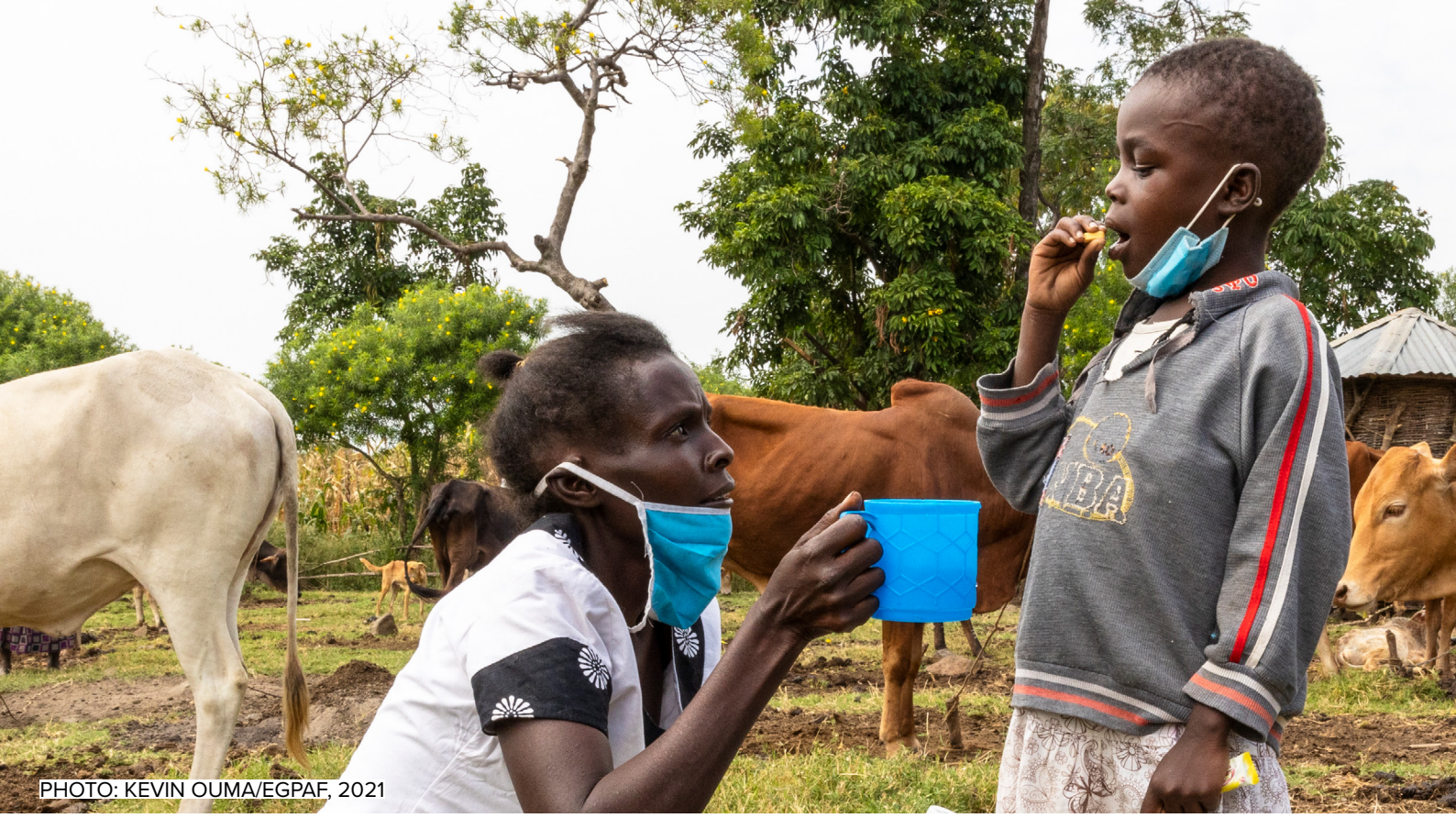

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GAP·f Global Accelerator for Paediatric formulations WHO Hosted Network

PAEDIATRIC DTG IMPLEMENTATION CONSIDERATIONS FOR NATIONAL PROGRAMMES

APRIL 2022

CDC Centers for Disease Control and Prevention

Clinton Health Access Initiative

Elizabeth Glaser Pediatric AIDS Foundation
Fighting for an AIDS-free generation

medicines patent pool

Access Campaign
Médecins Sans Frontières

PATA

PEPFAR

USAID
From the American People

World Health Organization

Background

In mid-2021, national HIV programmes began to transition treatment for children living with HIV dolutegravir (DTG) 10 mg scored, dispersible tablets, also known as paediatric DTG (pDTG). Rapid introduction and rollout of pDTG is a priority to implement the World Health Organization (WHO) guidelines and ensure that children living with HIV receive the best available first- and second-line HIV treatment as soon as possible. It is important to note that a single pDTG switch should occur irrespective of the availability of a viral load (VL) test/result, or the value of the latest VL result, while maintaining or optimizing children on an abacavir/lamivudine (ABC/3TC) backbone. Currently, over 30 countries have plans for adoption and rollout of pDTG.

