



**13<sup>TH</sup> WORLD CONGRESS OF THE  
WORLD SOCIETY FOR PEDIATRIC  
INFECTIOUS DISEASES**  
DURBAN, SOUTH AFRICA

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14-17 NOV  
2023



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# Updates on Paediatric Antiretroviral Treatment

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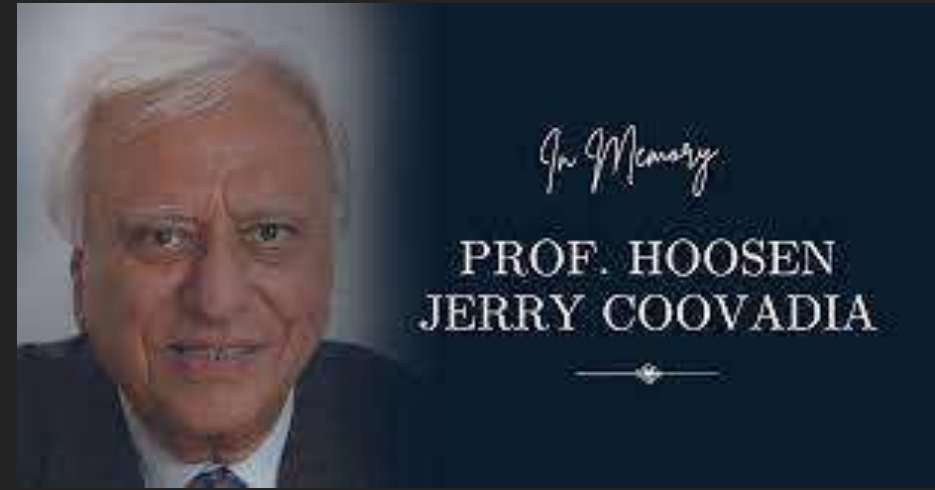
UKZN / AHRI



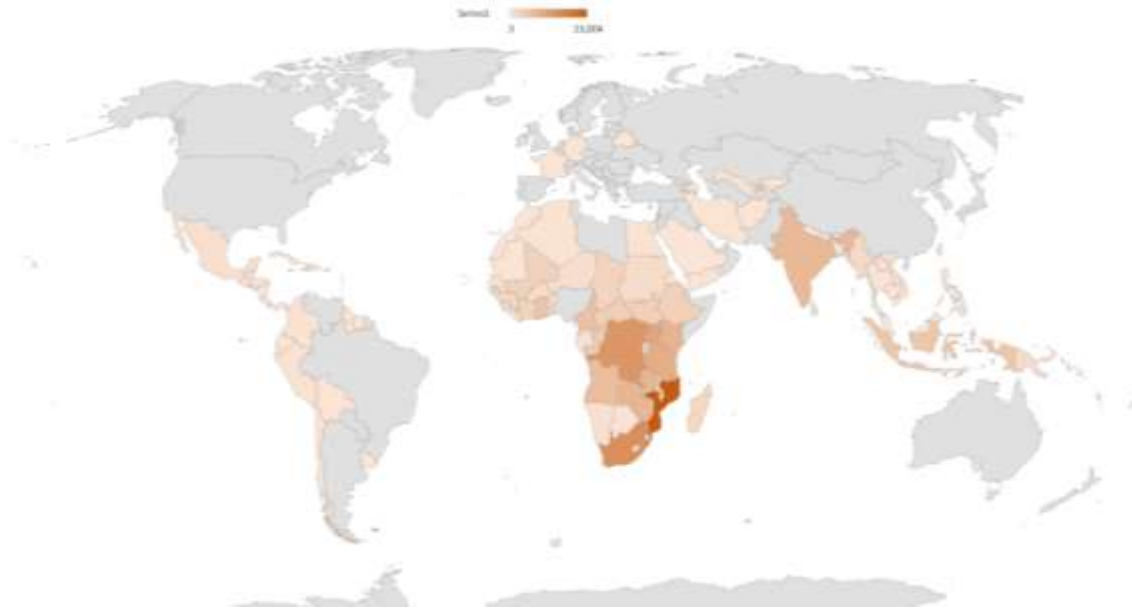
# Acknowledgement

1940 – 2023

Leader bridging medicine,  
activism and research



# Paediatric HIV Landscape

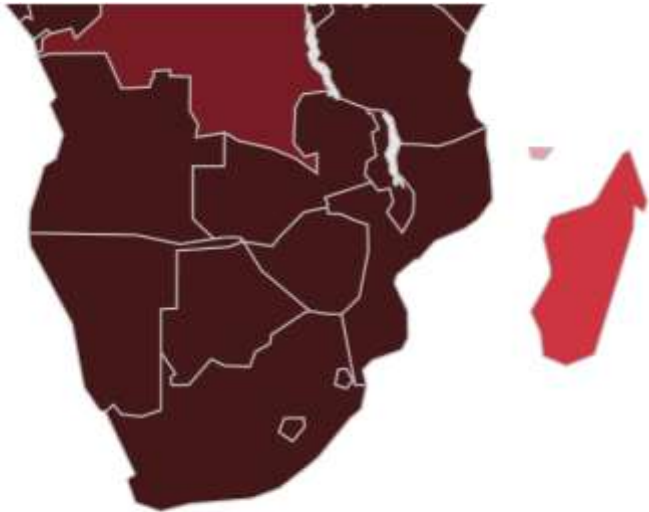


## New Paediatric HIV infections

Eastern/Southern Africa	44%
Western/Central Africa	39%
Asia/Pacific	9%

- Despite falling incidence rates - approximately **130 000 newly infected children with HIV**
- Approximately **84 000 AIDS-related deaths** in children
- Approximately 1.5 million children (<14 years) living with HIV

