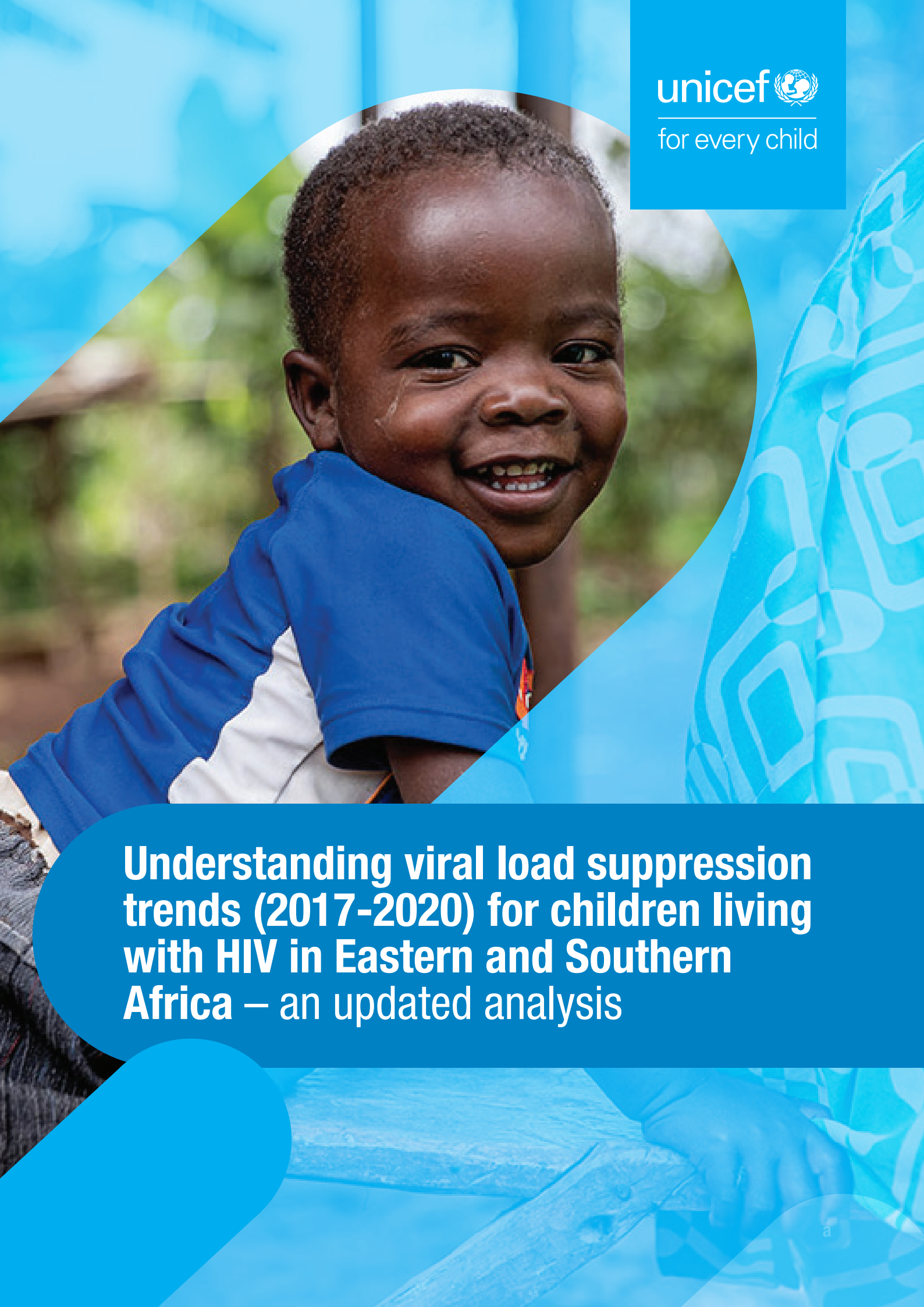

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Understanding viral load suppression trends (2017-2020) for children living with HIV in Eastern and Southern Africa – an updated analysis

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Understanding viral load suppression trends (2017-2020) for children living with HIV in Eastern and Southern Africa

—

an updated analysis

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Acronyms

ART	Antiretroviral Therapy
ARV	Antiretroviral
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
CLHIV	Children Living with HIV
DBS	Dried Blood Spot
DRV/r/DAR	Darunavir/ritonavir
DTG	Dolutegravir
EFV	Efavirenz
ESA	Eastern and Southern Africa
LIMS	Laboratory Information Management System
LPV/r	Lopinavir-ritonavir
NVP	Nevirapine
Post-IAC	Post-Intensive Adherence Counselling
RAL	Raltegravir
VL	Viral Load
VLS	Viral Load Suppression

Executive Summary

Among the 940,000 children (aged 0-14 years) living with HIV in Eastern and Southern Africa, only two-thirds are on life-saving treatment.[1] Children living with HIV have lower treatment coverage and lower viral load suppression (VLS)[2] compared to adults, increasing their risk of morbidity and mortality. In 2022, there were 36,000 AIDS-related deaths among children within Eastern and Southern Africa.[3] While progress has been made, it remains far too slow to achieve the global goal of ending AIDS by 2030.

To ensure evidence-driven policies and programmes for paediatric HIV, in 2019 UNICEF commissioned a study of VLS trends and associated factors in Malawi, Uganda and Zimbabwe from 2016 to 2018. Laboratory Information Management Systems (LIMS) data were analyzed and triangulated with a review of health records and key informant interviews from Malawi. Findings confirmed that children living with HIV have sub-optimal viral suppression. One out of three children who had a viral load (VL) test had not achieved viral suppression. Challenges within health systems, lack of child-friendly regimens, being younger in age, and inconsistent support to children and caregivers were all detriments to viral suppression while longer duration on treatment and post-intensive adherence counseling (post-IAC)[4] supported successful viral suppression.

This report provides an updated analysis of VL monitoring among children in Malawi, Uganda and Zimbabwe covering 2017 to 2020. The purpose was to assess any changes in paediatric VLS, noting that new drug regimens have been recommended by the World Health Organization (WHO) and COVID-19 has impacted the region.

A limitation was missing data for key variables. Although data completeness had improved since the earlier study, there were still considerable data missing for key variables, such as ART regimen, duration on ART, and reasons for a VL test. The absence of other variables in the LIMS design such as weight and co-morbidities further limited both analyses.

Within four years, VLS in children reached 77.6% in 2020 - an improvement from 64% in 2017, 65% in 2018, and 67% in 2019. The analysis also found that more children were receiving a VL test as compared to previous years. Routine clinical follow up was the main reason for VL testing. Encouragingly, VL testing increased both following post-IAC and for suspected treatment failure. VLS following post-IAC increased steadily, from 29.6% in 2017 to 60.9% in 2020. The study also found an increase in antiretroviral (ARV) regimen options for children and an increased proportion of children on Dolutegravir from 3.2% in 2019 to 29% in 2020, reflecting WHO recommendations.[5]

While the study's findings are encouraging, the recommendations point to an urgent need for governments and programmers to accelerate routine and post-IAC VL testing, continue to scale up more efficacious and palatable drug regimens for children, and strengthen the quality and use of laboratory data to ensure that children living with HIV enjoy treatment success and positive health outcomes.

1 https://aidsinfo.unaids.org/, (July 2023)

2 Viral load suppression is defined as an HIV viral load of less than 1,000copies/ml of blood

3 https://aidsinfo.unaids.org/, (July 2023)

4 Post-Intensive Adherence Counseling is conducted following an unsuppressed routine viral load test. The counselling is for three months with a viral load test repeated at the end of the three months.

