

Pediatric Dolutegravir Introduction for Children Living with HIV (CLHIV) in Zimbabwe: Lessons from Early Adopter Sites

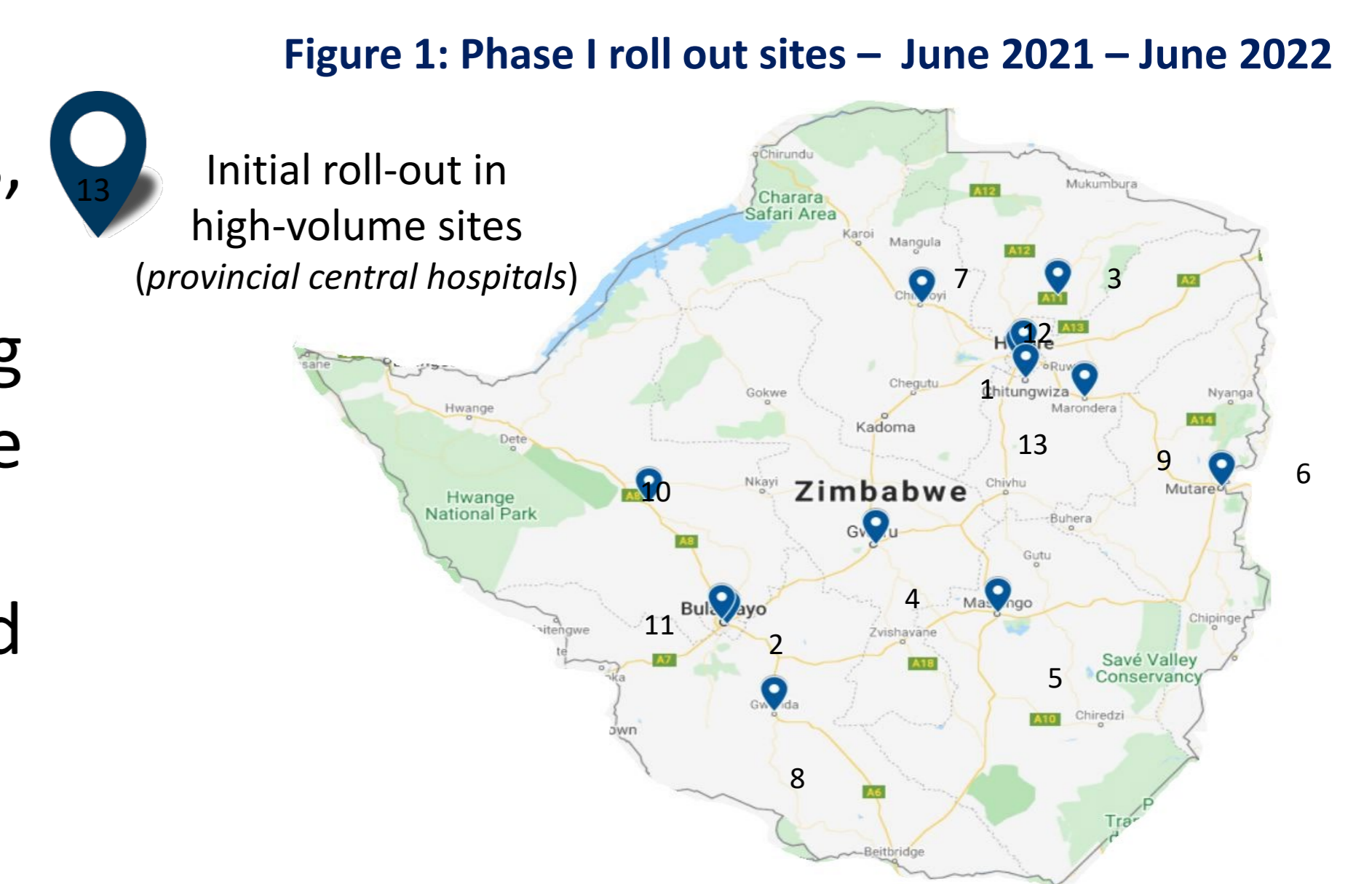
Charity Giyava¹, Thandiwe Chirindo¹, Nicole Kawaza¹, Alexio Mangwiro¹, Chipso Chimhundu², Angela Mushavi³, Precious Andifasi³, Justice Nyakura³, Brian Komtenza³

