Clinical characteristics and reasons for switching to long-acting cabotegravir + rilpivirine in routine care: Insights from the Nordic VALHALLA study

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Key Takeaways

- **VALHALLA is an on-going study in Denmark, Finland, and Sweden assessing reasons why people living with HIV and their health care providers opted to switch to cabotegravir + rilpivirine long-acting treatment**
- **Baseline results show that switching to CAB+RPV LA in routine clinical care is driven by patient preference particularly due to better fit for lifestyle, convenience of less frequent dosing and to reduce daily reminders of living with HIV.**

Background

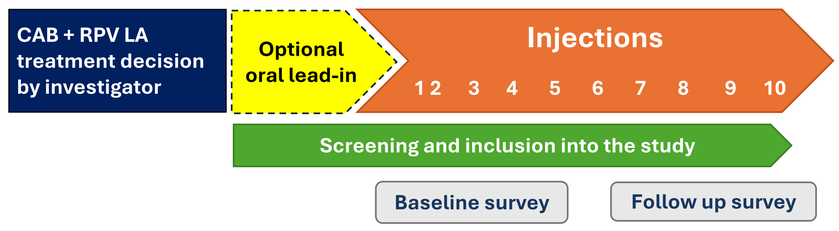
- Cabotegravir (CAB) + rilpivirine (RPV) is the first complete long-acting (LA) regimen recommended by treatment guidelines[1] for the maintenance of HIV-1 virologic suppression in patients who are virally suppressed.
- Despite the success of daily oral antiretroviral therapy (ART), challenges still exist for some people living with HIV associated with drug interactions, adherence, pill burden and stigma[2,3]. CAB + RPV LA injections every 2 months for HIV treatment offer a less frequent dosing alternative to daily oral ART and may address some of these challenges associated with daily oral ART.
- The VALHALLA study (The VAlue for people Living with HIV of being on an AntiretrovirAL Long-Acting Cabotegravir + Rilpivirine regimen) is a non-interventional, prospective and retrospective study in people living with HIV receiving CAB+RPV LA as part of routine clinical care in Denmark, Finland and Sweden.
- The study aims to describe the clinical characteristics of people switching to CAB+RPV LA, and to explore the factors associated with the decision to switch, from both the patients' and healthcare providers' (HCP) perspectives as well as overall patients' treatment satisfaction/experience.
- Here we report the baseline clinical characteristics collected from medical records, and reasons for switching, which were assessed through surveys administered at study entry.

Methods

Figure 1. VALHALLA Study Design

Non-interventional, prospective and retrospective, multicenter, study in Denmark, Finland, and Sweden

Key eligibility criteria:
- ≥ 18 years of age
- Documented HIV-1 infection
- Virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen
- Prescription of CAB + RPV LA issued independently from entering the study according to SmPC



- Participants could be included into the study at any time between the decision to be switched to CAB + RPV LA and 10th injection (**Figure 1**).
- **Key outcome measures**: Primary: Participants' primary reasons for switching to CAB+RPV LA. Secondary: participants-reported supporting reasons for switching, HCP-reported reasons for switching, understanding of population characteristics switching to LA in the Nordics, treatment satisfaction, impact for quality of life
- **Baseline Survey:** HIV-TSQ 12-item status questionnaire was administered at inclusion (before first injection or up to 5 weeks after 1st injection), assessing reasons for switching to long-acting therapy as well as people with HIV previous experience with oral ART.
- **Follow up survey**: Upon reaching 10th injection (18 months, +- 9 weeks), (or 7th injection*; 12 months, +- 6 weeks) all participants will complete the follow-up HIV-TSQs and HIVTSQc questionnaires. These will examine participants overall experience with LA therapy, treatment preference and satisfaction.

*Protocol amendment: for those recruited into the study from 1st of April 2024

Results

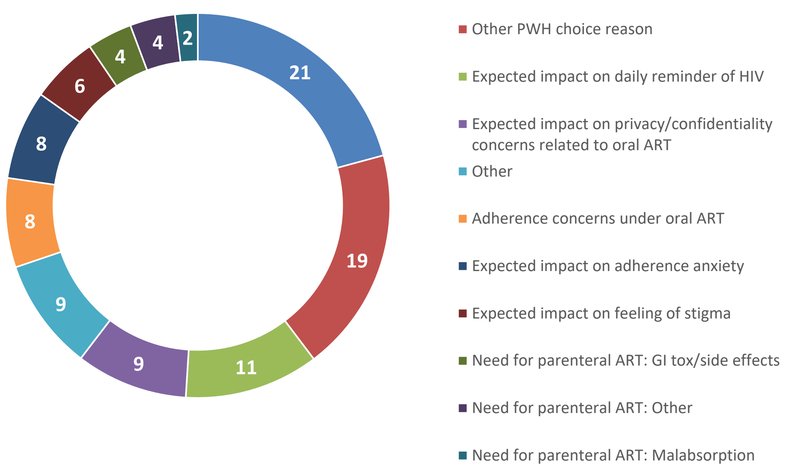
Table 1. Baseline Characteristics of Study Participants

