Perceived Implementation Barriers Decrease During Initial Stages of an Implementation Science Hybrid III Study (CUSTOMIZE) of Cabotegravir and Rilpivirine Long-Acting (CAB + RPV LA) in US Healthcare Settings: Healthcare Team Perspective

Maggie Czarnogorski,[1] Cindy Garris,[1] Paul Wannamaker,[1] Ronald D'Amico,[1] Deanna Merrill,[1] Colleen A. McHorney,[2] Larissa Stassek,[2] Sonal Mansukhani,[2] Jason Flamm,[3] Blair Thedinger,[4] Paul Benson,[5] Michael Wolfeiler,[6] Gary Sinclair,[7] William Spreen[1]

[1]ViiV Healthcare, Research Triangle Park, NC, USA; [2]Evidera, Bethesda, MD, USA; [3]Kaiser Permanente Sacramento, Sacramento, CA, USA; [4]Kansas City Free Health Clinic, Kansas City, MO, USA; [5]Be Well Medical Center, Berkley, MI, USA; [6]AIDS Healthcare Foundation, Los Angeles, CA, USA; [7]PrismHealth North Texas, Dallas, TX, USA

LBPEE42

Introduction

- Long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV) is an investigational therapy for HIV infection administered as intramuscular injections every 4 weeks (Q4W)[1,2]
  - Phase III studies in virologically suppressed adults with HIV infection showed noninferiority of Q4W intramuscular CAB LA + RPV LA to daily oral standard of care at 48 weeks[1,2]
- Once-monthly HIV treatment provides a less-frequent dosing option for patients than a daily oral pill, but it will require more frequent visits by patients to receive injections from a healthcare professional and could result in a need for additional resources in the clinical setting
- It is important to understand how to optimize administration of CAB LA + RPV LA from the perspectives of people living with HIV and the healthcare system
- Herein we report quantitative survey results of the perspectives of healthcare staff from a variety of US clinic settings on early implementation of CAB LA + RPV LA into routine HIV care

Methods

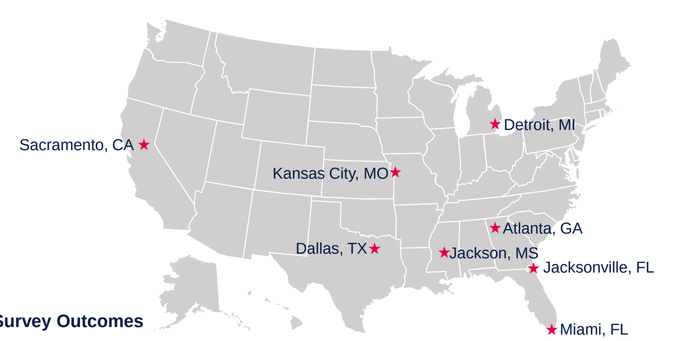
Study Design

- CUSTOMIZE is a novel, hybrid III, implementation-effectiveness study assessing healthcare staff perspectives over a 12-month period to determine the most effective strategies, barriers, and facilitators for successful implementation of the CAB LA + RPV LA injectable regimen in real-world settings; interim data from Month 4 are reported here
- **Primary objective:** Evaluate acceptability, appropriateness, and feasibility of delivering CAB LA + RPV LA
- **Secondary objectives:** Evaluate organizational facilitators and barriers as well as safety and efficacy measures of CAB LA + RPV LA
- Outcomes from the following 6 survey components are reported here:
  - Acceptability of intervention measure (AIM), intervention appropriateness measure (IAM), and feasibility of implementation measure (FIM) were 4-item surveys (baseline and Month 4) that utilized a 5-point rating scale (1 = completely disagree to 5 = completely agree)
  - Proportions and mean scores (higher scores more positive) were calculated
  - Barriers to implementation was a 23-item survey (baseline and Month 4) that also utilized a 5-point rating scale (1 = completely disagree to 5 = completely agree)
  - A 19-item survey (Month 4) assessed use (yes/no responses) and helpfulness (5-point rating scale; 1 = extremely helpful to 5 = not at all helpful) of toolkit resources and an 8-item survey (baseline and Month 4) assessed attitudes and expectations of staff study participants

