Photo: Eric Bond, 2020

Accelerating Access to Optimal Child-Friendly Antiretroviral Formulations:

Lessons Learned from Tanzania

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DNDi
Drugs for Neglected Diseases *initiative*

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Fighting for an AIDS-free generation

1. Background

Among the estimated 92,000 children aged 0–14 years living with HIV in Tanzania, only 59,623 (65%) were on antiretroviral therapy (ART) in 2019, and more than half of those on ART were prescribed suboptimal ART regimens. In 2015, Tanzania adopted the World Health Organization (WHO)–preferred first-line ART regimen of abacavir/lamivudine (ABC/3TC) plus lopinavir/ritonavir (LPV/r) for all HIV-infected children weighing less than 20 kilograms (kg). However, by 2018, 67% of children on first- and second-line ART in Tanzania were still receiving zidovudine/lamivudine (AZT/3TC) plus nevirapine (NVP) in part because the liquid and fixed-dose dispersible formulations of NVP were easier to administer. In May 2019, more than half of all children below 10 years of age receiving ART were still on an NVP-based regimen at the 424 health care facilities supported by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) (Table 1).

Table 1. ART by Age Group in EGPAF-Supported Health Care Facilities, May 2019

Age Group	% on NVP	% on EFV	% on LPV/r1	% on LPV/r2
0–4 yrs	57%	17%	20%	6%
5–9 yrs	57%	32%	6%	4%
10–14 yrs	42%	44%	2%	6%
15–19 yrs	16%	68%	0%	4%

NVP = nevirapine; EFV = efavirenz; LPV/r1 = as first line; LPV/r2 = as second line.

1.1 Barriers to optimizing pediatric ART

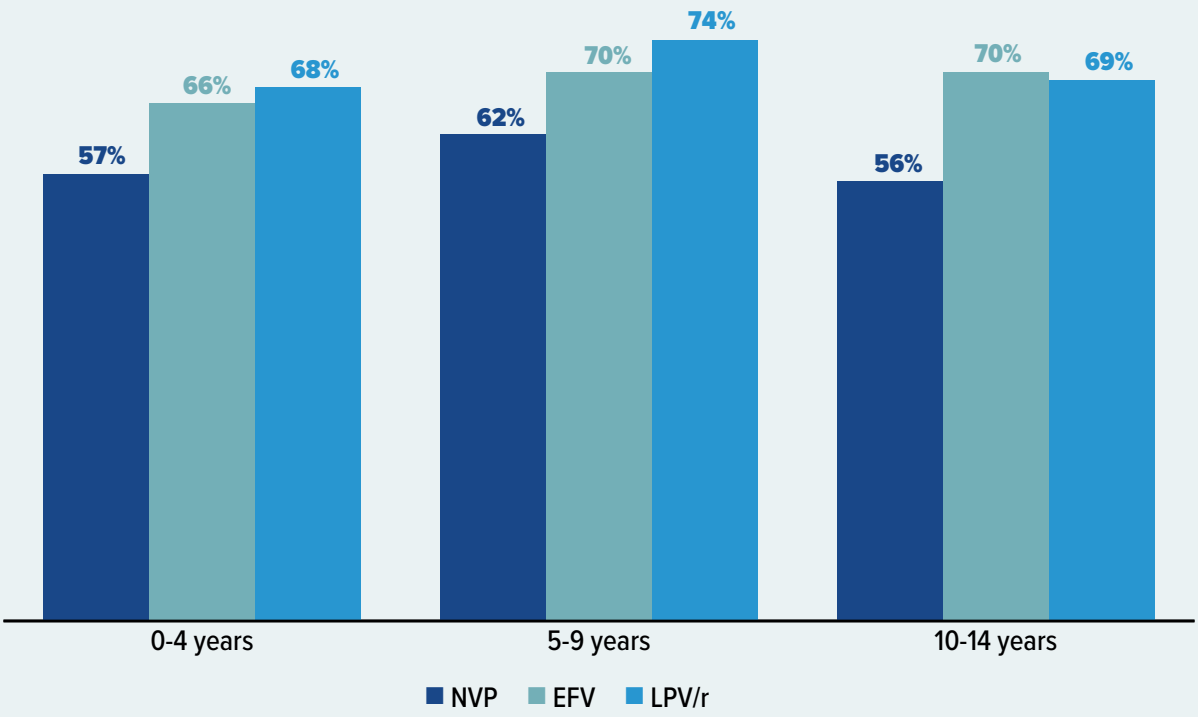
A number of barriers prevented children on ART from accessing the optimal regimens recommended in the country's national guidelines. Barriers included but were not limited to

