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CUSTOMIZE: OVERALL RESULTS FROM A HYBRID III IMPLEMENTATION-EFFECTIVENESS STUDY EXAMINING IMPLEMENTATION OF CABOTEGRAVIR AND RILPIVIRINE LONG-ACTING INJECTABLE FOR HIV TREATMENT IN US HEALTHCARE SETTINGS; FINAL PATIENT AND PROVIDER DATA

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11th IAS Conference on HIV Science; July 18-21, 2021; Virtual

Disclosures

- Maggie Czarnogorski is an employee of ViiV Healthcare and owns stock in GlaxoSmithKline

Introduction

- Cabotegravir (CAB) and rilpivirine (RPV) is the first complete and only approved long-acting (LA) injectable regimen recommended by treatment guidelines indicated for the maintenance of virologic suppression in people living with HIV-1[1-3]
- CAB + RPV LA administered monthly or every 2 months is an alternative to daily oral dosing, requires regular clinic visits for injections, and may need additional resources in a clinical setting
- To achieve optimal patient health outcomes with this novel therapy, it is necessary to understand how to best support implementation into routine clinical care
- Healthcare provider and patient participant perspectives following implementation of once-monthly CAB + RPV LA in diverse US healthcare settings through 12 months in the CUSTOMIZE study are reported

1. Cabenuva [prescribing information]. ViiV Healthcare; 2021. **2.** Vocabria [prescribing information]. ViiV Healthcare; 2021. **3.** Panel on Antiretroviral Guidelines for Adults and Adolescents. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed June 16, 2021.

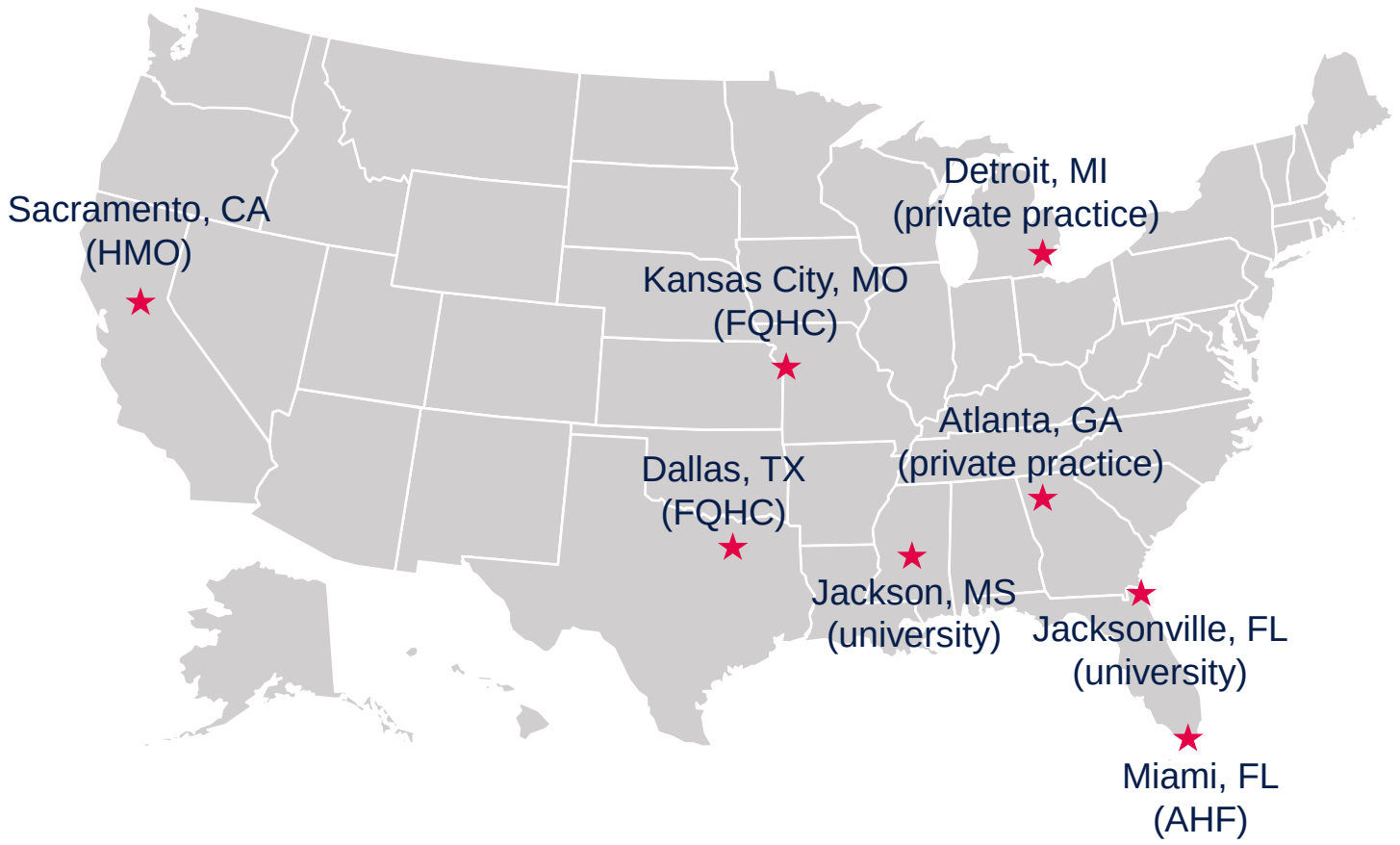
Methods

- CUSTOMIZE is a phase IIIb, hybrid III implementation-effectiveness study that examined barriers to, facilitators of, and effective strategies for successful implementation of the CAB + RPV LA injectable regimen in US clinical practice settings
- Healthcare staff (including physicians, nurses/injectors, and front desk staff/administrators) from 8 US clinics completed surveys and interviews at baseline, Month 4, and Month 12
- Virologically suppressed PLHIV received monthly CAB + RPV LA injections after a 1-month oral lead-in of CAB and RPV
  - Patient participants completed surveys at baseline, Month 4, and Month 12
  - A subset also completed interviews at baseline and Month 12
- Interviews were recorded, transcribed, and analyzed using ATLAS.ti (version 8.1)

CAB, cabotegravir; LA, long-acting; PLHIV, people living with HIV-1; RPV, rilpivirine.

