Outcomes of Children and Adolescents with Viraemia while on Dolutegravir

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BACKGROUND

Paediatric dolutegravir (DTG) formulations were introduced in many sub-Saharan countries in 2019. However, little is known about the outcomes of DTG failure in children and adolescents living with HIV.

METHODS

- The Ndovu Study is a multi-country prospective cohort in Kenya, Mozambique, Lesotho and Tanzania enrolling people living with HIV on DTG for at least 6 months who have a viral load of ≥1000 copies/ml within 3 months of enrollment.
- Participants are followed for 12 month with viral load measurement every 3 months, and drug-resistant testing for those who fail to suppress viral load below 200 copies/ml.
- All participants receive enhanced adherence interventions at enrolment and monthly. The primary outcome is viral load <200 copies/ml. We describe the 3-month outcomes of the first 592 children enrolled in Kenya.
- Proportions of participants with viral loads <200, 200-999 and ≥1000 and those with DTG-associated drug resistance mutations (DRMs) were determined.

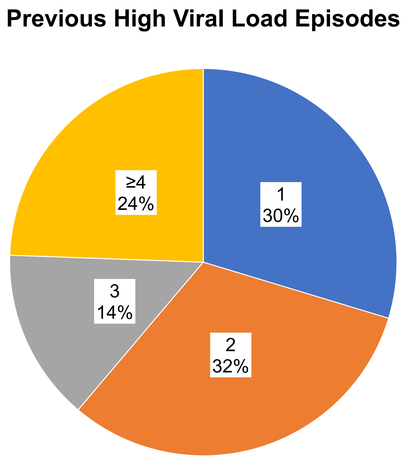
Table 1: Baseline characteristics of children and adolescents with viraemia while on DTG

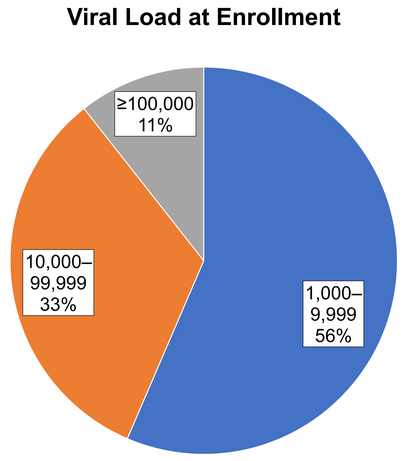
Characteristic	N (%)
Sex	592
Male	300 (51%%)
Age	592
1-4 years	45 (7.6%)
5-9 years	90 (15.2%)
10-14 years	160 (27.0%)
15-19 years	297 (50.2%)
CD4 count available (N=592)	318 (53.7%)
Nadir CD4 Category (N=318)	
<200	60 (18.9%)
200-349	51 (16.0%)
≥350	207 (65.1%)
Enrollment regimen	592
Abacavir/Lamivudine/Dolutegravir	167(28.2%)
Zidovudine/Lamivudine/Dolutegravir	39 (6.6%)
Tenofovir/Lamivudine/Dolutegravir	386 (65.2%)

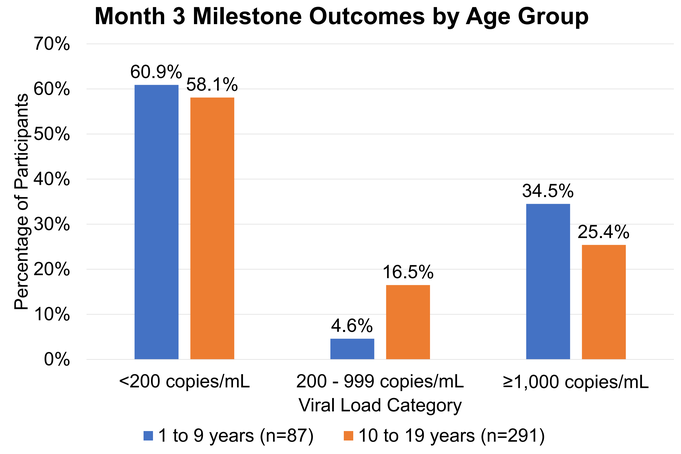
High rates of persistent viraemia in children and adolescents failing DTG despite enhanced adherence interventions.

RESULTS

- Between March and November 2025, 592 children and adolescents aged 1-19 years were enrolled. The median age was 15 years (IQR 10.4-17.9). The median time on DTG was 3.5 years and median VL at enrolment was 6,028 copies/ml. Most participants, 436 (74%) had been switched from another regimen to DTG, with 225 (52%) being a protease inhibitor-based, and 210 (48%) being non-nucleoside reverse transcriptase inhibitor-based. Majority of participants, 378 (64%) had more than one prior high VL.
- All participants received at least one enhanced adherence intervention, 573/592 (97%) received 2 and 510 (86%) received 3 or more.
- At the time of reporting, 496 (84%) had received a month-3 milestone and viral load results were available for 378/496 (74%). Of these, 222/278 (59%) had VL <200 copies/ml. Suppression was lowest (58%) in the age group 10-19 years.
- Drug resistance test was done for 66/104 (64%) of those with VL≥ 1000, results were available for 55/66 (83%) and 15/55 (27%) had major DTG-associated DRMs.
- Two participants aged 15-19 years died before the month-3 milestone, one from Kaposi Sarcoma and the other from Pulmonary TB.







CONCLUSIONS

- This study found high rates of persistent viraemia in children and adolescents failing DTG in-spite of enhanced adherence interventions.
- The study highlights the need for further research on interventions for the pediatric population with DTG failure.

ACKNOWLEDGEMENT

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PLAIN LANGUAGE SUMMARY

After 3 months of follow up of children with high viral loads (above or equal to 1000 copies/ml) while on dolutegravir, high rates of up to 41% failed to suppress the virus to less than 200 copies/ml despite adherence counselling interventions.