Healthcare Staff Perspectives on the Implementation of HIV Injectable Treatment: Interim Results From the Cabotegravir and Rilpivirine Implementation Study in European Locations (CARISEL)

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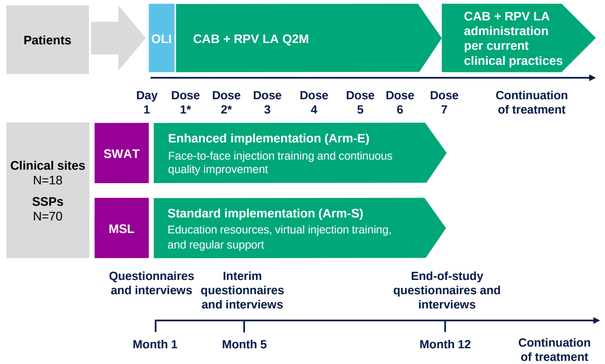
Introduction

- 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) 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 study staff participant (SSP) perspectives on CAB + RPV LA treatment and implementation support in the CARISEL study.

Methods

- CARISEL is a Phase 3b multicenter, open-label, hybrid type III implementation-effectiveness study assessing the acceptability, appropriateness, and feasibility of CAB + RPV LA injections and implementation support in HIV centers across five European countries.
- SSPs from 18 clinics across Belgium, France, Germany, the Netherlands, and Spain completed quantitative questionnaires on CAB + RPV LA treatment and implementation support at Months 1 and 5 of the 12-month study.
- Quantitative questionnaires included:
  - Acceptability of Intervention Measure (AIM).
  - Intervention Appropriateness Measure (IAM).
  - Feasibility of Intervention Measure (FIM).
  - Acceptability of Implementation Measure (AIM-Imp).
  - Implementation Appropriateness Measure (IAM-Imp).
  - Feasibility of Implementation Measure (FIM-Imp).
- Opinions on barriers and facilitators to implementation were also collected, along with a survey to assess the appropriateness of the settings for administration of CAB + RPV LA, toolkits, and general expectations.
- Clinical data on time in clinic for appointments were also collected at Months 1, 2, and 6.

Figure 1. Study Design

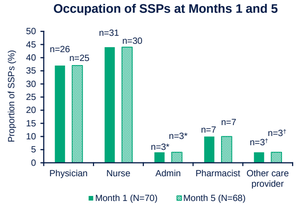


*Dose 1 was received at Month 1, dose 2 at Month 2, with the remaining doses Q2M thereafter.
Arm-E, enhanced arm; Arm-S, standard arm; CAB, cabotegravir; LA, long-acting; MSL, medical scientific liaison; OLI, oral lead-in; Q2M, every 2 months; RPV, rilpivirine; SSP, study staff participant; SWAT, skilled wrap around team.

- Centers were randomized to either Arm-E or Arm-S to understand the level of support needed for successful implementation (**Figure 1**).

Results

Figure 2. SSP Characteristics

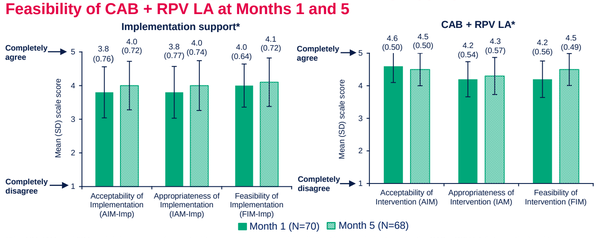


Country, n (%)	Month 1 (N=70)	Month 5 (N=68)
Belgium	15 (21)	15 (22)
France	25 (36)	23 (34)
Germany	8 (11)	8 (12)
The Netherlands	8 (11)	8 (12)
Spain	14 (20)	14 (21)
Arm, n (%)		
Enhanced arm (Arm-E)	34 (49)	33 (49)
Standard arm (Arm-S)	36 (51)	35 (51)

*Two of the admin staff hold a hybrid role of nurse/admin. †An error in the SSP classification was noticed during the analysis phase: two of the "other care provider" SSPs were physicians. Arm-E, enhanced arm; Arm-S, standard arm; SSP, study staff participant.

