Staff Perspectives on the Burden of Daily Oral Antiretroviral Therapy and Clinical Implementation of Switching to Cabotegravir + Rilpivirine Long-Acting: Mixed-Methods Findings From the VOLITION Trial

P077

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Key Takeaways

- **Healthcare staff found it highly acceptable and feasible to switch people who were naive to treatment and newly suppressed with oral therapy to long-acting cabotegravir plus rilpivirine (CAB+RPV LA)**
- **The transition from daily oral pills to CAB+RPV LA addressed unmet patient needs by reducing adherence-related anxiety, decreasing stigma associated with daily medication and disclosure of HIV status, and lessening daily reminders of HIV status**
- **Healthcare staff reported varying implementation needs for CAB+RPV LA, ranging from no operational changes to anticipated adaptations in staffing, insurance support, and scheduling**

Plain Language Summary

- Healthcare staff involved in the VOLITION study were asked about giving people a choice of study treatment after a course of daily pills
- Staff believed that switching from daily pills to cabotegravir plus rilpivirine, a long-acting injection (CAB+RPV LA) given every 2 months reduced the daily reminder of HIV status and eased adherence-related anxiety and stigma
- The switch to CAB+RPV LA was viewed as highly acceptable and practical to implement in clinical settings, supporting its routine use as an early treatment option for people starting HIV therapy

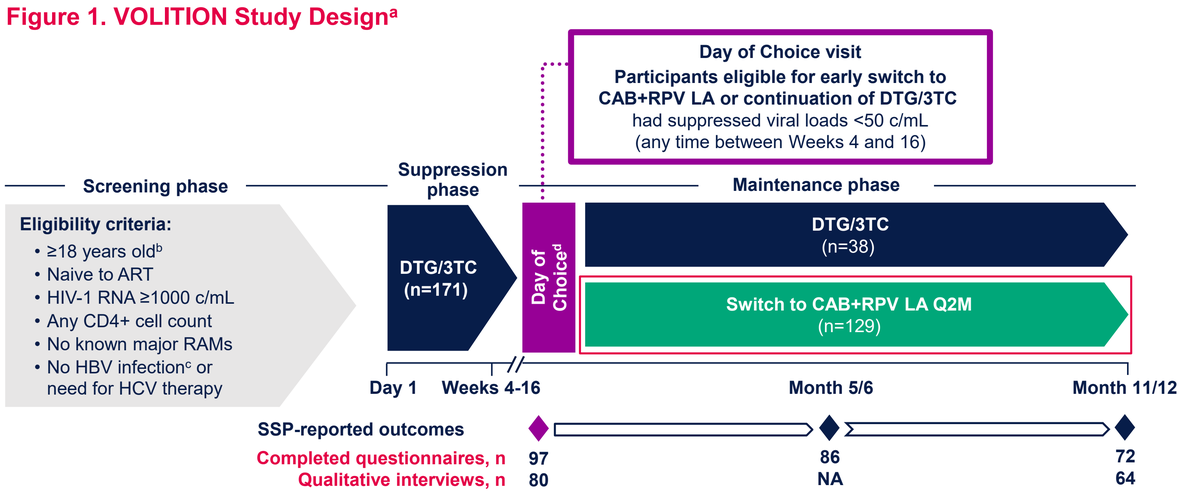
Introduction

- While highly effective, daily oral antiretroviral therapy (ART) imposes persistent psychosocial burdens, including adherence anxiety, stigma, and a constant daily reminder of HIV status[1]
- After rapid suppression on daily oral ART among participants naive to treatment in the phase 3b VOLITION study, 85% (129/151) of participants chose to switch to long-acting cabotegravir plus rilpivirine (CAB+RPV LA), with a high rate (88%) having suppressed viral loads at Month 11[2]
- Understanding staff perspectives is important as healthcare professionals ultimately determine whether a new treatment approach can be implemented and when it is offered in routine care[3,4]
- Here, we report the perspectives of the VOLITION staff study participants (SSPs) on treatment burden and care optimization when offering early switch to CAB+RPV LA after rapid virologic suppression with dolutegravir plus lamivudine (DTG/3TC) in people with HIV-1 who are naive to ART

