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Healthcare Staff Perceptions of Feasibility and Acceptability on Implementing Injectable HIV Pre-exposure Prophylaxis Into Standard of Care: Baseline Results From the PrEP Implementation Study for Cabotegravir Long Acting for Men in the Real World (PILLAR)

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Key Takeaways

- **PILLAR is the first HIV trial to include transgender men**
- **Healthcare staff in the United States providing care to men who have sex with men (MSM) and transgender men reported long-acting cabotegravir (CAB LA) for PrEP to be highly acceptable and feasible to implement into standard of care**
- **Staff study participants (SSPs) were least concerned about CAB LA administration, efficacy, or individuals feeling stigmatized by CAB LA**
- **The PILLAR study will support healthcare staff with strategies and tools to address areas of concern identified at baseline**

Introduction

- Long-acting cabotegravir (**CAB LA**) is the **first approved long-acting injectable for the prevention of HIV-1**[1]; data are needed to evaluate the best administration process in clinical settings
- PILLAR evaluates the **feasibility and acceptability of implementation strategies** for delivering **CAB LA for PrEP to men who have sex with men (MSM) and transgender men** in low- and high-volume PrEP sites across the United States
  - Based on community input, Black transgender women were included in the sister study, EBONI (Poster 1550[2] and Poster 1547[3])
- Here, we report staff study participants' (SSPs') baseline perceptions of implementation before study sites commenced enrollment and used implementation strategies

Methods

- 86 SSPs from 17 clinics completed surveys on implementation outcomes assessed using the **Acceptability of Intervention Measure (AIM)** and **Feasibility of Intervention Measure (FIM)**[4]
  - Implementation was staggered; at the time of the analysis cut-off, not all clinics had started implementation
- High-volume site (HVS; >50 people per month) and low-volume site (LVS; ≤50 people per month) definitions were based on pooled feasibility data from potential eligible sites across the United States
- Descriptive statistical analyses across site volume (HVSs vs LVSs) were performed using 2-sample *t* tests and Fisher's Exact tests

Results

Baseline Demographics of SSPs

- Among the 86 SSPs, 38 were from HVSs and 48 were from LVSs (Table)
  - 50% identified as female, 55% were White, and 64% were non-Hispanic/Latinx (64%); most who prescribe medication were HIV or infectious disease specialists (79%)

Table. SSP Demographic Characteristics (N=86)

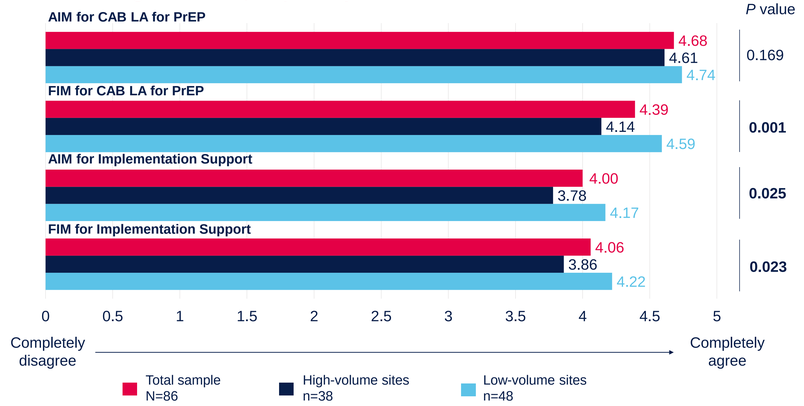
Characteristic	High-volume sites n=38	Low-volume sites n=48
Gender, n (%)		
Cisgender male	15 (40)	19 (40)
Cisgender female	20 (53)	23 (48)
Other genders[a,b]	3 (8)	6 (13)
Age, mean (SD), y	42.0 (11.4)	40.3 (11.4)
Race, n (%)		
White/Caucasian	24 (63)	23 (48)
Black	0	13 (27)
Other races[c]	14 (37)	12 (25)
Ethnicity, n (%)[d]		
Hispanic/Latinx	13 (34)	8 (17)
Provider type, n (%)		
Physician/Physician Assistant	18 (47)	14 (29)
Nurse/Nurse Practitioner	6 (16)	8 (17)
Medical Assistant	3 (8)	4 (8)
Pharmacist	3 (8)	4 (8)
Office administrator/clinic administrator	1 (3)	6 (13)
Other roles[e,f]	9 (24)	16 (33)
Specialty, n (%)[g,h]		
Infectious disease/HIV specialist	19 (70)	14 (93)
Internal medicine/ primary care/general doctor/ family practitioner	7 (26)	7 (47)

