

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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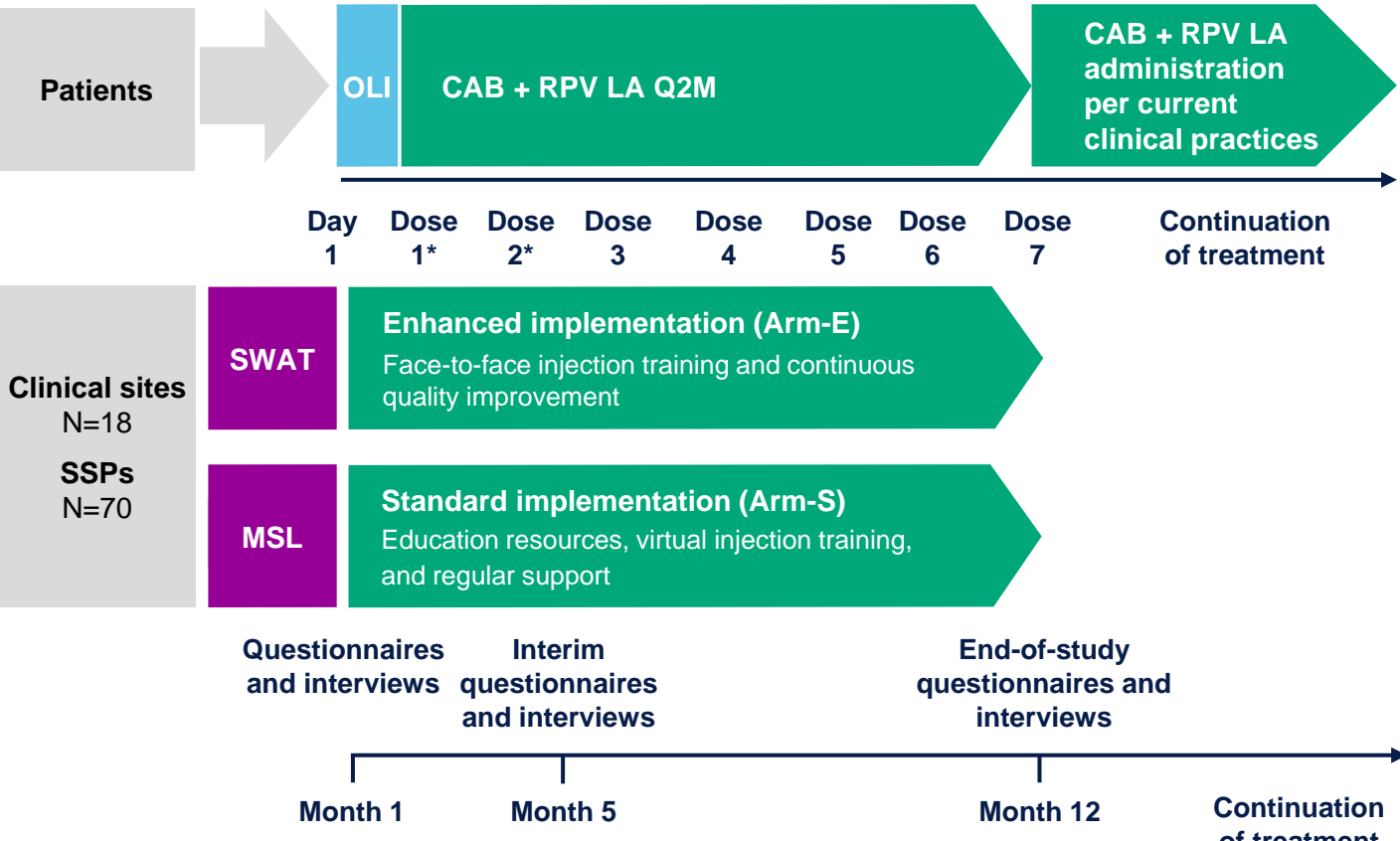
Introduction

- 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 monthly³⁻⁵ or every 2 months⁶ 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