- poor palatability of LPV/r, especially the liquid formulation;
- inability for younger children to swallow whole LPV/r tablets due to their size;
- unavailability of LPV/r liquid at lower-level health facilities due to its cold chain requirement;
- frequent stock-outs of pediatric formulations at the health-care-facility level leading to improvised use of adult formulations in the pediatric population;
- countrywide stock-outs of pediatric formulations, especially LPV/r liquid and 100/25 mg tablets;
- poor data quality and availability for quantification and supply planning of pediatric ARVs due to incomplete records and out-of-date data systems (e.g., Electronic Logistics Management Information System [e-LMIS]); and
- lack of confidence among health service providers in prescribing, and monitoring, pediatric ARVs.

2. Steps Taken to Transition Children to WHO-Recommended LPV/r Solid Formulations and Dolutegravir 50 mg Tablets

The main goal of ART for children is to achieve viral suppression and preserve, enhance, or reconstitute the immune system to avert opportunistic infections in order to promote optimal growth and development. An EGPAF Tanzania review of data up to September 2019 found that children receiving NVP showed low viral suppression rates compared with those receiving LPV/r- and EFV-based regimens. Children 0 to 4 years of age showed the lowest viral load suppression, possibly because the majority were receiving suboptimal regimens (see Figure 1). The results were shared in the pediatric technical working group, of which recommended countrywide transition to solid LPV/r based regimen for all <20kgs and to DTG50mg based regimen for 20kgs and above. The recommendations were adopted by MOHCDGEC and started transitioning children weighing 20 kg and above to dolutegravir (DTG) 50 mg tablets.

Figure 1. Viral supression <1000c/ml by regimen by age group as of September 30th, 2019



Following the release of WHO recommendations in 2018 on the use of LPV/r solid formulations in children weighing less than 20 kg and DTG 50 mg tablets for children weighing more than 20 kg, a national pediatric technical working group (PTWG), including a range of different stakeholders, engaged in developing a transitioning and roll-out plan. To ensure rapid uptake of the WHO recommendations, the National AIDS Control Programme (NACP) took the following steps:

1. Approved WHO-recommended pediatric ARVs and developed an implementation guideline taking into consideration the country context
2. Updated the national guidelines to include LPV/r granules and DTG 50 mg tablets as recommended by the WHO

3. Worked with the Tanzania Medical and Drugs Authority to register and to include LPV/r 40/10mg granules formulation in the essential medicines list
4. Forecasted and ordered the LPV/r granules as an emergency
5. Developed an introduction and transitioning plan for LPV/r solid formulations and DTG 50 mg tablets
6. Developed and adapted training materials for trainers and health care workers, including job aids and information, education, and communication materials for caregivers
7. Trained trainers on transitioning of children to LPV/r solid formulations and DTG 50mg and reinforced training in follow-up and site monitoring visits
8. Trained health care workers in providing LPV/r solid formulations and DTG 50 mg tablets to eligible children according to body weight and ability to swallow

2.1 Goal and objectives of the pediatric ARV optimization work in Tanzania

GOAL: Streamline and accelerate the introduction of new child-friendly ARV formulations, and transition all children to optimal regimens as recommended in the Tanzania guidelines.

OBJECTIVES

1. Field-test and adapt training tools, and train health care workers to administer the new formulations.
2. Review policy and guidelines to adopt new formulations.
3. Document and disseminate lessons learned in the adoption and transitioning to optimal regimens to inform future transitions.

