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Introduction

- In 2023, Black women represented approximately 50% of all HIV diagnoses in women in the United States¹
- Oral pre-exposure prophylaxis (PrEP) persistence among Black women is low, with <20% persistence at 6 months²
- Long-acting cabotegravir (CAB LA) administered every 2 months via intramuscular injection is the first approved LA agent for PrEP³
- EBONI (NCT05514509) was a phase 4 study evaluating implementation strategies for the delivery of CAB LA to adult Black cisgender and transgender women across infectious disease, primary care, and women's health clinics in "Ending the HIV Epidemic" jurisdictions in the United States
- We present participant outcomes through Month (M) 12 with CAB LA from the EBONI (NCT05514509) study, the first US implementation study in Black women evaluating CAB LA for PrEP

Methods

- EBONI was a 12-month, phase 4, hybrid effectiveness-implementation science trial assessing CAB LA integration at 20 practice sites in Black cisgender and transgender women. M12 implementation questionnaires assessed acceptability of CAB LA, as well as injection pain, local reactions, and overall experiences with CAB LA. Acceptability of CAB LA was evaluated using the validated Acceptability of Intervention Measure. Clinical assessments included HIV incidence, persistence, safety, and tolerability
- M12 semi-structured interviews (n=42) were informed by the Proctor outcomes framework and the Consolidated Framework for Implementation Research, with specific focus on acceptability, appropriateness, feasibility, and overall study experiences. A thematic analysis and descriptive quantification of theme endorsement across participants was conducted. Thematic saturation was reached for key themes. Representative quotes illustrating key themes were selected¹
- Table 1 depicts patient participant demographics at baseline and M12. At baseline, 163 women initiated CAB LA, with 99 and 42 completing M12 implementation questionnaires and interviews, respectively. The median age and gender were similar for quantitative and qualitative samples

Table 1. Demographics Characteristics at Baseline and M12

Characteristic, n (%) ^a	Quantitative		Qualitative
	Baseline (N=163)	M12 (n=99)	M12 (N=42)
Gender identity			
Cisgender woman	122 (75)	78 (79)	33 (79)
Transgender woman	41 (25)	21 (21)	9 (21)
Age			
Median (IQR), years	35 (29-42)	37 (30-43)	35 (29-43)
Race			
Black or African American	163 (100)	99 (100)	42 (100)
Ethnicity			
Hispanic or Latine	6 (4)	2 (2)	3 (7)
Not Hispanic or Latine	150 (92)	95 (96)	39 (93)
Unknown/Prefer not to answer ^b	7 (4)	2 (2)	0(0)

IQR, interquartile range. ^aUnless otherwise indicated. ^bUnknown was reported at baseline and "prefer not to answer" was reported at M12.

¹Representative quotes were determined through the third-party thematic analysis of interview data; a subset of quotes from those identified during analysis were included here.

