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Moving to long-acting PrEP

No HIV acquisitions among women on cabotegravir long-acting injectable PrEP despite mostly short injection delays in the US OPERA Cohort

AIDS 2026

26–31 July • Rio de Janeiro, Brazil

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The Longitudinal Cohort

Summary

What is your main question?

- How do women fare on cabotegravir long-acting (CAB LA) pre-exposure prophylaxis (PrEP)?

What did you find?

- CAB LA PrEP was highly effective in routine care, with no HIV acquisitions observed among women over a median of 13 months of follow-up, despite 44% of women receiving one or more late injection

Why is it important?

- PrEP is a key primary prevention strategy in the fight against HIV, but women often experience poorer outcomes with oral PrEP, in part due to adherence challenges. Effective PrEP options supporting adherence, such as long-acting PrEP options, could help bridge this gap.

Disclosures

- American Academy of HIV Medicine: Board member
- ViiV Healthcare: Advisory board

- This research was funded by ViiV Healthcare.

The potential effects of relevant financial relationships with ineligible companies have been mitigated. Any clinical recommendations are based on evidence and are free of commercial bias.

HIV and women in the US

~20% of new HIV diagnoses in the US are in women

- 18% cisgender women
- 2% transgender women

Pre-exposure prophylaxis (PrEP) is a key primary prevention strategy for preventing acquisition of HIV infection and ending the HIV epidemic

- 3 out of 4 PrEP options are indicated to protect against HIV acquisition from receptive vaginal sex
- In the US, women receive disproportionately less PrEP than men, relative to their HIV prevention need

Cabotegravir long-acting PrEP

1st long-acting injectable PrEP option

- Approved in the US in December 2021

Approved for adults and adolescents, without restriction by exposure route

- Superior efficacy compared to daily oral TDF/FTC in both cisgender and transgender women

Objectives

1. Compare the populations of women starting CAB LA or oral PrEP in the US
2. Describe patterns of CAB LA PrEP utilization among women
3. Assess the real-world effectiveness of CAB LA PrEP to prevent HIV acquisition in women

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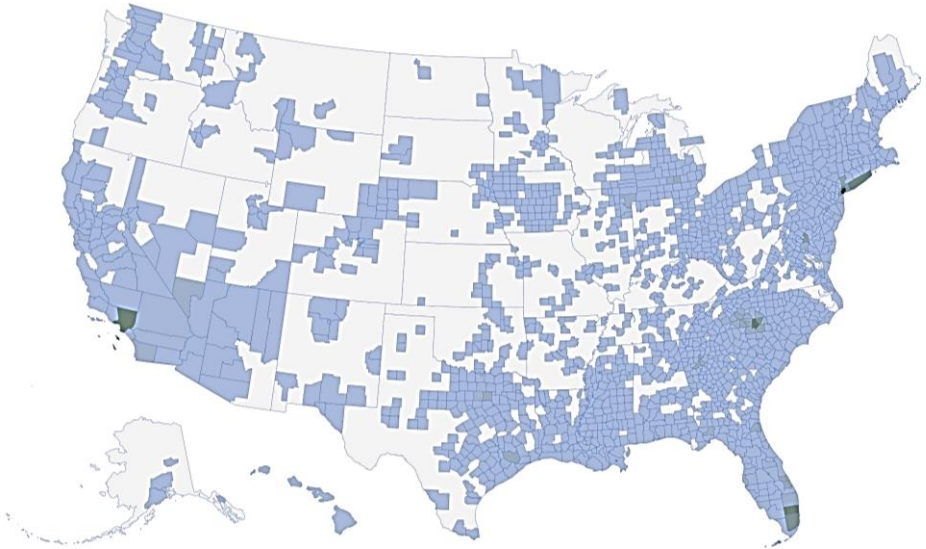
The Longitudinal Cohort



