Perspectives on the Acceptability, Appropriateness, Feasibility, Barriers, and Facilitators From Patients Receiving Cabotegravir + Rilpivirine Long-Acting Injectable Treatment (CAB + RPV LA): Interim Results From the Cabotegravir and Rilpivirine Implementation Study in European Locations (CARISEL)

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Introduction

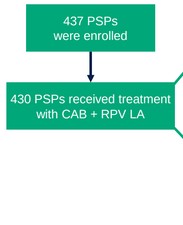
- Cabotegravir (CAB) plus rilpivirine (RPV) is the first complete long-acting (LA) regimen recommended by treatment guidelines[1,2] for the maintenance of HIV-1 virologic suppression.
- CAB + RPV LA administered monthly[3–5] or every 2 months[6] may address some challenges associated with daily oral antiretroviral therapy, such as fear of inadvertent disclosure, anxiety related to staying adherent, and the daily reminder of HIV status.
- CARISEL (NCT04399551) is a Phase 3b, multicenter, open-label hybrid type III implementation-effectiveness study that examines the acceptability, appropriateness, and feasibility of CAB + RPV LA injections and implementation support in HIV centers across Belgium, France, Germany, the Netherlands, and Spain.
- This interim analysis summarizes patient study participant (PSP) perspectives on CAB + RPV LA implementation in the CARISEL study.

Methods

- Virologically suppressed patients were enrolled across 18 European clinics to receive CAB + RPV LA injections every 2 months.
- This interim analysis includes data from patient surveys conducted at Month 1 and Month 4 (prior to the first and third injections, respectively), with satisfaction of HIV treatment (HIV Treatment Satisfaction Questionnaire [HIVTSQ]) measured at Day 1 (prior antiretroviral therapy), Month 1 (CAB + RPV oral lead-in), and Month 4 (CAB + RPV LA).
- Acceptability Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility Intervention Measure (FIM) are 4-item questionnaires that use a 5-point rating scale (1 = completely disagree to 5 = completely agree) to evaluate the acceptability, appropriateness, and feasibility of the regimen, respectively.
- Additional questionnaires assessed attitudes and expectations of patients regarding the CAB + RPV LA regimen.
- Clinical data on time in clinic for appointments were also collected at Months 1, 2, and 6.
- The univariate distribution of every survey item was tabulated and summarized using standard distributional statistics.

Results

Figure 1. Baseline Characteristics

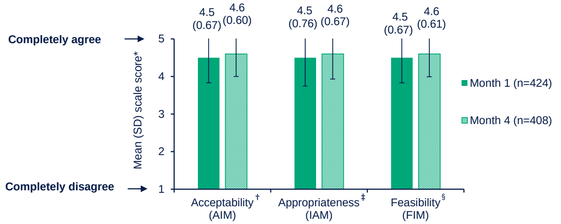


Parameter	Treated PSPs (n=430)
Age group, years, n (%)	
<35	80 (19)
35 to <50	221 (51)
≥50	129 (30)
Female (sex at birth), n (%)	109 (25)
Female (self-identified gender), n (%)	115 (27)
Race, n (%)	
White	336 (78)
Black/African American	76 (18)
Asian	9 (2)
Other	9 (2)
Mean BMI (SD), kg/m^2	25.6 (4.1)
Country, n (%)	
Belgium	71 (17)
France	171 (40)
Germany	54 (13)
The Netherlands	38 (9)
Spain	96 (22)

BMI, body mass index; CAB, cabotegravir; LA, long-acting; PSP, patient study participant; RPV, rilpivirine; SD, standard deviation.

- Overall, 25% of PSPs were female, 30% were 50 years of age or older, and 18% were Black/African American (**Figure 1**).
- At Month 1, 424/430 (98.6%) PSPs completed questionnaires; 408/430 (94.9%) completed the Month 4 questionnaire.

