Perceptions of Cabotegravir + Rilpivirine Long-Acting (CAB + RPV LA) From People Living With HIV (PLHIV) in the CARLOS Study

EPE0863

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Key Takeaways

- **Almost half of the participants experienced challenges related to their prior daily oral therapy before switching to cabotegravir + rilpivirine long-acting (CAB + RPV LA), including fear of their HIV status being disclosed, anxiety relating to adherence requirements, and a daily reminder of their HIV status.**
- **HIV treatment satisfaction improved after 6 months of CAB + RPV LA, driven mainly by a wish to continue treatment, convenience, and fit with lifestyle.**
- **Most participants preferred CAB + RPV LA over daily oral therapy at Month 6, primarily due to convenience, adherence concerns, and pill fatigue.**

Introduction

- CAB + RPV LA administered monthly or every 2 months (Q2M) is the first complete LA regimen recommended by treatment guidelines for the maintenance of HIV-1 virologic suppression.[1–3]
- The less frequent dosing offered by CAB + RPV LA may help address some concerns associated with daily oral therapy, including fear of disclosure, stigma, anxiety around medication adherence, and the daily reminder of HIV status.[4]
- CARLOS is a non-interventional, multicenter, prospective study in people living with HIV (PLHIV) receiving CAB + RPV LA dosed Q2M in routine care in Germany.
- Here, we present Month 6 patient-reported outcome data and data on implementation from the perspective of PLHIV receiving CAB + RPV LA in the CARLOS study.

Methods

- Participant demographic data were collected from medical records.
- Patient-reported outcomes were collected via:
  - Standardized instruments:
    - Treatment satisfaction (HIV Treatment Satisfaction Questionnaire status version [HIVTSQs])
    - Acceptability of injections (“Acceptance of injection site reactions [ISRs]” domain of the Perception of Injection [PIN] questionnaire).
  - Exploratory questions relating to:
    - Psychosocial challenges related to HIV
    - Preferences, acceptability, and difficulties relating to LA treatment and the logistics of administration
    - Treatment preference.
- For outcomes assessed at baseline, Month 2, and Month 6, only participants that completed surveys at both time points were included; participants with missing data were excluded.

Results

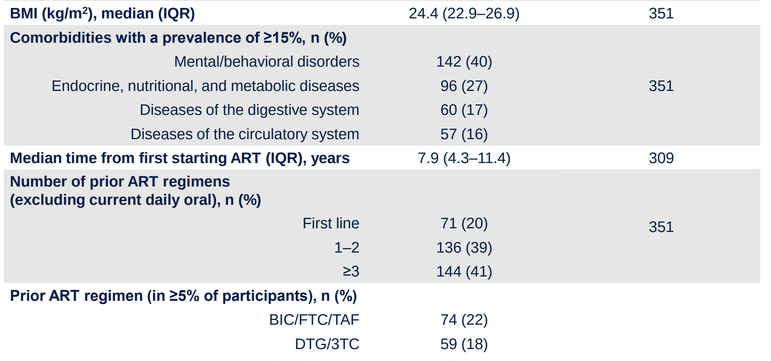
Table 1. Baseline Characteristics

Variable	CAB + RPV LA Q2M	n
Median age (IQR), years	42.7 (35.0–51.0)	351
≥50 years, n (%)	92 (26)	
Male (sex at birth), n (%)	333 (95)	351
BMI (kg/m²), median (IQR)	24.4 (22.9–26.9)	351
Comorbidities with a prevalence of ≥15%, n (%)		
Mental/behavioral disorders	142 (40)	351
Endocrine, nutritional, and metabolic diseases	96 (27)	
Diseases of the digestive system	60 (17)	
Diseases of the circulatory system	57 (16)	
Median time from first starting ART (IQR), years	7.9 (4.3–11.4)	309
Number of prior ART regimens (excluding current daily oral), n (%)		
First line	71 (20)	351
1–2	136 (39)	
≥3	144 (41)	
Prior ART regimen (in ≥5% of participants), n (%)		
BIC/FTC/TAF	74 (22)	337
DTG/3TC	59 (18)	
DTG/3TC/ABC	37 (11)	
RPV/FTC/TAF	31 (9)	
EVG/COBI/FTC/TAF	31 (9)	
DTG/RPV	24 (7)	
DRV/COBI/FTC/TAF	18 (5)	

