

# Compliance With Quality Guidelines in HIV Anti-Retroviral Treatment Interventions at Kisii Teaching and Referral Hospital

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## Abstract:-

### ➤ Background:

HIV-AIDS remains a critical determinant of human morbidity and mortality with profound impact on the lives of those infected and affected. Antiretroviral Treatment (ART) aims to reduce morbidity and mortality among people living with HIV (PLHIV) and improve their health. The use of ART also contributes to preventing new HIV infections. To achieve ART goals, implementing programs must comply with the relevant local Ministry of Health guidelines by ensuring ART services adhere to set standards. There have been concerns regarding adherence to the Ministry of Health guidelines regulating the implementation of ART interventions and the effect of compliance or lack of it on HIV treatment outcomes.

### ➤ Methods:

This descriptive retrospective and prospective study sought to assess compliance with Ministry of Health guidelines in the delivery of ART services to PLHIV. Key informant interviews were conducted with health care providers to identify structural factors influencing compliance with guidelines on ART service quality. Three hundred and sixty-seven records of PLHIV who received ART services at KTRH in 2019 were selected through systematic sampling and compliance performance of select quality of care indicators assessed against recommendations of ARV guidelines. Viral suppression levels of PLHIV were also assessed as a proxy measure of the quality of ART treatment outcomes.

### ➤ Results:

Out of the 367 files reviewed, female and male PLHIV comprised (67.3%) and (32.7%) respectively. The mean and median ages of the PLHIV were 42 years. The majority of the PLHIV (62.9%) were married. The mean compliance level of the quality indicators assessed against the guidelines was (73.9%), significantly below the expected (100%) ( $t=3.038$ ,  $p=0.014$ ). WHO staging was done for (99.7%) PLHIV, (99%) were assessed for treatment adherence, (98.9%) were screened for TB, and (55%) were provided with TB IPT. PLHIV with 4 clinical visits 3 months apart in the 12 months were (95.4%); (71.7%) received baseline CD4 test; while (71%) received their most recent VL test in 2019. The PLHIV initiated on

ART within 2 weeks of HIV diagnosis were (69%); (67%) received sCrAg test, while (12%) got their initial VL test at least 6 months after ART initiation. The mean compliance level of Health Care Providers (HCP) perceptions regarding ART services compliance with quality guidelines was (68%) against the expected 100% ( $t=6.971$ ,  $p<0.001$ ). Perception scores on specific services were - ART initiation (75%), adherence counselling (50%), viral load testing (75%), CD4 testing (50%), sCrAg testing (75%), GeneXpert testing (75%), and pharmacy services (75%).

### ➤ Conclusion:

There was weak compliance with the guidelines on use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya (2018) in the delivery of critical clinical ART services, which could negatively affect health outcomes for PLHIV. The study has recommended measures to address the compliance gaps.

**Keywords:-** Quality, ART, Compliance, Guidelines, Standards, Viral Load Suppression.

## I. INTRODUCTION

The concept of quality is a fundamental underpinning in health care service delivery across many health programs, including HIV Antiretroviral Treatment interventions. Using ART reduces morbidity and mortality among PLHIV and curtails new HIV infections. To achieve these ART goals, implementing programs must comply with the relevant local Ministry of Health (MoH) guidelines by ensuring ART services adhere to set standards. Quality is often understood, perceived, and defined differently by different people. Indeed, in the context of healthcare, defining quality remains a significant challenge, occasionally leading to confusion and misunderstanding in health care service delivery. However, what is constant in most definitions of quality appears to be the need to measure and improve quality (Deming, 1986; Donabedian, 1966). Moreover, the inherent commonality across various definitions of quality is reference to guidelines and standards of service delivery and expected satisfaction or outcomes. This study applied the definition of quality by the MoH's Kenya HIV Quality Improvement Framework (KHQIF), which describes quality in the HIV program implementation context to imply the degree to which a health

service meets or exceeds established professional standards and client expectations (MOH, 2014a).

