

Integrating Long-Acting Injectable Cabotegravir for PrEP Into Standard of Care for Cisgender Women, Transgender Women, Transgender Men, and Men Who Have Sex With Men: Results From the PILLAR & EBONI Studies

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Key Takeaways

- Healthcare staff in the United States were extremely positive or positive about implementing long-acting cabotegravir (CAB LA) and perceived it would be highly feasible to implement CAB LA into practice
- At baseline, healthcare staff were developing implementation plans for CAB LA with clinic sites serving men who have sex with men (MSM) and transgender men having more detailed implementation plans in place for offering CAB LA appointments than those serving cisgender and transgender women
- The PILLAR and EBONI studies will support healthcare staff with strategies and tools to develop their plans to build staff and clinic capacity

Introduction

- EBONI and PILLAR are phase IV implementation science trials evaluating the integration of CAB LA into standard of care at 40 clinics across the United States
- EBONI and PILLAR focus on populations with the highest incidence of HIV in the United States,¹ many of whom have not used PrEP, thus filling a necessary information gap
- EBONI enrolls Black cisgender and transgender women, and PILLAR enrolls MSM and transgender men
 - EBONI reported that SSPs from clinics in the United States perceived Black women as highly appropriate for receiving CAB LA (see Poster 1550)²
 - PILLAR SSPs reported high levels of feasibility and acceptability of implementing CAB LA in low- and high-volume PrEP sites serving MSM and transgender men across the United States (see Poster 1559)³
- Here we report CAB LA implementation plans among SSPs

Methods

- SSPs (n=117) from 23 EBONI clinics completed surveys from August 2022 to July 2023
- SSPs (n=86) from 17 PILLAR clinics completed surveys from April to October 2022
- Surveys were administered before participant enrollment and implementation of study activities
- Survey responses, including SSPs' perceptions of implementing CAB LA, plans for integration, and estimation of resources needed for integration, were collected
- Various clinic types were selected to enroll diverse populations, with SSPs having a breadth of clinic roles

Results

Demographics of SSPs

- In EBONI and PILLAR, respectively, 57% and 50% of SSPs identified as cisgender women, SSP mean age was 42 and 41 years, 17% and 23% were physicians, and 50% and 48% of SSPs who prescribed medication were HIV specialists (Table 1)

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References: 1. CDC. *HIV Surveillance Report*. 2023;34. 2. Richmond et al. *IDWeek* 2023; Boston, MA. Poster 1550. 3. Torres et al. *IDWeek* 2023; Boston, MA. Poster 1559.

