

The Use and Utility of Toolkits in Supporting Cabotegravir + Rilpivirine Long-Acting Implementation in the CARISEL (Cabotegravir And Rilpivirine Implementation Study in European Locations) Study

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Key Takeaways

- CARISEL is a Phase 3b, multicenter, open-label, hybrid type III implementation-effectiveness trial examining strategies to support the implementation of cabotegravir + rilpivirine long-acting (CAB + RPV LA) dosed every 2 months (Q2M) across five European countries.
- We present analytic and self-reported data on toolkit use and perceived utility among patient study participants (PSPs) and staff study participants (SSPs).
- There was overall positive feedback about the toolkits by both PSPs and SSPs, with SSPs mentioning the training video, poster, website, and injection materials in their feedback.
- Overall, although clinics had access to different training sessions at study start (Arm-S vs. Arm-E), all toolkit materials were well received and aided the implementation of CAB + RPV LA.

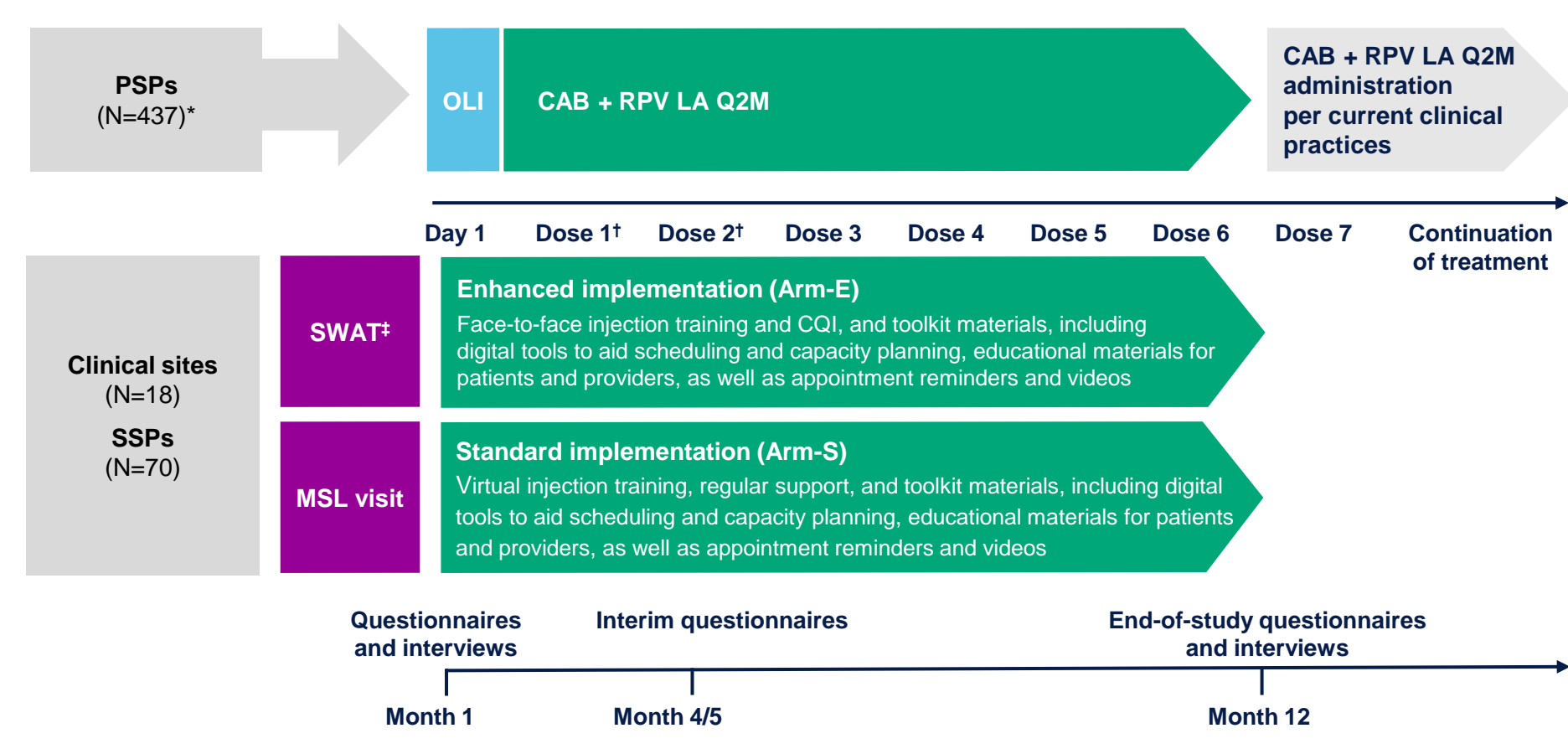
Background

- CAB + RPV LA administered Q2M is the first complete LA maintenance regimen recommended for virologically suppressed people living with HIV-1 (PLWH).^{1,2}
- CAB + RPV LA is indicated for PLWH without present or past viral resistance to non-nucleoside reverse transcriptase inhibitors and integrase inhibitors.^{1,2}
- 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.
- The CARISEL study provided PSPs and SSPs with toolkits to support the implementation of CAB + RPV LA in HIV clinics across Europe.
- Here, we present analytic and self-reported data on toolkit use and perceived utility among PSPs and SSPs.

Methods

- CARISEL is 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 [Arm-E] and Standard arm [Arm-S]) to better understand the level of support needed for successful implementation (Figure 1).
- Both implementation arms received provider and patient toolkits.
- SSPs in Arm-E received face-to-face training at a skilled wrap-around team (SWAT) meeting, including a global presentation on implementation. Two Arm-E SSPs per clinic also participated in continuous quality improvement (CQI) calls.
- Toolkit materials included digital tools to aid scheduling and capacity planning, educational materials for patients and providers, as well as appointment reminders and videos (Figure 2).
- Quantitative questionnaires about toolkits were collected at Month 1, Month 5, and Month 12 for SSPs, and at Month 1, Month 4, and Month 12 for PSPs.
- Toolkit analytics (access and downloads) were collected monthly, and qualitative data on toolkits were collected at Month 12 for both SSPs and PSPs.

