

# Need for Improved HIV Testing Prior to and During Pre-Exposure Prophylaxis with Cabotegravir Long-Acting Injections in Routine Clinical Care in the United States

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OPERA<sup>®</sup>  
The Longitudinal Cohort

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## Background

- Of ~1.2 million people in the US who could benefit from pre-exposure prophylaxis (PrEP) in 2021, ~30% received a PrEP prescription<sup>1</sup>
- Cabotegravir long-acting (CAB LA) PrEP was approved by the FDA for HIV prevention in December 2021
- Per CDC guidelines and the CAB LA PrEP US Prescribing Information, HIV-1 testing should be performed before starting CAB LA PrEP and before each subsequent injection, using an antigen/antibody (Ag/Ab) blood test (laboratory or point-of-care) with HIV RNA assay confirmation of negative Ag/Ab tests

## Objective

To describe the frequency and type of HIV testing prior to CAB LA PrEP injections in routine clinical practice in the US

## Methods

### OPERA<sup>®</sup> cohort

- Database of prospectively collected electronic health records
- >1 million patients receiving routine care in 103 clinics across the US and Puerto Rico

### Study population

- Individuals without HIV
- ≥12 years old
- ≥1 CAB LA injection between 21DEC2021 and 31MAR2023
- Censoring at first of (a) study end (30JUN2023), (b) HIV acquisition, (c) CAB LA discontinuation, (d) death, or (e) loss to follow-up (12 months after last contact)

### HIV Testing Measurement

- Presence of any HIV test ordered ≤1 week or ≤4 weeks before/at each injection
  - Ag/Ab (point-of-care or laboratory test)
  - HIV RNA (qualitative or quantitative PCR test)

### Analyses

- For each injection, the presence of a test ≤1 week or ≤4 weeks before/at the injection was obtained.
- For each person, the proportion of all injections with a test was calculated
- The proportion of injections with test per person was described with frequencies and medians (IQR) across all individuals

## Results

Table 1. Characteristics at first injection and follow-up of CAB LA PrEP users (N=560)

	CAB LA PrEP Users n (%)
12-19 years old	15 (3)
20-29 years old	218 (39)
30-39 years old	186 (33)
40-49 years old	76 (14)
50-59 years old	39 (7)
60+ years old	26 (5)
Women	75 (13)
Transgender	31 (6)
Black race	177 (32)
Hispanic ethnicity	162 (29)
Any STI <sup>a</sup> within 12 month before CAB LA initiation	237 (42)
Any prior oral PrEP use	492 (88)

<sup>a</sup> Sexually transmitted infections include syphilis, gonorrhea, chlamydia, chancroid, lymphogranuloma venereum, mycoplasma genitalium, HCV, HBV, primary HSV-2, trichomoniasis

Figure 1. HIV testing ≤1 week before/at the first CAB LA injection (N = 560)

