Outcomes Among People With Viraemia While on Dolutegravir-Based ART in a Large Prospective Cohort

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BACKGROUND

- The WHO and multiple countries in resource limited settings recommend switch to PI after two consecutive HIV viral loads (VL) ≥1000 copies/mL while on a dolutegravir (DTG) based regimen without a drug resistance test
- There is limited data to support this strategy

METHODS

- Ndovu is a multi-country prospective cohort study evaluating HIV-1 viral suppression among participants with VL ≥1000 copies/mL after at least six months of DTG-based ART
- Adherence is assessed at every visit using the MMAS-8 score and participants receive enhanced adherence interventions every month
- VL is measured every 3 months with drug resistance testing for all VL ≥1000 copies/mL
- Predictors of viral suppression (VL <200 copies/mL) are assessed using multivariable logistic regression
- We present 3 month outcomes of the first 2,994 participants enrolled in Kenya

RESULTS

- Between March 3 and December 8, 2025, 2,994 participants were enrolled across 131 sites in Kenya
- Table 1 summarises their baseline characteristics

Table 1: Baseline Characterstics

Characteristic	N = 2,994
Age, median (min, max)	38.2 (1.2, 93.2)
Female sex	1,812 (60.5%)
Time on DTG in years, median (IQR)	4.7 (2.6, 5.6)
Enrollment DTG regimen	
TDF/3TC/DTG	2,709 (90.5%)
ABC/3TC/DTG	186 (6.2%)
AZT/3TC/DTG	85 (2.8%)
TAF/3TC/DTG	14 (0.5%)
Prior other ART regimen	2,120 (70.8%)
Enrollment VL Category, copies/mL	
1,000 to 9,999	1,724 (57.6%)
10,000 to 99,999	837 (28.0%)
≥100,000	433 (14.5%)
Adherence level, MMAS-8 score	
Low adherence, 0 to 5	1,676 (56.0%)
Medium adherence, 6 to 7	1,013 (33.8%)
High adherence, 8	305 (10.2%)
Substance use in adults ≥20 years old	331 (13.8%)

68% of participants with high VL (41% if two consecutive high VLs) achieve viral suppression within 3 months; VL of ≥10,000 copies/mL and a history of prior high VL were associated with non-suppression

RESULTS contd…

- Of 1,821 (61%) who had completed the month 3 visit by December 8 2025, 1,252 (68%) had VL <200 copies/mL
- Factors associated with non-suppression included enrolment VL of ≥10,000 copies/mL and a history of more than one prior high VL (table 2)

Table 2: Predictors of Viral Suppression

Characteristic	VL<200	VL ≥200	Unadjusted OR	Adjusted OR
Enrollment VL Category, copies/mL				
1,000 to 9,999	783 (71.7)	309 (28.3)	Ref.	Ref.
10,000 to 99,999	311 (63.1)	182 (36.9)	0.67 (0.54-0.85, p=0.001)	**0.74 (0.59-0.94, p=0.014)**
≥100,000	158 (64.0)	89 (36.0)	0.70 (0.52-0.94, p=0.017)	**0.73 (0.54-0.99, p=0.039)**
Previous High VL ≥1,000 copies/mL				
No	771 (78.7)	209 (21.3)	Ref.	Ref.
Yes	481 (56.5)	371 (43.5)	0.35 (0.29-0.43, p<0.001)	**0.38 (0.31-0.47, p<0.001)**
Time on DTG, years	4.3 (1.8)	3.8 (1.9)	1.14 (1.08-1.20, p<0.001)	1.10 (1.04-1.16, p=0.002)
Age Category, years				
≥20	1030 (70.8)	424 (29.2)	Ref.	Ref.
1 to 19	222 (58.7)	156 (41.3)	0.59 (0.46-0.74, p<0.001)	0.78 (0.61-1.00, p=0.052)
Sex				
Female	761 (69.8)	330 (30.2)	Ref.	Ref.
Male	491 (66.3)	250 (33.7)	0.85 (0.70-1.04, p=0.115)	0.85 (0.69-1.05, p=0.132)
Adherence level (MMAS-8)				
Low adherence, 0 to 5	711 (65.3)	377 (34.7)	Ref.	Ref.
Medium adherence, 6 to 7	443 (75.1)	147 (24.9)	1.60 (1.28-2.00, p<0.001)	1.37 (1.08-1.73, p=0.009)
High aderence, 8	98 (63.6)	56 (36.4)	0.93 (0.66-1.32, p=0.676)	0.96 (0.67-1.39, p=0.813)

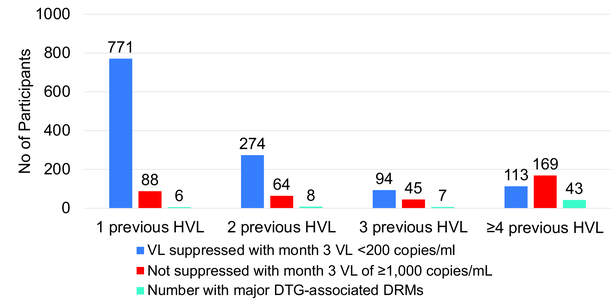
- Viral suppression was highest among participants with only one episode of viraemia (79%) and lowest (36%) among those with four or more prior high VLs (table 3)
- 41% of participants with two consecutive VLs of ≥1,000 copies/mL at enrollment suppressed by month 3

Table 3: Virological Suppression and DTG DRMs by Previous High VL

Total number of Previous High VL	VL Suppressed (VL <200 copies/mL)	Not Virologically Suppressed		Number (%) of those with VL ≥1,000 copies/mL with DRT Results	Number (%) with Major DTG-associated DRMs
		VL 200 to 999 copies/mL	≥1,000 copies/mL		
1	771 (78.7%)	121 (12.3%)	88 (9.0%)	44 (50.0%)	6 (13.6%)
2	274 (72.1%)	42 (11.1%)	64 (16.8%)	35 (54.7%)	8 (22.9%)
3	94 (58.8%)	21 (13.1%)	45 (28.1%)	19 (42.2%)	7 (36.8%)
4+	113 (36.2%)	30 (9.6%)	169 (54.2%)	98 (58.0%)	43 (43.9%)

RESULTS contd…

Figure 1: VL Suppression and Major DTG DRMs by Number of Previous HVLs



CONCLUSION

- We identify subgroups of participants with DTG failure who are likely to suppress without a change in ARV regimen, and those who are likely to have major DTG-associated resistance mutations
- The suppression rate in participants with two consecutive high VLs suggest that the WHO recommendation to switch to PI after a second high VL will lead to many unnecessary drug switches

ACKNOWLEDGEMENT

This study is funded by the Gates Foundation and sponsored by the University of Nairobi. We thank the study participants, leadership and personnel at the 131 participating facilities in Kenya, the nine county health teams and leadership (Bungoma, Homa Bay, Kiambu, Kisumu, Machakos, Mombasa, Nairobi, Siaya and Trans Nzoia), and the Ministry of Health through the National AIDS and STI Control Program

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PLAIN LANGUAGE SUMMARY

We found that many people who have two high viral load test results while on dolutegravir (DTG) for HIV treatment are still able to suppress the virus without changing treatment. This suggests that the current WHO guidance of switching to a different type of drug (a protease inhibitor, or PI) after a second high viral load could lead to many unnecessary drug switches.