


# Standardized enhanced adherence counseling for improved HIV viral suppression among children and adolescents in Homa Bay and Turkana Counties, Kenya

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## Abstract

Viral suppression is suboptimal among children and adolescents on antiretroviral therapy (ART) in Kenya. We implemented and evaluated a standardized enhanced adherence counseling (SEAC) package to improve viral suppression in children and adolescents with suspected treatment failure in Homa Bay and Turkana. The SEAC package, implemented from February 2019 to September 2020, included: standard procedures operationalizing the enhanced adherence counseling (EAC) process; provider training on psychosocial support and communication skills for children living with HIV and their caregivers; mentorship to providers and peer educators on EAC processes; and individualized case management. We enrolled children and adolescents aged 0 to 19 years with suspected treatment failure (viral load [VL] >1000 copies/mL) who received EAC before standardization as well as those who received SEAC in a pre-post evaluation of the SEAC package conducted in 6 high-volume facilities. Pre-post standardization comparisons were performed using Wilcoxon-Mann-Whitney and Pearson's chi-square tests at a 5% level of significance. Multivariate logistic regression was performed to identify factors associated with viral resuppression. The study enrolled 741 participants, 595 pre- and 146 post-SEAC implementation. All post-SEAC participants attended at least 1 EAC session, while 17% (n = 98) of pre-SEAC clients had no record of EAC attendance. Time to EAC following the detection of high VL was reduced by a median of 8 days, from 49 (interquartile range [IQR]: 23.0–102.5) to 41 (IQR: 20.0–67.0) days pre- versus post-SEAC (P = .006). Time to completion of at least 3 sessions was reduced by a median of 12 days, from 59.0 (IQR: 36.0–91.0) to 47.5 (IQR: 33.0–63.0) days pre- versus post-SEAC (P = .002). A greater percentage of clients completed the recommended minimum 3 EAC sessions at post-SEAC, 88.4% (n = 129) versus 61.1% (n = 363) pre-SEAC, P < .001. Among participants with a repeat VL within 3 months following the high VL, SEAC increased viral suppression from 34.6% (n = 76) to 52.5% (n = 45), P = .004. Implementation of the SEAC package significantly reduced the time to initiate EAC and time to completion of at least 3 EAC sessions, and was significantly associated with viral suppression in children and adolescents with suspected treatment failure.

**Abbreviations:** ART = antiretroviral therapy, CI = confidence interval, EAC = enhanced adherence counseling, EGPAF = Elizabeth Glaser Pediatric AIDS Foundation, IQR = interquartile range, OR = odds ratio, PLHIV = people living with HIV, SEAC = standardized enhanced adherence counseling, VL = viral load.

**Keywords:** antiretroviral therapy, children and adolescents, enhanced adherence counseling, suspected treatment failure

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We received a waiver of informed consent for the use of retrospective data. Prospective interviews were conducted after obtaining informed consent from those age ≥ 18 years, mature minors, and consent from parents and assent from children and adolescents for those aged 10 to 17 years. All data were kept confidential and only the study team had access to patient data. All study procedures were carried out in accordance with relevant guidelines and regulations.

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

The study was approved by Kenyatta National Hospital-University of Nairobi Ethics Research Committee on 30 July 2018 and Advarra Institutional Review Board in the US on 30 August 2018. It was also reviewed in accordance with the U.S. Center for Disease Control and Prevention (CDC) human research protection procedures and was determined to be research, but the CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes and clearance provided on 12 September 2019.

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## 1. Introduction

By the end of 2020, an estimated 37.7 million people were living with HIV (PLHIV) globally, including 1.7 million children and adolescents under 15 years of age.<sup>[1]</sup> The highest burden of HIV is in eastern and southern Africa with 55% of PLHIV, 45% of new HIV infections, and 46% of AIDS-related deaths.<sup>[1]</sup>

In Kenya, estimated HIV prevalence was 4.2% among adults aged 15 to 64 years in 2020.<sup>[1]</sup> Among the estimated 1.4 million PLHIV in Kenya, 82,000 are children and adolescents under 14 years of age.<sup>[1,2]</sup> Antiretroviral therapy (ART) coverage among children 0 to 14 years is estimated at 68% nationally, 70% in Homa Bay, and 49% in Turkana counties.<sup>[3]</sup> Adolescents and young people still bear the brunt of the HIV epidemic due to limited access to HIV information and services, stigma, and discrimination.<sup>[4,5]</sup>