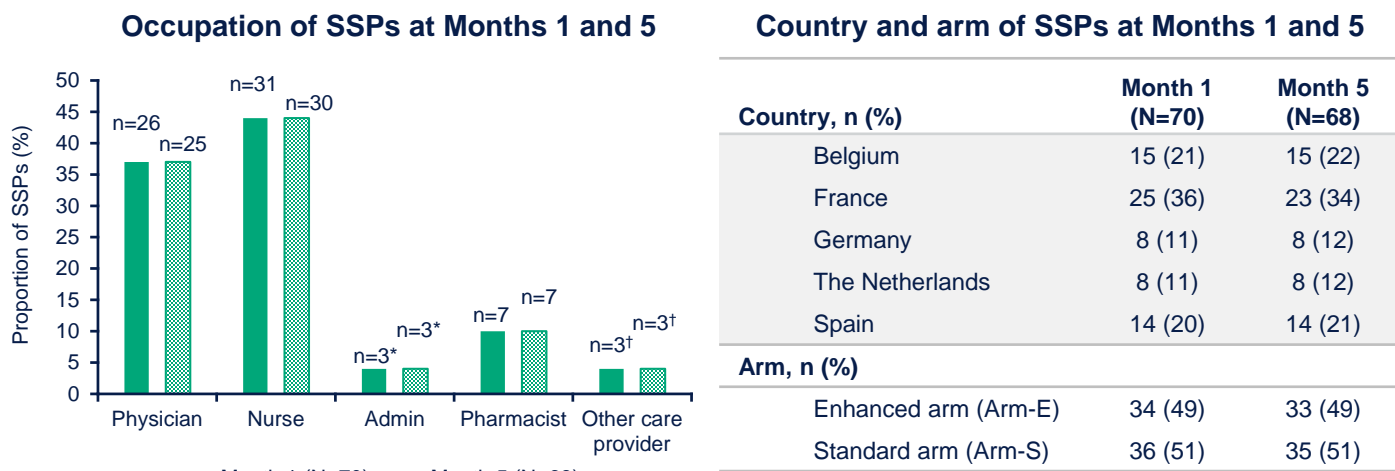


*Dose 1 was received at Month 1, dose 2 at Month 2, with the remaining doses Q2M thereafter.
Arm-E, enhanced arm; Arm-S, standard arm; CAB, cabotegravir; LA, long-acting; MSL, medical scientific liaison; OLI, oral lead-in; Q2M, every 2 months; RPV, rilpivirine; SSP, study staff participant; SWAT, skilled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

