One-Year Implementation Outcomes of Cabotegravir Long-Acting Injectable PrEP in Men Who Have Sex With Men (MSM) & Transgender Men (TGM): Findings From the PILLAR Study

Poster TUPEE116

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Key Takeaways

- In PILLAR, men who have sex with men (MSM) and transgender men (TGM) found cabotegravir long-acting (CAB LA) highly acceptable and easily fit into their lives, with little to no pre-exposure prophylaxis (PrEP) stigma or anxiety concerns reported.
- Participants reported benefits of Q2M visits including additional opportunities to test for sexually transmitted infections (STIs).
- Implementation resources (e.g. educational brochures/videos, websites) and strategies (e.g. flexible scheduling, reminders) effectively supported CAB LA use.
- Almost all MSM and TGM in PILLAR were happy they switched from oral PrEP to CAB LA and would recommend CAB LA to other people who could benefit from it.

Introduction

- MSM and TGM account for 67% and <1% of new HIV diagnoses in the United States (US), respectively.[1,2]
- CAB LA administered every 2 months (Q2M) via intramuscular injection is the first approved LA agent for PrEP in adults and adolescents.[3,4]
- PILLAR (NCT05374525) is a 12-month Phase 4 effectiveness–implementation hybrid study evaluating implementation strategies for the delivery of CAB LA for PrEP to MSM and TGM across infectious disease clinics in the US.
  - Zero cases of HIV acquisition among MSM and TGM have been reported with CAB LA through Month 12 in PILLAR.[5]
- PILLAR is the first industry-led HIV implementation science trial to gender align participants per community request and includes TGM, who are often not included in clinical studies.
- We present implementation outcomes and experiences of MSM and TGM after 12 months of CAB LA use in the PILLAR study.

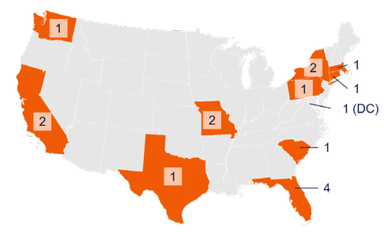
Methods

- A total of 17 sites in the US were included in the study. Sites were randomized 2:1 to routine implementation (RI) and dynamic implementation (DI).
  - RI: standard of care.
  - DI: standard of care and enhanced support (implementation facilitation and support strategies and tools).
- Participating clinics included:

Non-profit and community-based organizations (n=6) | Academic/research institutions (n=4) | Federally qualified health centers (n=4) | Private clinics (n=3)

- Quantitative data were collected via self-completed electronic surveys
  - Participants evaluated the feasibility and acceptability of CAB LA using the validated Feasibility of Intervention Measure (FIM) and Acceptability of Intervention Measure (AIM) questionnaires, respectively.[6]
  - Differences in implementation outcome by arm were assessed using t-tests.
- Qualitative data were obtained from semi-structured telephone interviews with a sample of participants.
  - Interview topics were informed by the Consolidated Framework for Implementation Research and Proctor implementation outcomes taxonomy.[7,8]
  - Interviews were analyzed using a framework analysis approach.

Clinic Site Locations



Results

- Overall, 201 participants enrolled between May 2022 and August 2023; 142 completed Month 12 surveys and 44 completed qualitative interviews.
- Most participants (94%) were MSM, 23% were Black, and 39% were Hispanic (**Table 1**).

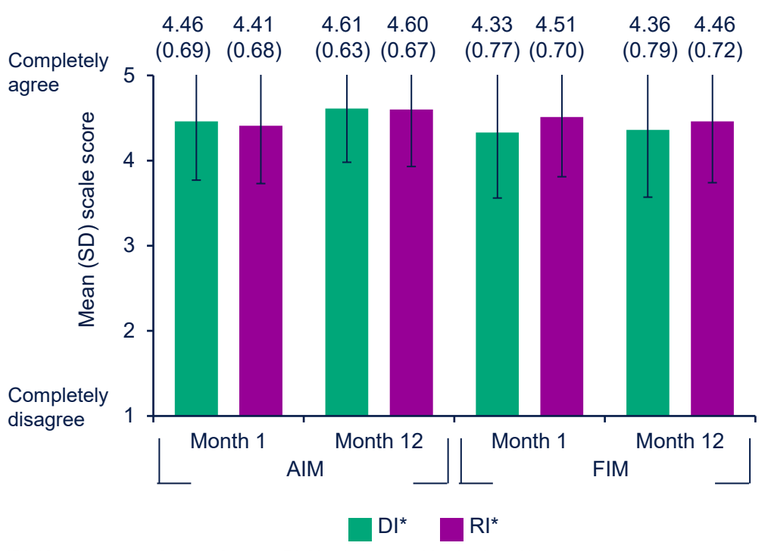
Table 1. Demographic Characteristics at Baseline and Month 12