ART adherence challenges are the main barrier to achieving viral suppression among children and adolescents. Suppressing viral load (VL) to HIV RNA levels <1000 copies/mL is essential for reducing morbidity, mortality, and transmission.<sup>[6,7]</sup>

In Kenya, viral suppression is much lower among children (0–14 years) than adults (67.1% vs. 90.6%).<sup>[8]</sup> This is partly because children and adolescents rely on others to administer their medications and to ensure clinic attendance. Additionally, caregivers may face psychosocial and economic barriers that directly affect child medication adherence and clinic attendance.<sup>[4,5,9]</sup>

To ensure successful treatment, identify adherence problems, and determine whether ART regimens should be switched, the World Health Organization recommends routine VL testing within 6 months of initiating ART, and every 6 months thereafter for HIV-positive children and adolescents. The most common cause of high VL in children and adolescents on ART is poor adherence.<sup>[10–13]</sup> The Kenyan ART guidelines, in alignment with World Health Organization guidance, recommend that ART clients with VL >1000 copies/mL undergo at least 3 enhanced adherence counseling (EAC) sessions, followed by a repeat VL test after at least 3 months of good adherence.<sup>[14]</sup> EAC is a targeted counseling strategy designed to help clients identify individual barriers to adherence and develop strategies to improve viral suppression. Clients are considered suppressed when repeat VL results are <1000 copies/mL, while VL results ≥1000 copies/mL signal treatment failure and clients are switched to an appropriate alternate (second- or third-line) ART regimen.

Cases of children and adolescents failing first-line ART are discussed by facility multidisciplinary teams prior to switching to second-line therapy. Regional or national HIV clinical technical working groups review cases of children and adolescents who have failed both first-line and second-line regimens and determine whether HIV drug resistance testing should be conducted before switching ART regimens. Completion of this process can take between 6 and 12 months, however, which leads to a delay in regimen switches.

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) supported HIV care and treatment facilities in Homa Bay and Turkana counties, where pediatric ART coverage is 91% and 70%, respectively.<sup>[3]</sup> Kenya Ministry of Health data from 2019, indicate, however, that only about 60% of children and adolescents with a VL ≥1000 copies/mL received the recommended 3 minimum EAC sessions, suggesting EAC guidelines were not being uniformly implemented. EGPAF developed and implemented a standardized enhanced adherence counseling (SEAC) package and this study evaluated the effect of the SEAC package on viral suppression in children and adolescents with suspected treatment failure.

## 2. Methods

We conducted a quasi-experimental pre-post study to evaluate treatment outcomes among children and adolescents (aged

0–19 years) with VL ≥1000 copies/mL who received EAC services before and after the introduction of a SEAC package. For the pre-SEAC period, patient-level data were abstracted retrospectively from paper and electronic medical records of clients who had high VL between October 2016 and September 2018. After implementation of the SEAC package in January 2019, post-SEAC data were prospectively abstracted from paper and electronic medical records of clients who had high VL from February 2019 to September 2020.

The study was conducted in 6 high-volume health facilities purposively selected to provide sufficient numbers of children and adolescents with suspected treatment failure. Homa Bay County in western Kenya has a high HIV prevalence (19.6%), while Turkana County in northern Kenya has a lower HIV prevalence (6.8%).<sup>[8]</sup> Viral suppression among children ages 0 to 14 years receiving care in Homa Bay and Turkana counties was 85% and 58%, respectively, in 2020.<sup>[4]</sup> We selected the facilities in Homa Bay and Turkana counties that had the greatest number of unsuppressed clients based on VL tests done between October 2017 to September 2018. These facilities included county referral hospitals in both counties, sub-county hospitals and health centers. We used probability proportional-to-size sampling, based on the volume of VL tests by facility and age group (0–9, 10–14, and 15–19 years) for a sample size of 1311. All HIV-positive children and adolescents ages 0 to 19 years were enrolled in the study if they: were receiving ART at a study facility, had been on ART for at least 6 months, and had a last VL test result of ≥1000 copies/mL done within the last 6 months. In the standard of care EAC program, within a week of receiving VL results (after at least 6 months of ART), clients who have a last VL test result of ≥1000 copies/mL are contacted to attend an EAC session. Clients are required to attend at least 3 EAC sessions, a minimum of 2 weeks apart. The first counseling session focuses on treatment literacy for adolescents and caregivers for younger children. During this session, the adherence counselor supports the client to identify individual barriers to optimal ART adherence. The counselor then supports the client to develop relevant strategies to overcome the barriers through development of an adherence plan. ART adherence plans are reviewed by the counselor and adjusted jointly with the client in the second and third sessions, with any emerging issues discussed.