Locations and Types of Clinics in CUSTOMIZE

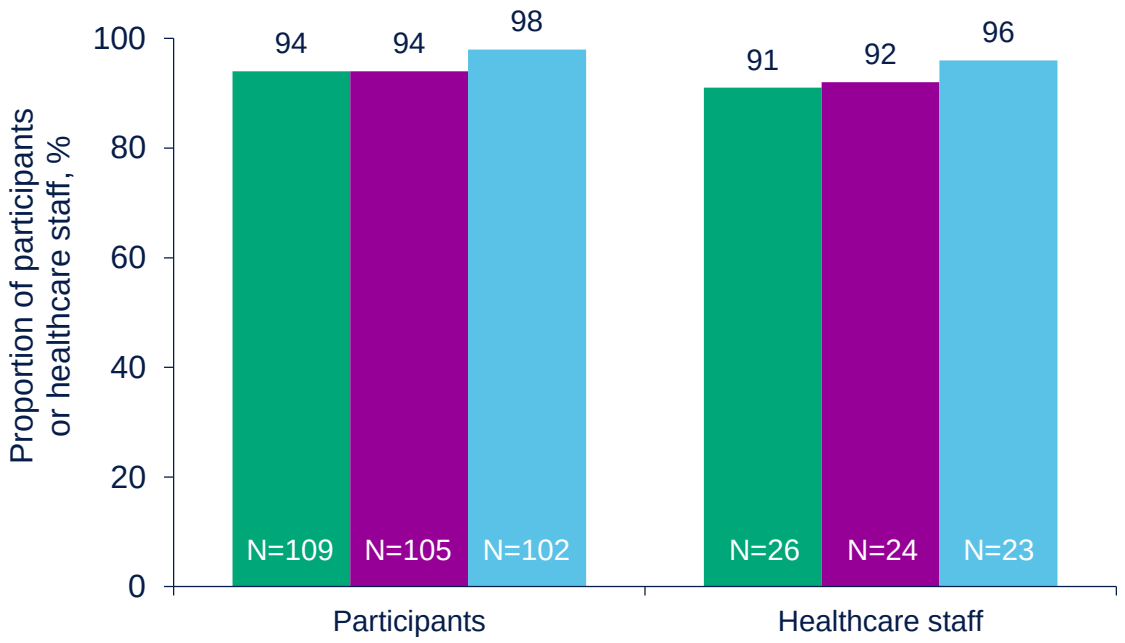
- Healthcare staff and participants enrolled in CUSTOMIZE were from 5 different clinic types in 8 cities across the United States
- Clinic types included
  - Federally qualified health centers (FQHCs; n=2)
  - University practices (n=2)
  - Private practices (n=2)
  - AIDS Healthcare Foundation (AHF) clinics (n=1)
  - Health maintenance organizations (HMOs; n=1)



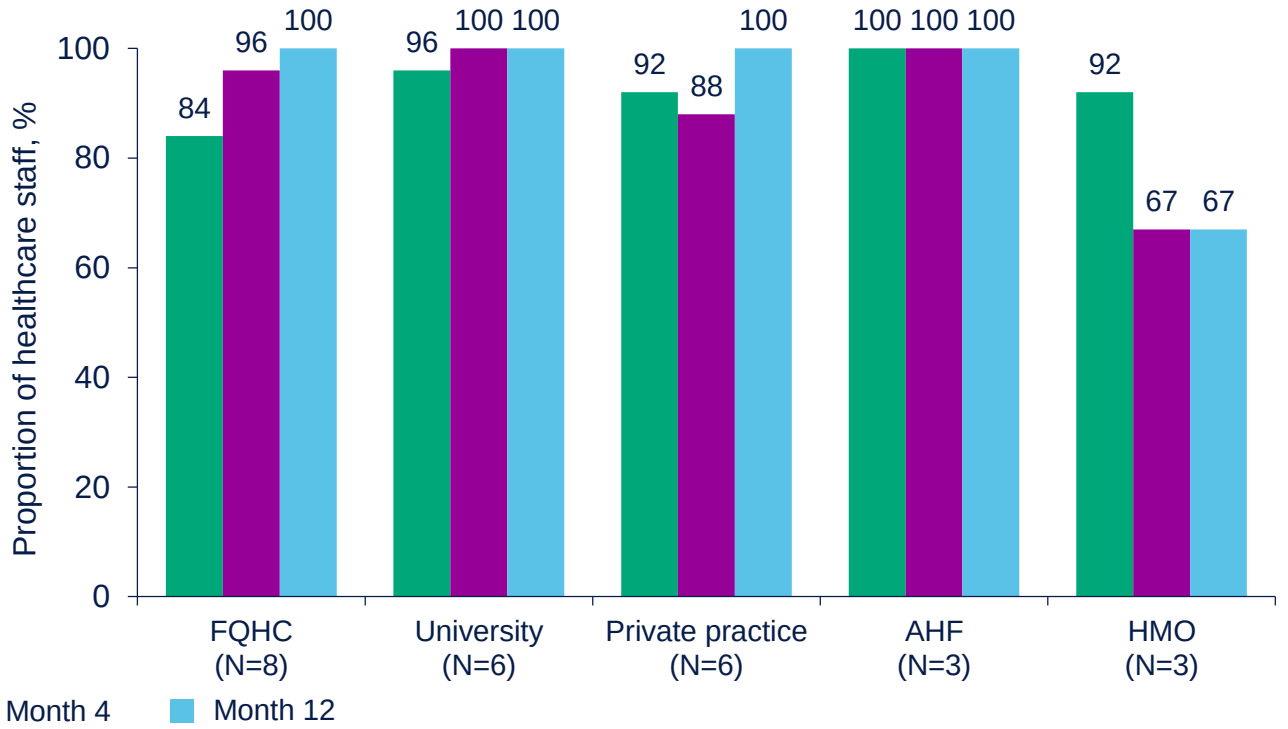
Participants and Healthcare Staff Across Clinic Types Found CAB + RPV LA Acceptable to Implement

