CAB + RPV LA IMPLEMENTATION OUTCOMES AND ACCEPTABILITY OF MONTHLY CLINIC VISITS IMPROVED DURING COVID-19 PANDEMIC ACROSS US HEALTHCARE CLINICS (CUSTOMIZE: HYBRID III IMPLEMENTATION-EFFECTIVENESS STUDY)

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Introduction

- Cabotegravir (CAB) and rilpivirine (RPV) have been approved in the United States, Canada, Australia, and Europe as the first complete long-acting (LA) injectable regimen indicated for the maintenance of virologic suppression in people living with HIV-1 (PLHIV)[1,2]
- CUSTOMIZE is a phase IIIb, 12-month, hybrid III implementation-effectiveness study evaluating the implementation of CAB + RPV LA in US healthcare settings from the perspectives of healthcare providers and PLHIV
  - CUSTOMIZE started in July 2019 and continued during and after March 2020 when much of the United States began COVID-19 pandemic–related closures
- This analysis evaluates the impact of the COVID-19 pandemic on CAB + RPV LA implementation outcomes in CUSTOMIZE

Methods

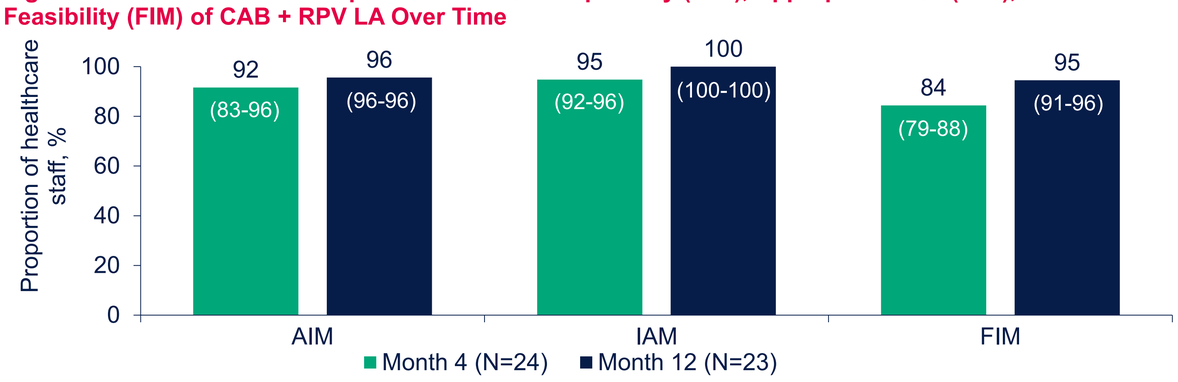
- CUSTOMIZE is a single-arm study that enrolled virologically suppressed PLHIV at 8 US clinics to receive monthly CAB + RPV LA injections after a 1-month oral lead-in
- Patient participants with a COVID-19–impacted visit were defined as those with a COVID-19–related protocol deviation on file (eg, missed or rescheduled injection visit, quarantine, COVID-19 diagnosis, clinic closure)
- This analysis includes data from healthcare staff and participant surveys conducted before COVID-19 at Month 4 (~November to December 2019) and during COVID-19 at Month 12 (~October 2020) and from interviews at Month 12
  - Acceptability of intervention measure (AIM), intervention appropriateness measure (IAM), and feasibility of intervention measure (FIM) were 4-item questionnaires that used a 5-point rating scale (1 = completely disagree to 5 = completely agree) to assess the acceptability, appropriateness, and feasibility of CAB + RPV LA implementation, respectively
  - Attitudes, experiences, and preferences regarding the CAB + RPV LA regimen were assessed in survey questions and compared between participants with and without COVID-19–impacted visits

Results

Healthcare Staff Perceptions

- Healthcare staff (separated into 3 groups: physicians and principal investigators, nurses and injectors, and office administrators) from 8 US clinics completed surveys at Month 4 (N=24) and Month 12 (N=23)
  - Healthcare staff were from federally qualified health centers, private practices, and university practices (25% each) or AIDS Healthcare Foundation clinics and health maintenance organizations (13% each)
- The proportion of healthcare staff who agreed or completely agreed that CAB + RPV LA was acceptable, appropriate, and feasible to implement increased during COVID-19 (Month 12) compared with before COVID-19 (Month 4; Figure 1)
- Before COVID-19, at Month 4, the most frequently reported concern among healthcare staff was awareness of missed injection visits (46%), which decreased during COVID-19 at Month 12 (22%)
- More healthcare staff disagreed that the following were barriers to implementation at Month 12 vs Month 4:
  - Patient failing CAB + RPV LA due to missed injection visits (78% vs 42%)
  - Management of patients' other care needs (74% vs 42%)
  - Patient transitioning from oral to injectable treatment (91% vs 79%)