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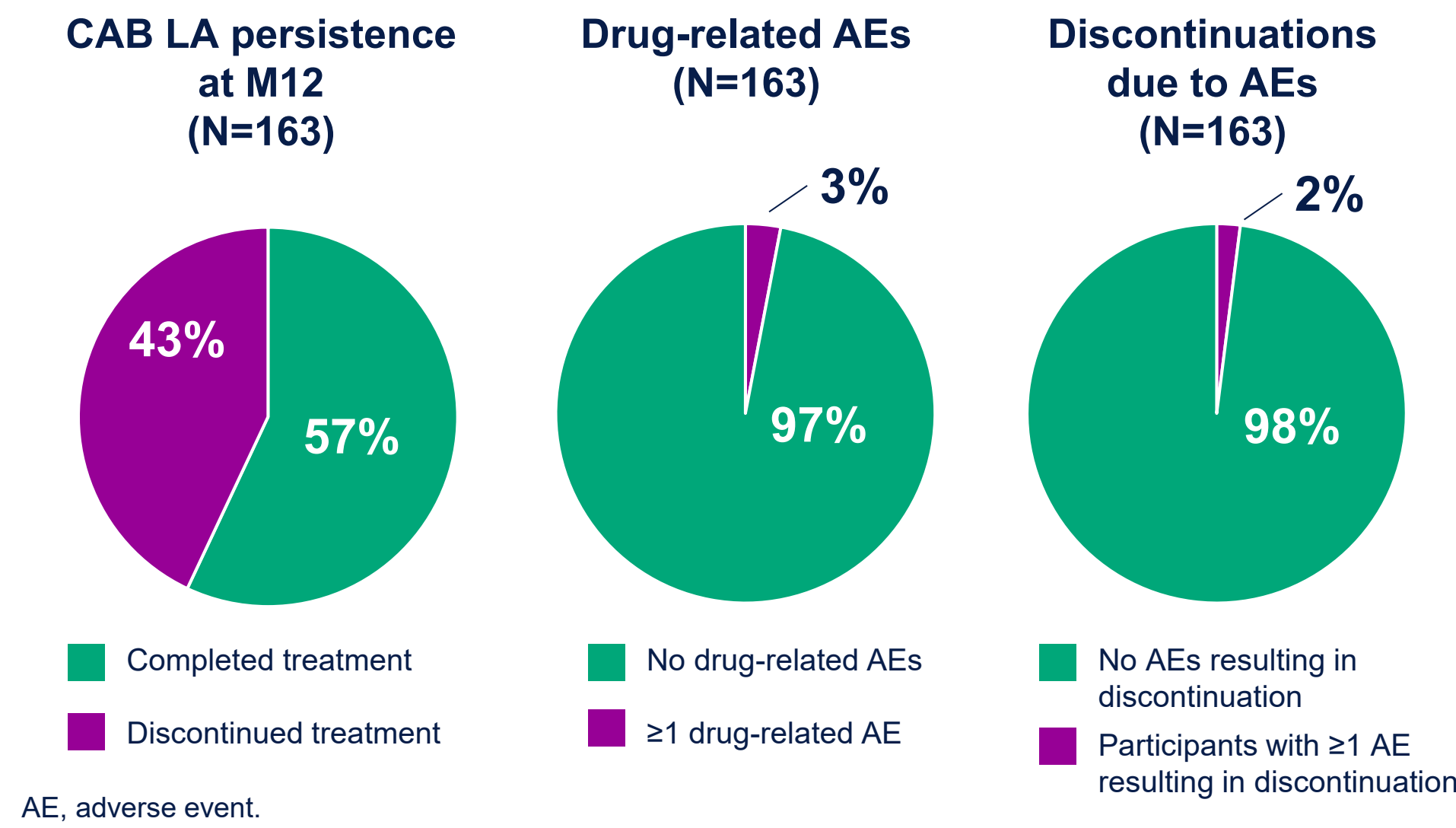
References: 1. US Centers for Disease Control and Prevention. <https://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-and-prevalence-2025.html>. Accessed January 15, 2026. 2. Pyra et al. *J Racial Ethn Health Disparities*. 2022;9:820-829. 3. Aprelude [prescribing information]. Durham, NC: ViiV Healthcare; 2025.

Key Takeaways

CAB LA was highly effective and safe in Black women

➔ No cases of HIV acquisition occurred among Black women in EBONI

Figure 1. CAB LA Persistence and Adverse Events Through M12



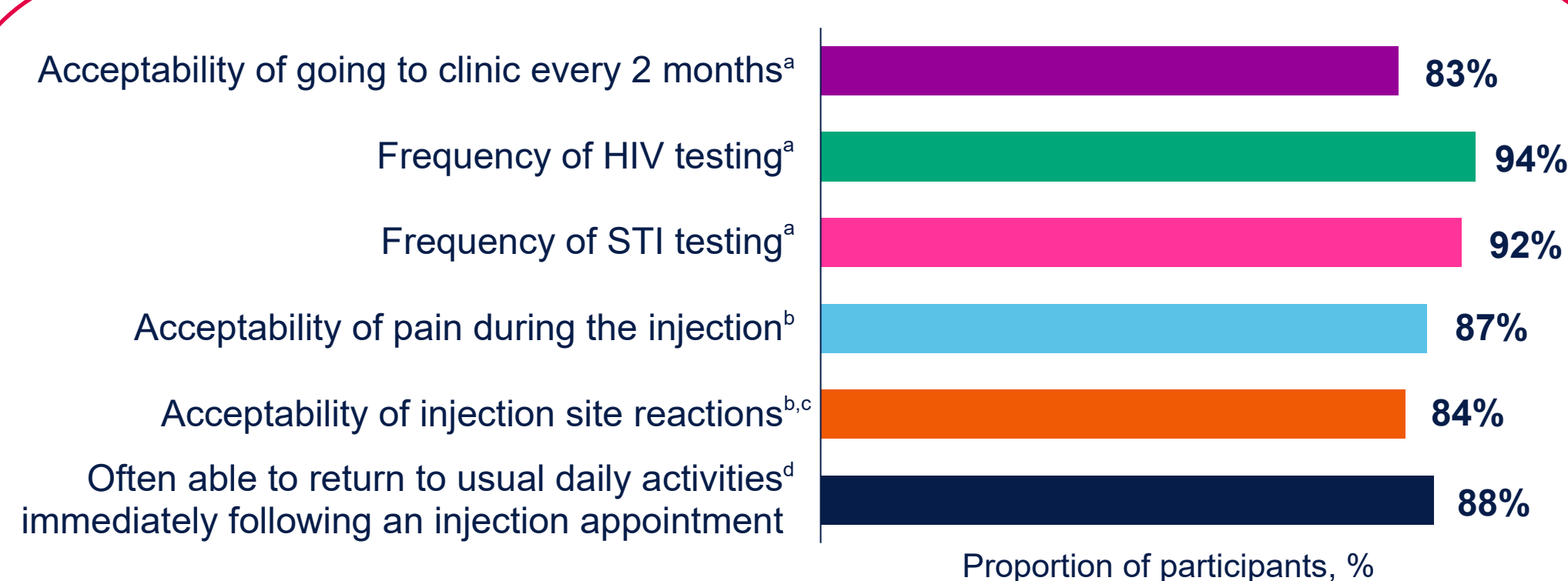
AE, adverse event.