5 World Health Organization. Updated Recommendations on First-Line and Second-Line Antiretroviral Regimens and Post-Exposure Prophylaxis and Recommendations on Early Infant Diagnosis of HIV. Supplement to the 2016 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treatment and Preventing HIV Infection. https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf

1.0 Introduction

Children living with HIV can enjoy long and healthy lives while taking ARV medicines that slow or stop the virus from multiplying. However, global estimates have found that children lag behind adults in both accessing lifesaving ART and achieving VLS.[6]

Eastern and Southern Africa accounts for 63% of all children (aged 0-14 years) living with HIV globally.[7] As compared to 83% of adults, only 63% of children living with HIV in the region are on ART.[8] Achieving VLS is crucial to reducing child morbidity and mortality yet, once on treatment, many children living with HIV are either not monitored for VL or have sub-optimal VLS.[9]

In 2018, UNICEF responded to the urgent need to better understand and improve VLS in children with HIV by commissioning a study on the proportions, trends, bottlenecks and facilitators of VLS among children who are on ART. The study focused on three of the ESA countries where VLS was lower among children when compared to adults - Malawi, Uganda and Zimbabwe.

Since the initial study's launch in 2021, several global events occurred, including the COVID-19 pandemic and the introduction of new consolidated HIV treatment guidelines by WHO.[10] To understand how these developments may have affected VL testing and suppression rates, UNICEF commissioned an updated analysis to include laboratory data for 2019 and 2020 in the same three countries.

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6 https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(21)00265-4/fulltext

7 https://aidsinfo.unaids.org/

8 https://aidsinfo.unaids.org/

9 Pham M., et. Al. (2022) Viral load monitoring for people living with HIV in the era of test and treat: progress made and challenges ahead – a systematic review. BMC Public Health (2022) 22:1203. https://doi.org/10.1186/s12889-022-13504-2

10 https://www.who.int/publications/i/item/9789240031593

2.0 Methods

The updated review entailed secondary data analysis of LIMS data from Malawi, Uganda and Zimbabwe of children aged <15 years in the period 2017-2020.

Ethical approval was received from the research ethical regulatory authorities in the three countries, including the National Health Sciences Research Committee in Malawi, the Medical Research Council of Zimbabwe, the Uganda National Council for Science and Technology, and the National Health Laboratory Services in Uganda.

The Ministries of Health in Malawi, Zimbabwe and Uganda provided access to raw LIMS data. A data cleaning process included discarding records that did not have VL results, were duplicates, did not indicate age or the indicated age was above 14 years.

The primary outcome was virologic suppression, defined as having <1000 copies of viral RNA/ml of blood plasma. Data sets were combined by year and analyzed using STATA version 17.0. First, descriptive analysis of continuous variables was undertaken. Second, to determine association between VLS and the categorical variables, cross-tabulations were conducted providing the frequency in each category and proportion of children with/without VLS. Intergroup comparisons were conducted for sample type, ARV regimen and duration on ART. To determine the factors associated with VLS and direction of association, the 2020 data set was used by conducting multinominal regression for the category independent variables against the outcome (VLS). Adjusted ratios (OR) and 95% confidence interval (CI) were calculated at p-value of 0.05. The following sub-categories were used as the reference: Female for Sex, <1 year for age group, <1 year for period on ART, First-line NVP and 2nd Line LPV/r for the ARV regimen, Routine for Reason for VL test, Dried Blood Spot for Sample type. The missing and “other” were dropped in the logistic regression as it was not clear which categories of clients were categorized as “other”.

Study limitations included incomplete data on ART regimen, duration on ART, and reason for VL test – all of which were less than 95% complete for the four years, limiting the extent of data analysis. (See Appendix 1 for data completeness by country.) A further limitation was the lack of certain variables in the LIMS design, such as nutrition status, co-morbidities, and weight, that are important for ascertaining child health outcomes.

63%
of children living with HIV in ESA are on treatment

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3.0 Findings

3.1 Data quality

Overall, there were noticeable improvements in the quality of the LIMS data for the period 2019 and 2020 (see Table 1). Follow-up with countries indicated that missing data was either because recording was not done by the health provider or data entry clerk, or data entry was incomplete/had errors.

Table 1: Completeness of the eligible LIMS data from Malawi, Uganda and Zimbabwe

Variable	Subcategories	2017 n(%)	2018 n(%)	2019 n(%)	2020 n(%)
Country	Malawi	14,160 (19.7)	27,796 (22.9)	38,178 (24.1)	21,896 (16.6)
	Uganda	43,891 (61.0)	73,172 (60.3)	97,114 (61.2)	76,328 (57.8)
	Zimbabwe	13,890 (19.3)	20,402 (16.8)	23,347 (14.7)	33,763 (25.6)
	Total Eligible	**71,941 (100)**	**121,370 (100)**	**158,639 (100)**	**131,987 (100)**
Sex		71,313 (99.1)	120,438 (99.2)	156,321 (98.5)	130,398 (98.8)
Reason for VL test		58,621 (81.5)	100,905 (83.1)	140,365 (88.5)	113,170 (85.7)
ARV Regimen		42,673 (59.3)	70,634 (58.2)	34,521 (21.8)	89,290 (67.7)
Duration on ART		48,337 (67.1)	86,602 (71.4)	119,996 (75.6)	81,624 (61.8)
Blood sample Type		58,057 (80.7)	27,796 (22.9)	97,114 (61.2)	131,987 (100)

3.2 Viral load testing trends

Figure 1 presents the number of children who had a VL test and whose data was eligible for analysis. Since the initial study, progress on viral VL testing and VLS has varied by year and by country.

There was a general increase in the number of children who had a VL test over the years with a decline in Malawi and Uganda in 2020 that coincided with the onset of the COVID-19 pandemic.

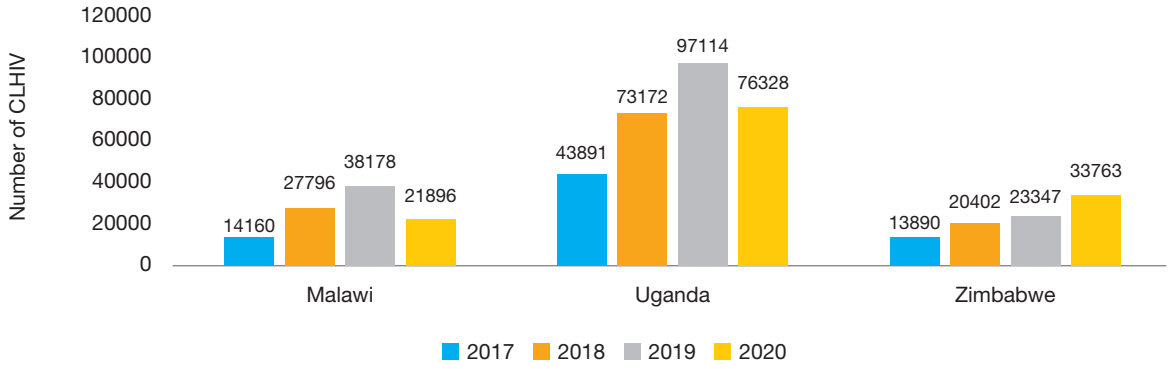


Figure 1: Number of children living with HIV that were eligible for analysis in LIMS from 2017 to 2020

The highest proportion of children with a VL test were aged 5-9 years, followed by young adolescents aged 10-14 (Table 2). Routine monitoring remained the main reason for VL testing. Dried blood spot (DBS) remained the main testing method used, however, the number of tests performed using plasma has been increasing since 2019.

