Optimizing the Clinic Flow Process for Integration of Cabotegravir + Rilpivirine Long-Acting Into Routine Care: Findings From Cabotegravir And Rilpivirine Implementation Study in European Locations (CARISEL)

MOPEE26

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Key Takeaways

- **Understanding how to overcome barriers and achieve optimal implementation of cabotegravir plus 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 study participants (SSPs) from CARISEL, a Phase 3b hybrid type III implementation–effectiveness trial, are presented to examine the processes for optimizing the implementation of CAB + RPV LA for the treatment of HIV-1 in virologically suppressed adults.**
- **Quantitative and qualitative data from SSPs demonstrated that process flows varied slightly across clinics and countries, yet there were many common components.**
- **CARISEL data suggest implementation processes were incorporated into routine care and were acceptable compared with other HIV routine appointments in European clinics.**

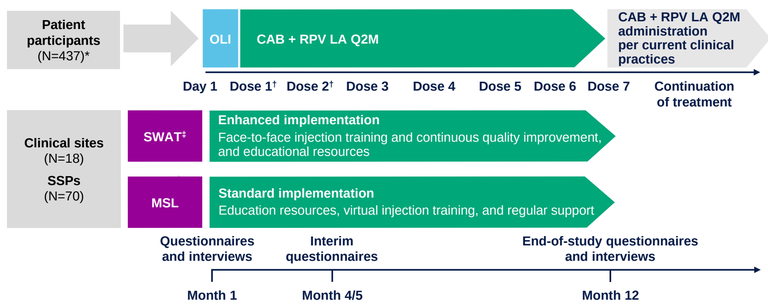
Background

- CAB + RPV LA administered Q2M is the first complete LA maintenance regimen indicated 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 psychosocial 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) was 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.
  - CAB + RPV LA dosed Q2M was efficacious, with 87% of participants in CARISEL maintaining HIV-1 virologic suppression, consistent with the four large Phase 3/3b CAB + RPV LA trials.[3–7]
- Here, we present data examining the processes for optimizing the implementation of CAB + RPV LA for the treatment of HIV-1 in virologically suppressed adults.

Methods

- CARISEL was an open-label switch study that enrolled virologically suppressed PLWH to receive CAB + RPV LA dosed Q2M.
- Sites were randomized to one of two implementation arms (Enhanced arm and Standard arm) to better understand the level of support needed for successful implementation (**Figure 1**).

Figure 1. Study Design

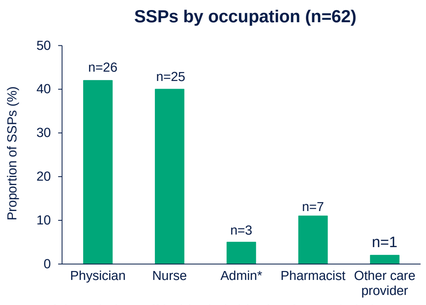


- Quantitative and qualitative data regarding clinic processes were collected from SSPs from across Belgium, France, Germany, the Netherlands, and Spain at Months 1, 5, and 12.
  - Quantitative data were obtained using study-specific survey items.
  - Qualitative data were obtained from semi-structured qualitative interviews on CAB + RPV LA implementation. Interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment framework and Proctor outcomes.[8,9]
- Clinic implementation processes for CAB + RPV LA were summarized in three distinct phases: pre-appointment, during appointment, and after clinic visit.

*437 patient participants enrolled, and 430 received CAB + RPV LA.
†Dose 1 was received at Month 1, Dose 2 at Month 2, with the remaining doses Q2M thereafter.
‡To 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 and how to work through challenges, as well as how to introduce continuous quality improvement.
CAB, cabotegravir; LA, long-acting; MSL, medical science liaison; OLI, oral lead-in; Q2M, every 2 months; RPV, rilpivirine; SSP, staff study participant; SWAT, skilled wrap-around team.

