

Title: Viral Suppression among HIV-Positive Women Starting Antiretroviral Therapy (ART) Before or During Pregnancy in Lesotho

Track and category: C103

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Background: Reaching maximal viral suppression is critical for preventing perinatal transmission. One hypothesized benefit of Option B+ (life-long ART for all HIV-positive women) is improved viral suppression in subsequent pregnancies.

Methods: This was an observational prospective cohort study of HIV-positive pregnant women conducted at 13 clinics in three Lesotho districts. Factors that may be associated with HIV viral load (VL) suppression were assessed. VL was obtained between June 2014-November 2015 in 104 women at enrollment (any ANC visit) and delivery. Three women were excluded due lack of ART dates; 13 were excluded because delivery VL was obtained ≥ 3 weeks post-delivery. Undetectable VL was defined as < 20 c/mL. Adherence was measured by seven-day self-reported recall. Logistic regression analysis was conducted to detect an association between ART initiation timing (before pregnancy or during ANC) and undetectable VL.

Results: All women received NNRTI-based ART (85.2% Efavirenz-based); 75/88 (87.2%) reported 100% adherence. Mean ART duration was 40.8 months in women starting ART prior to pregnancy (n=43) and 4.1 months for those starting during ANC (n=45); only 3/88 (3.4%) had < 4 weeks ART. Enrollment VL was undetectable in 26/43 (60.5%) women starting ART pre-pregnancy and 10/45 (22.2%) starting during-ANC. Delivery VL was undetectable in 32/43 (74.4%) women on ART pre-pregnancy and 18/45 (40.0%) of women who started ART during-ANC. Of 52 women with detectable enrollment VL, 18 (34.6%) (9 pre-pregnancy, 9 during-ANC) achieved undetectable VL by delivery. Four women with undetectable enrollment VL experienced an increase in VL by delivery (3 pre-ANC, 1 during-ANC). Women starting ART pre-pregnancy were 5.4 and 4.3 times more likely to have undetectable VL at enrollment ($p < 0.0001$) and delivery ($p < 0.001$), respectively, than those starting during-ANC. Fifty women (56.8%) had delivery VL < 20 c/mL, 19 (21.6%) had 20-999 c/mL and 19 (21.6%) had $> 1,000$ c/mL.

Discussion: Most women received > 4 weeks ART and reported high adherence. However, only 56.8% achieved profound viral suppression to < 20 c/mL; 78.4% reached suppression to $< 1,000$ c/mL. While women starting ART pre-pregnancy were more likely to have undetectable VL than those starting during-ANC, almost one quarter still had detectable VL > 20 c/mL at delivery, with 11.6% having VL $> 1,000$ c/mL.

Kommentar [RN1]: This is unclear – during ANC - those who have started during ANC??

Kommentar [MG2]: Changed to pre-pregnancy to clarify

Kommentar [RN3]: One blip, sustained???

Kommentar [MG4]: Unfortunately we don't have data to answer this question at this time

Kommentar [RN5]: At enrollment – no wonder!!!! At delivery matters – would only leave data at delivery .

Kommentar [MG6]: Agree delivery is most important but I would prefer to leave both. The fact that only 61% on ART pre-pregnancy were undetectable at enrollment is important

Table 1. HIV-infected women by treatment initiation pre-ANC and initiation at first or subsequent ANC visit

	ANC N=43	During-ANC N=45	Total N=88
Woman's age, mean (SD), range	30.9 (5.5), 22 – 42	26.8 (4.7), 18 – 37	28.9 (5.5), 18 – 42
ART regimen, N (%)			
TDF + 3TC + EFV	26 (61.9)	44 (97.8)	70 (80.5)
AZT+3TC+NVP	4 (9.5)	1 (2.2)	5 (5.8)
AZT+3TC+EFV	5 (11.9)		5 (5.8)
TDF + 3TC + NVP	4 (9.5)		4 (4.6)
Other	3 (7.1)		3 (3.5)
Duration of treatment (months), mean, SD, range	40.8 (26.1), 1.9 - 104.1	4.1 (2.0), 0 - 8.1	22.0 (25.9), 0 - 104.1
Duration of treatment, N (%)			
>4 weeks	43 (100)	42 (93.3)	85 (96.6)
< 4 weeks	0	3 (6.7)	3 (3.4)
Adherence, N (%)			
100%	39 (95.1)	36 (80.0)	75 (87.2)
≥80%	1 (2.4)	7 (15.6)	8 (9.3)
≥50%	1 (2.4)	1 (2.2)	2 (2.3)
<50%	0	1 (2.2)	1 (1.2)
VL copies/mL at enrollment visit, N (%)			
Undetectable (<20)	26 (60.5)	10 (22.2)	36 (40.9)
20 to <400	12 (27.9)	10 (22.2)	22 (25.0)
400 to <1000	0	1 (2.2)	1 (1.1)
1000 to <10,000	0	6 (13.3)	6 (6.8)
10,000 to <100,000	4 (9.3)	12 (26.7)	16 (18.2)
100,000 to <1 million	1 (2.33)	6 (13.3)	7 (8.0)
VL copies/mL at delivery, N (%)			
Undetectable (<20)	32 (74.4)	18 (40.0)	50 (56.8)
20 to <400	6 (14.0)	13 (28.9)	19 (21.6)
400 to <1000	0	0	0
1000 to <10,000	1 (2.3)	4 (8.9)	5 (5.7)
10,000 to <100,000	4 (9.3)	8 (17.8)	12 (13.6)
100,000 to <1 million	0	2 (4.4)	2 (2.3)

Kommentar [KS7]: i am not sure that this table adds too much extra than what is stated in the results. may want to remove to get the word count under 350.

Kommentar [MG8]: This will be deleted. I moved up important points into the Results