Figure 1. Study Design and Toolkit Outline

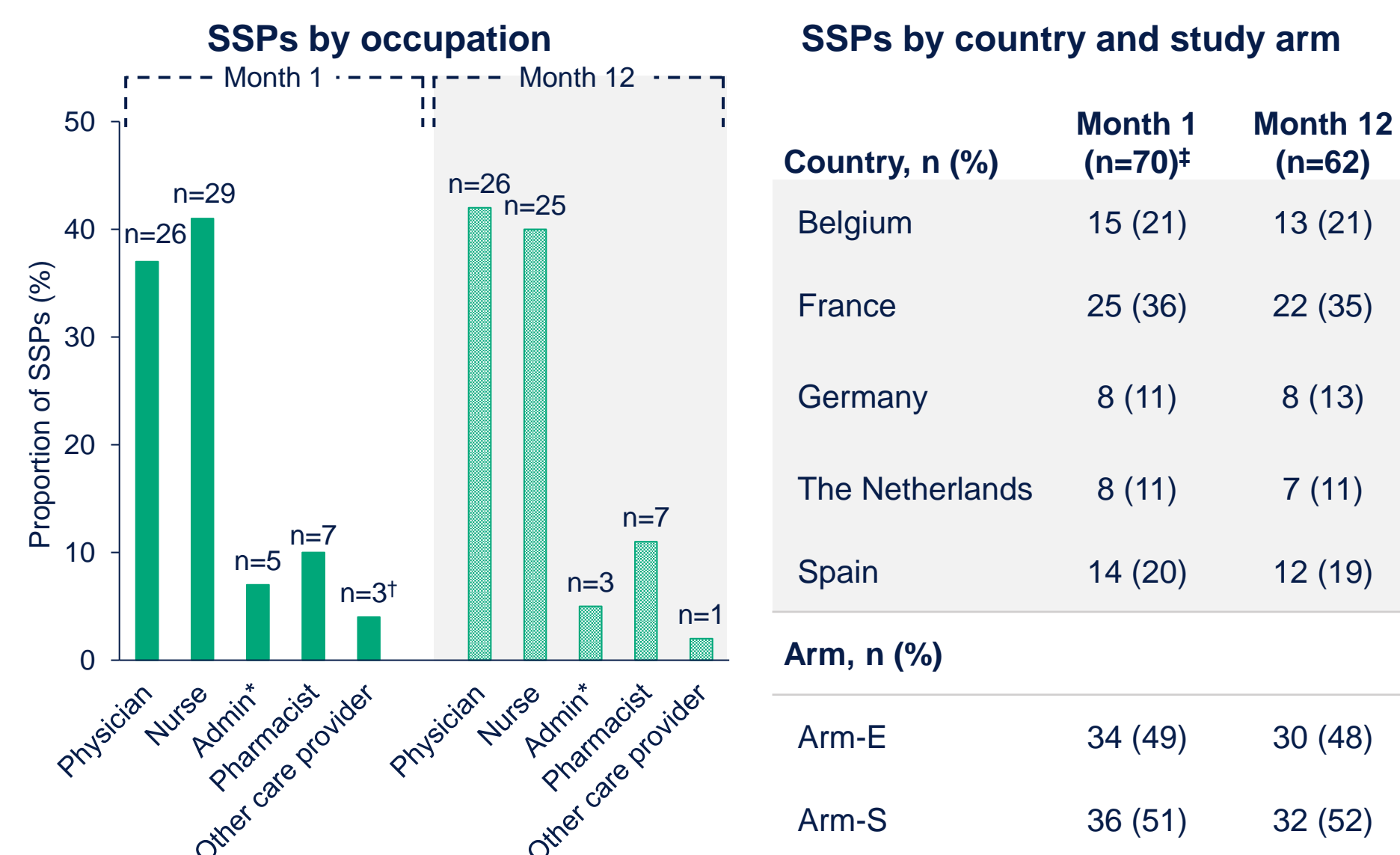


*437 PSPs enrolled, and 430 received CAB + RPV LA. †Dose 1 was received at Month 1, Dose 2 at Month 2, with the remaining doses Q2M thereafter. ‡To introduce CAB + RPV LA to clinic staff and discuss what might make implementation easier and/or what might make it difficult prior to first injection at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

Figure 2. Toolkit Materials

Results

Figure 3. SSP Baseline Characteristics



*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.

- Overall, 70 SSPs were enrolled in the study; most were physicians and nurses (Figure 3).
- Of the 70 SSPs who completed baseline surveys and interviews, 62 went on to complete them at Month 12.

