



EVALUATION AND PERFORMANCE MEASUREMENT PLAN (EPMP) FINAL REPORT: ENHANCED ADHERENCE STUDY



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



REPUBLIC OF KENYA



MINISTRY OF HEALTH

EVALUATION AND PERFORMANCE MEASUREMENT PLAN (EPMP) FINAL REPORT: ENHANCED ADHERENCE STUDY

FOA # and Cooperative Agreement #: NU2GGH001948-01-00

STUDY TITLE: EVALUATION OF ENHANCED ADHERENCE COUNSELING AS A STRATEGY TO OPTIMIZE ADHERENCE, RETENTION AND VIRAL SUPPRESSION AMONG CHILDREN AND ADOLESCENTS, IN HOMA BAY AND TURKANA COUNTIES, KENYA.

Cooperative Agreement Partner: Elizabeth Glaser Pediatrics AIDS Foundation

Contacts:

Name: Dr Rose Otieno-Masaba
Role: Principal Investigator
Title: Associate Director Public Health Evaluations
Address: Fidelity Insurance Centre, Mezzanine Floor | Waridi Lane, Off Mahiga Mairu Avenue, Waiyaki Way, Westlands Rd,
Country: Kenya
Telephone: 254204454081/2/3
Email: rmasaba@pedaids.org

Name: Dr Eliud Mwangi
Role: Co-Principal Investigator
Title: County Director
Address: Fidelity Insurance Centre, Mezzanine Floor | Waridi Lane, Off Mahiga Mairu Avenue, Waiyaki Way, Westlands Rd,
Country: Kenya
Telephone: +254204454081/2/3
Email: emwangi@pedaids.org

Funded By:

Funding Agency: US Centers for Disease Control and Prevention (CDC)

Announcement Number: GH001948

Award Title: Supporting the Implementation and Expansion of High Quality, Sustainable and Comprehensive HIV Prevention, Care and Treatment Programs in the Western Region and Turkana County of the Republic of Kenya under the President's Emergency Plan for AIDS Relief (Timiza90 Project).

Sponsoring institutions:

Ministry of Health, Kenya, Homa Bay and Turkana Counties; CDC- Centers for Disease Control and Prevention (CDC), USA

TABLE OF CONTENTS

List of Acronyms and Abbreviations	3
Executive Summary	4
Project Background	6
Methodology	7
Implementation of a Standardized EAC package.....	7
Evaluation Objectives	8
Evaluation Design.	8
Overview of Evaluation Design	8
Study Population	8
Inclusion Criteria	9
Sampling Strategy and Sample size	9
Data collection Methods and Rationale.	11
Quantitative Methods.	11
Qualitative methods.....	11
Data Handling Procedures.....	11
Data Analysis Plan	12
Evaluation Limitations	13
Stakeholder Engagement	14
Ethical Considerations.....	14
Key Evaluation Findings	14
Quantitative findings.....	14
Qualitative findings.	22
Accessing the health facility and services	22
Disclosure.....	22
Adherence and retention.....	22
Challenges to adherence and retention	23
Adherence facilitators	23
Acceptability of enhanced adherence counseling	23
Transitioning to adult care	24
Key Takeaways.....	25
Conclusion	27
Dissemination	28
Appendices	28
References	29

LIST OF ACRONYMS AND ABBREVIATIONS

ADS	Associate Director for Science
CALHIV	children and adolescents living with HIV
APoC	Adolescent Package of Care
ART	antiretroviral therapy
CCC	comprehensive care clinic
CDC	U.S. Centers for Disease Control and prevention
CHMT	County Health Management Team
DHIS2	District Health Information System2
EAC	enhanced adherence counselling
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
ERC	ethical review committee
FGD	focus group discussion
HCW	health care worker
HTC	HIV testing and counseling
ICF	informed consent form
IDI	in-depth interview
IRB	institutional review board
LTFU	loss to follow-up
MDT	multi-disciplinary team
MNCH	maternal, newborn, and child health
MoH	Ministry of Health
NASCOP	National AIDS STI Control Program
ODK	open data kit
OI	opportunistic infections
PE	peer educator
PII	personal identifiable information
PLHIV	people living with HIV
RA	research assistant
S/CHMT	Sub/County Health Management Team
SEAC	standardized enhanced adherence counseling
SOC	standard of care
SOP	standard operating procedure
SSL	secure socket layer
STF	suspected treatment failure
UNAIDS	Joint United Nations Program on HIV and AIDS
VL	viral load
WHO	World Health Organization

EXECUTIVE SUMMARY

PROJECT BACKGROUND

HIV viral suppression is an indicator of successful anti-retroviral therapy (ART) and is the “3rd 95” of the UNAIDS 95-95-95 treatment target to end the HIV/AIDS epidemic. Suppressing viral load among people living with HIV to less than 1,000 copies/ml is essential for reducing HIV-associated morbidity, mortality, and further virus transmission. Although Kenya has made considerable progress towards reaching the “3rd 95” in the adult population, with approximately 90% of adults 15–64 years on ART virally suppressed as of 2018, viral suppression among children and adolescents remains suboptimal at 67.1%. Barriers to providing effective HIV services to adolescents and young people include limited access to HIV information and services, stigma, and discrimination, among others.

PURPOSE

In order to improve health outcomes among children and adolescents living with HIV (CALHIV), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) implemented a standardized enhanced adherence counseling (SEAC) package that aligns with the Kenya National guidelines on ART use for treatment and prevention of HIV in EGPAF-supported health facilities in Homa Bay and Turkana Counties. We conducted an evaluation of the SEAC with the overall objective of evaluating implementation and effectiveness of a standardized EAC package offered to virally unsuppressed children and adolescents (0-19 years of age) as compared to the current EAC package at EGPAF-supported sites in Homa Bay and Turkana Counties. The SEAC package included enhanced appointment management, home visits and individualized HIV case management among other interventions.

METHODOLOGY

We purposively selected six EGPAF-supported health facilities that had the greatest number of virally unsuppressed CALHIV in Homa Bay and Turkana Counties between October 2017 to September 2018. We used a mixed methods approach to: 1) evaluate key program implementation and patient outcome indicators pre- and post-SEAC standardization using routinely collected program data; and, 2) assess care giver and provider perceptions of EAC, and facilitators and barriers to receiving or providing these services. The study was conducted from February 2019 to September 2020. Key indicators assessed in the pre-/post-SEAC standardization periods are timeliness and completion of EAC sessions.

DATA ANALYSIS

We described and compared the demographic and clinical characteristics, and outcomes of patients in the pre-SEAC and SEAC periods. The results were presented using frequencies and proportions based on characteristics such as sex, age, ART regimen before EAC, County and type of health facility. Depending on the distribution, we used mean, standard deviations, median and interquartile range to describe continuous variables. We further assessed factors associated with viral non-suppression using univariate and multivariable logistic regression. Thematic content analysis was used for qualitative analysis.

LIMITATIONS

The main limitation was the use of retrospective data to assess key process and outcome indicators in the pre-EAC standardization period. Because these data had already been collected when the evaluation was initiated, the study team was not able to fully address gaps in data quality and completeness. Poor filing systems in most of the health facilities resulting in missing or lost files, contributed to missing data.

FINDINGS

A total of 741 clients were included in the analysis: 595 in pre-SEAC and 146 in post-SEAC period. Whereas 16.5% (98/595) of the pre-SEAC patients did not attend an EAC visit, all (100%) of post-SEAC participants attended at least one (the first) EAC visit. The time between high viral load test result to first EAC visit was reduced by 8 days, from a median of 49 (IQR: 23.0-102.5) pre-SEAC, to 41 (IQR: 20.0-67.0) days post-SEAC ($p=0.006$). Time to completion of at least 3 sessions was reduced by 12 days; from a median of 59 (IQR: 36.0-91.0) pre-SEAC, to 47.0(IQR: 33.0-63.0) days among clients in the SEAC period ($p=0.002$). Similarly, a significantly greater percentage of patients completed the recommended minimum 3 EAC sessions in the post- (91.1%) as compared to pre-SEAC (81.1%) periods ($p=0.004$). Finally, a greater proportion of clients who received EAC post-standardization had viral suppression after 3 sessions (55% [67/122] vs. 39.6% [145/373]; p -value=0.023). In the multivariable model, SEAC was significantly associated with viral suppression (odds ratio [OR] 1.6; 95% Confidence Interval [CI] 1.1-2.3).

Findings from the qualitative analysis showed that participants generally expressed satisfaction with the quality of care received and stated that they were supported to understand their condition and monitor progress. However, there were concerns regarding clinic flow with the organization of services, as adolescents and caregivers outlined that they would sometimes dedicate whole days to attending the clinic and attributed this to disorganization in retrieving files (resulting in patients not being seen on a 'first-come, first-serve basis), low number of providers available, and patient volume.

Regarding clinic safety and privacy, majority of adolescents cited stigma as a barrier to clinic attendance and were concerned with being seen in clinic waiting areas, or even on their way into the HIV clinic.

Health care workers (HCW) associated late receipt of test results or non-disclosure of HIV status with poor adherence among adolescents. There were requests from caregivers to receive facility support for disclosure either through individual or group counseling.

