

PATIENT PERSPECTIVES ON IMPLEMENTATION OF A LONG-ACTING INJECTABLE ANTIRETROVIRAL THERAPY REGIMEN IN HIV US HEALTHCARE SETTINGS: INTERIM RESULTS FROM THE CUSTOMIZE STUDY

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Introduction

- Barriers to maintaining high adherence to antiretroviral therapy (ART) include challenges with daily dosing, such as remembering to take medication on time, difficulties taking medication when away from home, and concerns regarding being stigmatized for having HIV^{1,2}
- Additional treatment options, including alternative dosing/delivery methods that negate the need to take a daily pill(s), may be beneficial for some people living with HIV
- Long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV) administered as a monthly intramuscular injection is an effective treatment in virologically suppressed adults with HIV-1 infection^{3,4}
- CAB + RPV LA offers a less-frequent dosing alternative to daily oral pills but requires more frequent clinic visits; it is important to understand how to optimize administration of CAB + RPV LA in routine care from the perspective of people living with HIV

Methods

- CUSTOMIZE is a single-arm, multicenter, hybrid III implementation study assessing patient and provider perspectives over a 12-month period to identify barriers and facilitators and to determine the most effective strategies for successful implementation of the CAB + RPV LA injectable regimen in US healthcare settings
- Virologically suppressed patients were enrolled across 8 US clinics to receive monthly CAB + RPV LA injections following an oral lead-in of ~4 weeks
- This interim analysis includes data from patient surveys conducted at baseline and Month 4 (prior to the first and fourth injections, respectively)
 - Month 4 surveys were completed by February 2020
 - Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM) are 4-item questionnaires that use a 5-point rating scale (1 = disagree to 5 = completely agree) to evaluate the acceptability and appropriateness of the regimen, respectively
 - Additional 7- and 10-item questionnaires assessed attitudes and expectations of patients regarding the CAB + RPV LA regimen
- Univariate distribution of every survey item was tabulated and summarized using standard distributional statistics; subgroups were compared with Fisher exact tests

Results

- 109 and 105 patients from 8 sites completed the baseline and Month 4 surveys, respectively
- 86% (n=94) patients were men; mean age was 39 years (Table)
- 37 (35%) patients were from federally qualified health centers, 12 (11%) were from university health centers, 26 (25%) were from private practices, 15 (14%) were from AIDS Healthcare Foundation clinics, and 15 (14%) were from health maintenance organizations

Table. Baseline Demographics

Parameter	Participants (N=109)
Age, mean (range), y	39 (20-65)
<35, n (%)	52 (48)
35-49, n (%)	31 (28)
≥50, n (%)	26 (24)
Male, n (%)	94 (86)
Race/Ethnicity, n (%)	
Black/African American	38 (35)
White/Caucasian/European heritage	64 (59)
American Indian/Alaskan Native	5 (5)
Multiple	2 (2)
Hispanic/Latino	29 (27)
Non-Hispanic/Latino	80 (73)
Body mass index, mean (SD), kg/m ²	28.1 (6.3)

Perceptions and Experiences Prior to Receiving CAB + RPV LA

- At baseline, the most common patient-reported concerns with taking daily oral HIV therapy were hiding oral ART from others, remembering to take daily ART, and running out of ART (Figure 1)
 - Men were significantly more likely than women to report having no concerns with prior daily HIV medications (50.5% vs 21.4%; $P<0.05$)
 - Women were significantly more likely than men to report concerns about remembering to take their daily HIV medications (42.9% vs 18.9%; $P<0.05$)
 - Participants aged 40 to 49 years were the most likely to report hiding their daily HIV medications from others ($P<0.05$)
- Interest in a more convenient treatment option was a top reason (83%) for choosing CAB + RPV LA treatment

Figure 1. Patient-Reported Concerns With Taking Daily Oral HIV Medications (Baseline)