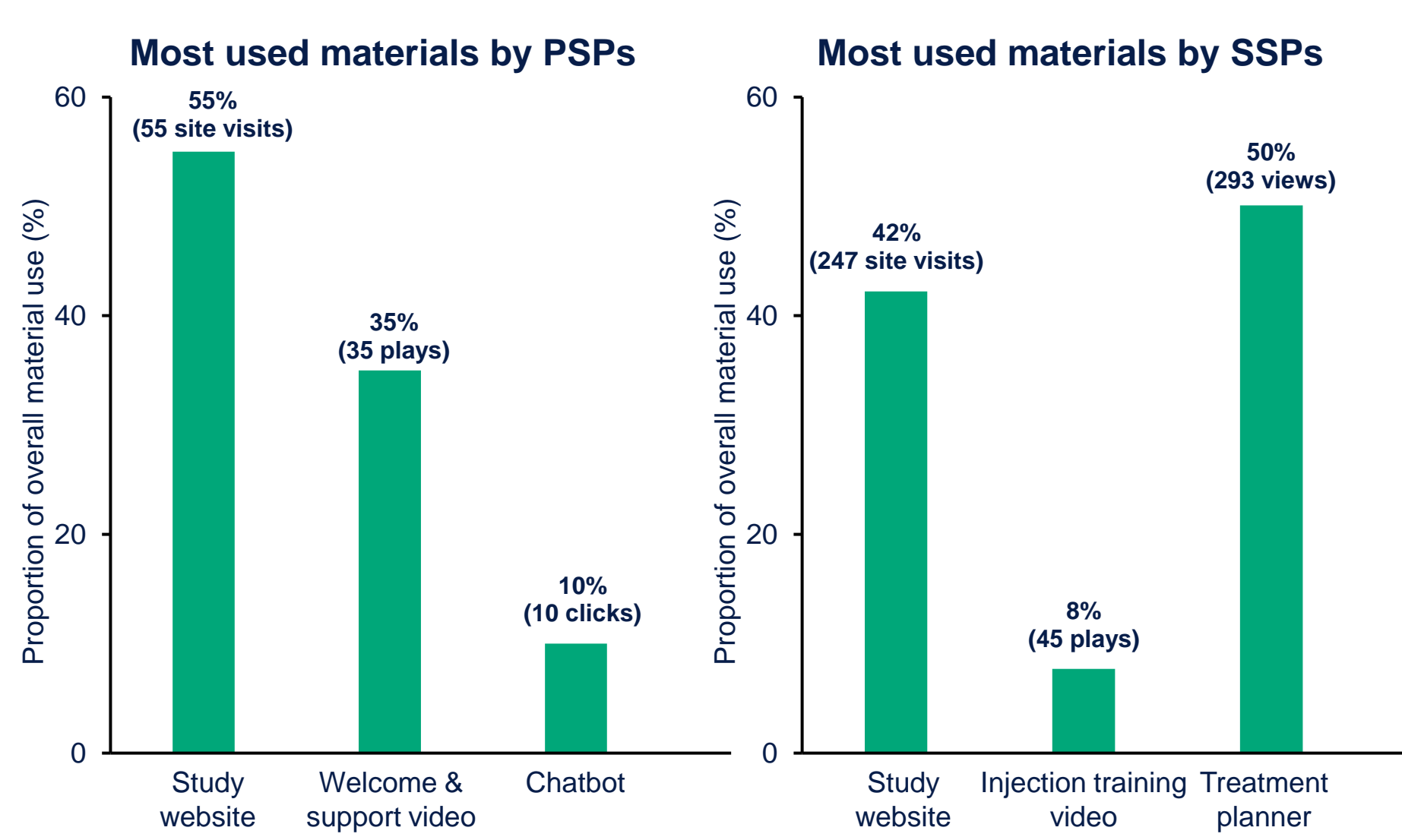
Table 1. PSP Baseline Characteristics

	Treated PSPs (n=430)
Age, years	
Mean (standard deviation)	44.2 (10.1)
Median (range)	44.0 (22-76)
≥50 years, n (%)	129 (30)
Sex at birth, n (%)	
Male	109 (25)
Female	321 (75)
Gender (self-reported), n (%)	
Male	315 (73)
Female	115 (27)
Race, n (%)	
White	336 (78)
Non-White	94 (22)
Ethnic, n (%)	
Hispanic or Latinx	32 (7)
Not Hispanic or Latinx	398 (93)
Country, n (%)	
Belgium	71 (17)
France	171 (40)
Germany	54 (13)
The Netherlands	38 (9)
Spain	96 (22)

- 430 PSPs received CAB + RPV LA (Table 1).

