High acceptability and preference for pediatric dolutegravir 10mg among patients in Nigeria at 1- and 6-month follow up, an observational study

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Background:

Nigeria is an early adopter country of the generic formulation of pediatric dolutegravir 10mg (pDTG) that became accessible in December 2020, and introduced pDTG with operational research in 2021. Prior to pDTG introduction, the preferred first line ART for children was lopinavir/ritonavir-based regimen. The National Guidelines for HIV Prevention Treatment and Care was revised in 2020 and recommend dolutegravir (DTG) based regimen as the preferred first-line antiretroviral therapy (ART) among children <20kg. This study aims to assess the acceptability and preference of pDTG among patients newly initiated or transitioned to the drug. Findings from the study were used to guide national scale-up.

Methods:

Pediatric patients weighing >3kg and <20kg were enrolled between September and December 2021 in 7 ART sites across 7 states (Akwa-Ibom, Benue, Cross river, Lagos, Plateau, Rivers and Sokoto). Study participants who attained 20kg were transitioned to the DTG 50mg formulation and discontinued from the study.

Acceptability and experiences were assessed through surveys conducted with patients and their caregivers as respondents at 1 and 6 months following pDTG initiation using a structured questionnaire. Participants were asked about side effects, ease of administration, and regimen preferences. Data from 1- and 6-month follow-ups were analyzed for frequencies and trends using Microsoft Excel. The patients' viral load outcomes were also analyzed for statistical significance using chi square.

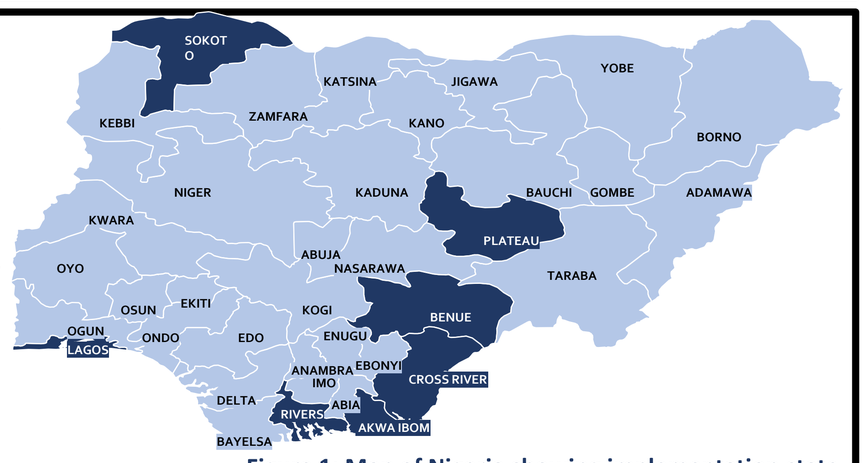
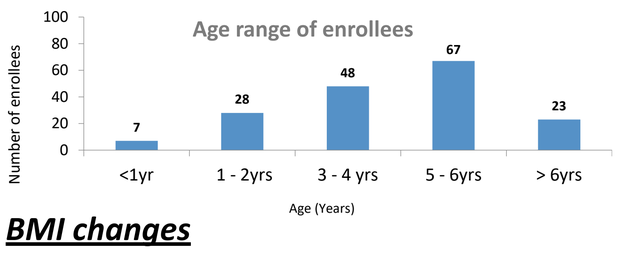
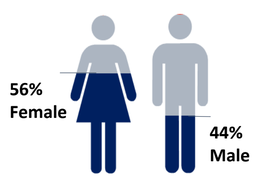


Figure 1: Map of Nigeria showing implementation state

Results:

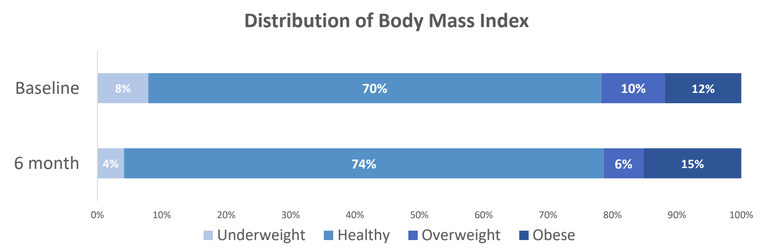
The study enrolled 180 patients and the mean age was 4.7 years, with 91% being treatment experienced.





BMI changes

The proportion of underweight children was higher at baseline (8%) than at month 6 (4%).

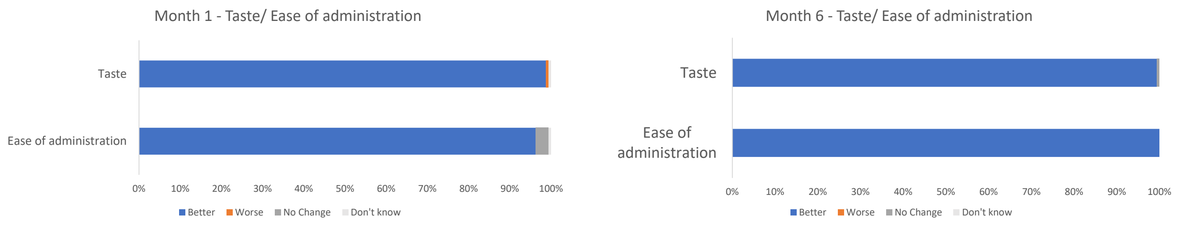


Regimen preference

At month 1, 99% of the treatment experienced respondents preferred the pDTG-based regimen to their previous regimen, this increased to 100% at month 6.