Table 1. SSP Demographics

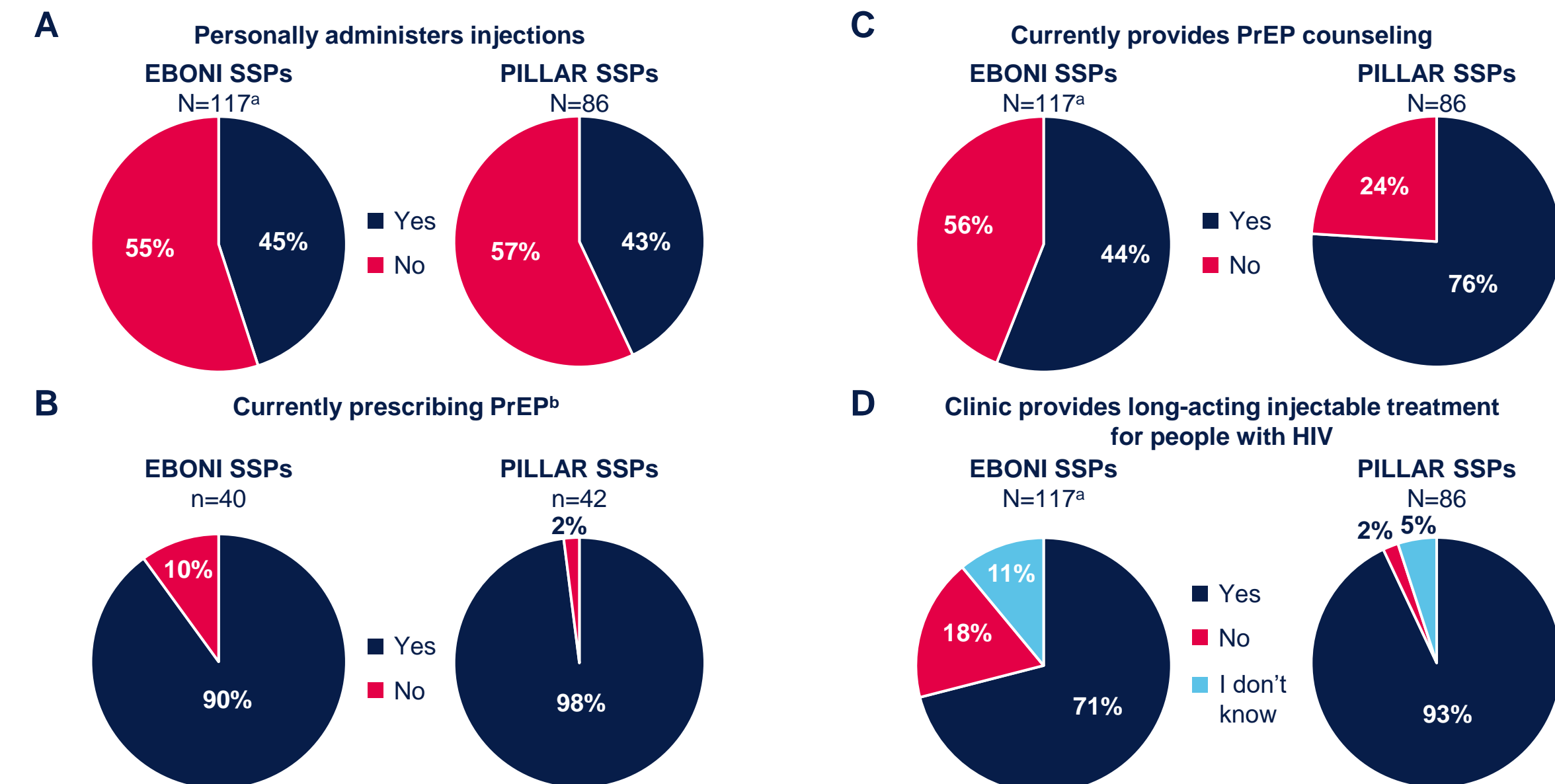
Characteristic	EBONI (N=117) ^a	PILLAR (N=86)
Gender, n (%)		
Cisgender female	67 (57)	43 (50)
Cisgender male	31 (27)	34 (40)
Other genders ^b	12 (10)	2 (2)
Prefer not to answer	7 (6)	7 (8)
Age, mean (SD), y	42 (11)	41 (11)
Race, n (%)		
White/Caucasian	39 (33)	47 (55)
Black/African American	44 (38)	13 (15)
Other races ^c	26 (22)	17 (20)
Prefer not to answer	8 (7)	9 (10)
Ethnicity, n (%)		
Hispanic/Latinx	27 (23)	21 (24)
Prefer not to answer	6 (5)	10 (12)
SSP role, n (%) ^d		
Physician	20 (17)	20 (23)
Nurse practitioner	18 (15)	6 (7)
Nurse	12 (10)	8 (9)
Medical assistant	14 (12)	7 (8)
Administrator (office/clinic)	12 (10)	7 (8)
Physician assistant	2 (2)	12 (14)
PrEP educator/navigator	6 (5)	5 (6)
Pharmacist	5 (4)	7 (8)
Social work/case manager	2 (7)	2 (2)
Other provider ^e	8 (7)	12 (14)
Specialty (>1 selection allowed), n (%) ^f	n=40	n=42
HIV specialist	20 (50)	20 (48)
Infectious disease specialist	12 (30)	13 (31)
Other specialty ^g	24 (60)	16 (38)

