Experiences From Early Introduction of Paediatric Dolutegravir 10mg (pDTG) in Malawi

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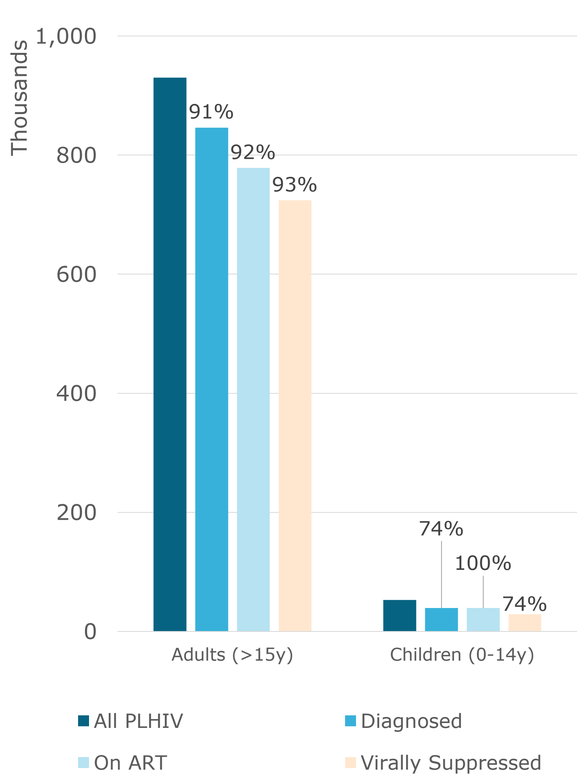
BACKGROUND

At the end of 2020, Malawi achieved 91-94-94 progress against the 90-90-90 fast-track targets for HIV treatment by 2020 (UNAIDS data, 2021). As such, the Antiretroviral Therapy (ART) coverage in Malawi was at 86%, relative to the global coverage rate of 73%.

Despite the remarkable scale-up of HIV treatment in Malawi, paediatric ART coverage (73%) lagged that of adults (86%) in 2020, and the annual mortality rate in children living with HIV (CLHIV) was nearly three times that of the adult population (~3% versus ~1%, respectively).

Between 2020-2021, viral load suppression (VLS) outcomes remained lowest in children (74%) compared with 93% in adults (MPHIA 2020/21).

Malawi HIV Treatment Cascade - 2021



The low VLS amongst CLHIV has largely been attributed to a lack of optimal regimens for HIV treatment, with children in Malawi taking either LPV/r- or NVP-based regimens until June 2021.

DESCRIPTION

To address treatment disparities between age groups, Malawi was among the early adopters of the novel, child-friendly, generic pediatric dolutegravir 10mg dispersible and scored tablets (pDTG).

Although the DTG 50mg formulation has been accessible to children ≥20kg since 2018, pDTG expands access to more optimal DTG regimens for the most vulnerable children <20kg in weight.

In June 2021, pDTG was rolled out by the Ministry of Health (MoH) as the preferred pediatric first line (1L) ART regimen through a phased introduction, guided by an interim policy update to existing guidelines.

The phased approach targeted ~7,000 children above four weeks of age, weighing between 3 - 19.9 kgs for immediate transitioning before the end of 2021, and a total of ~11,444 children by December 2022.

MoH conducted nationwide site visits between July and December 2021 in order to assess early implementation with an intention to document insights on patient safety, product experience, health care worker (HCW) capacity, and support troubleshooting ahead of national scaleup.