Globally, HIV-AIDS remains a critical determinant of human morbidity and mortality with profound impact on the lives of those infected and affected. The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated the global HIV burden at 37.9 million people living with HIV in 2019. Sub-Saharan Africa, where Kenya lies, accounted for 30% of the global HIV pandemic (UNAIDS, 2019). In Kenya, 1.3 million people (4.9%) were living with HIV in 2019. Kisii County, where Kisii Teaching and Referral Hospital (KTRH) is located, was among 7 high HIV burden counties in Kenya, with 6.1% HIV prevalence (NASCO, 2020). Kisii County borders high HIV burden counties of Kisumu (17.5%), Homa Bay (19.6%), and Migori (13%). The County's HIV prevalence lately assumed an upward trajectory, hence this study's geographical focus. The County's ART coverage was 79% (adults) and 80% (children), respectively. Similarly, the County had viral load suppression rate of 60% for adults (NASCO, 2020) and children 48% (NASCO, 2018). There is need to optimize ART coverage, ART retention, and viral suppression respectively to 90% for PLHIV to realize better health outcomes for PLHIV (NACC, 2014). Compliance with MoH guidelines recommendations for ART interventions is thus vitally important to achieving these outcomes. In the case of Kisii, ART coverage, retention, and viral suppression outcomes glaringly appear sub-optimal hence the necessity to interrogate compliance with guidelines in the delivery of ART interventions that contribute to these outcomes.

Antiretroviral treatment, also known as highly active antiretroviral therapy (HAART), is critical in managing HIV disease. It refers to using three or more ARV drugs to treat HIV infection. ART involves lifelong treatment for fighting HIV, lowering the amount of virus in the body to protect itself against opportunistic infections (WHO, 2015). ART has transformed HIV-AIDS into a manageable chronic disease, and high-quality service delivery is a factor for the intervention to be accessible and effective. Quality ART interventions improve health by reducing morbidity and mortality for PLHIV by restoring and preserving immunity through viral suppression. Quality ART interventions also contribute to preventing new HIV infections, including mother-to-child transmission of HIV, PMTCT (WHO, 2019b).

In the case of Kisii County, HIV prevalence, ART coverage, and viral suppression outcomes statistics seemed to suggest gaps in the quality of ART interventions. Compromised quality of ART services can affect access to and utilization of ART services with domino effect on expected ART outcomes. All ART interventions are required to adhere to set quality benchmarks in terms of SOCs and standard operating procedures (SOP) guiding service delivery and utilization. The Kenya Ministry of Health published and is currently implementing guidelines on use of Antiretroviral Drugs for Treating and Preventing HIV Infection (2018). The guidelines provide a national policy framework for standards of care (SOC) and service delivery in HIV prevention, care,

and treatment. This study focused on the extent of compliance by KTRH with the "Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya (NASCO, 2018)" (hereinafter the guidelines) in the delivery of high-quality ART interventions in its HIV clinical settings. The study considered compliance with the guidelines and prescribed standards in providing quality HIV treatment services as an essential tool for promoting health, preventing disease, and reducing mortality among PLHIV and the general population. The study also focused on viral load suppression among PLHIV as a measure of ARV treatment success.

Studies have shown compliance with guidelines and set standards of care to significantly contribute to the delivery of quality ART interventions for PLHIV, thereby improving ART outcomes for PLHIV by suppressing HIV replication to prevent disease and death (Kumarasamy *et al.*, 2011). Such studies have mainly focused on individual PLHIV-level treatment compliance factors as crucial determinants of ART outcomes for PLHIV. For instance, (Akileswaran *et al.*, 2005; Fairall *et al.*, 2008) have argued, that clinical immunologic and virologic outcomes of HAART are largely achievable through optimal adherence by PLHIV to ART treatment, which view, Silveira *et al.* (2002) have concurred with. They assert that PLHIV adherence to ART leads to rapid drop in viral loads to undetectable levels leading to expected ART outcomes. However, it is overly ambitious, unrealistic, and unreasonable to expect to achieve quality and optimal ART outcomes without appreciating the role of health-facility related factors in influencing compliance with quality standards in the provision of quality ART interventions. This study pivoted from the patient-centric approach to focus on health-facility-related compliance factors in the delivery of quality of ART services for better ART outcomes.

The study's main objective was to assess the level of compliance with quality guidelines in HIV ART interventions at Kisii Teaching and Referral Hospital (KTRH) in Kisii County. Specifically, the study sought to (i) identify structural factors influencing compliance with guidelines on quality of ART interventions, (ii) assess compliance with national MoH ART guidelines in the ART clinical service delivery processes, and (iii) assess viral load suppression levels of PLHIV on ART at KTRH as a measure of quality of ART intervention outcomes.