Child's Weight	No. of pDTG 10mg Daily Tablets *90-count bottle*	No. of ABC/3TC 120/60 mg Daily Tablets *30- or 60-count bottle*
3 to 5.9 kg	0.5	1
6 to 9.9 kg	1.5	1.5
10 to 13.9 kg	2	2
14 to 20 kg	2.5	2.5

90-tablet Packaging Overview

Experiences from pDTG early adopter countries have highlighted some implementation and administration complexities surrounding pDTG's 90-count bottles. The challenges are primarily associated with dispensing pDTG to children weighing less than 10kg, because the 90-count bottle equates to a four- to six-month supply for children who start pDTG at 3kg to 5.9kg and a two-month supply for children 6kg to 9.9kg. Multi-month dispensing (MMD) for children two years and older offers programmatic and cost savings benefits for patients and providers, including the opportunity to reduce exposure to COVID-19 by minimizing clinic visits. However, some healthcare providers may have difficulty in ensuring that caregivers adhere to one-month medical follow-up visits after initiation or transition to a pDTG-based regimen. Most children in the 3kg to 5.9kg weight band will move to the 6kg to 9.9kg weight band, and their dosage will need to increase from 0.5 to 1.5 tablets per day before the 90-count bottle is empty. Additionally, there may be concerns about the potential for monotherapy with pDTG due to the lack of alignment between the number of pills in the 30- or 60-count bottles of ABC/3TC and pDTG 90-count bottles. As a result, rebottling of pDTG has been considered as a potential strategy to address these concerns.

To ensure children are transitioned to pDTG safely and effectively, the GAP-f pDTG Task Team would like to offer the following considerations for national HIV programmes, implementing partners, and service providers.

Usage considerations for all scored, dispersible pediatric antiretrovirals (ARVs)[1]

- **Do not rebottle or repackage bottles of ARVs.** Tablets should remain in the original packaging to maintain the quality and stability of the product.

- **If included, retain the desiccant packet in each bottle.** If included, desiccants are necessary to maintain the stability and quality of the tablets in the bottle. Desiccant packets must remain in each bottle and should not be thrown away.

1 These recommendations have been developed based on implementation best practices as well as guidance from product manufacturers (Viatris [formerly Mylan]; Macleods)

- **Split tablets with dry, clean hands.** Unused half-tablets should be placed back into the bottle after they are split in order to ensure their stability. The half-tablet does not need to be given at the next dose. After they are split, unused tablets can be used at any time prior to the expiration date on the bottle, as long as the unused tablets remain in the bottle.

Implementation considerations

- **Policy alignment.** Align national MMD policies, guidelines, and information, education and communication (IEC) materials with implementation recommendations. As strategies for multi-month packaging of ARVs are adopted, it will be important to update national MMD policies – or release product-specific technical circulars – and ensure job aids for healthcare workers and caregivers align with the clinical support implementation considerations outlined further below.

- **Quantification, availability, and accurate dispensing.** In the context of pDTG introduction, it is important to ensure sufficient quantification of both pDTG and ABC/3TC. As strategies for managing 90-count bottles are adopted, it will be important for the Ministry of Health and key technical stakeholders to quantify and supply enough ABC/3TC to clinics in order to align with the planned dispensing of pDTG 90-count bottles. At the clinic level, a sufficient amount of medicine equivalent to, or in some cases greater than, the number of days between clinic appointments should be dispensed. In the context of pDTG, the full and equivalent amount of both pDTG and ABC/3TC tablets should be dispensed and explained to caregivers so that the child will never be at risk of receiving monotherapy. One strategy to avoid monotherapy is to ask caregivers to bring the bottles of ARVs back with them to the child's clinic visits to monitor adherence.

- **Clinical support provision.** Clinicians and community health workers should actively follow up with caregivers and children to ensure adherence to clinic visits regardless of the number of tablets dispensed at the previous visit. To closely monitor children on new HIV treatment, national programs can implement relevant, appropriate, and effective methods to regularly adjust weight-based doses and ensure adherence to clinic appointments. If feasible, clinical support implementation considerations include conducting:

    - Treatment preparation counseling with caregivers and providing a demonstration on administration

    - Home visits or phone calls at two weeks to ensure that caregivers can administer the drugs as instructed, to remind them of their next appointment, and to ensure they bring remaining tablets with them

    - Phone calls followed by home visits to caregivers if any clinical visits are missed

    - Reviews to ensure that pharmacy records, individual patient records, and messaging reinforce the need for caregivers to return for clinic visits and counseling.

For more specific resources and guidance to support pDTG introduction, visit the HIV New Product Introduction Toolkit.

ABOUT THE PDTG TASK TEAM OF GAP-f'S PRODUCT ACCESS AND TREATMENT DELIVERY (PATD) WORKING GROUP

The pDTG Task Team is a forum for coordination among partners involved in introduction of pDTG scored, dispersible tablets. The pDTG Task Team is a platform to share what partners are already doing, identify where work can complement each other and most importantly identify the gaps that need to be addressed and where GAP-f could help ensure that paediatric DTG can be scale-up as quickly as possible. Organizations participating in the pDTG Task Team include: Clinton Health Access Initiative (CHAI), Drugs for Neglected Diseases initiative (DNDi), Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Global Fund to Fight AIDS, Tuberculosis and Malaria, International AIDS Society (IAS), International Center for AIDS Care and Treatment Programs (ICAP), Médecins Sans Frontières (MSF), Medicines Patent Pool (MPP), Paediatric-Adolescent Treatment Africa (PATA), UNAIDS, UNICEF, US Agency for International Development (USAID), US Centers for Disease Control and Prevention (US CDC), US Department of State, World Health Organization (WHO).

ABOUT THE GLOBAL ACCELERATOR FOR PAEDIATRIC FORMULATIONS (GAP-f)

GAP-f is a WHO Network hosted within the Research for Health Department in the Science Division and was created to respond to the paediatric treatment gap. Following the resolution at the 69th World Health Assembly on promoting innovation and access to quality, safe, efficacious, and affordable medicines for children, GAP-f was conceived to build on and formalize the model developed within the HIV community to provide a sustainable mechanism that ensures that safer, more effective, and more durable paediatric formulations are developed and made available to children against an accelerated timeline. More information is available at https://www.who.int/initiatives/gap-f.

Signatory: This brief was developed by the GAP-f pDTG Task Team

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