Acceptability

Participants vs healthcare staff



Healthcare staff by clinic type

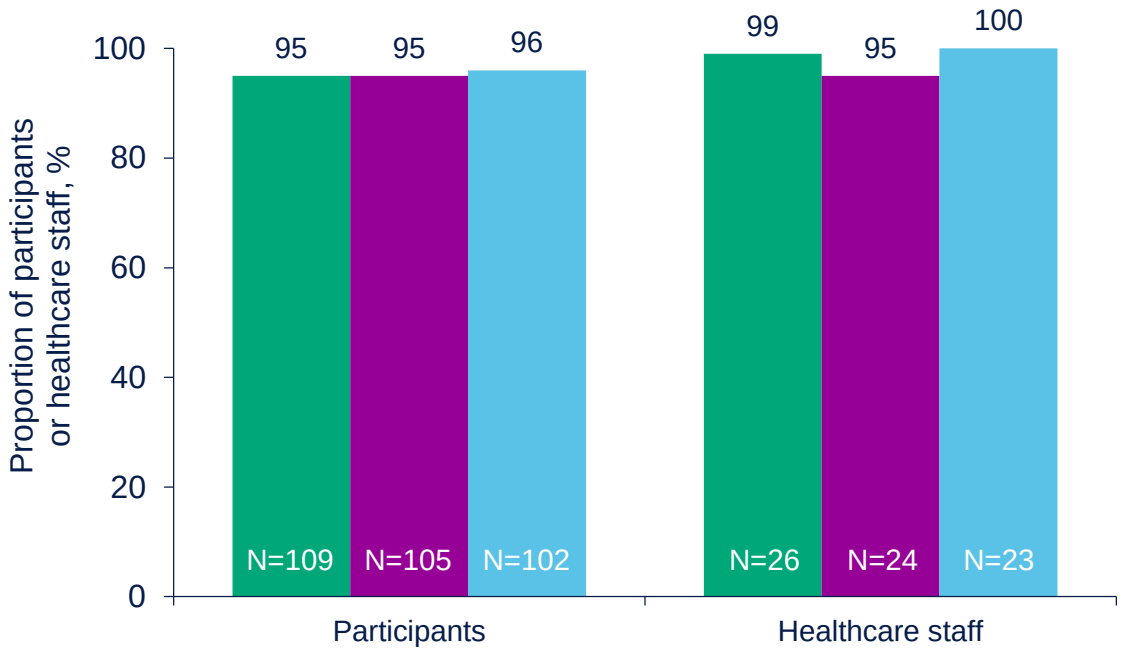


AHF, AIDS Healthcare Foundation; AIM, acceptability of intervention measure; CAB, cabotegravir; FQHC, federally qualified health center; HMO, health maintenance organization; LA, long-acting; RPV, rilpivirine. AIM was a 4-item survey that utilized a 5-point rating scale (1 = completely disagree to 5 = completely agree). Each bar represents the mean proportion of participants or healthcare staff who agreed or completely agreed with each of the following 4 AIM statements: CAB + RPV LA meets my needs (participant) or approval (healthcare staff); CAB + RPV LA is appealing to me; I like the idea of CAB + RPV LA; and I welcome CAB + RPV LA.

