P116

Overcoming Barriers and Achieving Optimal Implementation of Cabotegravir and Rilpivirine Long-Acting (CAB + RPV LA): Staff Study Participant (SSP) Results From the CAB + RPV Implementation Study in European Locations (CARISEL)

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Key Takeaways

- **Understanding how to overcome barriers and achieve optimal implementation of cabotegravir + rilpivirine long-acting (CAB + RPV LA) dosed every 2 months (Q2M) is important as staff transition patients from oral treatment to CAB + RPV LA.**
- **Data from staff participants in a Phase 3b hybrid type III implementation–effectiveness trial are presented to highlight strategies to achieve optimal CAB + RPV LA implementation.**
- **Across diverse European clinical settings and participants, quantitative and qualitative data demonstrated that implementation barriers decreased over time.**
- **Perceptions about CAB + RPV LA were positive throughout implementation.**
- **Tips for optimizing the implementation of CAB + RPV LA covered concrete and manageable suggestions, including providing education about the LA intramuscular treatment.**

Background

- CAB + RPV LA is the first complete injectable regimen dosed Q2M that is a recommended option in European and US treatment guidelines for virologically suppressed people living with HIV-1 (PLWH).[1,2]
- CAB + RPV LA reduces dosing frequency compared with daily oral antiretroviral therapy, and may help address concerns including fear of disclosure, anxiety around medication adherence, and daily reminders of HIV status.
- CAB and RPV Implementation Study in European Locations (CARISEL; NCT04399551) is a Phase 3b, multicenter, open-label, hybrid type III implementation–effectiveness trial examining strategies to support the implementation of CAB + RPV LA dosed Q2M across five European countries.
  - CARISEL is the first study in which all participants switched from daily oral therapy to CAB + RPV LA dosed Q2M.
  - CAB + RPV LA dosed Q2M was efficacious, with 87% of participants in CARISEL maintaining HIV-1 virologic suppression and 0.7% having virologic non-response at Month 12 (intention-to-treat exposed, Snapshot analysis).[3]
- Here, we present the barriers and strategies for optimal implementation of CAB + RPV LA from staff participants in the CARISEL study.

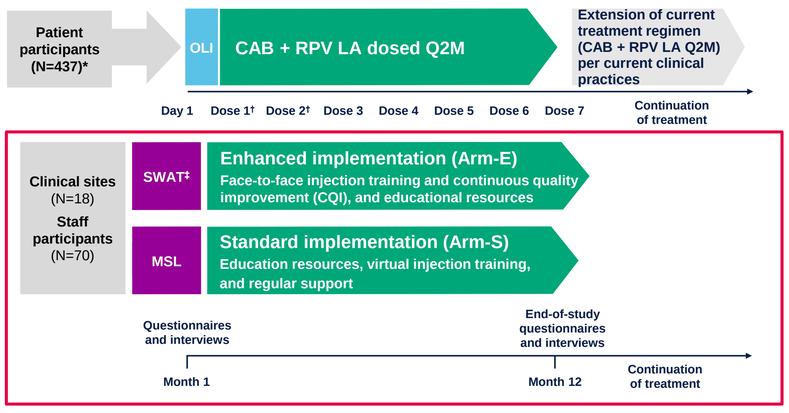
Methods

- Quantitative and qualitative data on the barriers and facilitators for optimal implementation were analyzed from Month 1 and Month 12 from staff participants in 18 sites across Belgium, France, Germany, the Netherlands, and Spain (**Table 1**).
- Quantitative data were obtained using the Associated Person, Facilitators, and Barriers (Exploration, Preparation, Implementation, and Sustainment [EPIS] Framework) measure.
- A 31-item measure was used to assess any barriers to successful implementation of the CAB + RPV LA injection treatment in the participant's clinic/practice.
- Qualitative data were obtained from semi-structured qualitative interviews on CAB + RPV LA implementation.
  - Interview guide topics were informed by the EPIS framework and Proctor outcomes.[4,5]

Table 1. Staff Participant Sample Size for Quantitative and Qualitative Data by Time Point