#### ➤ *Structural factors affecting compliance with quality guidelines in ART service delivery*

Regarding the structural factors influencing compliance with guidelines on quality of ART interventions, the study investigated the extent to which prevailing human resources, physical infrastructure, equipment/supplies, information system, and policies complied with ART intervention requirements.

In Kenya, according to the Kenya Health Policy 2014-2030, the number of health care providers is generally well below the WHO recommended average of (21.7) doctors and 228 nurses for 100,000, leading to inadequacy in the workforce, skills mix, and competence hence impacting

capacity for compliance with health service delivery quality requirements (MOH, 2014a, 2014b). In developing countries, where ART need is highest, one to two physicians and two to seven nurses are recommended for 1000 ART patients (Hirschhorn *et al.*, 2006). A study by Kinfu *et al.* (2009) pointed to critical health workforce shortage and training in Kenya, where the proportion of physicians per thousand population was 0.14.

Adequate physical space is an integral component of physical infrastructure in the ART service delivery continuum. Space availability or lack of it affects HTS, clinical consultation, laboratory, pharmacy, psychological counseling, and management information services in various forms. In settings where adequate space to serve clients is lacking, clinics may experience substantial strain in providing treatment to PLHIV due to confidentiality concerns. In such settings, high workload may cause clinical staff to compromise confidentiality of patients, as demonstrated by a study in Vietnam which showed lack of confidentiality affected timely initiation of ART and PLHIV healthcare-seeking behavior (Tran *et al.*, 2012). Efficient and reliable supply chain system that ensures adequate and timely availability of pharmaceutical, non-pharmaceutical, and laboratory commodities and supplies is imperative for an effective and high-quality ART program. According to the Ministry of Health, weak supply systems potentially result in commodity stock-outs leading to PLHIV going without drugs hence negatively affecting quality of treatment outcomes. Weak laboratory networks also compromise laboratory treatment monitoring services (NACC, 2014).

Health care settings also require a robust health information management system (HIS) to deliver quality ART services. Continuous processes of routine analysis, use of health and ART program data, and strengthening of systems to meet patient and program needs are critical (MOH, 2014b). A study in Kenya concluded that routine data quality assessments (RDQA) were useful in identifying EMR data quality problems and revealed strong association between RDQAs with meaningful improvements in data quality (Muthee *et al.*, 2018). The WHO has also prioritized the need for quality data collection, reporting, and use of indicators and enhancing interoperability of health information systems to guarantee quality of services (WHO, 2019b). Policies and guidelines are also a necessary institutional and structural requirement for delivery of quality health care services. The primary policy document underpinning this study was the Kenya ARV Guidelines (NASCOP, 2018). Other policy documents included the Kenya Quality Model for Health (MOH, 2014a) and the Kenya HIV Quality Improvement Framework (MOH, 2014b). These policies define quality of care indicators and set quality benchmarks that ART services need to comply with (NASCOP, 2018).

➤ *Compliance with ART guidelines in ART clinical service provision as provided in the standard package of care for PLHIV*

ART forms the foundation of HIV chronic care and management. Extensive use of ART has led to reduction of AIDS-defining morbidity and mortality the world over

(Kumarasamy *et al.*, 2005; Palella *et al.*, 1998). Therefore, health care providers have a significant clinical role in improving health for PLHIV by delivering quality ART interventions leading to optimal viral suppression, a critical measure of HIV treatment outcome. Since evidence of quality service delivery primarily lies in compliance with standards of care and relevant guidelines for service implementation, health care providers and health facilities providing ART services need to ensure the services satisfy the set quality recommendations. Key ART services include ART initiation, CD4 baseline testing, monitoring treatment adherence, viral load testing to monitor treatment outcomes, nutritional interventions, and other laboratory tests to detect and treat life-threatening opportunistic infections like TB and cryptococcal meningitis (WHO, 2017).