Characteristic, n (%)	Baseline (quantitative sample) (N=201)	Month 12 (quantitative sample) (n=142)	Month 12 (qualitative sample) (n=44)
Age, years			
18–25	20 (10)	11 (8)	4 (9)
26–35	82 (41)	54 (38)	13 (30)
36–49	64 (32)	47 (33)	18 (41)
≥50	35 (17)	30 (21)	9 (20)
Gender identity			
MSM	189 (94)	136 (96)	39 (89)
TGM	12 (6)	6 (4)	5 (11)
Race			
Black	46 (23)	38 (27)	12 (27)
Not black	138 (69)	94 (66)	32 (73)
Missing/Unknown	17 (8)	10 (7)	0
Ethnicity			
Hispanic/Latinx	78 (39)	46 (32)	11 (25)
Not Hispanic/Latinx	120 (60)	95 (67)	33 (75)
Missing/Unknown	3 (1)	1 (1)	0
Partnered*			
Yes	82 (44)†	64 (45)	14 (32)
No	99 (53)†	75 (53)	22 (50)
Prefer not to answer/unknown	5 (3)†	3 (2)	8 (18)

*Relationship status includes: dating but not living with a partner; dating and living with a partner; domestic partnership or civil union/married. †n=186; excludes participants with missing data (n=15).
MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; TGM, transgender men.

- Participants found CAB LA highly acceptable and feasible at baseline (mean [SD]: AIM, 4.44 [0.69]; FIM 4.41 [0.74]), and Month 12 (mean [SD]: AIM 4.61 [0.64]; FIM, 4.41 [0.76]).
  - Scores were similar by implementation arm (**Figure 1**), with no statistically significant differences in change from baseline to Month 12 between arms.

Figure 1. Acceptability and Feasibility of CAB LA



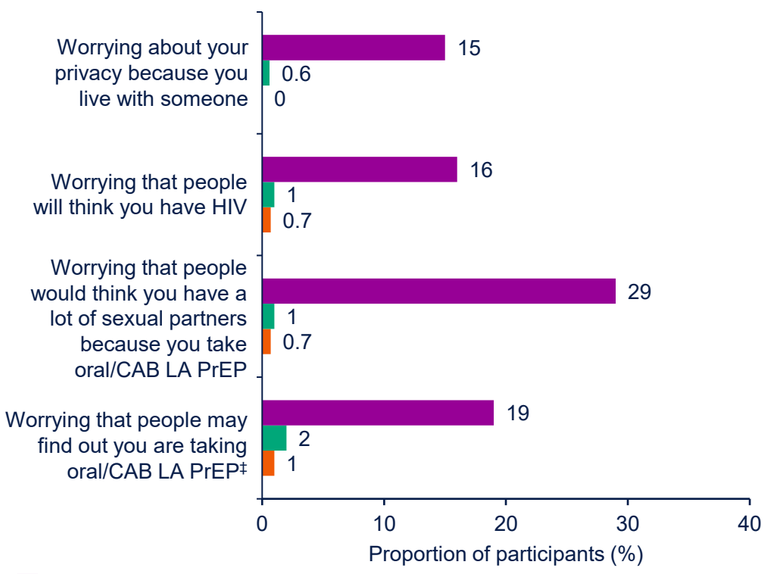
*DI: Month 1, n=105; Month 12, n=77; RI: Month 1, n=77; Month 12, n=63.
AIM, Acceptability of Intervention Measure; CAB, cabotegravir; DI, dynamic implementation; FIM, Feasibility of Intervention Measure; LA, long-acting; RI, routine implementation; SD, standard deviation.

