

# TOOLKIT: TRANSITION TO PEDIATRIC DOLUTEGRAVIR (pDTG)



## L'Initiative is committed to combating pediatric HIV

Although significant progress has been made in the global HIV and AIDS epidemic in the past 20 years, the context for children and adolescents in terms of access to testing, care and treatment remains alarming: in 2020, only 54 per cent of 0-14-year-olds had access to treatment, compared to 74 per cent of those over 15.

The West and Central Africa region carries a particularly heavy burden; 30 per cent of new HIV infections occur in children and only 35 per cent are on treatment.

We have the tools needed to make a difference, so this is not an acceptable situation. L'Initiative shares continual reminders through its technical assistance work and the projects it supports, that as adults we need to redouble our efforts for the benefit of children.

■ **Prevention of mother-to-child transmission (PMTCT)** is a critical catalyst, and testing must be systematically offered to pregnant women who need to be successfully retained or re-engaged in the health system.

■ Access to **early child diagnosis** is a priority and the potential for widespread roll-out of GeneXpert type point-of-care testing must be capitalized upon. In 2022, we need to make the most of these platforms so that they can be used for early HIV testing.

■ Efforts are needed around **disclosure of HIV diagnosis**, by working with people experienced in community engagement, such as adolescent peer educators.

■ Finally, at a time when the powerful molecule DTG, now available in pediatric formulation, has been added to our arsenal of ARVs, we urgently need this to be available everywhere.

## Key messages

- The WHO recommends using DTG as the preferred first-line treatment for all adults, adolescents and children over four weeks of age.
- A new formulation of DTG 10 mg dispersible scored tablets has been approved by the stringent drug regulatory authority.
- This new formulation will allow children to have access to DTG, provided they weigh between 3kg and 20 kg, and for the WHO preferred first-line treatment regimen to be applied for all children living with HIV.
- For children weighing 20kg or more, DTG 50 mg monotherapy film-coated tablets are recommended in combination with abacavir (ABC) and lamivudine (3TC). For children weighing 30kg or more, a fixed-dose combination of tenofovir, lamivudine and dolutegravir is recommended.
- The transition to pediatric DTG will help to streamline treatment for children and adults, simplify scheduling and supply plans, and reduce treatment costs for children while providing the best available treatment to improve roll-out and treatment outcomes.

# TOOLKIT FOR PROGRAM EXPERTS



As part of L'Initiative's contribution to the collective effort, it has put together a range of documents in a toolkit for **program experts** working on pediatric HIV, and on the transition to pDTG in particular.

A description of all the tools can be found in the table on pages 3 and 4.

## 1\_Recommendations & transition plan

Materials to support making updates to documents that set out standards (recommendations, national strategic plans) and tools to assist with planning and implementing the transition to pDTG.

## 2\_Quantification & ordering

When new and more effective ART options, such as pDTG-based ART, become available in a country, the preferred approach is to ensure rapid transition to optimal products rather than prioritizing using up stocks of less effective products. Here you will find transition support tools to help estimate transition costs and help with order scheduling.

## 3\_Training & SOPs

The transition process involves programs anticipating and developing tools to help optimize treatment. In this folder you can access to materials to support the design and delivery of key messages and practical tools for clinicians, patient and caregiver groups, and staff working in hospitals. These key resources include things such as memos on

products, outlining their main characteristics and methods of use, practical tools, such as posters displaying graphic algorithms to support decisions around switching to new treatment, and training materials to ensure the new product is adopted effectively.

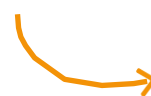
Follow this link to view or download a highly educational film for health workers:

<https://www.newhivdrugs.org/search?q=Pediatric+DTG+Overview+Video+for+Healthcare+Workers+%28English%2C+French%2C+Swahili%29>

## 4\_Library & other resources

This section includes broader information related to the results from clinical trials and other studies on access to ARVs for children living with HIV.

All the resources in this toolkit have been compiled into four zip files that can be downloaded from L'Initiative's website.