Observational **P**harmaco-
Epidemiology **R**esearch & **A**nalysis

> 172,000 people with HIV

> 911,000 people <u>without HIV</u>

> 86,000 people ever received PrEP

Study Population

Inclusion criteria

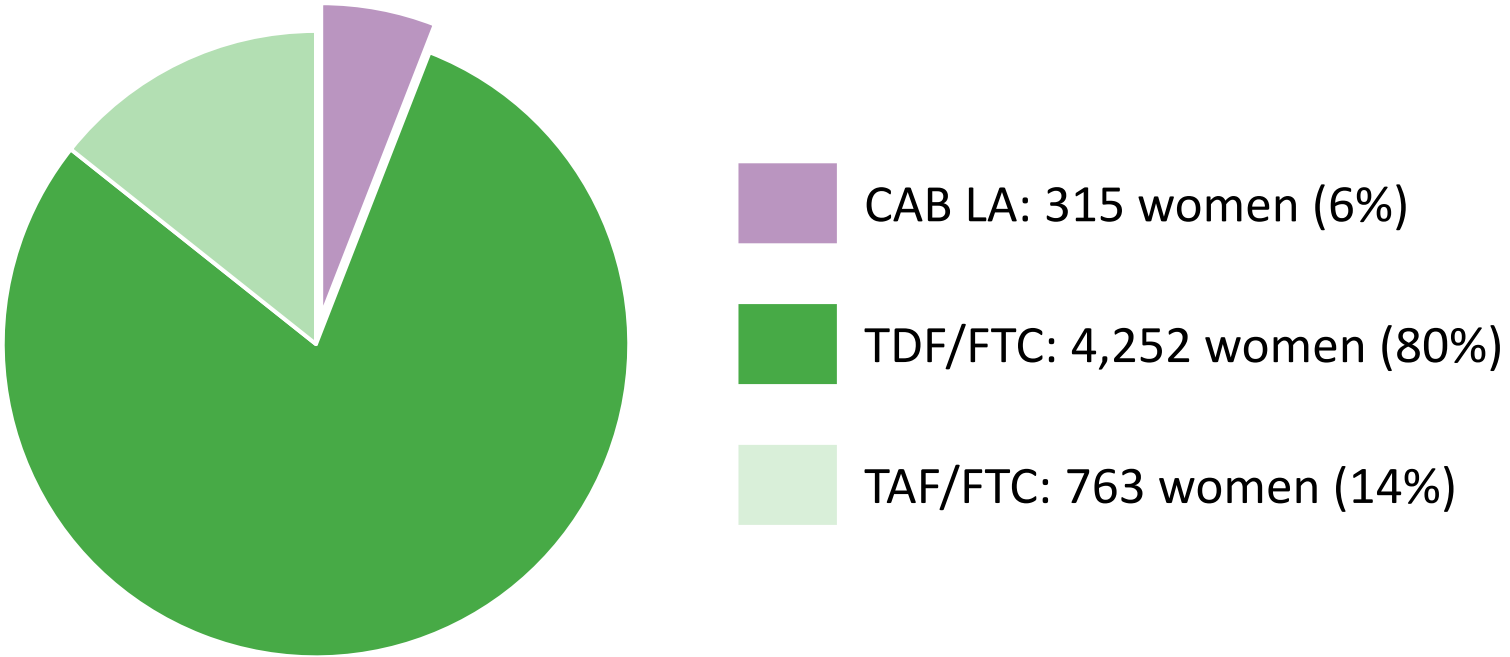
- Cisgender or transgender women
- ≥18 years old
- ≥1 CAB LA PrEP injection between 21 December 2021 and 31 December 2024

Follow-up through the 1st of:

- Loss to follow-up (12 months after last clinical encounter)
- Death
- Study end (30 April 2025)

1. PrEP use among women

5,330 women started PrEP
(Dec 2021-2024)*



* LEN LA PrEP had not been approved at the time of this study

Characteristics at PrEP start

	Women on CAB LA PrEP N = 315	Women on Oral PrEP N = 5,015
Age, median (IQR)	28 (23, 37)	29 (24, 37)
Black race, n (%)	135 (43)	2,123 (42)
Transgender, n (%)	102 (32)	938 (19)
BMI ≥30 kg/m^2, n (%)	130 (43)	814 (35)
Medicaid recipient, n (%)	118 (38)	409 (8)
HIV tests in past 2 weeks, n (%)	263 (84)	4,167 (83)

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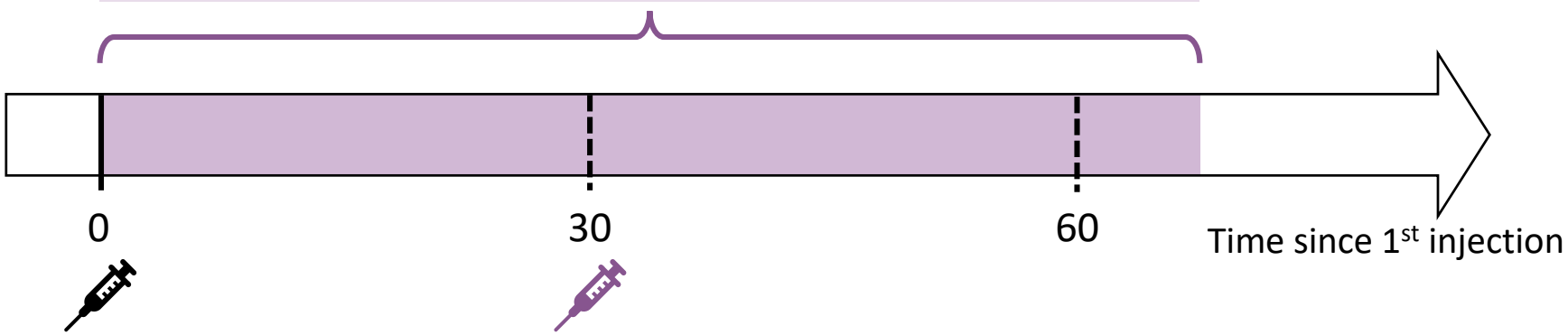
2. Patterns of CAB LA PrEP utilization in women