# Paediatric HIV Landscape – South Africa



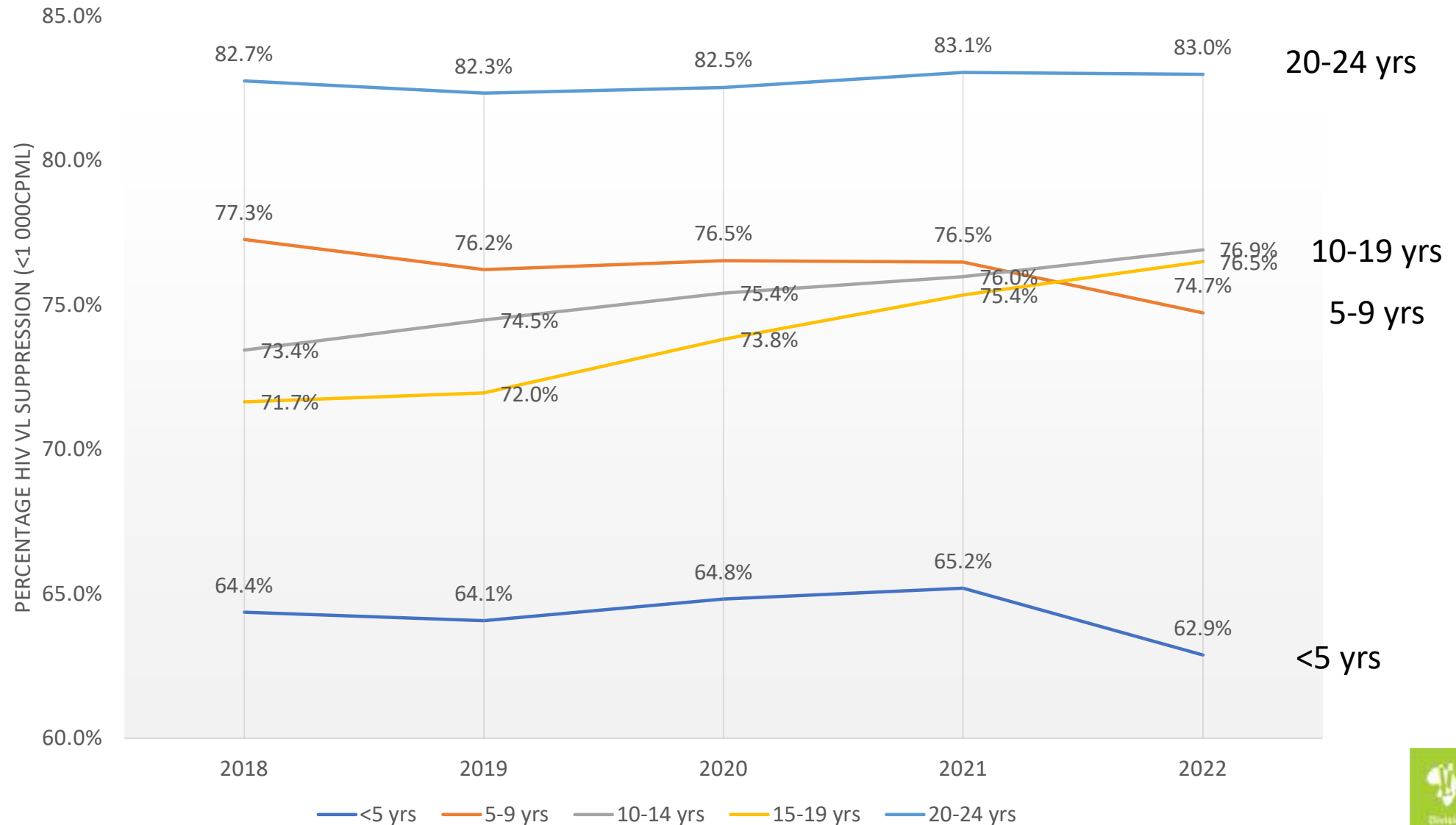
## New HIV infections in 2022

- Children (<15 years): 8 000 (4600 – 31 000)
- All Ages: 160 000 (120 000 – 230 000)
- Change since 2010: -57%

## People living with HIV

- Children (<15 years): 230 000 (140 000 – 520 000)
- All Ages: 7 600 000 (5 400 000 – 9 900 000)
- Prevalence 17.8 (11.9 – 23.2)

# Viral Load Suppression (<1000 c/ml)



# 2023 ART Clinical Guidelines

## Key Changes



- Adolescents
  - Change in eligibility criteria for TLD
  - First VL/eGFR – 3 months
- Children
  - Change in eligibility criteria for DTG
  - New formulation pDTG dispersible tabs
  - First VL/eGFR – 3 months
- Neonates
  - Dosing for premature babies
- Cotrimoxazole Prophylaxis
  - Change in eligibility criteria

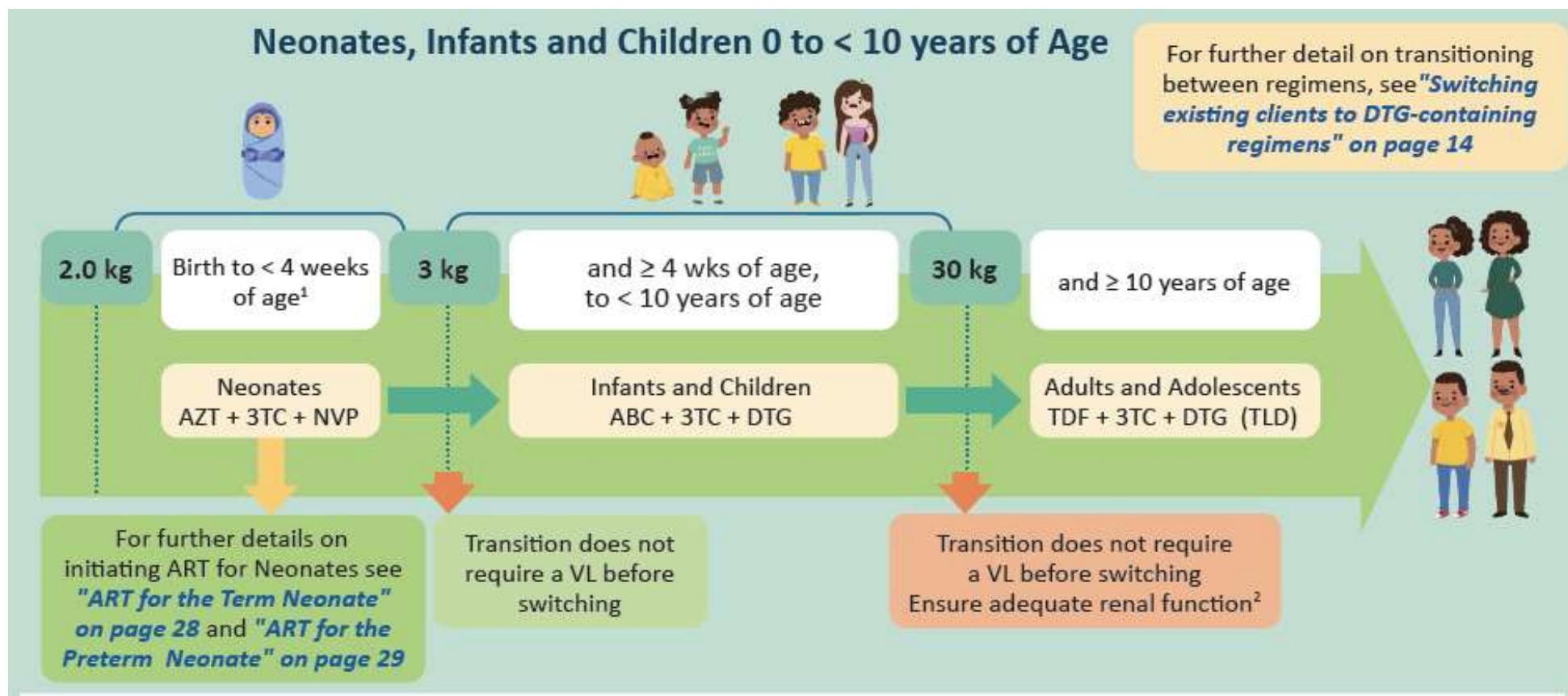


# Adolescents

- Eligibility for transition to Tenofovir/Lamivudine/Dolutegravir (TLD)
  - Previous guidelines: transition when  $\geq 35\text{kg}$  **and** 10 years
  - New guideline: transition when  $\geq 30\text{kg}$  **and** 10 years
  - Rational: Change is in-line with the WHO HIV Guideline/more experience with TDF use in adolescents
- Timing of first VL/eGRF
  - Previous guidelines: Done at 6 months
  - New guideline: Done at 3 months
  - Rational: Earlier identification of treatment failure (most likely due to adherence issues) and interventions to address