The expansion of ARV regimen options to children and the transition to globally recommended regimens is presented in Table 2 and Figure 2. The largest transition of ARV regimen was to first-line Dolutegravir (DTG), from 3% in 2019 to 29% in 2020, and first-line Lopinavir-ritonavir (LPV/r), from 11% in 2019 to 32% in 2020. These regimens were mostly replacing first-line Nevirapine (NVP) which declined from 62% in 2017 to 11% in 2020. This trend reflects the countries' roll-out of more efficacious paediatric regimens in line with the WHO 2021 guidelines for paediatric HIV treatment.[11,12]

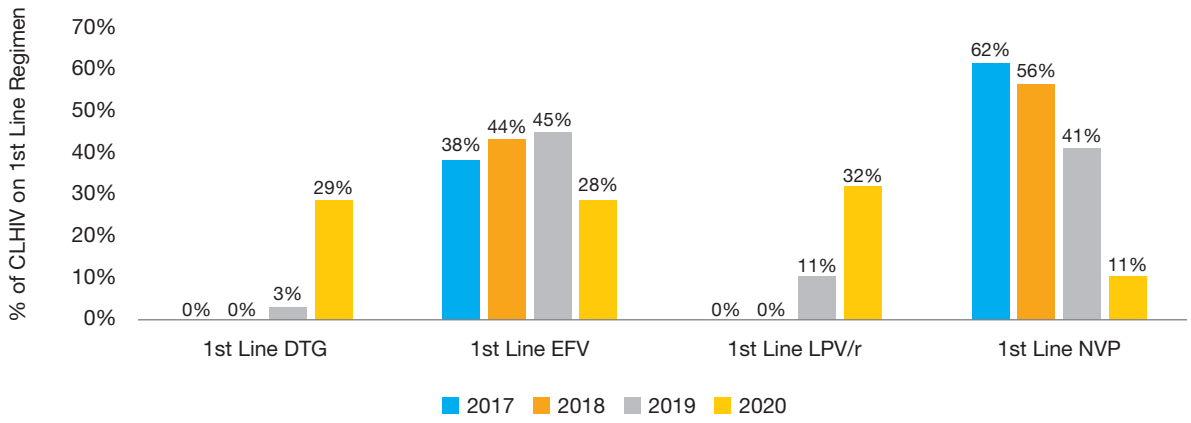


Figure 2: Transitioning first-line ARV regimen

WHO strongly recommends routine VL monitoring to assess children's progress on ART and intensive adherence counselling (IAC) when there is suspected treatment failure. Following IAC, a VL test is repeated and a decision made to adjust or change the treatment regimen. Routine testing was consistently the main reason for a VL test across all three countries, ranging from 77.4% in 2017,

11 WHO. Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivering and Monitoring: Recommendations for a Public Health Approach. 2021. https://www.who.int/publications/i/item/9789240031593

12 WHO. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treatment and Preventing HIV Infection. https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf

78.3% in 2018, 81.9% in 2019, and 78.5% in 2020. There was an increase in the small proportion of children who had a VL test for suspected treatment failure, from 0.2% in 2017 to 1.2% in 2020. There was also an increase in the proportion of children who had a post-IAC VL test, from 3.9% in 2017 to 5.8% in 2020. (See Appendix II for country-specific data).

Table 2: Demographics, reason for test, regimen, duration on ART

Variable	Subcategories	2017 n(%)	2018 n(%)	2019 n(%)	2020 n(%)
	Total	**71,941 (100)**	**121,370 (100)**	**158,639 (100)**	**131,987 (100)**
Mean Age, years		8.5 (SD=3.7)	8.5 (SD=3.6)	8.9 (SD=3.6)	9.1 (SD=3.6)
Mean Duration on ART, years		4.4 (SD=2.7)	4.7 (SD=2.8)	4.8 (SD=3.5)	4.8 (SD=2.9)
Age Group (years)	<1	3,958 (5.5)	3,215 (2.6)	4,675 (3.0)	4,413 (3.3)
	1-4	7,648 (10.6)	15,282 (12.6)	17,764 (11.2)	12,651 (9.6)
	5-9	34,169 (47.5)	60,543 (49.9)	74,249 (46.8)	60,611 (45.9)
	10-14	26,166 (36.4)	42,330 (34.9)	61,951 (39.0)	54,312 (41.2)
Sex	Female	38,073 (52.9)	62,936 (51.9)	83,107 (52.4)	68,887 (52.2)
	Male	33,240 (46.2)	57,502 (47.4)	73,214 (46.1)	61,511 (46.6)
	Missing	628 (0.9)	932 (0.8)	2,318 (1.5)	1,589 (1.2)
Reason For Test	Routine Monitoring	55,676 (77.4)	94,966 (78.3)	129,874 (81.9)	103,566 (78.5)
	Suspected Treatment Failure	147 (0.2)	632 (0.5)	1,351 (0.9)	1,601 (1.2)
	Post - IAC (Intensive Adherence Counselling)	2,774 (3.9)	5,141 (4.2)	8,821 (5.5)	7,713 (5.8)
	Other	24 (0.0)	166 (0.1)	277 (0.2)	290 (0.2)
	Missing	13,320 (18.5)	20,465 (16.9)	18,316 (11.5)	18,817 (14.3)
Current Regimen	1st Line DTG	0	20 (0.0)	915 (0.6)	20,246 (15.3)
	1st Line EFV	14,428 (20.1)	24,132 (19.9)	13,310 (8.4)	19,945 (15.1)
	1st Line LPV/r	0	0	3,125 (2.0)	22,345 (16.9)
	1st Line NVP	23,257 (32.3)	31,246 (25.7)	12,230 (7.7)	7,523 (5.7)
	1st Line Others	0	5 (0.0)	128 (0.1)	851 (0.6)
	2nd Line ATV/r	605 (0.8)	1,956 (1.6)	2,192 (1.4)	7,862 (6.0)
	2nd Line LPV/r	4,187 (5.8)	7,471 (6.2)	2,420 (1.5)	9,455 (7.2)
	2nd Line RAL/Others	0	2 (0.0)	54 (0.0)	355 (0.3)
	3rd Line DRV/Others/ DAR/r	0	1 (0.0)	19 (0.0)	147 (0.1)
	Other	196 (0.3)	5,801 (4.8)	128 (0.1)	561 (0.4)
	Missing	29,268 (40.7)	50,736 (41.8)	124,118 (78.2)	42,697 (32.4)
Duration on ART	<1	4,959 (6.9)	6,468 (5.3)	12,206 (7.7)	9,503 (7.2)
	1-4	26,787 (37.2)	47,073 (38.8)	57,038 (36.0)	39,217 (29.7)
	5-9	14,605 (20.3)	28,865 (23.8)	44,056 (27.8)	28,911 (21.9)
	10-14	1,986 (2.8)	4,196 (3.4)	6,665 (4.2)	3,993 (3.0)
	Missing	23,604 (32.8)	34,768 (28.7)	38,674 (24.3)	50,363 (38.2)
Sample Type	DBS	39,488 (54.9)	25,836 (21.3)	51,611 (32.5)	70,428 (53.4)
	Plasma	18,563 (25.8)	1,960 (1.6)	45,503 (28.7)	61,559 (46.6)
	Missing	13,890 (19.3)	93,574 (77.1)	61,525 (38.8)	0

Table 3 shows that the number and proportion of children receiving VL testing due to suspected treatment failure increased across the four years.