¹Clinton Health Access Initiative, HIV Access Program, Harare, Zimbabwe, ²Clinton Health Access Initiative, HIV Access Program, Boston, USA,

³Ministry of Health and Child Care, PMTCT, Harare, Zimbabwe

BACKGROUND

- Zimbabwe has 49,640 CLHIV on ART of which 43.19% take suboptimal legacy formulations.
- National policy revisions in 2018 enabled CLHIV <20kg to access more optimal Dolutegravir (DTG) regimens, but the lack of an affordable formulation for CLHIV ≤20kg still presented barriers for younger children.
- The availability of the generic pediatric DTG 10mg dispersible and scored tablets (pDTG) for CLHIV weighing 3-20kg above 4 weeks of age since late 2020 expanded access to more optimal regimens, with the potential to improve adherence and clinical outcomes.
- Supported by CHAI, the MoHCC planned a phased rollout of pDTG in 2021 to generate experience and lessons before national scale-up.
- Phase I consisted of 13 high-volume sites targeting 1,766 CLHIV on regimens by December 2021.



METHODS

- A **transition plan** was compiled through iterative stakeholder consultations to guide implementation, covering pDTG eligibility, dosing, administration, pharmacovigilance, and vigilant uptake monitoring strategies referred to as 'enhanced monitoring'.
- Enhanced monitoring** was designed to track key indicators such as viral suppression rates, adherence to clinical dosing guidance, regimen appropriateness, adverse events (including weight gain), and product uptake.
- Quantification of pDTG** for early adopter sites relied on 2018 weight-band assumptions (WBA), as the assessments necessary to update the WBA in 2020 were delayed due to COVID-19 disruptions.
- Implementing partners (IPs) were mobilized to support procurement, clinical mentorship, and uptake monitoring.
- pDTG eligibility memo** was developed and distributed to Phase I sites to guide HCWs in transitioning and initiating children to pDTG.
- Facility-level orientations** immediately followed product arrival in June 2021, reaching 246 HCWs nurses, doctors, pharmacists, and counselors.
- Support visits** were tailored to provide additional support to facilities lagging in transitioning children to pDTG and improve uptake in the Phase I sites.
- Continuous on-the-job training and mentorship** for all nursing staff and new doctors assigned to various facility access points was conducted for improved confidence to initiate and transition all eligible children onto pDTG 10mg. Pediatric wards, Opportunistic Infection (OI) departments and, Family and Child Health (FCH) wards were especially targeted for capacity strengthening.
- Counselling job aids** were developed to guide HCWs in explaining to caregivers the benefits of pDTG, and overall experience with DTG use in adults.

RESULTS

- Despite rapid product distribution and capacity-building efforts, early monitoring visits signalled a slow pDTG transition, missing original scale-up timelines by three months.
- Key bottlenecks identified included unavailability of recent viral load (VL) results, long turnaround of results leading to clinicians' hesitancy to transition children without results and children not presenting to facilities for clinically guided transitions.
- Other bottlenecks included HCW attrition and COVID-19 lockdown restrictions affecting healthcare access.
- In response, updated VL guidance, mentorship approaches, and materials for HCWs and caregivers were disseminated in collaboration with clinical IPs to strengthen messaging and follow-up.
- Community outreaches encouraged the presentation of CLHIV for clinical review and accurate weight-guided transitioning to pDTG.
- Once travel restrictions eased in late 2021, a follow-up WBA showed 20.2% of the CLHIV being <20kg, relative to the 31.1% (2018) used for introduction planning. These weight band changes therefore further contributed to underconsumption at the time of introduction due to overestimation of the under 20kg population.
- For course correction, the WBA observations informed re-forecasting of pediatric antiretroviral medicines in February 2022 and pDTG redistribution.
- These concerted efforts yielded increased CLHIV transitions from 15% (n=257) in September 2021 to 52% (n=920) of the scaleup target by March 2022.