SSP, staff study participant. ^aData for 1 participant have yet to be transferred and analyzed. ^bTransgender man (EBONI, n=2), non-binary (EBONI, n=1; PILLAR, n=1), gender queer (EBONI, n=2; PILLAR, n=1), other (EBONI, n=7; PILLAR, n=7). ^cNative American (EBONI, n=1), mixed race (EBONI, n=14; PILLAR, n=4), other race (EBONI, n=7; PILLAR, n=6). ^dAfter rounding to whole numbers, proportions add to 99%. ^eLab tech (EBONI, n=1; PILLAR, n=3), front desk/scheduler (PILLAR, n=1), other provider (EBONI, n=19; PILLAR, n=8). ^fIncludes only SSPs who responded "Yes" to "Do you prescribe medications as part of your role?" ^gInternal medicine/primary care/general doctor/family practitioner (EBONI, n=19; PILLAR, n=14), immunologist (EBONI, n=1), women's health/gynecologists and gynecologists (EBONI, n=3), other (EBONI, n=1; PILLAR, n=2).

SSPs' Current Experience With PrEP and Injectable Treatment

- SSPs in EBONI and PILLAR had similar experience with PrEP and injections (Figure 1A-B); however, more SSPs in EBONI answered "no" to whether PrEP counseling was provided at the clinic (Figure 1C), and more answered "no" or "I don't know" when asked if the clinic provided LA injectable treatment for people with HIV (Figure 1D)

Figure 1. SSPs Experience With (A) Administering Injections, (B) Prescribing PrEP, (C) Providing PrEP Counseling, and (D) Whether the Clinic Provides Long-Acting Injectable Treatment for People With HIV



^aData for 1 participant have yet to be transferred and analyzed. ^bIncludes only SSPs who responded "Yes" to "Do you prescribe medications as part of your role?" SSP, staff study participant.

Acceptability and Feasibility of Implementing CAB LA

- A high proportion of SSPs in EBONI (93% [109/117]) and PILLAR (85% [73/86]) felt extremely positive or positive about implementing CAB LA in the clinic
 - The majority of SSPs in EBONI (73% [85/117]) and 53% (46/86) of SSPs in PILLAR perceived implementation would be "very easy" or "somewhat easy"
- SSPs in EBONI perceived PrEP clinics (99% [116/117]), STD/STI or sexual health clinics (98% [115/117]), and the Department of Health's clinics (97% [113/117]) to be "very appropriate" or "appropriate" settings for administering CAB LA (Table 2)
- SSPs in PILLAR perceived PrEP clinics (98% [84/86]), HIV specialty clinics (95% [82/84]), and STD/STI or sexual health clinics (92% [79/86]) to be "very appropriate" or "appropriate" for administering CAB LA (Table 2)

Table 2. SSP-Reported Appropriateness of Settings for Administering CAB LA

Proportion of participants who reported "very appropriate" or "appropriate," n (%)	EBONI (N=117) ^a	PILLAR (N=86)
PrEP clinic	116 (99)	84 (98)
STD/STI or sexual health clinic	115 (98)	79 (92)
HIV specialty clinic	110 (94)	82 (95)
Department of Health clinic	113 (97)	75 (87)
Community health center	111 (95)	76 (88)
Women's health practice/center	108 (92)	75 (87)
Primary care clinic/practice	107 (91)	75 (87)
Hospital outpatient	78 (67)	47 (55)
Infusion center	69 (59)	45 (52)
At home/home-based care	70 (60)	43 (50)
Community-based organization	77 (66)	44 (51)
Retail pharmacy (eg, CVS, Walgreens)	57 (49)	38 (44)
Other pharmacy	56 (48)	34 (40)
Other (eg, schools, mobile clinics, prisons) ^b	41 (35)	10 (12)

CAB LA, long-acting cabotegravir; SSP, staff study participant. ^aData for 1 participant have yet to be transferred and analyzed. ^bThis item was optional.