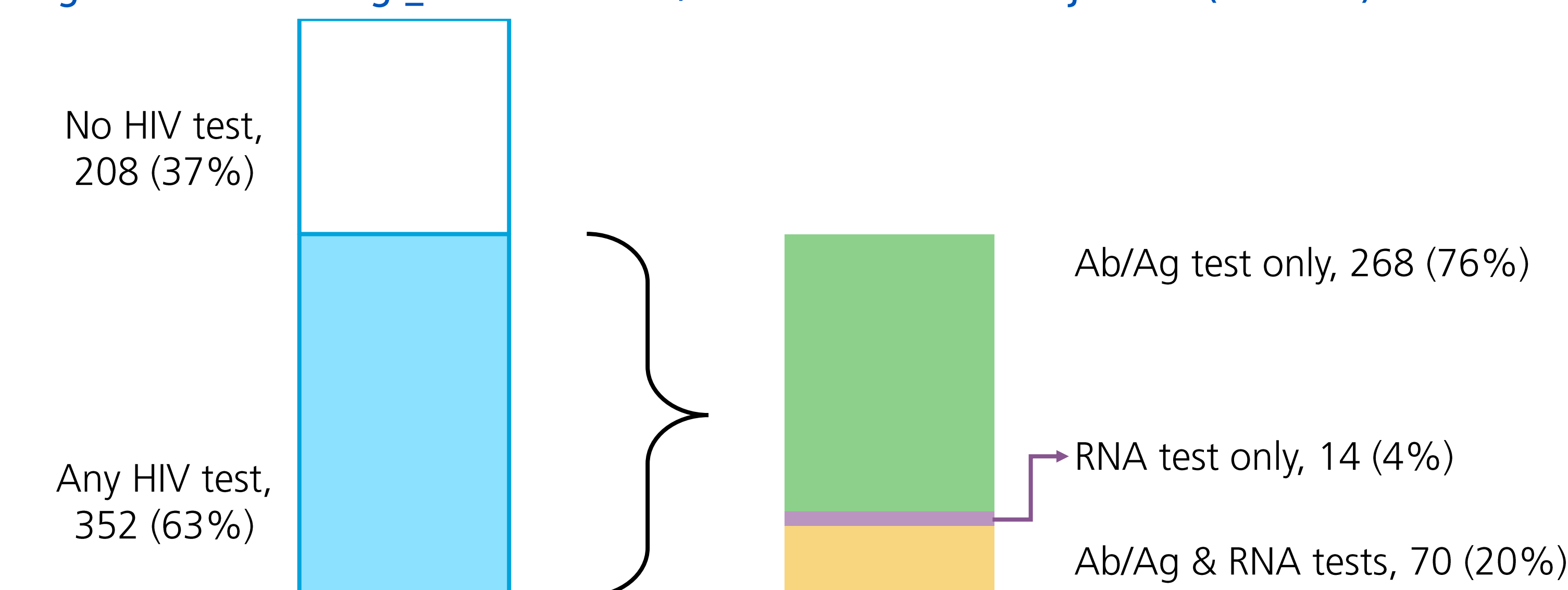
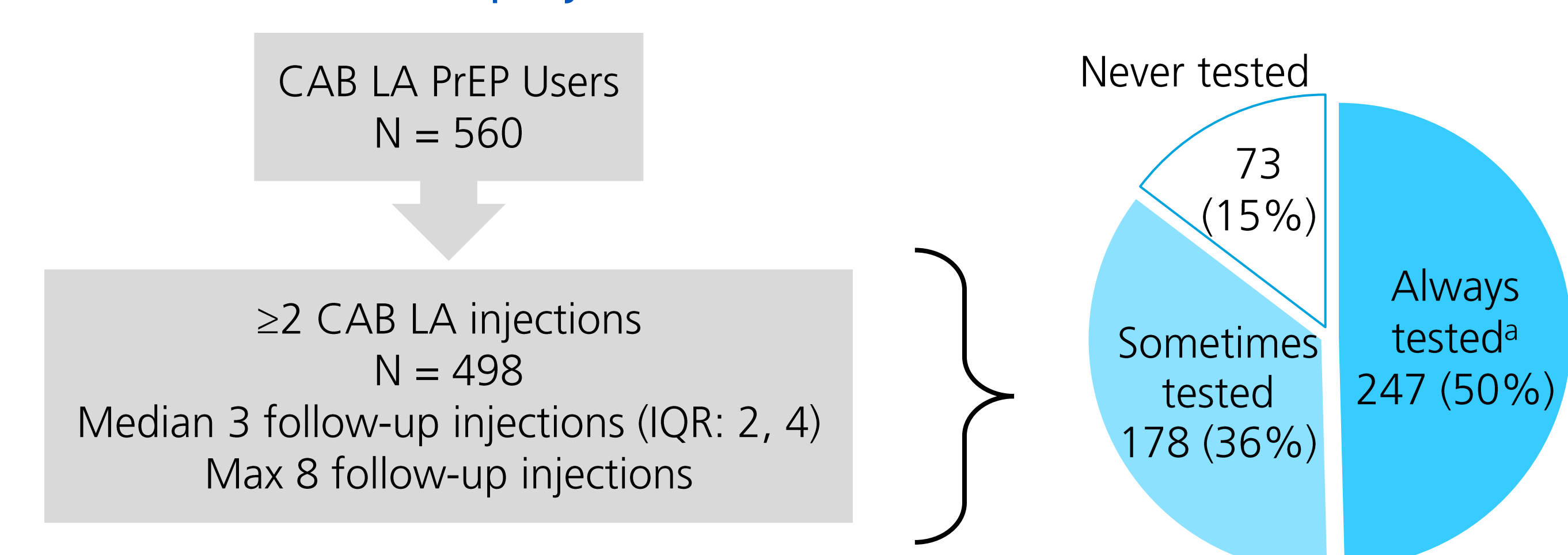


