ENSURING ACCESS TO THE FULL RANGE OF WHO-RECOMMENDED OPTIMAL PEDIATRIC ANTIRETROVIRAL REGIMENS: GUIDANCE FOR QUANTIFICATION AND SUPPLY PLANNING

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

DNDi
Drugs for Neglected Diseases *initiative*

1. INTRODUCTION

Recent breakthroughs in the development and commercialization of effective, child-friendly antiretroviral (ARV) formulations mean that more children living with HIV (CLHIV) should have access to life-saving antiretroviral therapy (ART). However, ART coverage for infants and children still lags behind coverage for adults.[1] Increased efforts are needed at global and national levels to support national HIV programs in achieving their goals of ensuring that HIV-exposed infants and children are diagnosed early, placed on optimal ART regimens and achieve viral load suppression. To do this, national HIV programs must quantify, procure, and supply the full range of optimal pediatric ARVs. This includes first-, second-, and third-line treatments, as well as alternative and backbone products needed to deliver WHO-recommended ART for children 0 to 15 years of age and as they grow and transition from one treatment regimen to another. Quantifying and planning for the full portfolio of effective, child-friendly pediatric ARV formulations will ensure that CLHIV adhere to their treatment, achieve viral suppression, and live healthy and productive lives.

2. TARGET AUDIENCE AND OBJECTIVES

This guidance is intended for national program managers; technical and clinical advisors; procurement entities; funding agencies; implementing partners; and civil society organizations involved in advocacy, quantification, procurement, distribution, and scale-up of optimal pediatric ARVs. It aims to ensure that these stakeholders are well informed to advocate for and support sustainable access to the full portfolio of optimal pediatric ARVs needed to implement the WHO HIV treatment guidelines. It includes specific guidance on the what, why, who, when, and how of quantifying and supplying the full range of pediatric ARVs.

3. GUIDANCE FOR ENSURING ACCESS TO THE FULL PORTFOLIO OF OPTIMAL PEDIATRIC ARVS

A. WHAT IS THE FULL PORTFOLIO OF OPTIMAL PEDIATRIC ARVS?

The 2021 consolidated WHO HIV treatment guidelines recommend the use of dolutegravir (DTG) in combination with a dual nucleoside reverse transcriptase inhibitor (NRTI) backbone as the preferred first-line regimen for infants and children from 4 weeks of age and weighing more than 3 kg. For children who are failing on first-line DTG, WHO recommends a boosted protease inhibitor in combination with an optimized NRTI backbone as a second-line regimen. For children who do not tolerate DTG, a two-NRTIs backbone combined with lopinavir/ritonavir is recommended as an alternative regimen. For neonates who are diagnosed with HIV before 4 weeks of age, WHO recommends a two-NRTI backbone combined with raltegravir as a first-line regimen or combined with nevirapine as an alternative regimen. The full range of pediatric ARV products needed to implement the 2021 WHO guidelines is shown in Appendix 1.

The WHO Optimal Formulary and Limited Use List for Antiretroviral Drugs for Children describes the minimum number of ARV drug formulations needed to deliver WHO-recommended preferred and alternative first-, second-, and third-line ART regimens for infants and children.[2] Using this document as a reference, national HIV programs can develop accurate quantification and supply plans needed to deliver the full portfolio of WHO-recommended ART regimens for infants and children, including the NRTI backbone products.[3]

B. WHY IS ACCESS TO THE FULL PORTFOLIO OF OPTIMAL PEDIATRIC ARVS IMPORTANT?

Quantification, which includes both forecasting and supply-planning processes,[4] is a supply chain activity with outputs critical for program planning, budgeting, estimating pediatric ARV needs and costs, advocating for resource mobilization, and informing manufacturer production cycles and shipment schedules. Timely and accurate quantification, procurement, and distribution of all WHO-recommended optimal pediatric ARVs allows for rapid and sustainable transition to new products as well as an uninterrupted supply, ensuring the following:

- More infants living with HIV and CLHIV are put on optimal treatment
- Higher treatment adherence with more potent, acceptable, and palatable formulations, with the right regimens resulting in sustained viral load supression in children given that children have consistently lower rates of viral suppression than do adults[1]
- Minimal stock ruptures in supply, resulting in fewer switches due to supply challenges
- Availability of alternatives for children who are intolerant to a particular regimen
- Availability of second- and third-line options for those with treatment failure