The guidelines recommend all PLHIV be initiated on ART in the shortest time possible upon diagnosis of HIV infection (NASCOP, 2018). A study in Ethiopia showed (67%) ART initiation as per guidelines recommendation (Bayisa *et al.*, 2020), while a South African study revealed (40.4%) ART initiation compliance of (Lilian *et al.*, 2020). Baseline CD4 cell count testing is significantly important in detecting severe immune suppression in PLHIV (WHO, 2017). All PLHIV (CD4% for children  $\leq 5$  years old) should receive baseline CD4 testing. Where  $CD4 \leq 200$  cells/mm<sup>3</sup> (for adults and adolescents) cryptococcal antigen (sCrAg) test is automatically recommended to screen for cryptococcal infection (NASCOP, 2018). Viral load is the preferred test for monitoring response to ART and establishing treatment failure. All PLHIV should receive initial viral load test at least (6) months after ART initiation, then at 12 months and subsequently annually (NASCOP, 2018). According to Mannheimer *et al.* (2005), PLHIV with optimal adherence are likely to achieve optimal viral load suppression (VLS) within twelve months of sustained HAART. However, new evidence has shown that achieving VLS within (6) months of sustained ART is realistic. (NASCOP, 2018). A study in South African revealed that key laboratory tests including HbA1c (29.2%), Scr, eGFR and potassium (38.2%) and lipids (40.4%) were performed but significantly below guideline recommendations (Rampersad *et al.*, 2019).

Implementation of TB infection control measures is highly recommended in all healthcare settings to reduce the risk of TB transmission among patients, HCWs, and people who frequent the health care settings. The guidelines recommend screening of all PLHIV at every clinic visit for TB. All PLHIV screened negative should be evaluated for initiation on isoniazid preventive therapy (IPT), while those screened positive must complete the prescribed diagnostic requirements. All PLHIV diagnosed with TB/HIV co-infection should start anti-TB treatment immediately and initiate ART as soon as anti-TB medications are tolerated, preferably within 2 weeks. Those with TB/HIV co-infection and already on ART should start anti-TB treatment immediately and continue ART (NASCOP, 2018). A study on HIV policy and implementation review in Malawi reported (100%) compliance with TB IPT treatment for PLHIV and adequate availability of IPT commodities. The

study showed (60%) compliance with TB screening requirements (Dasgupta *et al.*, 2016).

#### ➤ *Viral Load Suppression (VLS) Levels of PLHIV*

The term viral load (VL) describes the amount of HIV in the blood. The more HIV in the blood, the higher the VL and vice versa. Most HIV programs use VL tests to measure the amount of HIV's genetic material in a blood sample. Viral load suppression (VLS) is defined as having less than detectable level (LDL) or <400 viral copies per millilitre (mL) of plasma which is a vital indicator of treatment success in PLHIV. People living with HIV who achieve VLS suppression have a very low risk of transmitting the virus (NASCO, 2020). Suppressing HIV reproduction is, therefore, key to preventing HIV-related infections and deaths while improving the health of PLHIV. In current HIV management practice, ART is the major treatment option for suppressing HIV replication, hence reducing plasma viremia to undetectable level (Mezzaroma *et al.*, 1999; Sufka *et al.*, 2003). Significant decline in VL correlates with immunologic improvement through anticipated rise in CD4 count hence, reduced frequency of opportunistic infections, progression to AIDS, and death. Conversely, higher viral loads are associated with higher risk of HIV disease progression and death. To measure quality of ART outcomes for PLHIV, the study reviewed viral suppression levels of PLHIV to determine treatment success or failure.

## II. METHODOLOGY

The study was conducted at the HIV comprehensive care clinic of Kisii Teaching and Referral Hospital, a level 6 hospital in Kisii County. The hospital provides promotive, preventive, curative, and rehabilitative healthcare to a population of up to 3 million people. The facility also operates as medical teaching, training, and research school. The hospital's HIV program provides comprehensive prevention, care, and treatment services, including PLHIV identification, ART initiation, and ART treatment monitoring to approximately 4,500 PLHIV under a team of medical service providers from different specialties. This was a descriptive retrospective and prospective study that primarily relied on existing hospital records of PLHIV. The study reviewed 367 PLHIV files sampled from 4,452 PLHIV records to collect quantitative data through chart abstraction method. Qualitative data was collected through key informant interviews with purposively sampled health care providers (7). The study targeted PLHIV who had been on ART for at least six months and who must have attended at least two (2) clinic appointments in the year 2019. The key informants included an HTS provider, psychological counselor, health records and information officers, laboratory technologist, pharmacist, and clinician who had managed ART services in the various service delivery points for longer than 6 months and consented to participate in the study. Simple random

sampling was applied to select the 1<sup>st</sup> patient file; then systematic sampling was applied where every 4<sup>th</sup> file was selected until 367 files were obtained for chart abstraction.