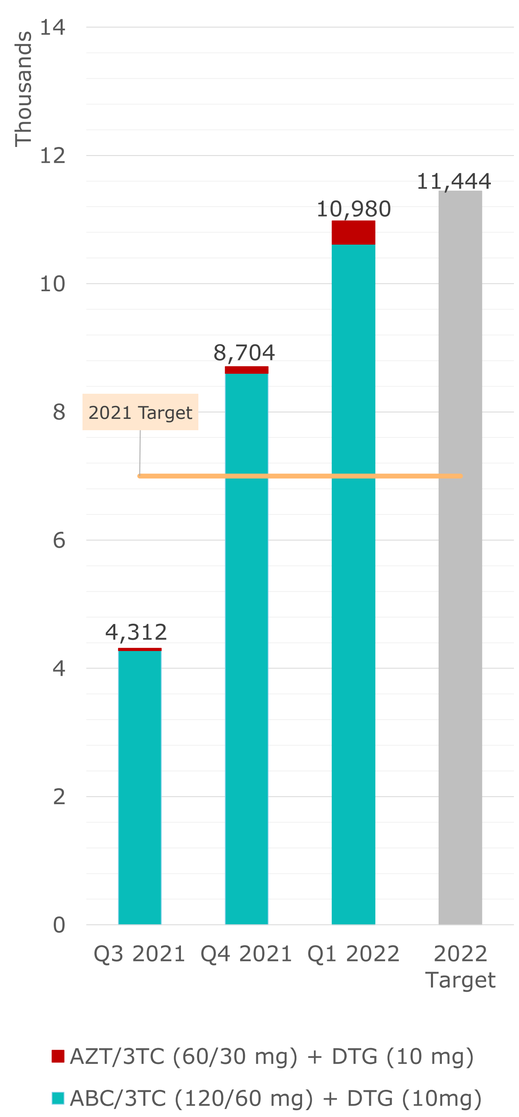
OBJECTIVES

1. To understand rollout progress for pDTG initiations and transitions according to defined targets.
2. To collect baseline data on pre-transition viral load suppression rates.
3. To monitor commodity inventory and actual dispensation.
4. To collect feedback on product experience and adverse events reported as part of enhanced monitoring.
5. To generate early lessons to inform scale-up.

RESULTS

Uptake of pDTG has been assessed at the end of each quarter following the first product arrival in June 2021 and is seen to be on an upward trend.

pDTG Uptake, By Quarter



- The majority of pDTG enrollments are seen for ABC/3TC (120/60 mg) containing regimen, settling at ~96.7% of enrolments by Q1 2022.
- The remainder of children on pDTG are on the backbone of AZT/3TC (60/30 mg).

pDTG uptake has been rapid, as children enjoy the taste and caregivers find it easy to administer

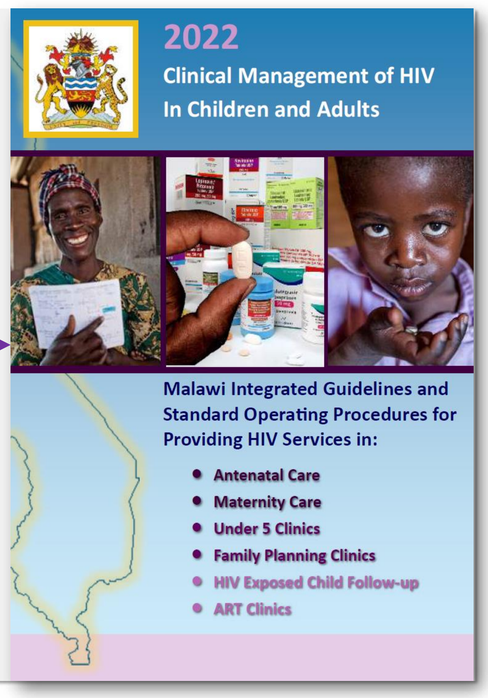
As of March 2022:

- HIV guidelines recommend DTG for PLHIV >3kgs.
- All districts have been trained on pDTG updates.

Weight (kg)	Regimen	Conditions / Instructions	ART patient card
Under 3kg	-	No routine ART. Consult DHA in special cases.	
3 – 19.9kg	**15PP**	Use paediatric ABC/3TC+ paediatric DTG 10mg.	paediatric
20.0 – 24.9kg	**15PA**	Use paediatric ABC/3TC tablet + adult DTG 50mg.	paediatric
25.0 - 29.9kg	**15A**	Use adult ABC/3TC tablet + adult DTG 50mg.	adult
30kg +	**13A**	TDF/3TC/DTG 300/300/50mg	adult

99% *of CLHIV (0-14years) above 3kgs are accessing DTG in Malawi.*

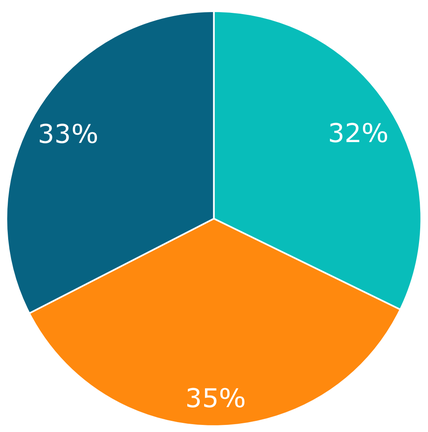
81% *of all CLHIV (0-14 years) are currently on ART across >750 ART sites.*



Pre-transition Viral Load

- November 2021 data confirmed that HCWs did not consider VL status a precondition to pDTG transition:
  - nearly a third of CLHIV on ART were transitioned with undocumented VL results,
  - just under a third transitioned while doing well on their current regimen, and
  - the remaining children were transitioned while virally unsuppressed.