C. WHO SHOULD SUPPORT QUANTIFICATION AND SUPPLY PLANNING?

National level

For quantification and supply planning to be useful and effective, the right people need to be involved in each step of the process.[4] In addition to considering the advice of procurement and supply chain experts, it is critical to take into consideration the needs and perspectives of national program managers, clinicians, caregivers and patients. For this reason, stakeholders invloved in the provision of pediatric HIV services and the management of pediatric ARVs, including the caregivers of CLHIV, should be consulted during the process. The national HIV program should create a national technical working group (TWG) that includes, for example, program managers, technical experts, policymakers, logistics managers, procurement experts, clinical service providers with experience in pediatric HIV, caregivers, and other civil society representatives. This group should meet frequently—at least every quarter—to review forecasting assumptions and supply plans and to update quantification for the full range of optimal pediatric ARVs. Donors and funding agencies, including national goverments, should contribute to, and be informed of, the outcomes of the TWG quantification efforts to ensure the availability of adequate resources.

Global level

Although they are not directly involved in national quantification processes, the ARV Procurement Working Group (APWG), the WHO-led Paediatric Antiretroviral Drug Optimization (PADO) group, and the Pediatric Antiretroviral Working Group (PAWG) play an important role. For example, the APWG consolidates demand forecasts from countries and shares them with manufacturers, which facilitates commercial planning. This ensures alignment of supply and demand to avoid any production capacity constraints on pediatric ARVs. Country programs are strongly encouraged to share their pediatric ARV demand forecasts with the APWG for alignment and coordination of procurement, especially for ARVs for which small quantities are needed (e.g. third-line, alternatives). National program managers and procurement experts should monitor the APWG website for updates on supply availability and manufacturer capacity constraints.[5] The PADO produces a list of ARVs, first released by the PADO group in 2013, to address the fragmented market of pediatric ARVs. The list has reduced the number of unnecessary formulations, and has become a critical tool for focusing research and development efforts and resources.[6] Based on this, the WHO guidelines recommend a limited set of regimens for children. The PAWG provides technical guidance on weight-band dosing as well as pharmacokinetic and acceptability studies of ARV drugs for children.[7] The set of regimens and appropriate dosing is critical in the development of accurate forecasts. National program managers should monitor the WHO website and announcements on new or updated WHO treatment guidelines.

ARV manufacturers, donors and national governments also have an important role to play. Manufacturers should keep national programs and global stakeholders updated on product availability, shipment timelines and any anticipated supply constraints. Donors and funding agencies, including national governments, should contribute to and be informed of the outcomes of TWG quantification efforts to ensure adequate resources are made available to meet the needs of a full portfolio of ARVs.

D. WHEN TO QUANTIFY AND PLAN FOR THE FULL PORTFOLIO OF OPTIMAL PEDIATRIC ARVS

Quantification and supply planning is an iterative process that involves reviewing and updating quantification data and assumptions regularly. Given that quantfication of pediatric ARVs differs from that of adult ARVs and supply planning of pediatric ARVs should also support client-centered care,[3] frequent meetings are needed to review and update data and ensure changes are reflected in the forecasts and supply plans. National programs should constantly scan the pipeline of new formulations under development. For example, the recently published 2021 HIV Market Report by CHAI lists three pediatric products (fixed-dose pediatric ABC/3TC/DTG, pediatric DRV/r 120/20 mg and pediatric TAF) currently in development but still a few years away from commercial availability in low and middle-income countries. National programs should be on the lookout for new WHO recommendations, and an updated optimal formulary and be prepared to phase-out legacy formulations and phase-in new formulations immediately following stringent regulatory authority approval. For example, full U.S. Food and Drug Administration approval of the 4-in-1 fixed-dose combination of abacavir/lamivudine/lopinavir/ritonavir (30 mg/15 mg/40 mg/10 mg) is expected soon,[8] and national programs are therefore encouraged to plan early for its incorporation into the pediatric ARV portfolio while ensuring a stable supply of all regimens needed.

E. HOW TO ENSURE AN APPROPRIATE AND STABLE SUPPLY OF A FULL PORTFOLIO OF PEDIATRIC ARVS

Pediatric ARVs include a wider range of products compared to ARVs for adults, including different formulations and varying doses and strengths to accommodate for rapid changes in weight and growth, as well as the need for first-, second-, and third-line regimens and alternative regimens. Figure 1 summarizes the different aspects that need to be considered in quantifying for the full portfolio of ARVs.