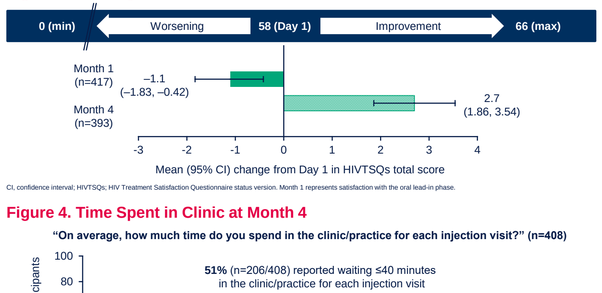
Figure 2. Acceptability, Appropriateness, and Feasibility of CAB + RPV LA



*Mean (SD) scores represent distributional characteristics at the timepoint. †M4, n=403. ‡M1, n=423; M4, n=403. §M4, n=401. AIM, Acceptability of Intervention Measure; CAB, cabotegravir; FIM, Feasibility of Intervention Measure; IAM, Intervention Appropriateness Measure; LA, long-acting; M, month; RPV, rilpivirine; SD, standard deviation.

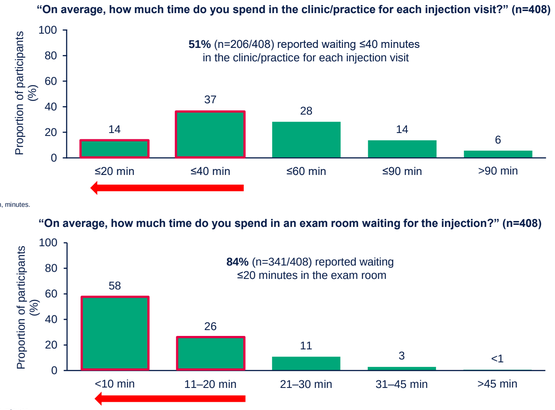
- At both timepoints, most PSPs found CAB + RPV LA injections highly acceptable, appropriate, and feasible (**Figure 2**).
- HIVTSQ scores increased over time, with most PSPs "satisfied" or "very satisfied" with treatment (**Figure 3**).
- Overall, 26.8% (n=107/399) of PSPs reported maximum satisfaction at Month 4.
- At Month 1, a small decrease in HIVTSQ score was observed compared with Day 1, although an increase was observed at Month 4 (**Figure 3**).

Figure 3. HIVTSQ Scores Over Time



CI, confidence interval; HIVTSQs; HIV Treatment Satisfaction Questionnaire status version. Month 1 represents satisfaction with the oral lead-in phase.

Figure 4. Time Spent in Clinic at Month 4



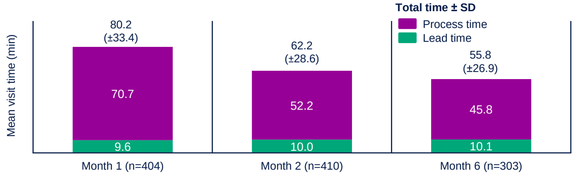
- The majority of PSPs spent ≤40 minutes in clinic for a CAB + RPV LA injection visit (**Figure 4**).
- 84% of PSPs spent ≤20 minutes waiting in the exam room for the CAB + RPV LA injection visit.

Figure 5. Overall Visit Time Between Month 1 and Month 6

Lead time = actual start time of appointment – arrival time

Process time = actual end time of appointment – actual start time of appointment

Total time = actual end time of appointment – arrival time

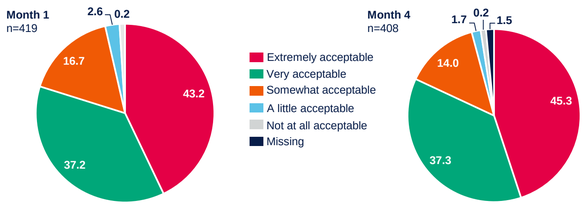


SD, standard deviation.

- A 30.4% (24.4-minute) reduction in mean appointment duration was observed from Month 1 to Month 6, which was mostly driven by a decrease in process time (**Figure 5**).

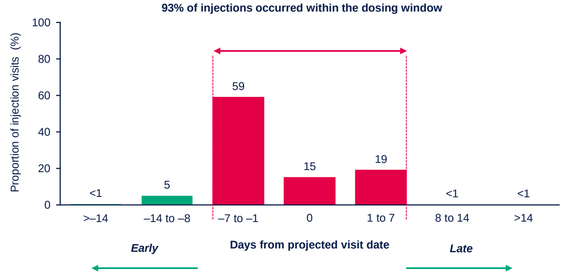
Figure 6. Acceptability of Clinic Visits at Months 1 and 4

"How acceptable is it to you to come to the clinic/practice for your injection visit every 2 months?"