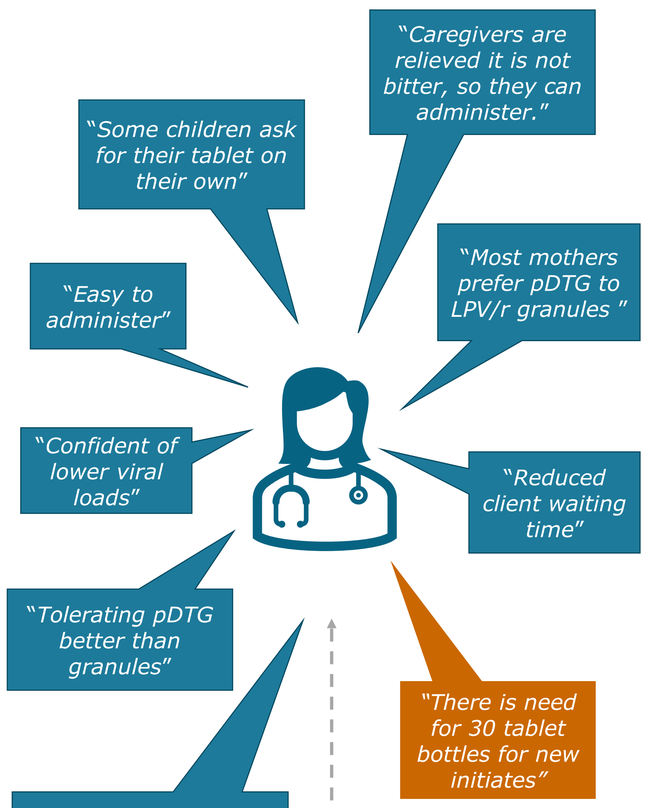
Pre-Transition Viral Load Status by November 2021 (n=1,853)



RESULTS

Data showed that HCW perceptions of pDTG are mostly positive, with calls to have smaller pack sizes for smaller children and new initiates.

HCW and Caregiver Experiences



- Caregiver experiences shared by HCWs were positive, with no reported side effects.
- Pharmacovigilance systems in place for continued monitoring.

LESSONS

- Early monitoring showed VL result availability was not a barrier to pDTG access, consistent with WHO messaging that while VL monitoring remains a good practice, it is not to be considered a precondition to transitions.
- By December 2021, 8,704 children were on pDTG out of the targeted 7,000 representing a 124% transition rate for 2021. This means ~60% of the 2022 transition target was achieved ahead of schedule.
- By March 2022, 10,980 children were on pDTG against a target of 11,444 thus reaching ~95% of the 2022 transition target.
- An effective rollout was made possible through stakeholder collaboration and cooperation, site-level orientations, site visits, distribution of healthcare worker materials, and community support.
- HCWs relied on interim policy guidance and regular clinical mentorship. Early pDTG insights were critical to 2022 HIV guideline revisions.
- During the COVID-19 pandemic, a staged transition ensured a stable supply chain.
- Regular site visits ensured quick identification of over-consumption to prevent stockouts through product re-distribution as needed and onward order placement.
- Due to easier tolerability, administration, and palatability, caregivers, CLHIV, and HCWs in targeted sites preferred pDTG over LPV/r.

CONCLUSIONS

Malawi was one of the first countries to roll out pDTG nationwide. Better clinical profile and tolerability of pDTG are expected to improve VLS rates.

1. pDTG is a very promising regimen for children 3 -19.9 kgs.
2. pDTG is well tolerated, easy to administer, and has a pleasant taste, thus bolstering adherence.
3. The 10mg formulation for DTG has expanded DTG access to nearly all children in care in Malawi, therefore gaps between children and adults in mortality rates are expected to close.

Malawi's experience as a best practice for rapid adoption of child-friendly treatment can be adopted by national HIV programs.

ACKNOWLEDGEMENTS

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