Implementation of Cabotegravir and Rilpivirine Long-Acting (CAB + RPV LA): Primary Results From the CAB + RPV Implementation Study in European Locations (CARISEL)\(^1\)

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Key Takeaways

- 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.

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 with daily oral antiretroviral therapy, and may help address concerns including fear of discositis, anxiety around medication adherence, and daily reminder of HIV status\(^2\).
- CAB and RPV LA Implementation Study in European Locations (CARISEL, NCT014939551) 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 oral therapy to CAB + RPV LA dosed Q2M.
- CAB + RPV LA dosed Q2M was efficacious, with 87% of participants in CARISEL maintaining HIV-1 virologic suppression and 0.7% of participants having HIV-1 RNA ≥50 copies/mL at Month 12 (intention-to-treat exposure, Snapshot analysis)\(^3\).
- Here, we present the results on the acceptability, appropriateness, and feasibility of CAB + RPV LA implementation support from the perspective of staff participants.

Methods

- CAB + RPV LA is an open-label, single-arm switch study that enrolled virologically suppressed PLWH to receive CAB + RPV LA dosed Q2M.
- Staff participants at 18 clinics across Belgium (n=4), France (n=6), Germany (n=2), the Netherlands (n=2), and Spain (n=4) were randomized to one of two implementation arms: (Arm E) Standard arm [Arm-S] to better understand the level of support needed for successful implementation (Figure 1); and (Arm C) CARISEL, an intervention arm designed to test if the different implementation strategies would affect acceptance, appropriateness, and feasibility of CAB + RPV LA, regardless of implementation arm.
- An analysis of covariance (ANCOVA) was performed for the statistical analysis of change in AIM, IAM, and FIM of CAB + RPV LA.
- Qualitative data were obtained from semi-structured qualitative interviews on CAB + RPV LA implementation support from a subset of study sites. The Proctor outcomes framework identifies key implementation outcomes that should be considered and evaluated during a study. The Proctor outcomes framework highlights key phrases that guide and describe the implementation process and identify common and unique factors within, and across, settings. The Proctor outcomes framework outlines key implementation outcomes that should be considered and evaluated during a study.

Results

- Mean AIM-imp, IAM-imp, FIM-imp, and IM-imp scale scores remained high (3.8) and stable for all levels of acceptability, appropriateness, and feasibility of implementation support through Month 12 (Table 3).
- Implementation measures 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.
- Mean AIM-imp, IAM-imp, FIM-imp, and IM-imp scores remained high (4.3) and stable for levels of acceptability, appropriateness, and feasibility of implementation support through Month 12 (Figure 3).
- All intervention measures were similar, regardless of implementation arm.

Figure 1. Study Design

![Study Design](https://via.placeholder.com/150)

Table 1. Implementation Support

<table>
<thead>
<tr>
<th>Task</th>
<th>Staff satisfaction</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time spent in the clinic during study visits</td>
<td>67 minutes</td>
<td>High</td>
</tr>
<tr>
<td>EDs</td>
<td>1</td>
<td>High</td>
</tr>
<tr>
<td>HIV-1 RNA</td>
<td>0.7%</td>
<td>High</td>
</tr>
<tr>
<td>HIV-1 RNA</td>
<td>5%</td>
<td>High</td>
</tr>
</tbody>
</table>

Figure 2. Baseline Characteristics

![Baseline Characteristics](https://via.placeholder.com/150)

Figure 3. Staff Participant Acceptance at Month 12

![Staff Participant Acceptance](https://via.placeholder.com/150)

Figure 4. Staff Participant Perception of Acceptability, Appropriateness, and Feasibility of CAB + RPV LA

![Staff Participant Perception](https://via.placeholder.com/150)

Figure 5. Staff Participant Acceptability at Month 12

![Staff Participant Acceptability](https://via.placeholder.com/150)

Figure 6. Implementation at Month 12

![Implementation at Month 12](https://via.placeholder.com/150)

Figure 7. Time Spent in the Clinic at Month 12

![Time Spent in the Clinic](https://via.placeholder.com/150)

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 “very” or “extremely acceptable” across thirds of participants in both arms finding the time spent in clinic was “very” or “extremely acceptable” across thirds of participants in both arms.

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