Plans for CAB LA Integration Into Care

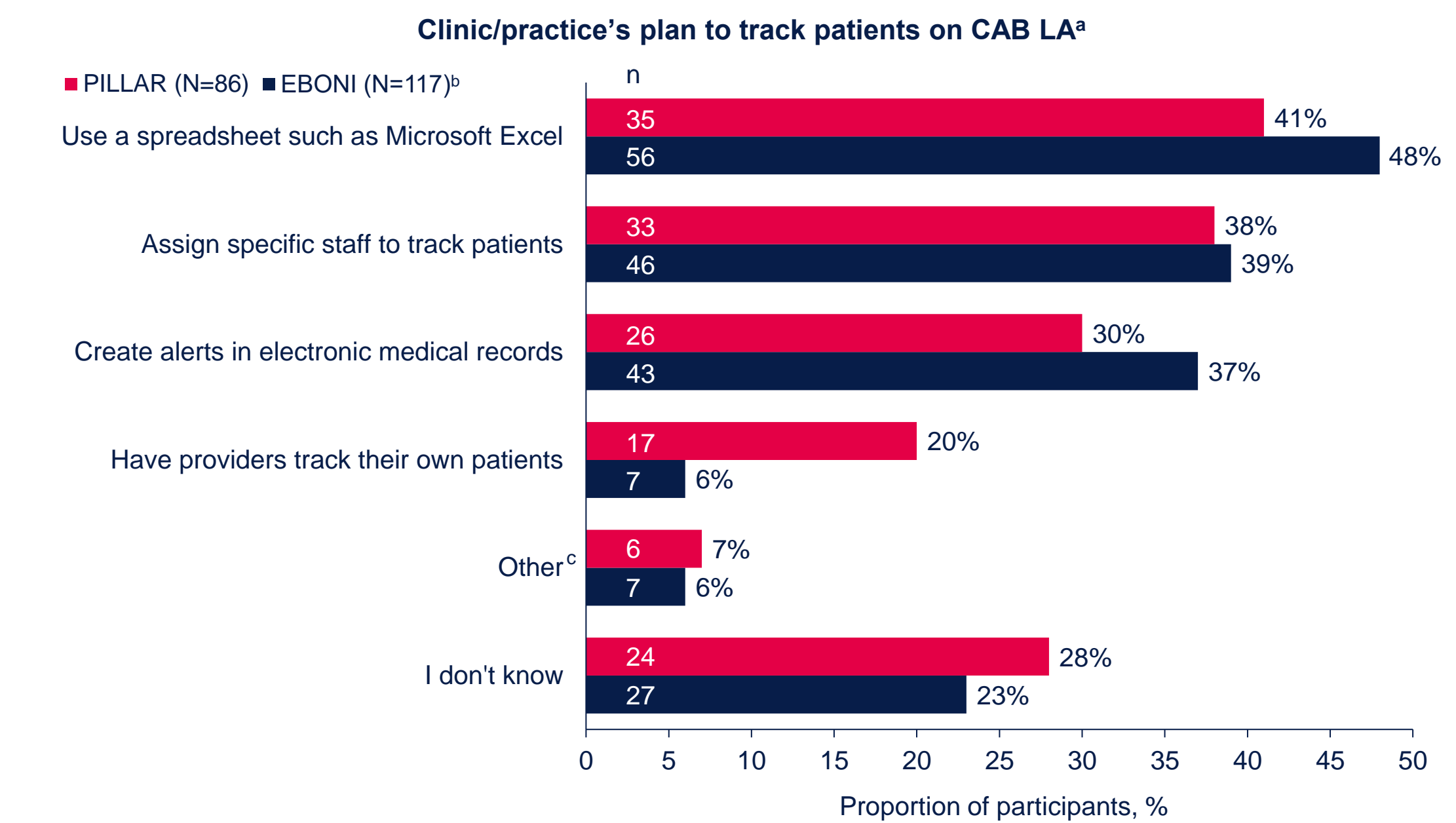
- Compared with EBONI, a higher proportion of SSPs in PILLAR reported:
 - Being able to manage more CAB LA patients per week and having more staff prepared to give injections (Table 3)
 - Planning to have providers track patients (Figure 2)
 - Planning to offer drop-in injection options (Figure 3)
- More SSPs in EBONI reported having a specific person to follow up with no-shows and planning to create roles to coordinate the CAB LA program (Table 3)
- Various appointment reminder tools are in place and used in similarly high proportions across both studies; however, a higher proportion of SSPs in PILLAR reported using email and postal reminders (Table 3)