Methods

- VOLITION (NCT05917509) was a multicenter, non-randomized, parallel-group, open-label implementation–effectiveness study conducted at 45 sites across Europe, North America, and South America (Figure 1)[2]
- Study objectives were to evaluate SSP-rated acceptability and feasibility of early switching to CAB+RPV LA and to explore SSP perceptions of treatment burden, unmet patient needs, and implementation considerations of early switch to CAB+RPV LA
- SSPs (n=102) completed validated quantitative assessments at Day 1, Day of Choice (DoC), Month 5/6, and Month 11/12
  - A subset (n=64) participated in qualitative interviews at DoC and Month 11/12
- Summary statistics were used for continuous variables
- For qualitative data, a preliminary codebook was developed, then coding for the SSP interviews was carried out using ATLAS.ti software (version 22.0 or higher)

Figure 1. VOLITION Study Design[a]



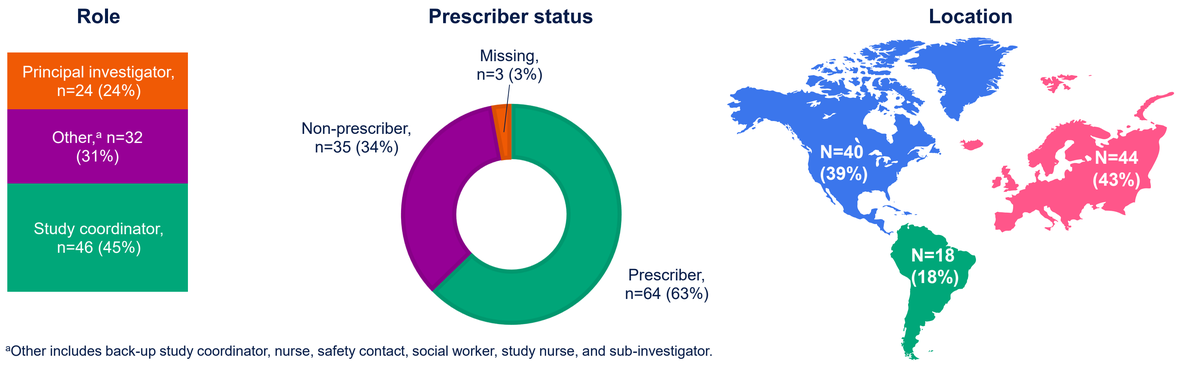
ALT, alanine transaminase; anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; Q2M, every 2 months; RAM, resistance-associated mutation; ULN, upper limit of normal. [a]VOLITION was conducted at 45 sites across the United States (n=15), Spain (n=8), France (n=5), Italy (n=4), Argentina (n=4), Chile (n=4), Germany (n=3), and Canada (n=2). [b]Or older, if required by local regulations. [c]Participants positive for HBsAg were excluded. Participants negative for anti-HBs but positive for anti-HBc were excluded only if HBV DNA was detected. [d]Participants proceeded to DoC at the study visit following their first plasma HIV-1 RNA result <50 copies/mL (Week 4 at the earliest but no later than Week 16). Participants must have had a suppressed viral load <50 copies/mL to qualify for the optional switch to CAB+RPV LA. The exclusion criteria for switching included: treatment-emergent ALT ≥5 × ULN; ALT ≥3 × ULN and bilirubin ≥1.5 × ULN (with >35% direct bilirubin); and pregnancy.

Results

Study Staff Were From a Variety of Geographic Regions, Performed a Variety of Roles, and Included Both Prescribers and Non-Prescribers

- Study staff roles, prescriber status, and location are described in Figure 2

Figure 2. SSP Demographic Characteristics (N=102)

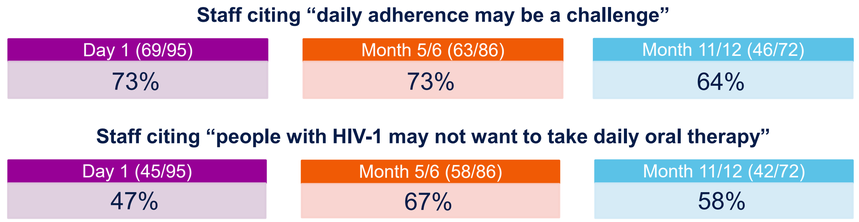


[a]Other includes back-up study coordinator, nurse, safety contact, social worker, study nurse, and sub-investigator.

