P-545

Feasibility, Fidelity, and Effectiveness of Administering Cabotegravir + Rilpivirine Long-Acting (CAB + RPV LA) in Infusion Centers

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Key Takeaways

- **Quantitative and qualitative data demonstrated that patient study participants (PSPs) found administration of cabotegravir + rilpivirine long-acting (CAB + RPV LA) at infusion centers (ICs) feasible and acceptable, with 95% of participants very or extremely satisfied with the ICs' care.**
- **Adherence was high, with 98% of injections administered within the dosing window or earlier; no instances of virologic failure were recorded and injection site reactions (ISRs) were mostly mild to moderate in severity, consistent with data from the Phase 3/3b CAB + RPV LA program.**
- **The data from the GLACIER study suggest that using alternative sites of care such as ICs may improve treatment convenience with CAB + RPV LA and enable broader access for people living with HIV (PWH).**

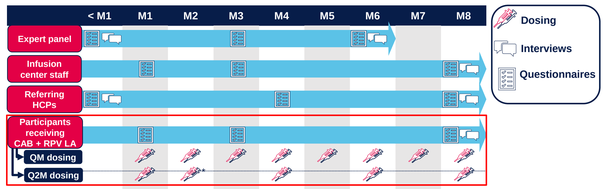
Introduction

- CAB + RPV LA is the first and only complete LA injectable regimen, administered monthly (QM) or every 2 months (Q2M) via gluteal intramuscular injections, recommended by treatment guidelines for the maintenance of HIV-1 virologic suppression.[1–3]
- ICs may be an appealing option for both PWH and healthcare providers (HCPs) as they have the potential to ease the burden of additional appointments, administrative work including benefits verification and prior authorizations, and drug ordering in HIV specialty clinics, as well as providing PWH greater flexibility in where they choose to receive treatment.
- GLACIER (NCT04982445) was a Phase 4 implementation study examining the feasibility of delivering CAB + RPV LA at ICs from the perspective of PSPs, HCPs, and IC staff.
- Here, we present PSP perspectives on, and clinical outcomes with, CAB + RPV LA administration at ICs over 8 months in the GLACIER study.

Methods

- GLACIER comprised two phases:
  - Generation and refinement of the blueprint; an expert panel of HCPs and IC stakeholders collaborated and designed an implementation blueprint for CAB + RPV LA administration at ICs.[4]
  - Implementation of CAB + RPV LA in routine clinical care using the blueprint.
- Thirty-four ICs located in the United States (US) participated in the study.
- PSPs who were receiving or interested in receiving CAB + RPV LA were referred by their HCP to receive CAB + RPV LA via routine care at ICs across the US; 44 PSPs were enrolled from November 18, 2021 to June 30, 2023.
- Data on PSPs' experiences with CAB + RPV LA were collected throughout the implementation phase at baseline, Month (M) 3, and M8 (**Figure 1**).
  - Quantitative data were obtained via surveys, including the Feasibility of Intervention Measure (FIM), the Acceptability of Intervention Measure (AIM), and implementation questionnaires.
    - FIM and AIM were rated on a 1–5 Likert scale: 1 "completely disagree"; 2 "disagree"; 3 "neither agree nor disagree"; 4 "agree"; 5 "completely agree."
    - The primary endpoint was the proportion of PSPs who agree or completely agree (a score of 4 or higher) across all items on the FIM at M8.
- Clinical outcomes included fidelity (adherence) to the dosing window, effectiveness, and safety and tolerability.
- Semi-structured qualitative interviews were completed with a subset of participants.

Figure 1. Study Design



*A second loading dose at M2 was only administered to participants who had no prior CAB + RPV LA experience.
CAB, cabotegravir; HCP, healthcare provider; IC, infusion center; LA, long-acting; M, month; QM, monthly; Q2M, every 2 months; RPV, rilpivirine.

Results

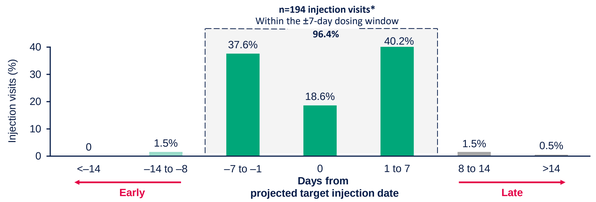
Table 1. Baseline Characteristics

Characteristic, n (%)*	PSPs (n=44)
Age, median, years (range)	46 (24–72)
Female sex at birth	9 (20)
Race	
Black or African American	23 (52)
White	19 (43)
Other races†	2 (5)
Highest level of education	
High school or equivalent	12 (28)
Some college‡	5 (12)
Bachelor's degree	14 (33)
Graduate degree§	9 (21)
Prefer not to answer	3 (7)
Employment‖¶	
Employed full-time	30 (70)
Retired	4 (9)
Other**	9 (21)
Previously received CAB + RPV LA‖	
No	22 (51)
Yes, 1 injection	5 (12)
Yes, 2 injections	5 (12)
Yes, ≥3 injections	11 (26)
Dosing schedule	
QM	24 (55)
Q2M	20 (45)

