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-efficacy trial examining strategies to support the implementation of CAB + RPV LA 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).

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.
- CAB And RPV Implementation Study in European Locations (CARISEL; NCT03499551) is a Phase 3b, multicenter, open-label, hybrid type III implementation-efficacy trial examining strategies to support the implementation of CAB + RPV LA dosed Q2M across five European countries.
- The CARISEL study provided SSPs and PSPs 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 skill swap 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 assessment instruments 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 PSPs and SSPs.

Results

- 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.

- The most used toolkit material was the digital tools to aid scheduling and capacity planning, educational materials for patients and providers.

- Of the 110 PSPs that participated in the interviews, 82% (n=90) reported using the treatment planner.
- 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.

- 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, clinic staff 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.

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 tools to aid implementation, 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.

Figure 1. Study Design and Toolkit Outline

Figure 2. Toolkit Materials

Figure 3. SSP Baseline Characteristics

Figure 4. Most Used Toolkit Materials by PSPs and SSPs

Figure 5. SSP Satisfaction With Toolkit Materials at Month 12

Figure 6. Information Sources Used by PSPs

Figure 7. PSP Satisfaction With Toolkit Materials at Month 12

Figure 8. PSP Feedback on Materials

Figure 9. SSP Feedback on Toolkit Materials

Table 1. PSP Baseline Characteristics

References:


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