	Month 1	Month 12
Quantitative data	n=70	n=62
Qualitative interviews	n=70	n=62

Figure 1. Study Design



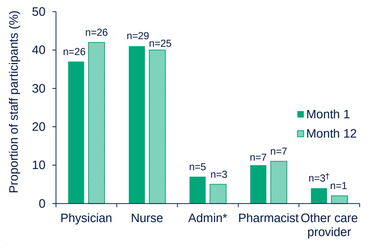
*437 patient participants enrolled, 430 received CAB + RPV LA.
†Dose 1 was received at Month 1, Dose 2 at Month 2, with the remaining doses Q2M thereafter.
‡Introduce CAB + RPV LA to clinic staff and discuss what might make implementation easier and/or what might make it difficult prior to first injection at the site. Meetings discussed implementation plans, how to work through challenges, as well as how to introduce CQI.
MSL, medical scientific liaison; OLI, oral lead-in; SWAT, skilled wrap-around team.

- CARISEL is an open-label switch study that enrolled virologically suppressed PLWH to receive CAB + RPV LA dosed Q2M. Centers were randomized to one of two implementation arms (Arm-E and Arm-S) to better understand the level of support needed for successful implementation; staff participants are the focus of this analysis (**Figure 1**).

Results

Figure 2. Baseline Characteristics

Staff participants by occupation



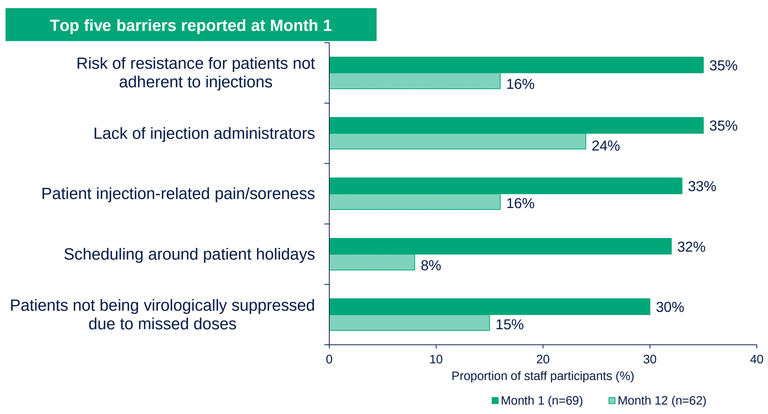
Staff participants by country and study arm

Country	Month 1 (n=70)‡	Month 12 (n=62)
Belgium	15 (21)	13 (21)
France	25 (36)	22 (35)
Germany	8 (11)	8 (13)
The Netherlands	8 (11)	7 (11)
Spain	14 (20)	12 (19)
Arm		
Arm-E	34 (49)	30 (48)
Arm-S	36 (51)	32 (52)

*Two of the admin staff hold a hybrid role of nurse/admin. †An error in the staff participant classification was noticed during the analysis phase: two of the "Other care provider" staff participants were physicians. ‡One staff participant completed their survey ≥14 days after the window for data collection had closed; therefore, their data were excluded from the results.

- 70 staff participants completed the Month 1 survey; 62 completed the Month 12 survey (**Figure 2**).
- Most staff participants were physicians and nurses across five diverse European healthcare settings.

Figure 3. Barriers to Implementation at Months 1 and 12 (Survey Data)

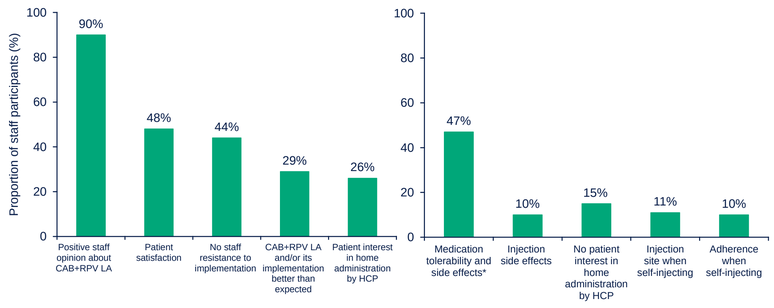


- All top five barriers reported at Month 1 markedly decreased by Month 12 (**Figure 3**).
- This trend was seen across all countries and provider types.