Results

Figure 2. SSP Characteristics at Month 12



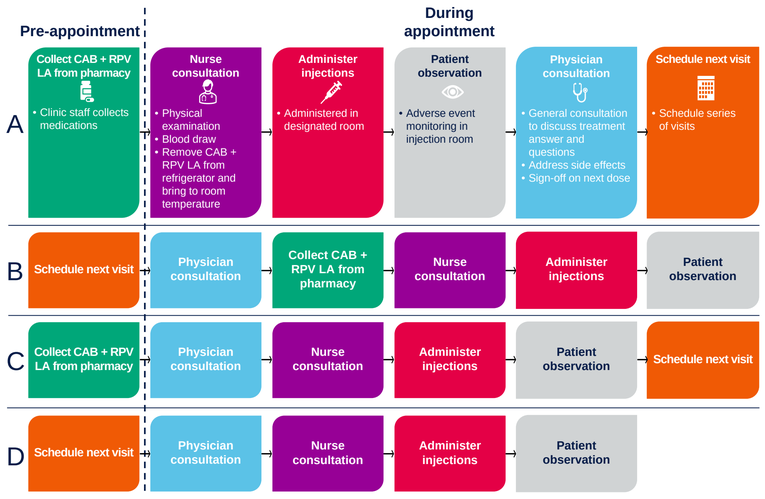
SSPs by country

Country, n (%)	Month 12 (n=62)
France	22 (36)
Belgium	13 (21)
Spain	12 (19)
Germany	8 (13)
The Netherlands	7 (11)

*Two of the admin staff hold a hybrid role of nurse/admin.
SSP, staff study participant.

- Overall, 62 SSPs completed interviews and surveys at Month 12; most were physicians or nurses (**Figure 2**).

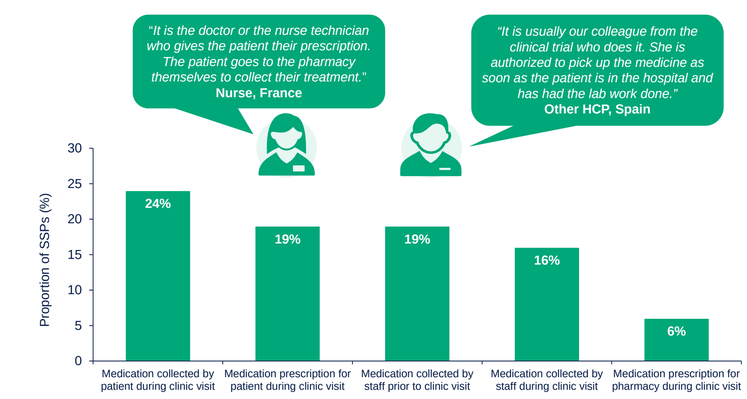
Figure 3. Example Clinic Visit Process Flows



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

- Pre-appointment processes included sending appointment reminders, preparation of paperwork, and arranging the medication pick-up process with the pharmacy (**Figure 3**).

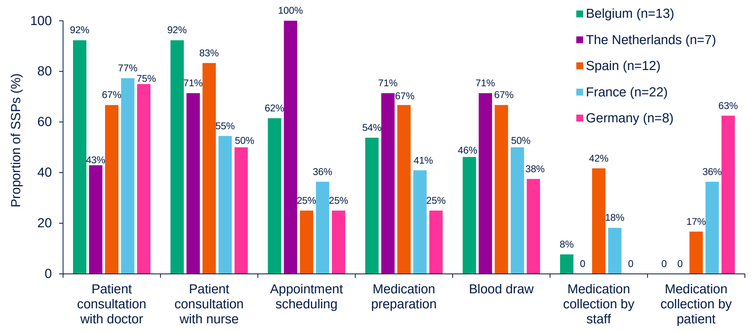
Figure 4. Medication Collection Processes Reported by SSPs*,†



*Data reported in Month 12 qualitative interviews. †n=62.
HCP, healthcare provider; SSP, staff study participant.

- Qualitative interview data revealed that medication collection processes differed; some SSPs (24%, n=15/62) reported patient participants collected CAB + RPV LA during clinic visits, while others (19%, n=12/62) had staff collect it from the pharmacy prior to visits (**Figure 4**).
- Some sites in Germany and France reported that prescriptions were given to the patients during a clinic visit to allow for medication pick-up prior to their next appointment (19%, n=12/62).

Figure 5. Processes in CAB + RPV LA Clinic Visits at Month 12 by Country*



*Data reported in Month 12 qualitative interviews. Only processes reported by ≥40% of SSPs in any country are included. Clinic appointment processes may still have occurred without being discussed in interviews.
CAB, cabotegravir; LA, long-acting; RPV, rilpivirine; SSP, staff study participant.

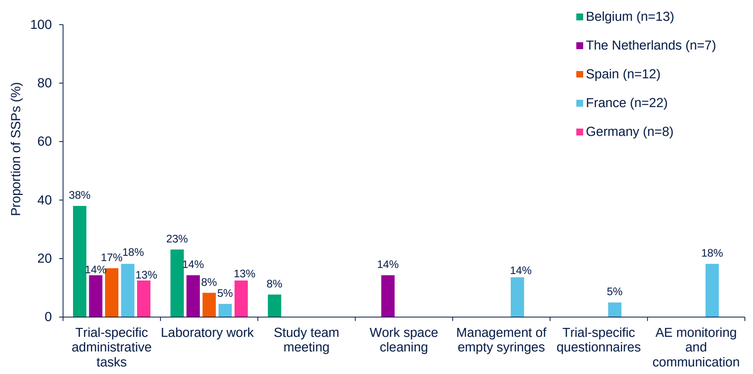
- **Figure 5** shows process components across countries.
- Qualitative interview data demonstrated that clinic appointment process components were similar across countries: patients consulted with a nurse or doctor, medication was brought to room temperature, injection was administered, and patients were monitored for 10 minutes.