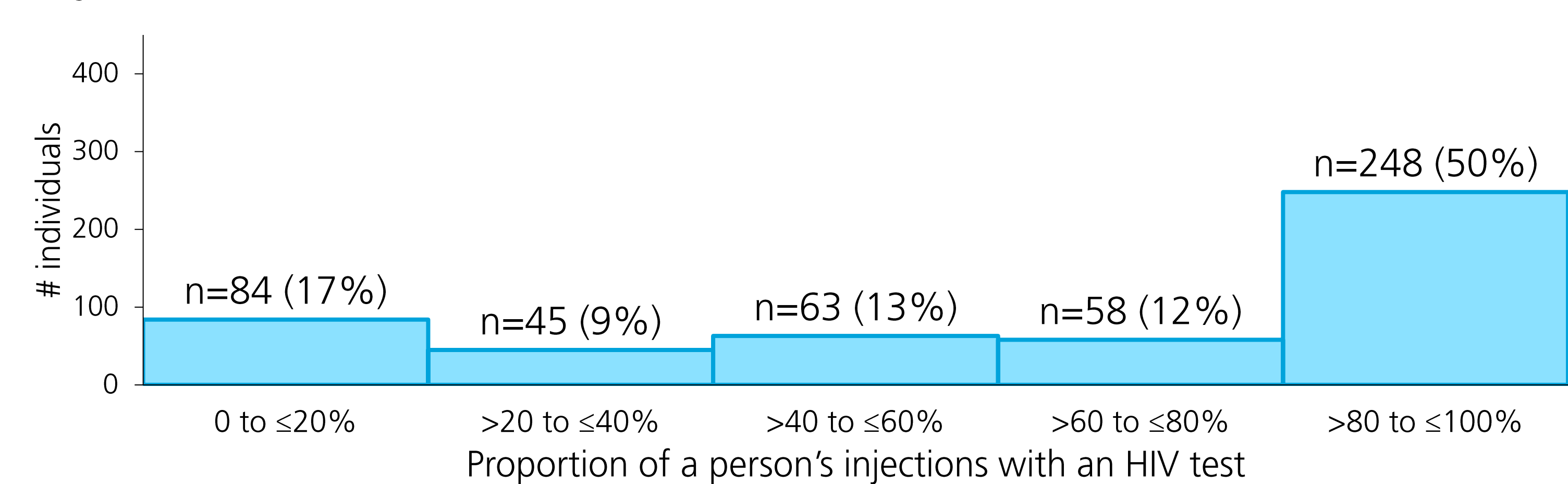
Figure 2. CAB LA PrEP users with ≥2 injections and frequency of HIV testing ≤1 week before/at each follow-up injection



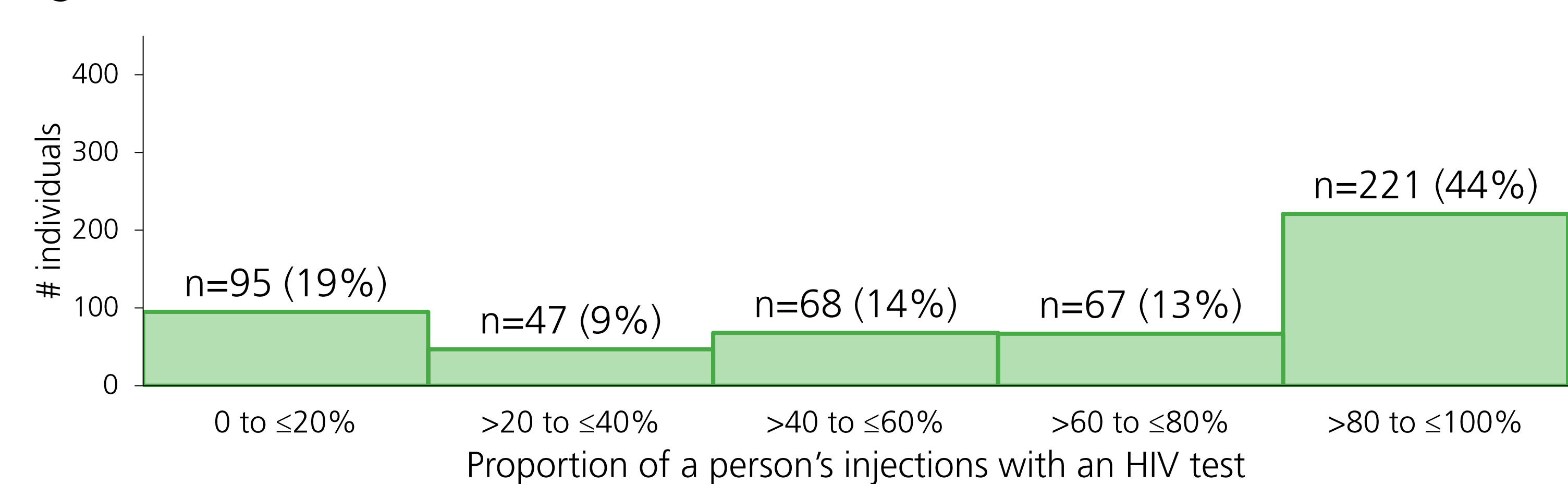
<sup>a</sup> 29 individuals (6%) received both Ag/Ab and RNA tests at each follow-up injection