Regarding retention, a challenge to appointment keeping was school-related conflicts. Some students did not want to explain their absence from school, or found appointments coincided with class sessions or examinations. Observations during data abstraction revealed that health care workers did not appropriately capture qualitative components of EAC, such as their assessment of patients' barriers to adherence and adherence plans. HCW explained that this was due to lack of appropriate tools to capture the required information and hence tended to mostly rely on recall.

KEY TAKEAWAYS

Standardization of EAC improved all EAC process and patient outcome indicators measured in the evaluation, including completion of EAC and viral load suppression. Programs could strive to adopt standardized EAC, and implement it with fidelity in all facilities to ensure that all patients with suspected treatment failure are able to benefit. Tools for documenting qualitative components of EAC sessions can be refined, and HCW would benefit from additional training on proper documentation to improve the quality of the information captured and utility for patient management.

Despite improvement in viral suppression after standardization of EAC, overall suppression remained suboptimal. Programs could identify and mitigate other barriers to viral suppression in this group of patients. Children and adolescents may benefit from a comprehensive multidisciplinary and holistic approach including barrier identification and management of existing treatment failure towards VL suppression and optimal clinical outcome.

PROJECT BACKGROUND

Kenya has an estimated national HIV prevalence of 0.7% among children <15 years, corresponding to a total of 106,807 children and adolescents living with HIV [1-3]. ART coverage among children 0-14 years is estimated at 68% country wide, 70% in Homa Bay and 49% in Turkana counties [2]. Adolescents and young people, especially young women, still bear the brunt of the HIV epidemic due to limited access to HIV information and services, stigma, and discrimination [4,5]. Non-adherence to anti-retroviral therapy (ART) remains the main barrier to achieving viral suppression among adolescents and children living with HIV. Some of the factors contributing to poor adherence include lack of information among caregivers and adolescents, pill burden, unfriendly pediatric formulations, lack of caregiver support for the children, among others.[6] To address some of these barriers to adherence, initiatives such as caregiver treatment literacy sessions, simplification of regimen while undertaking ART optimization to all, family model of care referred to as PAMA (PAPA-MAMA; PAPA for father and MAMA for mother) care model for children and caregivers and operation triple zero clubs for adolescents when implemented have demonstrated improvement in viral suppression.

Viral suppression is an indicator of successful ART and is the “3rd 95” of the UNAIDS 95-95-95 strategy, an ambitious treatment target to end the HIV/AIDS epidemic. Suppressing viral load (VL) to less than 1,000 copies/ml is essential for reducing HIV-associated morbidity and mortality, and further transmission of the virus [7].

Viral suppression among children and adolescents in Kenya is suboptimal at 67.1% nationally as compared to adults at 90% [3]. This is partly because, children and adolescents rely on others to administer their medications and to ensure clinic attendance. On the other hand, caregivers may face psychosocial and economic barriers that directly impact medication adherence and clinic attendance [8-11].

To ensure successful treatment, identification of adherence challenges and determining whether ART regimens should be switched, the World Health Organization (WHO) recommends routine assessment of viral loads (within 6 months of initiating ART, and every 6 months for children, adolescents and young adults and every 12 months for adults) in all PLHIV on ART. WHO further recommends achievement of viral load suppression in those with high plasma VL $\geq 1,000$ copies/ml (suspected treatment failure) by addressing the common reasons for high VL [12,13]. Poor adherence is the most common cause of high VL in PLHIV, particularly among children and adolescents on ART [14]. WHO also recommends enhanced adherence counselling (EAC) for PLHIV with VL $\geq 1,000$ copies/ml followed by a repeat VL test after 3 months of good adherence [12,13].

The Kenyan ART guidelines recommend a minimum of three EAC sessions for PLHIV with VL $\geq 1,000$ copies/ml. Changes in VL are detected through a repeat VL test conducted after 3 months of good adherence support. Clients with repeat VL $< 1,000$ copies/ml are considered to be virally re-suppressed and are, therefore, maintained on the same ART drug regimen while those with persistent VL greater than or equal to 1,000 copies/ml are deemed to have failed current treatment, and are thereafter, switched to the appropriate alternate treatment (second or third line) ART drug regimen [15-18]. All children and adolescents failing first-line are discussed in the facility multidisciplinary team (MDT) prior to change of ART to second-line. Children and adolescents failing an alternative first-line regimen and second line regimen are discussed with the Regional or National HIV Clinical technical working group (TWG) who decide on whether they need to have an HIV drug resistance test (DRT) before a regimen switch. This process has been known to take long, therefore leading to a delay in regimen switch. The delay occurs both at the facility level and regional TWG and NASCOP. From the facility, health care workers (HCW) sometimes delay or submit poorly documented case summaries which the TWG cannot use to make decision; TWG may recommend more EAC sessions, home visits and directly observed therapy (DOTS) before requesting for DRT; Once DRT results are received in the facility, more time is spent waiting for decision from NASCOP and availability of commodity at site. Program data collected in HIV care and treatment facilities supported by Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in Homa

Bay, and Turkana counties in 2016 indicates that just 40 percent of children and adolescents with a VL $\geq 1,000$ copies/ml receive the recommended three minimum EAC sessions, suggesting Ministry of Health (MOH) guidelines around EAC are not being uniformly implemented. EGPAF developed and implemented a standardized enhanced adherence counseling (SEAC) package that aligns with MOH guidelines and evaluated its effectiveness in achieving viral suppression in children and adolescents, 0-19 years with suspected treatment failure. The evaluation was conducted from February 2019 to September 2020.

The total cost of implementation was \$265,945.

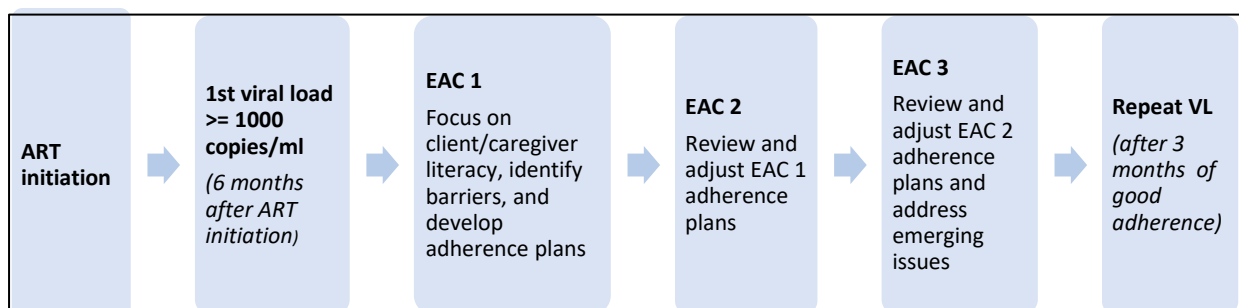
METHODOLOGY

IMPLEMENTATION OF A STANDARDIZED EAC PACKAGE

EGPAF developed a SEAC package based on the Kenya National guidelines on ART use for treatment and prevention of HIV [15,16]. This was to support the adherence counselor and other cadres to ensure provision of quality EAC sessions for children, adolescents, and their caregivers. The SEAC package included 1) standard operating procedures (SOPs) to operationalize the EAC process, 2) training of providers on psychosocial support and communicating with children, adolescents, and their caregivers using a standard curriculum, 3) provision of mentorship to providers and peer educators. Mentorship entailed support supervision and ensuring that the procedures were implemented appropriately, 4) Improved appointment management: this was done using appointment dairies or Ushauri, a digital platform that sends patients short message services (SMS) reminders 3 days and 1 day before a scheduled clinic day and 5) individualized case management, with each EAC patient allocated to a case manager who ensured that the barriers to adherence were identified and tackled both at facility and community level. The package ensured implementation of the case management both at facility and especially at community level. Cases were closed after establishment of a re-suppression of a previously high VL. 6) EAC tools and job aids were provided to the health facilities.

Implementation steps for SEAC included the following: 1) Children and adolescents with VL $\geq 1,000$ copies/ml received at least 3 EAC sessions. Using the VL register, all children and adolescents with VL $\geq 1,000$ copies/ml were identified and discussed in the facility MDT for HIV management. The adherence counsellor or assigned case manager contacted the patient and scheduled an appointment for the EAC sessions within a week of receiving the high VL results. 2) A repeat VL test was done at completion of the EAC sessions (at least 3 months after the last VL) and with satisfactory adherence (figure 1). 3) Those with viral load suppression were transitioned back to regular care with the adherence plan including sustaining the interventions that led to viral suppression. 4) Clients who did not have viral suppression were referred to the MDT for preparation for second- or third-line treatment. These cases were then summarized and referred to the regional technical working group (TWG) for decision making. The SEAC package was implemented in the study facilities from January 2019 and rolled out to all EGPAF supported health facilities beginning in March 2019.

FIGURE 1: THE ENHANCED ADHERENCE COUNSELLING CASCADE



EVALUATION OBJECTIVES

Overall objective: To evaluate implementation and effectiveness of a standardized EAC package offered to virally unsuppressed children and adolescents (0-19 years of age) as compared to the current EAC package at EGPAF-supported sites in Homa Bay and Turkana Counties.