# Children

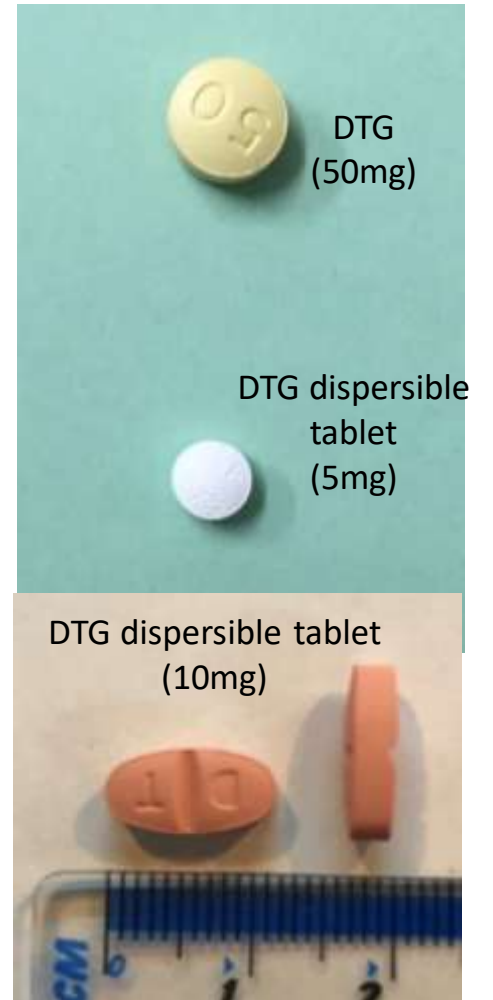
- Eligibility for DTG and introduction of paediatric Dolutegravir (pDTG) dispersible tablets





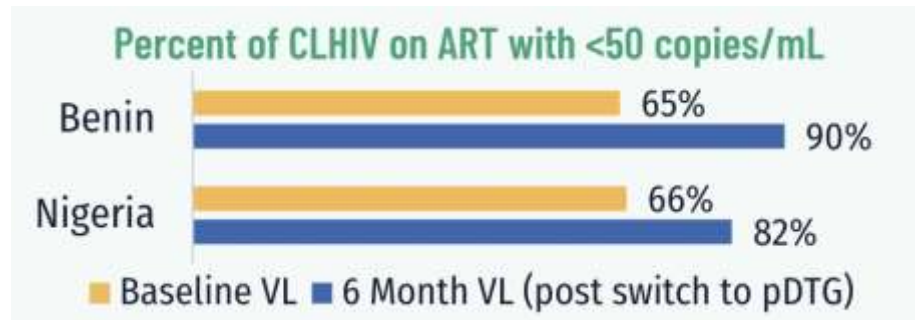
# Transition to pDTG

- Data from IMPAACT P1093 and Odyssey trial support the FDA and EMA approval of paediatric Dolutegravir in the form of dispersible tablets from 3kg and 4 weeks of age.
- Odyssey trial demonstrated the superior efficacy of DTG based therapy compared to standard of care for treatment naïve and experienced children
- Neonatal dosing of dolutegravir - IMPAACT 2023 and PETITE studies
- Fixed-dose combination of ABC/3TC/DTG (ALD - 600/300/50mg) can be used for children >25 kgs(120/60/10mg) (IMPAACT 2019) completed
- New Fixed-dose combination being developed:
  - ALD (120/60/10mg) (IMPAACT 2019) completed
  - ALD (60/30/5mg) – under development
  - TAF/FTC/DTG (Universal study) are under study

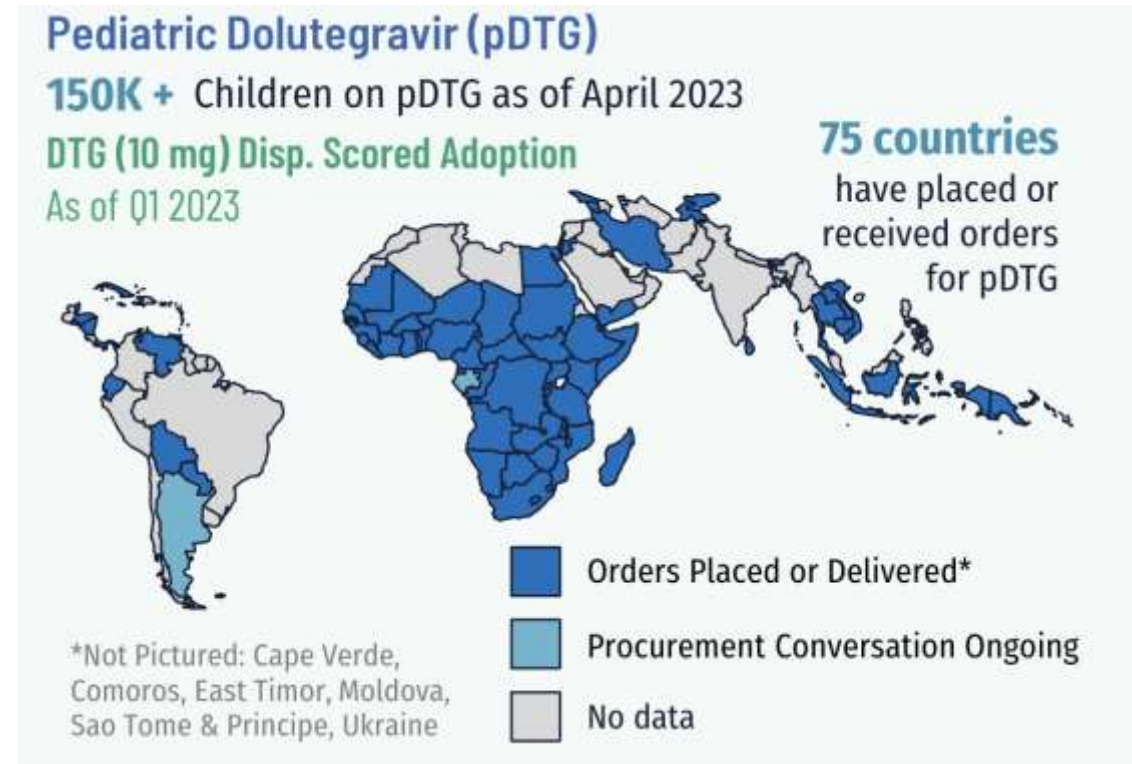


# Transition to pDTG

- Rapid adoption of paediatric DTG by countries across the world
- Early data from country programs:
  - **Torpedo Study:** At 6 months – increase in viral load suppression in Benin and Nigeria by 25% and 16% respectively



- **Mozambique:** Over 80% viral suppression rate after 2 years of switching to DTG
- **Uganda:** Improved viral suppression from 76% in 2021 to 89% in 2022