3TC, lamivudine; ABC, abacavir; ART, antiretroviral therapy; BIC, bictegravir; BMI, body mass index; CAB, cabotegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EVG, elvitegravir; FTC, emtricitabine; IQR, interquartile range; LA, long-acting; Q2M, every 2 months; RPV, rilpivirine; TAF, tenofovir alafenamide.

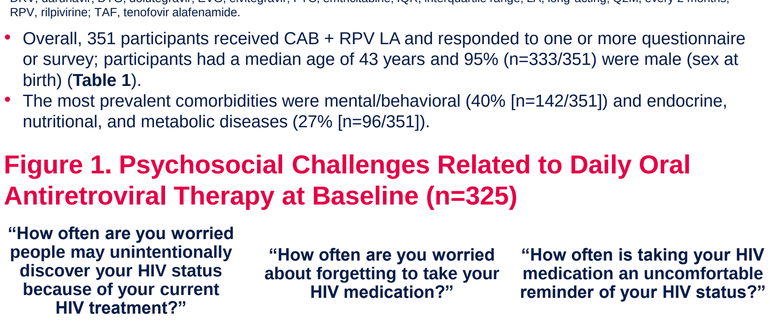
- Overall, 351 participants received CAB + RPV LA and responded to one or more questionnaire or survey; participants had a median age of 43 years and 95% (n=333/351) were male (sex at birth) (**Table 1**).
- The most prevalent comorbidities were mental/behavioral (40% [n=142/351]) and endocrine, nutritional, and metabolic diseases (27% [n=96/351]).

Figure 1. Psychosocial Challenges Related to Daily Oral Antiretroviral Therapy at Baseline (n=325)



- Before LA treatment, participants reported (“always”/“often”) experiencing fear of disclosure of HIV status (21% [n=67/325]), anxiety relating to adherence requirements (30% [n=96/325]), and a daily reminder of HIV status (28% [n=92/325]) (**Figure 1**).
- Overall, 49% (n=158/325) of participants reported “always”/“often” to at least one question on the psychosocial challenges of HIV.

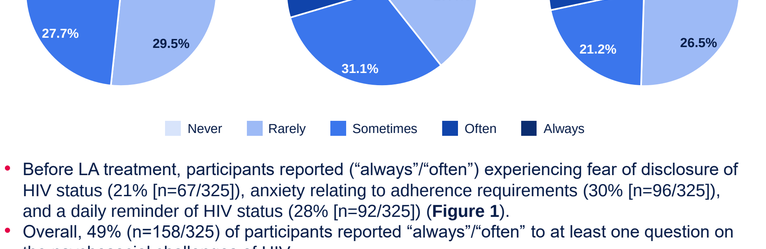
Figure 2. Change in Acceptability of ISRs From Baseline to Month 6 (n=249)



*PIN score (“Acceptance of ISRs” domain of the PIN questionnaire) range: 1 = “totally acceptable” to 5 = “not at all acceptable.”
†PIN questionnaire completed before injections 2 and 4, and relates to ISRs after injections 1 and 3, respectively.
ISR, injection site reaction; PIN, Perception of Injection; SD, standard deviation.

