We present the results on the acceptability, appropriateness, and feasibility of cabotegravir + rilpivirine long-acting (CAB + RPV LA) dosed every 2 months (Q2M) from the perspective of staff participants through Month 12 of a Phase 3b hybrid type III implementation-effectiveness trial.

Despite most participating European study sites having no prior CAB + RPV LA experience, high implementation acceptability, appropriateness, and feasibility levels were seen regardless of implementation arm.

Some context-specific factors, such as time to reach optimal implementation, may benefit from different levels of implementation support.

Key Takeaways

**Introduction**

- CAB + RPV LA dosed Q2M is a recommended regimen in Europe and US treatment guidelines for virologically suppressed people living with HIV-1 (PLWH).1
- CAB + RPV LA reduces dosing frequency compared to daily antiretroviral therapy, and may help address concerns including fear of disclosure, anxiety around medication adherence, and daily reminder of HIV status.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.
- CARISEL is the first study in which all participants switched from daily antiretroviral therapy, and may help address concerns including fear of disclosure, anxiety around medication adherence, and daily reminder of HIV status.2
- Continuous quality improvement (CQI) is a process to support improving care by identifying problems, planning a solution, studying the results, and acting accordingly.3 The CQI process is documented through Plan, Do, Study, and Act cycles.

**Methods**

- CARISEL is an open-label, single-arm study that enrolled virologically suppressed PLWH to receive CAB + RPV LA dosed Q2M.4
- Staff participants at 18 clinics across Belgium (n=4), France (n=6), Germany (n=2), the Netherlands (n=3), and Spain (n=4) were randomized to 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).
- Staff participants completed 4-item measures rated on a 1–5 Likert scale: 1 “completely disagree”; 2 “disagree”; 3 “neither agree nor disagree”; 4 “agree”; 5 “completely agree” on acceptability (IAM), appropriateness (IAM), and feasibility (FIM) of implementation and intervention.
- An analysis of covariance (ANCOVA) was performed for the statistical analysis of change in IAM, IAM, and FIM of CAB + RPV LA.
- Qualitative data was obtained from semi-structured qualitative interviews on CAB + RPV LA, interview guide topics were informed by the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework4 and Proctor outcomes. The EPIS framework highlights key phrases that guide and describe the implementation process and identify common and unique factors within, across, and settings. The Proctor outcomes framework identifies key implementation outcomes that should be considered and evaluated during a study.

**Results**

- Mean IAM/IAM/FIM-Imp-Imp scores remained high (4.3) and stable for levels of acceptability, appropriateness, and feasibility of implementation support through Month 12 (Figure 3).
- Implementation measure scores were similar over time, regardless of the level of support by implementation arm.
- An ANCOVA (primary analysis, n=60) controlling for provider type showed no significant difference between arms.

**Conclusions**

- In CARISEL, despite most participating European study sites having no prior CAB + RPV LA experience, high implementation acceptability, appropriateness, and feasibility levels were seen regardless of implementation arm.
- Time spent in the clinic was similar between Arm-E and Arm-S, with roughly two-thirds of participants in both arms finding the time spent in clinic either “very” or “extremely acceptable.”
- Most staff participants reported optimal implementation within 3–6 months across both arms, with more sites in Arm-S reporting they were still working towards optimal implementation at Month 12 compared to Arm-E.
- CARISEL data show that while acceptability, appropriateness, and feasibility were comparable across arms, there may be some context-specific factors, such as time to reach different levels of implementation support.

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**References**