

QUALITATIVE PATIENT-PARTICIPANT PERSPECTIVES ON IMPLEMENTATION OF MONTHLY CABOTEGRAVIR AND RILPIVIRINE LONG-ACTING (CAB+RPV LA) INJECTABLE IN THE UNITED STATES (CUSTOMIZE)

Cindy Garris,¹ Larissa Stassek,² Ronald D'Amico,¹ Marybeth Dalessandro,³ Sheila Adkins,⁴ Blair Thedinger,⁵ James B. Brock,⁶ Daniela Chiriboga-Salazar,⁷ **Maggie Czarnogorski¹**

¹ViiV Healthcare, Research Triangle Park, NC, USA; ²Evidera, Seattle, WA, USA; ³ViiV Healthcare, Collegeville, PA, USA; ⁴GlaxoSmithKline, Collegeville, PA, USA; ⁵KC CARE Health Center, Kansas City, MO, USA; ⁶University of Mississippi Medical Center, Jacksonville, MS, USA; ⁷University of Florida at Jacksonville, Jacksonville, FL, USA

Introduction

CAB and RPV are approved 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}

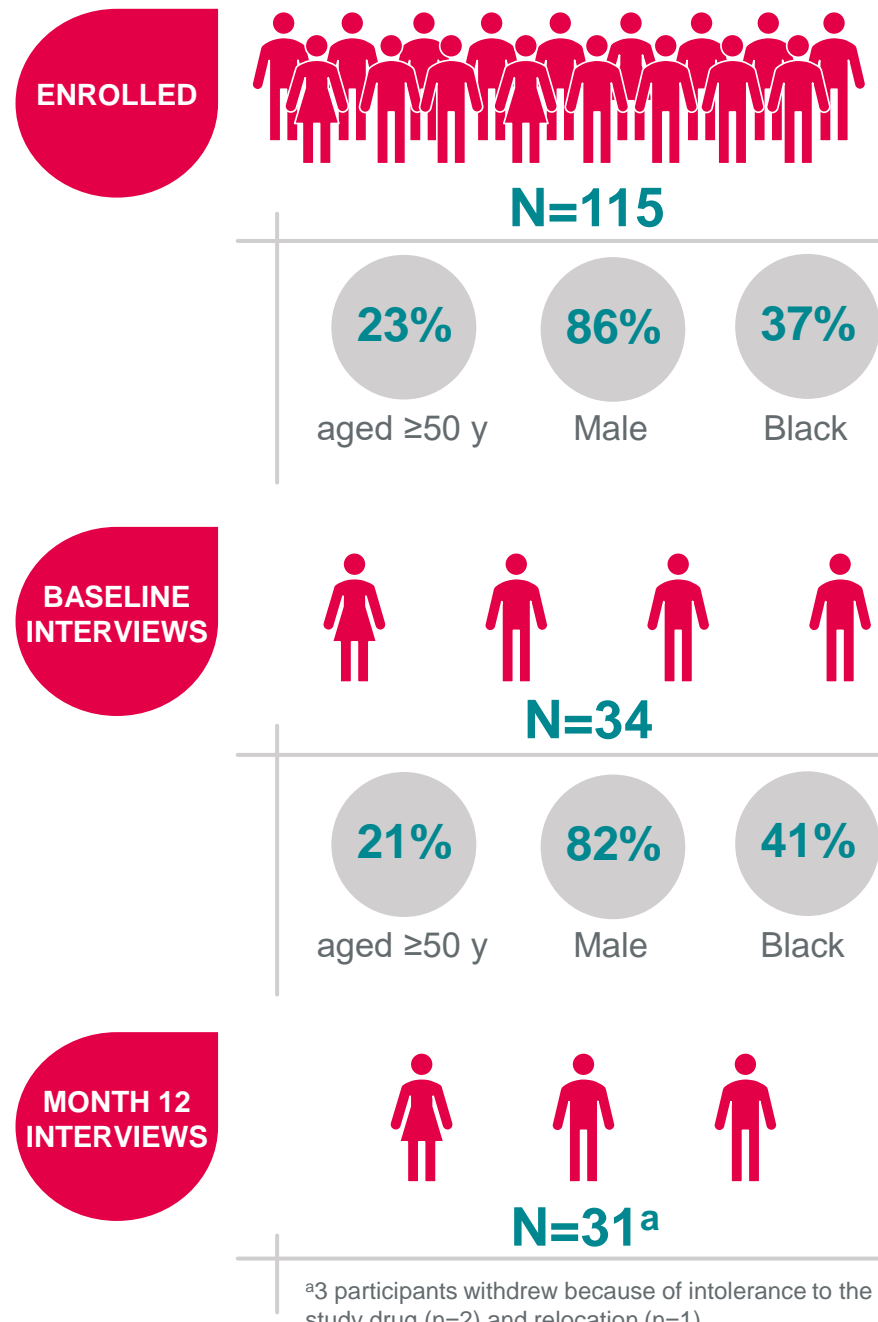
CAB + RPV LA administered monthly^{3,4} or every 2 months⁵ by a healthcare provider may address challenges associated with daily oral ART, such as stigma, pill burden/fatigue, and adherence