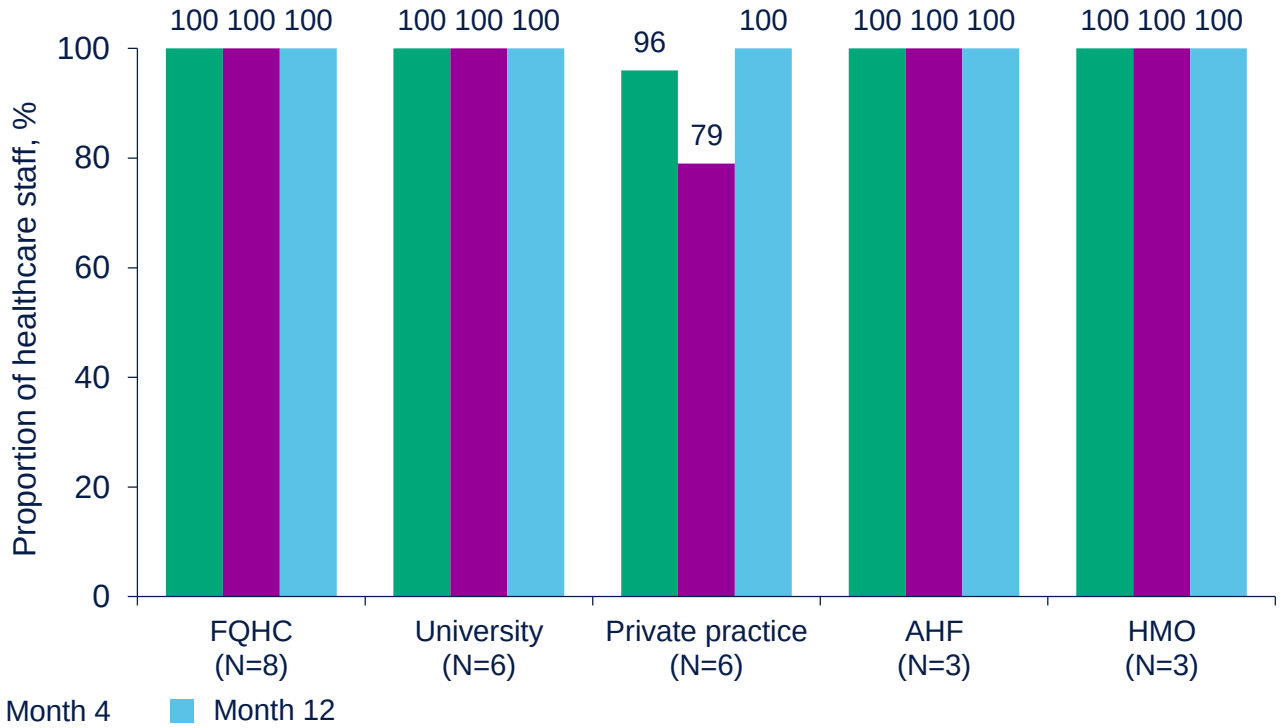
Participants and Healthcare Staff Across Clinic Types Found CAB + RPV LA Appropriate to Implement