- Almost half (44%, 67/151) of participants had not taken oral PrEP in the 6 months before initiating CAB LA
- The majority (61%; n=100/163) of participants were of childbearing potential, of whom 6% (n=6/100) experienced a pregnancy
- Persistence on CAB LA was 74% at M6 (120/163) and 57% at M12 (n=93/163), with 69% to 89% receiving injections within the ±7-day window through M12 (Figure 1)
- Drug-related adverse events (3%; n=5/163) were rare, with 2% (n=3) of participants discontinuing due to adverse events

CAB LA delivery experiences were positive after 12 months

➔ Over 80% of Black women reported going to the clinic every 2 months was acceptable

Figure 2. Experience of CAB LA Delivery at M12



STI, sexually transmitted infection. ^aRatings of "very acceptable" and "acceptable" were combined to define acceptability. ^bRatings of "totally acceptable," "very acceptable," and "moderately acceptable" were combined to define acceptability. ^cSkip logic item; only participants reporting "yes" were required to provide a response (n=38). ^d5-point Likert scale responses of "always" and "often" were combined to define often.

- Overall, women who experienced injection pain or local reactions found both acceptable (87% and 84%, respectively; Figure 2)
- Pain decreased for subsequent injections after the first injection. Median pain improved by 3 points between the first (5.0) and most recent (2.0) CAB LA injections (10-point scale where 0 = no pain and 10 = extreme pain)
- The majority (88%) of participants resumed daily activities immediately after injection appointment
- Interviews at M12 aligned with 14% and 62% noting no and minor pain, respectively, with strategies for relief being pain medication and cold or warm compresses or walking/stretching. A representative quote of the theme is:

"No. But the soreness for the first couple, well, really the first one, the soreness was particularly not bad, but it took some getting used to, but after that, nothing's really been negative." – Cisgender woman, 37

- Women found the frequency of HIV (94%) and sexually transmitted infection testing (92%) acceptable through M12 (Figure 2). Through M12, 15 sexually transmitted infections were identified (gonorrhea, n=7; chlamydia, n=7; syphilis, n=1) among 13 women (8%; n=5 cisgender women, n=8 transgender women)
- Most participants interviewed at M12 endorsed the acceptability (79%) and feasibility (60%) of CAB LA; example determinants of these themes included CAB LA being more convenient than oral PrEP and having a positive injection experience with minimal side effects. Some participants felt CAB LA had an unfavorable injection schedule. A representative quote of the theme is:

"It has really met my expectations, to be honest, because it's got a really simple process and very simple and straightforward...it also allows me to be able to, since it's like once every two months,...do everything else that I need to do...like go to work, travel, and do other things...." – Cisgender woman, 31