SPECIFIC OBJECTIVES

1. TO ASSESS IMPLEMENTATION OF THE STANDARDIZED EAC PACKAGE AT EGPAF-SUPPORTED SITES

1. Assess the uptake of the EAC package by children and adolescents with suspected treatment failure pre- and post-standardization
2. To compare the coverage and timeliness of EAC package and related services pre- and post-standardization
3. Assess the acceptability of, and satisfaction with EAC package pre- and post-standardization

2. EVALUATE ADHERENCE AND HEALTH OUTCOMES AMONG CLIENTS RECEIVING EAC PRE- AND POST-STANDARDIZATION

1. Compare demographic and clinical characteristics of patients accessing EAC package pre- and post-standardization
2. Assess client adherence to clinic visits and pharmacy pick-ups pre- and post-standardization
3. Describe health outcomes among clients who receive EAC pre- and post-standardization
4. Describe client, care giver and provider perceptions of EAC, and facilitators and barriers to receiving or providing these services.

EVALUATION DESIGN

OVERVIEW OF EVALUATION DESIGN

This is a process and outcome evaluation with a pre-post study design to evaluate specific treatment outcomes among children and adolescents receiving the standardized EAC package after suspected treatment failure, and after switch to second- and third-line ART regimens. We employed a mixed methods approach for this evaluation. Retrospective data for the pre-intervention were abstracted for the period October 2016 to September 2018, while prospective data were collected from February 2019 to September 2020.

The main outcome was the proportion of clients with documented treatment failure who achieved viral suppression after receiving the standardized EAC intervention and adherence of 95% and above as documented in the patient charts. The assessment of adherence was based on an adherence plan developed specific for the patient during the first EAC session.

We further assessed client, care giver and provider perceptions of EAC, and facilitators and barriers to receiving or providing these services using focus group discussions and in-depth interviews.

STUDY POPULATION

The study was conducted in six high-volume health facilities supported by EGPAF in Homa Bay and Turkana Counties. Homa Bay County is a county in western Kenya with high HIV prevalence (18.5%), while Turkana County is a county in Northern Kenya with a low HIV prevalence (3.0%). Viral suppression among children receiving care in Homa Bay County is 85% and 58% in Turkana County [2]. The population of Homa Bay County has poor health seeking behavior. The main drivers of the HIV epidemic include, early sexual debut, cultural practices such as wife inheritance, and growing number of key and priority populations. Turkana County on the

other hand has a population with a pastoralist lifestyle. The biggest obstacle to healthcare is access, due to long distance to health facilities, and poor health seeking behavior [3]. The health facilities included in the evaluation were purposively selected to provide sufficient numbers (enough to provide 80% power at a 95% confidence level to demonstrate a 10-15% increase in viral suppression pre-post EAC intervention) of children and adolescents with suspected treatment failure. The purposively selected study sites were: Homa Bay County referral hospital, Marindi Sub- County hospital, Kitare and Nyagoro health centers in Homa Bay County and Lodwar County referral hospital and Kakuma mission hospital in Turkana County. We aimed to conduct the evaluation in 4 facilities in Homa Bay and 3 facilities in Turkana counties. In Turkana County, we were only able to conduct the study in two facilities. One facility in Turkana participated for just two months and a second facility was not accessible at the time of the evaluation. EGPAF program transitioned out of the county before we could complete data collection. Through an amendment, the Turkana facilities were later replaced with 3 facilities in Homa Bay, but participant enrollment was not possible due to the COVID-19 pandemic. We only enrolled 54% of the expected sample size.

As at September 2017 these facilities had at least 1,080 children and adolescents aged 0-19 years enrolled in care, of whom about 34.4% (371/1,080) had suspected treatment failure.

INCLUSION CRITERIA

Children and adolescents

- 0-19 years old
- HIV positive on ART for at least 6 months
- Last VL \geq 1000 copies/ml
- Parental/guardian consent
- Provides assent (for 10-17-year-old)
- Provides consent (for mature minors and those 18-19 years)

Parents/caregiver

- Parent or caregiver to a child/adolescent on ART with VL $>$ 1000 copies/ml
- Provides consent

Healthcare worker, peer educators and adherence/psychosocial support counselors

- Working in the facility for at least 3 months
- Provides services to children and adolescents
- Provides consent

Informed consent was obtained for prospective interviews, focus group discussions (FGDs) and in-depth interviews (IDIs) from those \geq 18 years, mature minors, and consent from parents and assent from children and adolescents for those aged below $<$ 18 years before study procedures were conducted. We received a waiver for written and obtained verbal consent for the FGDs. Informed written consent was also received from health care workers, peer educators and adherence/Psychosocial support counselors. Consenting process was done with eligible participants in a private location with a witness present in the case of an illiterate participant.

SAMPLING STRATEGY AND SAMPLE SIZE

We purposively selected facilities that had the greatest number of unsuppressed patients based on VL tests done between October 2017 to September 2018. In the selected facilities, we captured data from the records of all patients who were unsuppressed over the period Oct 2016 – Sep 2018, (pre-intervention). Similarly, we

captured data from the records of all patients who were unsuppressed for the post-implementation period, that is, February 2019 – September 2020.

We aimed for a minimum sample size of 1,361. We performed two-sample test to determine whether the proportion virally suppressed in the pre-intervention group A, p_A , is different from the proportion in the post-intervention group B, p_B . The hypotheses are:

$$H_0: p_A - p_B = 0$$

$$H_1: p_A - p_B \neq 0$$

where the ratio between the sample sizes of the two groups is

$$k = n_A/n_B = n_A/n_B$$

Formulas

The following formula was used to compute the sample size:

$$n_A - kn_B \text{ and } n_B$$

$$= (p_A(1 - p_A)k + p_B)(z_{1 - \frac{\alpha}{2}} + z_{1 - \beta}p_A - p_B)2n_A - kn_B \text{ and } n_B$$

$$= (p_A(1 - p_A)k + p_B(1 - p_B))(z_{1 - \frac{\alpha}{2}} + z_{1 - \beta}p_A - p_B)2$$

Where

- $k = n_A/n_B$ is the matching ratio
- α is Type I error
- β is Type II error, meaning $1 - \beta$ is power

Sample size was calculated with an estimated 80% power at a 5% level of significance to demonstrate a minimum 10% increase in viral suppression due to the standardized EAC, adjusted for facility clustering (design effect 1.5), and estimates of missing records or lost to follow-up (20%). We used probability proportional-to-size sampling, based on the volume of VL tests by facility and age group; 0-9, 10-14, 15-19 years.

We assumed a 4:1 pre/post implementation number of clients unsuppressed for the 0–9-year age group and 3:1 pre/post implementation number of clients unsuppressed for the 10–14-year age group and 15-19-year age groups. Table 1, below presents sample size, considering missing records for the retrospective cohort, or lost-to-follow up/missing records for prospective/post-intervention cohort, which may subsequently reduce the power to be able to demonstrate a difference. These estimates are unadjusted for facility clustering.

TABLE1: POWER ESTIMATES BASED ON ADJUSTED SAMPLE SIZE AT EFFECT SIZES OF 10 AND 15 PERCENT BY AGE GROUP

Age group	Unadjusted Sample size	Adjusted sample size (+20%)	Baseline (%)	Effect size	
				+10%	+15%
0-9	535	669	33	0.56	0.88
10-14	510	637	29	0.65	0.94
15-19	266	332	25	0.42	0.73
Total	1,311	1,638			

Note: Sample size estimated on approximately 4:1 for 0-9-year age group, and 3:1 for the 10-14 and 15-19 age groups, before and after EAC implementation.

DATA COLLECTION METHODS AND RATIONALE

We used both quantitative and qualitative data collection methods.

QUANTITATIVE METHODS

We abstracted data both retrospectively and prospectively and conducted structured interviews prospectively. Abstracted data included: date of HIV diagnosis, date of ART initiation, ART regimens, and medication dispensing pattern (e.g. monthly, multi-month dispensing), adverse events, and laboratory data, specifically VL results. Post SEAC data was collected using closed ended questionnaires. We interviewed all participants who were eligible, including not being virally suppressed in the study facilities. Interview questions addressed participant's socio-demographic information, such as age, education, family situation, disclosure status, social support and self-reported ART related knowledge and practices. Post-intervention participants were followed for a period of 9 months during which, time to EAC following a high VL, number, and dates of EAC attendance, repeat viral load were captured. Viral load data were abstracted from the facility VL sample and result tracking log and from the high VL follow-up register.

QUALITATIVE METHODS

Using qualitative methods, we conducted 16 FGDs with adolescents and caregivers pre- and post-intervention and 17 IDIs with healthcare workers, peer educators and adherence/psychosocial counselors. Participants for the FGDs had all provided data for either the pre-intervention or post-intervention. For the pre-intervention, a subset of participants whose data were retrospectively abstracted and were available during the study period were approached and requested to participate in the qualitative component of the study. Those willing were consented and given a chance to participate. The same applied to the post-intervention participants. The interview guides for FGDs and IDIs were semi-structured to assess satisfaction with services, facilitators and barriers to EAC and explore the thoughts and feelings of the participants on the topics. To maximize comfort and enhance participation, the 10 adolescent FGDs were organized by age group, with five FGDs each conducted with adolescents 12-14 years and 15-19 years. The groups were also organized by pre and post intervention. Parents/caregivers of children 0-9 years participated in six FGDs.