Results

- Twenty-four staff study participants, including physicians/principal investigators, nurses/injectors, and office administrators completed a survey at baseline and at Month 4 of implementation of CAB LA + RPV LA at 8 clinics across the United States (Figure 1)
  - 25.0% were employed by federally qualified health centers, 25.0% were in university practices, 25.0% were in private practices, and 12.5% each were in AIDS Healthcare Foundation clinics or integrated healthcare organizations
  - One site withdrew from the study after the baseline staff study participant surveys and interviews were completed; thus, baseline data include 26 staff study participants from 9 sites

Figure 1. Clinic Locations

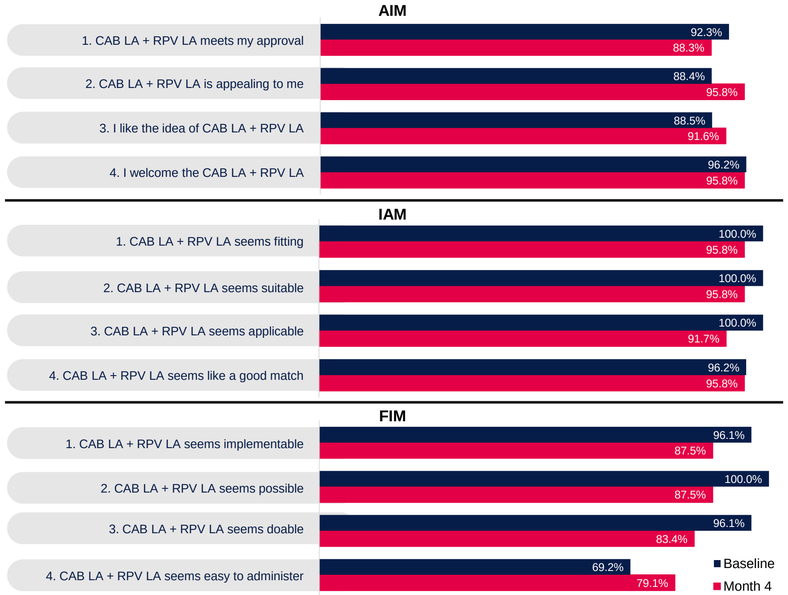


Survey Outcomes

AIM, IAM, and FIM

- Most participants (>84%) agreed/completely agreed that CAB LA + RPV LA was acceptable, appropriate, and feasible at baseline and Month 4 (Figure 2), with some variability by staff study participant type
  - Physicians had improved scores for the AIM measure at Month 4 vs baseline, indicating better acceptability of implementation of the CAB LA + RPV LA regimen in this group

Figure 2. Proportion of Staff Study Participants Who Agreed/Completely Agreed With Survey Questions About Acceptability, Appropriateness, and Feasibility of the Intervention

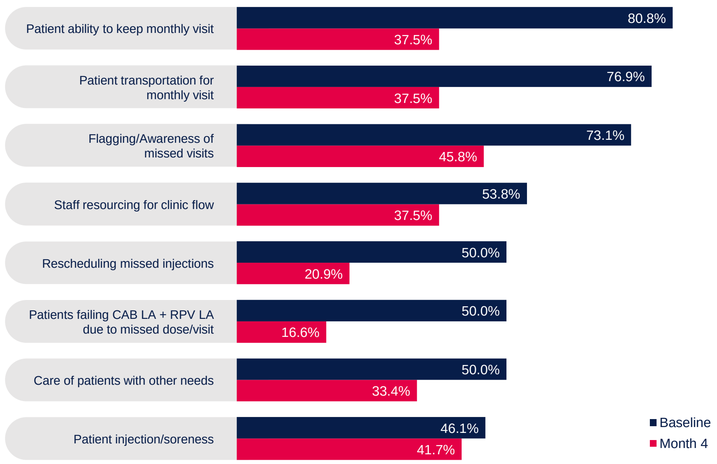


AIM, acceptability of intervention measure; CAB, cabotegravir; FIM, feasibility of implementation measure; IAM, intervention appropriateness measure; LA, long acting; RPV, rilpivirine. Each bar represents the proportion of staff study participants who agreed or completely agreed with the statement.