Parameter	Total	N
Male (sex at birth), % (n)	74 (39)	53
Median age, years (IQR)	45 (18)	53
Age categories		
<50 years, % (n)	60 (32)	
50-60 years, % (n)	32 (17)	
>60 years, % (n)	8 (4)	
Virus subtype, % (n)		53§
B	36 (19)	
C	8 (4)	
A/A-recombinant (A, A2, CRF01_AE, CRF02_AG)*	15 (8)	
Unknown	36 (19)	
CD4 T-cell count, cells/µl, median (IQR)	634 (456)	
Median time since HIV diagnosis, years (IQR)	13.5 (3)	50
CDC stage at baseline, % (n)		53
AB (combined data)	88 (47)	
C	12 (6)	
Median number of ART changes (IQR)	4 (4)	44
ARTs prior switch to CAB+RPV LA (>10% of switches), % (n)		53
DTG/3TC	21 (11)	
B/F/TAF	21 (11)	
DTG + F/TDF	13 (7)	
Other (<10%)	45 (24)	

*No A1/A6 subtype was reported (only reported for 34 participants)˙; §includes 1 participant with subtype D, and 2 participants with unknown subtype
B, bictegravir; CAB, cabotegravir; CDC. Centers for Disease Control; DTG, dolutegravir; F, emtricitabine; IQR, interquartile range; LA, long-acting; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; 3TC, lamivudine;

- Between September 2022 and December 2024, 53 PLHIV initiated CAB + RPV LA across 9 sites in Denmark, Finland, and Sweden in accordance with the SmPC.
- Baseline characteristics collected from the medical records of the cohort are shown in **Table 1**.
- Study participants had a median age of 45 years, with 74% being male. The most common virus subtype was B (36%), and the median time since HIV diagnosis was 13.5 years. The most common ART regimens prior to switching to CAB+RPV LA were DTG/3TC and B/F/TAF (both 21%).

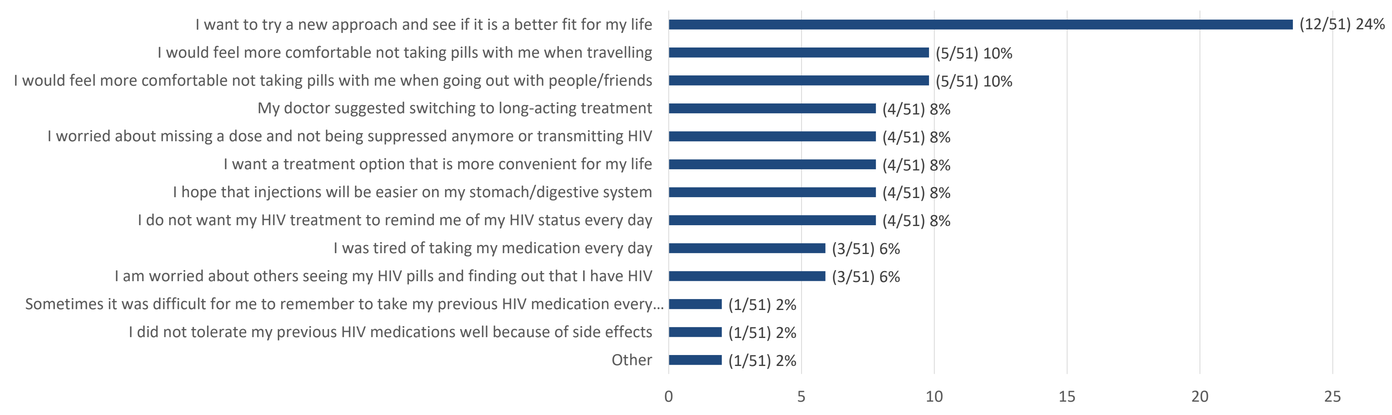
Figure 2. HCP perspective: Primary reasons for switching to CAB+RPV LA



- From the HCP perspective, the primary reasons (%) for switching to CAB+RPV LA for 53 participants were: **"convenience of less frequent dosing"** (n=11, 21%), **"expected impact on daily reminder of HIV"** (n=6, 11%), and **"expected impact on privacy/confidentiality concerns related to oral ART**" (n=5, 9%) (**Figure 2.)**