We selected providers working in the comprehensive care clinic (CCC) and other departments offering services specifically to children and adolescents.

DATA HANDLING PROCEDURES

Quantitative data were collected and entered into an Open Data Kit (ODK) Collect designed questionnaire database installed on tablets. Each tablet was password protected to ensure data security. An elaborate user authentication process was used to secure the data and control access to the data by authorized evaluation study personnel only. Each study staff member responsible for data collection had a unique username and password that was used to access their assigned study data collection tablets for data entry. The unique passwords were updated routinely by the data manager. The ODK Collect database was secured by Secure Socket Layer (SSL) installed on the tablets. This ensured security of personal identifiable information (PII) of study participants. The aggregate study database is structured to keep a log of details concerning access and change to the data by staff who have been granted official access to the database and the data. Access to the database was based on the level of use of the data (e.g., evaluation study staff with no direct role in the entry of data are restricted to read-only access). Security measures to protect study participant data include ensuring confidentiality, integrity, and availability of electronic data, restricting access to the EGPAF Server and encryption of both data stored and data in transit and applicable data transmission channels. The data

collection forms in ODK were employed data quality checks. The ODK Collect forms were encrypted whenever a form was filled, finalized, and submitted to the EGPAF Server by the evaluation staff. This ODK Collect data encryption capability ensured that transmission and storage of the data was of high quality and met all the standards for data security.

The data were encrypted and stored on a real time basis into a central database hosted in secure servers at the EGPAF office in Nairobi and backed up daily. In addition, the database and the data within was backed-up multiple times on secure and password-protected external hard-drives and kept in a locked area at the regional EGPAF offices and under the supervision of the data manager and the study coordinator. All data cleaning, data checks and data analyses was completed in consultation with the EGPAF biostatistician. The data were checked for quality assurance by the data manager and study coordinator weekly to avoid problems with data inconsistencies; randomly selected source documents were checked and compared with the data entered in the database for quality assurance. Once data were collected, only authorized evaluation staff had access to the electronic data.

The data manager was responsible for the confidentiality, integrity and security of all the databases and the data hosted within EGPAF offices, computers and servers. All the computers were password protected, with access to only authorized evaluation personnel.

All filled study questionnaires were kept in a locked storage area at the EGPAF regional offices in Homa Bay and Turkana Counties. No participant names or other personal identifying information were written on any data collection tool. All reports and other records were identified only by a unique study participant identification number, issued to the patient after consenting to take part in the study, captured on each data collection tool page to maintain confidentiality. A master link log matching the unique study participant identification number to the patient's CCC number was kept in a locked cabinet separate from all other study documents. Consent forms, which had participant names were stored in a separate folder from other documents and kept in a secure, lockable cabinet to maintain patient confidentiality and data security. The lockable cabinet was only accessible to authorized evaluation team members.

All electronic records were kept in password-protected computers. All electronic communications of study data are through password-protected, encrypted files. All data storage at the EGPAF country office were within a secure and protected server.

DATA ANALYSIS PLAN

DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

We described the demographic and clinical characteristics of the study population grouped by study group (Pre-SEAC and SEAC). The results were presented using frequencies and proportions based on characteristics such as gender, age, ART regimen pre-SEAC, County and type of health facility. Depending on the distribution, we used mean, standard deviations (SD), median and interquartile range (IQR) to describe continuous variables such as age, VL at EAC enrolment and the duration on ART pre-SEAC.

OBJECTIVE 1: TO ASSESS IMPLEMENTATION OF THE STANDARDIZED EAC PACKAGE AT EGPAF-SUPPORTED SITES

We compared the proportion of eligible children/adolescents (those with high VL results) who were offered/accepted EAC (pre-intervention) or standardized EAC (post-intervention). We also compared the proportions of these participants who initiated and completed all aspects of the EAC (pre-intervention) with the SEAC (post-intervention) including uptake of a minimum of 3 EAC sessions.

In addition, we compared the median time/duration from high VL results (time [days] from when the results were documented in the patients' charts) to the first EAC session and completion of all three sessions (pre-intervention and post-intervention).

OBJECTIVE 2: TO EVALUATE ADHERENCE AND HEALTH OUTCOMES AMONG PATIENTS RECEIVING EAC BEFORE AND AFTER STANDARDIZATION

We compared the median time/duration in days from both first high VL and EAC completion to either VL suppression or switch to second-or third-line regimen for patients receiving EAC (pre-intervention) with those receiving SEAC (post-intervention).

We also compared the proportion of patients lost to follow-up (LTFU), alive/dead, stopped medication and retained in care, pre/post SEAC.

Given that uptake, coverage, timeliness and patient outcomes, (adherence and retention) within facilities were correlated and varied between facility types, we fit logistic regression models to estimate the intervention effect accounting for potential intra-cluster correlation at univariate and multivariate level for factors assessed to have significant association with health outcomes. Odds ratios with their 95% confidence intervals were used to determine the effect size of the intervention. The data were analysed using SAS 9.4 statistical software.

All comparisons for objective 1 and 2 of proportions were made using the Pearson's chi-square test at 5% level of significance and at different groupings. In addition, to compare median time/duration across different demographic and clinical characteristics, the Wilcoxon Rank-sum test was used at 5% level of significance for the unmatched data.

OBJECTIVE 3: TO IDENTIFY FACILITATORS AND BARRIERS TO SEAC PACKAGE

Based on the interview guides, an initial codebook with codes and definitions organized around key themes was developed and shared among the researchers. The codebook was revised after reviewing and coding the first several transcripts. Following coding by two evaluation team members, reports were generated for each code and then analyzed using matrices and narrative summaries by participant group: adolescent pre/post, caregiver pre/post and HCW. A raw summary report was developed and further refined to describe patterns in the data by participant group and intervention period and addressed study objectives. The main codes derived and used to code the data were accessing the facility and services, disclosure, retention experiences, adherence experiences, enhanced adherence counseling, adolescent focused service delivery and transition to adult care. Interviews were transcribed and translated and coded using MAXQDA 2020 software.

EVALUATION LIMITATIONS

Our evaluation had several limitations. The evaluation of pre-SEAC period utilized retrospective data that is routinely collected at health facilities supported by EGPAF; we, therefore, had limited control over the data quality and completeness. Poor filing systems in most of the facilities resulting in missing or lost files, contributed to missing data. To account for missing data, we adjusted the sample size by +20%.

Documentation of EAC processes was poor due to inadequate tools for documenting qualitative findings during EAC. As a pre-/post-intervention observational design, improvements observed in patient outcomes, although assumed to be attributed to SEAC, may have been, in part, due to other changes within the health facilities or in the health system that could not be accounted for.

For the re-suppression analysis, 37% of pre-intervention and 16% of post-intervention patients did not get a repeat viral load during the study period; it is possible that these patients are more likely to remain unsuppressed compared to the 63% and 84% who successfully underwent retesting, pre and post-intervention

respectively. Our study sample was only 741 HIV positive children and adolescents against 7,917 children and adolescents on ART by September 2018 (EGPAF Knowledge Management System (EKMS)). Our findings may not be fully representative of the entire children and adolescent population on ART in Kenya but are representative of the children and adolescents in Homa Bay County. The sample in Turkana was relatively smaller than in Homa Bay and may not be representative of the children and adolescents in Turkana. Additionally, viral suppression greatly improved just before we implemented the SEAC, the sample for post-intervention was therefore too small to analyze and compare all the possible factors associated with viral suppression, given the small number of those not suppressed.

STAKEHOLDER ENGAGEMENT

EGPAF worked closely with various stakeholders throughout the course of the evaluation. These include, County Directors Health (CDH), Sub County, and County Health Management Teams (S/CHMT), health care workers (HCW) in all participating health facilities. The CDH and S/CHMT were involved at the formation of the intervention. S/CHMTs supported implementation within the County and Sub- County whereas facility HCW were engaged in the implementation of the intervention, follow-up of the children and adolescents and routine data capture and reporting at site level. Other implementing partners will also be engaged during dissemination meetings for purposes of utilization of results. The findings will be disseminated in the County and Sub- County forums and an intervention plan co-developed to guide the implementation of the best lessons learned.

ETHICAL CONSIDERATIONS

This protocol was approved by Kenyatta National Hospital-University of Nairobi Ethics Research Committee (KNH-UON ERC) (P301/05/2018) and the US EGPAF designated Institutional Review Board (IRB), Advarra (PRO 00029114). The study 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. A permit to implement the evaluation was received from NACOSTI (P/19/97481/27737). We received a waiver of informed consent for use of retrospective data.

Prospective interviews, FGDs and IDIs were conducted after obtaining informed consent from those 18-19 years, mature minors, and consent from parents and assent from children and adolescents for those aged below <18 years. To ensure protection of human subjects, all enrolled participants were assigned a unique study identification number (study ID), and data collection forms and data were linked to the patient using this study ID and CCC number. All data collected were kept confidential and only the study team had access to the individual patient level data. Further to this, staff working on this evaluation in addition to the protocol training received research ethics training to ensure compliance with human subjects' research requirements and signed a confidentiality agreement.

