Outcomes from the Transitioning children to Optimal Regimens of Paediatric Dolutegravir (TORPEDO) study at 6 months in Benin, Nigeria, and Uganda

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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 key outcomes of the clients over time and the experiences of the health care workers that are administering pDTG 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 **6-month findings from client outcomes and health worker surveys**. Future presentations will include follow-up periods and data sources.

Methods

- **Study population:** Pediatric patients in the study sites and between 3-<20kgs were eligible for inclusion (or greater than 20kgs if they can't swallow, in Benin and Uganda only) **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 19 sites in the study,6 in Benin, 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

12-month follow-up study timeline

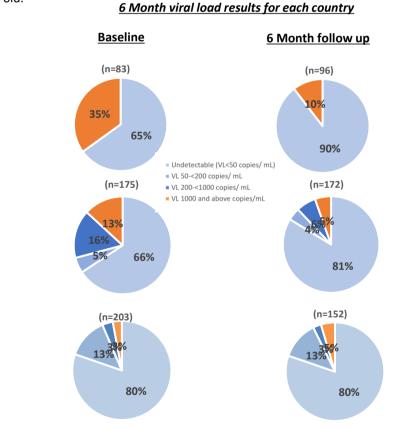
Enrollment/ baseline (3/6 months) 1-month surveys HCWs & patients/ caregivers

6-month surveys HCWs & patients/ caregivers + health records 12-month surveys HCWs & patients/ caregivers + health records

Results:

Client statistics

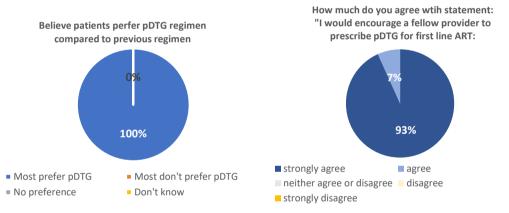
514 children were enrolled in the study between October 2021 to June 2022 (105 in Benin, 180 in Nigeria, and 229 in Uganda): 51% were male and 94% were treatment experienced on treatment 6+ months prior to initiating pDTG – mean time on treatment was 3.2 years. Most (94%) were switched from a ritonavir boosted lopinavir regimen that was tablets (83%) or pellets (14%). The average age was 5.2 years old.



Health Care Workers Observations

There were 89 respondents between April 2022 and June 2022 – 10% from Benin, 61% from Nigeria and 29% from Uganda. Most, 54% were physicians, 17% were nurses, and 11% clinical officers. 91% had 5+ years in health care and 79% 5+ years with HIV/AIDS

Preferences of using pDTG



There was high approval for prescribing pDTG and all respondents believe their clients prefer pDTG compared to previous regimen options.

Experience with prescribing pDTG

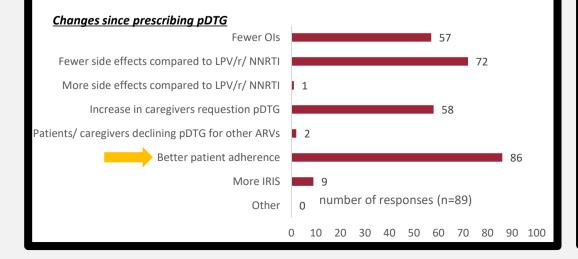
Respondents were asked an open ended question to share their experience with prescribing pDTG. The most frequent response, over 2/3 of respondents said they have seen improved weight gain and improved adherence for their patients:



"pDTG is just "IT" Adherence, Suppression and ease of administration. Just "IT" " – HCW in Nigeria

"Because the children's appetite is better, added weight and better adherence is being experienced." – HCW in Uganda

Results (continued):



Conclusions and Limitations

Conclusions:

- There is a strong preference for the pDTG based regimen compared to the previous regimen, from the study health care workers;
- Improved adherence and fewer side effects were also noticed.
- Viral load results improved, with more clients being undetectable and fewer having greater than 1000 copies/mL at 6 months in Benin and Nigeria.
- Uganda baseline viral load was higher than the other countries and did not see the same increase at 6 months.

Limitations:

- Surveys were self administered by the HCW.
- Viral load results were analyzed as a cross section and missing results may lead to not the same people at each time point.
- Further follow-up is needed to better understand longer-term effects of pDTG on patients' acceptability and health outcomes.





This work was made possible through the support of Unitaid.

The project also acknowledges all the participants at each of the study facilities in Benin, Nigeria, and Uganda