Pediatric Dolutegravir is Highly Preferred by Patients/Caregivers in Nigeria and Uganda at One-Month After Initiation

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Background

The pediatric formulation of the antiretroviral drug dolutegravir (pDTG-10mg) became available for children-living-with-HIV (CLHIV) weighing between 3kg - <20kg in 2021. This strawberry-flavored dispersible drug taken once daily is expected to optimally improve the treatment outcomes of this vulnerable population. The **Transitioning children to Optimal Regimens of Paediatric Dolutegravir (TORPEDO)** study was developed in preparation for widespread national adoption of pDTG, stakeholders are learning from early adopter sites to ensure successful and efficient rollouts.

Understanding the experiences of patients and caregivers early on after initiation allows facilities and programs to systematically learn about and address concerns that are affecting the recipients of pDTG and may inhibit the successful future roll out of pDTG.

We are presenting **1-month findings from patients/caregiver surveys**. Future presentations will include additional follow-up periods and data sources.

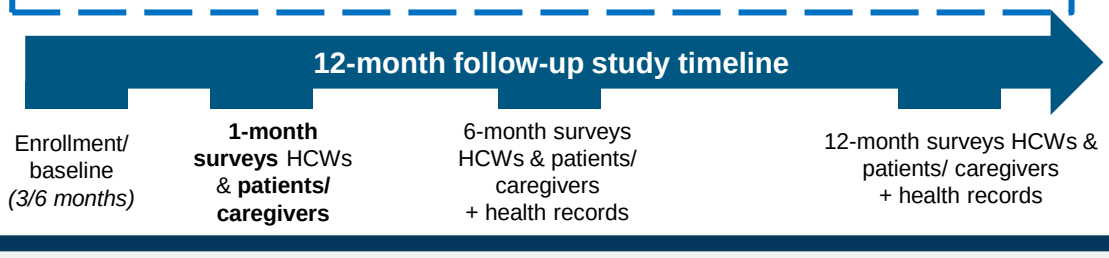
Methods

Study population: Pediatric patients in the study sites and between 3-<20kgs were eligible for inclusion.

Design: Mixed methods study design with 12 months of follow up. Data collection include: Baseline focus group discussions, trained HCW self administered surveys, patient/ caregiver interviews and patient health records collection including viral load/ lab monitoring, side effects and serious adverse events, discontinuations, and weight/ height

Sites: There are 13 sites in the study, 7 in Nigeria, 6 in Uganda

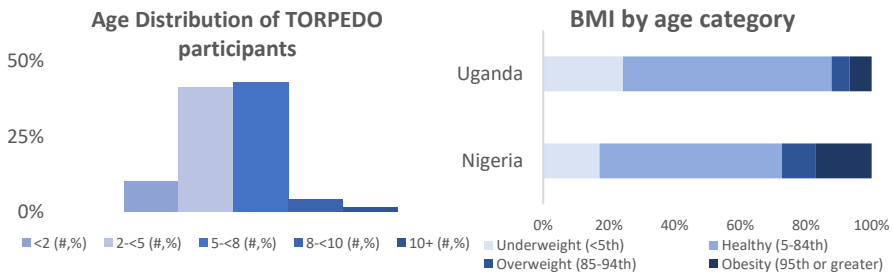
Survey: Administered during regular visit by health care workers and responded by either the patient, or the caregiver if the patient was not able to respond



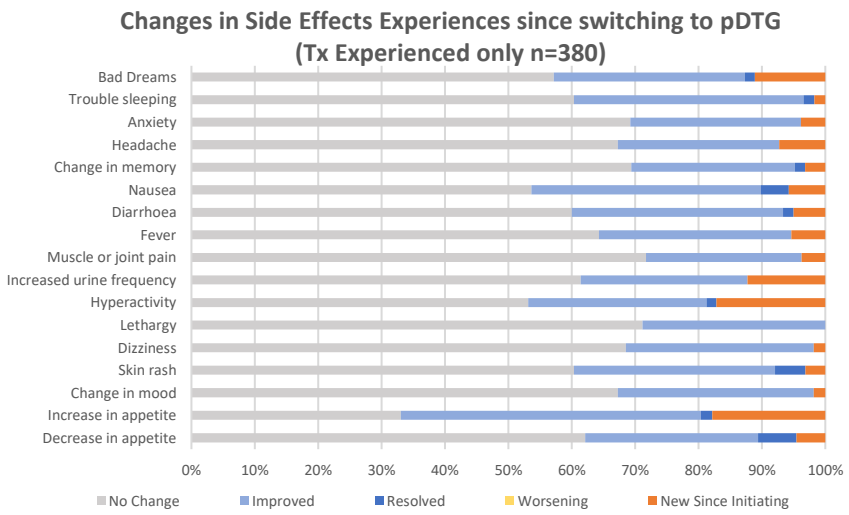
Results:

Baseline patient statistics

405 children were enrolled in the study between October 2021 to March 2022 (180 in Nigeria and 225 in Uganda): 49% were male and 94% were treatment experienced – mean time on treatment was 3.2 years, of which most (98%) were switched from a ritonavir boosted lopinavir regimen that was tablets (83%) or pellets (16%). The average age was 5 years old.