Appropriateness

Participants vs healthcare staff



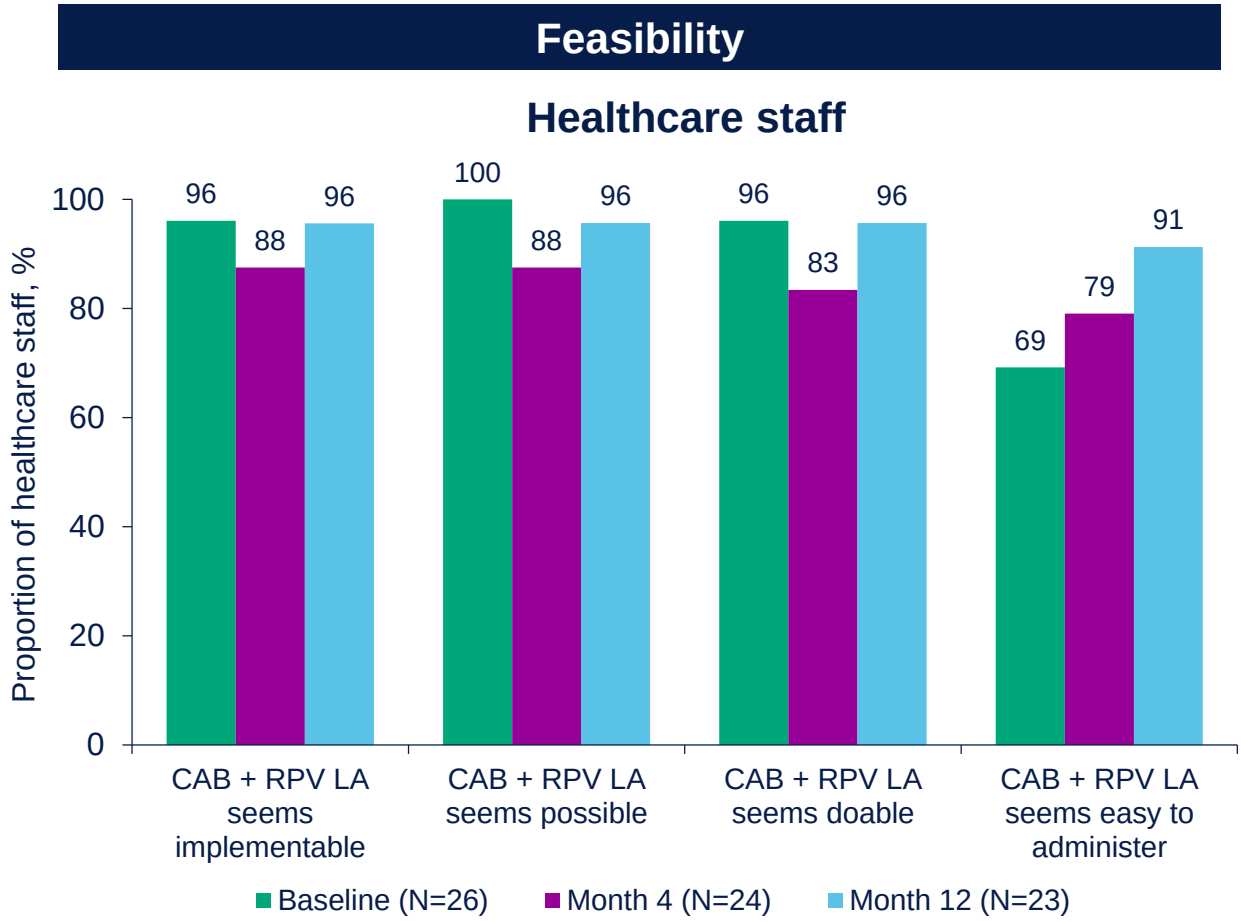
Healthcare staff by clinic type



AHF, AIDS Healthcare Foundation; CAB, cabotegravir; FQHC, federally qualified health center; HMO, health maintenance organization; IAM, intervention appropriateness measure; LA, long-acting; RPV, rilpivirine. IAM was a 4-item survey that utilized a 5-point rating scale (1 = completely disagree to 5 = completely agree). Each bar represents the mean proportion of participants or healthcare staff who agreed or completely agreed with each of the following 4 IAM statements: CAB + RPV LA is fitting; CAB + RPV LA is suitable; CAB + RPV LA is applicable; and CAB + RPV LA is a good match.

Healthcare Staff Found CAB + RPV LA Feasible to Implement Across Clinic Types

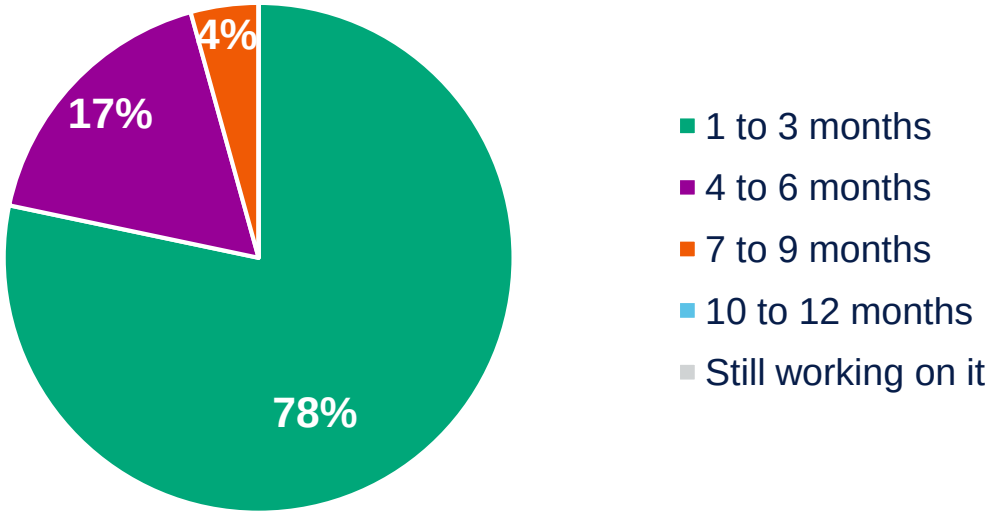
- Feasibility scores were generally high before any injections were provided
- At Month 4, feasibility scores generally decreased slightly as healthcare staff realized some adjustments may be needed in the clinic
- By Month 12 and despite COVID-19, feasibility scores increased, demonstrating that after a few months of initial implementation support, healthcare staff found LA HIV-1 therapy to be very feasible to implement in clinics
- At Month 12, the proportion of healthcare staff who agreed or completely agreed with all feasibility items was highest at FQHC, university, and HMO practices (100%) and lowest at private practices (80%)
  - 100% of healthcare staff at AHF practices agreed or completely agreed with the first 3 feasibility items; 67% felt that CAB + RPV LA seems easy to administer



AHF, AIDS Healthcare Foundation; CAB, cabotegravir; FQHC, federally qualified health center; HMO, health maintenance organization; LA, long-acting; RPV, rilpivirine. Feasibility of intervention measure was a 4-item survey that utilized a 5-point rating scale (1 = completely disagree to 5 = completely agree). Each bar represents the proportion of healthcare staff who agreed or completely agreed with the statement.

Most Healthcare Staff Felt Optimal Implementation Was Achieved in 1 to 3 Months

Month 12: How many months did it take to implement CAB + RPV LA optimally in your clinic/practice?[a]



