections on time.

The remainder had a median of 1 late injection, a median of 5 days outside the injection window

High Persistence on CAB+RPV LA

77% were still receiving CAB+RPV LA injections at study end



Most provider-reported reasons for discontinuation were logistical rather than due to injection site reactions or effectiveness concerns

Limitations: discontinuations were likely overestimated

- Oral bridging often not documented
- Observed returns to injections after long gaps
- Providers reported intentions to resume injections

Acknowledgements

This research would not be possible without the generosity of people on HIV on CAB+RPV LA, their OPERA caregivers, and the organizations that have contributed data to the OPERA cohort.

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OPERA® the longitudinal cohort