Figure 4. Providers' Positivity About Implementing CAB + RPV LA at Months 1 and 12

- Quantitative data showed most staff participants felt "very" or "extremely positive" about implementing CAB + RPV LA at Month 1 (76%, n=53/70) and Month 12 (76%, n=47/62) (**Figure 4**).

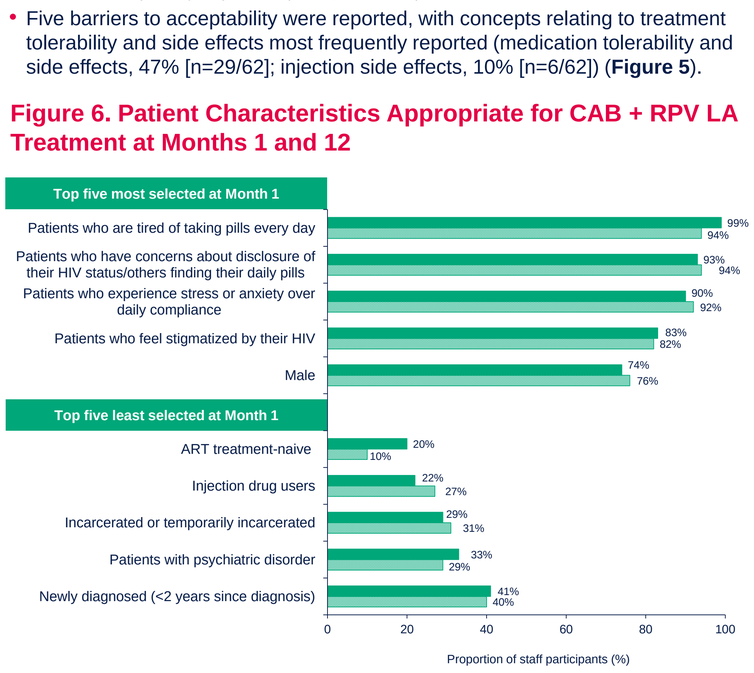
Figure 5. Acceptability at Month 12 (Facilitators of and Barriers to)



*Including concepts such as "efficacy," "tolerability," and "side effects."
HCP, healthcare professional.

- At Month 12, qualitative data showed 19 facilitators were reported by staff participants, with a positive staff participant opinion about CAB + RPV LA being the most frequently reported (90%, n=56/62).
- Five barriers to acceptability were reported, with concepts relating to treatment tolerability and side effects most frequently reported (medication tolerability and side effects, 47% [n=29/62]; injection side effects, 10% [n=6/62]) (**Figure 5**).

Figure 6. Patient Characteristics Appropriate for CAB + RPV LA Treatment at Months 1 and 12

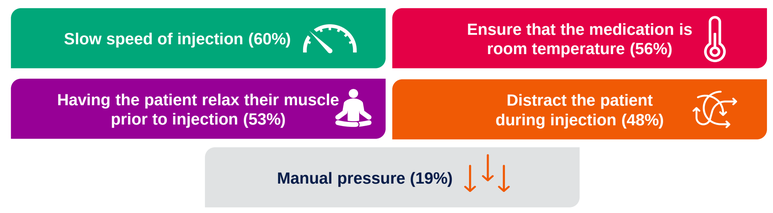


ART, antiretroviral therapy

- At Month 1 and Month 12, staff participants believed CAB + RPV LA was appropriate for a wide variety of patients (**Figure 6**).
- Notably, feeling burdened by daily pill taking as well as having a fear of inadvertent disclosure of HIV status were highlighted as patient characteristics more appropriate for CAB + RPV LA therapy; other characteristics were also rated at similarly high levels.