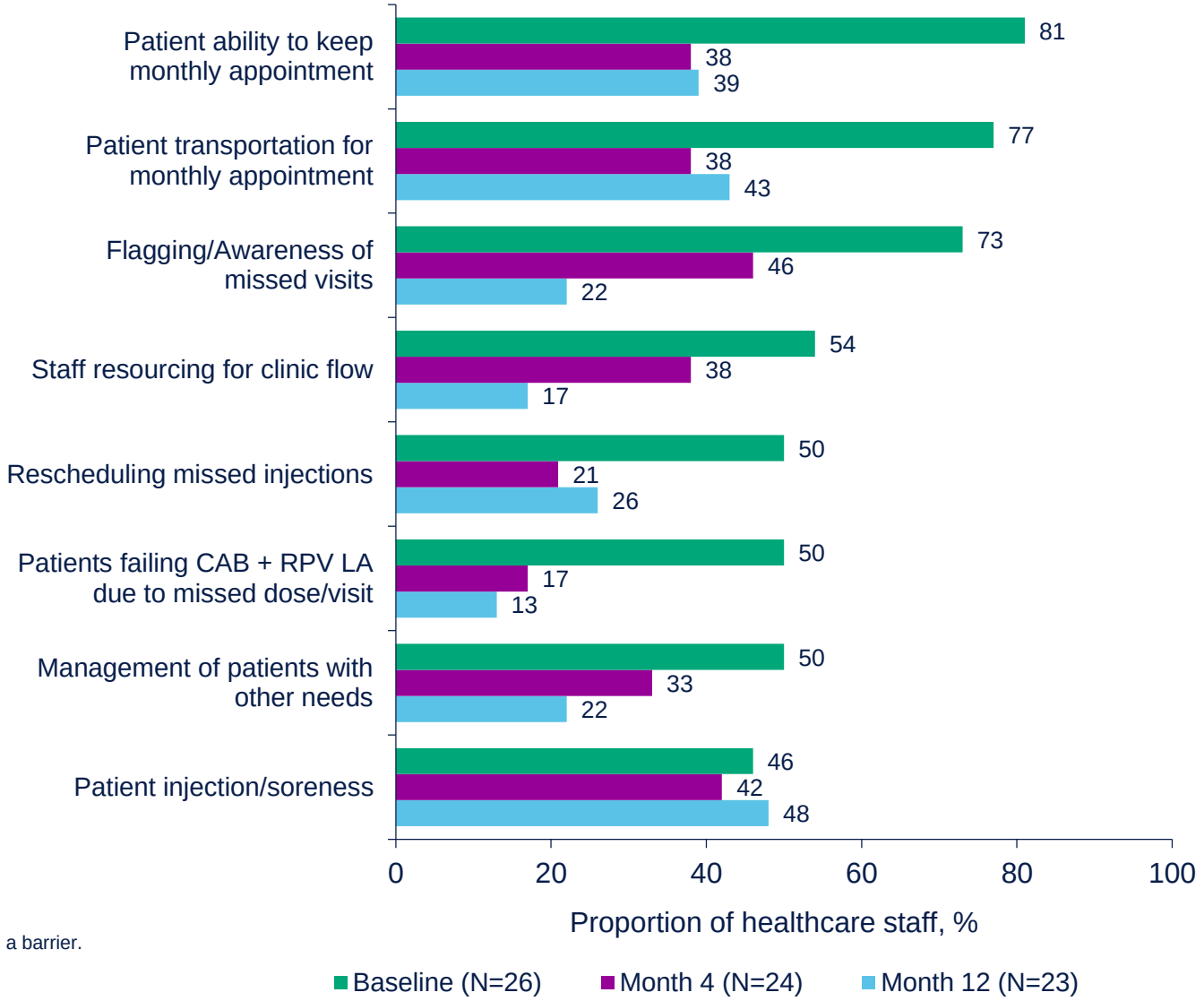
- No differences in time to optimal implementation were observed by type of healthcare staff
- HMO and university practices were least likely to report optimal implementation in 1 to 3 months (33% and 50% of healthcare staff, respectively)

- **Key strategies for successful clinic implementation[b]**
  - Good staff communication
  - Teamwork
  - Use of web-based treatment planner
- **Key implementation strategies for patient adherence[b]**
  - Good communication about dosing window
  - Effective appointment reminder systems
  - Designated staff for appointment tracking
- Healthcare staff were most positive about communication and least positive about strategic planning and organizational capacity

CAB, cabotegravir; HMO, health maintenance organization; LA, long-acting; RPV, rilpivirine. [a]Does not add up to 100% because of rounding. [b]Reported by healthcare staff in interviews at Month 12.

Perceived Barriers to Implementation Among Healthcare Staff Decreased From Baseline to Month 12

- At baseline, ability of patients to keep monthly visits, obtain transportation, and flag missed visits were the most frequently reported concerns among healthcare staff
- As perceived by healthcare staff, all barriers to implementation substantially decreased by Month 12 except for patient injection/soreness