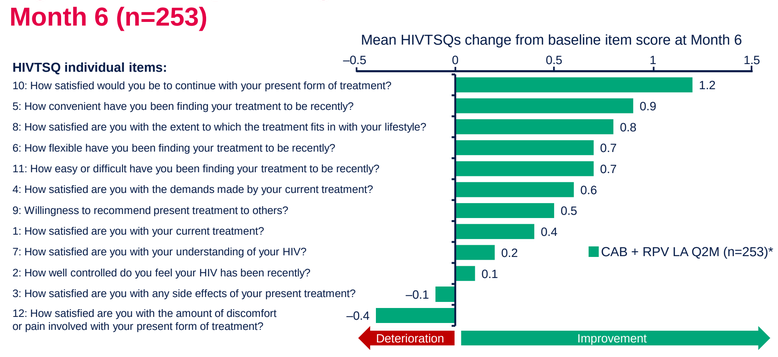
- Participants reported that ISRs experienced after their first injection were “very acceptable” (mean [SD], 2.15 [0.91]), which was maintained at Month 6 (2.09 [0.85]) (**Figure 2**).
  - Of the participants who discontinued due to ISRs, two completed the PIN questionnaire at discontinuation, reporting a moderate acceptability of ISRs (mean [SD], 3.00 [1.41]) after injection 1, which worsened at discontinuation (4.25 [0.35]).

Figure 3. Change in Total Treatment Satisfaction (HIVTSQs) at Month 6 (n=250)



*HIVTSQs: 12-item version. Range per item is 0–6: 0 = “very dissatisfied” and 6 = “very satisfied.” Total score = sum of items 1–11; item 12 presented separately. Range for total score is 0–66; positive changes indicate improvement.
CAB, cabotegravir; HIVTSQs, HIV Treatment Satisfaction Questionnaire status version; LA, long-acting; Q2M, every 2 months; RPV, rilpivirine.

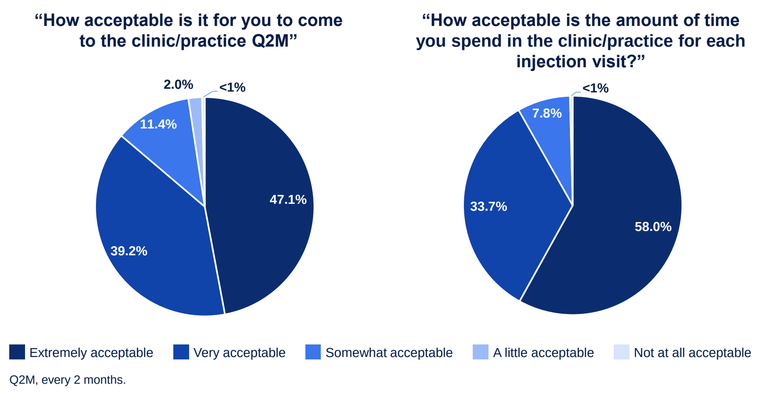
Figure 4. HIVTSQs: Changes in Individual Item Scores at Month 6 (n=253)



*Items 6 and 9, n=251; items 7, 8, 10, 11, and 12, n=252.
CAB, cabotegravir; HIVTSQs, HIV Treatment Satisfaction Questionnaire status version; LA, long-acting; Q2M, every 2 months; RPV, rilpivirine.

- In participants completing the HIVTSQs at baseline and Month 6, mean (SD) HIVTSQs score improved by +6.0 (10.8 [p<0.001]) from 54.9 (10.2) to 60.9 (6.5), driven mainly by a “wish to continue” current treatment, “convenience,” and “lifestyle fit” (**Figure 3** and **4**).