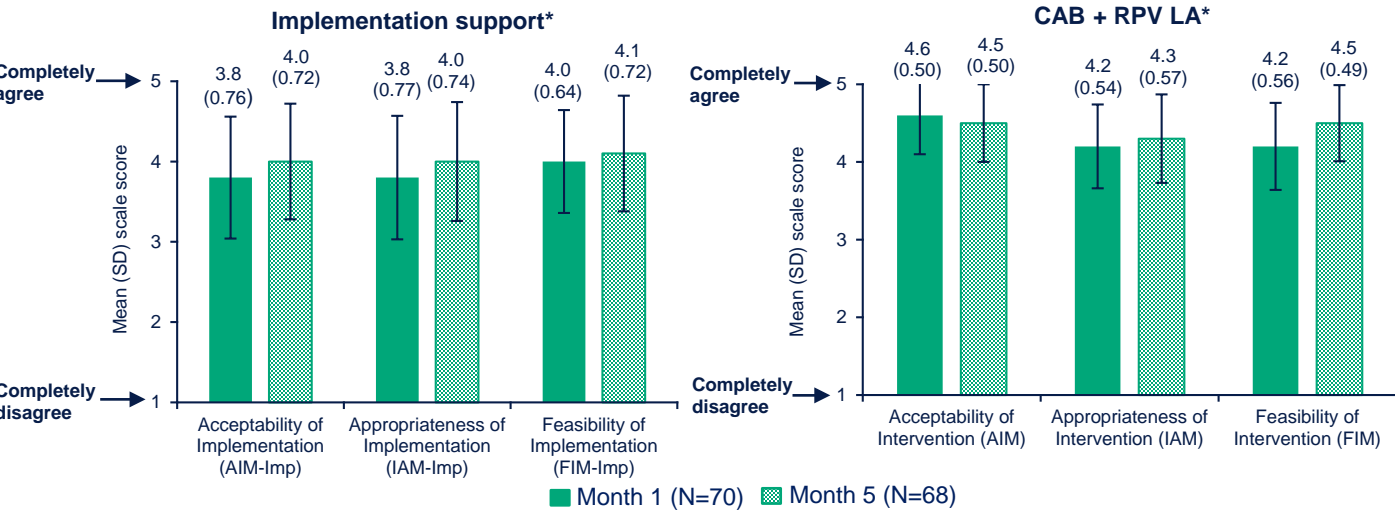
Figure 2. SSP Characteristics



*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).

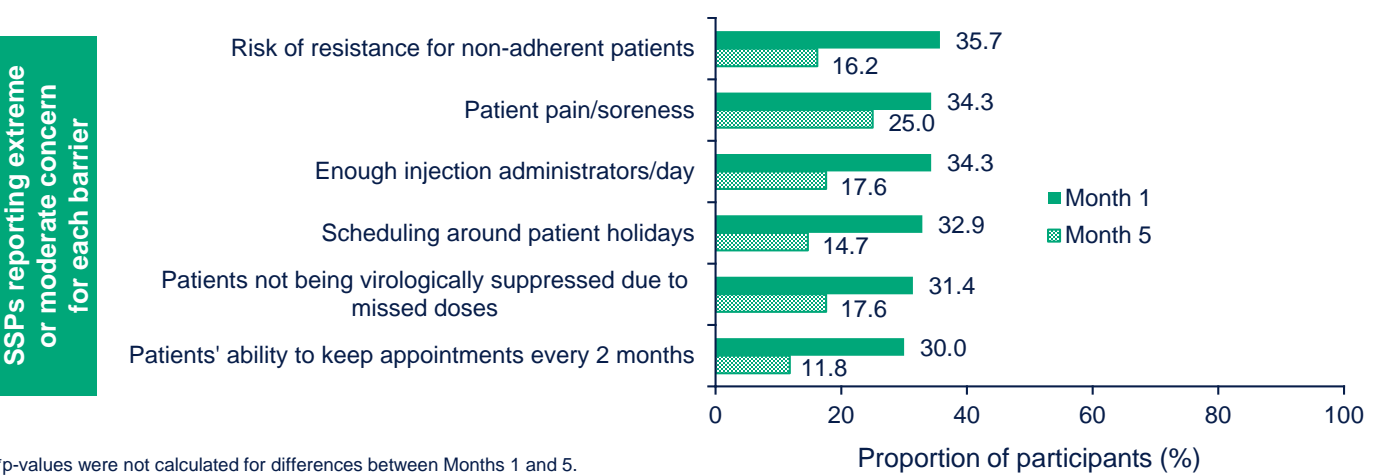
Figure 3. SSPs Reported High Levels of Acceptability, Appropriateness, and Feasibility of CAB + RPV LA at Months 1 and 5



*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.