Regarding structural factors affecting compliance with ART service delivery guidelines, the following were assessed: human resource, equipment/supplies, service delivery space, health information system and health policies. Regarding ART clinical service delivery processes affecting compliance with ART service delivery guidelines, the study reviewed: ART initiation, CD4 baseline testing, sCrAg Testing, nutritional assessment, adherence monitoring, viral load testing, TB screening/testing and IPT uptake. The study reviewed viral load suppression data of all PLHIV to determine viral suppression achievement against the recommendations in the guidelines. The results were documented either as service provided or not, and the frequency was captured where appropriate. The selected files were assessed against pre-determined ART service quality indicators provided in the Kenya AIDS Strategic Framework (2014/15-18/19) and the MoH guidelines.

The Quantitative data was collected on MS excel chart abstraction tool. Qualitative data was captured through face-to-face interviews with health care workers using a key informant interview guide to document health worker perspectives regarding structural factors in ART service delivery. The Quantitative data was analyzed using Statistical Package for Social Sciences (SPSS) Version 16.0, then descriptive statistics applied to summarize the data by calculating means, frequencies, and percentages. The qualitative data was analyzed by organizing the responses into themes and presented in descriptive format and direct quotations from the interviewees.

## III. RESULTS

#### ➤ *Socio-demographic Profile of PLHIV whose data were reviewed*

The PLHIV files reviewed were for 247 females (67.3%) and 120 males (32.7%). The mean and median ages was 42 years, (4.1%) were aged (8 – 14) years, (95.9%) aged (15 – 76) years, and (62.9%) were married. There were mixed findings from interviews in the HTS, ART clinic, nutrition, psychological counseling, laboratory, pharmacy, and HIS sections regarding structural factors affecting quality of ART interventions.

#### ➤ *Structural factors affecting compliance with quality guidelines in ART service delivery*

There were 5 medical staff in the ART clinic (2 clinical officers, 3 nurses and no medical doctor) against a requirement of up to 10 medical staff. Two nurses in the clinic were not trained in HIV ART clinical management (Table 1 and Table 2).

Personnel cadre	Available	Required
Medical doctors	0	1
Clinical officers	2	4
Nurses	3	5
Pharmacists	1	3
Laboratory Technologists	25	25
Health Information Officers	2	3
HIV Testing Services Providers	20	20
Psychological counselors	3	5

Table 1:- Distribution of personnel across ART service points

Type of training	Clinicians	Nurses	Pharmacists	Lab Techs	HIS officers	HTS providers
HIV ART clinical management	2	1				
HIV opportunistic infection treatment	2	1				
HIV counselling and testing						20
HMIS					2	
Drug and supplies management			1			
Phlebotomy				24		

Table 2:- Distribution of training across personnel cadres

Regarding structural factors in HIV Testing Services, HTS rooms were available but not standard hence did not meet HTS confidentiality requirements. A similar finding was evident in the adherence and psychological counseling section, where the protocol for adherence preparation, monitoring and support until viral load after 6 months on ART was not available either. Available adherence documentation tools included enhanced adherence forms and ART preparation register. In the ART clinic, equipment and supplies reported to be available were adult weighing scales, blood pressure machines, latex gloves, needles, syringes, and disinfectants. Weighing equipment for children under five and stethoscopes were not available. Adult weighing scales and blood pressure machines were also not available in adequate quantities. Only one non-standard consultation room was available for sharing with three clinicians hence compromising client confidentiality. No nutrition-specific room was available in the CCC. Except for the nutrition and opportunistic infections register, most ART service documentation registers and tools were available. The protocol for adherence preparation, monitoring, and support until viral load after six months on ART, Kenya ARV Guidelines 2018, and protocol for routine screening for cryptococcal meningitis for HIV-infected adults and adolescents were reported to be available but not produced for verification.