- 70 SSPs completed the Month 1 survey; 68 completed the Month 5 survey (**Figure 2**).

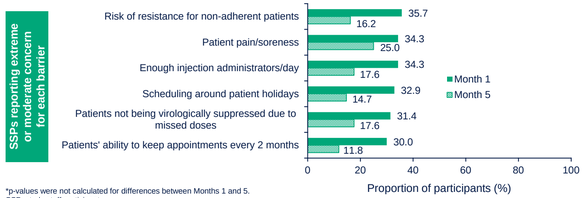
Figure 3. SSPs Reported High Levels of Acceptability, Appropriateness, and Feasibility of CAB + RPV LA at Months 1 and 5



*The AIM, IAM, and FIM are brief measures of acceptability, appropriateness, and feasibility. All were administered for the CAB + RPV LA (intervention) and the implementation support (noted with "-Imp"). AIM, IAM, FIM, AIM-Imp, IAM-Imp, and FIM-Imp are each 4-item measures scored 1–5; 1 = completely disagree and 5 = completely agree. Mean scores across four statements on 1–5 Likert scales with SDs are reported. CAB, cabotegravir; LA, long-acting; SD, standard deviation; SSP, study staff participant; RPV, rilpivirine.

- SSPs reported high levels of acceptability, appropriateness, and feasibility of CAB + RPV LA injections and implementation support at Month 1 (mean scale scores ≥3.8) and Month 5 (mean scale scores ≥4.0) where a score of 4 = "Agree" (**Figure 3**).
- In general, mean scores improved over time.

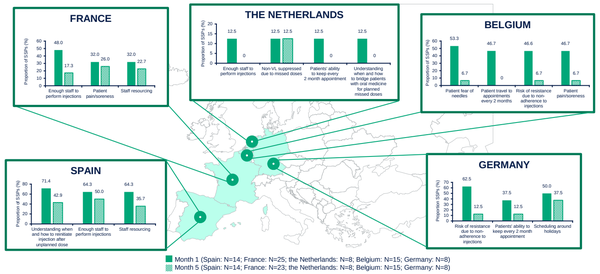
Figure 4. Top Six Implementation Concerns Decreased From Month 1 to Month 5*



*p-values were not calculated for differences between Months 1 and 5.
SSP, study staff participant.

- At Month 1 and Month 5, SSPs were either "moderately" or "extremely" concerned about risk of resistance due to non-adherence, patient pain/soreness, having enough staff to perform injections, scheduling around patient holidays, patients not being virologically suppressed due to missed doses, and patients' ability to keep appointments every 2 months (**Figure 4**).
- From Month 1 to Month 5, overall levels of concern about these barriers to implementation decreased.

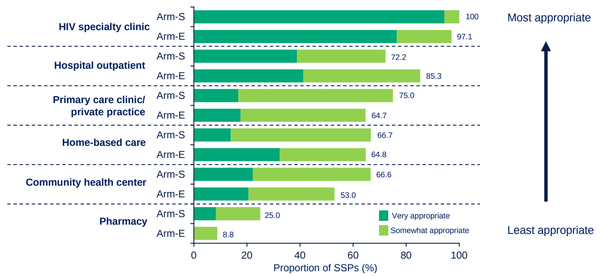
Figure 5. Top Three Concerns by Country at Months 1 and 5



2M, 2 months; SSP, study staff participant; VL, viral load.

- The top three concerns reported by SSPs at Month 1 nearly all decreased by Month 5 (**Figure 5**).

Figure 6. At Month 1, Many Settings Were Considered Appropriate for CAB + RPV LA



Arm-E, n=34; Arm-S, n=36. Arm-E, enhanced arm; Arm-S, standard arm; CAB, cabotegravir; LA, long-acting; RPV, rilpivirine; SSP, study staff participants.