Figure 2: Changes in pediatric weight band distribution in Zimbabwe (2016-2021)

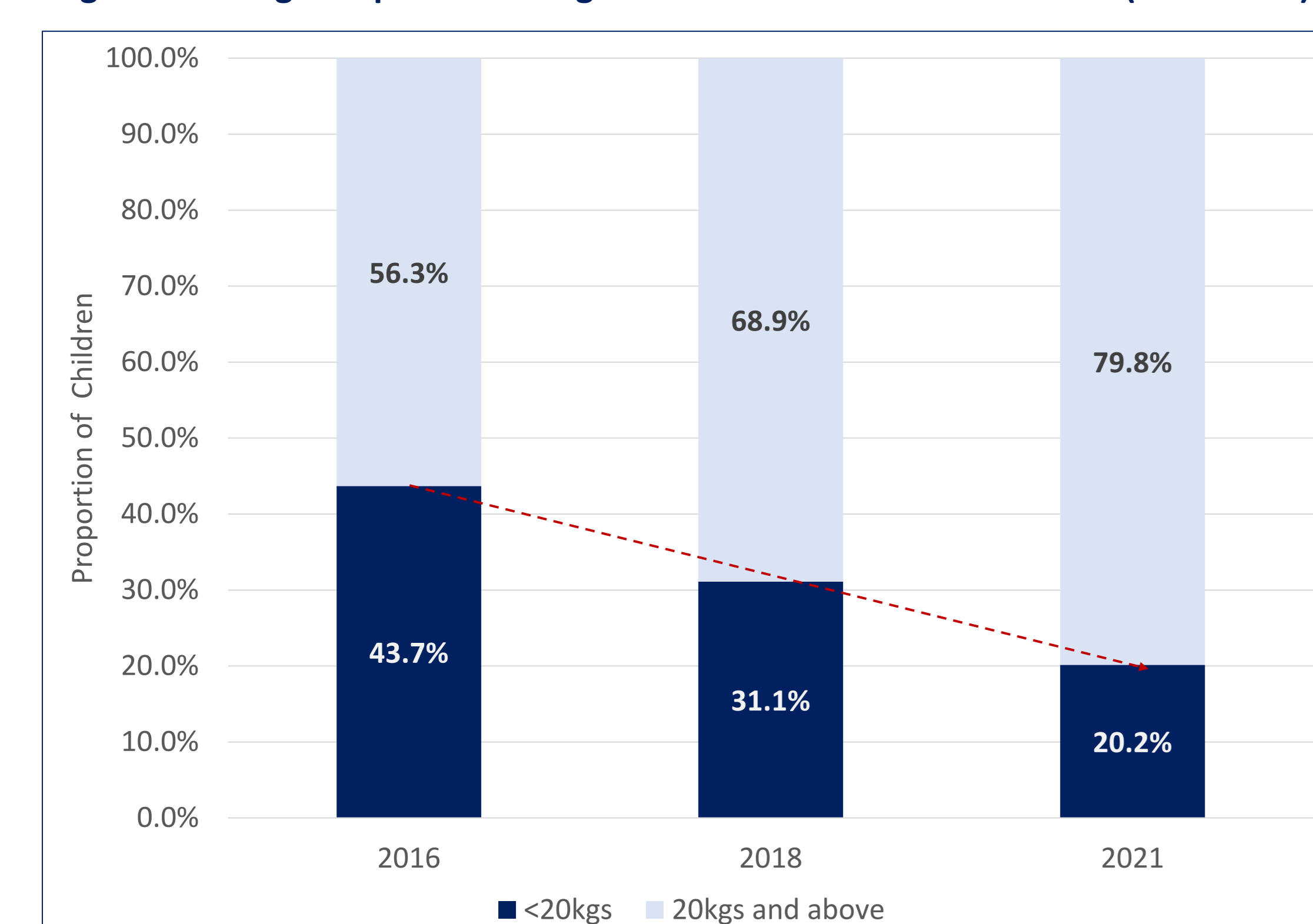


Figure 3: Site level progress towards initiating 70% of eligible children on pDTG (March 2022)