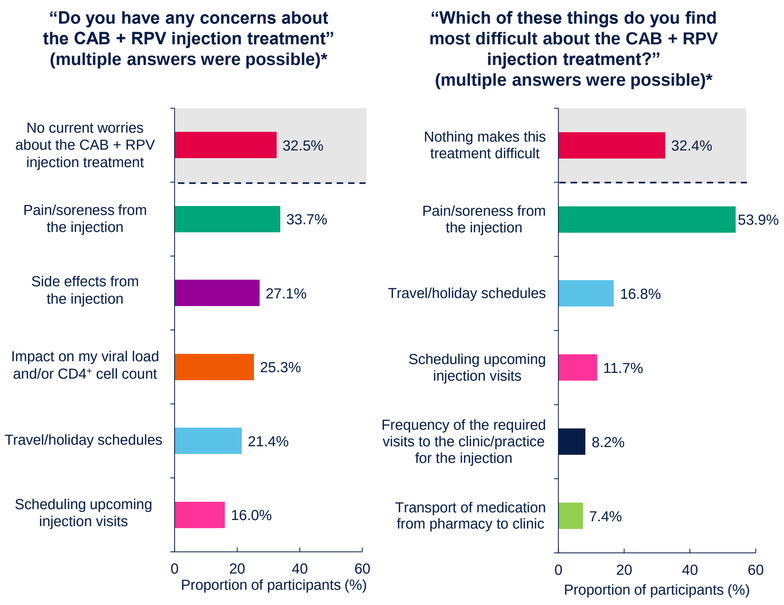
Figure 5. Acceptability of Clinic Visits (n=255)



Q2M, every 2 months.

- At Month 6, most participants reported that coming into the clinic Q2M (86% [n=220/255]) and the time spent in clinic per injection visit (92% [n=234/255]) was “very”/“extremely” acceptable (**Figure 5**).

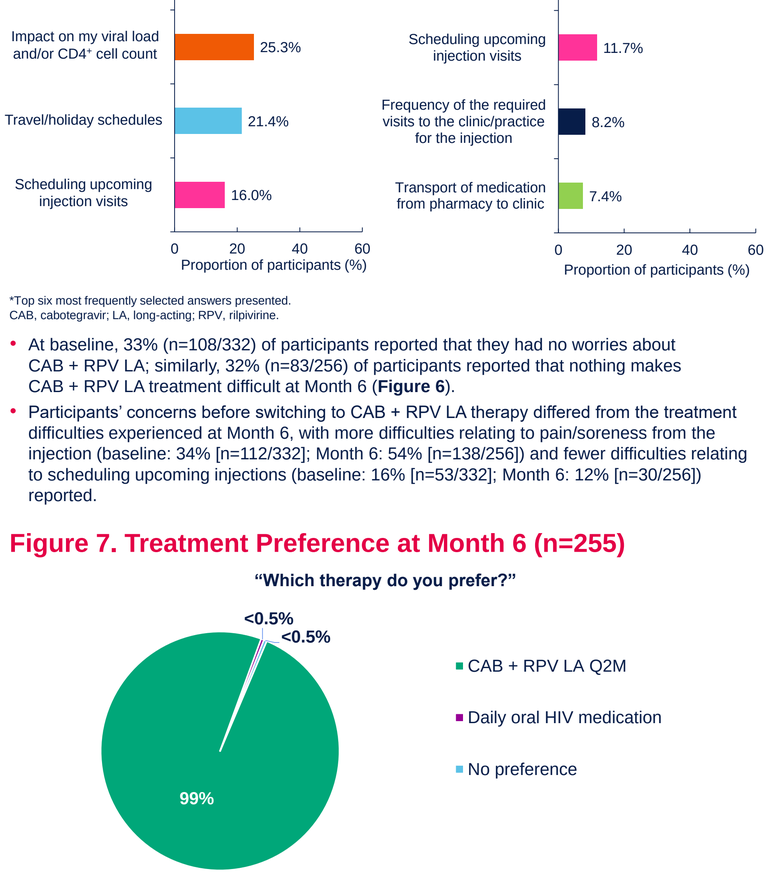
Figure 6. Most Common Concerns About CAB + RPV LA Therapy at Baseline (n=332) vs. Treatment Difficulties at Month 6 (n=256)



*Top six most frequently selected answers presented.
CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