Figure 1. Healthcare Staff Perspectives on the Acceptability (AIM), Appropriateness (IAM), and Feasibility (FIM) of CAB + RPV LA Over Time



Each bar represents the mean (range) proportion of healthcare staff who agreed or completely agreed with each of the 4 statements in the questionnaire. AIM, acceptability of intervention measure; FIM, feasibility of intervention measure; IAM, intervention appropriateness measure.

Participant Perceptions

Study Population

- Of 102 participants who were ongoing at Month 12, most were men aged <50 years (Table 1)
- At Month 12, 19% (19/102) of participants had ≥1 COVID-19–impacted visit because of missed or rescheduled visits, quarantine, COVID-19 diagnosis, or clinic closure
  - No participants with COVID-19–impacted visits withdrew from the study

Table 1. Baseline Characteristics Among Participants Impacted and Not Impacted by COVID-19

Parameter, n (%)	Total (N=102)	COVID-19 impacted (N=19)	Not impacted by COVID-19 (N=83)
Age, y			
20-49	79 (77)	17 (89)	62 (75)
≥50	23 (23)	2 (11)	21 (25)
Female	14 (14)	0	14 (17)
Race and ethnicity			
White or Caucasian or European heritage	59 (58)	14 (74)	45 (54)
Black or African American	36 (35)	3 (16)	33 (40)
American Indian or Alaskan Native	5 (5)	1 (5)	4 (5)
Multiple	2 (2)	1 (5)	1 (1)
Hispanic or Latino	28 (28)	12 (63)	16 (19)

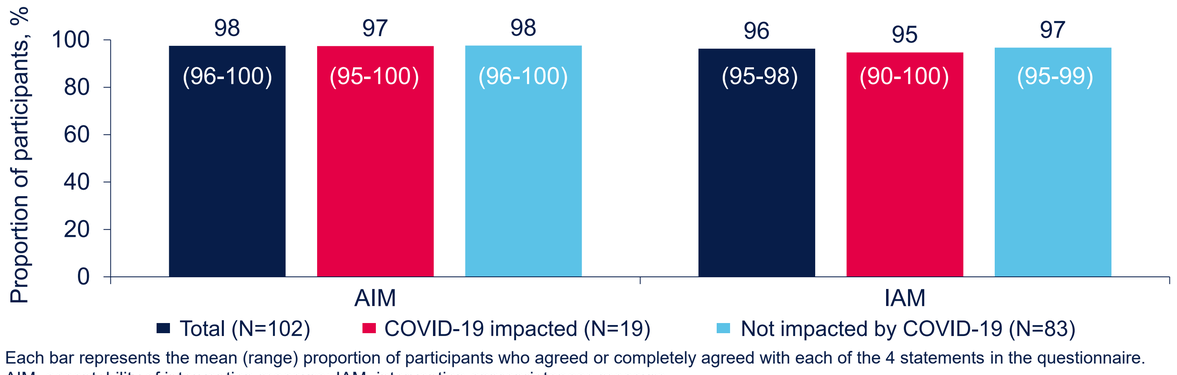
Virologic Outcomes

- All participants with available viral load data (n=101) maintained virologic suppression (HIV-1 RNA <50 c/mL) at Month 12
  - 1 additional participant with missing data at Month 12 due to a COVID-19 diagnosis maintained HIV-1 RNA <50 c/mL at an unscheduled visit at Month 13
- 8 participants received oral therapy with CAB + RPV tablets to cover a COVID-19–impacted injection visit
  - All 8 participants restarted LA therapy, and there were no virologic failures (2 consecutive HIV-1 RNA measurements ≥200 c/mL)

Survey Outcomes

- Among all participants, mean implementation scores increased during COVID-19 at Month 12 vs before COVID-19 at Month 4 (mean AIM score, 4.78 vs 4.61; mean IAM score, 4.76 vs 4.60)
- Most participants (≥95%) agreed or completely agreed that CAB + RPV LA was acceptable and appropriate to implement regardless of COVID-19 impact status (Figure 2)