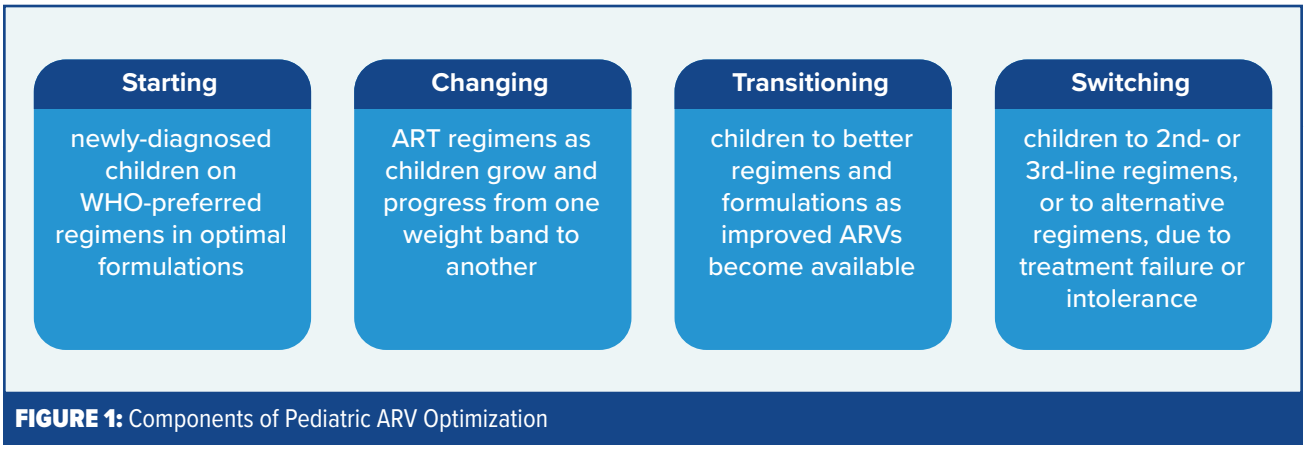

FIGURE 1: Components of Pediatric ARV Optimization

However, national programs face a number of challenges when quantifying the full range of pediatric ARV products by formulation, regimen, age group, and weight band.[9] Although quantification of pediatric ARVs should be based on weight bands, in most settings, weight data are not systematically collected and recorded in patient records. The absence of weight data makes it difficult to estimate needs for different ARV formulations as children grow and transition from one regimen to another, for example, from DTG 10 mg dispersible tablets for children weighing less than 20 kg to DTG 50 mg adult tablets for children weighing more than 20 kg. In addition, developmental milestones, such as the age when children can swallow tablets whole, will affect quantification for tablets that should not be cut, split, dissolved, or chewed (e.g., lopinavir/ritonavir tablets). Furthermore, it is risky to rely on historical consumption rates because they do not accurately reflect changing policies or the rapidly evolving epidemiology of pediatric HIV infections, such as declining rates of mother-to-child transmission or increasing rates of late diagnosis of HIV in older children, which should be taken into consideration during quantification. Finally, accurate quantification and supply planning of adult ARVs is critical to ensure that pediatric ARVs are not used as a "backup" when stocks of adult formulations run low, which can lead to shortages and/or stock outs of pediatric ARVs.

Table 1 lists common challenges encountered in quantification and supply planning of the full range of WHO-recommended optimal pediatric antiretroviral regimens and some proposed solutions.

TABLE 1. Callenges and Proposed Solutions for Quantifying the Full Portofolio of Optimal Pediatric ARVs