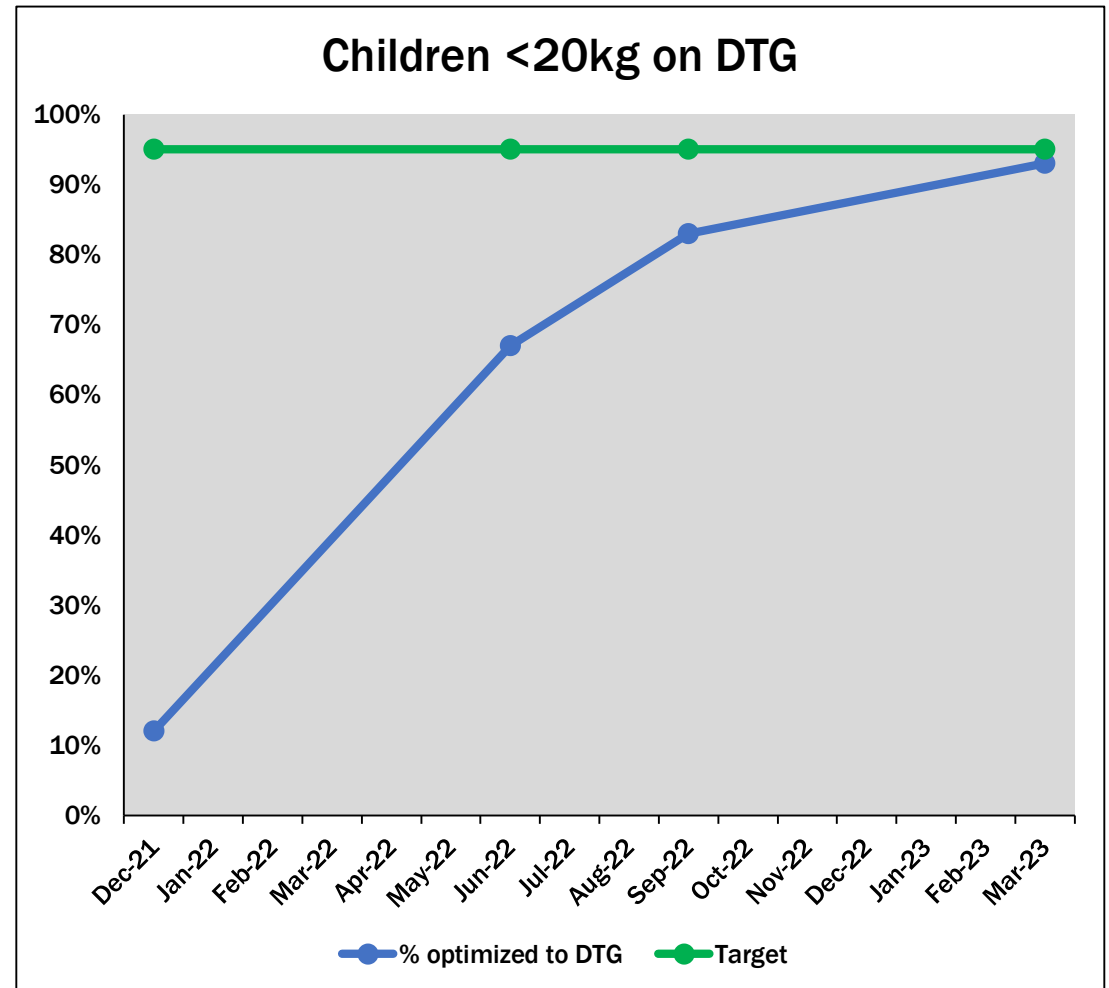
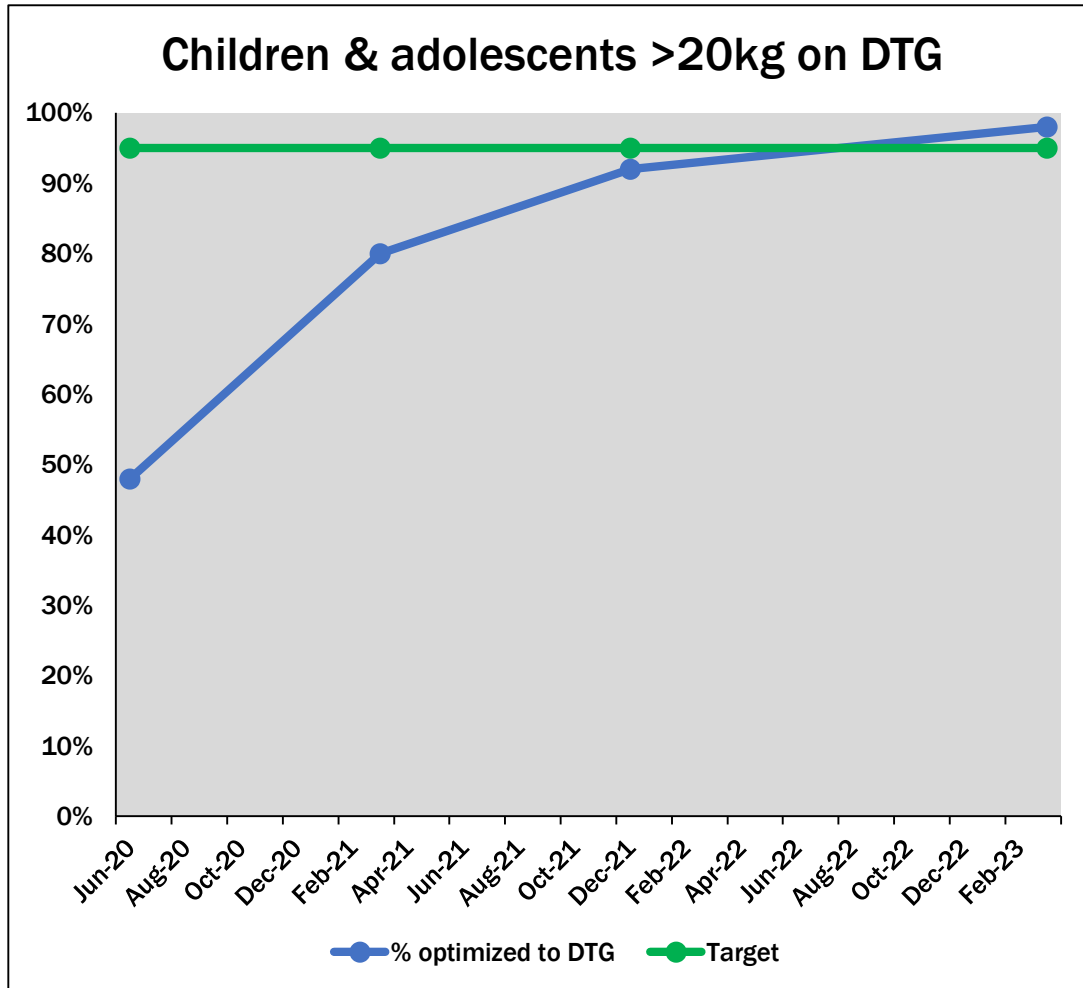


2023 CHAI HIV Mid-year Market memo [https://chai19.wpenginepowered.com/wp-content/uploads/2023/06/2023-CHAI-HIV-Mid-Year-Market-Memo\\_Final.pdf](https://chai19.wpenginepowered.com/wp-content/uploads/2023/06/2023-CHAI-HIV-Mid-Year-Market-Memo_Final.pdf)

Gill et al., PIDJ, June 2023 [online]

Ministry of Health AIDS Control Program, Eleanor Namusoke Magongo

# >90% of all CALHIV on DTG as optimal regimen, Uganda



# Noted improvement in VLS for CLHIV <20kg after pDTG optimization

**76%**  
**DECEMBER 2021**

**89%**  
**JUNE 2022**

**95%**  
**TARGET**

DTG not a magic bullet;

- adherence is KEY,
- emerging DTG resistance (4.1% intermediate-high level resistance)

Uganda program data

- Surveillance is critical – need to utilize program data for this

# Use of pDTG dispersible, scored tablets



pDTG is a scored, dispersible tablet (DT). Dispersible formulation allows **pDTG to be easily administered to children by dispersing and drinking the medicine in a small amount of water**, rather than having to swallow multiple pills, pellets, or granule formulations.