The CUSTOMIZE study reports perspectives of PLHIV after implementation of once-monthly CAB + RPV LA for 12 months in US healthcare settings

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

- 1** Virologically suppressed PLHIV were enrolled across 8 US clinics to receive monthly CAB + RPV LA injections after a 1-month oral lead-in of CAB and RPV
- 2** A subset of participants (3-6 per site) was randomly selected to complete semi-structured phone interviews before the first injection (baseline) and last injection (Month 12)
 - Interviews were conducted by September 2019 for baseline (before the COVID-19 pandemic) and by early fall 2020 for Month 12 (during the COVID-19 pandemic)
- 3** Interviews were guided by the Consolidated Framework for Implementation Research⁶ and recorded, transcribed, and coded using ATLAS.ti software (version 8.1)
 - Discussion topics included perceived barriers to and facilitators of receiving injections, participants' overall feelings about CAB + RPV LA, and plans for treatment after the study
 - Questions related to the COVID-19 pandemic were added to the discussion guide for Month 12
 - Not all participants were asked every interview question, and participants could provide ≥1 response to the same question; reported totals reflect the number of participants responding to a particular discussion topic out of the total number of participants interviewed at baseline or Month 12



Conclusions

- In baseline interviews, participants reported several challenges with daily oral ART that monthly CAB + RPV LA may help overcome, such as improving adherence and reducing fear of HIV status disclosure
 - Participants may have self-selected to answer positively to some baseline interview questions given their willingness to enroll in CUSTOMIZE
- Although participants reported initial concerns with the regimen, 87% were satisfied with CAB + RPV LA injections after 12 months
 - No clear differences by demographics were observed for treatment satisfaction among this small population of PLHIV
- Injection-related pain was noted by some participants, but most reported that pain improved over time
- At Month 12, 68% of participants believed that monthly clinic visits were beneficial, and 94% reported they planned to continue CAB + RPV LA treatment after the study ended
- Implementation data through 12 months in CUSTOMIZE suggest that CAB + RPV LA is a convenient and appealing alternative treatment option for PLHIV

Results | Interview Responses

BASELINE

Overcoming Challenges With Daily Oral Pills

- At baseline, 33 (97%) participants had ≥1 challenge taking daily oral ART, including concerns about adherence (n=19; 56%), dosing frequency (n=13; 38%), side effects (n=12; 35%), and hiding medications from others (n=12; 35%)

“...it was appealing just because one injection a month is a lot easier to keep track of than a pill every single day.”
— Male participant, 30

“I get really tired of taking pills... If you could just get an injection and then go about your way for a month... I thought that was pretty cool.”
— Female participant, 28

Advantages of CAB + RPV LA

- At baseline, participants reported CAB + RPV LA may help with adherence (n=17; 50%) or reduce fears of HIV status disclosure (n=10; 29%) when describing how CAB + RPV LA might meet the needs of other PLHIV
- 20 (59%) participants described the convenience of monthly appointments

“...That was my thing, always having to hide [my medications]...or be discreet when I take my pill. So be nice not to have to do that.”
— Female participant, 31

“I believe that it will benefit a lot of people in some of the same ways as it will benefit me as a comfort thing on the body or just all around convenience of it.”
— Male participant, 27

Challenges Receiving CAB + RPV LA Injections

- At baseline, 27 (79%) participants reported anticipated challenges of CAB + RPV LA, such as worry about side effects (n=15; 44%), discomfort or pain from injections (n=14; 41%), and difficulty missing work for appointments (n=6; 18%)