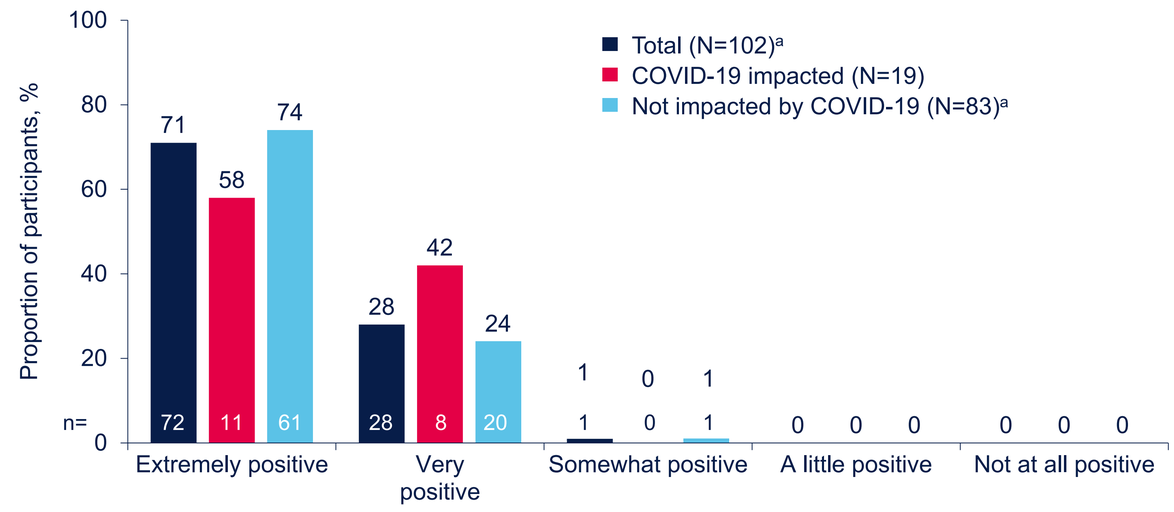
Figure 2. Participant Perspectives on the Acceptability (AIM) and Appropriateness (IAM) of CAB + RPV LA at Month 12 by COVID-19 Impact Status



Each bar represents the mean (range) proportion of participants who agreed or completely agreed with each of the 4 statements in the questionnaire. AIM, acceptability of intervention measure; IAM, intervention appropriateness measure.

- During COVID-19, at Month 12, most participants (89/102; 87%) found coming to the clinic monthly very or extremely acceptable, including those with COVID-19–impacted visits (18/19; 95%)
- Positivity about receiving CAB + RPV LA treatment was high among all participants during COVID-19, with 100% (19/19) and 98% (81/83) of participants who were impacted or not impacted by COVID-19, respectively, feeling very or extremely positive at Month 12 (Figure 3)

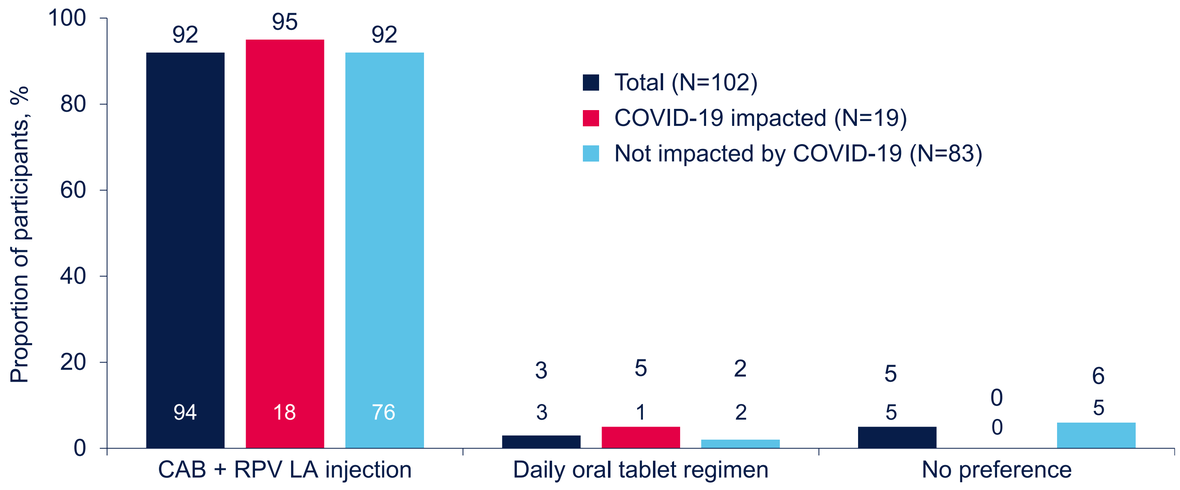
Figure 3. Participant Feelings About Receiving CAB + RPV LA Injection Treatment at Month 12 by COVID-19 Impact Status



[a]1 participant not impacted by COVID-19 had missing data.