Complete initiation

Among 315 women initiating CAB LA PrEP

80% (n = 252) **completed initiation***
Median 13 months of follow-up (IQR: 8, 19)

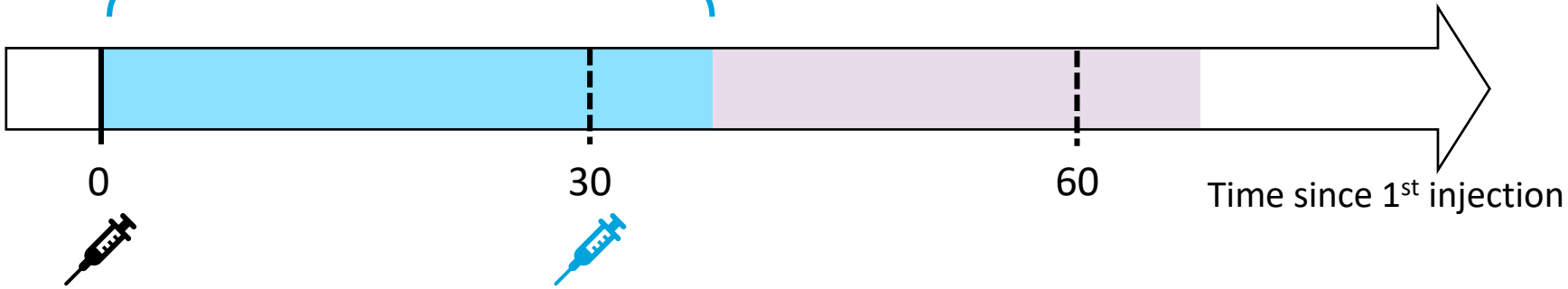


* ≤67 days after 1st injection

Timing of initiation injections

Among 252 women with complete initiation

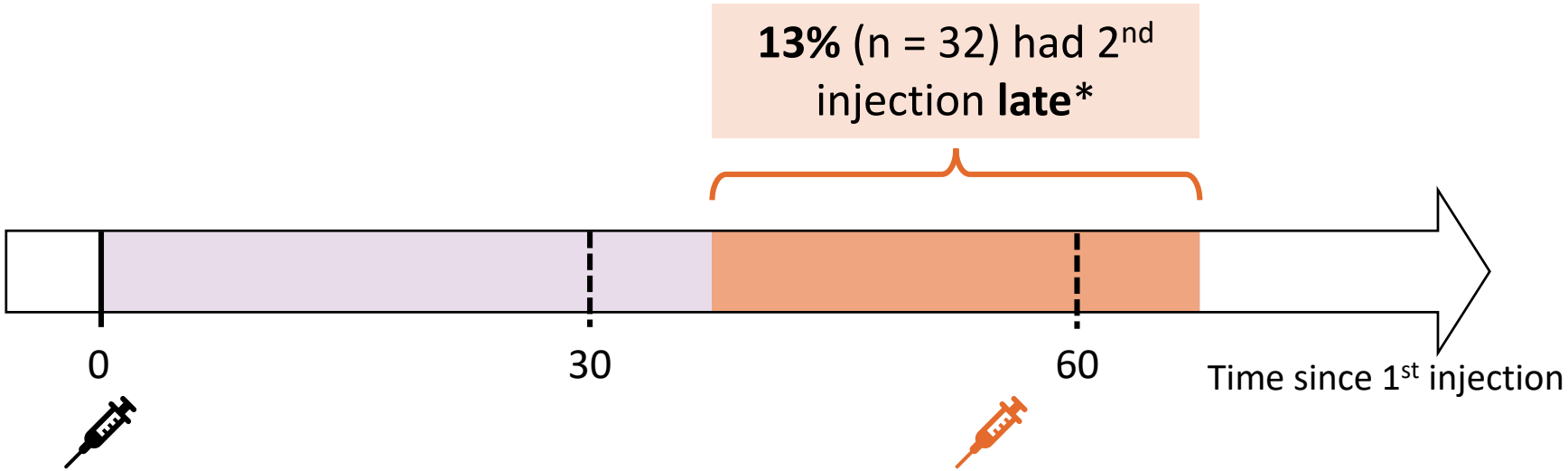
87% (n = 220) had 2nd injection **on time***