Since EAC guidelines were not being uniformly and consistently implemented, EGPAF developed a package to standardize and ensure fidelity to implementation of EAC guidelines to improve the quality and provision of EAC sessions. The package was based upon national ART guidelines and included: standard operating procedures to operationalize the EAC process, provider training on providing psychosocial support and communicating with children, adolescents, and their caregivers using a standard curriculum, mentorship to providers and peer educators, including supportive supervision and ensuring procedures were being implemented appropriately, and individualized case management, with each EAC client allocated to a case manager who ensured the barriers to adherence were identified and tackled at both the facility and community levels. This SEAC package ensured the implementation of a case management approach at both facility and community levels. Implementation of the SEAC package began at the study health facilities in January 2019.

The main outcome was a comparison of the proportion of clients with suspected treatment failure who achieved viral suppression before and after receiving the SEAC package. Secondary outcomes included pre-post comparisons of EAC uptake; time from VL result to start of EAC sessions; proportion of clients completing at least 3 EAC sessions; and proportion of clients receiving a repeat VL after completion of EAC. To assess the effect of SEAC program implementation on viral suppression, we undertook bivariate and multivariate analyses, adjusting for age, VL at EAC enrollment, ART regimen, duration on ART

prior to EAC, time to first EAC, amount of time to complete at least 3 EAC sessions, and type of facility.

**2.1. Statistical analysis**

We summarized categorical variables using frequencies, percentages/proportions, and continuous variables using medians and interquartile ranges (IQR). Descriptive summaries were stratified by study group: standard of care (pre-intervention) and SEAC (post-intervention). We used the Wilcoxon Rank sum non-parametric test at 5% level of significance, which considers the non-normal continuous variables related to time and age to compare: time to first EAC session, time to completion of 3 EAC sessions, duration on ART, and patient age.

Associations between clinical and demographic characteristics by HIV treatment and VL outcomes stratified by study arm were carried out by comparing proportions using the Pearson’s chi-square test at a 5% level of significance. Evaluation of confounders and patient characteristics associated with treatment and VL outcomes were also conducted using logistic regression models. Factors significantly associated with viral suppression were included in the bivariate logistic model and factors with significant odds ratios (ORs) in the bivariate analysis were included in the multivariable logistic model. Unadjusted and adjusted ORs with 95% confidence intervals (CI) were calculated to establish association strength. Data were analyzed using SAS version 9.4.