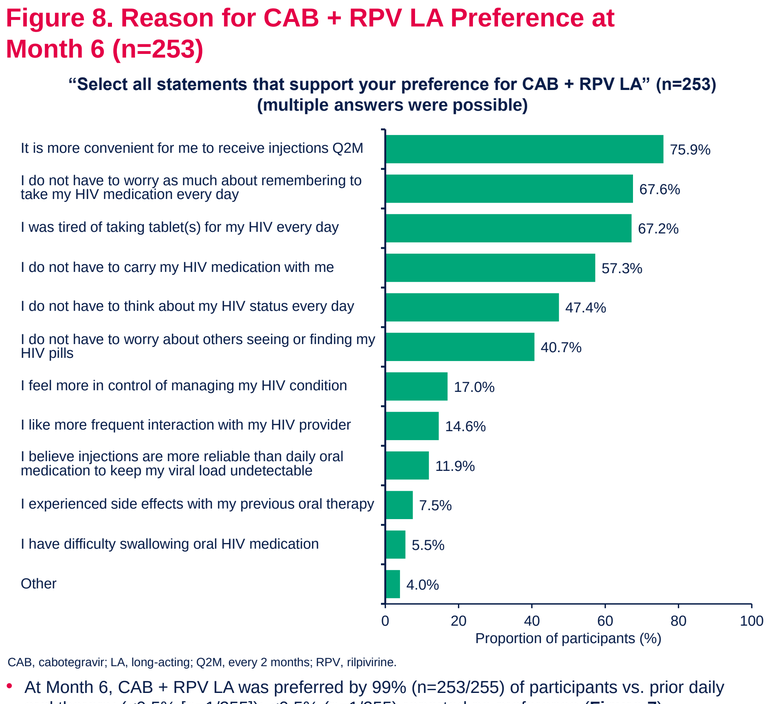
- At baseline, 33% (n=108/332) of participants reported that they had no worries about CAB + RPV LA; similarly, 32% (n=83/256) of participants reported that nothing makes CAB + RPV LA treatment difficult at Month 6 (**Figure 6**).
- Participants’ concerns before switching to CAB + RPV LA therapy differed from the treatment difficulties experienced at Month 6, with more difficulties relating to pain/soreness from the injection (baseline: 34% [n=112/332]; Month 6: 54% [n=138/256]) and fewer difficulties relating to scheduling upcoming injections (baseline: 16% [n=53/332]; Month 6: 12% [n=30/256]) reported.

Figure 7. Treatment Preference at Month 6 (n=255)



CAB, cabotegravir; LA, long-acting; Q2M, every 2 months; RPV, rilpivirine.

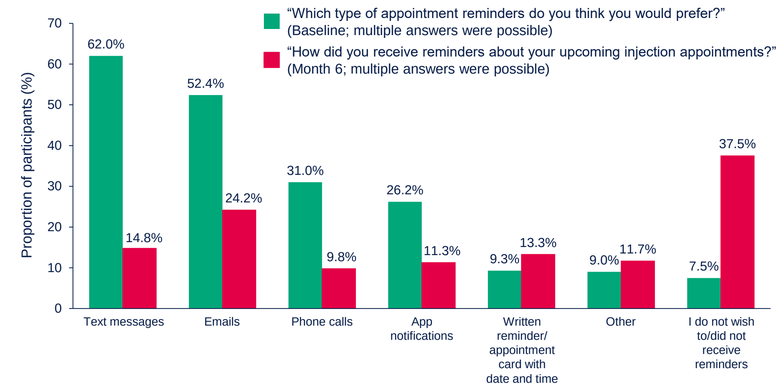
Figure 8. Reason for CAB + RPV LA Preference at Month 6 (n=253)



CAB, cabotegravir; LA, long-acting; Q2M, every 2 months; RPV, rilpivirine.