In the HIV clinic pharmacy, ARVs and most opportunistic infection drugs were available except Amphotericin and IPT for TB. The pharmacy waiting area where PLHIV receive drugs was insufficient to accommodate many PLHIV seeking pharmacy services due to covid-19 measures put in place by the hospital leading to long waiting

time for service delivery. The single-room pharmacy lacked adequate space for drug store, consultation, and drug dispensing hence compromising inventory management efficiency and client confidentiality. The study revealed stock-outs of reagents and essential supplies in the laboratory, which led to the rescheduling of CD4, TB, and sCrAg tests and delayed access to these critical services by PLHIV. The laboratory ships blood samples to test adult PLHIV VL externally due to lack of operational capacity to provide on-site viral load testing for all PLHIV. Laboratory test requests are performed using relevant forms and results documented in MoH-approved registers. The HIV service delivery policies visibly displayed included HIV testing algorithm, GeneXpert algorithm, protocol for routine screening for cryptococcal meningitis for PLHIV, and protocol for viral load monitoring of patients on ART (1st Line or 2nd Line).

In the HIS section, the filing area lacked adequate space (filing cabinets were strewn in the ART clinic walkways); current versions registers were available, key HIS policies available were; filing SOP and KHQIF guide. Data and performance review guide and DQA protocol were not available. The national reporting system (Kenya Health Information System) is used for HIV program reporting. There was an electronic medical records system for capturing and monitoring PLHIV clinical data. The reported quality improvement activities included routine data verification, data quality audits, and data quality review meetings steered by quality improvement and work improvement teams. Further analysis of health care provider perception on compliance with quality guidelines regarding ART interventions provided to PLHIV revealed significantly low perception scores (Table 3)

Service	HCP perception score on ART service compliance with quality guidelines					Target	% Score
	EE	MAE	MME	MSE	DNME		
ART initiation			3			4	75%
Adherence counseling				2		4	50%
Viral load testing			3			4	75%
CD4 testing				2		4	50%
sCrAg testing			3			4	75%
GeneXpert testing			3			4	75%
Pharmacy services			3			4	75%
Mean					100%	68%	
t=6.971, p<0.001							

Table 3:- Analysis of Health Care Service Providers perception score on compliance with quality guidelines in the delivery of ART services at KTRH

Using one-sample t-test, the mean perception index on compliance level (68%) was significantly below the expected 100% (t=6.971, p<0.001).

**NB:** [5 = Exceeds expectations (EE), 4 = Meets all expectations (MAE), 3 = Meets most expectations (MME), 2 = Meets some expectations (MSE), 1 = Does not meet expectations (DNME)]

➤ *Compliance with National ART Guidelines in ART Clinical Service Delivery*

Most ART services were not provided to PLHIV consistently as per the recommendations of the guidelines

(Table 4.9). Clinical staging was done for (99.7) PLHIV, adherence assessment (99%), TB screening (98.9), follow-up clinical visits (95.4%), baseline CD4 test (71.7%), most recent VL test in 2019 (71%), ART initiation within 2 weeks of HIV diagnosis (69%), sCrAg test (67%), IPT (55%), initial VL test at least 6 months after ART initiation (12%). The Ministry of Health guidelines on use of antiretroviral drugs for treating and preventing HIV infection in Kenya (2018) recommend that all PLHIV be provided with these services. The recommendations thus do not allow for less than 100% compliance for the services reviewed in this study. The calculated average compliance was (73.9%) (Ttable 4).

Variable (Type of service)	Frequency (%)	Compliance level		Total %	(N=)
		No	Yes		
PLHIV done for WHO staging	Frequency (%)	0.3	99.7	100	367
PLHIV assessed for adherence	Frequency (%)	1.0	99.0	100	367
PLHIV received TB screening	Frequency (%)	1.1	98.9	100	367
PLHIV had 4 clinical visits 3 months apart in the 12 months	Frequency (%)	4.6	95.4	100	367
PLHIV received baseline CD4 test	Frequency (%)	28.3	71.7	100	367
PLHIV received most recent VL test in 2019	Frequency (%)	29.0	71.0	100	367
PLHIV initiated on ART within 2 weeks of HIV diagnosis	Frequency (%)	31.0	69.0	100	367
PLHIV receive sCrAg test	Frequency (%)	33	67.0	100	55
PLHIV provided with IPT	Frequency (%)	45.0	55.0	100	362
PLHIV received initial VL test at least 6 months after ART initiation	Frequency (%)	88.0	12.0	100	367
Mean		26.7	73.9	100	
		t=3.038, p=0.014			

Table 4:- Distribution of ART service types and compliance outcomes

Using one-sample t-test, the mean compliance level (73.9%) was significantly below the expected 100% (t=3.038, p=0.014).