2.2 Transitioning to optimal regimens

Tanzania conducted transitioning in phases: phase 1 focused on hospitals; phase 2 focused on health centers and dispensaries with 1,000 or more recipients of care; and phase 3 focused on facilities with between 500 and 1,000 recipients of care (phase 3a) as well as a mixture of facilities with less than 500 recipients including prevention of mother-to-child HIV transmission (PMTCT) stand-alone facilities (phases 3b and c). Transitioning started with adults and adolescents transitioning to tenofovir/lamivudine/dolutegravir (TLD) and DTG 50mg in February 2019. In July 2019, children weighing 20 kg and above were transitioned at facilities that had DTG. The phased approached was used because the country had stock-outs of some commodities, especially LPV/r 100/25 mg tablets, while some commodities were overstocked (e.g., AZT/3TC/NVP pediatric formulations). Therefore, the transition plan attempted to balance wastage while transitioning to optimal regimens.

Children weighing less than 20 kg were struggling to swallow LPV/r whole tablets. In addition, LPV/r syrup was poorly tolerated by children and difficult to store due to the cold chain requirement. For these reasons, the NACP chose to introduce LPV/r granules, which were newly available in the global market, were more palatable, and did not require cold chain. The official communication to start transitioning to LPV/r granules was released on January 6, 2020. The guidance was as follows:

1. The distribution of LPV/r granules to 365 health facilities out of 5,000 facilities in the country that provide care and treatment services—of which 191 were hospitals and 174 were high-volume facilities—was to be part of the phase 1, push system for

granules. The push system included 26 sites out of 315 facilities supported by EGPAF at that time in five regions. The remaining facilities were asked to order from Medical Store Department (MSD) after being trained. MSD is an autonomous department under the Ministry of Health, Community Development, Gender, Elderly and Children responsible for develop, maintain and manage an efficient and cost effective system of procurement, storage and distribution of approved medicines and medical supplies required for use by the public health services. Children weighing 6 to 9.9 kg were prioritized for transitioning to LPV/r solid formulations, while children weighing 10 kg and above continued with their current regimen until the legacy formulations were depleted in the country.

2. Children weighing less than 6 kg should receive LPV/r liquid formulations.
3. Children 20 kg and above were transitioned to a DTG-based regimen in all sites with DTG.

NB: The LPV/r granules push list covered the TLD/DTG phase 1 health facilities.

Photo: Makopano Letsatsi, 2021

Table 2. Assumptions in Quantification and Transitioning Children to an Optimal Regimen while Considering Phasing Out NNRTI-Based Regimens

Patient Group	%	% Regimen	ARV Regimen	Formulation	% Weight Band
< 4 kg, 0–3 m	2%	37%	ABC/3TC + LPV/r	ABC120/3TC60 dispersible tabs + LPV80/r20 syrup	5%
4–9.9 kg, 4 m–3 y	4%		ABC/3TC + LPV/r	ABC120/3TC60 dispersible tabs + LPV40/r10 granules	11%
10–19.9 kg, 3–6 y	31%		ABC/3TC + LPV/r	ABC120/3TC60 dispersible tabs + LPV100/r25 tabs	84%
20–30 kg	36%	36%	ABC + 3TC + DTG	ABC120/3TC60 dispersible tabs + DTG50 tabs	100%
> 30 kg	20%	20%	TDF + 3TC + DTG	TDF300/3TC300/DTG50 tabs	100%
> 30 kg, alt TLD	4%	4%	TDF + 3TC + EFV	TDF300/3TC300/EFV600 tabs	100%
20–30 kg, 1 L EFV or NVP, transitioned to LPV/r	2%	2%	AZT + 3TC + LPV/r	AZT60/3TC30 dispersible tabs + LPV100/r25 tabs	100%
20–30 kg, 1 L EFV or NVP, transitioned to ATV/r	1%	1%	ABC + 3TC + ATV/r	ABC600/3TC300 scored tabs + ATV300/r100 tabs	100%

NNRTI = non-nucleoside reverse transcriptase inhibitor; ARV = antiretroviral; kg = kilograms; m = months; y = years; 1L= first line, TLD = tenofovir/lamivudine/dolutegravir; EFV = efavirenz; NVP = nevirapine; ATV/r = atazanavir/ritonavir; ABC = abacavir; 3TC = lamivudine; LPV/r = lopinavir/ritonavir; DTG = dolutegravir; TDF = tenofovir disoproxil fumarate; AZT = zidovudine

3. Revolutionizing Access to Quadrimune for Young Children Living with HIV (REACH) Project Tanzania

With the support of the Drugs for Neglected Diseases initiative (DNDi), EGPAF provided technical assistance to the MOHCDGEC to accelerate pediatric ARV optimization in the EGPAF/USAID Boresha Afya Project regions.