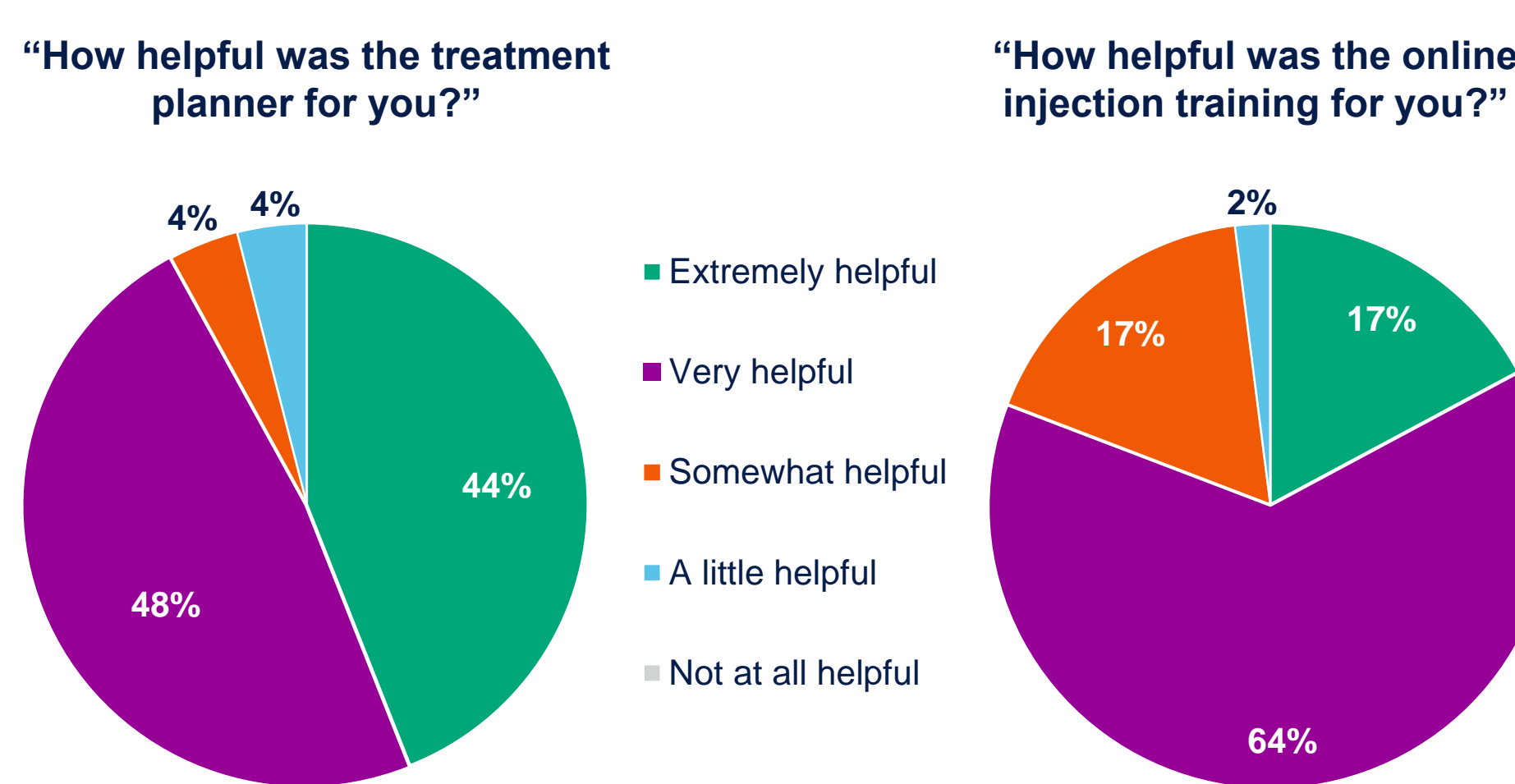
- A total of 379 PSPs from France (n=147), Spain (n=87), Belgium (n=68), Germany (n=43), and the Netherlands (n=34) completed the survey through Month 12.
- Overall, 110 PSPs from France (n=36), Belgium (n=27), Spain (n=23), Germany (n=12), and the Netherlands (n=12) participated in interviews.