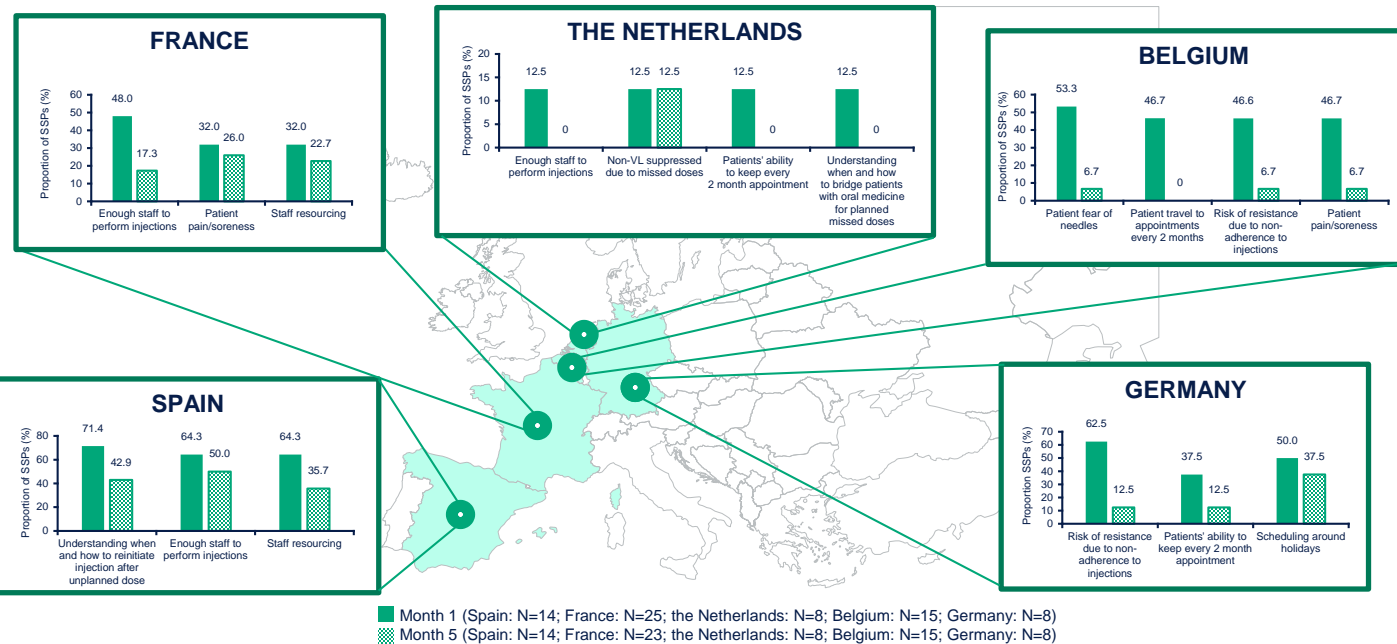
Figure 4. Top Six Implementation Concerns Decreased From Month 1 to Month 5*



*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.

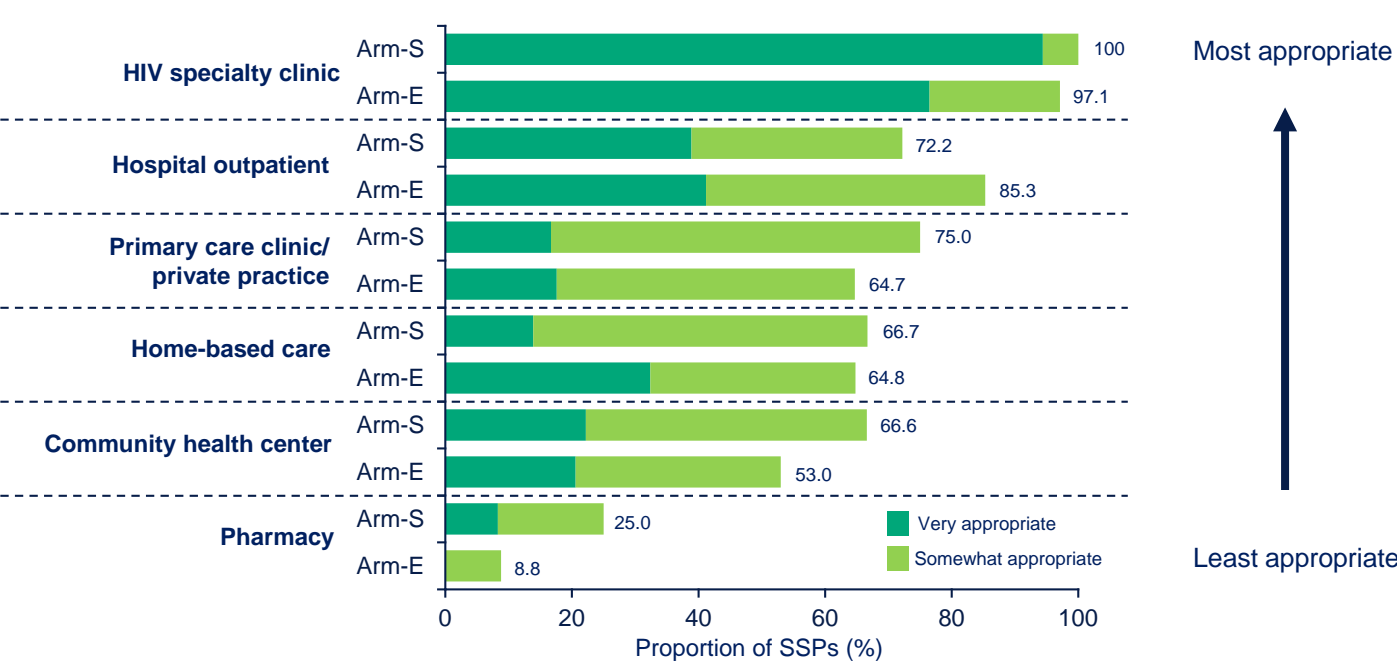
Figure 5. Top Three Concerns by Country at Months 1 and 5