The project implemented the following activities:

Figure 2. Activities implemented to accelerate pediatric ARV optimization

ACTIVITY 1 Rapid Landscape Assessment	ACTIVITY 2 Adapting Tools for Health Care Providers and Caregivers	ACTIVITY 3 Documentation and Dissemination of Lessons Learned
• Guideline/job aids updated • Essential medicines list updated • Product transitioning plan to shorten time to patient access created • Review consensus assumptions for forecasting • Ordering and reordering • Engaged civil society and UN agencies to create demand • Disseminated circular/ official document to start transitioning at health facility	• Adapted ICAP materials • Developed training package for health workers • Training of trainers (TOTs) • Other implementing partners given materials to train health workers in respective regions • Included regional and district pharmacists • Job aids developed for health workers and caregivers/guardians • Site-monitoring visits by TOT and regional supervisors	• Disseminated training resources, lessons learned, and implementation guidance to support smooth future products adoption through • annual stakeholder meeting; • pediatric technical working group; and • clinical subcommittee.

UN = United Nations; ICAP = International Center for AIDS Care and Treatment Programs; TOT = trainer of trainer

In addition to national-level activities, EGPAF supported health facilities directly through coaching and mentorships to fast-track the transitioning process.

The following strategies were employed:

- Train regional and district mentors and supervisors and assign them a minimum of two health facilities to mentor.
- Develop quarterly mentorship and coaching schedules for mentors to visit sites during clinical visits.
- Rearrange clinical visits for child-centered family clinics, where parents come on the same day and are served together with the child by one clinician addressing family needs for optimization of care.

- Print job aids and dosing charts and insert them in the files of all children after assessment and transition to an optimal regimen.
- Conduct caregiver engagement sessions to assess successes and challenges in administering LPV/r tablets to children and/or demonstrate how to prepare and administer LPV/r granules.
- Include a disclosure session to children (partial and full), depending on the age and understanding of the child with the aim of enhancing adherence to treatment.

3.1 Achievements and success factors

Most of the planned activities for transitioning children to LPV/r solid formulations and DTG 50 mg tablets according to national guidlines were implemented as scheduled. The following factors played an important role in fast-tracking the transition:

- Thirty-two trainers and 814 health care workers were trained in administering LPV/r granules, covering 210 health care facilities and reaching 1,141 children 0–4 years of age.
- LPV/r was already part of the 2015 revised guidelines, and therefore the essential medicines list, dosages, and standard operating procedures required an amendment only.
- Pediatric ARV optimization gained momentum after the adult TLD transition was completed.
- Stock-outs of EFV 200 mg and LPV/r 100/25 mg tablets accelerated the transitioning of children weighing 20 kg and above to DTG 50 mg tablets, where this formulation was available, meanwhile ordering granules for those weighing less than 20 kg.
- Training materials were readily available to adapt (e.g. ICAP granules administration instruction materials)
- Several different stakeholders (the Clinton Health Access Initiative, Faith-Based Action for Scaling Up Testing & Treatment for Epidemic Response, UNICEF, and EGPAF) contributed funds and support for workshops and consensus meetings.
- Other stakeholders and development partners (e.g., UNICEF, WHO, and U.S. government agencies) were engaged.
- The PTWG consistently followed up with the MOHCDGEC on action plans on pediatric-friendly ARV formulations.
- Vehicles were coordinated and supported to distribute and redistribute ARVs from zonal MSD, regions, council, and health facilities to health facilities to ensure uninterrupted stock availability for refills after transition.