Figure 4. Most Used Toolkit Materials by PSPs and SSPs



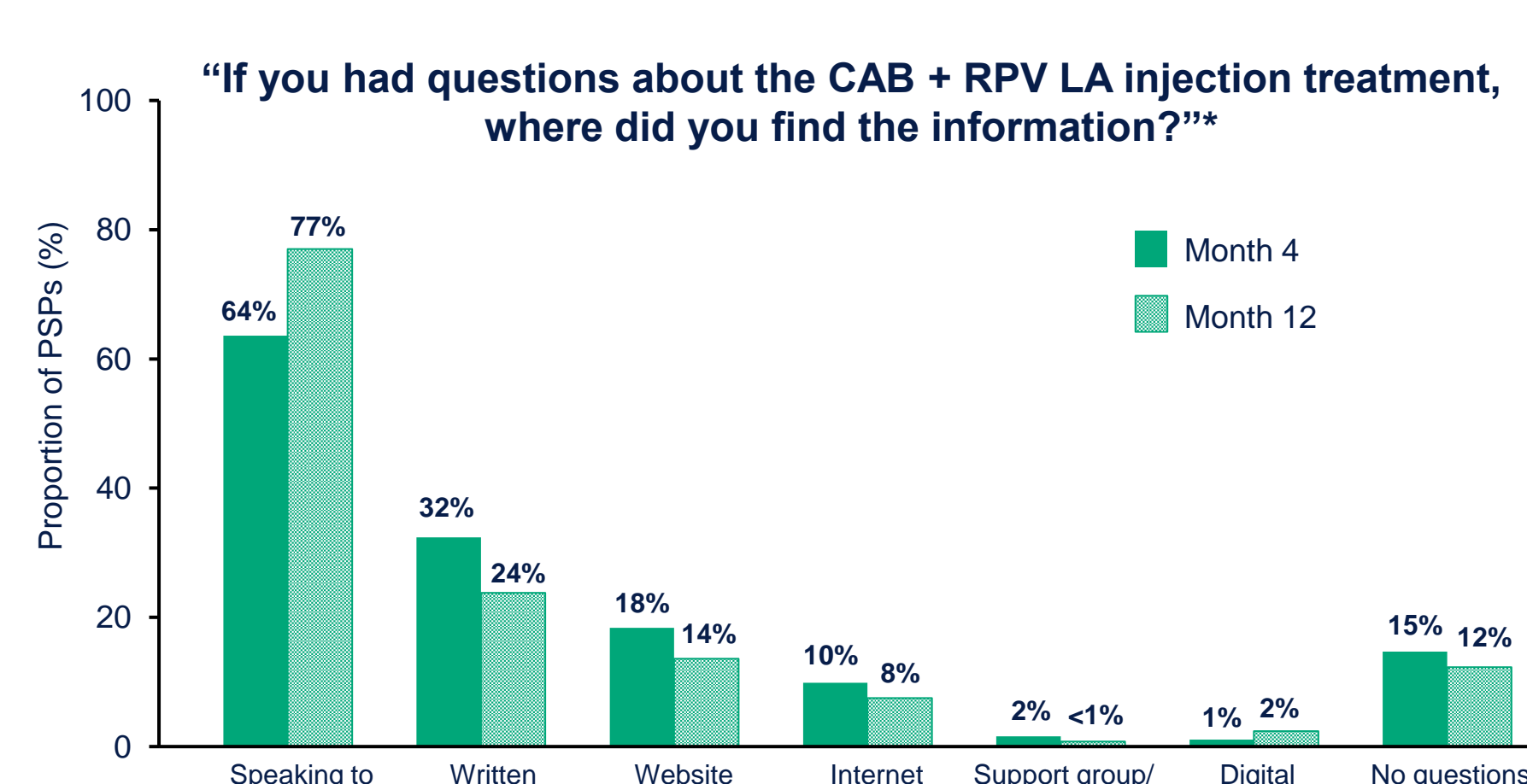
- The most used PSP material was the website that hosted educational materials (Figure 4).
- Analytics showed that the most used SSP material was the digital treatment planner, which was utilized to support the scheduling of injections within the ±7-day window.
- Among the 25 SSPs who reported using the treatment planner, analytics showed there were 293 views; 41 SSPs reported using the injection training video, with the analytics recording a total of 45 plays.

Figure 5. SSP Satisfaction With Toolkit Materials at Month 12



- At Month 12, of the 25 SSPs who used the treatment planner, 92% (n=23) found it very to extremely helpful (Figure 5).
- Of the 41 SSPs who used the online injection training, 80% (n=33) found it very to extremely helpful.