- At Month 12, most participants (94/102; 92%) preferred CAB + RPV LA injection vs daily oral therapy, including most (18/19; 95%) who had COVID-19–impacted visits (Figure 4)
- 97% (99/102) of all participants and 95% (18/19) of COVID-19–impacted participants indicated they will use CAB + RPV LA as treatment going forward

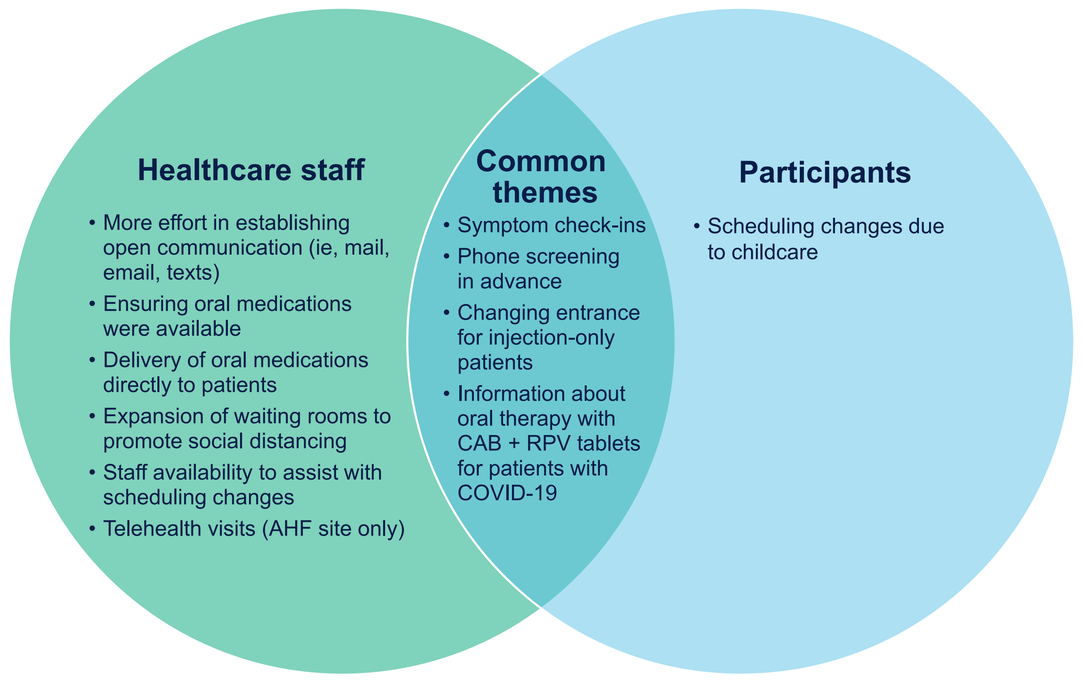
Figure 4. Participant HIV-1 Treatment Preference at Month 12 by COVID-19 Impact Status



Changes Made During the COVID-19 Pandemic

- During interviews at Month 12, healthcare staff and participants described multiple changes made in the clinic to facilitate CAB + RPV LA implementation during the COVID-19 pandemic (Figure 5)

Figure 5. Changes Made During COVID-19 as Reported by Healthcare Staff and Participants



AHF, AIDS Healthcare Foundation.

Conclusions

- During the COVID-19 pandemic, CAB + RPV LA implementation remained highly acceptable and appropriate among healthcare staff and participants in CUSTOMIZE
- 8 participants were given temporary oral therapy for missed injection visits and maintained uninterrupted ART, all of whom restarted LA therapy without virologic failure
- Acceptability of attending monthly clinic visits, preference for LA ART, and treatment effectiveness remained high among participants, including the 19 participants with COVID-19–impacted visits
- Despite healthcare disruptions caused by the COVID-19 pandemic, implementation data from CUSTOMIZE suggest that CAB + RPV LA is an appealing treatment option from the perspective of both healthcare providers and PLHIV

Acknowledgments

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References

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