Table 3: Suspected treatment failure and post-IAC disaggregated by age group

Variable	Age (years)	2017 n(%)	2018 n(%)	2019 n(%)	2020 n(%)
	Total	**147 (100)**	**632 (100)**	**1,351 (100)**	**1,601 (100)**
Suspected Treatment Failure	<1	10 (6.8)	11 (1.7)	29 (2.1)	32 (2.0)
	1-4	14 (9.5)	143 (22.6)	231 (17.1)	247 (15.4)
	5-9	62 (42.2)	236 (37.4)	536 (39.7)	648 (40.5)
	10-14	61 (41.5)	242 (38.3)	555 (41.1)	674 (42.1)
Post - IAC	**Total**	**2,774 (100)**	**5,141 (100)**	**8,821 (100)**	**7,713 (100)**
	<1	75 (2.7)	46 (0.9)	87 (1.0)	107 (1.4)
	1-4	743 (26.8)	1,280 (24.9)	1,863 (21.1)	1,380 (17.9)
	5-9	1,075 (38.8)	2,330 (45.3)	3,730 (42.3)	3,289 (42.6)
	10-14	881 (31.8)	1,485 (28.9)	3,141 (35.6)	2,937 (38.1)

3.3 Viral load suppression trends

All countries showed improved VLS in children from 2017 to 2020 (Table 4 and Figure 3). There were differences between countries; Uganda had the highest VLS rate and Malawi had the lowest. The upward trend of VLS from 2017 to 2020 was observed at the same period with the increased use of DTG as first-line treatment for children. DTG is clinically superior, has greater tolerability, and bolsters adherence due to fewer side effects, better palatability and easier administration than older options. At the same time, countries changed their second-line regimens and, as of 2020, there were significant proportions of children on second and third-line regimens.[13]

Table 4: VLS trends

Variable	Subcategories	2017 n(%)	2018 n(%)	2019 n(%)	2020 n(%)
	Total	**71,941 (100)**	**121,370 (100)**	**158,639 (100)**	**131,987 (100)**
VLS	46,196 (64.2)	79,211 (65.3)	110,650 (69.8)	102,453 (77.6)	102,453 (77.6)
VL	25,745 (35.8)	42,159 (34.7)	47,989 (30.2)	29,534 (22.4)	29,534 (22.4)
Country	Malawi	8,188 (57.8)	14,608 (52.6)	22,536 (59.0)	14,980 (68.4)
	Uganda	29,415 (67.0)	51,278 (70.1)	71,790 (73.9)	63,166 (82.8)
	Zimbabwe	8,593 (61.9)	13,325 (65.3)	16,324 (69.9)	24,307 (72.0)
Age Group (years)	<1	2,724 (68.8)	2,065 (64.2)	3,326 (71.1)	3,450 (78.2)
	1-4	6,847 (59.0)	12,841 (55.7)	16,109 (61.6)	14,309 (74.4)
	5-9	19,782 (65.5)	35,706 (67.7)	46, 636 (70.8)	42,197 (78.1)
	10-14	16,843 (64.4)	28,599 (67.7)	44,579 (72.0)	42,497 (78.3)
Sex	Female	25,395 (66.7)	42,369 (67.3)	59,340 (71.4)	54,163 (78.6)
	Male	20,402 (61.4)	36,233 (63.0)	49,687 (67.9)	47,149 (76.7)

13 Second- and third-line therapy are treatments given when the previous treatment does not work or stops working.

Variable	Subcategories	2017 n(%)	2018 n(%)	2019 n(%)	2020 n(%)
Reason For Test	Routine Monitoring	37,066 (66.6)	64,084 (67.5)	93,637 (72.1)	83,374 (80.5)
	Suspected Treatment Failure	54 (36.7)	208 (32.9)	545 (40.3)	837 (52.3)
	Post IAC	822 (29.6)	1,668 (32.5)	3,648 (41.4)	4,699 (60.9)
	Other	5 (20.8)	47 (28.3)	116 (41.9)	161 (55.5)
1st Line Current Regimen	1st Line DTG	0	20 (100.0)	833 (91.0)	16,460 (81.3)
	1st Line EFV	11,013 (76.3)	18,109 (75.0)	9,785 (73.5)	15,072 (75.6)
	1st Line LPV/r	0	0	2,303 (73.70)	19,338 (86.5)
	1st Line NVP	13,743 (59.1)	19,889 (63.7)	8,124 (66.4)	5,778 (76.8)
	1st Line Others	0	3 (60.0)	74.2 (95)	738 (86.7)
2nd Line Current Regimen	2nd Line ATV/r	468 (77.4)	1,453 (74.3)	1,617 (73.8)	6,466 (82.2)
	2nd Line LPV/r	3,305 (78.9)	5,636 (75.4)	1,788 (73.9)	7,204(76.2)
	2nd Line RAL/ Others	0	2 (100.0)	36 (67.9)	288 (81.4)
3rd Line Regimen	3rd Line DRV/ Others/DAR/r	0	1 (100.0)	15 (78.2)	124 (84.4)
Duration on ART (years)	<1	3,267 (65.9)	3,828 (59.2)	7,693 (63.0)	7,108 (74.8)
	1-4	17,175 (64.1)	30,605 (65.0)	39,226 (68.8)	32,248 (82.2)
	5-9	9,867 (67.6)	20,393 (70.7)	32,806 (74.5)	23,111 (79.9)
	10-14	1,577 (79.4)	3,315 (79.0)	5,383 (80.8)	3,164 (79.2)
Sample Type	DBS	23,239 (58.9)	13,220 (51.2)	33,165 (64.2)	51,544 (73.2)
	Plasma	14,364 (77.4)	1,388 (70.8)	38,625 (84.9)	50,909 (82.7)

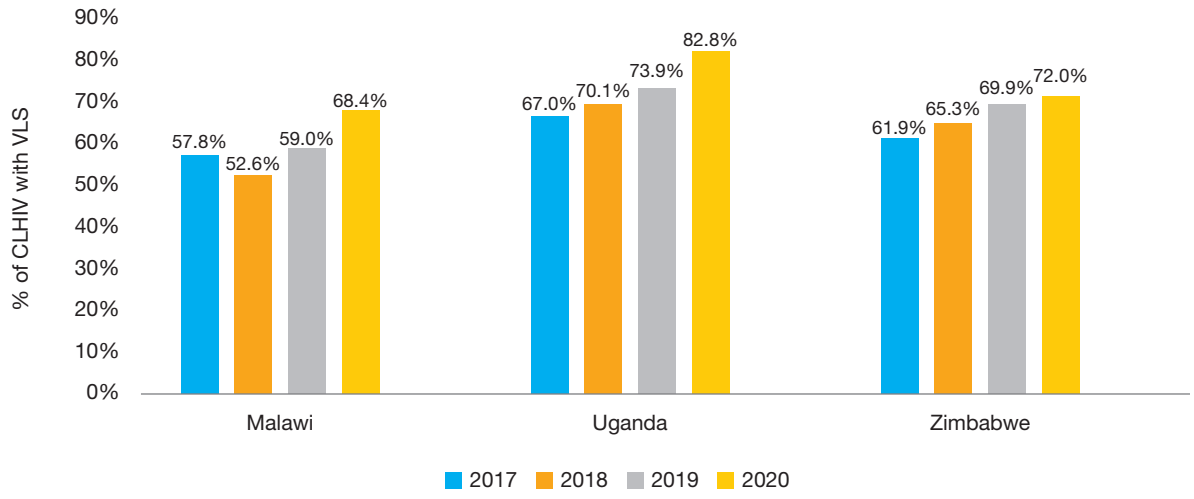


Figure 3: VLS trend by country

VLS within age groups also improved across the years, as shown in Figure 4.