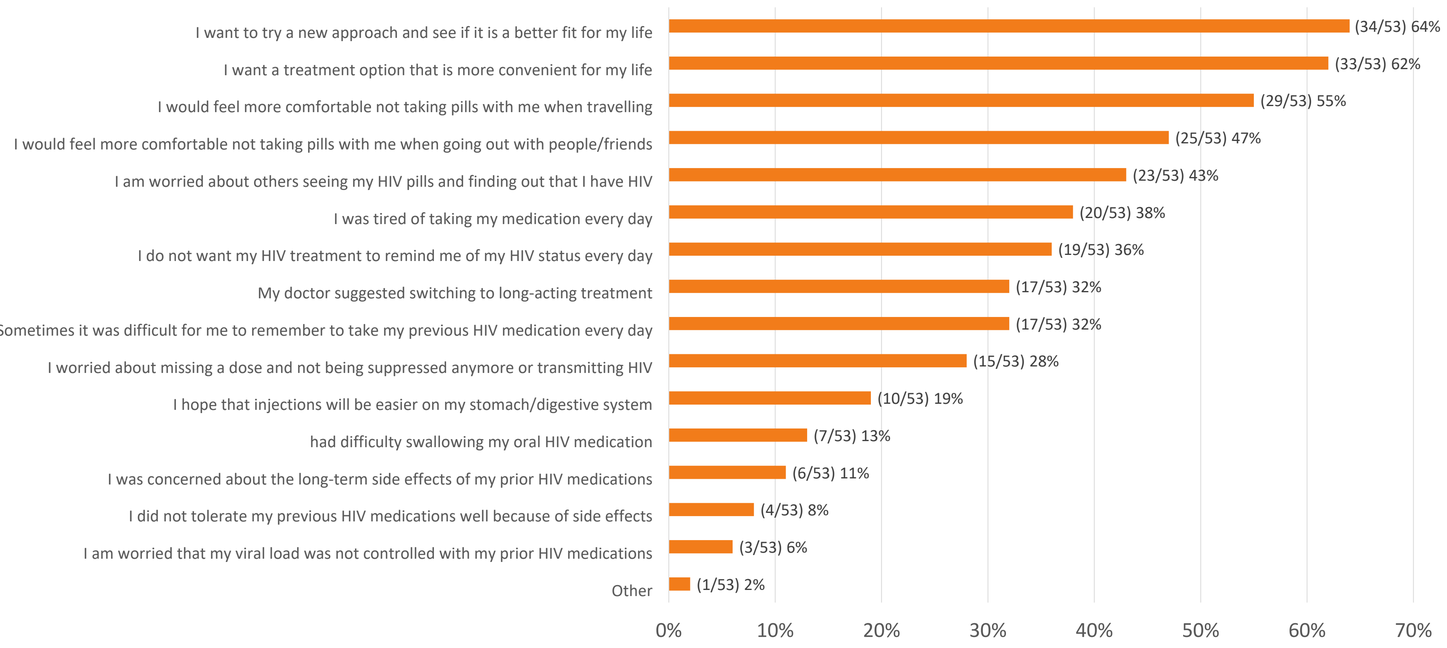
*PWH: people with HIV; after rounding, proportions total 101%

Figure 3. People with HIV perspective: Primary reasons for choosing CAB+RPV LA



- From the participants perspective (51 responses), the most common primary reasons for switching were **"trying a new approach and seeing if this is a better fit for life**" (24%), "**feeling more comfortable not taking pills along when meeting people/friends"** (10%) and **"feeling more comfortable not taking pills when travelling**" (10%). (**Figure 3**).

Figure 4. People with HIV perspective: Reasons for switch to CAB + RPV LA (most important and multiple-choice reason combined)



- Considering all the factors together (multiple choice question) that influenced participants to select CAB + RPV LA, the decision to switch was mainly motivated by **convenience, improved alignment with their lifestyle, and a lower pill burden** (**Figure 4**).

Conclusions

- The switch to CAB+RPV LA was primarily driven by **patient preferences** for a better fit with their lifestyle, including the convenience of not having to take daily pills
- HCPs highlighted the **convenience** of less frequent dosing as a significant factor for switching to CAB+RPV LA
- These baseline data provide insights into who may benefit most from CAB+RPV LA (i.e people with hiv struggling with daily oral therapy) and inform future strategies to optimize HIV care
- The impact of switch to CAB + RPV LA to treatment satisfaction and PLHIV quality of life will be explored further once the study is complete.

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References: 1. European AIDS Clinical society; guidelines for management of people living with HIV in Europe 2024. Available from: https://eacs.sanfordguide.com/.Accessed Sep 5th, 2025**. 2**. Clark L et al. *Population Medicine.* 2020;2(October):33. **3**. Akinwunmi B et al. Eur J Public Health. 2021;31(3):567-575.

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