3.2 Challenges and actions taken to overcome them

Despite the successes in transitioning children to optimal regimens, and in particular introducing the new LPV/r granule formulation, implementation faced some challenges that required specific actions to overcome them. Those challenges and responses included the following:

- **DELAYED RELEASE OF THE REVISED NATIONAL GUIDELINES:** The NACP released a circular in January 2020 describing the changes in guidelines and guiding health care workers on how to transition to LPV/r granules and DTG 50 mg tablets.
- **LACK OF MATERIALS IN LOCAL LANGUAGES FOR HEALTH CARE WORKERS AND CAREGIVERS:** The materials available at the global level were in English and required translation into Swahili for effective use in the local context.
- **EXCESS STOCK OF LEGACY FORMULATIONS (E.G., NVP, LPV/R SYRUP):** Large stocks of legacy products at the facility level caused delays in the start of transitioning due to the need to balance wastage with the benefits of transitioning patients to optimal regimens. Transitioning was therefore conducted in phases and some stocks were shipped to other countries (e.g., Eswatini, Ghana, Zimbabwe, and Sao Tome) that were still using non-nucleoside reverse transcriptase inhibitors as a first line.
- **INSUFFICIENT SUPPLIES OF NEW FORMULATIONS AT THE FACILITY LEVEL:** To ensure uninterrupted stocks at the facility level, ARVs were redistributed between health facilities and a plan was developed to ensure that high-volume sites had enough stock for 12 months following active transitioning. In addition, multi-month dispensing was delayed until more reliable supplies were available.
- **INABILITY OF CHILDREN WEIGHING LESS THAN 15 KG (3 YEARS) TO SWALLOW WHOLE TABLETS:** When quantifying for LPV/r solid formulations, it was assumed that all children over 10 kg in weight could swallow LPV/r whole tables. However, it was found that children weighing up to 15 kg (3 years) could not swallow whole tablets. A form was developed to identify which caregivers were cutting, crushing, or dissolving LPV/r tablets before administration. Children who could not swallow whole tablets were transitioned to LPV/r granules. However, that led to overstocks of LPV/r 100/25 mg tablets as children had to remain on LPV/r granules for longer than expected. Subsequent orders for LPV/r granules were doubled to adjust for the higher weight band and age for transitioning children to tablets.
- **VARIABLE COMPETENCY AMONG CAREGIVERS ON LPV/R GRANULE ADMINISTRATION:** Preparation of LPV/r granules was not well understood, and therefore some caregivers mixed it with large amounts of food material that the child could not finish. Caregivers reported refusal, vomiting, and spitting among children. Specific pediatric clinics were established for ART review and to demonstrate preparation and administration. Following the clinics, 70% of caregivers reported confidence in preparing and administering LPV/r granules.
- **FORMULATIONS (E.G., GRANULES, TABLETS) NOT CAPTURED IN CARE- AND TREATMENT-MONITORING TOOLS:** Due to lack of reporting by formulation, consumption data were not reliable and assumptions in quantification considered age and weight only. A paper-based system was put in place to document the number of boxes of granules dispensed per child. It is recommended to review and revise the database to include formulations in addition to the regimen.
- **FRAGMENTED OWNERSHIP AND MONITORING OF THE TRANSITION PROCESS:** In the absence of a central coordinating mechanism, it was left to implementing partners to work with facility staff to identify children and effect the transition. No national data were presented on the progress of transitioning in order to guide implementation. This was discussed in the national PTWG, and every implementing partner was required to present progress on a quarterly basis. Implementing partners kept a record of the transitioning process to inform future transitioning.

Box 1. Children's ability to swallow LPV/r whole tablets

Almost two-thirds of children aged 0–4 years receiving LPV/r tablets assessed on swallowing ability could not swallow LPV/r tablets whole. As a result, caregivers reported crushing, cutting, and/or dissolving the tablets in water for hours before administration. Such practices are discouraged, because they reduce the effectiveness of the treatment. In response, EGPAF used a differentiated service delivery model to build the capacity of caregivers to address the identified challenges. The inability to swallow forced health care providers to increase the age/weight for prescribing and transitioning to granules, which led to a temporary surplus of LPV/r 100/25 mg tablets and a shortage of LPV/r granules in some regions immediately after starting transitioning. The new age/weight range and ability to swallow whole tablets was taken into consideration in the subsequent quantifications of LPV/r tablets and granules.