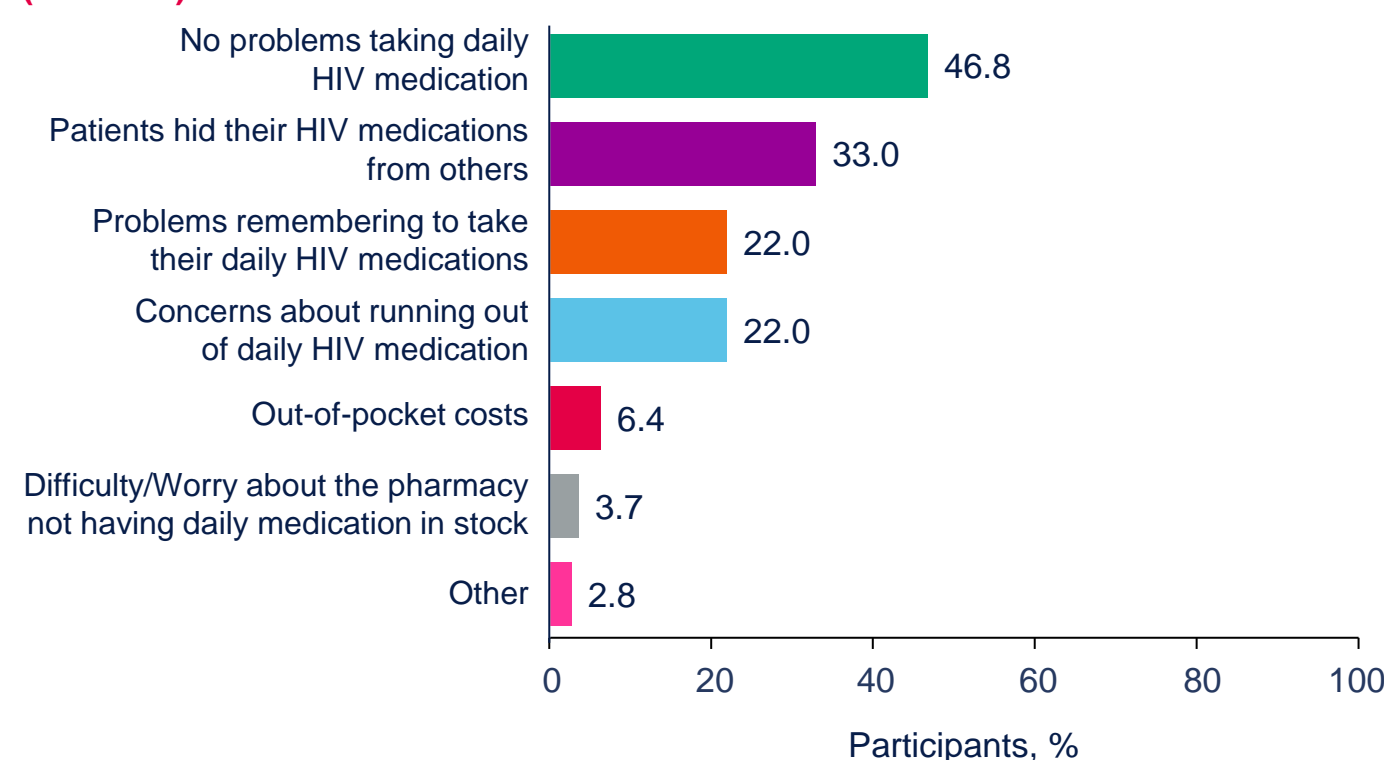
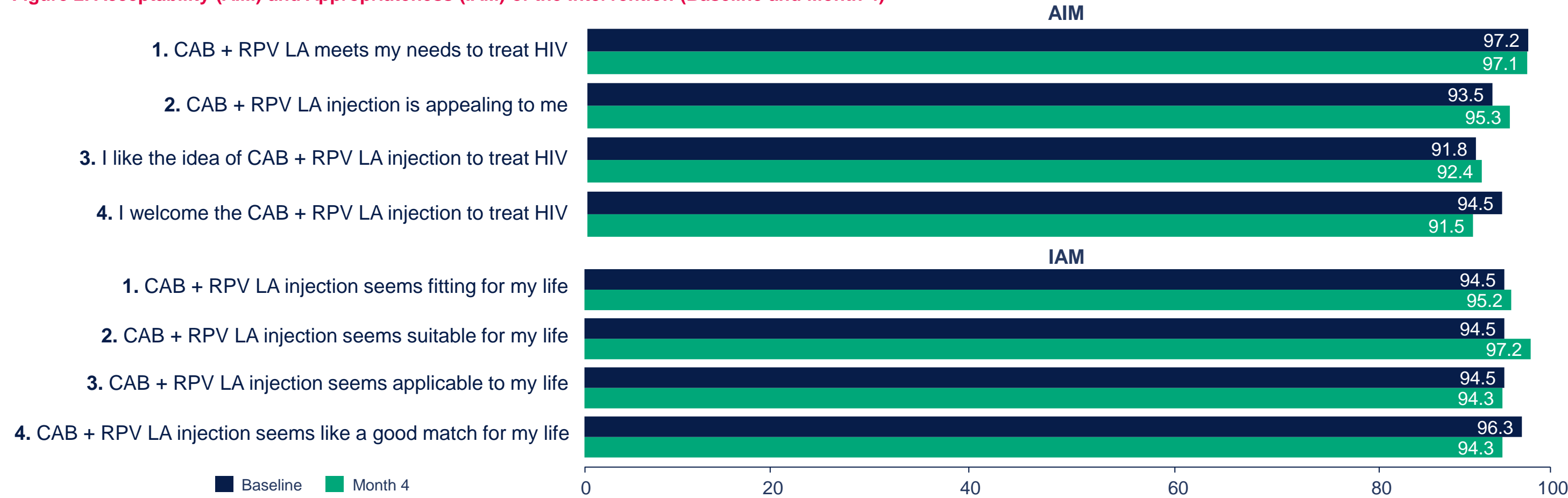