Quantification and supply planning challenges	Proposed solutions
Obtaining data on the number of children needing ARVs by weight band.	• Include weight data in relevant national databases (e.g. electronic patient records). • In the absence of this data, use standard age-to-weight conversions to estimate the weight band breakdown of the relevant children[3]. For example, if weight band data is not available, the CHAI Simple Tool has an option to use data organized by age group to estimate the weight breakdown.
Estimating the proportion of CLHIV who will have adverse drug reactions, intolerance or virological failure and require alternative, second-line or third-line ARV regimens.	• Strengthen existing national pharmacoviginance systems to capture and document data on intolerance and adverse drug reactions. • Strengthen routine viral load monitoring as per WHO recommendations to ensure that each child on ART receives at least one viral load test every 12 months. • If national data is not available, use published scientific data on adverse drug reactions, intolerance and virological failure (e.g. the ODYSSEY Trial[10]) when developing the quantification assumptions. • In absence of this data, use viral load surpression data when developing the assumptions.
Estimating quantities of ART needed when combined with treatments for co-infections such as TB (e.g. double dosing of DTG when combined with TB treatment)	• Estimate the proportion of children on ART who are also on TB treatment and adjust quantification to account for double dosing.
Adjusting for developmental milestones and administration challenges that can impact adherence to treatment.	• Validate at what age children are able to swallow whole tablets (e.g. DTG 50mg tablets for children > 20 kg[3]). • Factor in the proportion or number of children who will outgrow the weight bands (e.g. some children will outgrow the <20kg weightband and switch to DTG 50mg tablets). • Consider providing fixed-dose combination ARV formulations to reduce the administration burden of prescribing and giving a combination of different formulations. • Provide client-centered care that includes training of clinicians and counselling of caregivers in ARV administration, and service delivery models such as multi-month dispensing and facility-based, family-centered care.
Securing stocks of low-volume products, such as alternative, second- and third-line ARV regimens, while avoiding wastage due to expiration before use	• Minimize fragmentation of pediatric ARV volumes by adhering to WHO Optimal Formulary and Limited-Use List. • Share national forecasts for low-volume products with the global APWG secretariat for consolidation and sharing with manufacturers. • Deliberately plan for small volume products by placing orders early (at least 6 months in advance) and in quarterly order cycles to avoid expiration prior to use.
Overstocks of sub-optimal legacy products	• Quantity for the full range of optimal pediatric ARVs and do not wait for exhaustion of the existing stock of suboptimal product. • National programs and funding agencies should allow and budget for disposal of existing, sub-optimal legacy stocks.[9] • Suppliers should be flexible and allow for adjustments or cancellation of orders of suboptimal products.

The Elizabeth Glaser Pediatric AIDS Foundation's Quantification and Budgeting for Rapid and Sustainable Access to New Pediatric Antiretroviral Therapies technical brief outlines key steps for quantifying the full portfolio of optimal pediatric ARV products needed for different treatment regimens and weight bands, estimating the cost, and developing a supply plan. It also includes useful tables regarding recommended dosing, current product pricing, cost per patient per year, and other core data required for timely and accurate pediatric ARV quantification and budgeting.

Quantification of optimal pediatric ARVs should be in accordance with the current WHO treatment guidelines and WHO Optimal Formulary and Limited-use List. As new formulations are introduced, such as the DTG 10 mg dispersible tablet, it is imperative to quantify and introduce new treatment regimens within the context of the full optimal ARV portfolio. During the quantification process, the national TWG should develop accurate assumptions about the numbers of CLHIV who need first-line regimens as well as the proportion who need alternative, second-line, and third-line regimens. In addition, they should estimate the need for different formulations based on the weight (or age if weight information is not available) of CLHIV currently on ART, as well as the predicted number of children who will be newly diagnosed with HIV. The assumptions should account for the following:

1. Percentage of neonates expected to be diagnosed through birth testing given improved access to HIV diagnoses for neonates using point-of-care early infant HIV diagnosis testing
2. Number of new infants and children who are expected to be diagnosed with HIV
3. Number of CLHIV on ART by weight band to estimate the quantities of each ART regimen by wieght band
4. Expected percentage of children who will have virological failure and transition from first-line to second-line treatment, and of children who will fail second-line and transition to third-line treatment
5. Percentage of children who will not tolerate first-line treatment and will need to transition to the alternative first-line treatment

The assumptions about virological failure and intolerance should be based on national intolerance data (if available), reports on adverse drug reactions, treatment failure rates, and published scientific data; for example, data from the recently published ODYSSEY Trial show that after 36 weeks of the study, 19% of enrolled HIV-positive children weighing less than 14 kg had confirmed VL> 400c/mL [10]. It is critical to monitor (if feasible, on a monthly basis) the uptake and consumption of all pediatric ART formulations. This allows for recalculating of the total ART regimens (i.e., all lines of treatment) requirements and costs and updating of supply plans accordingly to reflect the observed trends over time.

One of the challenges of quantifying pediatric ARVs is the mismatch between the demand for ARVs and the production capacity of manufacturers, which often leads to oversupply and/or undersupply of pediatric ARV stocks. National HIV programs can mitigate this challenge by sharing their national forecasts for the full portfolio of pediatric ARVs with the APWG for consolidation and sharing at the global level to ensure that manufacturers know what to expect and don't over- or underproduce.