Photo: Eric Bond, 2020

4. Results

Between June 2018 and June 2020, the proportion of children on ART taking DTG- and LPV/r-based regimens increased from 0% to 57% and from 9% to 29%, respectively. At the same time, the proportion of children on ART prescribed suboptimal NVP- and EVF-based regimens decreased from 49% to 6% and from 42% to 7%, respectively. Over the same period, viral load suppression rates among children on ART increased overall from 60% to 83%. An EGPAF survey of 175 health care providers and 148 caregivers found high levels of confidence among those providers and caregivers regarding LPV/r preparation and administration. The primary challenges reported by health care providers were calculating the dose of LPV/r, the ability to build sufficient knowledge among caregivers in LPV/r preparation and administration, and stock-outs of ARV drugs. Among the 63 caregivers who reported a challenge with LPV/r administration, 36 mentioned vomiting as the main challenge and 11 noted ARV shortages during a refill visit.

4.1 Proportion of children transitioned and viral suppression rates

The number and proportion of children on optimal regimens at EGPAF-supported sites increased from 392 children (9%) in June 2018 to 4,052 children (87%) by June 2020, including 1,350 children (29%) who were on LPV/r-based regimens. Within the same period, the viral load suppression rate among children increased from 60% to 83%, whereby an improvement is seen across all regimens, including the suboptimal NVP- and EFV-based regimens.

Figure 3:. Trends in the Proportion of Children on ART by Regimen

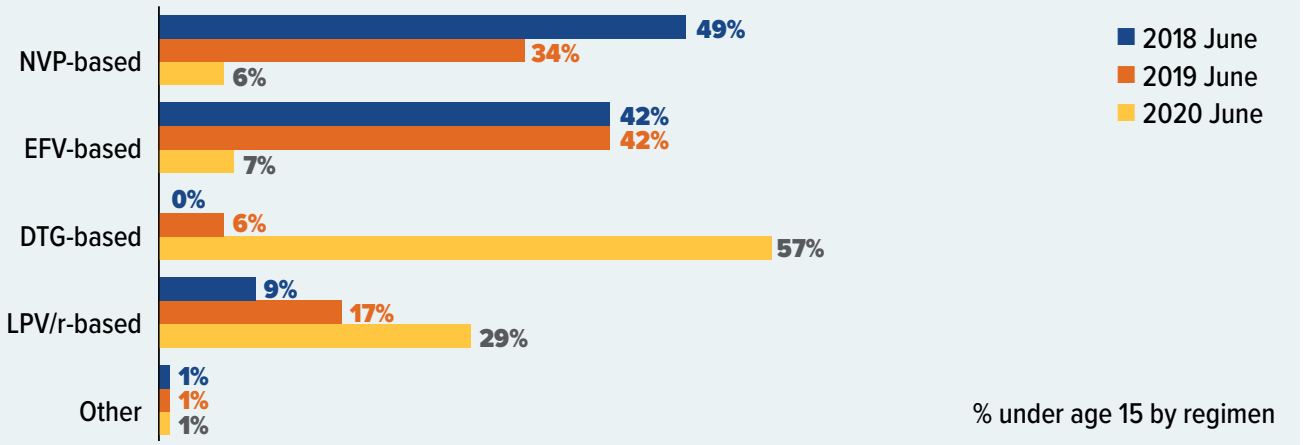
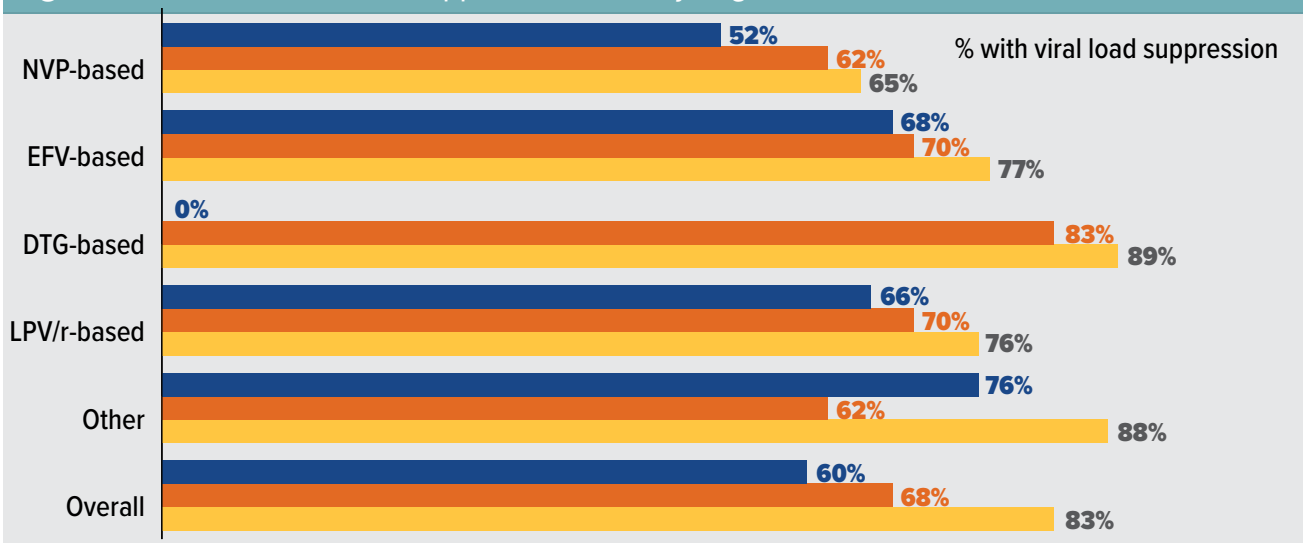