- At Month 6, CAB + RPV LA was preferred by 99% (n=253/255) of participants vs. prior daily oral therapy (<0.5% [n=1/255]); <0.5% (n=1/255) reported no preference (**Figure 7**).
- Supporting reasons for LA treatment preference included convenience, not having to worry about remembering to take HIV medicine, and being tired of taking tablet(s) everyday (**Figure 8**).
- For the participant who preferred daily oral therapy (<0.5% [n=1/255]), supporting reasons included “I believe daily oral medication is more reliable than injections to keep my viral load undetectable” and “I feel more in control of managing my HIV.”

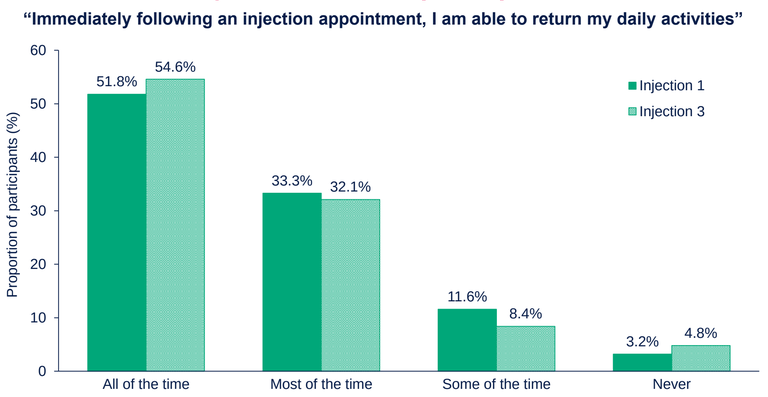
Figure 9. Preference for Reminder Type at Baseline (n=332) and Reminder Types Received at Month 6 (n=256)*



*Other reminders preferred at baseline: face-to-face reminder from an HCP (3.9%), by post (3.0%), and other (2.1%); other reminders received at Month 6: face-to-face reminder from an HCP (4.7%) and other (7.0%).
HCP, healthcare provider.

- Over a third of participants (38% [n=96/256]) did not receive appointment reminders at Month 6, despite most participants (62% [n=206/332]) reporting a preference for appointment reminders via text message at baseline (**Figure 9**).

Figure 10. Ability to Return to Daily Activities Following CAB + RPV LA Injections 1 and 3 (n=249)



- Most participants were able to return to daily activities “all of the time”/“most of the time” after injection 1 (85% [n=212/249]) and injection 3 (87% [n=216/249]) (**Figure 10**).
- Most participants did not need to take time off work following CAB + RPV LA injection 1 (83% [n=206/249]) and injection 3 (83% [n=207/249]).

Conclusions

- Before switching to CAB + RPV LA therapy, a large proportion (49%) of participants in this real-world setting “always” or “often” experienced psychosocial challenges related to daily oral therapy, including either a fear of their HIV status being disclosed, anxiety relating to adherence requirements, or a daily reminder of HIV status.
- After receiving their first injection, participants reported high acceptability of ISRs, which was maintained over 6 months of CAB + RPV LA therapy.
- A statistically significant improvement in treatment satisfaction was observed after switching from daily oral therapy to CAB + RPV LA; this was driven mainly by a wish to continue treatment, convenience, and fit with lifestyle.
- The majority of participants felt that coming into the clinic Q2M and the time spent in clinic per injection was “very”/“extremely” acceptable.
- Most participants preferred LA therapy over daily oral therapy at Month 6, primarily due to the convenience of Q2M injections and having fewer concerns about adherence.

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References: **1.** U.S. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. 2022. Available from: https://clinicalinfo.hiv.gov/en/guidelines. Accessed May 2023. **2.** Gandhi RT, et al. *JAMA*. 2023;329(1):63–84. **3.** European AIDS Clinical Society. Guidelines Version 11.1. 2022. Available from: https://www.eacsociety.org/media/guidelines-11.1_final_09-10.pdf. Accessed May 2023. **4.** De Los Rios P, et al. *AIDS Behav*. 2021;25(3):961–972.

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