Frequent meetings are needed to review and update pediatric HIV data and assumptions to account for changes and make adjustments to quantification and supply plans based on up-to-date data. Supply planning should include frequent review of stocks in-country, including expiry dates, and expected stocks in the procurement pipeline (confirmed and planned orders with the estimated delivery dates) to avoid supply imbalances—shortages as well as overstocks and wastage.

Forecasting and supply-planning software and databases of pediatric ARVs are currently available and in use in countries, for example, CHAI Simple Tool, Quantimed, USAID Global Health Supply Chain Program Quantification Analytics Tool, and The New Horizons: Advancing Pediatric HIV Collaborative quantification tool (an Excel-based tool constructed to generate an annual estimate of pediatric patient need for second- and third-line HIV treatment).

4. CONCLUSIONS AND RECOMMENDATIONS

To ensure access to the full range of WHO-recommended optimal pediatric ARV regimens, it is recommended that all stakeholders involved in quantification and supply planning processes do the following:

- National programs should ensure the full portfolio of pediatric ARV regimes is included in the quantification and supply-planning process per the most current WHO guidelines and Optimal Formulary and Limited-use List. While most CLHIV will be prescribed first-line treatment (in low- and middle-income countries, 97% of children on ART are on first-line treatment, and only 3% receive second-line ART[11]), it is important to remember those children on alternative, second-line, and third-line treatment regimens.
- A range of perspectives, including those of clinicians, caregivers, and procurement and supply chain experts, should be considered throughout the quantification and supply-planning process to ensure that quantification is accurate, sufficient, and efficient and that it meets the needs and expectations of clinicians and caregivers.
- Ongoing monitoring and updating of quantification results should be done frequently and should involve reviewing and updating consumption data, assumptions used, stocks on hand and in the pipeline, new products under development, status of products' stringent regulatory authority approval, and new WHO guidelines as well as funding needs, commitments, and gaps.
- Funding commitments by donors and ministries of health should include the full portfolio of pediatric ART regimens.
- Global partners, for example, the APWG, PAWG, and PADO group, have a a critical role to play in advocating with manufactcrers for an adequate, uninterrupted, and sustainable supply of pediatric ARV formulations, particularly low-volume alternative, second- and third-line treatments.

APPENDIX 1:
CURRENT WHO GUIDELINES[12]

Table 1. Preferred and Alternative First-line ART Regimens for Children and Neonates

Population	Preferred First-line Regimen	Alternative First-line Regimen	Special Circumstances
Children from 4 weeks of age and weighing more than 3 kg	ABC + 3TC + DTG[a]	ABC + 3TC + LPV/r TAF[b] + 3TC (or FTC) + DTG	ABC + 3TC + EFV (or NVP) ABC + 3TC + RAL[c] AZT + 3TC + EFV[d] (or NVP) AZT + 3TC + LPV/r (or RAL)
Neonates up to 4 weeks of age and weighing up to 3 kg	AZT (or ABC) + 3TC + RAL[e]	AZT + 3TC + NVP	AZT + 3TC + LPV/r[f]

ABC = abacavir; AZT = zidovudine; DTG = dolutegravir; EFV = efavirenz; FTC = emtricabine; LPV/r = lopinavir/ritonavir; NVP = nevirapine; RAL = raltegravir; TAF = tenofovir alafenamide; 3TC = lamivudine.

a For age and weight groups with approved DTG dosing, from 4 weeks of age and 3 kg.

b For age and weight groups with approved TAF dosing.

c RAL can be used as an alternative regimen only if LPV/r solid formulations are not available.

d EFV should not be used for children younger than 3 years of age.

e Neonates starting ART with a RAL-based regimen should transition to DTG as soon as possible. WHO guidelines provide new dosing guidance for ABC for neonates. However, due to limited availability of ABC syrup, AZT syrup remains an effective option to combine with 3TC for the first 4 weeks of life.

f LPV/r syrup or granules can be used if starting after 2 weeks of age.

