

QUALITATIVE FINDINGS FROM A HYBRID III IMPLEMENTATION-EFFECTIVENESS STUDY TO EXPLORE PERSPECTIVES OF HEALTHCARE STAFF ON EARLY IMPLEMENTATION OF CABOTEGRAVIR AND RILPIVIRINE LONG-ACTING INJECTABLE IN THE UNITED STATES (CUSTOMIZE)

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Introduction

Long-acting (LA) cabotegravir (CAB) + rilpivirine (RPV) administered as intramuscular injections monthly is an effective treatment in virologically suppressed adults with HIV-1 infection^{1,2}

- This novel treatment paradigm will require more frequent patient visits than oral therapies, thereby involving more staff training resources in the clinic setting to administer the injections

Methods

CUSTOMIZE is an implementation-effectiveness study assessing the perspectives of healthcare staff on the barriers to and facilitators of successful implementation of the CAB + RPV LA injectable regimen in a variety of US HIV clinics

This is an interim analysis of interviews conducted at baseline (before any injection was given) and after the initial implementation phase (Month 4)

1 Semistructured qualitative interviews were conducted at baseline and after Month 4 with physicians, nurses/injectors, and office administrators who had no experience with CAB + RPV LA prior to CUSTOMIZE

- Month 4 interviews were all completed by February 2020

2 Sites were provided with a suite of implementation support tools and resources, including websites for staff and patients, online training tools, a web-based treatment planner, patient fact sheet and video, and a consultation aid

3 The metaimplementation strategy in this study was facilitation plus toolkits. The toolkit was a suite of implementation-support tools for staff and patients that included online education, face-to-face injection training, a web-based treatment planner, videos, and more

4 Consolidated Framework for Implementation Research guided the interviews to evaluate barriers to and facilitators of implementation and included 5 major domains³:

- Inner setting
- Outer setting
- Intervention characteristics
- Characteristics of individuals
- Process of implementation

5 Interviews were recorded, transcribed, and coded using ATLAS.ti (Berlin, Germany) and then analyzed for common themes and concepts

WHO **24** Participating healthcare staff

- 8 Physicians/Principal investigators
- 8 Nurses/Injectors
- 8 Office administrators

WHERE **8** US clinics

- 2 Federally qualified health centers (FQHCs)
- 2 University health centers
- 2 Private practices
- 1 AIDS Healthcare Foundation (AHF) clinic
- 1 Health maintenance organization (HMO)

WHEN

Interviews were completed at baseline and at Month 4

HOW

Baseline interviews were conducted in person; Month 4 interviews were conducted by phone; each interview was 60 minutes

WHY

Healthcare team perspectives on implementation are key successful components of implementation strategies. Each clinical setting has unique challenges and opportunities. The qualitative interview provided data and insight on what implementation strategies worked best in what setting and for which type of provider

Results | Interview Responses

Perceived Advantages of CAB + RPV LA for Patients

At baseline, providers reported that injectable CAB + RPV LA had the potential to remove the daily oral dose reminders of HIV (20%), reduce the stigma of possessing pill bottles of HIV medication (38%), and improve the ability of patients to live/travel without having to worry about carrying or losing pills (31%). Providers stated that assessing patient interest, reviewing electronic health records for patient adherence to appointments, and team meetings facilitated patient identification.

“I think it will be a really good treatment for patients who may forget to take their drug periodically. Some of the feedback we've received is that, 'Oh, I travel frequently, and, if I'm getting an injection, I don't need to worry about if I've left my drug at home or how am I going to obtain my drug.'”
— Injector, HMO, Baseline

“There tends to be stigma when it comes to HIV. I think it's something that will be a benefit to...young people who are newly diagnosed and really don't want to carry around a pill bottle every day or have to hide their medications from family and friends.”
— Injector, FQHC, Baseline

Mapping an Implementation Process

A major consideration when planning for implementation of CUSTOMIZE was the need to internally map the patient flow process: Identifying designated rooms, training nursing staff, identifying a person responsible for tracking appointment schedules, and creating a system for rescheduling and reminders.