SSP, staff study participant.
[a]Gender queer (LVS, n=1), non-binary (HVS, n=1), and "prefer not to answer" (HVS, n=2; LVS, n=5). [b]After rounding to whole numbers, proportions add to 101% in the individual HVS and LVS populations. [c]Asian (HVS, n=4; LVS, n=3); mixed race (HVS, n=4), other race (HVS, n=2; LVS, n=4), and "prefer not to answer" (HVS, n=4; LVS, n=5). [d]In total, 10 individuals preferred not to answer (HVS, n=4; LVS, n=6). [e]PrEP educator/PrEP navigator (HVS, n=1; LVS, n=4), laboratory staff/technician/phlebotomist (HVS, n=1; LVS, n=2), social worker/case manager (HVS, n=1; LVS, n=1), front desk staff/scheduler (HVS, n=1), and clinical research/research/study coordinator, certified pharmacy concierge/technician, or director of clinical operations/research (HVS, n=3; LVS, n=5). [f]After rounding to whole numbers, proportions add to 99% in the total sample and LVS population and 101% in the HVS population. [g]This question was applicable among SSPs who prescribe medication (total, n=42; HVS, n=27; LVS, n=15) and multiple responses could be selected. [h]Not represented in the table, other specialties included internal medicine and pediatrics as well as sexual health (HVS, n=1; LVS, n=1).

Feasibility and Acceptability

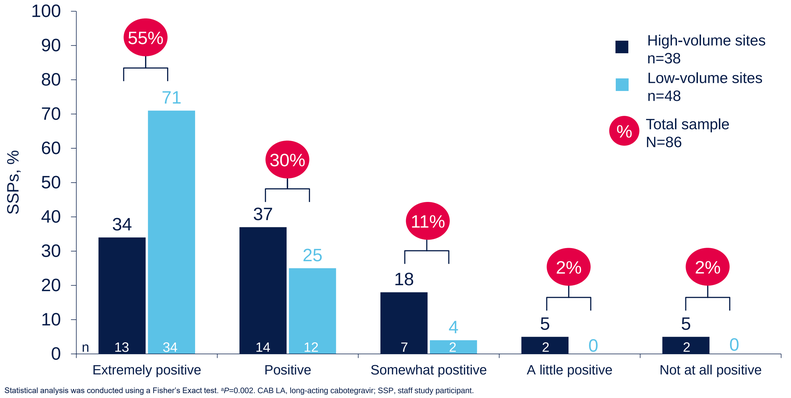
- SSPs reported high mean levels of **feasibility and acceptability** of implementing CAB LA (AIM, 4.7; FIM, 4.4) and **implementation support** (AIM, 4.0; FIM, 4.1); with generally significantly higher levels reported by LVS versus HVS SSPs (Figure 1)
- Overall, **SSPs were "extremely positive" (55%) or "positive" (30%) about implementing CAB** LA for PrEP at their clinic/practice (Figure 2); with generally higher positive perceptions of LVS versus HVS SSPs

Figure 1. SSPs' Perceptions of Acceptability and Feasibility of Implementing CAB LA for PrEP, Assessed Using AIM and FIM, Respectively



Comparison of the means by clinic volume was performed using a 2-sample *t* test. Statical analyses were performed comparing means from HVS and LVS clinics. AIM, Acceptability of Intervention Measure; CAB LA, long-acting cabotegravir; FIM, Feasibility of Intervention Measure; SSP, staff study participant.