* ≤37 days after 1st injection

Timing of initiation injections

Among 252 women with complete initiation



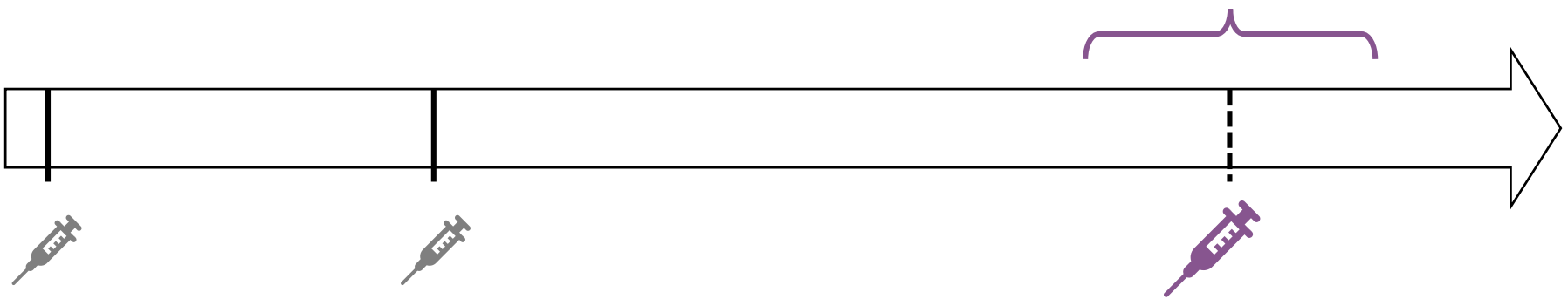
* 38-67 days after 1st injection

Maintenance injections

Among 252 women with complete initiation

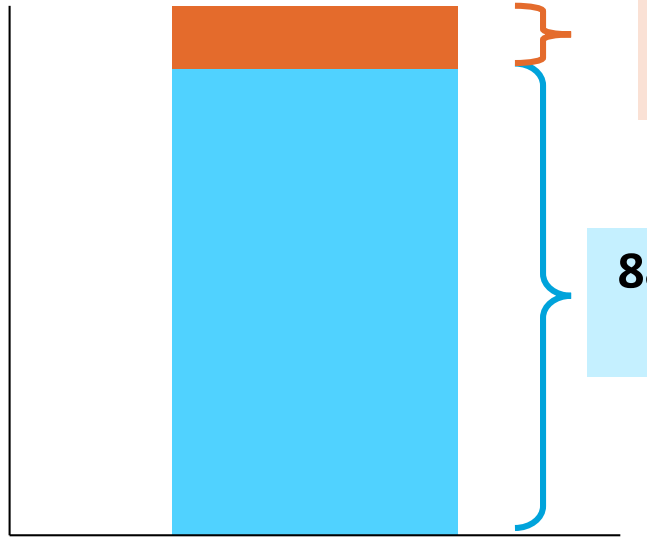
83% (n = 210) had **≥1 maintenance injection**

Median 4 maintenance injections per woman (IQR: 2, 9)



Timing of maintenance injections

Among 1,193 maintenance injections received



1,193 maintenance injections

12% late
(n = 141)

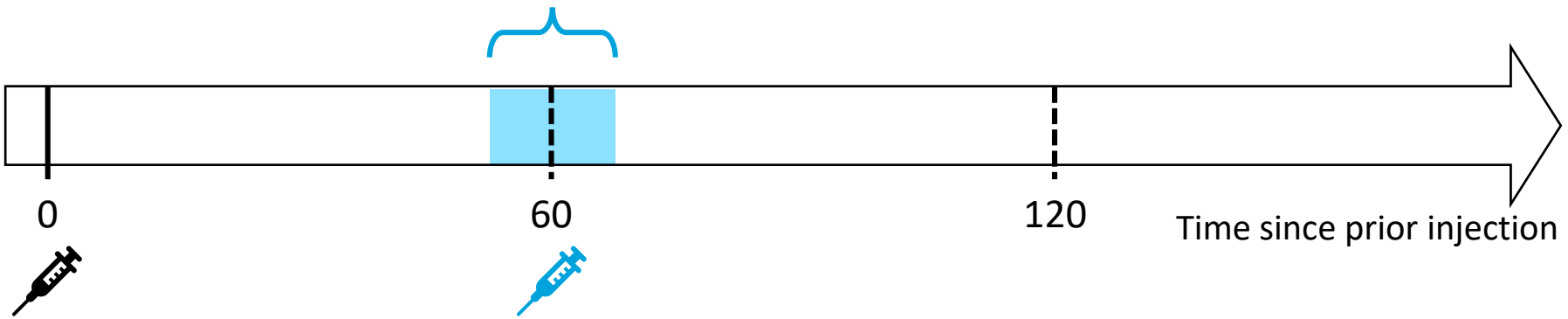
88% on time
(n = 1,052)

Late injections received a median of 8 days late (IQR: 3, 17)