- Qualitative data supported the quantitative data, with 98% (n=43/44) of participants discussing how CAB LA fit well into their daily lives at Month 12.

> (...) I don't have to be concerned about missing doses and I just go in for the injection and I leave the same day. No issues usually. So it's no problem (MSM)

- Stigma concerns were reported by 15–29% of participants with oral PrEP at baseline. These concerns were reported by only 1–2% of participants with CAB LA at Month 6 and remained low to Month 12 (**Figure 2**).
- At baseline, 53–54% of participants reported concerns around forgetting to take and running out of oral PrEP. Conversely, at Months 6 and 12, related concerns with CAB LA around forgetting and missing an injection visit were reported by 2–9% of participants.

Figure 2. Stigma Reported With Oral PrEP and CAB LA



*Skip logic errors present in survey programming resulted in fewer participants who had taken oral PrEP answering questions. †All participants were asked if they had any concerns about CAB LA, and those reporting yes were asked about their specific concerns. ‡(Month 6, n=159; Month 12, n=140); participants who responded "Often/all the time" to, "How often are you worried that people may find out that you are taking CAB LA?"
CAB, cabotegravir; LA, long-acting; PrEP, pre-exposure prophylaxis.

Pain Experienced After First and Most Recent CAB LA Injection

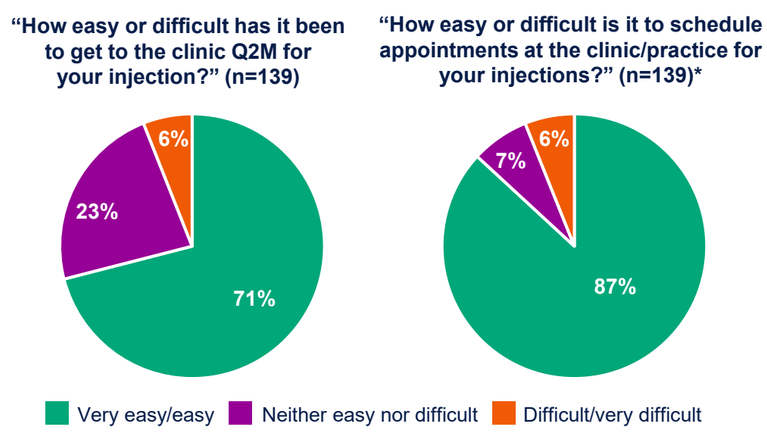
- In the Month 12 surveys, the level of pain reported by participants for the first injection was generally higher than that reported for their most recent injection.
  - Participants experiencing no pain to mild pain increased from 51% to 76% between the first and most recent injection.*
- During qualitative interviews at Month 12, 6 (n=6/44;14%) participants who reported pain and discomfort from CAB LA injections discussed that the pain had become more manageable over time. Some of these participants also noted that the pain from injections had decreased with subsequent injections, consistent with quantitative data.

> It's been pretty good. The only problem was in the beginning injection site pain, but that was about it. The first two, maybe, were a little painful and then now and again there is some more pain. (MSM)

*Pain was assessed via a visual analog scale, with patients asked to rate their pain during their most recent injection visit between 0 ("no pain") and 10 ("extreme pain"). 0–4 = no pain to mild pain.

- At Month 12, most participants (94%) reported no difficulty with getting to the clinic Q2M or scheduling CAB LA appointments (**Figure 3**).

Figure 3. Ease of Getting to the Clinic Q2M or Scheduling CAB LA Appointments



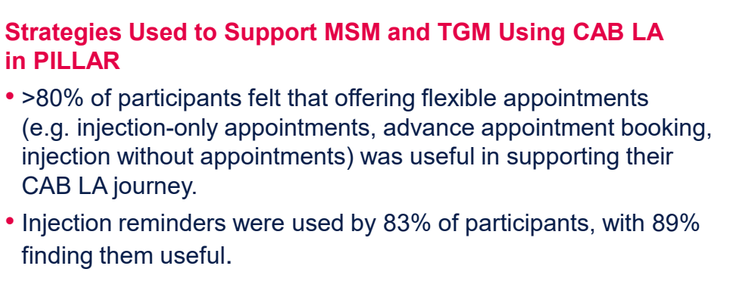
*Excludes participants with missing data (n=61) and one participant who responded "I have not scheduled any appointments at the clinic/practice".
CAB, cabotegravir; LA, long-acting; Q2M, every 2 months.