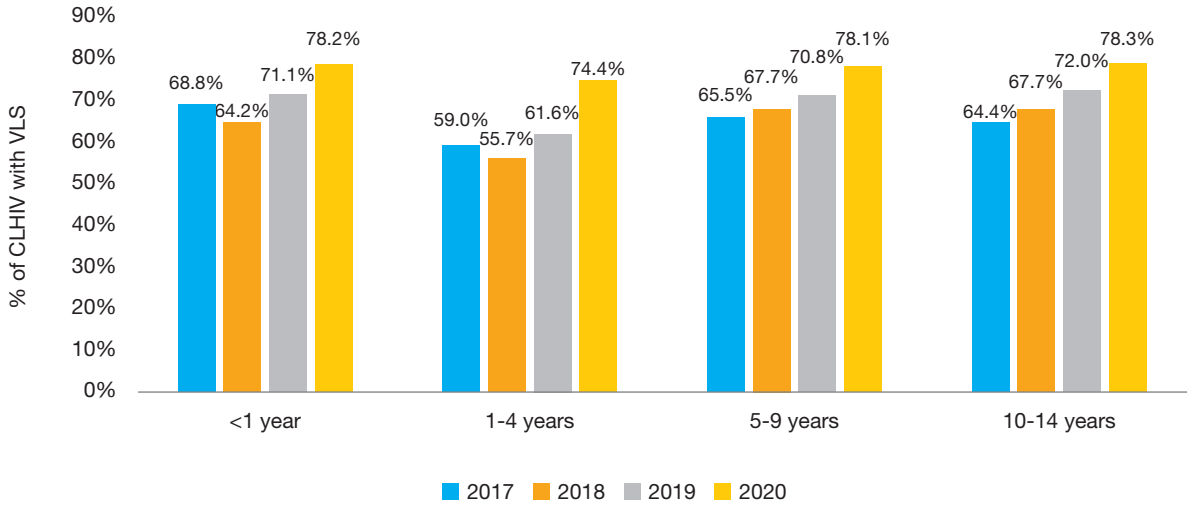


Figure 4: VLS trend by age group

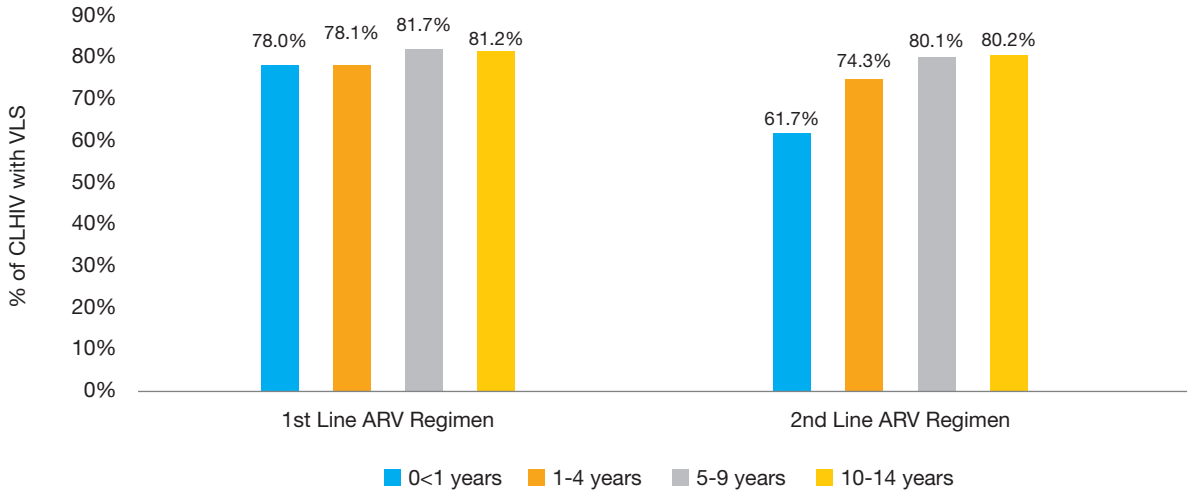


Figure 5: VLS by age group and ARV regimen in 2020

As seen in Figure 6, post-IAC VLS showed a noticeable improvement from 30% (822/2,774) of children who had post-IAC VLS in 2017 to 61% (4,669/7,713) in 2020.

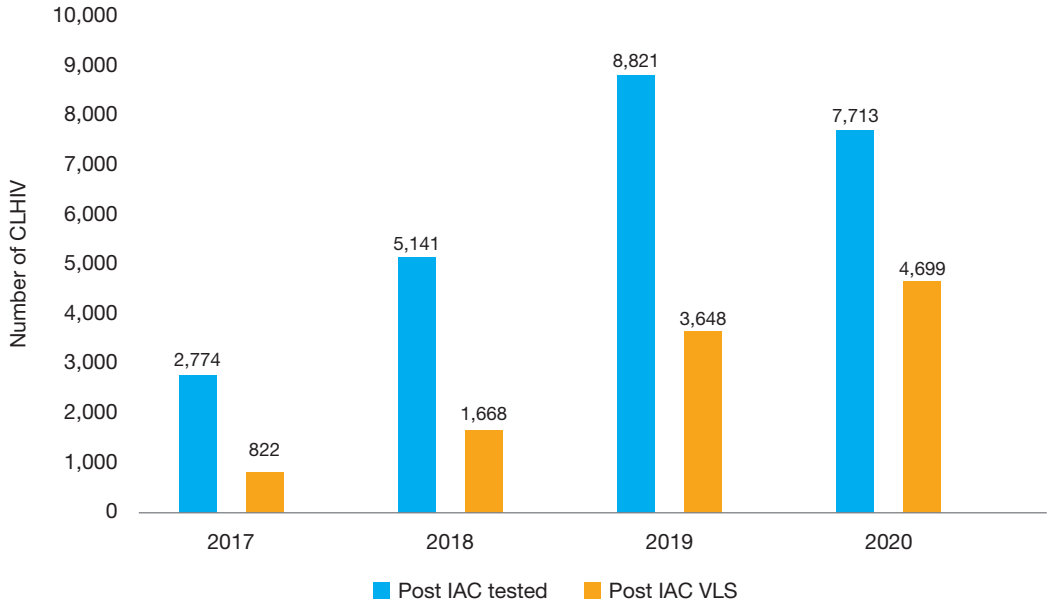


Figure 6: Post-IAC testing trend and VLS

While many countries have made strides to shift to plasma testing as a more accurate measurement of VL, a large number are still using DBS. DBS samples are a cost-effective method for VL monitoring in limited resource settings where samples are referred from remote areas to central laboratories. In this study, 82.7% of the children who had a VL test using plasma had a suppressed VL compared to 73.2% who had a test using a DBS sample (Table 4). (See Appendix 3 for a closer analysis between sample type, countries and ART regimen).

3.4 Factors associated with viral load suppression

In 2020, the COVID-19 pandemic disrupted health services throughout Eastern and Southern Africa. Many countries accelerated action to ensure paediatric HIV services were available and accessible. To lend insight on the impact of the pandemic on children living with HIV, the study looked specifically at data from 2020 to identify factors contributing to or deterring from VLS.

In determining the factors associated with VLS, a multinomial regression analysis was conducted for children on first- and second-line ARV regimen (Table 5 and Table 6). For children on first-line ARV regimen, in 2020 the following variables were predictors of VLS: sex, age, ARV regimen, reason for test, and sample type. Children were more likely to be virally suppressed if they were female, older in age, on first-line DTG or LPV/r, received a VL test due to routine monitoring, and provided a plasma sample.

ART optimization with protease inhibitor-based and/or dolutegravir-based regimens was a significant factor in influencing improved VLS. Children on first-line DTG and LPV/r had an increased likelihood of VLS compared to those on first-line NVP or first-line EFV. Children who had a VL test due to post-IAC or suspected treatment failure had reduced likelihood of VLS compared to those who had a routine VL test. Children who had a VL test on a plasma sample were more likely to have a VLS result compared to those who had a VL test on a DBS sample.