Timing of maintenance injections

Among 210 women with ≥1 maintenance injection

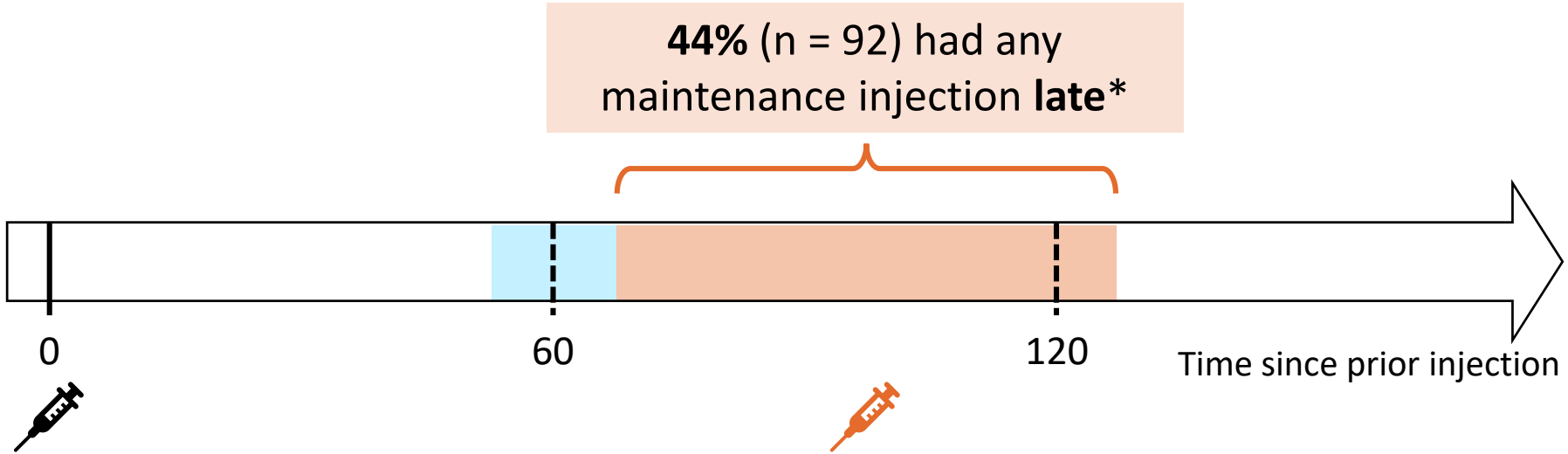
56% (n = 188) had 100% of maintenance injections **on time***