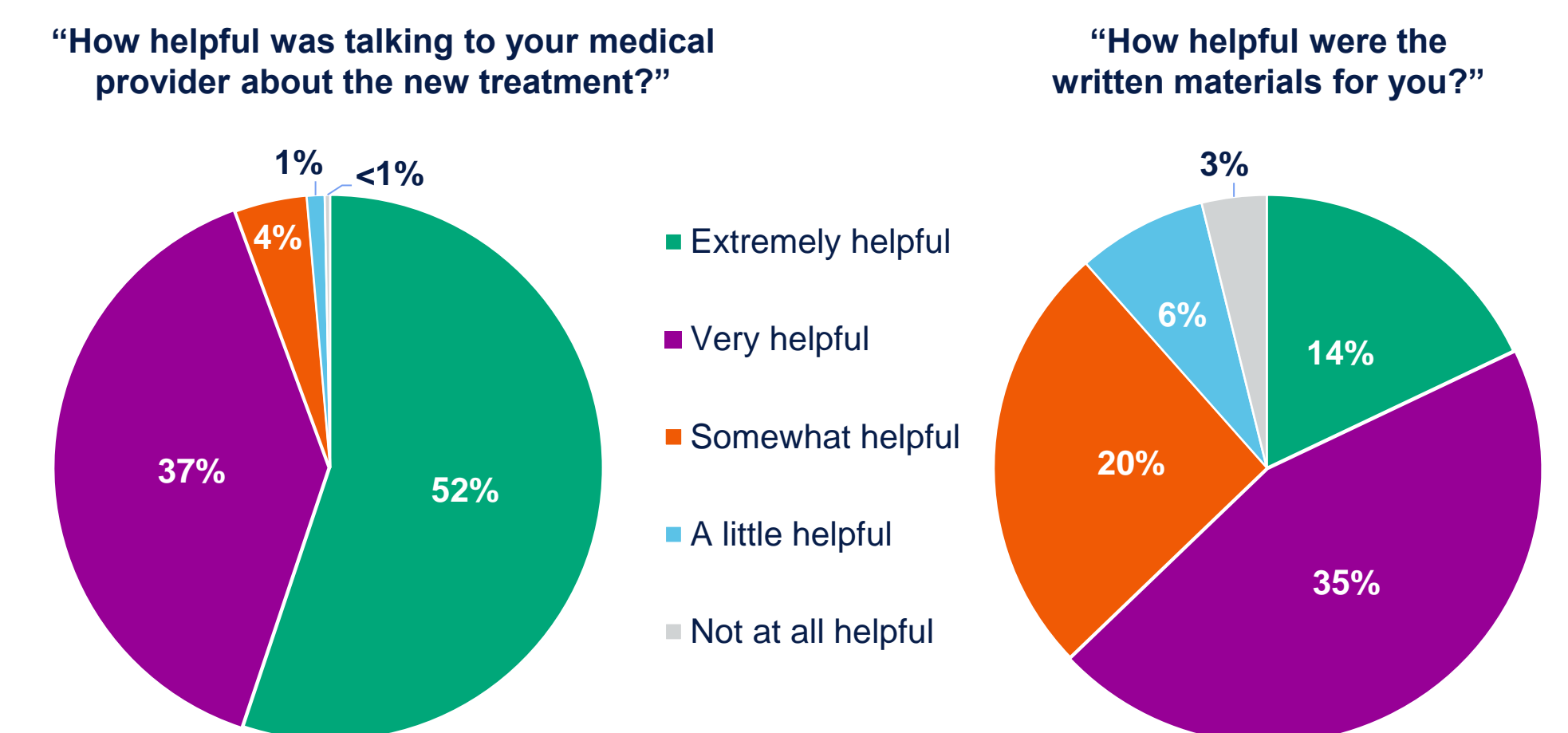
Figure 6. Information Sources Used by PSPs



*Responses are not mutually exclusive.

- Figure 6 shows PSPs most frequently got information from their healthcare provider (HCP) (Month 4, 64%; Month 12, 77%) or written materials (Month 4, 32%; Month 12, 24%).
- Toolkit materials were most utilized and helpful at implementation start (1-3 months), with usage decreasing over time.