Implementation

- At baseline, ability of patients to keep monthly visits, transportation, and flagging missed visits were the most frequently reported concerns
- All perceived barriers to implementation substantially decreased by Month 4 (Figure 3)

Figure 3. Top Rated Barriers to Implementation at Baseline and Month 4[a]



CAB, cabotegravir; LA, long acting; RPV, rilpivirine. [a]Each bar represents the proportion of staff study participants who agreed or completely agreed that a given item was a barrier.

Toolkit Resources

- At Month 4, staff study participants indicated that the most used toolkit resources were facilitation group calls (79.2%), hot/cold packs (75.0%), and a patient video of what to expect (66.7%)
- Staff study participants indicated that the hot/cold pack for patients and the face-to-face injection training for staff study participants were the most helpful toolkit items (Figure 4)

Figure 4. Helpfulness of Toolkit Resources[a]

Toolkit materials for staff study participants, %	Toolkit materials for patients, %
Face-to-face injection training (58.3)	Hot/Cold pack (66.7)
Study factsheet (54.2)	What to expect factsheet (54.2)
Online/Video injection training (54.2)	What to expect video (50.0)
Web-based treatment planner (41.7)	Patient handbook (45.8)
Instructional card for packaging (37.5)	Injection flashcard (37.5)
Website for staff (33.3)	Website for patients (29.2)
Consultation aid (33.3)	FAQ chat bot (16.7)
Patient reminder service (mobile app and text) (29.2)	Trial guide mobile app (12.5)
Facilitation group calls by staff (29.2)	
Web-based clinical capacity tool (4.2)	

FAQ, frequently asked question. [a]Proportion of responses that indicated "extremely helpful," "very helpful," and "somewhat helpful" were combined.

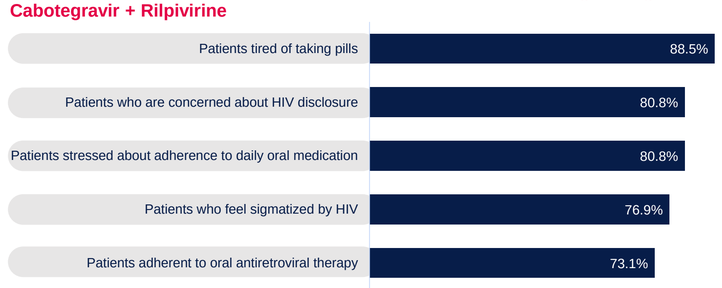
Attitudes and Expectations

- Most staff study participants (83%) reported they believed patients found the time spent in the clinic for each CAB LA + RPV LA treatment to be "extremely acceptable" or "very acceptable"
- 83% of the staff study participants felt "extremely positive" or "very positive" about implementing CAB LA+ RPV LA treatment

Survey at Baseline: Appropriate Patients

- Characteristics most commonly reported by physicians that made patients living with HIV appropriate candidates for CAB LA + RPV LA were those who did not desire to take pills (88.5%), patients with concerns about HIV status disclosure (80.8%), and patients experiencing stress or anxiety over daily adherence with oral medications (80.8%; Figure 5)

Figure 5. Top 5 Characteristics of Appropriate Candidates for Long-Acting Cabotegravir + Rilpivirine



Limitation

- The survey results should be interpreted with caution due to the small sample size of the staff study participants included in the study; however, the observed results from the staff study participant surveys at baseline and Month 4 were supportive of implementation of the CAB LA + RPV LA treatment paradigm in real-world settings

CONCLUSIONS

- At baseline through Month 4, a large majority of staff study participants across the HIV care settings found CAB LA + RPV LA to be acceptable, appropriate, and feasible
- By Month 4, a smaller proportion of staff study participants reported barriers to implementation vs baseline
- The attitudes of staff study participants about implementing CAB LA + RPV LA in their clinic/practice were positive initially, and concern regarding barriers seemed to decrease during implementation
- Final data will be presented next year after study completion

Acknowledgments

This analysis was funded by ViiV Healthcare. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by MedThink SciCom and funded by ViiV Healthcare.

References

1. Swindells S et al. *N Engl J Med*. 2020;382:1112-1123. **2.** Orkin C et al. *N Engl J Med*. 2020;382:1124-1135.

Corresponding author: Maggie Czarnogorski; maggie.x.czarnogorski@viivhealthcare.com