POLICY BRIEF — JULY 2020

CONSIDERATIONS FOR INTRODUCING NEW ANTIRETROVIRAL DRUG FORMULATIONS FOR CHILDREN

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Considerations for introducing new antiretroviral drug formulations for children: policy brief

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ABBREVIATIONS

3TC	lamivudine
ABC	abacavir
APWG	ARV Procurement Working Group
ATV/r	ritonavir-boosted atazanavir
AZT	zidovudine
DRV/r	ritonavir-boosted darunavir
DTG	dolutegravir
EFV	efavirenz
FTC	emtricitabine
LPV/r	ritonavir-boosted lopinavir
NNRTI	non-nucleoside reverse-transcriptase inhibitor
NRTI	nucleoside reverse-transcriptase inhibitor
NVP	nevirapine
RAL	raltegravir
TAF	tenofovir alafenamide
TDF	tenofovir disoproxil fumarate
TB	tuberculosis
VL	viral load
VS	viral suppression

1. BACKGROUND

This policy brief is for country-level programme managers, technical advisers and procurement bodies involved in the process of procuring, introducing and scaling up optimal antiretroviral therapy for infants and young children living with HIV in low and middle-income countries. With multiple new antiretroviral drug options and the availability of new evidence, antiretroviral therapy for children is a dynamic and rapidly evolving space. Although critical tools such as the antiretroviral drug optimal formulary are periodically updated to support product selection *(1)*, programmes must stay informed and up to date on availability of currently used antiretroviral drug formulations for children and anticipated new products to ensure that all children have access to the best available treatment for HIV infection. Implementing the new WHO recommendations for infants and children requires carefully considering the existing regimens in use, antiretroviral drugs for children in stock and in the pipeline and timelines for the availability of newly approved antiretroviral drug formulations for children. This publication outlines what national HIV programmes should be aware of for short- to medium-term (12–24 months) planning.

Current WHO guidelines

In 2018, WHO published up-to-date recommendations on using antiretroviral drug regimens for treating and preventing HIV infection *(2)*. These guidelines recommend a dolutegravir (DTG)-based regimen as the preferred first-line regimen for children for whom approved DTG dosing is available.

WHO also recommends DTG combined with an optimized nucleoside reverse-transcriptase inhibitor (NRTI) backbone as the preferred second-line regimen for people living with HIV, including children, for whom a non-DTG based regimen has failed.

WHO gives priority to antiretroviral drugs that have demonstrated efficacy and safety. However, data on efficacy are often limited or delayed for children. WHO therefore maintains that safety and pharmacokinetic data should remain the basis for considering any new antiretroviral drugs for infants and children living with HIV, and evidence of superior efficacy among adults is sufficient to support use among children. Evidence of the superiority of DTG compared with ritonavir-boosted lopinavir (LPV/r) from studies among adults were extrapolated in making the recommendation to include DTG as the preferred drug for infants and children *(3)*. However, in the absence of formulations and dosing for infants and young children, LPV/r-containing regimens are an acceptable alternative given their superiority over non-nucleoside reverse-transcriptase inhibitor (NNRTI)-based regimens.

Table 1. Preferred and alternative first-line antiretroviral therapy regimens

Population	Preferred first-line regimen	Alternative first-line regimen
Children	ABC + 3TC + DTG[a]	ABC + 3TC + LPV/r or RAL[b] TAF + 3TC (or FTC) + DTG[c]
Neonates	AZT + 3TC + RAL[d]	AZT + 3TC + NVP

[a] For age and weight groups with approved DTG dosing.
[b] RAL should be used as an alternative regimen only if LPV/r solid formulations are not available.
[c] For age and weight groups with approved TAF dosing.
[d] Neonates starting antiretroviral therapy with an RAL-based regimen should transition to an LPV/r solid formulation as soon as possible.