Figure 6. Scheduling Future Appointments*

*Data reported in Month 12 qualitative interviews. †Clinic appointment processes may still have occurred without being discussed in interviews.

- Some SSPs discussed scheduling future appointments during the injection visit (45%, n=28/62)† (**Figure 6**).

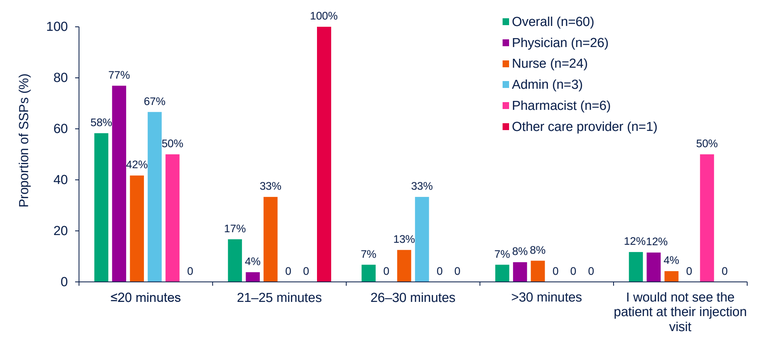
Figure 7. Processes After Injection Visits*,†



*Discussed by SSPs at Month 12 qualitative interviews; processes after injections may still have occurred without being discussed in interviews. †n=62.
AE, adverse event; SSP, staff study participant.

- Across all countries, the most common post-visit task (non-study specific) SSPs discussed was laboratory work (**Figure 7**).

Figure 8. Average Time Spent With Patient for Injection Visits*

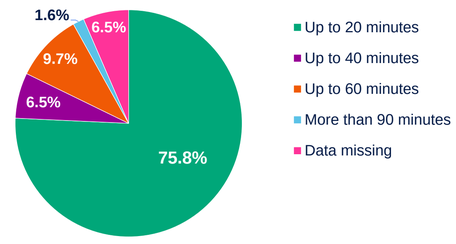


*Month 12 quantitative data (n=60).
SSP, staff study participant.

- Over 50% (n=35/60) of SSPs reported spending 20 minutes or less with patients at visits (**Figure 8**).

Figure 9. Time Spent per Week Following Up With Patients to Ensure Appointment Attendance*

"How much time per week is spent following up with patients to ensure their attendance at the next injection appointment?"

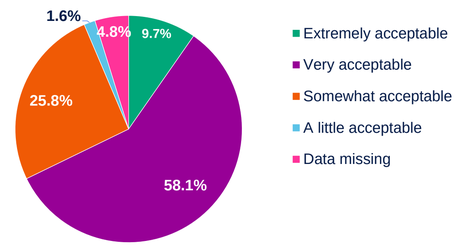


*Month 12 quantitative data (n=62).

- Most (76%, n=47/62) SSPs reported they spent 20 minutes or less per week ensuring appointment attendance (**Figure 9**).

Figure 10. Time Spent in Clinic*

"Overall, how acceptable do you think patients find the time spent in the clinic for each injection?"



*Month 12 quantitative data (n=62).

- The majority of SSPs (68%, n=42/62) thought that patients found the time they spent in clinic "very"/"extremely" acceptable (**Figure 10**).

Conclusions

- Although process flows varied slightly, there were many common components across clinics and countries, including patients consulting with a nurse or doctor, bringing medication to room temperature, and monitoring patients for 10 minutes.
- The majority of SSPs spent 20 minutes or less with a patient per injection visit; most SSPs also reported spending 20 minutes or less per week following up with patients to ensure appointment attendance.
- CARISEL data suggest implementation processes for CAB + RPV LA could be incorporated into routine care in European HIV clinics with relative ease.
- Overall, data from CARISEL support CAB + RPV LA as a therapeutic alternative to daily oral therapy that can be readily incorporated into a European clinical setting in a timely manner, with similar process flows across clinics.

Acknowledgments: This study was funded by ViiV Healthcare. The authors thank everyone who has contributed to the CARISEL study, including all patient 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 Poppie Cooper of Scimentum (Nucleus Global), with funding provided by ViiV Healthcare.

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