Figure 2. Acceptability (AIM) and Appropriateness (IAM) of the Intervention (Baseline and Month 4)



Each bar represents the proportion of patients who agreed or completely agreed with the statement. AIM, Acceptability of Intervention Measure; IAM, Intervention Appropriateness Measure.

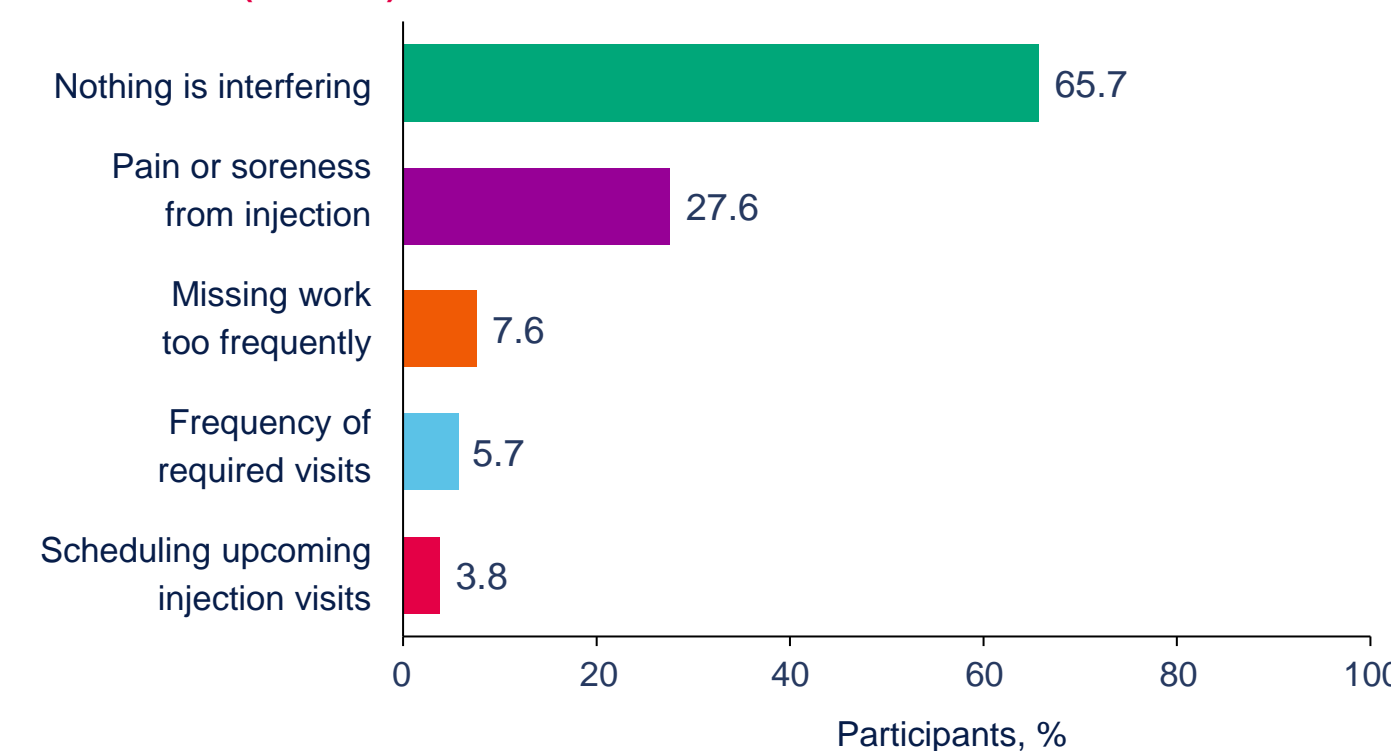
AIM and IAM

- At baseline and Month 4, most participants (>91%) agreed or completely agreed that CAB + RPV LA was acceptable and appropriate (Figure 2)