Many clinic administrators are planning on mapping the days that they have fewer providers (more rooms available) and scheduling injection visits for those days

Determine staffing and training needs

Develop an appointment tracking system

Consider using clinical staff for appointment scheduling/rescheduling

Managing Logistical Challenges

At Month 4, some providers (21%) reported that purchasing a refrigerator for storage was critical to facilitate implementation of CAB + RPV; most (71%) staff reported no change in official clinic hours.

Key best practices identified were scheduling patients in the first 7 days of the treatment window to allow for flexibility in rescheduling if needed; clinically trained staff should be responsible for scheduling; and missed appointments should be followed-up on ≤24 hours.

“I would say [the types of changes necessary for implementation are] making sure that we had a decent refrigerator that could store enough of the product in it...and then making sure that it was holding temperature accurately all the time.”
— Office administrator, private practice, Month 4

“I think there's going to need to be a dedicated person, maybe two, above and beyond having the MAs and the nurses who are seeing patients as far as training to do the actual injections themselves. But there would certainly need to be a follow-up tracker to know who has missed their appointments and chase those people down who have started that medication. So there's going to have to be something above and beyond just scheduling patients and some follow-up for missed appointments.”
— Office administrator, FQHC, Month 4

“We're coming up with a process by which these people can identify people who are reliable, for example, that may notify us 30 minutes before coming to the visit so we can kind of get the medication and start—so the medication can be warm, right, by the time they come here. They come to the clinic, so it's shortened the time of their visit.”
— Principal investigator, university, Month 4

Facilitators of CAB + RPV LA Implementation

Support tools (75%; eg, web-based treatment planner [13%], “what to expect” patient video [25%]), reminder systems (79%), patient transport options (33%), and cross-departmental collaboration (8%) were critical facilitators of implementation. Maintaining a day that works best for patients between Days 1 and 28 of the month and setting reminders on their phone helped reinforce the date.

“Everybody likes the video that tells them what to expect...They get more relaxed about things once they see the video; it takes away a lot of the anxiety.”
— Office administrator, AHF, Month 4

“I would say our pharmacist, our research team, and the pharmacy department were instrumental in helping us with the work on our flow and what was discussed for the patients.”
— Injector, university, Month 4

“As an organization, [we] have a [ride-sharing] account that's already part of our policy...If a patient needs assistance getting to the clinic, we order a [ride share] for them, so we shouldn't really have a transportation barrier.”
— Principal investigator, AHF, Month 4

High Rates of Patient Acceptance/Positive Attitudes

Many staff members (46%) noted high rates of patient acceptance and positive attitudes toward the treatment facilitated successful implementation of CAB + RPV LA. Injection pain was an initial concern (42%); however, after the first injection, few patients expressed concerns to staff about pain.

“We do have a few patients who were leery initially because of their fear of injections, but all of them after their first one said that they really had nothing to worry about.”
— Injector, FQHC, Month 4

“Nobody has expressed any interest in dropping off; they're all really happy with it...It's been really accepted; it's been well embraced by the patients who are on it.”
— Principal investigator, AHF, Month 4

“I guess the surprising part is I have patients who otherwise take pills multiple times, some multiples pills a day, but even some of them have expressed it's quite a relief to not take an HIV-related pill every day.”
— Principal investigator, FQHC, Month 4

Conclusions

Some staff had initial concerns about implementation; however, at the interim analysis, these concerns were perceived as surmountable, requiring minor purchases, practical changes in clinic workflow, and small tweaks to the scheduling and follow-up systems. Overall, study participants viewed operationalizing CAB + RPV LA as an important and achievable goal that will facilitate patient preferences and treatment adherence

- Patient interest heightened
- the desire of staff members to implement the CAB + RPV LA regimen in their clinics
- Staff members are optimistic that monthly CAB + RPV LA is manageable with minimal disruption to routine HIV care in US settings
- Additional data will be presented following completion of the Month 12 analysis, which will include any impacts of COVID-19

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References 1. Swindells et al. *N Engl J Med.* 2020;382:1112-1123. 2. Orkin et al. *N Engl J Med.* 2020;382:1124-1135. 3. Consolidated Framework for Implementation Research. Tools and templates. <https://cfirguide.org/tools/tools-and-templates>. Accessed August 17, 2020.