* 53-67 days after previous injection

Timing of maintenance injections

Among 210 women with ≥1 maintenance injection

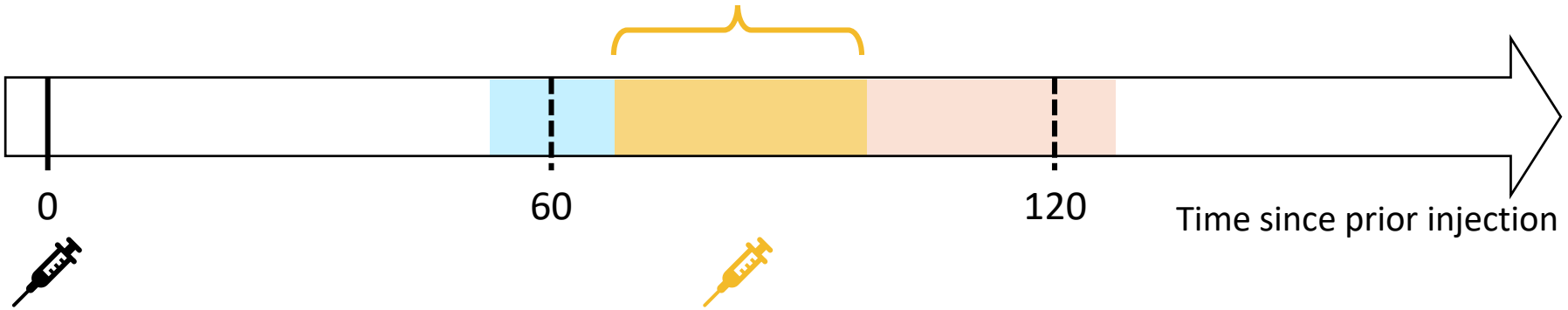


* 68-127 days after previous injection

Timing of late maintenance injections

Among 92 women with ≥1 late maintenance injection

89% (n = 82) had ≥1 **short delay** not requiring reinitiation*

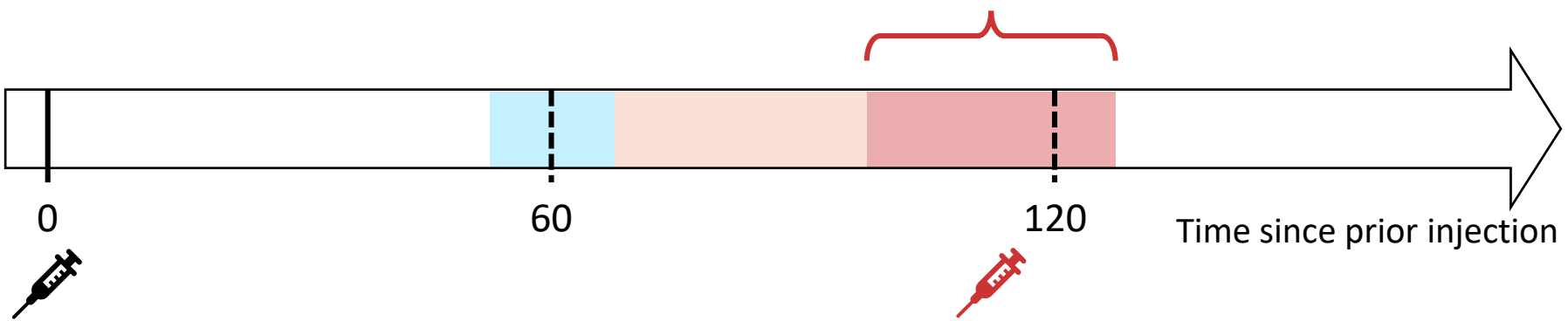


* 68-97 days after previous injection

Timing of late maintenance injections

Among 92 women with ≥1 late maintenance injection

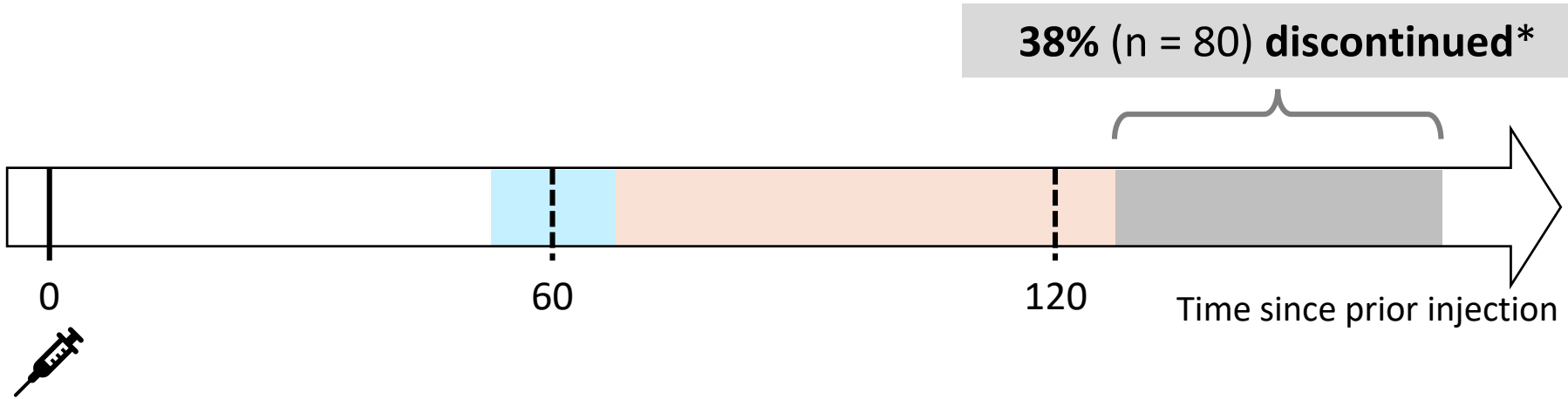
15% (n = 14) had ≥1 **long delay** requiring reinitiation*