- Most interviewed participants (68%) discussed the benefit of more frequent clinic visits with CAB LA injections, specifically mentioning:
  - Having more interaction with healthcare providers (HCPs), which facilitated discussion of other health issues;
  - More frequent STI testing, which provided reassurance;
  - Building rapport and a relationship with staff at the clinic.

> No, I don't have any challenges. Actually I, I think it's, it's really good for me to go in to see my primary every 2 months … So this way it's forced me to go in every 2 months and then, in addition, to get my shots we do other tests and we talk about, you know – so I think that I, I feel more confident. I feel better about my health, you know, because I get to see my provider every 2 months (MSM)

- Implementation support, including education brochures, expectation videos, and digital platforms, were reported as useful by 66–75% of participants (**Figure 4**).
- Use of supports were relatively similar across arms.

Figure 4. Resources Used by MSM and TGM in PILLAR



*Resources offered in the RI arm only. †Resources offered in the DI arm only. ‡Includes only participants who reported using each resource: education brochures (n=84), education videos (n=40, DI arm only), CAB LA information website (n=25, RI arm only), and CAB LA information website/app (n=32, DI arm only). Percentages reflect the proportion of participants who reported "useful" or "extremely useful" out of those participants who reported using each resource.
CAB, cabotegravir; DI, dynamic implementation, LA, long-acting; MSM, men who have sex with men; RI, routine implementation; TGM, transgender men.

- During qualitative interview at Month 12, 39% (n=17/44) of participants shared overall positive experience surrounding the tools they received in the study.

> The accessibility, definitely of the website. The portal was really helpful; I think it can be hard to keep track of handouts, so having that to go back on and refer to can be helpful. They seemed really comprehensive, pretty patient-centered language, all layman's terms, which was really helpful (TGM)

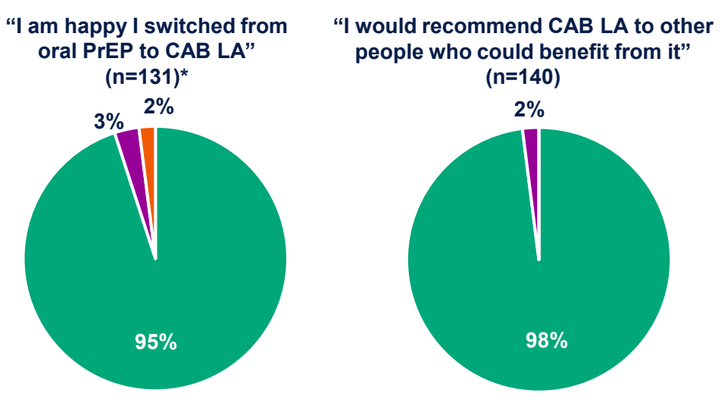
Strategies Used to Support MSM and TGM Using CAB LA in PILLAR

- >80% of participants felt that offering flexible appointments (e.g. injection-only appointments, advance appointment booking, injection without appointments) was useful in supporting their CAB LA journey.
- Injection reminders were used by 83% of participants, with 89% finding them useful.

> I think it's been for the most part convenient based off of my current schedule ... You know, they've been able to find another time so there is enough flexibility there in the schedule, which is helpful … (TGM)

- Of the participants with a history of oral PrEP use, 95% were happy they switched to CAB LA and 98% would recommend CAB LA (**Figure 5**).

Figure 5. PrEP Preference at Month 12



*Excludes participants without prior oral PrEP experience (n=9) and participants with missing data (n=61).
CAB, cabotegravir; LA, long-acting; PrEP, pre-exposure prophylaxis

Conclusions

- Participants in PILLAR found CAB LA to be feasible and acceptable in their lives.
- MSM and TGM reported little to no PrEP stigma and anxiety concerns with CAB LA at Month 6 which remained consistent to Month 12.
- MSM and TGM discussed benefits of Q2M clinic visits, including more interaction with HCPs which facilitated discussion of other health issues and more frequent STI testing.
- Flexible scheduling, reminders, and educational tools effectively supported CAB LA use to enhance PrEP uptake and adherence.

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