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).

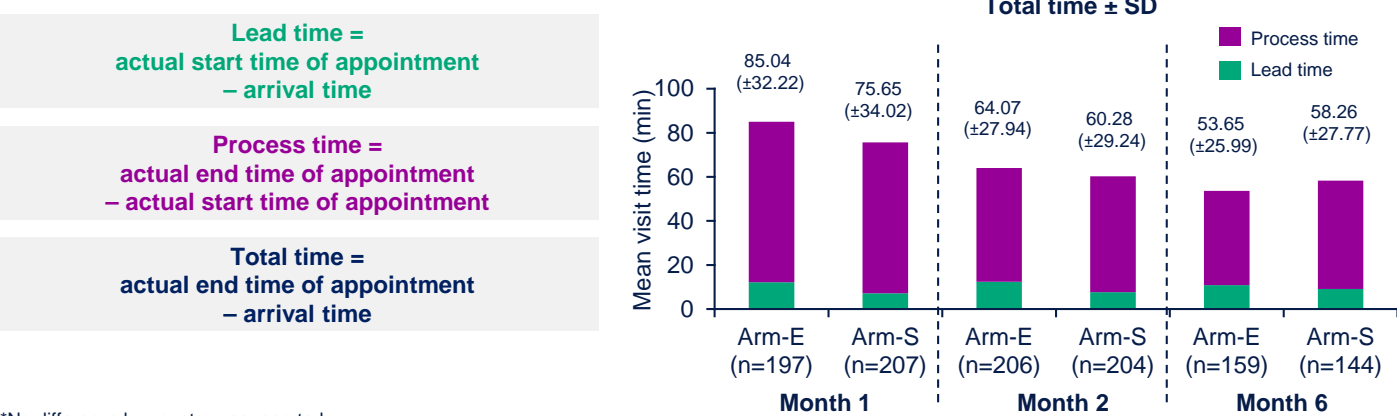
Figure 6. At Month 1, Many Settings Were Considered Appropriate for CAB + RPV LA



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).

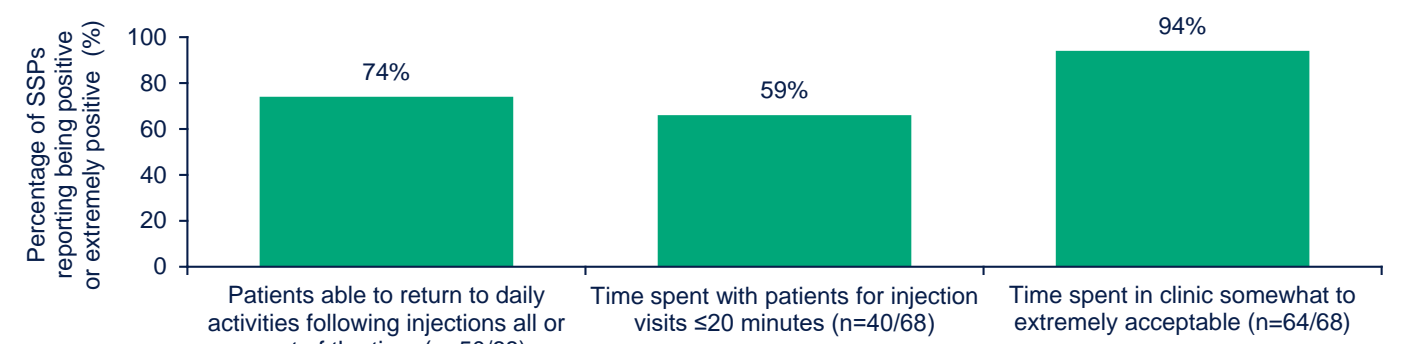
Figure 7. Overall Visit Time Decreased in Arm-E and Arm-S* Between Month 1 and Month 6