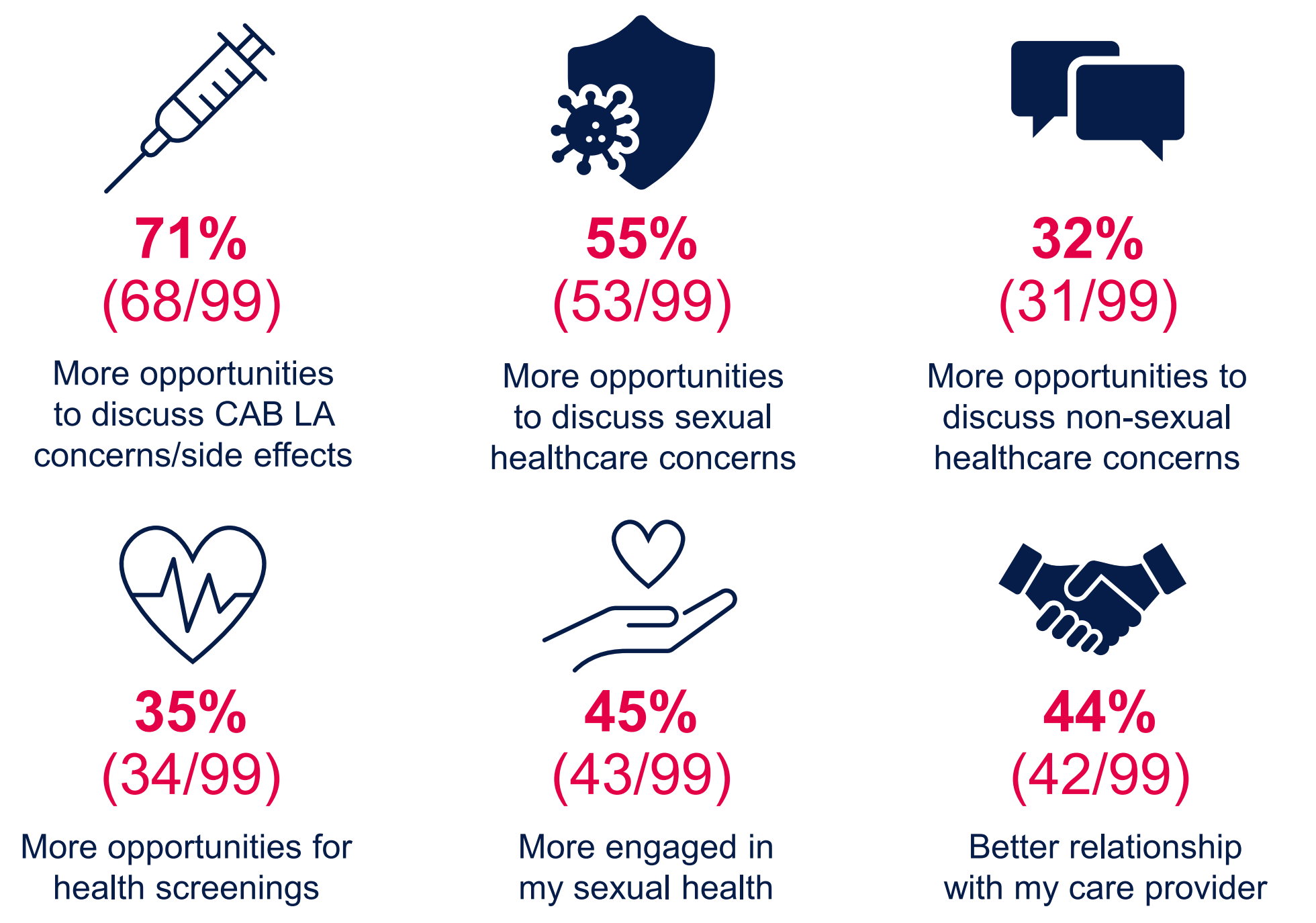
Conclusions

- The EBONI study adds robust evidence showing CAB LA for PrEP, offered through infectious disease clinics, women's health clinics, and primary care clinics, is highly effective and acceptable among Black women
- Discontinuation between baseline and M12 may highlight variability in perceived need for PrEP or care continuity
- High persistence relative to oral PrEP,² no HIV acquisition, rare occurrence of adverse events, and ancillary clinical benefits observed in EBONI further demonstrate that CAB LA can meet the needs of diverse populations

CAB LA in-person visits every 2 months had ancillary benefits

➔ Black women reported that in-person visits for CAB LA provided more opportunities for other health screenings and to discuss sexual health

Figure 3. Participant-Reported Benefits of In-person CAB LA Injection Visits at M12



Participants were allowed to select more than one response.