KEY EVALUATION FINDINGS

QUANTITATIVE FINDINGS

A total of 741 records of children and adolescents with high viral load (VL \geq 1,000 copies/ml) were included in the analysis. Table 1 presents the demographic and clinical characteristics of the study population. There were 595 pre-standardized EAC records, of which 50.4% (300/595) were female, and 146 post-standardization records of which 47.9% (70/146) were female. Majority of study participants were aged 10-14 years; that is, 38.5% in the pre- and 45.9% in the post-standardization period. The mean age was 10.9 years (standard deviation (SD)=4.5 years) and 11.3 years (SD=4.1 years) among the pre- and post-standardization group

respectively. Median VL at EAC enrolment was significantly higher pre-SEAC; 9,560 copies/ml (IQR, 2,580-42,410) as compared with 3,481 copies/ml (IQR:1,660-20,162) post-SEAC.

Patients who received EAC had been on ART for a median duration 6.3 (IQR: 3.2-8.9) and 7.4 (IQR: 4.3-9.4) years in the pre-standardization and post-standardization groups, respectively. Majority of the patients during both pre- standardization and post-standardization were from Homa Bay County. Similar proportions of records were obtained from facilities representing various levels of the health system; about 60% were from the county referral hospitals in both Homa Bay and Turkana counties. Over 91% in both groups (pre-standardization and post-standardization) were active in care at the time of the evaluation while 10 (1.3%) had died, 2.3% (2/89) from Turkana and 1.3% (8/652) from Homa Bay county. All who died were in the pre-standardization group.

TABLE 1: DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE PRE- AND POST-SEAC STUDY POPULATIONS

Characteristics	Pre-standardization (N=595) n (%)	Post-standardization (N=146) n (%)	Total
Gender			
Female	300 (50.4%)	70 (48.0%)	370(49.9%)
Male	295 (49.6%)	76 (52.0%)	371(50.1%)
Age (years)			
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 enrolment n, Median (IQR) copies/ml	593, 9,560 (2,580-42,410)	146, 3,481 (1,666-20,162)	739, 7970 (2,150-37,700)
ART regimen before EAC			
NNRTI-based	420 (70.6%)	65 (44.8%)	485(65.4%)
PI-based	175(29.4%)	77 (53.1%)	252(34.1%)
Other	0 (0%)	3 (2.1%)	3(0.4%)
ART duration prior to EAC n, Median (IQR), years	562, 6.3 (3.2-8.9)	146, 7.4 (4.3-9.4)	708, 6.6 (3.4-9.1)
County	n=595	n=146	N=741
Homa Bay	523(88%)	129(88%)	652(87.9%)
Turkana	72(12%)	17(12%)	89(12.0%)
Facility			
County referral hospital (Level 5)	377 (63.4%)	87 (60.0%)	464(62.6%)

Sub-county hospitals (level 4)	19 (3.2%)	4 (2.8%)	23(3.1%)
Health centers (Level 3)	199 (33.4%)	54 (37.2%)	253(34%)

NNRTI-based: AZT/3TC/NVP, AZT/3TC/EFV, ABC/3TC/NVP, ABC/3TC/EFV, TDF/3TC/EFV, TDF/3TC/NVP

PI-based: AZT/3TC/LPV/r, ABC/3TC/LPV/r.

Table 2 shows key process indicators of EAC implementation in the pre- and post-standardization periods, namely uptake, time to first EAC visit, completion of a minimum of 3 EAC sessions, repeat VL results and treatment switch to an optimal regimen. All EAC process indicators improved after EAC was standardized. Whereas all patients in the SEAC period attended, at a minimum, the first EAC visit, 16.5% (n=98) of clients in the pre-standardized EAC period patients had no record of attending any EAC visit.

The time period between high VL test result and first EAC visit was reduced by 8 days; from a median of 49 (IQR: 23.0-102.5) pre-SEAC, to 41 (IQR: 20.0-67.0) post SEAC, (p=0.006). Furthermore, time to completion of at least 3 EAC sessions reduced by 12 days; from a median of 59.0 (IQR: 36.0-91.0) pre- SEAC, to 47.0(IQR: 33.0-63.0) with SEAC, (p=0.002). Similarly, a significantly greater percentage of patients completed the required minimum 3 EAC sessions, in the post, (91.1%), as compared to pre-SEAC (81.1%), p=0.004. There was no significance difference in proportions who subsequently had repeat VL results available, 92.6% (n=373) and 91.7% (n=122) in the pre-SEAC and SEAC groups respectively after receiving a minimum of three EAC sessions, p-value=0.756. Finally, a greater proportion of clients who received SEAC post-standardization had viral suppression after 3 sessions (55% [67/122] vs. 39.6% [(145/373], p=0.023). Of those not suppressed following 3 EAC sessions, 43.9% (97/221) in the pre-SEAC period, and 11% (6/55) in the post-SEAC period (p-value<0.001) were switched to 2nd and 3rd line ART regimen. Forty-nine participants from the SEAC group had not been switched by the time data collection ended. The switch occurred in a median period of 118 (IQR 47-254) versus 299 (IQR 225-411) days (p-value=0.013) in the pre- and post-SEAC periods, respectively.

TABLE 2: EAC UPTAKE, TIMELINESS, COMPLETION AND VIRAL LOAD OUTCOME IN THE PRE- AND POST-SEAC PERIODS

Characteristics	Pre-SEAC period (N=595) n (%)	Post-SEAC period (N=146) n (%)	p-value
EAC uptake			
Attended 1 st EAC	497 (83%)	146 (100%)	<0.001 ^a
EAC uptake by sex:			
Male	254/295 (86%)	76/76 (100%)	0.001 ^a
Female	243/300 (81%)	70/70 (100%)	<0.001 ^a
EAC uptake by age (years):			
0-9	193/227 (85%)	44/44 (100%)	0.006 ^a
10-14	184/229 (80%)	67/67 (100%)	<0.001 ^a
15-19	120/139 (86%)	35/35 (100%)	0.020 ^a
Time to 1st EAC (weeks)			
< 2	66 (14.1%)	28 (19.2%)	0.137 ^a
2 to < 4	81 (17.3%)	25 (17.1%)	0.959 ^a

4 to < 8	108 (23.1%)	45 (30.8%)	0.059 ^a
≥ 8	213 (45.5%)	48 (32.9%)	0.007 ^a
Time to EAC uptake (days) N, median (IQR)	595, 49.0 (23.0-102.5)	146, 41.0 (20.0-67.0)	0.006 ^b
Number of EAC sessions completed			
3	403(81.1%)	133 (91.1%)	0.004a
<3	94(18.9%)	13 (8.9%)	<0.001a
Time between First and Third EAC (days)			
< 90			
≥ 90	330 (74.4%) 103 (25.6%)	119 (88.8%) 15 (11.2%)	0.002a 0.002a
Time to complete minimum three EAC sessions N, median days (IQR)	403, 59.0 (3.06-91.0)	133, 47.0 (33.0-63.0)	0.002 ^b
VL test done after three EAC sessions	92.6% (373/403)	91.7% (122/133)	0.756 ^a
VL test result after EAC N, median copies/ml (IQR)	373, 2,637 (363-21,996)	122, 1,250 (245-6,000)	0.010 ^b
VL test result after EAC			
Suppressed (<1,000 c/mL)	145(39.6%)	67 (54.9%)	0.002 ^a
Unsuppressed (≥1,000 c/mL)	221 (60.4%)	55 (45.1%)	0.006 ^a
Results not available	7 (1.9%)	0(0%)	na
Switched ART regimen after high repeat VL result	43.9%* (97/221)	11%** (6/55)	<0.001 ^a
Time to ART regimen switch N, median days (IQR)	595, 118 (47-254)	146, 299 (225-411)	0.013 ^b

^a Chi-square test. ^b Wilcoxon Ranksum test (difference in medians).

c/mL: copies/milliliter; EAC: enhanced adherence counseling; IQR: interquartile range; SEAC: standardized enhanced adherence counseling

*All switched to PI-based regimens.

**1 switched to ABC+3TC+ATVr, 1 switched to ABC+3TC+DTG, 1 switched to

ABC+3TC+DTG+LPVr, 1 switched to ABC+3TC+RPV+DTG, 2 switched to TDF+3TC+DTG

Results of the univariate and multivariable logistic regression analyses are presented in Table 3. In the univariate analysis, SEAC was significantly associated with viral suppression, (odds ratio [OR]1.6; 95% Confidence Interval [CI], 1.1-2.3). Furthermore, receiving services in facilities in Homa Bay County was significantly associated with viral suppression OR, 2.3 (95% CI, 1.3-4.1). There was however no difference in viral suppression between facilities of different levels.

In the multivariable analysis, patients who received the SEAC had 1.6-fold (95% CI, 1.1-2.3) higher odds of being virally suppressed compared to those who had not received SEAC. Receiving services in Homa Bay

County facilities was also significantly associated with viral suppression, AOR 2.3; 95% CI, 1.3-4.1). compared to Turkana County facilities.