Table 2. Preferred and Alternative Second-line ART Regimens for Children

Population	Failing First-line Regimen	Preferred Second-line Regimen	Alternative Second-line Regimen
Children from 4 weeks of age and weighing more than 3 kg	ABC + 3TC + DTG[a]	AZT + 3TC + LPV/r (or ATV/r)	AZT + 3TC + DRV/r[b]
	ABC (or AZT) + 3TC + LPV/r	AZT (or ABC) + 3TC + DTG[a]	AZT (or ABC) + 3TC + RAL
	ABC (or AZT) + 3TC + EFV	AZT (or ABC) + 3TC + DTG[a]	AZT (or ABC) + 3TC + LPV/r (or ATV/r[c])
	AZT + 3TC + NVP	ABC + 3TC + DTG	ABC + 3TC + LPV/r (or ATV/r[c])

ABC = abacavir; ATV/r = atazanavir/ritonavir; AZT = zidovudine; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; LPV/r = lopinavir/ritonavir; NVP = nevirapine; RAL = raltegravir; 3TC = lamivudine.

a As of July 2021, the U.S. Food and Drug Administration and the European Medicines Agency have approved DTG for infants and children older than 4 weeks and weighing at least 3 kg.

b DRV/r should not be used for children younger than 3 years and should be combined with appropriate dosing of ritonavir.

c ATV/r can be used as an alternative to LPV/r for children older than 3 months, but the limited availability of suitable formulations for children younger than 6 years, the lack of a fixed-dose formulation, and the need for separate administration of the ritonavir booster should be considered when choosing this regimen.

Table 3. Summary of Sequencing Options for First-line, Second-line, and Third-line ART Regimens and Preferred and Alternative First-line Regimens for Children

Population	First-line Regimen	Second-line Regimen	Third-line Regimen
Children from 4 weeks of age and weighing more than 3 kg	Two NRTIs + DTG	Two NRTIs + LPV/r (or ATV/r)	DRV/r[a] + 1–2 NRTIs ± DTG[b] Optimize the regimen using a genotype profile for children younger than 3 years
	Two NRTIs + LPV/r	Two NRTIs + DTG	
	Two NRTIs + NNRTI	Two NRTIs + DTG	Two NRTIs + (ATV/r, LPV/r, or DRV/r[a]) ± DTG[b]

ATV/r = atazanavir/ritonavir; DRV/r = darunavir/ritonavir; DTG = dolutegravir; LPV/r = lopinavir/ritonavir; NNRTI- non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor.

a Darunavir cannot be used for children younger than 3 years.

b For children older than 4 weeks and weighing more than 3 kg.

APPENDIX 2:
KEY RESOURCES AND TOOLS FOR QUANTIFICATION AND SUPPLY PLANNING

RESOURCE	LINK
Amuge on behalf of the ODYSSEY trial team. Dolutegravir-based ART is superior to standard of care in children living with HIV, International Workshop of HIV Pediatrics, July 2021	https://odysseytrial.org/
ARV Procurement Working Group (APWG)	https://www.arvprocurementworkinggroup.org/home
CHAI Simple Tool	https://www.newhivdrugs.org/quantification-and-forecasting
Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; July 2021	https://www.who.int/publications/i/item/9789240031593
JSI. Quantification of Health Commodities. A guide to forecasting and supply planning for procurement. January, 2017	https://www.jsi.com/resource/quantification-of-health-commodities-2017
Quantification and Budgeting for Rapid and Sustainable Access to New Pediatric Antiretroviral Therapies: Technical Brief: Elizabeth Glaser Pediatric AIDS Foundation; 2020	https://www.pedaids.org/resource/quantification-and-budgeting-for-rapid-and-sustainable-access-to-new-pediatric-antiretroviral-therapies/
2021 HIV Market Report: The state of the HIV market in low- and middle-income countries, Issue 12, October 2021, Clinton Health Access Initiative	https://www.clintonhealthaccess.org/2021-hiv-market-report-the-state-of-the-hiv-market-in-low-and-middle-income-countries/
The 2021 optimal formulary and limited-use list for antiretroviral drugs for children: policy brief. Geneva: World Health Organization; 2021	https://apps.who.int/iris/handle/10665/340949
Mohammed P, Linden A, Reilly M (2019) Quantifying pediatric patient need for second- and third-line HIV treatment: a tool for decision-making in resource-limited settings. PLoS ONE 14 (11): e0224226	https://doi.org/10.1371/journal.pone.0224226
Transitioning to the 2021 optimal formulary for antiretroviral drugs for children: implementation considerations. Policy brief: World Health Organization; 2021	https://www.who.int/publications/i/item/9789240031371

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