LA CAB/RPV in Pregnancy: Bi-Monthly Dosing in the Setting of Predicted Reduced Rilpivirine Exposure

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BACKGROUND

- Long-acting cabotegravir/rilpivirine (LA CAB/RPV) is an effective and highly acceptable alternative to daily oral ART in non-pregnant populations.
- Physiologic changes during pregnancy may reduce antiretroviral drug exposure.
- Pharmacokinetic modeling suggests adequate cabotegravir exposure with monthly or every other month dosing; however, concerns exist that rilpivirine concentrations may fall below the protein-adjusted EC95, prompting recommendations for **monthly** dosing during pregnancy (**see Figure 1**).
- Real-world data on every other month LA CAB/RPV use throughout pregnancy are extremely limited.

Objective: To describe virologic, obstetrical, and perinatal outcomes among pregnant persons maintained on **every other month LA CAB/RPV throughout pregnancy**.

METHODS

- **Design:** Multi-center retrospective chart review
- **Population:** Pregnant persons with HIV prescribed every other month LA CAB/RPV between January 2021 and September 2025
- **Inclusion criteria for this analysis**:
  - Conceived while receiving **every other month LA CAB/RPV**
  - Continued every other month dosing throughout pregnancy and delivery
  - No concomitant oral ART
- **Data collected**:
  - Maternal demographics
  - Longitudinal HIV-1 RNA during pregnancy
  - Delivery characteristics
  - Neonatal outcomes (gestational age, birth weight, infant HIV status)

PLAIN LANGUAGE SUMMARY:
This study looked at pregnant women with HIV who continued receiving long-acting injectable HIV treatment every two months during pregnancy. All participants remained virally suppressed with no cases of HIV transmission to infants, suggesting this dosing schedule may be a promising option, though larger safety and drug level studies are still needed.

• Every other month LA CAB/RPV maintained viral suppression throughout pregnancy with no virologic failures or perinatal transmissions in people who became pregnant while receiving it.
• Supports the needs for prospective pharmacokinetic studies evaluating LA CAB/RPV in pregnancy

RESULTS

- **N = 15** pregnant cisgender women met inclusion criteria
- **Virologic outcomes**
  - 93% entered prenatal care with HIV-1 RNA < 50 copies/mL
    - One has HIV-1 RNA 36 copies/mL
  - Median HIV RNA measurements during pregnancy: **3 (IQR 3–5)**
  - **100% maintained virologic suppression (<20 copies/mL)** throughout pregnancy and delivery
  - No viral blips or virologic failure observed
- **Pregnancy and Delivery**
  - Majority vaginal deliveries
  - Cesarean deliveries for obstetrical indications only
  - Median gestational age at delivery: **37 weeks (range 25–38)**
  - Median birth weight: **2,330 g (range 767–2,750)**
  - One spontaneous abortion
- **Infant Outcomes**
  - No cases of perinatal transmission
  - All infants HIV-negative on serial PCR testing through 4 months of age

Table 1: Baseline Demographics

Characteristics	N=15
Age at first prenatal visit, median (IQR)	32 (26,34)
Sex/Gender, n (%)	
Cis-gender female	15 (100)
Race, n (%)	
Black/African American	11 (73)
White	4 (27)
Ethnicity	
Non-Hispanic	14 (93)
Place of Birth	
US Born, n (%)	14 (93)
Time since HIV diagnosis in years, median (IQR)	14 (5,29)
Perinatal HIV acquisition, n (%)	5 (33)
Prior NNRTI use, n (%)	8 (53)

Table 2: Delivery and Neonatal Outcomes

	N=15
Birth Outcomes, n (%)	
Live Birth	14 (93)
Spontaneous Abortion	1(7)
Gestational age at delivery, median (IQR)	37 (25, 38)
Mode of Delivery, n (%)	
Vaginal	12 (86)
Birth weight, grams, median (IQR)	2330 (767, 2750)
Neonatal HIV status at 4 months	
negative	15 (100)

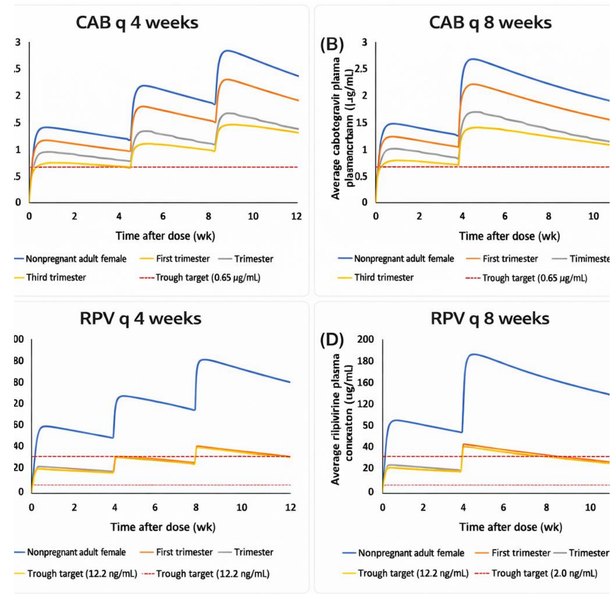
CONCLUSIONS

- In this small multi-center cohort of pregnant persons maintained on **every other month LA CAB/RPV**, sustained virologic suppression and favorable perinatal outcomes were observed, with **no perinatal HIV transmissions.**
- These findings highlight the urgent need for **prospective pharmacokinetic and safety studies** to determine whether every other month LA CAB/RPV can be considered a viable treatment option during pregnancy.

LIMITATIONS

- No control or comparator group
- Small sample size
- Bias**:**
  - selection bias
  - publication bias
  - confirmation bias

Figure 1: Modeling CAB/RPV concentrations in pregnancy.
Modified from Atoyebi S, et al. *



*Atoyebi S, et al. Physiologically-based pharmacokinetic modelling of long-acting injectable cabotegravir and rilpivirine in pregnancy. Br J Clin Pharmacol. 2025 Apr;91(4):989-1002. doi: 10.1111/bcp.16006. Epub 2024 Feb 10. PMID: 38340019; PMCID: PMC11992663.