Figure 4. Trends in Viral Load Suppression Rates by Regimen



4.2 Results of health care provider survey

In January 2021, EGPAF conducted a survey of 175 health care workers to collect feedback on their experience in counseling caregivers on the preparation and administration of LPV/r 2-in-1 granules. Of the 175 health care workers interviewed, 45% were prescribers, 40% were dispensers, and 15% were counselors. The challenges in transitioning children to LPV/r granules most frequently reported by those assessed were as follows: dose calculations by health care workers (27%); lack of sufficient knowledge by caregivers (26%); and stock-outs (25%).

Table 3. Dosage Chart for LPV/r 2-in-1 Granules

Formulation (unit for dosing)	3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg	
	a.m.	p.m.	a.m.	p.m.	a.m.	p.m.	a.m.	p.m.	a.m.	p.m.
LPV/r 40/10 mg granules (sachet)	2	2	3	3	4	4	5	5	6	6

LPV/r = lopinavir/ritonavir; mg = milligram; kg = kilograms.

The majority reported that they were very confident with their level of knowledge in guiding caregivers on how to prepare and administer LPV/r granules to children (84.6% and 85.7%, respectively). Among those assessed, 77% reported always using job aids when counseling caregivers and 88% reported that the job aids were very useful. At the same time, 46% reported that their primary concern was caregiver knowledge on preparation and administration of LPV/r granules. Health care workers reported that the most frequent questions asked by caregivers during counseling sessions concerned the types of food they would use during preparation (38%), what to do when a child vomits (38%), and how much food to use for each sachet of granules (14%). They also reported that the most frequent worries expressed by caregivers were as follows: too many sachets to administer (41%), vomiting (27%), and the preparation time (16%). Overall, about half (48%) of the health care workers assessed reported good acceptance of the drug by the children/caregivers.

Table 4. Health Care Provider Survey Results

Variable	Number (n)	Proportion (%)
Level of confidence among HCP on LPV/r preparation and administration (n = 175)		
Very confident	148	86
Partially confident	26	14
Not confident at all	1	0
Primary worry among HCP during LPV/r transition (n = 175)		
Caregiver's knowledge	80	46
No worries	42	24
Taste	25	14
Too many sachets	20	11
Availability of medicine	8	5
Most frequent question asked by caregivers on LPV/r (n = 175)		
Type of food to use	67	38
What to do when the child vomits	67	38
Amount of food per sachet	24	14
Drug taste	17	10
Most frequent worry experienced by caregivers during LPV/r transitioning (n = 125)		
Too many sachets	52	42
Vomiting effect	34	27
Preparation time	20	16
Are the granules similar to other drug formulations	10	8
Lack of food for mixing with granules	9	7
Primary challenges experienced by HCP during LPV/r transitioning (n = 175)		
Dose calculations	47	27
Lack of sufficient knowledge on the caregiver side	46	26
ARV drugs out of stock	43	25