* 98-127 days after previous injection

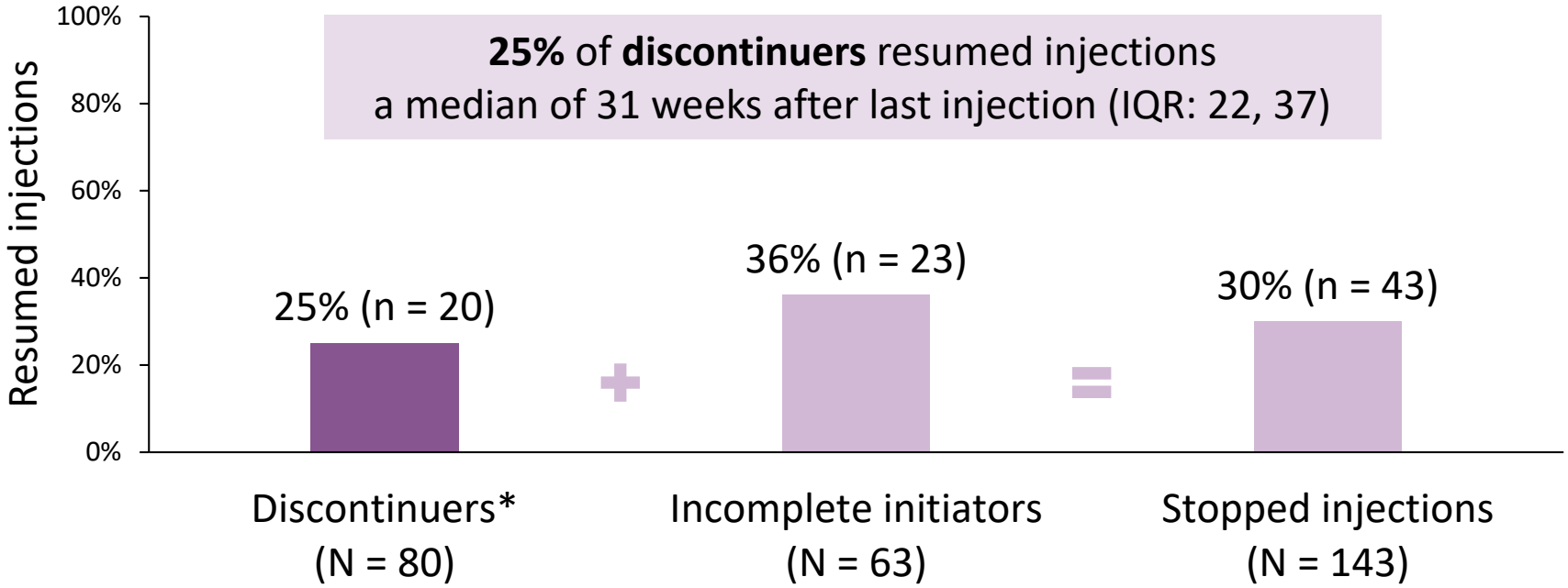
Discontinuation

Among 210 women with ≥1 maintenance injection



* >127 days without injection, corresponding to 2 missed injections

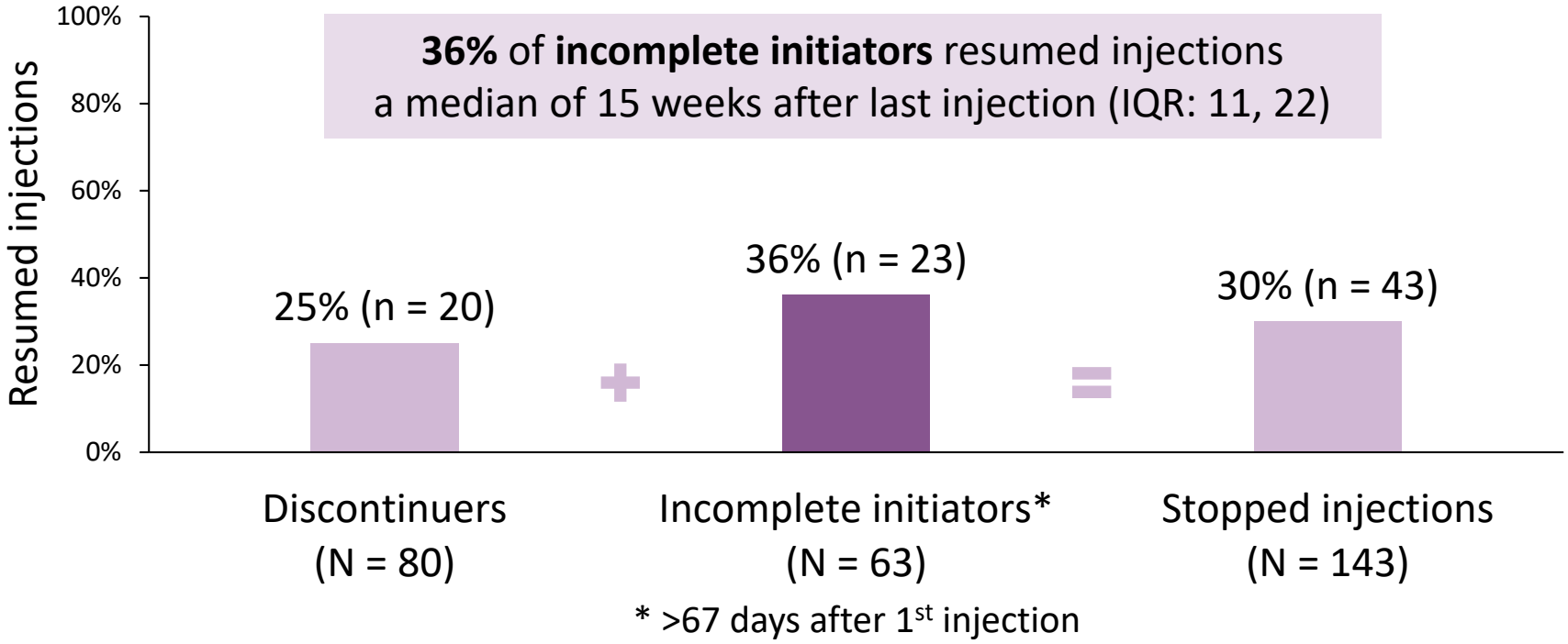
Resumption of injections



* >127 days without maintenance injection

Resumption of injections

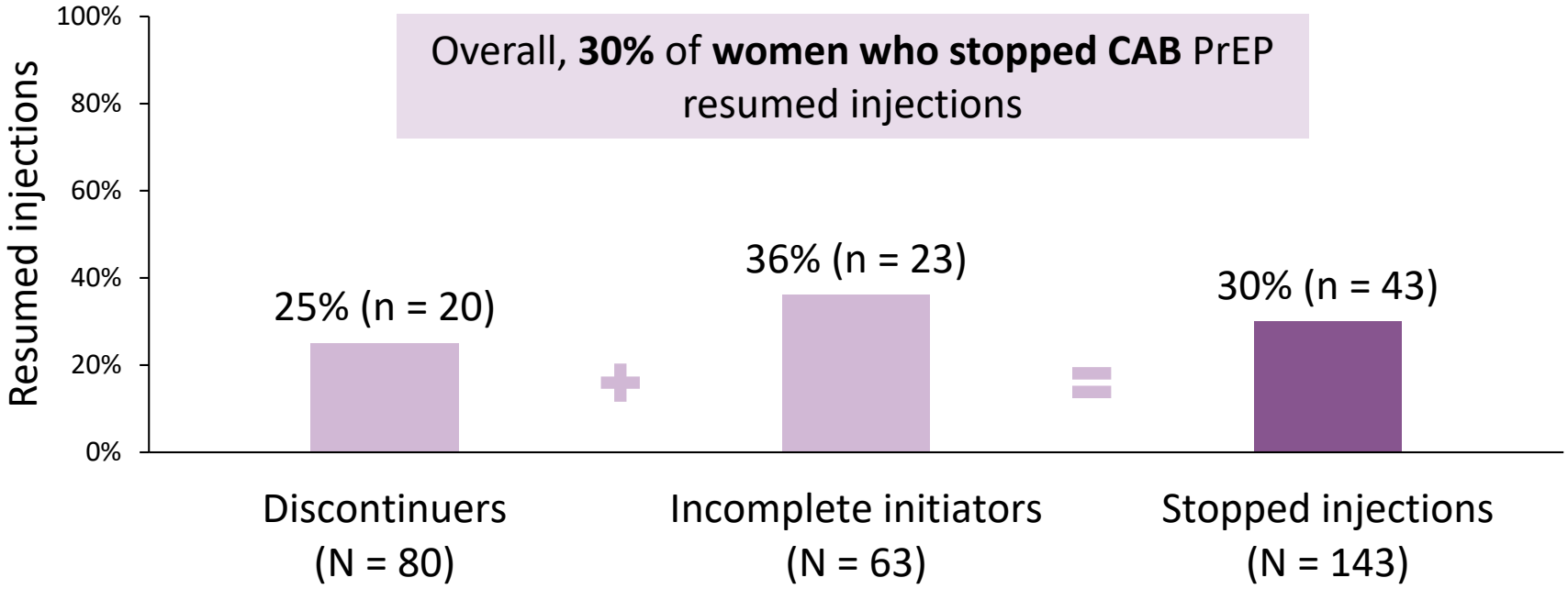
36% of **incomplete initiators** resumed injections
a median of 15 weeks after last injection (IQR: 11, 22)



* >67 days after 1st injection

Resumption of injections

Overall, **30%** of **women who stopped CAB** PrEP resumed injections



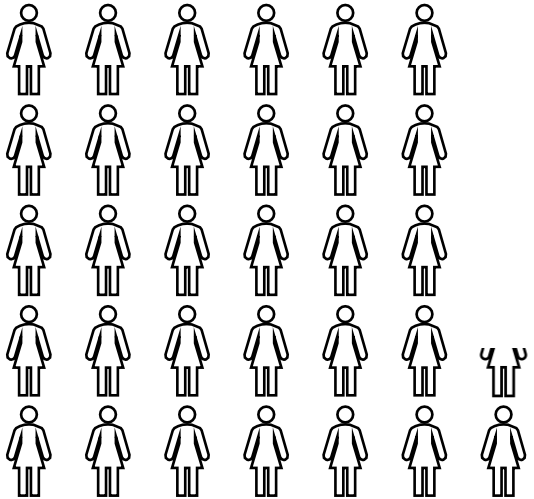
3. Effectiveness of CAB LA PrEP in women

Incident STI(s): 58/315 women (18%)

= 10 women

Incident STI(s): 58/315 women (18%)

Incident HIV: 0/315 women (0%)



= 10 women

Key Findings

CAB LA PrEP was highly effective at preventing HIV among women

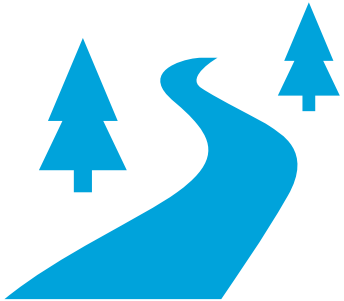
0 HIV acquisitions observed

88% of overall injections were on time

44% of women had at least 1 late injection

- Most delays were short and did not require reinitiation
- Incomplete oral bridging records may contribute to the overestimation of delays and discontinuation

PrEP use is dynamic



Continued interest in CAB LA PrEP as was evidenced by resumption of injections by women who did not complete initiation or even discontinued

A larger proportion of transgender women and women receiving Medicaid were on CAB LA PrEP than on oral PrEP

CAB LA PrEP was underutilized by women, representing only 6% of PrEP initiations in OPERA

PrEP is a powerful tool to end the HIV epidemic.

This study has demonstrated that **CAB LA PrEP is a viable and highly effective prevention strategy** in a diverse group of cisgender and transgender women who can benefit from PrEP.

Acknowledgements

This research would not be possible without the generosity of women on PrEP, their OPERA caregivers, and the organizations that have contributed data to the OPERA cohort.

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