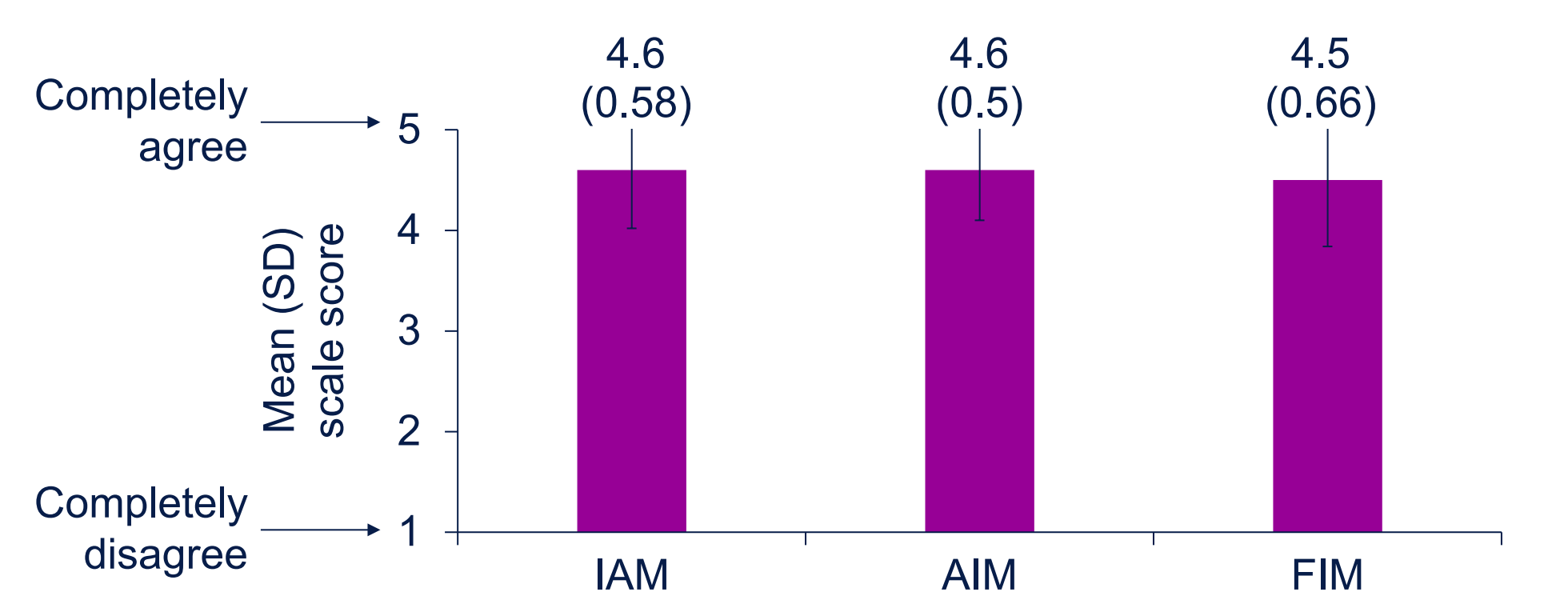
- Women noted benefits like better relationships with providers, enhanced screenings for health conditions like diabetes or high blood pressure, and increased engagement in their sexual health as benefits of in-person CAB LA injection visits (Figure 3)
- Many participants interviewed at M12 endorsed that the CAB LA injection schedule fit with their lifestyle (64%) and that there were benefits to visits every 2 months (41%). Example benefits included allowing for other screenings, vitals, and sexual health needs to be conducted or discussed. Representative quotes of these themes are:

"And look, they do a check-up every two months, so the best thing, and I love that I'm constantly being checked, because you know how your sexual health and your health in general is." – Cisgender woman, 25
 "...checking my blood pressure and all of my vitals and everything and doing that a lot more frequently. It's been helping me; I didn't know I was about to have high blood pressure until I started [CAB LA] and started coming in more frequently and checking my vitals more regularly." – Cisgender woman, 27

Satisfaction with CAB LA was high in Black women after 12 months

➔ Over 95% of Black women in EBONI would recommend CAB LA

Figure 4. Appropriateness (IAM), Acceptability (AIM), and Feasibility (FIM) of CAB LA at M12



AIM, Acceptability of Intervention Measure; FIM, Feasibility of Intervention Measure; IAM, Intervention Appropriateness Measure; SD, standard deviation. Figure reports the composite score of 4 items for each measure. Appropriateness, acceptability, and feasibility measures are rated on a five-point scale (1 = completely disagree to 5 = completely agree).

- Women in EBONI found CAB LA highly appropriate, acceptable, and feasible (Figure 4), with scores similarly high across gender (ranging from 4.4-4.9 across all 3 measures for transgender and cisgender participants)
- Overall, most women reported feeling "very positive" about initiating CAB LA (86%) and would recommend CAB LA (95%) to others who could benefit from it
- Participants interviewed at M12 endorsed their intent to continue using CAB LA (83%) and saw CAB LA as a long-term fit (57%). Barriers to continued use was not related to CAB LA: lifestyle changes (eg, getting married, change in sexual activity), finding another medication, or feeling it was no longer necessary. A representative quote of these themes is:

"Absolutely. I think it's a great match for women because we are already juggling so much and to have one less thing to worry about as far as like taking a pill is phenomenal. ...I think for, for busy women, it's perfect." – Cisgender woman, 40