Figure 2. SSPs' Feelings About Implementing CAB LA for PrEP at Their Clinic/Practice[a]

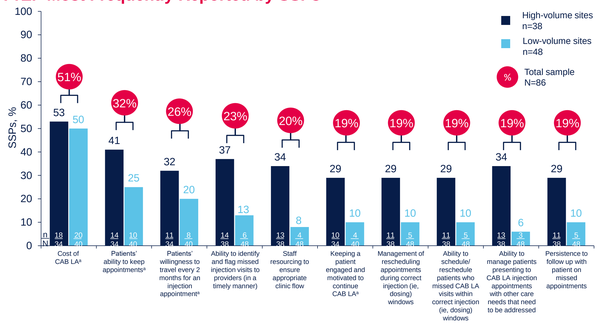


Statistical analysis was conducted using a Fisher's Exact test. [a]P=0.002. CAB LA, long-acting cabotegravir; SSP, staff study participant.

Barriers and Challenges

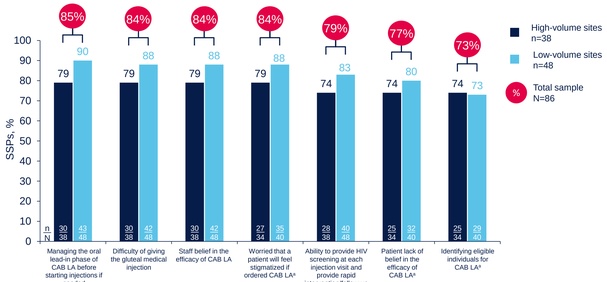
- Overall, the **top 3 perceived barriers** to delivering CAB LA included **medication cost** (51%), **patients' ability to keep appointments** (32%), and **patients' willingness to travel for 2-monthly appointments** (26%; Figure 3)
  - Generally, a higher proportion of HVS versus LVS SSPs reported being concerned about these barriers
- SSPs were **least concerned** about **managing the oral lead-in**, **giving the gluteal medical injection**, and the **efficacy of CAB LA** (Figure 4)

Figure 3. Barriers or Challenges to Delivering or Administering CAB LA for PrEP Most Frequently Reported by SSPs



Perceived barriers to CAB LA implementation were measured on a 5-point rating scale (1=extremely concerned to 5=not at all concerned). Barriers or challenges presented here were rated by SSPs as extremely or moderately concerned. [a]12 participants did not complete the question. CAB LA, cabotegravir long-acting; SSP, staff study participant.

Figure 4. Most Frequently Reported Barriers or Challenges to Delivering or Administering CAB LA for PrEP Most Rated by SSPs as "Slightly Concerned" or "Not at all Concerned"



Perceived barriers to CAB LA implementation were measured on a 5-point rating scale (1=extremely concerned to 5=not at all concerned). Barriers or challenges presented here were rated by SSPs as slightly or not at all concerned. [a]12 participants did not complete the question. CAB LA, long-acting cabotegravir; SSP, staff study participant.

Discussion

- Qualitative data are needed to better understand the reasons behind the perceptions captured in this quantitative survey
- Unmeasured factors that could be captured through qualitative data (eg, higher workload at HVSs) may have influenced differences between HVSs and LVSs

Conclusions

- At baseline, SSPs reported **CAB LA for PrEP to be highly acceptable and feasible to implement** into standard of care; LVS SSPs versus HVS SSPs reported higher acceptability and feasibility
- SSPs at HVSs may be more aware of PrEP introduction complexities than those at LVSs
- Most SSPs had few concerns about CAB LA administration, efficacy, or individuals feeling stigmatized by CAB LA
- The perceptions for identifying eligible individuals for CAB LA were different for men in PILLAR versus women in EBONI (See Poster 1550)[2]
  - In PILLAR, SSPs considered individuals' experiences and environmental factors rather than specific demographics[5]

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References: 1. US Food & Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention. Accessed August 22, 2023. **2.** Richmond et al. IDWeek 2023; Boston, MA. Poster 1550. **3.** Valenti et al. IDWeek 2023; Boston, MA. Poster 1547. **4.** Weiner et al. *Implement Sci.* 2017;12:108. **5.** Pilgrim et al. HIV DART and Emerging Viruses 2022; Los Cabos, Mexico. Poster HP5.

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