Daily Oral ART Remains a Meaningful Burden for Many People With HIV-1

- Daily adherence challenges for participants who were naive to treatment was the most frequently reported potential disadvantage of daily oral ART among responding staff and staff reported that people with HIV-1 may prefer long-acting alternatives to daily oral therapy (Figure 3)

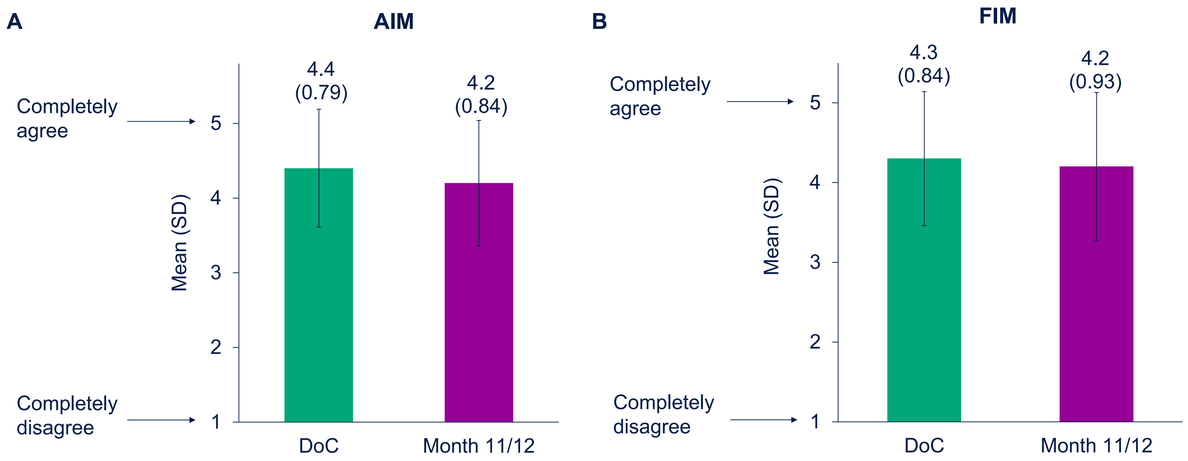
Figure 3. Daily Adherence Burden Was the Most Commonly Reported Limitation



Early Switching to CAB+RPV LA Was Viewed as Highly Acceptable and Feasible With Minimal Workflow Impact

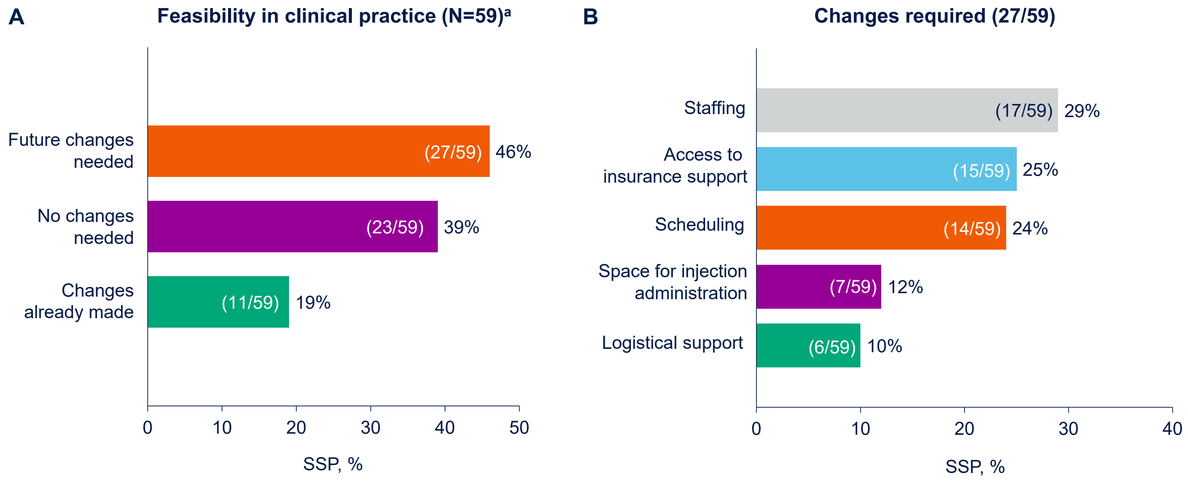
- For individuals whose viral loads became suppressed and who chose to switch, staff rated CAB+RPV LA highly acceptable and highly feasible (Figure 4)
- In qualitative interviews, 29/59 SSPs (49%) discussed the feasibility of giving participants the option to switch to CAB+RPV LA (Figure 5)