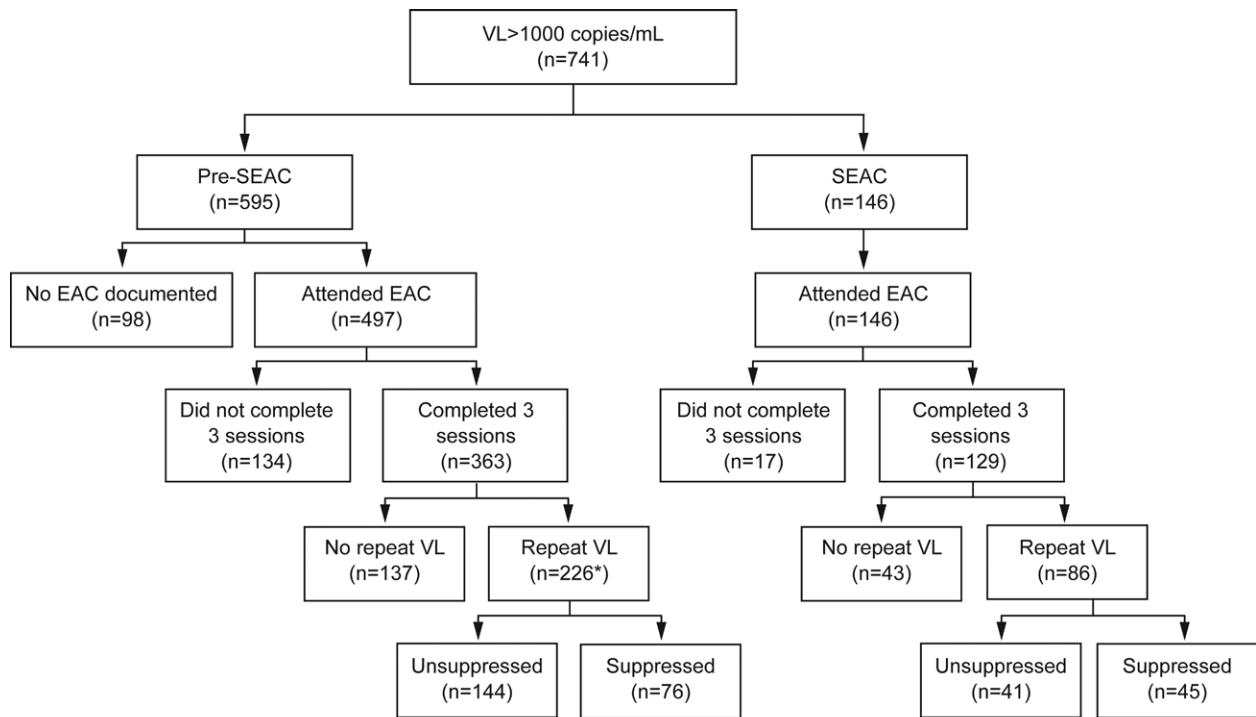
**3. Results**

Data were abstracted for 741 children and adolescent clients with high VL ( $\geq 1000$  copies/mL). Retrospective data were abstracted for 595 clients in the pre-SEAC period and 146 clients were enrolled in the post-SEAC period. Figure 1 shows the

overall number of enrolled participants. Analysis for viral suppression was only conducted for participants who completed the 3 EAC sessions as per the national guidelines. Table 1 presents the demographic and clinical characteristics of the study population. There were 50.4% (n = 300) and 48.0% (n = 70) females pre- and post-SEAC, respectively. The majority of study participants were aged 10 to 14 years (38.5% and 45.9% in the pre- and post-SEAC period, respectively). Mean ages were 10.9 years (standard deviation = 4.5 years) and 11.3 years (standard deviation = 4.1 years) in the pre- and post-SEAC program periods, respectively. VL at initiation of EAC was significantly higher among clients in the pre-SEAC period (9560 copies/mL; IQR: 2580–42,410), compared with 3481 copies/ml (IQR: 1660–20,162) in the post-SEAC period ( $P < .001$ ).

Clients in the post-SEAC period had been on ART (prior to EAC) significantly longer than clients in the pre-SEAC period, with a median duration of 7.4 (IQR: 4.3–9.4) years compared to 6.3 (IQR: 3.2–8.9) years, respectively ( $P = .030$ ). Similar proportions of records were obtained from facilities at various levels of the health system; about 60% were from the county referral hospitals in both Homa Bay and Turkana counties. Over 90% of children and adolescents in both groups were active in care at the time of the evaluation; 10 (1.4%) died. Overall, all post-SEAC period clients attended the first EAC visit, 146 (100%) while 17% (n = 98) of pre-SEAC period clients had no record of EAC attendance (Table 2).

The median time to EAC uptake following a report of high VL was reduced by 8 days, from 49 days (IQR: 23–102) in the pre-SEAC to 41 days (IQR: 20.0–67.0) in the post-SEAC period ( $P = .006$ ). Furthermore, median time to complete at least 3 EAC sessions was reduced by 10 days, from 56 days (IQR: 34–77) in the pre-SEAC period to 46 days (IQR: 32–63) in the post-SEAC period ( $P = .021$ ). Similarly, a significantly greater percentage of clients in the post-SEAC period completed the required minimum 3 EAC sessions within at least 3 months, 88.4% (n = 129) compared to 61.1% (n = 363) in the pre-SEAC period ( $P < .001$ ).