Figure 3. HIV testing ≤1 week before/at each follow-up CAB LA injection, among those with ≥2 injections (N = 498)

Any test – Median: 80% (IQR: 40, 100)



Ag/Ab test – Median: 75% (IQR: 33, 100)



HIV RNA test – Median: 0% (IQR: 0, 14)

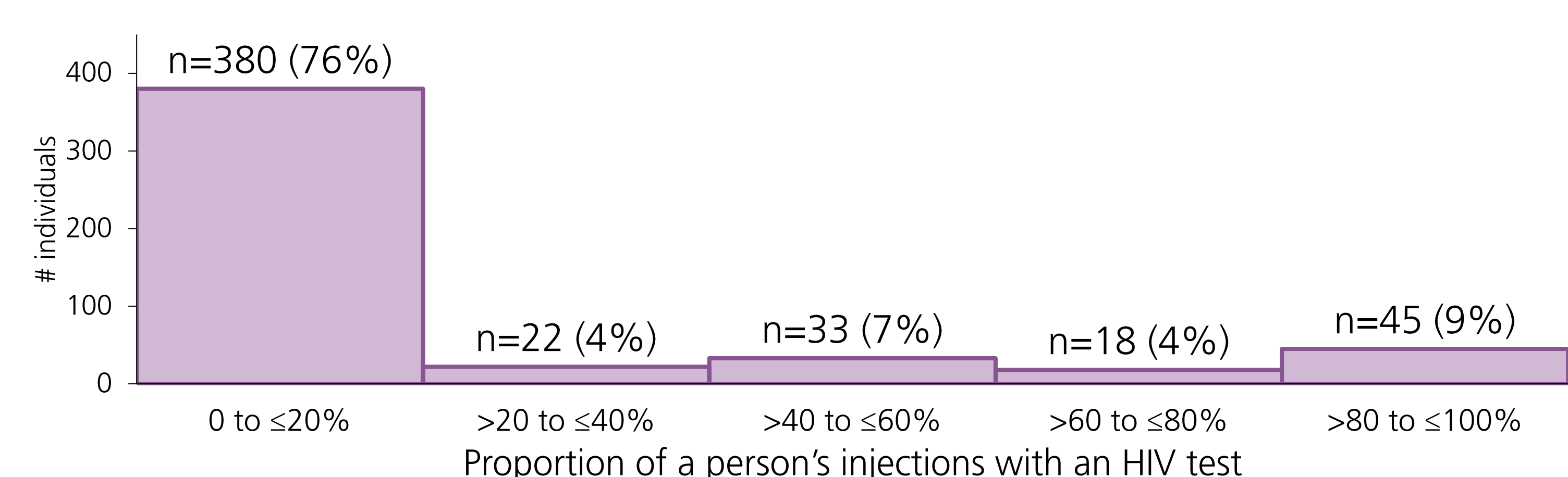


Table 2. HIV testing ≤4 weeks before/at CAB LA injections

	CAB LA PrEP Users
All CAB LA PrEP users	N = 560
Any HIV test ≤4 weeks before/at first injection, n (%)	435 (78)
CAB LA PrEP users ≥2 CAB LA PrEP injections	N = 498
HIV testing ≤4 weeks before/at the follow-up injection, <sup>a</sup> median (IQR)	100% (50%, 100%)

<sup>a</sup> For each person, the proportion of injections with a test was calculated. The distribution was then obtained across individuals

## Discussion

- Among 560 individuals on CAB LA PrEP, 37% did not receive any HIV test ≤1 week before the first injection (Fig 1)
- Among 498 individuals who received follow-up CAB LA PrEP injections:
  - 15% were never tested ≤1 week before their injections (Fig 2)
  - 50% were tested ≤1 week before every injection; only 6% received both Ag/Ab and RNA tests every time (Fig 2)
  - 17% of people were tested before ≤20% of their injections; 76% had an RNA test before ≤20% of their injections (Fig 3)
- Strengths: Large cohort of routine clinical care in the US
- Limitations:
  - Small number of injections per person
  - No information on HIV tests performed at non-OPERA clinics

## Key Findings

- During routine clinical care in the US, HIV testing among CAB LA PrEP users often did not conform to the label or CDC guidelines.
- Education on the need for HIV testing prior to all injections is necessary, as timely HIV diagnosis and switch to a full antiretroviral therapy regimen reduces the risk of developing resistance.

## References

1. CDC. Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2021. HIV Surveillance Supplemental Report 2023; 28(4).

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