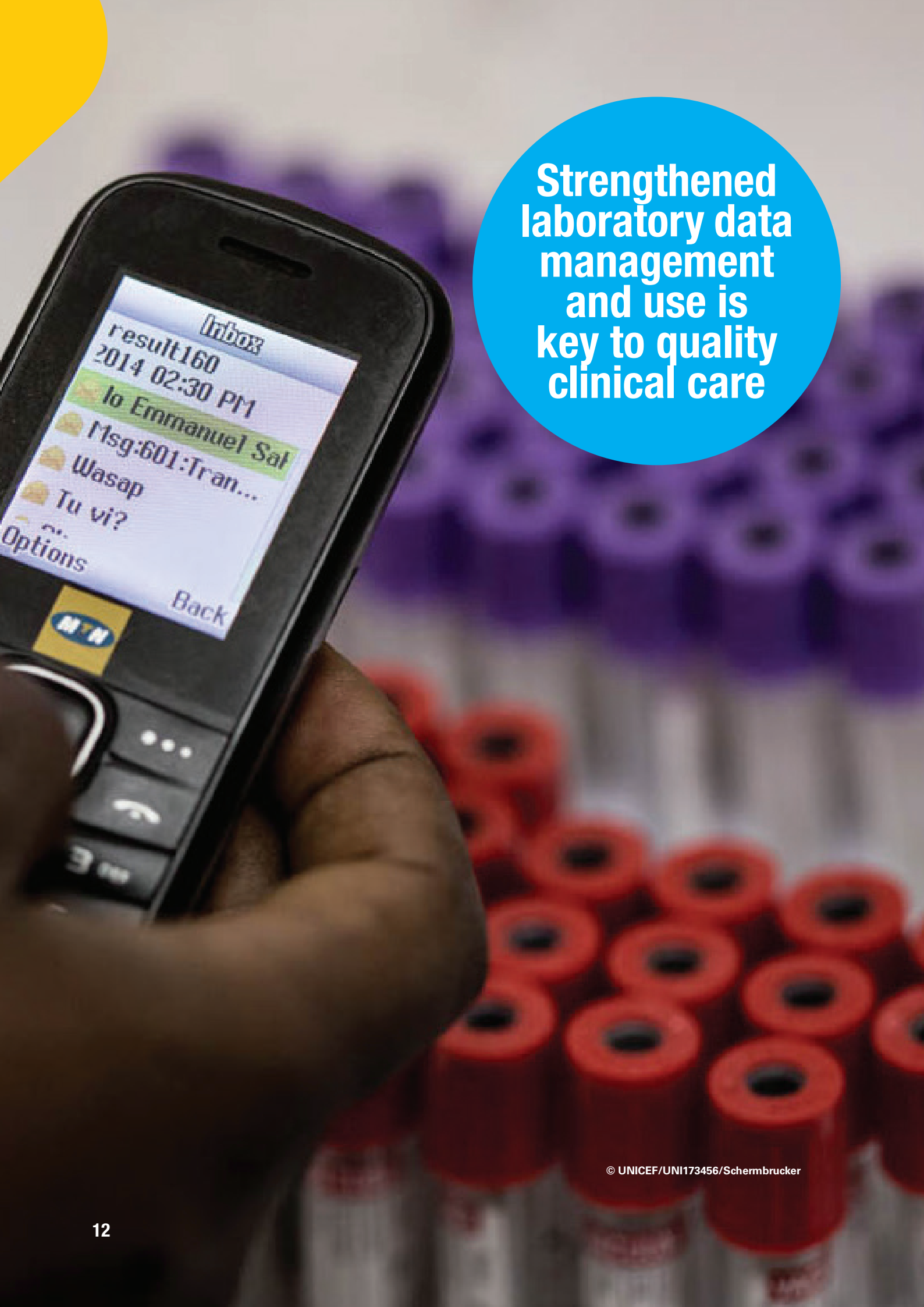
Table 5: Factors associated with VLS in 2020 for children living with HIV on first-line ARV regimen

Characteristics		2020 % (n)	OR adjusted (95%CI)	P-value
Sex	Female	81.8 (30,484/37,281)	Reference	
	Male	80.1 (26,659/33,296)	0.93 [0.89; 0.97]	0.001
Age groups (years)	0-<1	78.0 (991/1,271)	Reference	
	1-4	78.1 (7,741/9,906)	1.60 [1.24; 2.06]	<0.001
	5-9	81.7 (24,676/30,202)	2.13 [1.66; 2.74]	<0.001
	10-14	81.2 (23,978/29,531)	2.00 [1.52; 2.52]	<0.001
ART regimen	1st Line NVP	76.8 (5,778/7,523)	Reference	
	1st Line DTG	81.3 (16,460/20,246)	1.16 [1.08; 1.25]	<0.001
	1st Line EFV	75.6 (15,072/19,945)	0.91 [0.84; 0.98]	0.017
	1st Line LPV/r	86.5 (19,338/22,345)	1.59 [1.46; 1.73]	<0.001
	1st Line others	86.7 (738/851)	1.50 [1.20; 1.87]	<0.001
Reason for test	Routine	82.7 (53,098/64,181)	Reference	
	Post IAC	62.9 (2,926/4,649)	0.40 [0.37; 0.42]	<0.001
	Suspected Treatment Failure	50.6 (367/726)	0.29 [0.24; 0.34]	<0.001
Duration on ART (years)	0-<1	80.1 (3,813/4,761)	Reference	
	1-4	85.4 (21,669/25,388)	1.08 [0.99; 1.18]	0.082
	5-9	79.9 (20,383/25,528)	0.89 [0.82; 0.97]	0.009
	10-14	78.8 (2,865/3,635)	0.87 [0.77; 0.97]	0.016
Sample type	DBS	76.3 (28,763/37,713)	Reference	
	Plasma	86.2 (28,623/33,197)	2.3 [2.2; 2.4]	<0.001

Children on second-line ARV regimen had a similar pattern of predictors of VLS, except that sex and duration on ART were only predictors for children who had been on ART for 1-4 years (see Table 6).

Table 6: Factors associated with VLS in 2020 for children living with HIV on second-line ARV regimen

Characteristics		2020 % (n)	OR adjusted (95%CI)	P-value
Sex	Female	79.6 (7,382/9,278)	Reference	
	Male	78.4 (6,563/8,370)	0.97 [0.89; 1.07]	0.567
Age groups (years)	0-<1	61.7 (168/272)	Reference	
	1-4	74.3 (1,950/2,623)	1.82 [1.28; 2.59]	0.001
	5-9	80.1 (6,194/7,738)	2.17 [1.54; 3.07]	<0.001
	10-14	80.2 (5,646/7,039)	2.01 [1.42; 2.84]	<0.001
ART regimen	2nd Line LPV/r	76.2 (7,204/9,455)	Reference	
	2nd Line ATV/r	82.2 (6,466/7,862)	1.17 [1.07; 1.29]	0.001
	2nd Line RAL/Others	81.4 (288/355)	1.77 [1.22; 2.56]	0.003
Reason for test	Routine	81.5 (12,686/15,566)	Reference	
	Post IAC	58.7 (952/1,623)	0.46 [0.41; 0.53]	<0.001
	Suspected Treatment Failure	62.2 (186/299)	0.45 [0.33; 0.61]	<0.001
Duration on ART (years)	0-<1	73.7 (1,819/2,467)	Reference	
	1-4	81.8 (5,955/7,280)	1.31 [1.17; 1.47]	<0.001
	5-9	78.5 (2,049/2,609)	1.14 [0.99; 1.31]	0.068
	10-14	81.4 (201/247)	1.13 [0.79; 1.61]	0.494
Sample type	DBS	71.6 (7,383/10,312)	Reference	
	Plasma	89.3 (6,575/7,360)	3.14 [2.81; 3.51]	<0.001



Strengthened laboratory data management and use is key to quality clinical care

4.0 Conclusion and Recommendations

This study assessed national level data from LIMS from 2017 to 2020 on the VLS rate in children aged 0-14 years in Malawi, Uganda and Zimbabwe. The study confirmed that children living with HIV have sub-optimal viral suppression.

Nonetheless, there was encouraging progress. Despite many challenges facing countries, particularly in 2020, a greater number of children received VL testing for multiple reasons and were virally suppressed from 2017 to 2020.