➤ *Viral Load Suppression (VLS) Levels of PLHIV*

In the context of this study, viral load suppression (VLS) referred to having less than detectable level (LDL) or <400 of viral copies per millilitre (mL) of plasma, a vital indicator of treatment success in PLHIV. Viral load suppression is associated with diminishing HIV morbidity, mortality, and very low risk of transmitting HIV (NASCO, 2020). The study showed (90.7%) of PLHIV who received the initial VL test at least six months after ART initiation achieved viral suppression. Viral suppression for PLHIV who received initial VL test from seven months onwards after HAART initiation was (84.3%).

#### IV. DISCUSSION

➤ *Socio-demographic Characteristics of PLHIV whose data were reviewed.*

In this study, at (67.3%), most PLHIV were female, accounting for a female to male ratio of (2.06:1). This finding demonstrates HIV prevalence among women was double that of men, which corresponds to findings by the KENPHIA 2018 survey report that showed HIV prevalence in Kenya was twice as high among women (6.6%) compared to men (3.1%) (NASCO, 2020). The mean and median ages were 42 years, (4.1%) were aged (8–14) years, (95.9%) were aged (15–76) years, and (62.9%) were married.

➤ *Structural factors affect compliance with quality guidelines in ART service delivery.*

The study pointed to a critical shortage of human resources in ART service delivery [doctors (0%), nurses (60%), clinical officers (50%), HIS (67%), and pharmacists (33%)]. They are findings diametrically inconsistent with the Kenya Health Policy norms and standards that recommend adequate numbers, skills mix, and competence of the health workforce (MOH, 2014). However, the findings concur with a study in Vietnam that found human resources shortage to be very common in HIV clinics (Tran *et al.*, 2012). A study by Kinfu *et al.* (2009) also pointed to health workforce shortage and training in Africa to be direly critical. In Kenya, the proportion of physicians per 1000 population was 0.14. The WHO recommends 2.28 professional physicians per 1000 population. A study by Hirschhorn *et al.* (2006) recommended 1 to 2 physicians and 2 to 7 nurses for 1000 ART patients, especially in developing countries where ART need is highest.

The study revealed acute inadequate service delivery space in key ART service areas, occasioning strain and stress in ART service delivery due to confidentiality concerns and delayed service delivery. Tran *et al.* (2012) study in Vietnam revealed similar observations. Patients starting treatment late complained of health care workers occasionally discussing clients' HIV status in public because there were no confidential rooms for service delivery, leading to some patients avoiding seeking HIV care.

The study found the existing quality improvement and work improvement teams functionally weak. Data verification, data quality audits, and data quality review meetings were reported to be regularly undertaken but

without verifiable evidence. Some key policy documents in quality improvement, including the DQA protocol, data review guidelines, were not available, pointing to a glaring gap in compliance with data and service quality improvement requirements. The WHO technical guidance requires health facilities to establish, entrench, and sustain practical and functional quality improvement systems to maintain and improve the quality of HIV care (WHO, 2019b). A study in Kenya on the impact of RDQAs concluded that RDQAs are useful in identifying data quality problems and improving data quality (Muthee *et al.*, 2018).

➤ *Compliance with National ART Guidelines in ART Clinical Service Delivery*

Although the guidelines require (100%) compliance with scheduled clinic appointments, this study showed (95%) of PLHIV observed the scheduled ART clinic visits, consistent with results from a study in Uganda that reported (92%) compliance (Kunutsor *et al.*, 2010).

In this study, (72%) of PLHIV received baseline CD4 test and, (67%) with CD4  $\leq$  200 cells/mm<sup>3</sup> received sCrAg test. Although CD4 and sCrAg tests are routine on-site laboratory investigations, the reasons for low testing uptake were unclear. The findings are consistent with results of a study in South Africa on compliance with diabetic guidelines, which revealed key laboratory tests including HbA1c (29.2%), Scr, eGFR and potassium (38.2%), and lipids (40.4%) were performed but significantly below guideline recommendations (Rampersad *et al.*, 2019).