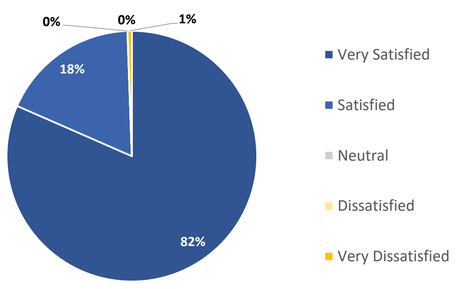
Taste/ Ease of administration

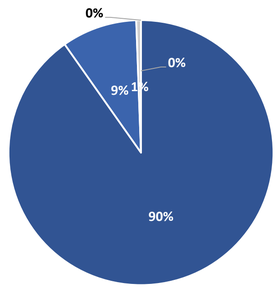
At month 1 and 6, 99% of respondents reported that pDTG tastes better than their previous regimen. At month 1, 96% of respondents reported that pDTG was easier to administer, this increased to 100% at month 6.



Satisfaction on current pDTG-based regimen

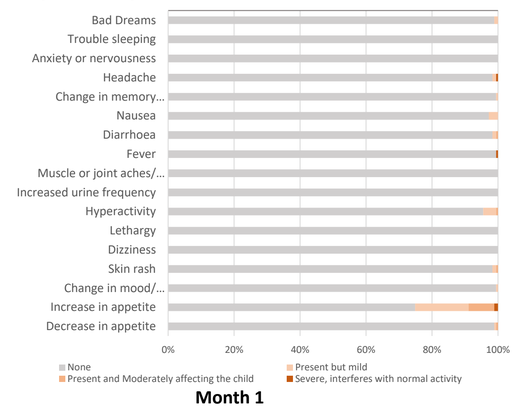
99% of respondents at both months 1 and 6 were satisfied or very satisfied with their pDTG regimen.

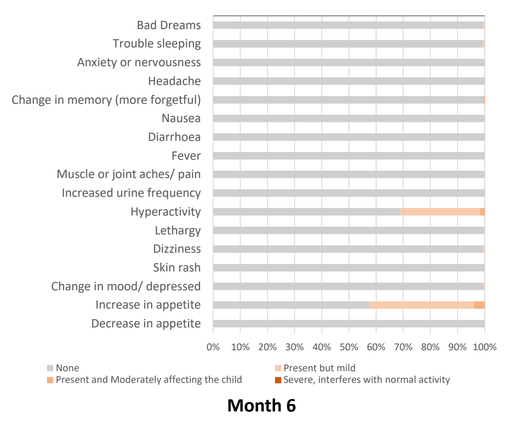




Self reported side effects

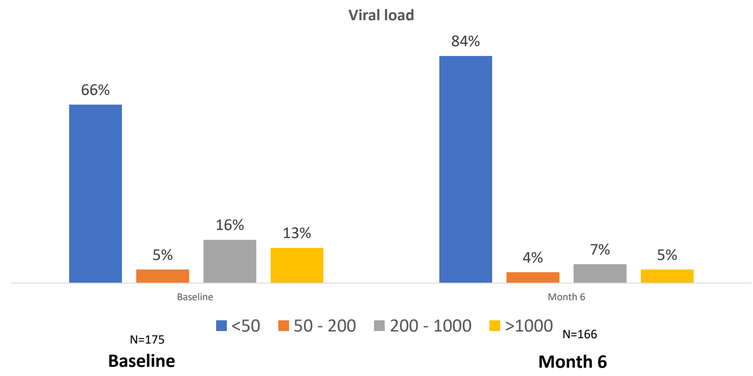
The most common side-effect reported at months 1 and 6 was increased appetite (25% and 43% respectively). 97% and 94% of respondents at months 1 and 6 respectively reported that the patient either gained weight appropriately or had no change in weight. Hyperactivity was reported by 29% of participants at month 6.





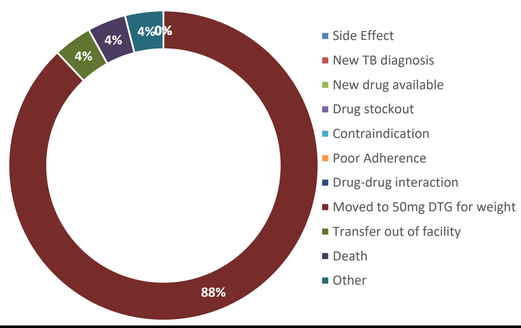
Patient's virologic outcomes

The percentage of participants who had viral load results <50 copies/ml increased from 66% at baseline to 84% at month 6. This increase was found to be statistically significant (p= <0.01)



Discontinuations

There were a total of 25 discontinuations from the study at month 6. 88% of discontinuations were moved to 50mg DTG for weight. Other reasons for discontinuation include death, withdrawal of consent and transfer out of the study facility.



Conclusion:

There is a high acceptability and preference for pDTG compared to LPV/r, with improved taste and ease of administration. The clinical outcomes of patient also improved while on pDTG. There was no toxicity-related discontinuations reported. With the favorable findings from the study to date, the National HIV Program has commenced scale-up of pDTG with an emphasis on pharmacovigilance. Further follow-up at 12 months will provide more evidence of pDTG's impact.

PRESENTED AT IAS 2023 – the 12th IAS Conference on HIV Science