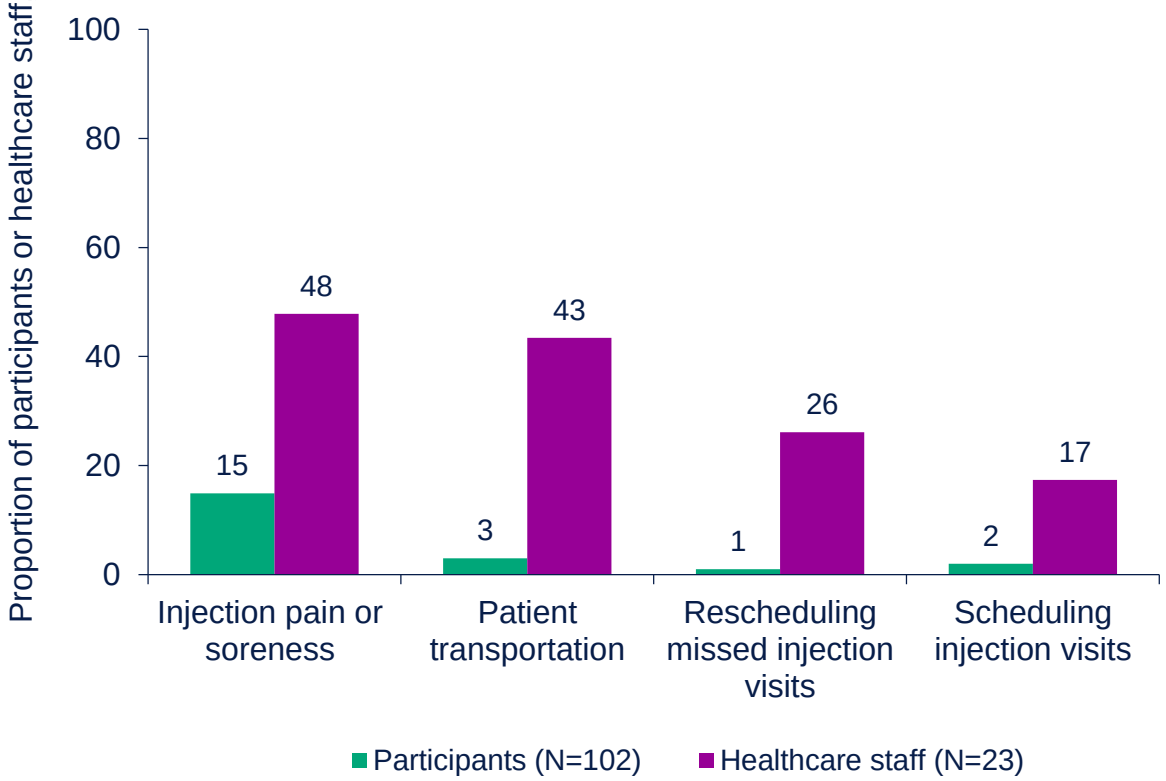


CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.
Each bar represents the proportion of healthcare staff who agreed or completely agreed that the item was a barrier.

Participants Reported Fewer Concerns Regarding Receiving CAB + RPV LA Injections Compared With Healthcare Staff at Month 12

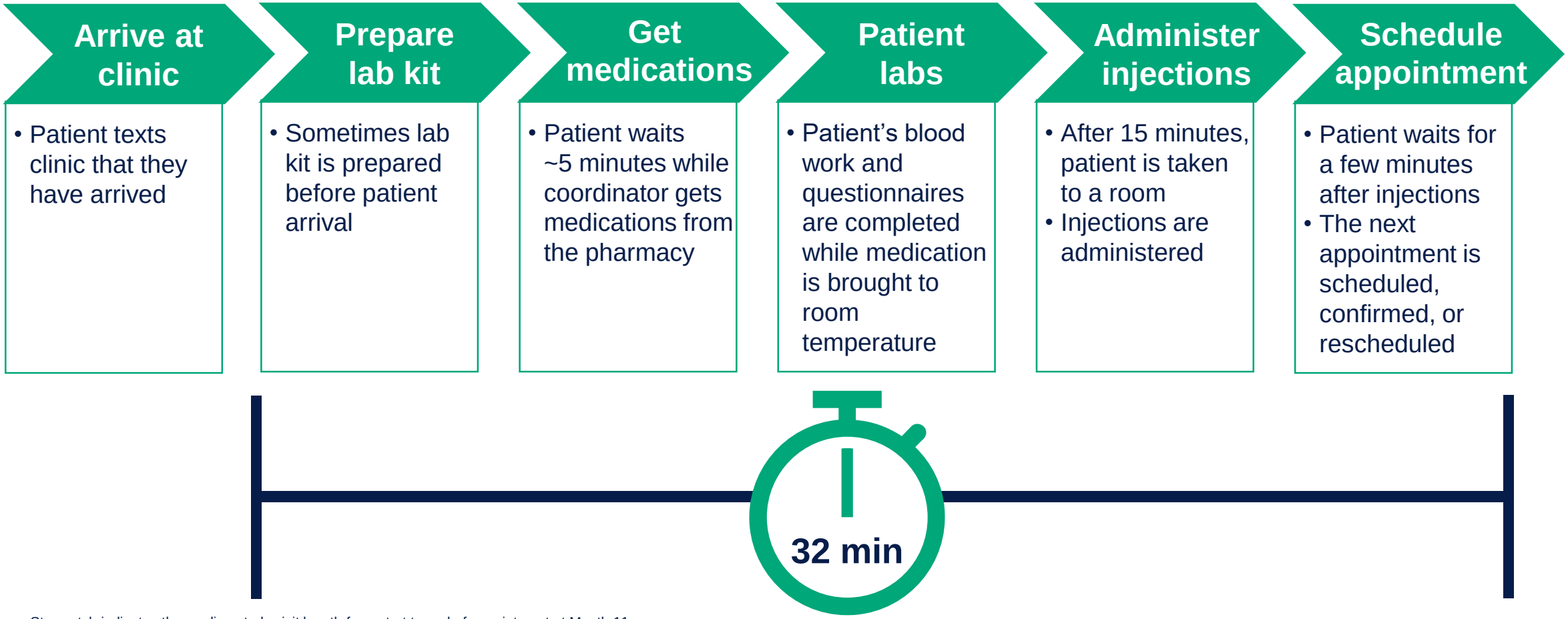
- At Month 12, 74% of participants reported that nothing interfered with their ability to receive CAB + RPV LA injections
- The factor most reported as interfering with participants' ability to receive injections was injection pain or soreness (15%)
- Participants reported fewer factors interfering with their ability to receive CAB + RPV LA injections compared with healthcare staff perceptions

Perceived barriers to implementation among participants and healthcare staff at Month 12



CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

Common Processes for Injection Visits Across Clinics



Stopwatch indicates the median study visit length from start to end of appointment at Month 11.