Expectations and Attitudes

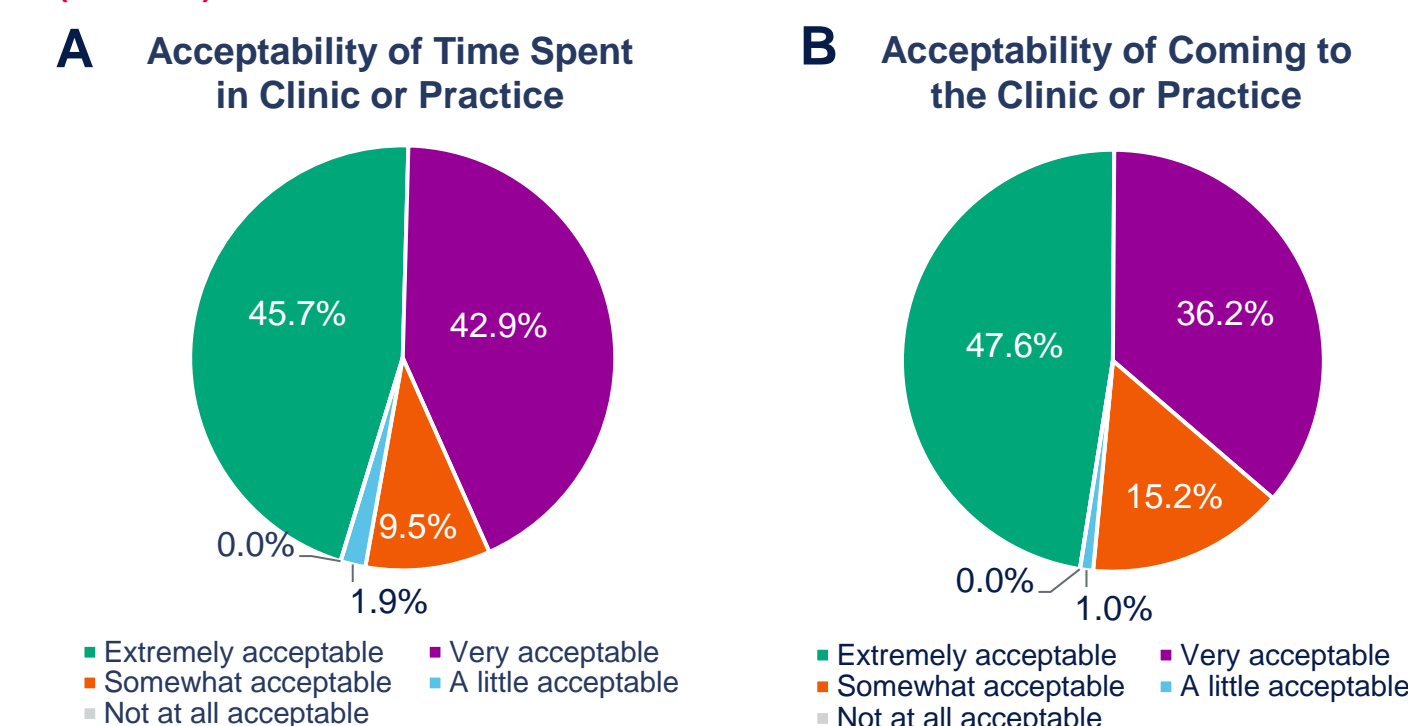
- Most participants (>91%) reported feeling very or extremely positive about receiving the CAB + RPV LA injection treatment at both baseline and Month 4
- At baseline, injection pain or soreness was the most common concern (57.8%) regarding CAB + RPV LA treatment
 - At Month 4, 28% of participants reported injection pain or soreness as a concern, and 65.7% reported no logistical challenges to receiving CAB + RPV LA injections (Figure 3)

Figure 3. Patient-Reported Factors Interfering With Ability to Receive the Intervention (Month 4)



- At Month 4, 89% of participants reported that the amount of time spent in the clinic/practice for each injection visit was very or extremely acceptable, and 84% reported that monthly clinic visits were very or extremely acceptable (Figure 4)

Figure 4. Patient-Reported Results on Acceptability of (A) Time Spent in the Clinic/Practice and (B) Coming to the Clinic/Practice for Each Injection Visit (Month 4)



- At Month 4, 93% of participants reported that scheduling injection visits was very or extremely convenient
 - Of the 84 participants who responded to the rescheduling question, 94% reported rescheduling visits to be very or extremely convenient

Adherence to Treatment

- For Months 2 to 4, 95% of injections occurred within a ± 7 -day dosing window around the target treatment date
 - The remaining 5% of injections occurred early (-8 to -14 days)
- No participant missed an injection or required oral therapy as of Month 4 of the analysis

Conclusions

- Most patient participants found CAB + RPV LA to be acceptable and appropriate
 - Majority reported that monthly injection appointments were highly acceptable
- The majority of patients reported no logistical challenges with monthly CAB + RPV LA injection visits, supported by high patient adherence to injection visits
- Initial implementation data suggest CAB + RPV LA is a convenient and appealing treatment option
- Additional data will be presented following completion of the Month 12 analysis, which will include any impact of COVID-19

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