Figure 7. PSP Satisfaction With Toolkit Materials at Month 12

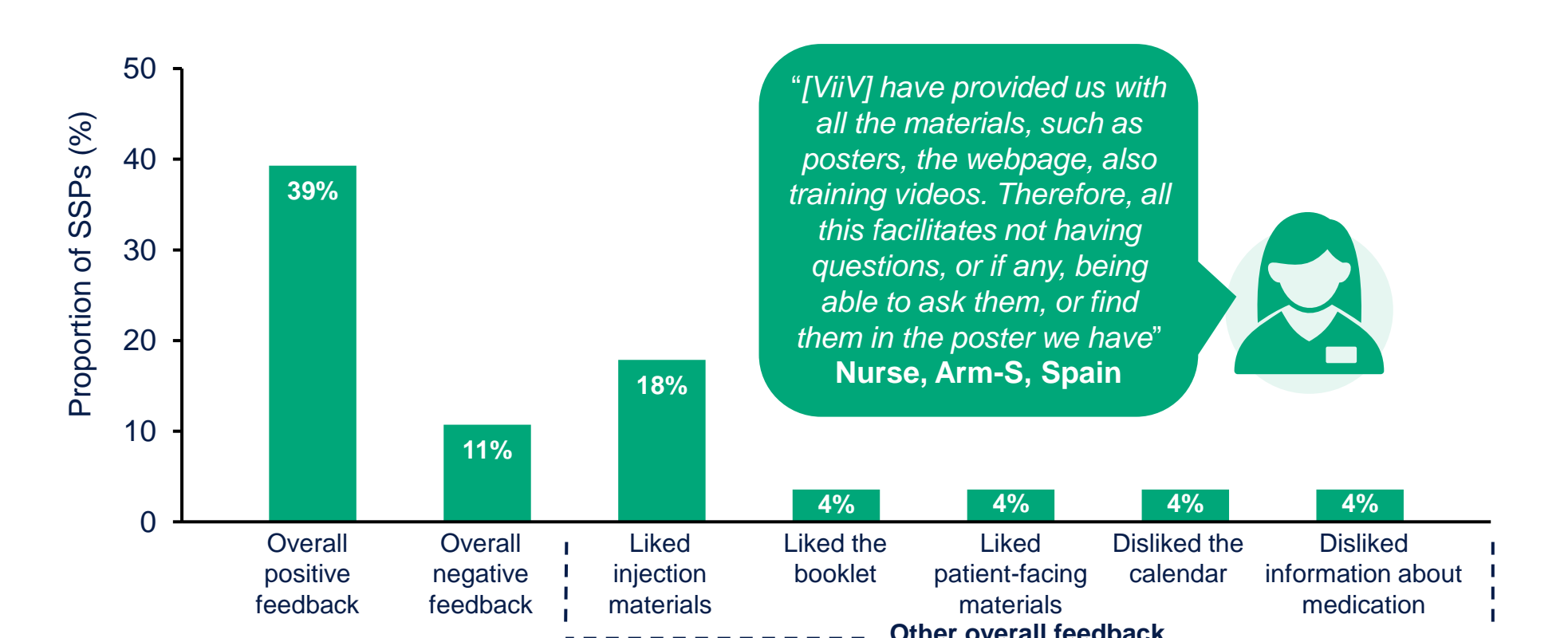


- Figure 7 shows that PSPs found the information from their HCP and written materials to be very to extremely helpful at Month 12 (89% [n=336/379] and 49% [n=184/379], respectively).

Figure 8. PSP Feedback on Materials

- Of the 110 PSPs that participated in the interviews, 82% (n=90) reported using the written materials, with 46% (n=51) noting that the written materials were helpful as they enabled them to gain a greater understanding of the treatment in their own time.
- Qualitative data, however, showed some PSPs preferred not to have written material, with some PSPs citing fear of disclosure as a contributing reason (Figure 8).
- In total, 28% (n=31/110) of PSPs reported using the study website; 8% (n=9/110) indicated that it was helpful, mentioning that the website was didactic and well explained, and provided useful information, such as other participants' experiences of the treatment.

Figure 9. SSP Satisfaction on Toolkit Materials



- At Month 12, 45% (n=28/62) of SSPs provided qualitative feedback on the toolkits; some specifically mentioned the training video, poster, website, and injection materials in their positive feedback.
- Feedback was generally positive, with only 11% (n=3/28) of SSPs providing overall negative feedback (Figure 9).
- Additionally, 7% (n=2/28) of SSPs reported that live injection demonstrations would improve the toolkit.

Conclusions

- CARISEL provided PSPs and SSPs with a range of tools over 12 months to support the implementation of CAB + RPV LA.
- All toolkits were used in both arms of the study.
- The most used toolkit materials were the digital treatment planner, the study website, and the injection training video.
- There was overall positive feedback about the toolkits, with SSPs mentioning the training video, poster, website, and injection materials in their feedback.
- Overall, although clinics had access to different training sessions at study start (Arm-S vs. Arm-E), all toolkit materials were well received and aided the implementation of CAB + RPV LA.