## Administration Instructions



Caregivers should be guided to **add the appropriate dose for weight of pDTG to clean water, stir until the tablet(s) dissolves, and administer to the child.**

- *The child should drink all of the water straight away or within no more than 30 mins.*
- *If dispersing between 0.5 or 1.5 DTG 10 mg tablets, 5 mL (1 teaspoon) of clean water should be used. When dispersing 2 or more tablets, 10 mL (2 teaspoons) of water should be used.*
- *If any medicine remains in the cup, add a small amount of additional water to the cup, swirl, and give to the child. Repeat as necessary.*



**Co-administration with ABC/3TC 120/60 mg DT:** pDTG can be **dispersed and administered in the same solution of clean water as ABC/3TC 120/60 mg DT.** When dispersing both products together, use 10-20 mL (2-4 teaspoons) of clean water and **ensure both medicines are properly dissolved** before administering. If not dissolved (i.e., lumping occurs), stir and slowly add water until all DTs are dissolved.



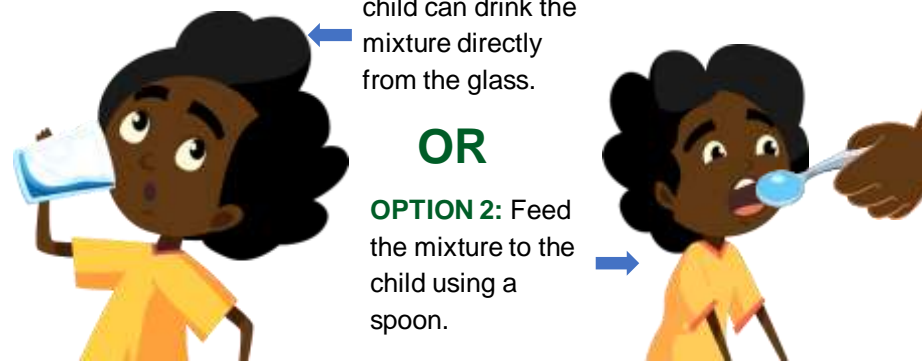


**Other liquids/foods (e.g. juice, milk, breast milk, yoghurt, porridge):** If a child is unable to use water, other age-appropriate liquids or foods may be used. Follow the above volume recommendations to ensure the child takes the full dose. If mixing with foods, the tablets can be crushed to aid in dissolution.



# How to administer pDTG in combination with ABC/3TC dispersible, scored tablets with water or other liquids

- pDTG & ABC/3TC dispersible, scored tablets can be dissolved and mixed in a small amount of water or other liquids prior to administration.
- pDTG & ABC/3TC dispersible, scored tablets can also be split/crushed before mixing them with water or other liquids.

STEP 1: DETERMINE THE DOSE		STEP 2: PREPARE THE pDTG & ABC/3TC MIXTURE		STEP 3: GIVE THE MIXTURE TO THE CHILD																			
<p>Add the correct number of pDTG &amp; ABC/3TC tablets to a clean, empty glass or cup based on the child's weight. (See Dosing Table)</p>  <table border="1"> <thead> <tr> <th>Weight</th> <th>No. of pDTG (10 mg) Daily Tablets</th> <th>No. of ABC/3TC (120/60 mg) Daily Tablets</th> </tr> </thead> <tbody> <tr> <td>3 – 5.9kg</td> <td>0.5</td> <td>1</td> </tr> <tr> <td>6 – 9.9kg</td> <td>1.5</td> <td>1.5</td> </tr> <tr> <td>10 – 13.9kg</td> <td>2</td> <td>2</td> </tr> <tr> <td>14 – 19.9kg</td> <td>2.5</td> <td>2.5</td> </tr> <tr> <td>20 – 24.9kg</td> <td>-</td> <td>3</td> </tr> </tbody> </table> <p><b>TIP:</b> If you are administering 0.5, 1.5 or 2.5 tablets, you can easily split the tablets down the middle on the solid line.</p>		Weight	No. of pDTG (10 mg) Daily Tablets	No. of ABC/3TC (120/60 mg) Daily Tablets	3 – 5.9kg	0.5	1	6 – 9.9kg	1.5	1.5	10 – 13.9kg	2	2	14 – 19.9kg	2.5	2.5	20 – 24.9kg	-	3	<p>Add 10mL (2 teaspoons) of clean water into the glass or cup and stir until the tablets dissolve.</p>  <p><b>TIP:</b> If the tablets do not dissolve completely (i.e., they lump together), stir and slowly add another 10ml (2 teaspoons) of extra water until the tablets fully dissolve.</p>		<p>Give the medicine to the child to drink. Make sure they drink all the medicine right away or within a maximum of 30 minutes.</p> <p><b>OPTION 1:</b> The child can drink the mixture directly from the glass.</p> <p><b>OR</b></p> <p><b>OPTION 2:</b> Feed the mixture to the child using a spoon.</p>  <p><b>TIP:</b> If any medicine remains in the glass, add a little more water to the glass and give it to the child. Repeat until no medicine remains in the glass.</p>	
Weight	No. of pDTG (10 mg) Daily Tablets	No. of ABC/3TC (120/60 mg) Daily Tablets																					
3 – 5.9kg	0.5	1																					
6 – 9.9kg	1.5	1.5																					
10 – 13.9kg	2	2																					
14 – 19.9kg	2.5	2.5																					
20 – 24.9kg	-	3																					

Note: Addition information on the ABC/3TC (120/60 mg) dispersible, scored tablets can be found on the NDoH [Knowledge Hub elibrary](#)  
 A demo video on the use of the product can be found [here](#)