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### LIST OF TOOLS 1/2

	DOCUMENT	DESCRIPTION	SOURCE	TYPE	FR / EN
<b>RECOMMENDATIONS &amp; TRANSITION PLAN</b>	1_WHO_guidelines_eng	Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach, 2021, chapter 4: antiretroviral therapy, p. 123.	WHO	PDF	EN
	2_pDTG Memo for programs	Memo to provide information to national HIV programs considering introducing pediatric tablets of scored and dispersible dolutegravir 10 mg.	CHAI	PDF	FR / EN
	Advocacy statement	Joint statement calling for urgent country scale-up of access to optimal HIV treatment for infants and children living with HIV	UNAIDS	Web page	FR / EN
	3_Guidance Note_WHO_eng	This guidance note outlines key considerations to facilitate effective transition to more clinically appropriate regimens as antiretroviral drugs and optimal dosage forms become available.	WHO	PDF	EN
	4_Transition Plan	An editable report (Word) and a template (Ppt) that governments can adapt as needed for the introduction of pDTG.	CHAI	Zip (Word & Ppt)	FR / EN
<b>QUANTIFICATION &amp; ORDERING</b>	1_Tool to assess transition financial impact	This Excel tool is a template for estimating the financial impact of patients switching to optimized and clinically superior regimens.	CHAI	Xls	EN
	2_Planning Tools Evaluations	This set of tools (Excel, PDF...) put together in a zip file can help programs to plan and evaluate strategies to gradually introduce various new treatment regimens for children, as well as for adults.	CHAI	Zip (Xls & PDF)	EN
	List of products pre-qualified by the WHO	List of medical products pre-qualified by WHO.	WHO	Web page	EN
	3_List of pediatric ARVs and optimal formulary (v2021)	Since 2011, the optimal formulary and limited-use list has provided clear guidance to national programs, procurement entities and funding agencies on the essential dosage forms of antiretroviral therapy for children needed to administer the treatment regimens recommended by WHO.	WHO	PDF	EN
<b>TRAINING &amp; SOPs</b>	1_pDTG_FAQs_NACP	This document is intended to help national HIV programs to adopt pDTG. This document provides a summary, including the advantages of pDTG over other ARVs, cost, dosage, administration, side effects and transition considerations.	CHAI	Word	EN
	<b>RESOURCES FOR COMMUNITIES</b>				
	1_pDTG_Poster_Health Centers	A poster to support demand generation of pDTG that can be used for distribution to communities and caregivers, or for display in health facilities.	CHAI	PDF	FR / EN / SW
	2_pDTG_FAQs_Community_Caregivers	This document provides in-depth information about pDTG and answers to FAQs for caregivers and communities to enable them to understand what the product is, why it is an optimal form of treatment, the dosage and how to administer it.	CHAI	PPT	FR / EN / SW
	3_Poster_AdministrationpDTG_Community_Caregivers	A poster that gives caregivers information on pDTG dosage and how to administer it to children.	CHAI	PDF	FR / EN / SW
4_Booklet_Overview_Community_Caregivers	This booklet provides key information on pDTG, including benefits, eligibility, dosage, administration, and side effects.	CHAI	PDF	FR / EN	



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### LIST OF TOOLS 2/2

	DOCUMENT	DESCRIPTION	SOURCE	TYPE	FR / EN
TRAINING & SOPs	RESOURCES FOR HEALTH PROFESSIONALS				
	Video for health professionals	Video for health professionals on the DTG 10mg scored dispersible tablet for children system	CHAI	Web page	FR / EN / SW
	1_JobAidGuide_Clinician_Counseling	Job aide to help health care workers when putting children on ART.	CHAI	PPT	FR / EN
	2_Clinician_Training_Plan_Counseling	Generic training program to be adapted to local contexts and corresponding training plans.	CHAI	PPT	FR / EN
	3_Poster_AdministrationpDTG_Clinician	Poster that provides instructions on how to administer DTG scored dispersible tablets (10 mg) at the same time as 120/60 mg dispersible tablets of abacavir and lamivudine (ABC/3TC).	CHAI	PDF	FR / EN
	4_pDTG_Overview	Reference document to be adapted and provided to health care workers when informing patients and their caregivers about pDTG.	CHAI	PPT	FR / EN
	5_Algorithm_Prescription	This document is intended to help health care professionals safely transfer children under 3 kg to an appropriate formulation of pDTG. See national guidelines for the treatment of children < 3 kg	CHAI	PPT	FR / EN
	6_Product_Profile	Product profile that provides a clinical overview of pDTG, market updates and implementation considerations and provides answers to frequently asked questions about this optimal product.	CHAI	PPT	EN
7_Dosage_pDTG_weight	Memo on weight-based pediatric prescribing.	CHAI	PPT	EN	
LITERATURE & OTHER RESOURCES	ODYSSEY clinical trials website	ODYSSEY assesses the efficacy and safety of a single daily dose of dolutegravir-based antiretroviral therapy compared to standard HIV treatment in HIV-positive children and adolescents.	Odyssey	Web page	EN
	Summary of ODYSSEY results	Results of the ODYSSEY clinical trial presented at CROI (Conference on Retroviruses and Opportunistic Infections) 2021.	Odyssey	Web page	EN
	IMPAACT P1093 clinical trial website	The safety, tolerability, efficacy and pharmacokinetics of DTG for infants and children aged four weeks to 12 years were demonstrated for 48 weeks.	Impaact	Web page	EN
	Directory_Research	CHAI maintains a repository of publications on relevant clinical trials and studies on new ARVs.	CHAI	Web page	EN
	1_Info_Prescription_HL	Highlights of prescribing information.	Mylan	PDF	EN