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

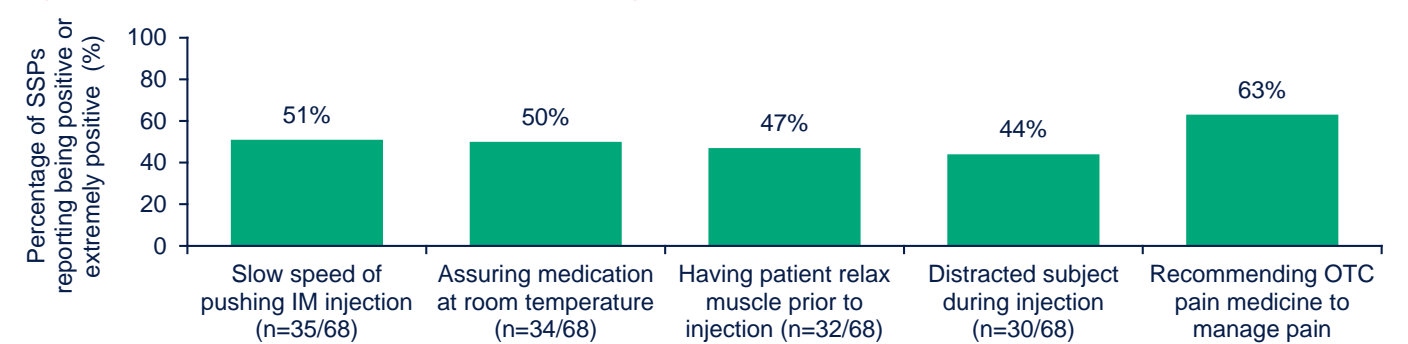
- Total appointment duration decreased across both arms, and a 37% (31.4-minute) reduction in total appointment duration was observed in Arm-E from Month 1 to Month 6 (Figure 7).
- Perceptions of patient experiences and techniques used to manage pain/soreness at Month 5 are shown in Figures 8 and 9.

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



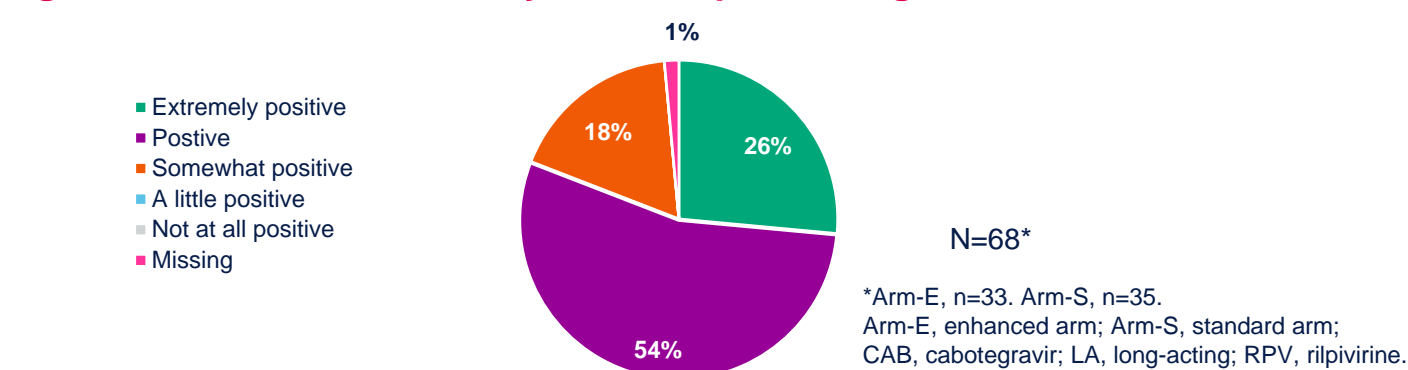
SSP, study staff participant.

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



- 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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