The findings reinforce recommendations to accelerate decentralized routine and post-IAC VL testing for children living with HIV and the use of those results for meaningful clinical care. Lessons learned from using point-of-care and near point-of-care sample collection for early infant diagnosis of HIV may help inform decentralized viral load testing.

The findings also emphasize the urgent need to complete the scale up to more efficacious and palatable drug regimens for children. DTG-based regimens can significantly improve virological suppression in young children who are as young as four weeks of age and weigh more than 3 kilograms.

Strengthened laboratory data management and use is key to quality clinical care. While this study found improvements across countries, there is still room to improve data quality. There is also an opportunity to systematically track treatment success and viral load coverage by disaggregating VLS data by age group, as this study did, and integrating LIMS data with health facility-based patient data and routine data from Health Management Information Systems. For example, LIMS data should be cross-analyzed with the number of children who are eligible for VL testing. Results that are returned to clinicians from LIMS are not necessarily entered in the ART registers where other clinical information is captured. In addition, LIMS does not capture a child's weight, an important variable in determining ARV regimen and dosage, or co-morbidities such as malnutrition or tuberculosis.

Efforts to scale up clinical and laboratory monitoring were evident by the increased numbers of children receiving VL testing and post-IAC. Although there were some episodic declines in VL testing during the early onset of the COVID-19 pandemic, health systems demonstrated a resilience to the many disruptions caused by the pandemic. At the same time, the steady increase in post-IAC is reassuring given the importance of providing ongoing adherence support and counselling to children and their caregivers.

While the study's findings are encouraging, the recommendations point to an urgent need for governments and programmers to accelerate routine and post-IAC VL testing, continue to scale up more efficacious and palatable drug regimens for children, and strengthen the quality and use of laboratory data to ensure that children living with HIV enjoy treatment success and positive health outcomes.

Appendix I. Data Completeness by Country

Table 7: Malawi data completeness

Characteristic	2017	2018	2019	2020
Raw LIMS data (before cleaning)	310,867	414,133	39,372	22,606
Data on children <15years received	14,756	28,990	39,372	22,606
Eligible children <15years with VL result (After Cleaning and Used for analysis)	100% (14,160)	100% (27,796)	100% (38,178)	100% (21,896)
Reason for VL test	99.6% (14,109)	98.7% (27,436)	99.5% (37,981)	99.8% (21,849)
Duration on ART	35.4% (5,019)	54.7% (15,210)	60.9% (23,255)	70.5% (15,444)
ART Regimen	0% (0)	0% (0)	1.2% (442)	35.6% (7,794)

Table 8: Uganda data completeness

Characteristic	2017	2018	2019	2020
Raw LIMS data (before cleaning)	43,891	73,172	1,254,291	76,328
Data on children <15years received	43,891	73,172	98,563	76,328
Eligible children <15years with VL result (After cleaning and Used for analysis)	100% (43,891)	100% (73,172)	100% (97,114)	100% (76,328)
Reason for VL test	99.8% (43,790)	99.8% (73,006)	99.3% (96,443)	99.0% (75,600)
Duration on ART	98.4% (43,210)	97.5% (71,308)	99.6% (96,710)	86.7% (66,180)
ART Regimen	97.0% (42,572)	95.7% (69,998)	32% (31,867)	97.0% (74,031)

Table 9: Zimbabwe data completeness

Characteristic	2017	2018	2019	2020
Raw LIMS data (before cleaning)	95,234	257,215	30,213	42,397
Data on children <15years received	13,890	20,402	24,689	34,518
Eligible children <15years with VL result (After Cleaning and Used for analysis)	100% (13,890)	100% (20,402)	100% (23,347)	100% (33,763)
Reason for VL test	5.2% (722)	2.3% (462)	25.3% (5,899)	46.6% (15,721)
Duration on ART	0.8% (108)	0.9% (174)	0% (0)	0% (0)
ART Regimen	0.7% (101)	1.1% (231)	9.5% (2,212)	22.1% (7,465)

Appendix II. VLS by country

Table 10: Proportion of children living with HIV in Malawi with VLS disaggregated by region, sex, age group, ART regimen, reason for test and duration on ART

Characteristics		2017 % (n)	2018 % (n)	2019 % (n)	2020 % (n)
Total Suppressed		57.8(8,188)	52.6 (14,608)	59.0 (22,536)	68.4 (14,980)
High VL		42.2(5,972)	47.4 (13,188)	41.0 (15,642)	31.6 (6,916)
Region	Northern	59.6 (866)	52.0 (1,496)	58.5 (2,200)	69.1 (1,515)
	Central	62.1 (2,885)	56.3 (4,106)	64.2 (6,934)	68.3 (3,993)
	Southern	55.0 (4,437)	51.1 (9,006)	56.8 (13,270)	68.4 (9,457)
	Missing			51.6 (132)	75.0 (15)
Sex	Female	61.9 (4,616)	55.7 (8,004)	61.2 (12,318)	68.2 (7,762)
	Male	53.0 (3,490)	49.1 (6,514)	56.7 (10,066)	68.8 (7,093)
	Missing	68.9 (82)	56.6 (90)	59.1 (152)	64.1 (125)
Age groups (years)	0-<1	66.0 (839)	62.2 (645)	66.8 (920)	69.2 (409)
	1-4	67.3 (105)	40.6 (2,169)	45.3 (2,988)	66.7 (2,311)
	5-9	55.5 (3,732)	52.6 (5,630)	57.6 (8,329)	67.1 (5,630)
	10-14	58.4 (3,512)	57.5 (6,164)	65.4 (10,299)	70.2 (6,630)
ART regimen	1st Line DTG	0	0	78.0 (39)	78.5 (2,463)
	1st Line EFV	0	0	75.7 (28)	58.5 (1,181)
	1st Line LPV/r	0	0	0	0
	1st Line NVP	0	0	58.7 (176)	68.3 (589)
	1st Line Others	0	0	0	0
	2nd Line ATV/r	0	0	77.8 (7)	0
	2nd Line LPV/r	0	0	60.9 (28)	63.8 (1,123)
	2nd Line RAL/Others	0	0	0	0
	3rd Line DRV/Others/DAR/r	0	0	0	78.6 (11)
	Others	0	0	0	0
	Missing	57.8 (8,188)	52.6 (14,608)	59.0 (22,258)	68.2 (9,613)
Reason for test	Routine	58.2 (8,128)	54.2 (14,138)	60.8 (21,550)	70.3 (13,250)
	Post IAC	19.2 (10)	27.9 (212)	35.2 (615)	56.8 (1,375)
	Suspected Treatment Failure	38.9 (28)	30.2 (123)	42.5 (211)	60.2 (200)
	Other	20.8 (5)	28.4 (47)	41.8 (112)	51.2 (125)
	Missing	33.3 (17)	24.5 (88)	24.4 (48)	63.8 (30)
Duration on ART (years)	0-<1	64.4 (1,073)	54.6 (1,990)	53.1 (1,691)	63.2 (1,273)
	1-4	48.5 (842)	47.9 (3,247)	55.8 (6,259)	67.8 (4,711)
	5-9	54.7 (843)	56.7 (2,425)	62.2 (4,766)	68.6 (3,673)
	10-14	70.7 (53)	58.2 (245)	73.5(875)	73.9 (833)
	Missing	58.8 (5,377)	52.9 (6,701)	59.9 (8,945)	69.6 (4,490)

Table 11: Proportion of children living with HIV in Uganda with VLS disaggregated by region, sex, age group, ART regimen, reason for test and duration on ART