“Side effect is the biggest one, and then the actual just injecting. I don't really like needles.”
— Male participant, 30

“Well, as far as the injection I would think my concerns would be rashes or swelling and pain at the injection site.”
— Male participant, 57

Tips from healthcare providers to ease injection discomfort

Stay active and stretch

Avoid sitting for long periods of time

Avoid rigorous exercise

Facilitators of CAB + RPV LA Implementation

- At baseline, participants reported receiving educational materials about CAB + RPV LA in various forms, including as verbal information from clinic staff (56%), printed materials (53%), and through a website or video (18%)

“I can say that I received my informed consent form, I got...all the login information for the video...a short video on how it would work and what resources I needed in case. And on their website, they have the assistant—virtual assistant...then I went on top of that and did my own research.”
— Female participant, 22

CAB + RPV LA for Long-Term Treatment

- At baseline, 23 (68%) participants reported that CAB + RPV LA could be a long-term treatment option for them, with 21 (62%) feeling confident it would be a good fit for their lifestyle

“I get the injection, I'm good to go. You know, it's going to fit in with my schedule. You know, it's going to fit in with my mental...I just feel that it's going to be more a time-saver, so that I don't have to worry, something I don't have to personally remind myself to do.”
— Male participant, 31

MONTH 12

- At Month 12, 27 (87%) participants reported satisfaction with CAB + RPV LA for reasons that included preferring monthly injections to daily pills (n=15; 48%) and feeling injections offered more privacy (n=4; 13%)

“Well, I've had a pretty positive experience with the injection treatments. It's definitely something that I prefer over oral pills. I like being able to keep it private, like not having to have medications in the medical cabinet, or having to go take medications if, you know, you have guests over...I love being able to have that privacy aspect and not have to worry about it mentally.”
— Male participant, 40

- At Month 12, 30 (97%) participants described what they liked about CAB + RPV LA, including the convenience of once-monthly injections (n=16; 52%) and that scheduling injection visits fit with their lifestyle (n=7; 23%)

- 21 (68%) participants described benefits of going to the clinic each month, with none complaining about visit length

“I figured it would be pretty convenient just in general but...it was a lot more convenient than I thought it would be. But I liked having to check in with my doctor, my nursing staff. They kept me very informed.”
— Male participant, 33

“Just go once a month. I love it, because it's one less medication I have to worry about getting, and it's just an hour inside the clinic and getting labs done when needed, and then getting the injection and go.”
— Male participant, 34

- At Month 12, 25 (81%) participants indicated clinic hours were not a barrier to receiving injections; 6 (19%) reported taking time off work for injection visits

- 11 (35%) participants reported pain or discomfort from injections; 8 (26%) noted that injection pain improved over time

- 24 (77%) participants reported that the COVID-19 pandemic did not impact their ability to receive CAB + RPV LA

“...the only challenge... was getting used to the discomfort from the injection site...it started off the pain would last for a couple of days. And after about six months, the pain would only last a couple of hours...But besides that, there were no other challenges.”
— Male participant, 28

“The COVID-19, the pandemic, does not affect my wanting to be...on the injectables. I'm very happy with the treatment and COVID-19 hasn't really impacted the way I want to receive treatment.”
— Male participant, 28

- At Month 12, the educational materials participants found most useful were the pamphlet (19%), verbal education from clinic staff (14%), reminder texts or calls (13%), and an educational video about the regimen (6%)

“the video was really, really good. I like the text messages, the reminder calls, those are going to be key. Like we really need them. It makes everyone's lives a little more easier. And for me I don't like a lot of written materials because I have to worry about, okay, where am I going to put it...”
— Male participant, 32

- At Month 12, 29 (94%) participants reported they planned to continue CAB + RPV LA treatment after CUSTOMIZE ended

- The most common reasons for wanting to continue included not wanting to return to daily oral pills (n=12; 39%) and convenience (n=7, 23%)

“[Oral pills every day] become a little too much work for me. So, I would rather just take the injections and just call it a month.”
— Female participant, 29

“It's a relief to know that it's something that's simple and it requires less time and it's just as effective or maybe even more effective. Kind of like it exceeded my expectations...”
— Male participant, 32