*Unless otherwise specified. †American Indian or Alaska Native (n=1) and multiple races (n=1). ‡Associate's degree in business, some college, associate's degree, 2 years of college, and associate's degree of applied science in culinary arts (n=1 each). §Master's degree (n=7) or doctoral degree (n=2). ‖One response was missing; percentages were calculated using n=43. ¶Not mutually exclusive; participants were instructed to select all that applied. **Self-employed, employed part-time, unemployed, and not working due to health (n=2 each), disabled (n=1).
CAB, cabotegravir; LA, long-acting; PSP, patient study participant; QM, monthly; Q2M, every 2 months; RPV, rilpivirine.

- Enrolled participants (n=44) had a median age of 46 years, 20% were female (sex at birth), and 51% had not previously received CAB + RPV LA (**Table 1**).
- Overall, 86% (n=38/44) and 64% (n=28/44) completed M8 questionnaires and interviews, respectively; six participants withdrew early from the study and study treatment.

Figure 2. Fidelity (Adherence) to the Treatment Window



*n=194, excluding one missed injection.

- Overall, 99% (n=194/195) of injections were administered, with one missed injection that was not covered by oral dosing.
- Of the total injections, 96% (n=187/194) of injections were administered within the treatment window, with a further 2% (n=3/194) administered early (**Figure 2**).

Effectiveness

- No participant met the confirmed virologic failure criterion (two consecutive HIV-1 RNA ≥200 copies/mL).
- At baseline, 90.6% (n=29/32) of participants had virologic suppression (HIV-1 RNA <50 copies/mL); all 32 participants had HIV-1 RNA <200 copies/mL. 12 participants at baseline did not have their viral load evaluated.
- At M7/8, 79% (n=27/34) had virologic suppression; 33 participants had HIV-1 RNA <200 copies/mL. At follow up, 4 participants did not have their viral load evaluated at M7/8.

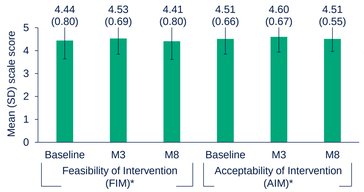
Table 2. Safety Summary*

	CAB + RPV LA QM (n=24)	CAB + RPV LA Q2M (n=20)	Overall (N=44)
Any AE, n (%)	8 (33)	5 (25)	13 (30)
Grade 1	7 (29)	3 (15)	10 (23)
Grade 2	0	2 (10)	2 (5)
Grade 3†	1 (4)	0	1 (2)
Any drug-related AE, n (%)	8 (33)	5 (25)	13 (29)
Any AE leading to withdrawal, n (%)	0	0	0
Any serious AE, n (%)	0	0	0
Any fatal AE, n (%)	0	0	0

*Represents participant-level data. †Imputed value of the grade, as the grade information for one participant is missing. No Grade 4 or 5 AEs occurred. AE, adverse event; CAB, cabotegravir; LA, long-acting; QM, monthly; Q2M, every 2 months; RPV, rilpivirine.

- No study withdrawal or treatment discontinuation was due to AEs (**Table 2**).
- Drug-related AEs were reported in 13 participants; a total of 12 participants reported 16 ISRs (Grade 1, n=9; Grade 2, n=2; Grade 3, n=1).
- The most frequently cited AEs included: injection site discomfort (14%, n=6) and injection site pain (14%, n=6); most AEs were Grade 1 or 2, and no serious AEs were reported.

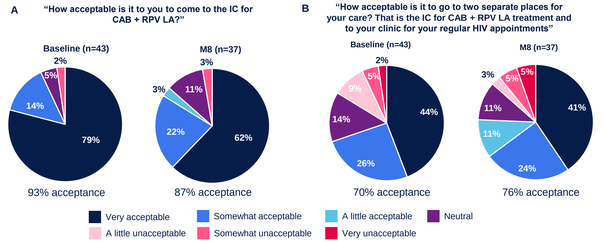
Figure 3. Feasibility and Acceptability of CAB + RPV LA Over Time



*Baseline, n=43; M3, n=36; M8, n=37.
CAB, cabotegravir; LA, long-acting; M, month; RPV, rilpivirine; SD, standard deviation.