Characteristics		2017 % (n)	2018 % (n)	2019 % (n)	2020 % (n)
Total Suppressed		**67.0 (29,415)**	**70.1 (51,278)**	**73.9 (71,790)**	**82.8 (63,166)**
High VL		33.0 (14,476)	29.9 (21,894)	26.1 (25,324)	17.2 (13,162)
Region	Central	74.1 (13,935)	76.4 (26,144)	81.1 (34,299)	86.9 (28,254)
	Eastern	58.4 (4,303)	61.4 (6,995)	64.8 (9,514)	78.0 (9,522)
	Northern	54.1 (3,522)	54.4 (4,929)	57.9 (8,682)	72.2 (8,617)
	Western	68.3 (7,655)	71.4 (13,210)	76.9 (19,295)	85.2 (16,773)
Sex	Female	68.9 (16,248)	71.7 (27,611)	75.2 (38,508)	83.4 (33,755)
	Male	64.7 (13,167)	68.3 (23,667)	72,5 (32,515)	82.0 (29,411)
	Missing	0	0	767	0
Age groups (years)	0-<1	66.0 (1,186)	54.8 (639)	62.7 (864)	69.0 (597)
	1-4	58.8 (5,913)	60.0 (9,346)	66.9 (11,305)	78.2 (9,391)
	5-9	69.8 (12,815)	72.7 (24,913)	75.6 (32,065)	84.0 (27,643)
	10-14	69.5 (9,501)	73.9 (16,380)	75.7 (27,556)	83.6(25,535)
ART regimen	1st Line DTG	0	100.0 (20)	92.1 (790)	81.6 (13,213)
	1st Line EFV	76.4 (10,987)	75.0 (18,024)	74.8 (8,625)	80.0 (10,661)
	1st Line LPV/r	0	0	73.6 (2,232)	87.0 (18,742)
	1st Line NVP	59.1 (13,715)	63.7 (19,860)	66.7 (7,779)	79.5 (4,625)
	1st Line Others	0	75.0 (3)	74.2 (95)	86.7 (738)
	2nd Line ATV/r	77.4 (468)	74.3 (1,440)	73.9 (1,561)	82.5 (6,257)
	2nd Line LPV/r	78.9 (3,301)	75.4 (5,623)	74.3 (1,734)	79.1 (6,067)
	2nd Line RAL/Others	0	100.0 (2)	68.5 (37)	81.4 (288)
	3rd Line DRV/Others/DAR/r	0	100.0 (1)	79.0 (15)	85.0 (113)
	Others	80.4 (152)	78.7 (4,541)	71.1 (91)	88.1 (494)
	Missing	60.1 (792)	63.7 (1,764)	74.8 (48,831)	85.7 (1,968)
Reason for test	Routine	69.6 (28,523)	72.5 (49,627)	76.7 (68,089)	84.5 (58,940)
	Post IAC	29.8 (809)	33.2 (1,453)	42.9 (3,026)	63.0 (3,299)
	Suspected Treatment Failure	33.8 (24)	38.5 (85)	38.6 (242)	58.2 (359)
	Missing	58.4 (59)	68.1 (113)	64.5 (433)	78.0 (568)
Duration on ART (years)	0-<1	66.7 (2,188)	65.0 (1,816)	66.5 (6,002)	77.9 (5,835)
	1-4	65.2 (16,293)	67.9 (27,291)	72.0 (32,967)	85.3 (27,537)
	5-9	69.1 (9,005)	73.1 (17,929)	77.0 (28,040)	82.5 (19,438)
	10-14	79.8 (1,524)	81.4 (3,069)	82,3 (4,508)	81.3 (2,331)
	Missing	59.5 (405)	62.9 (1,173)	67.6 (273)	79.1 (8,025)

Table 12: Proportion of children living with HIV in Zimbabwe with VLS disaggregated by region, sex, age group, ART regimen, reason for test and duration on ART

Characteristics		2017 % (n)	2018 % (n)	2019 % (n)	2020 % (n)
Total Suppressed		**61.9 (8,593)**	**65.3 (13,325)**	**69.9 (16,324)**	**72.0 (24,307)**
High VL		38.1 (5,297)	34.7 (7,077)	30.1 (7,023)	28.0 (9,456)
Region	Bulawayo	61.3 (1,599)	69.0 (1,841)	79.4 (2,286)	82.3 (1,840)
	Harare	63.6 (136)	76.8 (698)	76.2 (2,591)	79.2 (3,201)
	Manicaland	69.2 (27)	65.2 (1,874)	69.1 (629)	71.1 (2,912)
	Mashonaland Central	57.2 (273)	56.3 (526)	61.2 (721)	67.8 (1,668)
	Mashonaland East	58.0 (293)	67.8 (839)	69.8 (1,366)	71.2 (2,280)
	Mashonaland West	66.8 (324)	66.0 (1,755)	67.2 (2,149)	66.9 (3,559)
	Masvingo	62.0 (3,532)	61.8 (2,794)	64.8 (2,294)	70.0 (3,426)
	Mqtebeleland North	62.7 (994)	63.3 (574)	72.3 (1,169)	75.0 (1,670)
	Matebeleland South	63.1 (471)	63.4 (590)	66.6 (819)	75.3 (1,455)
	Midlands	61.5 (944)	66.5 (1,834)	67.1 (2,244)	68.0 (2,113)
	Missing			65.9 (56)	73.8 (183)
Sex	Female	64.2 (4,531)	67.1 (6,754)	72.3 (8,514)	74.3 (12,649)
	Male	59.2 (3,745)	63.3 (6,052)	67.2 (7,106)	69.4 (10,646)
	Missing	62.3 (317)	67.1 (519)	70.9 (704)	72.9 (1,016)
Age groups (years)	0-<1	78.6 (699)	77.3 (781)	80.4 (1,542)	82.7 (2,444)
	1-4	59.8 (829)	61.9 (1,326)	68.1 (1,816)	69.7 (2,607)
	5-9	63.0 (3,235)	66.3 (5,163)	69.5 (6,242)	70.0 (8,924)
	10-14	59.1 (3,830)	64.0 (6,055)	68.7 (6,724)	72.1 (10,332)
ART regimen	1st Line DTG	0	0	57.1 (4)	85.7 (784)
	1st Line EFV	55.3 (26)	74.6 (85)	65.0 (1,132)	70.3 (3,230)
	1st Line LPV/r	0	0	77.2 (71)	73.5 (596)
	1st Line NVP	66.7 (28)	55.8 (29)	65.0 (169)	66.9 (564)
	1st Line Others	0	0.0 (0)	0	0
	2nd Line ATV/r	0	76.5 (13)	69.0 (49)	74.4 (209)
	2nd Line LPV/r	80.0 (4)	92.9 (13)	66.7 (26)	63.6 (14)
	2nd Line RAL/Others	0	0	0	0.0 (0)
	3rd Line DRV/Others/DAR/r	0	75.8 (25)	0	0
	Others	57.1 (4)	0	0	0
	Missing	61.9 (8,531)	65.2 (13,160)	70.4 (14,873)	71.9 (18,910)
Reason for test	Routine	58.4 (415)	71.7 (319)	70.9 (3,998)	74.7 (11,184)
	Post IAC	42.9 (3)	21.4 (3)	29.2 (7)	48.1 (25)
	Suspected Treatment Failure	50.0 (2)	0	40.4 (92)	42.6 (278)
	Other			44.4 (4)	78.3 (36)
	Missing	62.1 (8,173)	65.2 (13,003)	70.1 (12,223)	70.9 (12,784)
Duration on ART (years)	0-<1	54.6 (6)	73.3 (22)	Missing	Missing
	1-4	59.7 (40)	72.8 (67)	Missing	Missing
	5-9	63.3 (19)	78.0 (39)	Missing	Missing
	10-14	0	100 (1)	Missing	Missing
	Missing	61.9 (8,528)	65.2 (13,196)	-	-


...accelerate VL testing, adherence support, and more efficacious regimens to ensure that children with HIV enjoy treatment success and positive health outcomes.

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