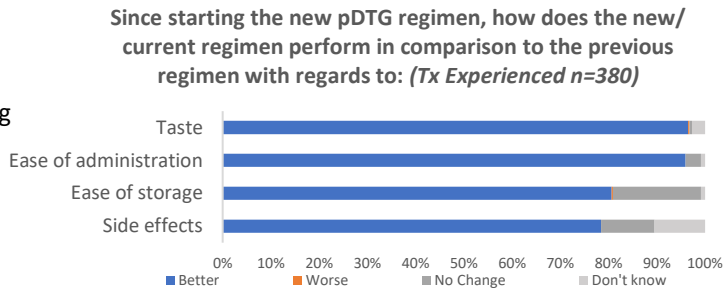


Observations of side effects with pDTG

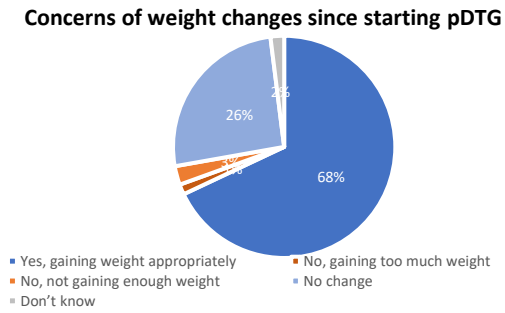


Observed experiences with using pDTG

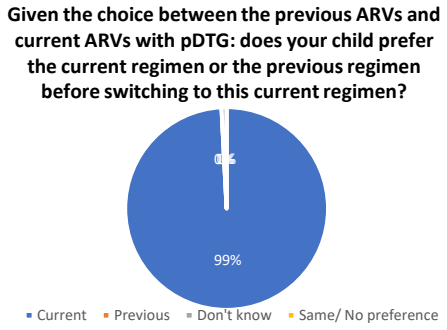
- Improved taste and ease of administration were the most frequently mentioned as being 'better' with pDTG compared to previous pediatric ARV regimens.

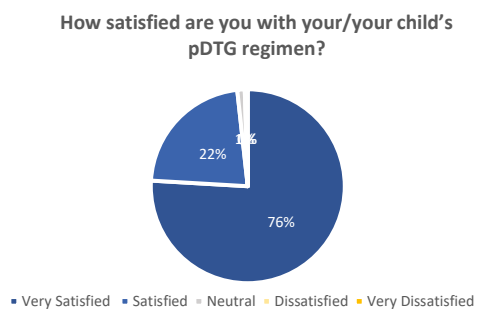


- When asked about experiencing side effects, 'increase in appetite' was the most frequently mentioned with 23% have some level of experience. However, weight gains were not a major concern:



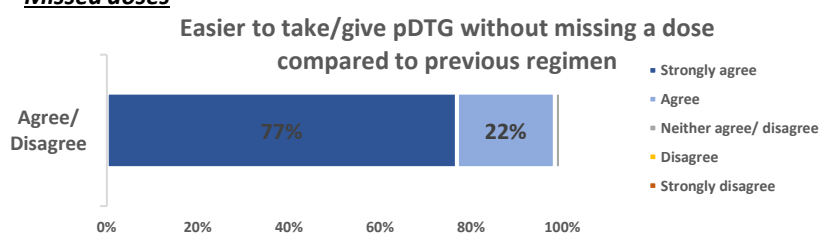
Satisfaction and Preferences of using pDTG





Results (continued):

Missed doses



"She is very happy to take the drugs unlike before." – caregiver in Nigeria

"Child told [me] that he likes this new drug because it's sweet and now drug is just once a day" – caregiver in Nigeria

Conclusions and Limitations

Conclusions:

- There is a strong preference for the pDTG based regimen compared to the previous regimen, which were mostly LPV/r based; finding show this is mostly due to improved taste and ease of administration.
- While increase in appetite was the most frequently mentioned side effect since starting pDTG, this is not concluded as a negative outcome based on the surveys that showed many of the respondents reported this as "improved" and subsequent questions of weight gains were not a concern.
- Fewer missed doses with pDTG is expected to lead to improved viral suppression and health outcomes.

Limitations:

- Surveys were administered by facility HCW which may bias responses.
- Most of the survey responders were the caregivers and not the patients directly responding.
- Further follow-up is needed to better understand longer-term effects of pDTG on patients' acceptability and health outcomes.

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