\*6 participants had VL sample collected, but no VL result

**Figure 1.** Flow chart of study participant enrollment. Study participants with viral load >1000 copies/mL, enrolled pre-standardization and post standardization of the enhanced adherence counseling (EAC) package and followed through EAC to completion of minimum 3 sessions. In both groups, participants who completed at least 3 EAC sessions and had a repeat viral load were assessed for viral suppression.

**Table 1****Demographic and clinical characteristics of the study populations, pre and post-standardized enhanced adherence counseling periods.**

Characteristics	Pre-SEAC period (N = 595) n (%)	Post-SEAC period (N = 146) n (%)	Total (N = 741) n (%)
Gender			
Female	300 (50.4%)	70 (48.0%)	370 (49.9%)
Male	295 (49.6%)	76 (52.0%)	371 (50.1%)
Age (yr)			
Mean (SD)	10.9 (4.5)	11.3 (4.1)	11.0 (4.4)
0–9	227 (38.1%)	44 (30.1%)	271 (36.6%)
10–14	229 (38.5%)	67 (45.9%)	296 (39.9%)
15–19	139 (23.4%)	35 (24.0%)	174 (23.5%)
Viral load at EAC enrollment, median (IQR) copies/mL	9560 (2580–42,410)	3481 (1666–20,162)	7970 (2150–37,700)
ART regimen before EAC			
NNRTI-based*	420 (70.6%)	66 (45.2%)	486 (65.6%)
PI-based†	175 (29.4%)	77 (52.7%)	252 (34.0%)
Other‡	0 (0%)	3 (2.1%)	3 (0.4%)
ART duration prior to EAC			
Median (IQR), years	6.3 (3.2–8.9)	7.4 (4.3–9.4)	6.6 (3.4–9.1)
County			
Homa Bay	523 (88%)	129 (88%)	652 (88.0%)
Turkana	72 (12%)	17 (12%)	89 (12.0%)
County referral hospital	377 (63.4%)	87 (60.0%)	464 (62.6%)
Health centers	199 (33.4%)	54 (37.2%)	253 (34%)
Sub-county hospitals	19 (3.2%)	4 (2.8%)	23 (3.1%)

ART = antiretroviral therapy, EAC = enhanced adherence counseling, IQR = interquartile range, SD = standard deviation, SEAC = standardized enhanced adherence counseling, VL = viral load.

\*Non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimens include: AZT/3TC/NVP, AZT/3TC/EFV, ABC/3TC/NVP, ABC/3TC/EFV, TDF/3TC/EFV, TDF/3TC/NVP.

†Protease inhibitor (PI)-based regimens include: AZT/3TC/LPV/r, ABC/3TC/LPV/r, ABC/3TC, ATV/r.

‡Other regimens include dolutegravir (DTG)-based regimen.

**Table 2****Enhanced adherence parameters for participants who completed 3 enhanced adherence counseling sessions as per guidelines.**

Characteristics	Level	Pre-SEAC period	Post-SEAC period	P value
		(N = 363) n (%)	(N = 129) n (%)	
EAC uptake by sex	Male	179 (49.3)	69 (53.5)	.420*
	Female	184 (50.7)	60 (46.5)	
EAC uptake by age (yr)	Median (IQR)	11.0 (7.0–14.0)	12.0 (9.0–14.0)	.250†
	0–9	139 (38.3)	36 (27.9)	
	10–14	136 (37.5)	64 (49.6)	
	15–19	88 (24.2)	29 (22.5)	
Time to EAC uptake	Median (IQR) days	49.0 (23.0–102.5)	41 (20.0–67.0)	.006†
Minimum 3 EAC session completed	Number completing 3 EAC session	363(61.1%)	129(88.4%)	<.001*
Time to complete the minimum 3 EAC sessions	Median (IQR) days	56.0 (34.0–77.0)	46.0 (32.0–63.0)	.021†
VL testing	VLs done after 3 EAC sessions	226(67.9%)	86(72.9%)	.311*
VL results after 3 EAC sessions	Median (IQR) (copies/ml)	3400 (623–25,200)	1580 (245–8588)	.036†
	Suppressed (<1000 copies/mL)	76 (34.6)	45 (52.3)	
	Unsuppressed (≥1000 copies/mL)	144 (65.4)	41 (41.7)	
	Results unavailable	6	0	

EAC = enhanced adherence counseling, IQR = interquartile range, SEAC = standardized enhanced adherence counseling, VL = viral load.

\*Chi-square test.