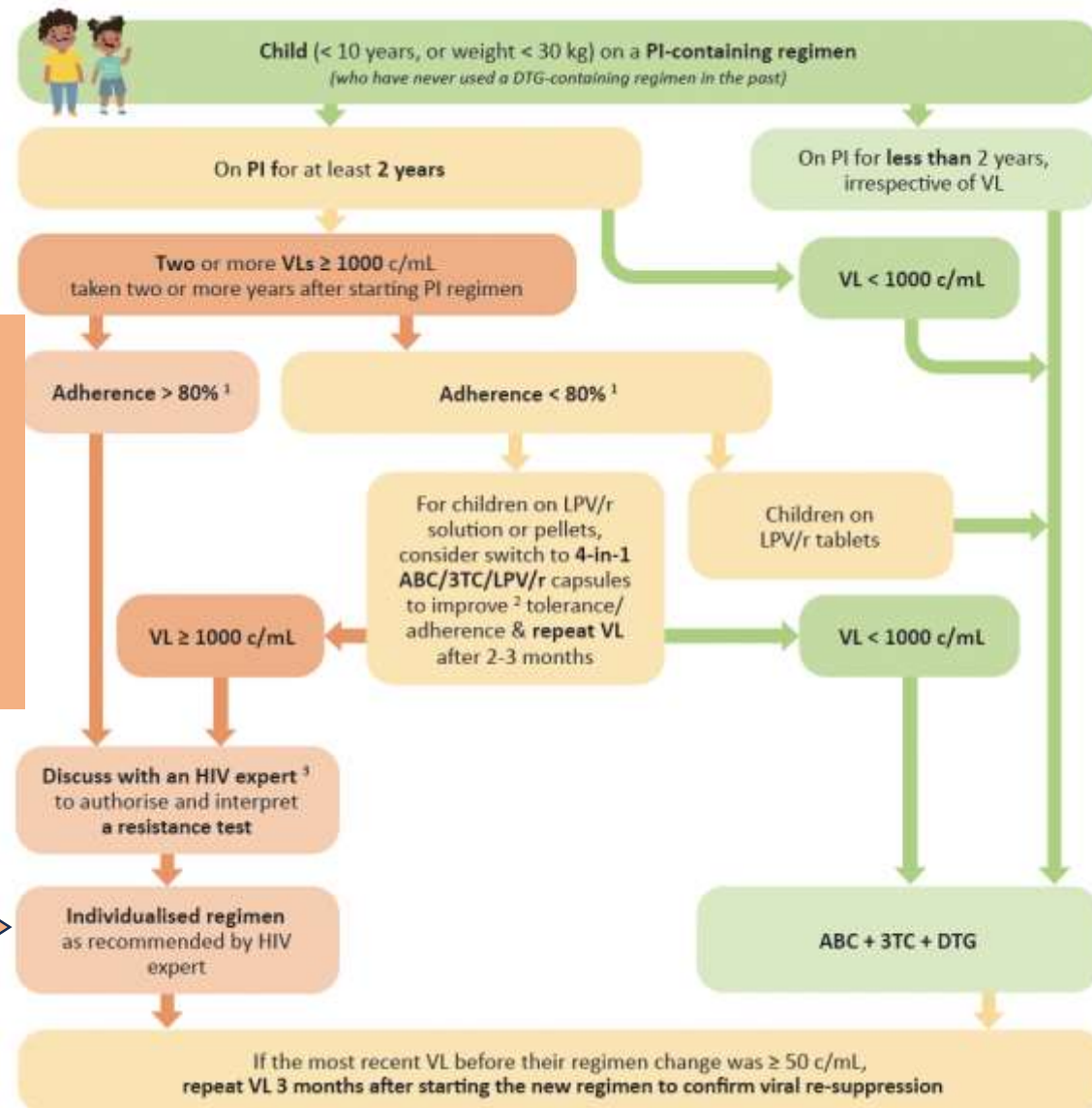
# Updated Dosage chart

	Abacavir + Lamivudine (ABC + 3TC)	Dolutegravir (DTG)	Dolutegravir when on Rifampicin	Abacavir (ABC)	Lamivudine (3TC)	Zidovudine (AZT)
Target dose	As for individual medicines <b>ONCE daily</b>	By weight band <b>ONCE daily</b>	By weight band <b>TWICE DAILY</b>	8 mg/kg/dose <b>TWICE daily</b> OR If $\geq 10$ kg: 16 mg/kg/dose <b>ONCE daily</b>	4 mg/kg/dose <b>TWICE daily</b> OR If $\geq 10$ kg: 8 mg/kg/dose <b>ONCE daily</b>	180 - 240 mg/m <sup>2</sup> /dose <b>TWICE daily</b>
Available formulations	Dispersible tablet FDC: ABC/3TC 120/60 mg Tablets FDC: ABC/3TC 600/300 mg ABC/3TC/DTG 600/300/50 mg	Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ABC/3TC/DTG 600/300/50 mg <b>DT AND FC TABLETS ARE NOT BIOEQUIVALENT</b>	Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ABC/3TC/DTG 600/300/50 mg <b>DT AND FC TABLETS ARE NOT BIOEQUIVALENT</b>	Sol. 20 mg/ml Tabs 60 mg (scored, dispersible), 300 mg (not scored)	Sol. 10 mg/ml Tabs 150 mg (scored)	Sol. 10 mg/ml Tabs 100 mg, 300 mg (not scored), FDC: AZT/3TC 300/150 mg
Wt. (kg)	Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3kg					
3 - 5.9	1 x 120/60 mg tab od	0.5 x 10 mg DT od	0.5 x 10 mg DT bd	3 ml bd OR 1 x 60 mg tab bd	3 ml bd	6 ml bd
6 - 9.9	1.5 x 120/60 mg tabs od	1.5 x 10 mg DT od	1.5 x 10 mg DT bd	4 ml bd OR 1.5 x 60 mg tab bd	4 ml bd	9 ml bd
10 - 13.9	2 x 120/60 mg tabs od	2 x 10 mg DT od	2 x 10 mg DT bd	Once daily dosing <b>&gt; 10 kg</b>	Once daily dosing <b>&gt; 10 kg</b>	12 ml bd OR 1 x 100 mg tabs bd
				4 x 60 mg tabs od OR 12 ml od	12 ml od	
14 - 19.9	2.5 x 120/60 mg tabs od	2.5 x 10 mg DT od	2.5 x 10 mg DT bd	5 x 60 mg tabs od OR 1 x 300 mg tab od	1 x 150 mg tab od	2 x 100 mg tabs am + 1 x 100 mg tab pm OR 15 ml bd
20 - 24.9	3 x 120/60 mg tabs od	3 x 10 mg DT od OR 1 x 50 mg FC tab od	3 x 10 mg DT bd OR 1 x 50 mg FC tab bd	1 x 300 mg tab + 1 x 60 mg tab od OR 6 x 60 mg tabs od		2 x 100 mg tabs bd OR 20 ml bd
25 - 29.9	1 x 600/300 mg tab od OR ABC/3TC/DTG FDC (600/300/50 mg) if eligible od	1 x 50 mg FC tab od OR FDC: ABC/3TC/DTG if eligible od	1 x 50 mg FC tab bd OR FDC: ABC/3TC/ DTG if eligible od + 50 mg DTG FC tab 12 hours later	2 x 300 mg tabs od	2 x 150 mg tabs od	1 x 300 mg tab bd OR 1 x AZT/3TC 300/150 mg tab bd
30 - 39.9		1 x 50 mg FC tab od OR FDC: TLD if eligible od	1 x 50 mg FC tab bd OR FDC: TLD if eligible od + 50 mg DTG FC tab 12 hours later OR FDC: ABC/3TC/ DTG if eligible od + 50 mg DTG FC tab 12 hours later			
$\geq 40$		FDC: ABC/3TC/DTG if eligible od				