TABLE 3: FACTORS ASSOCIATED WITH VIRAL SUPPRESSION (VL<1000 COPIES/ML) AMONG CHILDREN AND ADOLESCENTS ELIGIBLE FOR EAC IN HOMA BAY AND TURKANA COUNTIES

Variable	Unadjusted/Crude OR (95% CIs)	Adjusted/AOR* (95% CIs)
Pre-SEAC(Ref)	-	-
Post-SEAC	1.6 (1.0-2.3)†	1.7 (1.2-2.7)
Facility Type:		
Hospital (Ref)	-	-
Health Center	1.3 (0.97-1.9)	
Facility County:		
Turkana (Ref)	-	-
Homa Bay	2.3 (1.3-4.1)†	2.2 (1.2-4.1)
ART Regimen		
PI-based	1.0 (0.7-1.3)	
Non-based (Ref)	-	
Age (years)		
0-9 (ref)	-	
10-14	1.0 (0.7-1.5)	
15-19	0.9 (0.6-1.4)	
Gender		
Male (Ref)	-	
Female	1.2 (0.9-1.6)	
Time (days) to first EAC	0.99 (0.99-1.00)	
Days between 1 st and 3 rd EAC	0.99 (0.99-1.00)	
Time on ART Prior to EAC (years)	1.1 (1.0-1.1)‡	

Reference (ref). *adjusted for time to EAC/SEAC sessions, number of sessions completed, duration between sessions and repeat viral load results, age, viral load at enrolment, 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 data in at least one bivariate association.

Factors associated with VL suppression in the pre- and post-SEAC periods are shown in Table 4. The only factor associated with viral suppression in the multivariable analysis in either period was county with clients receiving care in Homa Bay having 2.0-fold (95% CI; 1.1-3.8) and 4.1-fold ((95% CI; 1.1-16.1) higher odds of VLS as compared to those in care in Turkana during the pre- and post-SEAC periods, respectively.

TABLE 4: FACTORS ASSOCIATED WITH VIRAL SUPPRESSION (<1,000 COPIES) IN THE PRE- AND POST-SEAC PERIODS.

Variable	Pre-standardization			Post-standardization		
	Unadjusted/Crude OR (95% CIs)	Adjusted/AOR (95% CIs)	p-value	Unadjusted/Crude OR (95% CIs)	Adjusted/AOR (95% CIs)	p-value
Facility						
County, sub-county Hospital (Ref)	-			-		
Health Center, dispensary	1.3 (0.97-1.9)			1.6 (0.8-3.4)		
Facility County						
Turkana (Ref)	-	-		-	-	
Homa Bay	2.3 (1.3-4.1) *	2.6 (1.4-4.7)	0.002	4.1 (1.1-16.1)*	4.1 (1.1-16.1)*	0.040
ART Regimen						
Non-PI Based (Ref)	-			-		
PI Based	0.9 (0.7-1.3)			0.98 (0.5-2.0)		
Age (years)						
0-9 (ref)	-			-		
10-14	1.0 (0.7-1.5)			1.6 (0.7-3.5)		
15-19	1.0 (0.6-1.5)			0.7 (0.3-1.9)		
Gender						
Male (Ref)	-			-		
Female	1.2 (0.9-1.6)			1.1 (0.5-2.2)		
Time (days) to first EAC	0.99 (0.99-1.0)			0.99 (0.99-1.0)		
Time to complete 3 EAC sessions	0.99 (0.99-1.0)			0.99 (0.99-1.0)		
Time on ART Prior to EAC (years)	1.1 (1.0-1.1) *	1.0 (0.9-1.1)	0.348	1.0 (0.9-1.1)		

This analysis included all participants who had data in at least one bivariate association.

* Significant bivariate, so included in multivariate analysis.

Results of the closed-ended questionnaires administered to clients and caregivers in the post-SEAC group are shown in table 5. Their characteristics are presented in Table 5. There were 81 adolescent and 65 parent/caregiver interviews conducted. A total of 58 (89.2%) and 78 (96.3%) children and adolescents were

attending school at the time of the interview. Majority, 69.2% (45/65), of the caregivers were the biological mothers of the children, while only 9.2% (6/65) of the caregivers were the biological fathers of the children. In regard to orphan hood status, 40.7% (33/81) and 23.1% (15/65) of adolescents and children had lost their father respectively, while 16.0% (13/81) and 16.9% (11/65) of adolescents and children had lost their mothers respectively; 7.4% (6/81) and 3.1% (2/65) adolescents and children had lost both parents respectively.

Majority, 84.6% (55/65) children and 93.8% (76/81) adolescents had their HIV status disclosed to them. In addition, 61.7% (50/81) and 69.2% (45/65) of adolescents and caregivers could not recall the ART regimen they were taking, or the child was taking respectively.

Among the 65 caregivers interviewed, majority 84.6% (55/65) were HIV positive with 98.2% (54/55) of them on ART but only 9.1% (11/54) of them could recall the ART regimen they were taking.

A small proportion, 18.5% (12/65), of caregivers belonged to a support group, and majority 83.3% (10/12) of them indicated that being a member of the support group had changed how they feel about the child or themselves. Overall, 91.3% (74/81), adolescents belonged to a support group, however 62.2% of those in support groups (46/74) indicated that being a member of a support group had changed the way they felt about themselves.

In assessment of the client adherence to clinic visits and pharmacy drug pick-ups, 83.9% (68/81) of adolescents indicated that they have ever missed school or work to pick up ARVs. Further, 59.3% (48/81) of adolescents and 33.8% (22/65) of caregivers indicated that they have ever forgotten to take their ARVs or give their child their ARVs while 12.3% (10/81) and 1.5% (1/65) of adolescents and caregivers respectively indicated that sometimes when they/the child feels worse when they take or give ARVs, they stop taking or giving the medicine.

In addition, 7.4% (6/81) of adolescents indicated that they sometimes stop taking ARVs when they feel well, while 16% (13/81) and 9.2% (6/65) of adolescents and caregivers had ever missed collecting their ARVs for themselves or for their child because they were unable to pick them up. Majority, 56.8% (46/81) and 66.2% (43/81), of adolescents and caregivers, respectively, pick their/child's ARVs themselves.

TABLE 5. CHILDREN/CAREGIVER AND ADOLESCENT CHARACTERISTICS (POST-SEAC GROUP)

		Adolescents (N=81), n(%)	Children(N=65), n(%)	Total (N=146), n(%)
Currently in school (Children/adolescents)	Yes	78(96.3%)	58(89.2%)	136(93.2%)
Relationship to child(caregiver)	Biological mother	Na	45(69.2%)	45(69.2%)
	Biological father	Na	6(9.2%)	6(9.2%)
	Other relative e.g., step parent, grandparent, etc.	Na	14(21.5%)	14(21.5%)
Father alive	Yes	48(59.3%)	49(75.4%)	97(66.4%)
Mother alive	Yes	68(84%)	54(83.1%)	122(83.6%)
Both parents deceased	Yes	6(7.4%)	2(3.1%)	8(5.5%)

Parents deceased, is the caregiver over 18 years	Yes	6(100%)	0(0%)	6(75%)
Caregiver HIV status	HIV positive	Na	55(84.6%)	55(84.6%)
	HIV negative, tested in the last 3 months	Na	6(9.2%)	6(9.2%)
	HIV negative, tested more than 3 months ago	Na	4(6.2%)	4(6.2%)
Caregiver on ART, if positive	Yes	Na	54(98.2%)	54(98.2%)
Caregiver knows ART regimen			42(77.8%)	42(77.8%)
Child/adolescent knows their HIV status	Yes	76/81(93.8%)	55/65(89.7%)	131(89.7%)
As the care giver to this child, do you belong to any support group?/do you belong to any support group	Yes	74(91.3%)	12(18.5%)	86(58.9%)
Has being a member of the support group changed how you feel about the child/yourself?	Yes	46(62.2%)	10(83.3%)	56(65.1%)
Knows regimen	Yes	31(38%)	20(30.7%)	51(34.9%)
Regimen, PI-based	Yes	47(61%)	29(45.3%)	76(53.9%)

In table 6, we looked at factors associated with viral suppression post-SEAC using additional variables as collected specifically for this group. There were no significant differences identified.

TABLE 6: VIRAL LOAD OUTCOMES POST-STANDARDIZATION AMONG CHILDREN AND ADOLESCENTS WHO COMPLETED 3 EAC SESSIONS WITH A DOCUMENTED VL RESULT, BY SELECTED CHARACTERISTICS.

Characteristic		Child/adolescent repeat viral outcome		Total N=122 N (%)	P-value
		Suppressed (<1000 copies), N=67, n (%)	Unsuppressed (>=1000 copies), N=55, n (%)		
Currently in school	Yes	64 (95.5)	51 (92.7)	115 (94.3)	0.509
	No	3 (4.5)	4 (7.3)	7 (5.7)	
Orphan	Yes	32 (47.8)	28 (50.9)	60 (49.2)	0.729
	No	35 (52.2)	27 (49.1)	62 (50.8)	
Parents deceased; caregiver over 18 years	Yes	3 (100)	2 (100.0)	5 (100.0)	na
Caregiver HIV status, (n=55)	HIV positive	26/29(89.6)	23/26(88.5)	49/55(89.1)	0.887
	HIV Negative	3/29(10.3)	3/26(11.5)	6/55(10.9)	
Caregiver on ART, if positive, (n=49)	Yes	26/26(100.0)	23/23(100.0)	49/49(100.0)	na
Caregiver knows own ART regimen, (n=49)	Yes	7/26(26.9)	3/23 (13.0)	10/49(20.4)	0.229

Knows regimen, caregivers/adolescents, (n=122)	Yes	24/67(35.8)	18/55(32.7)	42/122(34.4)	0.720
Child/adolescent knows their HIV status	Yes	63 (94.0)	55 (100.0)	118 (96.7)	0.065
	No	4 (6.0)	0 (0.0)	4 (3.3)	

QUALITATIVE FINDINGS

ACCESSING THE HEALTH FACILITY AND SERVICES

Participants generally expressed satisfaction with the quality of care received, and how they were supported to understand their condition and monitor progress. They noted helpfulness and dedication of service providers, with some of the service providers addressing issues beyond their disease management. Despite this, there were reports of compromises to service quality such as rude and inefficient service providers.