†Wilcoxon Rank sum test (difference in medians).

A higher proportion of participants had a repeat VL following SEAC, 72.9% (n = 86) compared to 67.9% (n = 226) pre-SEAC, though this did not reach statistical significance. The proportion of virally suppressed clients after receipt of 3 EAC sessions also increased with 52.3% (n = 45) in the post-SEAC compared to 34.6% (n = 76) in the pre-SEAC period (P = .004).

Bivariate analysis results in Table 3 show that the SEAC program was significantly associated with viral suppression, (OR: 1.7, 95% CI: 1.1–2.8).

Clients in Homa Bay Country have significantly higher rates of viral suppression than clients in Turkana County (OR: 3.53, 95% CI: 1.3–9.4). However, there was no difference in viral

suppression between facilities of different health system levels and between those who received the protease inhibitor-based and those on the non-nucleoside reverse transcriptase inhibitor-based regimen. Univariate analysis was conducted and no confounding was found based upon review of variables of interest.

In the multivariate-adjusted analysis, clients who received the SEAC package were 1.7 times (95% CI: 1.1–2.8) more likely to be virally suppressed on repeat VL testing compared to those who had not received the SEAC package. Receiving services in Homa Bay facilities compared to Turkana facilities (adjusted OR: 3.5 95% CI: 1.3–9.6) remained significant.



**Table 3**  
**Factors associated with subsequent viral suppression in clients with viral load >1000 copies/mL.**

Variable	Levels	Unadjusted/crude OR (95% CIs)	Adjusted OR (AOR)* (95% CIs)
Study group*	Pre-SEAC (ref)	—	—
	Post-SEAC	1.7 (1.1–2.8)†	1.7 (1.1–2.8)
Facility type	Hospital (ref)	—	—
	Health Center	1.2 (0.8–1.9)	—
Facility county*	Turkana (ref)	—	—
	Homa Bay	3.5 (1.3–9.4)†	3.5 (1.3–9.6)
ART regimen*	NNRTI (ref)	—	—
	PI-based	1.5 (1.0–2.4)†	1.4 (0.9–2.3)
Age (yr)	0–9 (ref)	—	—
	10–14	1.2 (0.8–2.0)	—
	15–19	0.9 (0.5–1.5)	—
Gender	Male (ref)	—	—
	Female	1.3 (0.8–1.9)	—
Time (days) to first EAC	Median (days)	0.99 (0.99–1.00)	—
Days between 1 <sup>st</sup> and 3 <sup>rd</sup> EAC	Median (days)	0.99 (0.99–1.00)	—
Time on ART Prior to EAC (years)	Median (years)	1.0 (0.98–1.1)‡	—

ART = antiretroviral therapy, CI = confidence interval, EAC = enhanced adherence counseling, NNRTI = non-nucleoside reverse transcriptase inhibitor, OR = odds ratio, SEAC = standardized enhanced adherence counseling.

\*adjusted for time to EAC/SEAC sessions, repeat VL results, age, VL at enrollment, regimen before EAC, ART duration prior to EAC, and type of facility.

†significant bivariate, so included in multivariate analysis.

‡ART time was dropped from multivariate model, as it did not retain significance in full model. This analysis included all participants who had completed 3 EAC sessions as per guidelines.

#### 4. Discussion

In this study, we found that implementation of the SEAC improved EAC parameters and subsequent viral suppression. EAC uptake was 100% following SEAC implementation, as compared to 83% in the pre-SEAC period. EAC before standardization was similar to what was found in other studies, but this improved following standardization. In 2 studies reporting viral suppression following EAC, EAC uptake ranged from 75% to 80% among PLHIV who had VL >1000 copies/mL, with lower proportions in the younger age categories.<sup>[15,16]</sup> In our study, among those who initiated EAC, clients in the post-SEAC period were more likely to complete the minimum 3 sessions compared to those in the pre-SEAC period. Similarly, the time taken to complete the 3 EAC sessions was reduced.