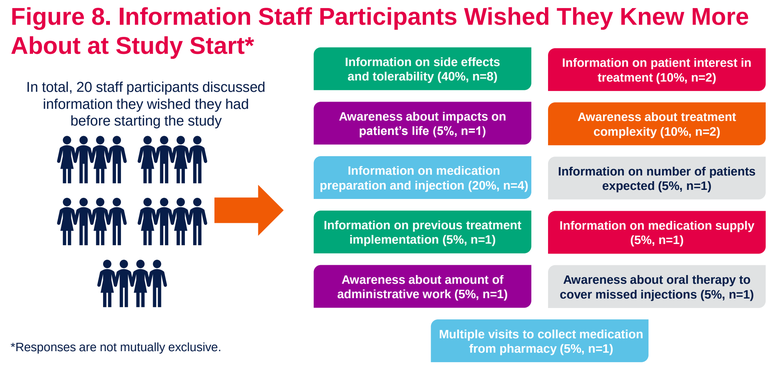
Figure 7. Top Tips for Reducing Pain With Mode of Administration at Month 12

"Which of the following techniques did you utilize to help minimize pain of the actual injection?" (n=62)



- Top tips (>50%) for reducing pain at Month 12 included: slow speed of pushing the injection (60%, n=37/62), medication at room temperature (56%, n=35/62), and relaxed muscle (53%, n=33/62) (**Figure 7**).

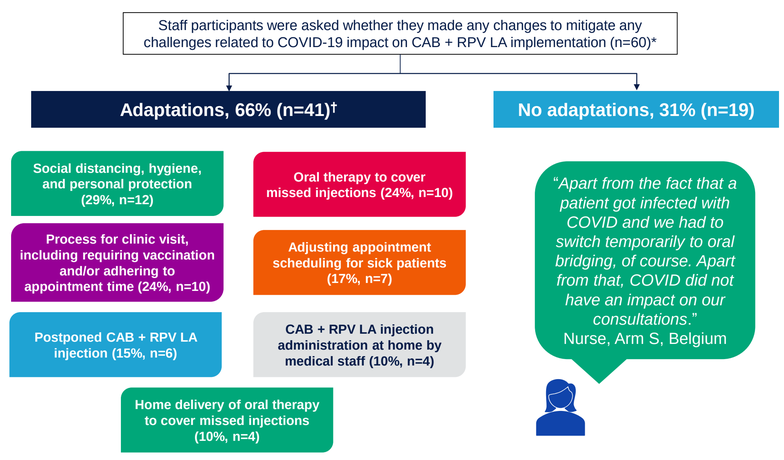
Figure 8. Information Staff Participants Wished They Knew More About at Study Start*



*Responses are not mutually exclusive.

- At Month 12, staff participants (32%, n=20/62) discussed the topics they wished they had more of before study start, including information on side effects and tolerability, to facilitate discussions with patients before injections, additional information about medication preparation and injections, and treatment complexity (**Figure 8**).
- Notably, most staff participants (68%, n=42/62) did not report wanting more information at study start.

Figure 9. Adaptations for COVID-19 Challenges



*n=60/62 discussed COVID-19 during their interviews. †Responses are not mutually exclusive.

Conclusions

- Quantitative and qualitative data from staff participants demonstrated that endorsement of implementation barriers decreased over time; perceptions about CAB + RPV LA were positive throughout implementation.
  - These results should be contextualized with the fact that participants in CARISEL were enrolled during the SARS-CoV-2 (COVID-19) pandemic, which disrupted healthcare service delivery globally.
- Tips for optimizing implementation success include using techniques to minimize injection discomfort and providing education about the treatment.
- Staff participants recognized that a wide range of patients may be appropriate for CAB + RPV LA.

Acknowledgments: This study was funded by ViiV Healthcare. The authors thank everyone who has contributed to the CARISEL study, including all study participants and their families, and the CARISEL clinical investigators and their staff, in Belgium, France, Germany, the Netherlands, and Spain. Editorial assistance was provided by Daniel Williams of Scimentum (Nucleus Global), with funding provided by ViiV Healthcare.

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