Clinic accessibility was a challenge across all participant groups, especially where the distance to the clinic was long or involved using fare to get to the clinic, and resulting in clinic attendance when transport funds is available. Regarding the organization of clinic services, adolescents and caregivers outlined that they would sometimes dedicate whole days to attending the clinic and attributed this to disorganization of files. Sometimes, the patient files could not be found at all and a separate sheet of paper was used. Since the files are meant to reflect the order of patients waiting in the queue, a lost file often resulted in other clients being seen first, even if the client with the lost file arrived first, prompting annoyance and resentment, resulting in patients not being seen on a "first-come, first-serve basis, number of providers available and patient volume.

On the day you have clinic, you cannot make other personal plans. So, this discourages you and at times you decide to come late, because you will leave late. (Caregiver, Post)

Mixed responses were given regarding clinic safety and privacy. However, many adolescents described stigma as a barrier to clinic attendance and were concerned with being seen in clinic waiting areas or even on their way into the HIV clinic.

DISCLOSURE

Adolescents provided general responses on disclosure, with few who described disclosing to family members or friends, but little emerged on disclosure to sexual partners or boy/girlfriends. Providers encouraged disclosure to friends, and a few adolescents outlined that it was easier to do so when one was healthy. Information and encouragement from facility staff was considered as supportive to disclosure.

When we come to hospital, we can find one doctor who sits us down and teaches us how you can disclose and a way to disclose. For example, if a doctor tells you even if you have this disease you are just the same as others and you can do what they do better, like going to school and farming. (Adolescent 12-14Y, Pre)

Providers linked late or non-disclosure with poor adherence among adolescents. There were requests from caregivers to receive facility support for disclosure either through individual and group counseling. Adolescents requested for support in disclosure at school, which was considered to help with adherence.

ADHERENCE AND RETENTION

Regarding retention, a challenge to appointment keeping was school-related conflicts. Some students did not want to explain their absence or appointments conflicted with classes or exams.

Sometimes it's during exams and you're not in good books with the teacher. Then the teacher says there will be no exams to those who are absent. (Adolescent 12-14Y, Pre)

Forgetfulness, travelling, lack of transport and being assigned duties by caregivers, such as looking after siblings during their clinic appointment time and helping out on the farm were also presented as challenges to appointment keeping. Among caregivers, they acknowledged the failure to master the date issued for returning to clinic as a barrier.

Helpful to appointment keeping was patient held appointment card, phone calls or text messages from the facility as pre-appointment reminders. Additionally, calls and/or home visits after missed appointments, strong adolescent-caregiver relationship and client-provider engagement in appointment scheduling were also mentioned.

CHALLENGES TO ADHERENCE AND RETENTION

Participants also described challenges to adherence which included getting home late (often due to chores or errands) and missing their scheduled drug taking time, side effects, forgetfulness, being in boarding school, lack of food, visitors at home and conflicts with caregivers. There seemed to be some confusion both from adolescents and their caregivers about whether or not they should take their drugs if they are late or skip altogether. Among children, challenges were attributed to caregivers who were disinterested in their children's care and those who had multiple caregivers.

ADHERENCE FACILITATORS

Facilitators to adherence were described as use of a device e.g., phone or alarm watches to remind drug taking time and others. Less frequently used methods included caregivers using negative consequences of adherence (e.g., reminding adolescents of those who became sick and died), communicating with a point person at school or church to remind an adolescent of their drug taking time. Adolescents made requests to be provided with devices for reminders such as watches as well as recommended continuous counseling and support and incentives for achieving viral suppression.

ACCEPTABILITY OF ENHANCED ADHERENCE COUNSELING

Specific to enhanced adherence counseling, both adolescents and caregivers were familiar with EAC, considered it to improve adherence, reduce viral load, and provide information and knowledge on adherence and suppression. It was considered useful for client- provider interaction, helping to fight stigma and engage family and caregivers in adherence.

Adolescents mentioned challenges with the way providers communicated with them, with some providers perceived as rude. There were also a couple of misconceptions regarding EAC that were raised, including understanding that once viral suppression was achieved one could stop medication and that one could have their regimen changed if they did not want to go for EAC. Refusal of EAC was mainly attributed to issues with the counselor, especially those who came across as harsh and quarrelsome.

Someone may refuse because of the poor attitude of the adherence counselor. The counselor can quarrel with you, 'you're digging your own grave,' instead of giving you options. (Caregiver, Post)

To facilitate uptake to EAC, adolescents cited getting encouragement from friends, caregivers, and providers. Other facilitators were reminders and home visits.

The most common suggestions to improve EAC uptake and address barriers could be grouped primarily into two categories, suggestions around improving interactions with providers and EAC delivery, like changing the frequency, location, or structure of sessions. Looking specifically at the suggestions related to providers, the most cited one was for providers to be friendlier. This was said frequently by adolescents in both pre- and post- intervention groups but mentioned only once by caregivers.

*Sometimes, you can come for the first time and the one who is in there, talks to you nicely and treats you nicely.
The next time you will want to come back (Adolescent, Pre)*

Participants across the caregiver and adolescent focus group discussions and in HCW interviews confirmed need for pediatric and adolescent specific days while outlining interventions that had been established in support of adolescent clinics, such as Operation Triple Z (OTZ), which was meant to encourage adherence and promote treatment literacy, and Red Carpet, a program that promoted fast tracking of services for adolescents during school days. There was appreciation for these clinics since they were free to express themselves and discuss matters that would otherwise not have been raised in mixed clinic set ups. Healthcare workers described in their interviews the need to understand adolescents well to be able to work with them.

TRANSITIONING TO ADULT CARE

In transitioning to adult care, adolescents outlined the need to adhere to their medication. One way which they considered themselves to prepare for adult care was being able to come to the facility on their own. A caregiver noted that it was the responsibility of parents to prepare adolescents for transition so they would continue accessing facility services. Another caregiver pointed out that transition and adherence could be compromised as adolescents enter into romantic/sexual relationships. Adolescents were concerned about future aspirations and how they would relate to their medication, such as being able to disclose their status to their intimate partners and childbearing. Treatment literacy was considered an important aspect of transitioning. Adolescents outlined topics covered during their literacy sessions on transition preparation as being responsible for their medication, living positively and making the right sexual choices.

Observations during data abstraction noted that health care workers did not appropriately capture qualitative components of EAC, such as their assessment of patients' barriers to adherence and adherence plans. HCW explained that this was due to lack of tools to capture this information and hence tended to mostly rely on recall.

KEY TAKEAWAYS

	Key Findings	Way Forward	Who/When to Implement
1.	EAC uptake, timeliness, completion and outcome (VLS) suppression improved after SEAC	Scale up SEAC, while maintaining fidelity to the implementation.	IPs/County MOH and other stakeholders. Immediate
2.	Despite improvements observed after SEAC, VLS among CALHIV who received EAC remains suboptimal	Further assessment of the root causes and possible strategies for improvement could be explored	IPs/County MOH. Immediate
3.	Outcomes in Turkana were suboptimal	Explore further the reasons why and develop targeted strategies for Turkana County	IPs/County MOH
4	Inadequate tools, varied EAC implementation and documentation	<ul style="list-style-type: none"> Expand EAC parameters, review and standardize case summary tools to capture information including qualitative data. Skill building for EAC providers in comprehensive summarizing counseling notes 	National level (NAS COP)- Immediate
5	Trend towards protracted delays in switching regimen or unnecessary longer EAC sessions	<ul style="list-style-type: none"> Establish national standards at all review levels and keeping TAT and QA to acceptable ranges Capacity building on treatment optimization for HCW Capacity building on presentation of case summary notes Fast track approvals Timely availability of commodities 	Multisectoral; NAS COP/ IPs/County MOH and stakeholders

6	Sub optimal pediatric and adolescent early disclosure and engagement in treatment	<ul style="list-style-type: none"> • Set standards including age for full disclosure and transition plan/process into adult treatment. • HCW skill building to engage pediatric and adolescents in their clinical management 	NASCOP/IPs/County MOH and stake holders
7	Unclear roles and expectations of caregivers including care of care giver programs to optimize adherence to treatment and clinic appointments	<ul style="list-style-type: none"> • Review and communicate caregiver roles and expectations including caregiver PSSG. 	NASCOP/IPs/County MOH and stakeholders
8.	Unfriendly health care worker attitude	<ul style="list-style-type: none"> • Annual one day HCW refresher sensitizations on client centered care including child and adolescent friendly services. • Continuous client exit feedback questionnaires for ongoing program improvements. • Regular communication skills building sessions for all HCW 	IPs/County MOH and stakeholders, Facility - immediate
9.	Multiple or conflicting bookings for EAC sessions and drug pick ups	<ul style="list-style-type: none"> • Harmonize EAC schedules with ART refill schedules. Adopt virtual counseling where applicable. 	IPs/County MOH and stake holders This has already been done in all EGPAF supported facilities in Homa Bay and could be sustained and rolled out to all facilities.
10	Perceived stigma and conflicts with school schedule and home duties	<ul style="list-style-type: none"> • Appointment management to match with school activities • Adopt school-based EAC sessions where feasible 	Facility/ individual level- immediate