Variable	Number (n)	Proportion (%)
Palatability	23	13
Language barriers	14	8
Lack of information, education, and communication materials	1	0
Frequency of job aid use reported by HCP (n = 175)		
Always	135	77
Once in a while	29	17
Never	11	6
Usefulness of job aids reported by HCP (n = 175)		
Very useful	154	88
Somehow useful	18	10
Never	1	6
Primary suggestion for filling the knowledge gap among HCPs on LPV/r preparation and administration (n = 46)		
On-site physical practice	22	48
Demonstrations on preparation and administration	17	37
More posters	6	13
Instructions on storage of granules	1	2
Key success from the use of LPV/r granules reported by HCPs (n = 133)		
Good acceptance of the drug by the children/caregivers	65	49
Good appetite and weight gain	22	17
Proper growth and development	15	11
Viral suppression	14	11
Multiple successes (more than one of the above)	17	13

HCP = health care provider; LPV/r = lopinavir/ritonavir; ARV = antiretroviral

4.3 Results of the caregiver survey

EGPAF also surveyed 148 caregivers to assess their perceptions of the preparation and administration of LPV/r granules compared with other formulations. Among those surveyed, 72% reported that the preparation and administration of LPV/r granules was easier than liquid and tablet formulations. Furthermore, 74% reported that they were very confident that they gave the drug correctly to their children in terms of preparation, dosing, and administration; 80% responded that the amount of granules given to their children was appropriate and that the child would finish the whole amount without any difficulties; and 70% perceived that the LPV/r taste was pleasant. Nearly all caregivers (94%) reported that they mixed LPV/r granules with food or drinks for administration. The most common food or drink used was porridge, followed by milk and smashed food like bananas and potatoes. More than three-quarters of the caregivers said they spent less than 5 minutes to prepare and administer granules, 79% and 77%, respectively. The challenges most frequently reported by caregivers were vomiting (57%), availability of granules for refill (17%), and unpleasant taste (12%).

Table 5. Caregiver Survey Results

Variable	Number (n)	Proportion (%)
Perception of caregivers on LPV/r preparation and administration compared with other formulations (n = 148)		
Easier to administer than syrup or tablet	107	72
Same challenges as syrup and tablet formulations	41	28
Level of confidence among caregivers on LPV/r preparation and administration (n = 148)		
Very confident	109	74
Partially confident	34	23
Not confident at all	5	3
Perception of caregiver on LPV/r granules dosage (n = 148)		
Appropriate for the child to finish one dose at a time	119	80
Too much for the child to finish one dose at a time	29	20
Perception of caregiver on LPV/r granules taste (n = 148)		
Pleasant	104	70
Unpleasant	44	30
LPV/r granules administration methods (n = 148)		
Mixed with food/drink	140	95
Plain then water	8	5
Time spent in preparation and administration of LPV/r granules (n = 148)		
Less than 5 minutes	117	79
5 to 10 minutes	21	14
More than 10 minutes	10	7

Variable	Number (n)	Proportion (%)
Main challenge reported by caregivers (n = 63)		
Vomiting	36	57
Shortage during refill visit	11	17
Refusal by child	5	8
Too many sachets	4	6
Unpleasant taste	7	12

LPV/r = lopinavir/ritonavir

Photo: Eric Bond, 2020

5. Lessons Learned

Transitioning children to new ARV formulations or regimens requires careful assessment and planning, accurate quantification and supply planning of the full range of WHO-recommended pediatric ARVs, updated national policies and guidelines, capacity building of health care providers and caregivers, and demonstrations and close follow-up thereafter to sustain quality of care. Standardized training, mentorship, monitoring, and evaluation tools need to be developed, harmonized, and used by all key stakeholders and implementers to avoid silos.

To support the transitioning of children to optimal regimens and the introduction of new formulations, some key programmatic factors need to be in place for successful uptake and roll-out:

Provision of simple transition guidance for country teams

Assessment of available stocks of pediatric ARVs to inform country transition plans

Assessment of whether manufacturing capacity can meet country demands

Development of a detailed transition plan with clear timelines, milestones, and targets as well as monitoring, progress review, and evaluation components

Training of health care workers that is coordinated (timed well) with transition plans

Advanced mentorship and support at all stages

Caregiver support for messaging in transition for adherenc

Community engagement to increase treatment literacy and demand for new products

Introduction of more efficient, patient-centered ARV delivery models

Strengthened supply chain, information, and pharmacovigilance systems

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