Table 3. SSP-Reported Plans for CAB LA Integration Into Care

Proportion of responses, n (%) ^a	EBONI (N=117) ^b	PILLAR (N=86)
Number of CAB LA patients clinic/practice can manage per week on an ongoing basis		
0-10	52 (44)	21 (24)
11-25	33 (28)	35 (41)
26-50	14 (12)	12 (14)
>50	3 (3)	7 (8)
I don't know	15 (13)	11 (13)
Number of people in clinic trained and prepared to give CAB LA injections, median (IQR)	4.0 (2.0, 6.0)	6.0 (3.0, 10.0)
I don't know	28 (24)	16 (19)
Estimated staff time/FTE hours needed per week to incorporate CAB LA into your clinic/practice for ~25 people ^c		
1%-20% FTE or 0.4-8 h of staff time	19 (16)	18 (21)
21%-40% FTE or 8.4-16 h of staff time	34 (29)	28 (33)
41%-60% FTE or 16.4-24 h of staff time	6 (5)	2 (2)
>60% FTE or >24.4 h of staff time	11 (9)	9 (10)
I don't know	47 (40)	29 (34)
Plan to create new role(s)/new position(s) to coordinate CAB LA program ^d		
Yes	19 (16)	5 (6)
No	28 (24)	34 (40)
Maybe	24 (21)	18 (21)
I don't know	46 (39)	29 (34)
Action taken if a patient does not show for a regularly scheduled appointment ^e		
Phone the patient to reschedule	104 (89)	71 (83)
Text the patient to reschedule	53 (45)	41 (48)
Email the patient to reschedule	52 (44)	37 (43)
Other ^f	51 (44)	63 (73)
Has a specific person in charge of following up on no-shows		
Yes	79 (68)	45 (52)
No	18 (15)	28 (33)
I don't know	20 (17)	13 (15)
Systems in place to remind patients of an upcoming appointment		
Phone call from staff	75 (64)	55 (64)
Automated phone call	52 (44)	42 (49)
Text message	71 (61)	53 (62)
Email	39 (33)	37 (43)
Other ^g	37 (32)	38 (44)