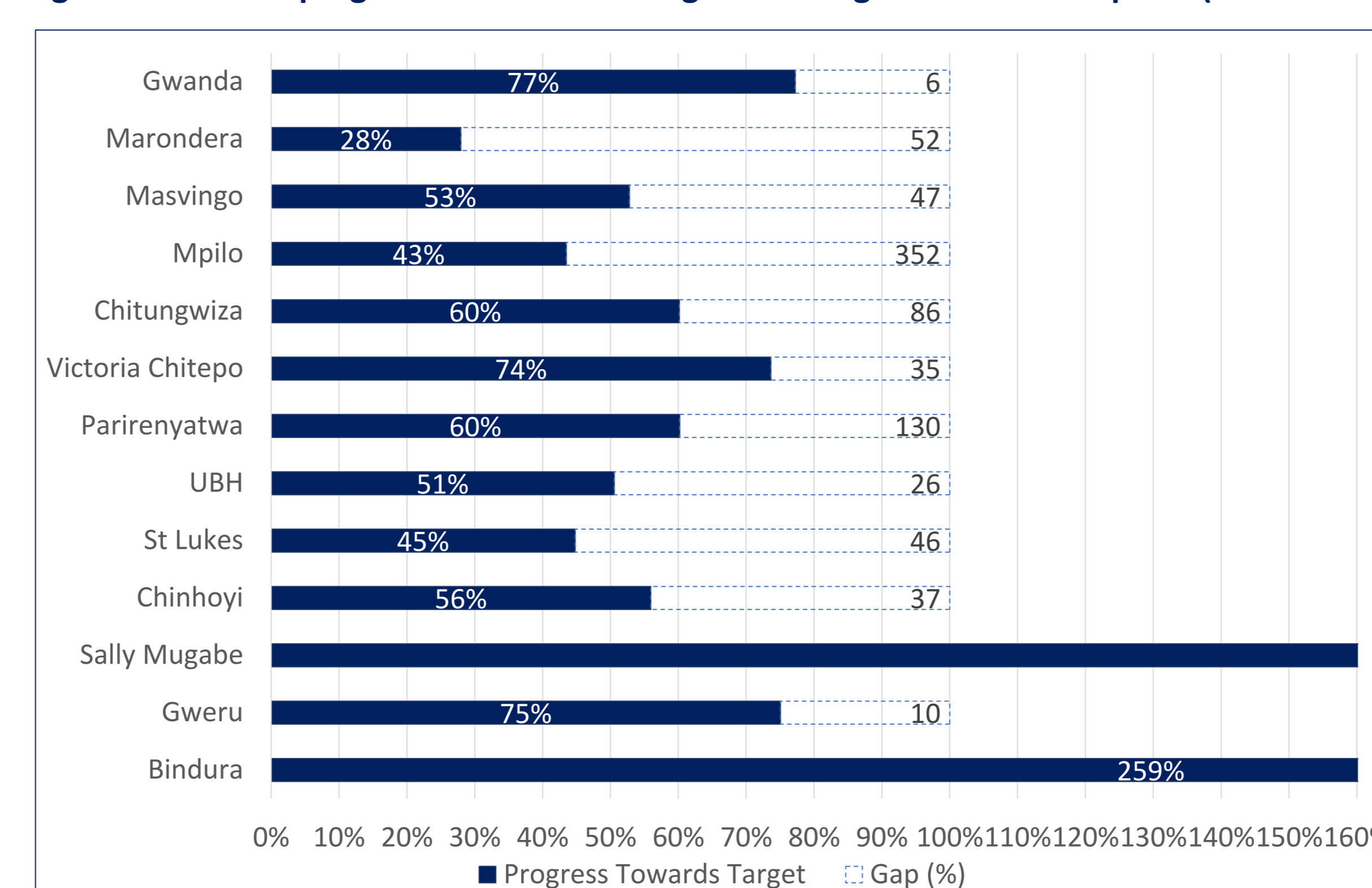
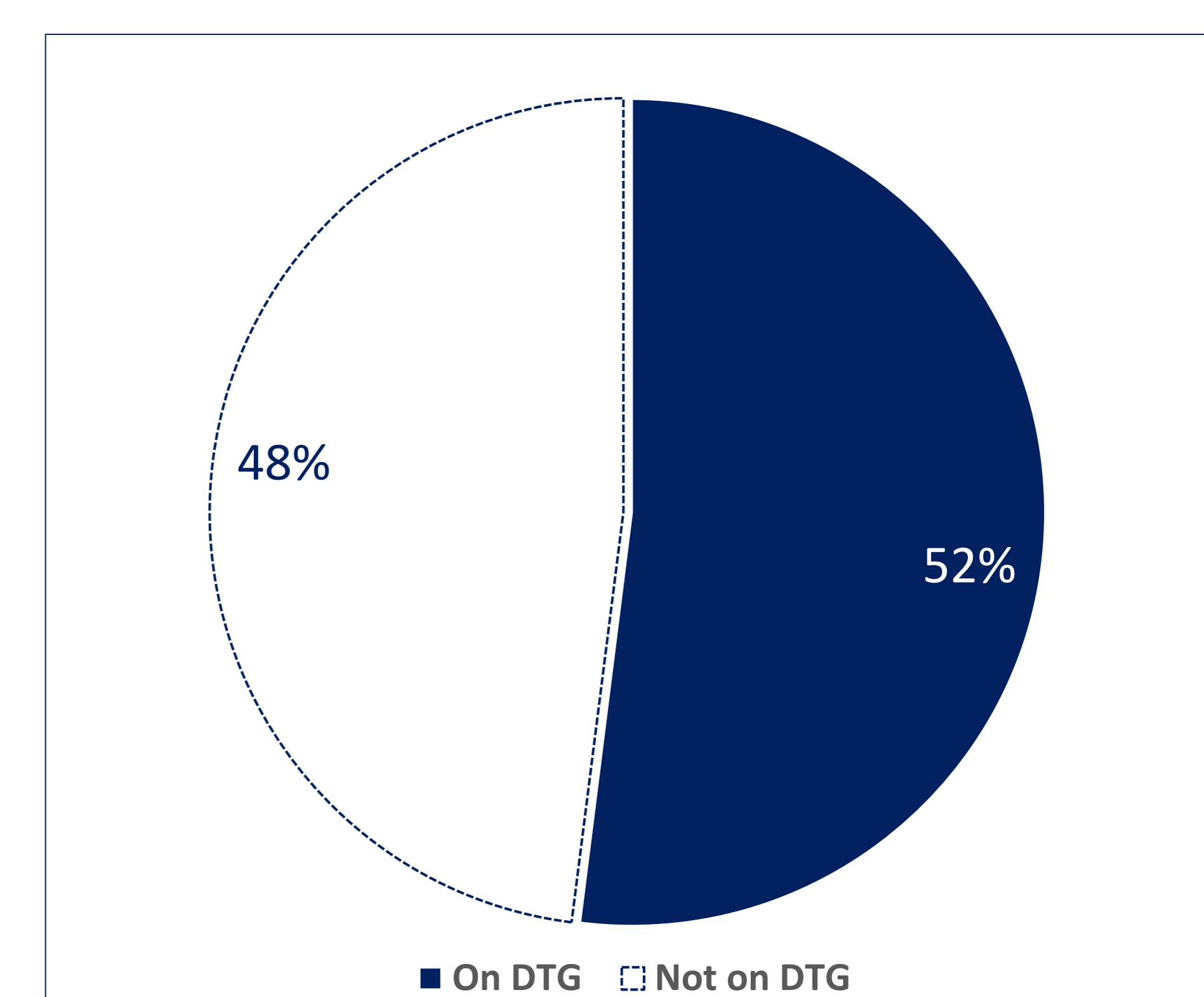


Figure 4: Phase I progress towards reaching the Phase I target (n=1,766)



CONCLUSIONS

- Active stakeholder collaboration and enhanced monitoring have been critical to pDTG introduction and rapid mitigation of unexpected transition bottlenecks, thus providing lessons at a smaller scale ahead of national rollout.
- Robust M&E systems are crucial to sustain target setting for regimen rollout and tracking uptake at facility level.
- The phased introduction of pDTG highlighted the need to continuously provide on-the-job training for HCWs to reinforce good practice of transition and pre-transitioning VL guidance.