- At M8, IC administration was highly feasible (FIM: mean score, 4.41) and acceptable (AIM: mean score, 4.51) (**Figure 3**).
- A total of 86% (n=37/43) participants "agreed" or "completely agreed" with all FIM items at baseline, and remained similar at M3 (86%, n=31/36) and M8 (84%, n=31/37).
- At baseline, 81% (n=35/43) of participants "agreed" or "completely agreed" with all AIM items; this proportion increased to 89% at both M3 (n=32/36) and M8 (n=33/37).

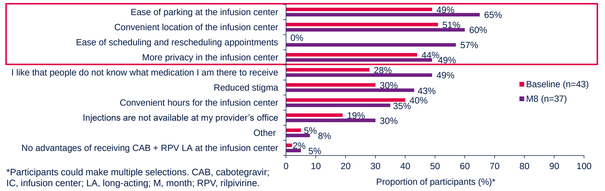
Figure 4. Acceptability of (A) Receiving CAB + RPV LA From an IC and (B) Two Locations for Care



CAB, cabotegravir; IC, infusion center; LA, long-acting; RPV, rilpivirine.

- At baseline and M8, most participants (≥87%) thought it was acceptable to come to the IC to receive CAB + RPV LA (**Figure 4A**).
- At baseline and M8, most participants (≥70%) thought it was acceptable to go to two locations for HIV care (**Figure 4B**).

Figure 5. Advantages of Going to the IC to Receive CAB + RPV LA



*Participants could make multiple selections. CAB, cabotegravir; IC, infusion center; LA, long-acting; M, month; RPV, rilpivirine.

- Advantages of ICs reported by PSPs included ease of parking, convenient location, ease of scheduling/rescheduling, privacy, others not knowing what medication they received, and reduced stigma (**Figure 5**).

Stigma or Discrimination at the IC

- When asked "*We know that people can be treated differently due to factors including, but not limited to, HIV status, gender, and race. Have you been treated differently, or experienced stigma or discrimination at the IC?*" 92% of participants reported experiencing no stigma or discrimination at ICs at M8.

Figure 6. Patient Perceptions of ICs at M8

CAB, cabotegravir; IC, infusion center; LA, long-acting; M, month; RPV, rilpivirine.

- At M8, 95% of participants reported being very or extremely satisfied with the ICs' care (**Figure 6**).
- Participants had generally positive views on ICs at M8:
  - 86% (n=32/37) were "somewhat" to "extremely satisfied" with the hours available at the IC.
  - 78% (n=29/37) found rescheduling appointments "somewhat" to "very easy."
  - 94% (n=34/36) were "very" or "extremely comfortable" with the IC managing CAB + RPV LA.
- Qualitative interviews highlighted positive views of IC administration, including staff relationships and continuity in care, as key acceptability factors:

> *The privacy. The discretion. That was my favorite part. Like, my doctor's office are careful. There is the side where HIV patients are treated, and then there's regular doctors on the opposite side. Well, if you come to the doctor's office enough, you will know that that's what that side is for.*

> *So, it's just the convenience factor of, it's all around between not having to take the pills, get it filled at the pharmacy... so I'd have to go to the pharmacy every month. And they're always out of stock. So, I'd have to wait 2 or 3 days for it to come in. So just the convenience of hopping in, hanging out for*

> *I'm used to my doctor's office, my doctors, staff there, they all know me... I have a relationship with them. So going into a new center... I was a little bit nervous, but then I just got to know them, and it was like, oh yeah, this is just like my doctor's office only more efficient.*

Conclusions

- In GLACIER, PWH found ICs to be a feasible and acceptable location for receiving CAB + RPV LA.
- High levels of adherence were observed, with 98% of injections received within the ±7-day dosing window or early.
- No participants had virologic failure, indicating that CAB + RPV LA successfully suppressed participants' viral load.
- CAB + RPV LA administration at ICs was well tolerated; ISRs occurred in 27% of participants, with mild-to-moderate pain and discomfort being the most frequently reported, consistent with data from the Phase 3/3b CAB + RPV LA program.
- ICs can be a valuable alternative site for CAB + RPV LA administration due to rapport with IC staff, continuity in care, reduction in logistical barriers, and the perception of stigma.
- Taken together, the use of alternative sites of care may improve convenience of treatment administration and expand access when HCP offices have limited capacity.

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