The goal of EAC is to assess possible barriers to adherence and to help the patient construct an adherence plan with concrete objectives after reviewing psychological, emotional, and socio-economic factors that may contribute to poor adherence. Immediate initiation of EAC in a patient identified to have high VL with timely completion of at least 3 EAC sessions is an essential component of the health care worker response to elevated VL and support to reach viral suppression or identify treatment failure. A delay in addressing a client's specific adherence barriers is likely to lead to adverse treatment outcomes.<sup>[17]</sup> One observation made during data collection was conflicting appointments for EAC and drug refills, which was an identified barrier to EAC uptake. Clients were receiving biweekly appointment dates from adherence counselors for EAC sessions and monthly appointment dates from clinicians for drug refills. Often, clients attended the drug refill appointments, but missed the EAC sessions, therefore, either not initiating EAC or not completing the 3 minimum sessions. None of the demographic and clinical characteristics were associated with uptake of EAC in the current results.

We found that facilities in Homa Bay County were associated with greater viral suppression after SEAC compared to facilities in Turkana County. This is likely because Turkana is a huge, sparsely populated county where much of the population leads a pastoral lifestyle. The biggest obstacle to healthcare in Turkana is access due to barriers such as the rough terrain with poor road networks, seasonal floods, long distances to health facilities, and poor health-seeking behaviors. Due to these challenges,

clients may not be able to adhere to clinic visits, particularly when more visits are required for EAC. In contrast, Homa Bay Country occupies a much smaller geographical area and has a larger population than Turkana. Clients in Homa Bay County have better access to healthcare, though health-seeking behaviors are also poor.

In our study, the proportion of children and adolescents who were virally suppressed following SEAC program implementation increased by almost 20%. However, viral suppression after 3 EAC sessions following SEAC implementation was still suboptimal compared to what has been reported in other studies.<sup>[18]</sup> Rates of viral suppression are lower among children and adolescents compared to adults and our data indicate children and adolescents continue to have lower suppression rates following EAC. In a meta-analysis of adolescents on ART, viral suppression rates ranged from 28% to 87%.<sup>[19]</sup> ART adherence, retention in care, and achieving viral suppression are substantial challenges in the clinical management of children and adolescents on ART.<sup>[4,5]</sup> It can be more difficult for providers to manage children and adolescents given the complexity of ART drug dosing and the need to adjust dosing as children grow.<sup>[20]</sup> Some barriers to viral suppression in children are more related to provider issues and thus, are unlikely to be addressed through adherence counseling.

We did not measure viral drug resistance in this study, but there is a possibility that clients with persistent elevated VL after EAC had developed resistance to their ART regimen, and would therefore benefit from a switch to a more optimal regimen.<sup>[21]</sup> Keeping clients longer on the same failing regimen is likely to expose them to disease progression and increased risk of mortality.<sup>[22–24]</sup>

Our study had some limitations. The study utilized retrospective data that is routinely collected at health facilities, therefore there were some challenges with data quality and completeness. A limitation of the pre-post study design is that observed changes were assumed to be due to the intervention, but may have been due to other changes within the health facilities or in the health system. Repeat VL testing during the study was suboptimal with 37% of clients in the pre-SEAC period and 16% in the post-SEAC period not receiving a repeat VL test during the study period. These clients were more likely to remain unsuppressed compared to clients who successfully underwent retesting in the pre- and post-SEAC periods. In addition, enrollment of study participants was stopped

early and the study was not able to meet its intended sample size due to the COVID-19 pandemic and related Ministry of Health and donor recommendations to reduce potential staff and client exposure. Finally, as our study was conducted in 6 high-volume facilities in 2 counties, our findings may not be representative of the entire child and adolescent population on ART in Kenya. The sampling method of probability proportional-to-size sampling minimized bias, as clients in the study sites had an equal chance of being selected.

Overall, implementation of the SEAC program improved uptake and time to EAC for children and adolescents with high VL. Despite improvement in viral suppression after SEAC implementation, overall suppression remained sub-optimal, which highlights the need to review other barriers to viral suppression in this group. Additional work must be done to effectively address individual and facility-level factors that affect ART adherence and viral suppression in children and adolescents, including further research on ART drug resistance, identification and management of treatment failure. In conclusion, our study shows that implementation of a standardized EAC package significantly improved uptake and time to interventions for children and adolescents with high VL, however overall suppression was still sub-optimal. A comprehensive, multidisciplinary, and holistic approach is needed to better manage HIV care for children and adolescents, including identifying client-specific ART adherence barriers, ensuring correct ART drug dosing, and improving identification and management of treatment failure.

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