# Updated Dosage chart

Lopinavir / ritonavir (LPV/r)	Abacavir + Lamivudine + Lopinavir/ritonavir	Lopinavir/ritonavir when on rifampicin (and for 2 weeks after stopping rifampicin)		# Atazanavir (ATV) + Ritonavir (RTV)	Efavirenz (EFV)	
300/75 mg/m <sup>2</sup> /dose LPV/r <b>TWICE daily</b>	<b>By weight band TWICE daily</b>	LPV/r std dose + super-boosting with ritonavir (RTV) powder <b>TWICE daily</b> (≥ 0,75 x LPV dose bd)	Double-dose LPV/r tabs <b>ONLY</b> if able to swallow whole LPV/r tabs <b>TWICE daily</b>	By weight band <b>ONCE daily</b>	By weight band <b>ONCE daily</b>	Target dose
Sol. 80/20 mg/ml Adult tabs 200/50 mg, Paed tabs 100/25 mg <b>TABLETS MUST BE SWALLOWED WHOLE</b> Pellets 40/10 mg per capsule <b>ONLY FOR USE IF NOT TOLERATING LPV/r SOLUTION. CAPSULES ARE NOT RECOMMENDED &lt; 6 MONTHS OF AGE</b>	Caps 30/15/40/10 mg <b>IF PATIENT IS ON RIFAMPICIN TB TREATMENT, ADD RTV POWDER (next column)</b>	Oral powder 100 mg/packet	Adult tabs 200/50 mg, <b>Paed tabs</b> 100/25 mg	ATV caps 150, 200 mg; RTV tabs 100 mg; FDC: ATV/RTV 300/100 mg RTV TABLETS AND ATV/r FDC TABLETS <b>MUST BE SWALLOWED WHOLE</b>	Caps/tabs 50, 200, 600 mg; FDC: TEE 300/200/600 mg; TABLETS <b>MUST BE SWALLOWED WHOLE</b>	Available formulations
Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3kg						Wt. (kg)
* 1 ml bd <b>OR</b> 2 capsules bd	2 capsules bd	LPV/r std dose (see purple column) + oral RTV powder 100 mg (1 packet) bd	Do not use double-dose LPV/r tabs	Not recommended	Not recommended	3 - 5.9
* 1.5 ml bd <b>OR</b> 3 capsules bd	3 capsules bd					6 - 9.9
2 ml bd <b>OR</b> 4 capsules bd <b>OR</b> 2 x 100/25 mg paed tabs am + 1 x 100/25 mg paed tab pm	4 capsules bd	LPV/r std dose (see purple column) + oral RTV powder 200 mg (2 packets) bd	3 x 100/25 mg <b>paed tabs</b> bd	ATV 1 x 200 mg cap od + RTV 1 x 100 mg tab or 100 mg oral powder (1 packet) od	1 x 200 mg cap/tab nocte	10 - 13.9
2.5 ml bd <b>OR</b> 5 capsules bd <b>OR</b> 2 x 100/25 mg paed tabs bd <b>OR</b> 1 x 200/50 mg adult tab bd	5 capsules bd		4 x 100/25 mg <b>paed tabs</b> bd <b>OR</b> 2 x 200/50 mg <b>adult tabs</b> bd		1 x 200 mg cap/tab + 2 x 50 mg caps/tabs nocte	14 - 19.9
3 ml bd <b>OR</b> 6 capsules bd <b>OR</b> 2 x 100/25 mg paed tabs bd <b>OR</b> 1 x 200/50 mg adult tab bd	6 capsules bd		6 x 100/25 mg <b>paed tabs</b> bd <b>OR</b> 3 x 200/50 mg <b>adult tabs</b> bd		2 x 200 mg caps/tabs nocte	20 - 24.9
3.5 ml bd <b>OR</b> 7 capsules bd <b>OR</b> 3 x 100/25 mg paed tabs bd <b>OR</b> 1 x 200/50 mg adult tab bd + 1 x 100/25 mg paed tab bd	Not recommended	LPV/r std dose (see purple column) + oral RTV powder 300 mg (3 packets) bd	8 x 100/25 mg <b>paed tabs</b> bd <b>OR</b> 4 x 200/50 mg <b>adult tabs</b> bd	1 x ATV/RTV 300/100mg FDC od <b>OR</b> ATV 2 x 150 mg caps od + RTV 1 x 100 mg tab or 100 mg oral powder (1 packet) od	2 x 200 mg caps/tabs nocte	25 - 29.9
5 ml bd <b>OR</b> 10 capsules bd <b>OR</b> 4x100/25 mg paed tabs bd <b>OR</b> 2x200/50 mg adult tabs b			2 x 200 mg caps/tabs nocte <b>OR</b> FDC: TEE if eligible od	≥ 40		

# Transition to DTG



PI based regimen > 2years or  
VL >1000 copies/ml

**Assumption** is that there will  
be several NRTI and ?PI  
mutations

PI based regimen < 2years or  
VL <1000 copies/ml

**Assumption** is apart from  
M184V, no other mutations



# Term and Near-term Neonates



**Baseline Assessment**

- Clinical review
- Bloods: confirmatory HIV PCR (or HIV VL), CD4 count, FBC +/- HIV drug resistance test if mother failing treatment on TLD2 or a protease inhibitor regimen
- Counsel parent / caregiver
- Ensure the mother is on ART, and advise that breastfeeding is recommended for all infants living with HIV.

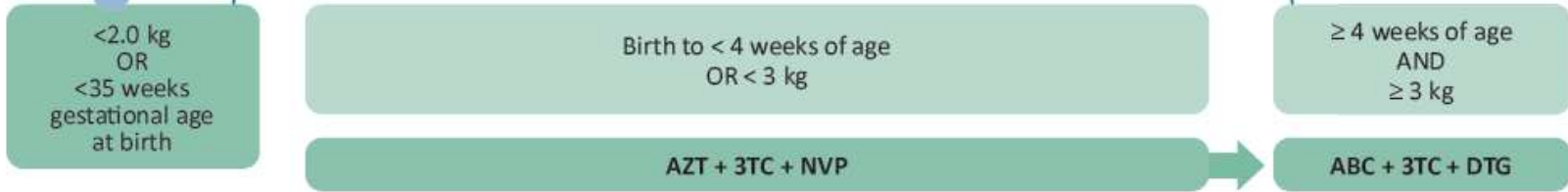
**Review after 1 week then 1-2 weekly**

- Clinical review and counselling
- Check baseline blood results
- If indeterminate / negative confirmatory HIV PCR test result, refer to Guideline for Family-Centered Transmission Prevention of Communicable Infections

**Review when 4 weeks of age**

- Clinical review and counselling
- If <3 kg, assess reasons for poor weight gain & manage appropriately, continue ART with AZT (12 mg/kg/dose twice daily) + 3TC (4 mg/kg/dose twice daily) + NVP (6 mg/kg/dose twice daily) until ≥3.0 kg
- If >3 kg, switch ART to ABC + 3TC + DTG (refer to ARV dosing chart for doses)
- Continue monitoring as per *"Monitoring on ART" on page 19*

	Zidovudine (AZT)		Lamivudine (3TC)		Nevirapine (NVP)	
Available formulation	Solution 10 mg/mL		Solution 10 mg/mL		Solution 10 mg/mL	
Weight (kg) at birth	Dose		Dose		Dose	
	AM	PM	AM	PM	AM	PM
≥2.0 – <3.0	10 mg (1 mL)	10 mg (1 mL)	5 mg (0.5 mL)	5 mg (0.5 mL)	15 mg (1.5 mL)	15 mg (1.5 mL)
≥3.0 – <4.0	15 mg (1.5 mL)	15 mg (1.5 mL)	8 mg (0.8 mL)	8 mg (0.8 mL)	20 mg (2 mL)	20 mg (2 mL)
≥4.0 – <5.0	20 mg (2 mL)	20 mg (2 mL)	10 mg (1 mL)	10 mg (1 mL)	30 mg (3 mL)	30 mg (3 mL)



**Baseline Assessment**

- Clinical review
- Bloods: confirmatory HIV PCR (or HIV VL), CD4 count, FBC +/- HIV drug resistance test if mother failing treatment on TLD2 or a protease inhibitor regimen
- Counsel parent / caregiver
- Ensure the mother is on ART, and advise that breastfeeding is recommended for all infants living with HIV

**Review after 1 week then 1-2 weekly**

- Clinical review and counselling
- Check baseline blood results
- If indeterminate / negative confirmatory HIV PCR test result, refer to Guideline for Family-Centered Transmission Prevention of Communicable Infections
- Monitor weight gain and adjust ARV doses

**Review when ≥4 weeks of age**

- Clinical review and counselling
- If <3 kg, continue AZT + 3TC + NVP
- If >3 kg, switch to ABC + 3TC + DTG (refer to ARV dosing chart for doses)
- Continue monitoring and evaluations as per *"Monitoring on ART" on page 19*