Summary of Changes Made Through Month 12 and Best Practices by Clinic Type

Infrastructure changes

Extended clinic hours
(FQHC, AHF, HMO, university, private practice)

Increased coordination with other departments
(FQHC, AHF, HMO, university)

Purchased new refrigerators
(FQHC, private practice)

Found available room space
(FQHC, AHF)

Attitude changes

FQHC
Implementation ease mitigated concerns regarding leadership support

University
A good tracking and reminder system addressed concerns regarding patients keeping their appointments

Private practice
Short wait times and increased patient-provider touchpoints eased concerns regarding length of injection visits

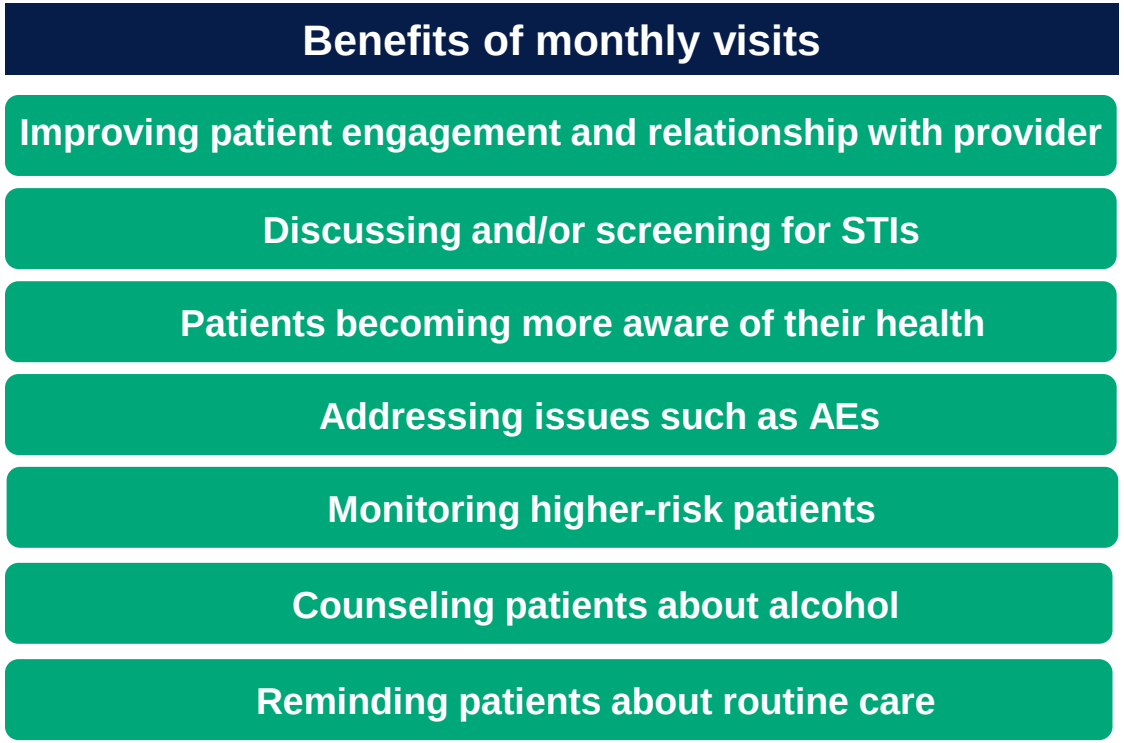
AHF/HMO
Patients' zealous acceptance of treatment was a great surprise

Clinic type	Summary of best practices
FQHC	• Calling the patient 2 days after the first injection to check in is reassuring to the patient and clinic staff
AHF	• Adding the Physician in Charge to their morning huddles; this will likely become an AHF-wide practice after commercialization
HMO	• Utilizing telehealth portal to send videos and product information to patients • Scheduling visits as far out as the clinic schedule allows (~3 months for their clinic)
University	• Booking >1 month in advance to prevent frequent overbooking • Designing their own EMR template for injection visits
Private practice	• Designating "before" and "after-hours" time slots for walk-in injections for people who must reschedule a visit

AHF, AIDS Healthcare Foundation; EMR, electronic medical record; FQHC, federally qualified health center; HMO, health maintenance organization.

Facilitators and Benefits of Monthly Clinic Visits

- Participants were offered educational and support items as part of the CUSTOMIZE toolkit
- At Month 12, the toolkit items most highly endorsed by participants as being very or extremely helpful were
  - Verbal information (98%)
  - Information and resources (89%)
  - Reminder calls (88%)
  - Reminder text messages (80%)
- 70% (16/23) of healthcare staff interviewed at Month 12 expressed that monthly visits provided an added benefit for patients



AE, adverse event; STI, sexually transmitted infection.

Conclusions

- Healthcare staff found CAB + RPV LA acceptable, appropriate, feasible, and sustainable to implement across diverse US clinic types, with most feeling that optimal implementation was achieved in 1 to 3 months
- Among healthcare staff, perceived barriers to implementation decreased from baseline by Month 12 and were mitigated with minor process adjustments that varied by clinic type
- Participants reported few barriers to monthly injection appointments
- CUSTOMIZE demonstrates that CAB + RPV LA can be successfully implemented across a wide range of US healthcare settings and was perceived as a convenient and appealing alternative treatment option by healthcare providers and PLHIV
- Overall, the CUSTOMIZE study provides important insights that inform CAB + RPV LA implementation in post-approval, real-world settings

CAB, cabotegravir; LA, long-acting; PLHIV, people living with HIV-1; RPV, rilpivirine.

Acknowledgments

- This study was funded by ViiV Healthcare
- The authors would like to acknowledge the healthcare staff and patient participants who participated in the study
- Editorial assistance and graphic design support were provided under the direction of the authors by MedThink SciCom and funded by ViiV Healthcare