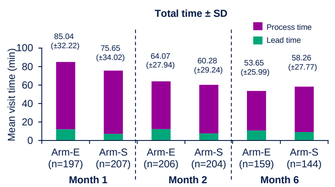
- Although HIV clinics were considered the most appropriate setting for CAB + RPV LA, other settings were also rated appropriate (**Figure 6**).

Figure 7. Overall Visit Time Decreased in Arm-E and Arm-S* 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

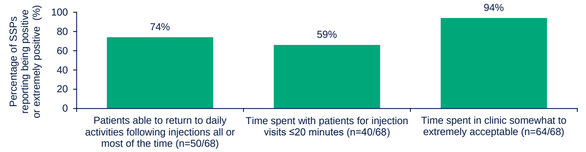
Total time = actual end time of appointment – arrival time



*No difference by country was reported.
Arm-E, enhanced arm; Arm-S, standard arm; SD, standard deviation.

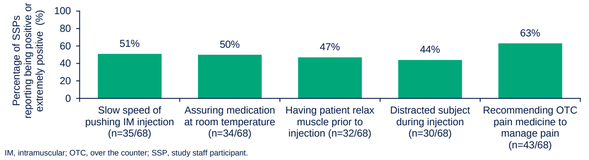
- Total appointment duration decreased across both arms, and a 37% (31.4-minute) reduction in total appointment duration was observed in Arm-E from Month 1 to Month 6 (**Figure 7**).
- Perceptions of patient experiences and techniques used to manage pain/soreness at Month 5 are shown in **Figures 8** and **9**.

Figure 8. Perceptions of Injection Visits and Return to Activities at Month 5



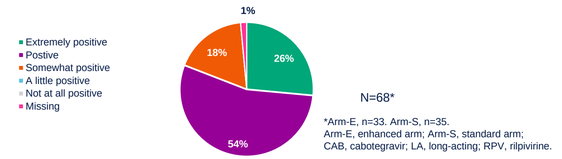
SSP, study staff participant.

Figure 9. Techniques Used to Manage Pain/Soreness at Month 5



IM, intramuscular; OTC, over the counter; SSP, study staff participant.

Figure 10. Providers' Positivity About Implementing CAB + RPV LA at Month 5



*Arm-E, n=33. Arm-S, n=35.
Arm-E, enhanced arm; Arm-S, standard arm; CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

- At Month 5, 80.9% of SSPs felt "extremely positive" or "positive" (Arm-E, 87.9%; Arm-S, 74.3%); overall, 98.5% of SSPs felt "somewhat" to "extremely" positive about implementing CAB + RPV LA (**Figure 10**).

Conclusions

- SSPs in HIV centers across five European countries found the CAB + RPV LA injection treatment and implementation to be acceptable, appropriate, and feasible.
- Implementation concerns varied between the five countries, though all those identified pre-implementation decreased within the first few months of CAB + RPV LA treatment in all countries.
- Although HIV clinics were considered the most appropriate setting by most staff, overall other locations were also deemed appropriate, such as primary care clinics and home-based care.
- Most SSPs found the time spent in clinic for CAB + RPV LA injections to be acceptable.
- At the interim analysis, most SSPs across Europe were positive or extremely positive about CAB + RPV LA implementation.

Acknowledgments

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References

1. U.S. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. 2021. Available from: https://aidsinfo.nih.gov/guidelines/html/1/ adult-and-adolescent-arv/15/virologic-failure. Accessed October 2021.
2. Saag MS, et al. *JAMA*. 2020;324(16):1651–1669.
3. Swindells S, et al. *N Engl J Med*. 2020;382(12): 1112–1123.
4. Orkin C, et al. *N Engl J Med*. 2020;382(12): 1124–1135.
5. Orkin C, et al. *Lancet HIV*. 2021;8(4):e185–e196.
6. Overton ET, et al. *Lancet*. 2020;396(10267): 1994–2005.

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