Compliance with timelines for ART initiation was significantly lower (31%) in this study, consistent with findings of a study in Ethiopia that showed (67%) of PLHIV started ART within the recommended timeline (Bayisa *et al.*, 2020). Similarly, a study in South Africa revealed overall uptake of same-day ART initiation at (40.4%). While the South African study associated healthcare worker attitude to low acceptability of same-day ART initiation (Lilian *et al.*, 2020), similarly, in this study, key informant interviews revealed similar concerns regarding health care provider attitude affecting ART services. However, the study didn't establish quantifiable attribution to sub-optimal ART initiation uptake.

Compliance with initial VL test within or at least (6) months of starting ART was disturbingly low (12%). The initial viral load test is essential to establish a baseline for monitoring ART treatment success. Findings of a study on compliance with diabetic guidelines in South Africa's Kwa Zulu Natal were even more startling. None of the sampled (750) patients received testing for their low-density lipoprotein or high-density lipoprotein as recommended by the local guidelines (Igbojiaku *et al.*, 2013).

This study demonstrated high compliance (98.9%) regarding TB screening. However, compliance with TB IPT treatment was significantly lower (55%). The findings contrast with results of a study in Malawi on HIV policy and implementation review, which reported (100%) compliance

with TB IPT treatment but found (60%) compliance with TB screening requirements (Dasgupta *et al.*, 2016).

➤ *Viral Load Suppression of PLHIV as a Measure of Quality of ART Outcomes*

In this study, (90.7%) of PLHIV who received initial VL test at least six months after ART initiation achieved viral suppression. Viral suppression for PLHIV who received late initial VL test was (84.3%). The findings contrast with those of the Kenya Population-based HIV Impact Assessment (KENPHIA) study which, showed Kisii County had viral load suppression rate of (60%) for adults (aged 15-64 years). The variation in the viral suppression may be due to the smaller sample size (46) used in the KENPHIA study. In addition, this study relied on routine data while the KENPHIA study used household survey data. Viral suppression outcomes may also vary from time to time.

## V. CONCLUSIONS

The results of this study, though encouraging, disappointingly confirm that HIV programs still face significant challenges in the effort to deliver high-quality ART interventions. The findings showed facility structural factors affect compliance with standards for the delivery of quality ART services. Overall compliance with the guidelines in the delivery of critical clinical ART services was poor, with the potential to negatively affect ART outcomes for PLHIV. Glaring gaps were observed regarding structural inadequacies in human resource availability, training, physical infrastructural capacity, critical laboratory, and pharmaceutical supplies. The internal quality improvement structures were either non-existent, functionally weak, or organized around the needs of the NGO funding the HIV program hence lacking a sustainability pathway beyond the exit of the said NGO. Some key policy documents were not available for reference and use in some service delivery points, which might result in the provision of non-standardized services by health care workers who may not be aware of the recommendations in the guidelines.

## RECOMMENDATIONS

The study recommends the following:

- There is need for the HIV comprehensive care clinic in-charge to institute and track measures regarding compliance performance - supervision, continuous medical education, coaching and mentorship.
- The hospital management team should adopt immediate and long-term measures to address the structural inadequacies, which compromise compliance with quality requirements in implementing the HIV ART program.
- With the technical guidance of the County AIDS and STI Coordinator, the hospital management team should develop or strengthen the hospital's structures for HIV program quality improvement to respond to the program's quality needs effectively and in a sustainable way.
- The County HIV program manager should ensure the availability and use of key policy documents in the various SDPs to guide the implementation of HIV ART interventions.

## ETHICAL DECLARATIONS

**Conflict of interest:** The authors declare no conflict of interest.

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**Ethical Approval:** Authorization to conduct the study was provided by the University's Board of Postgraduate Studies, ethical approval received from Jaramogi Oginga Odinga Teaching and Referral Hospital's Institutional Ethical Review Committee and research permit obtained from the National Commission for Science, Technology, and Innovation. The Medical Superintendent of KTRH, through the hospital's Department of Research, approved for the study to be conducted at the hospital. Informed consent was obtained from the health workers who participated in the key informant interviews and confidentiality was maintained during the interviews.

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