- Acceptability of coming to CAB + RPV LA injection visits appears to start and remain high between Month 1 and Month 4 (**Figure 6**).
- Most patients felt it was extremely/very acceptable to come to the clinic every 2 months for the injection visit.

Figure 7. Adherence of Injection Visits*

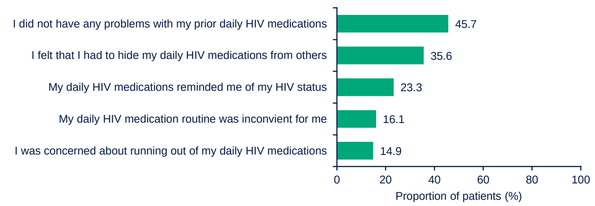


*n=1092/1171. As per July 6, 2021, when all PSPs completed their Month 4 visit. PSP, patient study participant.

- Overall, 93% of injection visits occurred within ±7 days of the target date (**Figure 7**).

Figure 8. Top Concerns With Daily HIV Medications at Month 1

Top five concerns* in response to: "**Before participating in this study, did you have any problems with your daily HIV medications?**" (n=421)

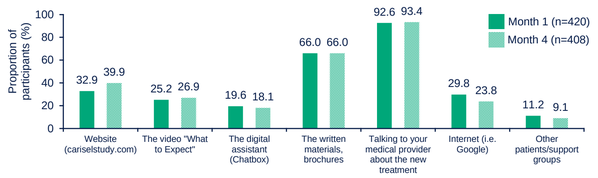


*Not mutually exclusive. The responses selected by PSPs comprised predefined response choices. PSP, patient study participant.

- At Month 1, the majority (54.3%) identified problems with taking daily oral therapy (**Figure 8**).

Figure 9. Helpfulness of Toolkit Materials

Perceived helpfulness* of materials and information shared by the medical staff at Months 1 and 4



*Proportion of patients selecting "extremely helpful" and "very helpful" reported only.

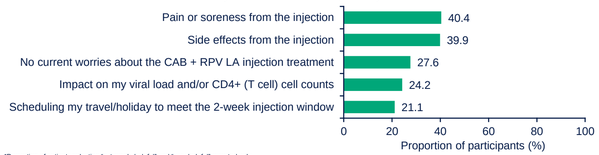
Top three helpful materials and information at Months 1 and 4

1. **Talking to your medical provider about the new treatment**
2. **The written materials, brochures**
3. **Website (cariselstudy.com)**

- Most PSPs felt that talking to their medical provider about the new treatment was the most helpful material/information shared at Months 1 and 4 (**Figure 9**).

Figure 10. Most Common Concerns About CAB + RPV LA Injection Treatment at Month 1

Top five concerns in response to: "**Do you have any concerns about the CAB + RPV LA injection treatment?**" (n=421)*



*Proportion of patients selecting "extremely helpful" and "very helpful" reported only.
CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

- At Month 1, the most common concerns about CAB + RPV LA injection treatment were pain or soreness and side effects from the injection (**Figure 10**).
- In total, 91.2% (n=372/408) of PSPs felt "very" or "extremely positive" about CAB + RPV LA treatment at Month 4, compared with 83.5% (n=350/419) at Month 1.

Conclusions

- CAB + RPV LA was observed to be an acceptable, appropriate, and feasible treatment option for the maintenance of HIV virologic suppression from Month 1 to 4.
- PSPs' satisfaction improved versus oral therapy and the oral lead-in phase, and the majority found clinic wait time, recovery time, and treatment information appropriate and acceptable.
- 96.6% of PSPs felt it was acceptable to come to the clinic/practice for an injection visit every 2 months.
- The average amount of time PSPs spent in clinic decreased over time.
- PSPs thought talking to a medical provider about the new treatment was the most helpful way to receive information about CAB + RPV LA.
- Interim data from CARISEL suggest CAB + RPV LA is an appealing alternative treatment option for people living with HIV.

Acknowledgments

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