		<ul style="list-style-type: none"> Enhanced treatment literacy among adolescents and caregivers for common treatment goals 	
11.	Forgetfulness regarding taking medication and keeping appointments by both adolescents and caregivers	<ul style="list-style-type: none"> Enhanced treatment literacy for adolescents to enhance treatment ownership and caregivers to support adolescents and children on treatment Encourage increased responsibility among transitioning adolescents to own their treatment Use of reminders, e.g., watches Treatment buddy, including for caregiver Aligning activities at home to time for taking medication Scale up case management 	Facility/individual level- Immediate
12.	Long waiting times at the facility during appointment days	<ul style="list-style-type: none"> Managing daily workload through appointment management by matching number of patients to available providers Explore queue management system Managing patient flow 	Facility level- ongoing

CONCLUSION

Implementation of standardized EAC improved uptake and time to interventions for children and adolescents with high VL. Despite improvement in viral suppression after standardization, overall suppression was still sub-optimal. Viral suppression after standardization was noted to have improved more in patients receiving services in facilities in Homa Bay as compared to those in Turkana. There was however no difference in viral suppression between patients receiving services in facilities of different levels.

The median delay between confirmation of failure and switch to a new regimen ranged from 4 to 10 months, an indication that there may be several factors impacting on compliance with the national switching guidelines. Some of the factors leading to this delay include, clinician skills gap, capacity of multi-disciplinary teams to make decisions on switching, decisions by the regional technical working groups to extend adherence sessions and the time it takes to get a DRT test result once a blood sample is submitted and eventually switch a regimen. This is of concern as it may contribute to increased morbidity, mortality, onward transmission, and resistance. Timing of interventions is especially crucial.

Other barriers to viral suppression in this group of patients could be reviewed. Children and adolescents may benefit from a comprehensive multidisciplinary and holistic approach including barrier identification, correct

dosage, and management of existing treatment failure towards VL suppression and optimal clinical outcomes. While participants perceived EAC as useful in addressing adherence, responsive strategies may include fewer clinic-based visits to address transport challenges and stigma, continual reassessment of treatment plans to ensure drug-taking times align with schedules, and additional adolescent-focused provider training and sensitization.

DISSEMINATION

A dissemination forum will be organized to present the results to the CHMT and discuss recommendations that can be adapted to improve EAC uptake and promote viral suppression among children and adolescents on HIV treatment. Results will also be shared through manuscripts and conference presentations where possible.

DISSEMINATION PLAN

	Target Audience	Action Point	Channel of Communication	Time and Place
1	CHMT, Facility In-charges, health care workers	Share evaluation findings and key recommendations to strengthen program implementation	Power point presentation	Homa Bay County, Virtual meeting on 1 st September 2021
2	NASCOP, County Director of health, CASCO	Submit signed copies of the report	Report	October 2021
3	Conference participants	Presentation in international conference	Abstracts	IAS 2021, ICASA
4	Peer reviewed Journal		Manuscript	

APPENDICES

Protocol, v6.1 dated 19 October 2019.

Appendix A-Communications skills training curriculum

Appendix B-EAC Tools

- Treatment Preparation Form
- Enhanced Adherence Counselling Package
- Pediatric Disclosure Checklist
- Check List for HIV Infected Adolescents
- Morisky Medication Adherence Scale (MMAS-4 & 8)
- Psychosocial assessment form
- MOH 2016 ART guidelines chapter on adherence counselling and Annex 9A
- Patient appointment diary
- NASCOP MOH case summary
- Home visiting forms
- CAGE-AID Screening for Alcohol and Drug Use Disorders for Adults
- ART Readiness Assessment
- PHQ-9 Depression Screening and Interpretation and Management

Appendix C-Job aids and SOPs

Appendix D Enhanced Adherence Counseling Follow up Form

Appendix E-Treatment literacy Register

Appendix F-Recruitment scripts
Appendix G-Informed consents/assent forms
Appendix H-Structured questionnaires
Appendix I- Data abstraction tool
Appendix J-FGD, IDI guides
Appendix K-Tracking log
Appendix L-Data quality control SOP
Appendix M-Master link log
Appendix N-Data confidentiality agreement
Appendix O-ODK Forms
Appendix P-AE Log
Appendix Q-Investigator CVs
Appendix R-Conflict of interest
Appendix S-Ethics training certificates
Appendix T-Budget outline

ATTRIBUTION OF SUPPORT

This project has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under the terms of insert grant number

DISCLAIMER

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention and other funding institutions. funding agencies.

ACKNOWLEDGEMENT

The authors appreciate the support provided by the study investigators, the EGPAF study team particularly the research assistants, EGPAF program staff, and the county governments of Homa Bay and Turkana whose work and dedication made this study possible. The authors would like to thank the study participants, without whom this evaluation would not have been possible.

REFERENCES

1. Kenya National Bureau of Statistics. [cited 21Jan2021] <https://www.knbs.or.ke/?wpdmpro=2019-kenya-population-and-housing-census-volume-i-population-by-county-and-sub-county>.
2. Kenya Country 2020 HIV estimates.
3. KENPHIA 2018. https://phia.icap.columbia.edu/wp-content/uploads/2020/04/KENPHIA-2018_Preliminary-Report_final-web.pdf

4. Shubber Z, Mills EJ, Nachega JB, et al. Patient-reported barriers to adherence to antiretroviral therapy: a systematic review and meta-analysis. *PLoS Med.* 2016;13(11):e1002183. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27898679>.
5. Marhefka SL, Koenig LJ, Allison S, et al. Family experiences with pediatric antiretroviral therapy: responsibilities, barriers, and strategies for remembering medications. *AIDS Patient Care STDS.* 2008;22(8):637-647. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/18627275>.
6. Talam NC, Gatongi P, Rotich J, Kimaiyo S. Factors affecting antiretroviral drug adherence among HIV/AIDS adult patients attending HIV/AIDS clinic at Moi Teaching and Referral Hospital, Eldoret, Kenya. *East Afr J Public Health.* 2008 Aug;5(2):74-8. PMID: 19024414.
7. UNAIDS, 90,90,90} https://www.unaids.org/sites/default/files/media_asset/90-90-90_en.pdf -19th Jan 2021.
8. Mwangi AN, Ng'ang'a Z, Wanzala P, Karanja SM. Factors Influencing Adherence To ARVs Among Patients Attending Comprehensive Care Clinic Within Jomo Kenyatta University Of Agriculture And Technology, Kiambu County, Kenya. *East Afr Med J.* 2014 Apr;91(4):109-14. PMID: 26859028
9. Barclay TR, Hinkin CH, Castellon SA, et al. Age-associated predictors of medication adherence in HIV-positive adults: health beliefs, self-efficacy, and neurocognitive status. *Health Psychol.* Jan; 2007 26(1):40-49. [PubMed: 17209696]
10. Hinkin CH, Hardy DJ, Mason KI, et al. Medication adherence in HIV-infected adults: effect of patient age, cognitive status, and substance abuse. *AIDS.* Jan 1; 2004 18(Suppl 1):S19-25. [PubMed: 15075494]
11. Silverberg MJ, Leyden W, Horberg MA, DeLorenze GN, Klein D, Quesenberry CP Jr. Older age and the response to and tolerability of antiretroviral therapy. *Arch Intern Med.* Apr 9; 2007 167(7):684-691. [PubMed: 17420427]
12. WHO consolidated ARV guidelines, second edition, June 2016 [cited 2021 Jan 20];1-259. Available from: <https://www.who.int/hiv/pub/arv/arv-2016/en/>
13. WHO. Technical Brief on HIV Viral Load Technologies 2010 [cited, 20/10/2021]. Available from: http://www.who.int/hiv/topics/treatment/tech_brief_20100601_en.pdf.
14. Martelli G, Antonucci R, Mukurasi A, Zepherine H, No"stlinger C (2019) Adherence to antiretroviral treatment among children and adolescents in Tanzania: Comparison between pill count and viral load outcomes in a rural context of Mwanza region. *PLoS ONE* 14(3): e0214014. <https://doi.org/10.1371/journal.pone.0214014>
15. MOH, Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya, 2016
16. MOH, Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya, revised,2018
17. MOH: Kenya's fast-Track Plan to End HIV and AIDS Amongst Adolescents and Young People AIDS, September 2015).
18. Kenya National AIDS and STI Control Program. Adolescent Package of Care in Kenya: A Healthcare Provider Guide to Adolescent Care. 2014.
19. Kenya HIV Country Profiles. MOH, NACC/NASCOP/UNAIDS.
20. UNAIDS Report 2020. <https://www.unaids.org/en/resources/documents/2020/unaid-data>. Accessed on 21Jan2021.