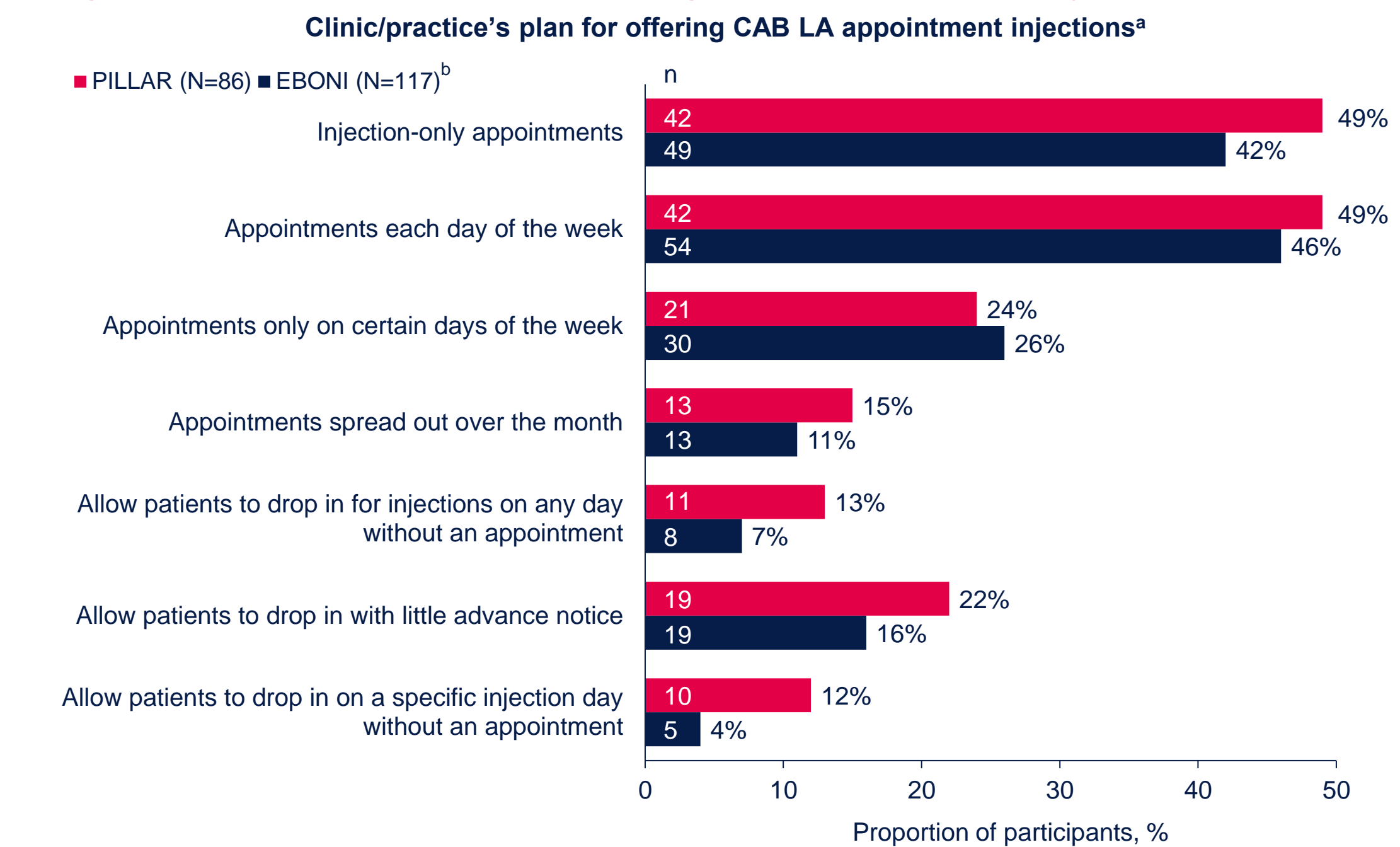
CAB LA, long-acting cabotegravir; FTE, full-time equivalent; IQR, interquartile range; SSP, staff study participant. ^aUnless noted otherwise, ^bData for 1 participant have yet to be transferred and analyzed. ^cAfter rounding to whole numbers, proportions of PILLAR SSPs add to 101%. ^dParticipants allowed to select more than one response. ^eSend the patient a postal letter to reschedule (EBONI, n=24; PILLAR, n=26), wait until the patient contacts the clinic/practice to reschedule (EBONI, n=4; PILLAR, n=16), charge the patient a fee for not showing up (EBONI, n=5; PILLAR, n=6), I don't know/not applicable to role (EBONI, n=11; PILLAR, n=11), other (EBONI, n=4; PILLAR, n=4). ^fPostal mail (EBONI, n=4; PILLAR, n=11), phone app notification (EBONI, n=19; PILLAR, n=13), I don't know (EBONI, n=12; PILLAR, n=11), other (EBONI, n=2; PILLAR, n=3).

Figure 2. Clinic/Practice's Plan to Track Patients on CAB LA



^aParticipants allowed to select more than one response. ^bData for 1 participant have yet to be transferred and analyzed. ^cOther responses in PILLAR: 340b reports, specific patient scheduling program, alerts on iPhone, Athena, nurse in charge of program, and custom tracking program in Microsoft Access; other responses in EBONI not specified. CAB LA, long-acting cabotegravir.

Figure 3. Clinic/Practice's Plan for Offering CAB LA Appointment Injections



^aParticipants allowed to select more than one response. ^bData for 1 participant have yet to be transferred and analyzed. CAB LA, long-acting cabotegravir.

Discussion

- SSPs reported having a wide range of roles in the clinic, all of which may have some interaction with patients receiving PrEP
- Our data from 40 study sites provide an outline for program planning to provide LA injectable PrEP to Black cisgender and transgender women, MSM, and transgender men

Conclusions

- A higher proportion of SSPs in PILLAR than EBONI had experience with PrEP counseling and LA injectable treatment for people with HIV
- Overall, SSPs in EBONI and PILLAR were positive about integrating CAB LA into care
- Compared with SSPs in EBONI, SSPs in PILLAR reported more detailed implementation plans for offering CAB LA appointments
 - Future analysis will report on how SSPs at clinics in PILLAR and EBONI have utilized implementation support and tools for integration of CAB LA into care
- At baseline, SSPs in EBONI and PILLAR attempted to develop implementation plans for CAB LA; proper planning sets clinics up for success regardless of population(s) served

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