Figure 4. Staff (A) Supported Early Switching (AIM) and (B) Anticipated Limited Implementation Challenges (FIM)[a]



[a]The Acceptability of Intervention Measure (AIM) was used to measure staff-rated acceptability of a clinical intervention and the Feasibility of Intervention Measure (FIM) was used to measure the perceived feasibility of implementing that intervention in real-world practice; on both the AIM and FIM, scores approaching 5 indicate the highest levels of acceptability and feasibility, respectively.[5]

Figure 5. SSP-Reported Feasibility of Providing Participants the Option to Switch to CAB+RPV LA

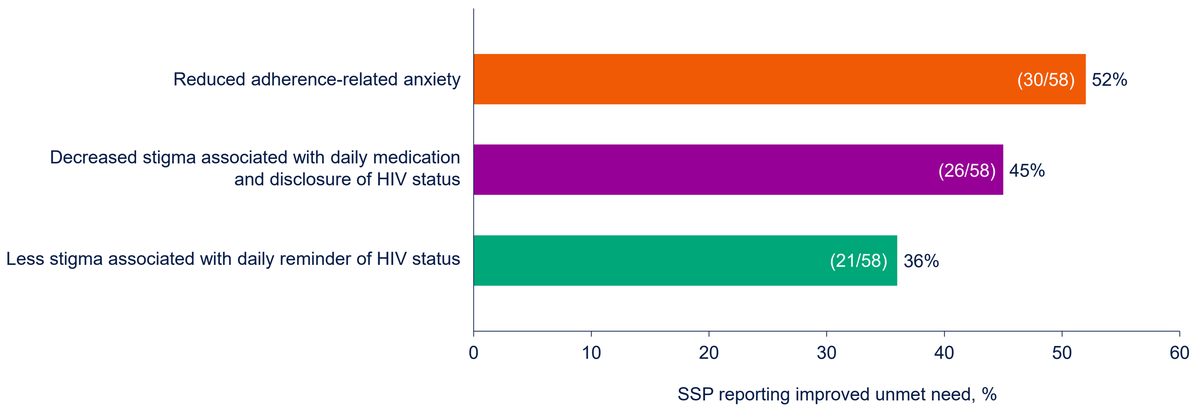


[a]Staff could have discussed more than one feasibility option in response to interview questions.

CAB+RPV LA Addressed Key Psychosocial Burdens Associated With Daily Oral ART

- In qualitative interviews conducted on the DoC, 97% of SSPs (71/73) expressed positive perceptions of CAB+RPV LA, citing reduced pill-taking burden, lower adherence-related anxiety, and decreased HIV stigma
- 91% of SSPs (58/64) reported that CAB+RPV LA addressed previously unmet patient needs; the most common unmet needs addressed were adherence-related anxiety (52%, 30/58), daily medication–associated stigma (45%, 26/58), and the daily reminder of HIV status (36%, 21/58; Figure 6)

Figure 6. Adherence Anxiety, Stigma, and Daily HIV Reminders Were Common Unmet Needs Addressed by CAB+RPV LA (Month 11/12)



Conclusions

- SSPs perceived daily oral ART as a persistent burden for people with HIV-1 who are naive to treatment
- By alleviating the persistent burden of daily oral therapy, the early switch to CAB+RPV LA was perceived to address critical unmet patient needs, most notably by reducing adherence anxiety and daily medication stigma
- Switching people with HIV-1 who are naive to treatment and newly suppressed from oral therapy to CAB+RPV LA was perceived as highly acceptable
- Despite some anticipated operational adaptations, particularly related to staffing, insurance support, and scheduling, staff rated early switching to CAB+RPV LA as highly feasible
- Together with participant-reported findings from the companion VOLITION analysis (see Poster P076), these staff perspectives reinforce the case for early-switch CAB+RPV LA protocols as a clinically viable and patient-centered approach to reducing treatment burden and stigma

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References: 1. de Los Rios et al. *AIDS Behav*. 2021;25:961-972. **2.** Córdova et al. *Open Forum Infect Dis*. 2026;ofag383. **3.** Nkodo et al. *BMC Health Serv Res*. 2026 [Epub ahead of print]. **4.** Gutner et al. *J Int AIDS Soc*. 2024;27:e26243. **5.** Weiner et al. *Implement Sci*. 2017;12:108.

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