# Pre-term Neonates

Gestational age at birth	Chronological age	Zidovudine (AZT)	Lamivudine (3TC)	Nevirapine (NVP)
		Solution 10 mg/mL	Solution 10 mg/mL	Solution 10 mg/mL
< 30 weeks	Birth - < 4 weeks	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily
	≥ 4 weeks - < 8 weeks	3 mg/kg/dose twice daily	4 mg/kg/dose twice daily	4 mg/kg/dose twice daily
	≥ 8 weeks - < 10 weeks	12 mg/kg/dose twice daily		6 mg/kg/dose twice daily
≥ 30 - < 35 weeks	Birth - < 2 weeks	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily
	≥ 2 - < 4 weeks	3 mg/kg/dose twice daily		4 mg/kg/dose twice daily
	≥ 4 - < 6 weeks		12 mg/kg/dose twice daily	4 mg/kg/dose twice daily
	≥ 6 - < 8 weeks	6 mg/kg/dose twice daily		

When weight is ≥2 kg and ≥35 weeks corrected gestational age, review ARVs and refer to table "ART for the Term Neonate" on page 28

# Cotrimoxazole prophylaxis

## Previous Paediatric STG and EML/National Guideline Recommendation

Cotrimoxazole prophylaxis recommended for:  
**both HIV-exposed and HIV-infected infants**

### Previous recommendations was made in the context of:

- No maternal ART.
- No infant prophylaxis (HIV).
- Cotrimoxazole showed benefit in those HIV-positive children with very low CD4 counts.

***This recommendation was considered during the review of both the Paediatric STGs and EML Review and review of the National ARV Programmatic Guidelines.***



# Recent evidence for Botswana and South African studies (1):

## No benefit for mortality or morbidity for HIV-exposed uninfected children (HEU)

### Botswana study (Lockman *et al*, 2017) :

- Prophylactic cotrimoxazole did not improve 18-month survival in HEU children
- Mortality at 18-months 2.4% in cotrimoxazole group and 2.6% in placebo group, difference 0.2%, 95% CI -0.15 to 1.0%,  $p = 0.70$ .

### South African Study (Daniels *et al*, 2019):

- No cotrimoxazole was not inferior to daily cotrimoxazole among breastfed HEU infants whose mothers are accessing a PMTCT programme.
- Cumulative probability of the composite primary outcome (*incidence of grade 3 or 4 common childhood illnesses or mortality in breastfed HEU infants by age 12 months*) was 0.114 (95% CI 0.076 to 0.147; 49 events) for cotrimoxazole group vs 0.0795 (0.044 to 0.115; 39 events) in the no cotrimoxazole group. Risk difference  $-0.0319$ .

# Recent evidence for Botswana and South African studies (2):

## POTENTIAL HARM

### Botswana study (Lockman *et al*, 2017) :

- Cotrimoxazole prophylaxis increased resistance to cotrimoxazole AND amoxicillin (1st line pneumonia treatment).

### South African Study (Daniels *et al*, 2019):

- Cotrimoxazole group was associated with microbiome dysbiosis and increase in resistance genes

- Lockman S, et al. Effect of co-trimoxazole on mortality in HIV-exposed but uninfected children in Botswana (the Mpepu Study): a double-blind, randomised, placebo-controlled trial. *The Lancet Global Health*. 2017;5(5):e491-e500.
- Daniels B, et al. Effect of co-trimoxazole prophylaxis on morbidity and mortality of HIV-exposed, HIV-uninfected infants in South Africa: a randomised controlled, non-inferiority trial. *The Lancet Global Health*. 2019;7(12):e1717-e27.

# Rationale to change

## Assumptions

- 270 000 live births to HIV+ women
- 1,7% viral transmission rate, 83% of transmission in first 6 months
- current definition of high-risk: > 1000 c/ml
- PJP incidence of 9.5 cases per 100 child years in the first year of life **without ART** (Morris, et al)

### 32520 high-risk infants

- Thus 552 HIV-positive children (1 in 10 may get PJP if not on ART)
- Thus 55 at risk of PJP (if not on ART)

*In SA with high birth PCR coverage and ART initiation, incidence may be less*

- Treating **32 480** high-risk HEIs to benefit 552 HIV-positive children of which **55** may get PJP is against policy norms and even ethics
- **Potential harm to 32 480 children**

## The National ARV Programmatic Guidelines and Paediatric STGs and EML

Current recommendation for cotrimoxazole use only in babies with positive HIV PCR results:

### Indications for Starting and Stopping Cotrimoxazole Preventive Therapy (CPT)

Age and HIV status	When to Start	When to Stop
HIV-positive infant under 1 year of age	All children under 1 year should be on cotrimoxazole irrespective of CD4% or clinical stage	
HIV-positive child 1-5 years of age	CD4% $\leq$ 25 %, WHO Stage 2, 3, and 4	Discontinue if CD4 count $>$ 25 %, regardless of clinical stage
HIV-positive child under 5 years of age with PJP infection	Start CPT after PJP treatment is completed	Continue CPT until 5 years of age and stop thereafter only if CD4 criteria in the older-than-five category are met
HIV-positive adults and children older than 5 years	CD4 count $\leq$ 200 cells/ $\mu$ L, WHO Stage 2, 3 and 4	Discontinue if CD4 count $>$ 200 cells/ $\mu$ L, regardless of clinical stage



# Conclusions

- Roll-out of new simple, easy to use regimens for children will go a long way in improving the lives of the children we treat
- Need to be advocates for children with HIV – expand access to optimized regimen with an ordered transition from LPV/r to pDTG
- We have an evolving HIV epidemic – need to change guidelines and practice to raise to the challenges
- Ending AIDS for children and adolescents with HIV by 2030 is an aspirational goal that is well worth striving towards





# WSPID 2023



**13<sup>TH</sup> WORLD CONGRESS OF THE WORLD SOCIETY FOR PEDIATRIC INFECTIOUS DISEASES**  
DURBAN, SOUTH AFRICA

**Durban**  
14-17 NOV 2023

PROGRAM AT A GLANCE

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As of 26 September 2023, subject to change

**Program Key**

- Plenary Symposium
- WSPID Symposium
- Society Symposium
- Meet the Professor
- Workshops
- Interactive Symposium
- World/Special Lecture
- E-Poster Discussions
- Sponsored Symposium
- Oral Presentations
- Opening/Closing Ceremony
- Nurses Symposium
- Networking
- Challenging Case Presentations
- E-Poster Rounds

Pre-registration / **LIVE** Live TV- Live Streamed **VOD** Recorded – On Demand

Invitation Needed

**Tuesday, 14 November 2023**

07:30-14:30	WSPID Research Workshop <b>VOD</b> <b>TICKET</b>	Hall B
10:00-10:30	Break	
11:00-12:30	Sponsored Symposium (Not included in main event CME/CPD Accreditation)	Hall A
12:30-12:45	Short Break	
12:45-14:15	Sponsored Symposium (Not included in main event CME/CPD Accreditation)	Hall A
14:15-14:45	Break	
14:45-16:15	Sponsored Symposium (Not included in main event CME/CPD Accreditation)	Hall A
15:30-16:30	Welcome Coffee	Exhibition
16:30-18:15	Opening Plenary Session: Pandemics & Politics in the Era of Fake News <b>LIVE</b>	Hall A

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Extended early bird registration: <https://protect-za.mimecast.com/s/4ICJCG5XMvfrBlgDCNtJz9?domain=reg.kenes.com>