

Relationship between Drug Use by Type and Virological Non-suppression among HIV-1 Patients on ART in Kisumu Central, Kenya

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Abstract—Virological Non-suppression (VNS) among HIV-1 patients on Anti-Retroviral Therapy (ART) is a global public health concern. Whereas previous studies have focused on socio-demographic factors as determinants of VNS, few studies in sub-Saharan Africa have investigated the potential association between type of drug used and VNS. This is more particularly so in Kisumu County, Kenya. The objective of the study was to explore the relationship between Drug Use by Type and VNS, measured through viral load levels, among HIV-1-positive individuals receiving ART in health facilities located in Kisumu Central Sub-County in Kenya. The population was 20,649 HIV-1 patients on ART. A random sample of size 384 was required based on Fisher's formula but data was accessed for only 322 participants. Data analysis involved descriptive and inferential statistics. Key findings indicated that the most commonly used drug was TDF/3TC/DTG which was categorized as "Very Strong". The least used drugs were AZT/3TC/ATVr and TDF/3TC/LPVr which were classified as "Moderately Strong" and "Strong", respectively. The lowest level of VNS was exhibited by patients on TDF/3TC/LPVr, a strong drug. Patients on TDF/3TC/ATVr, a drug of moderate strength, exhibited the highest level of VNS. Thus, TDF/3TC/LPVr, a "Strong Drug" was the most effective against VNS and not TDF/3TC/DTG classified as "Very Strong". ANOVA indicated significant differences in VNS across drug use by type at $\alpha=.05$ ($F=3.26, p=.012$). The study recommends that public health officials should regularly monitor ART efficacy, and to further consider replacing less effective ART drugs with more effective ones.

I. INTRODUCTION

HIV-1 is the most common type of HIV that causes AIDS. HIV-1 Virological Non-Suppression (VNS) is a condition that refers to the inability to achieve or maintain suppression of viral replication despite being on antiretroviral therapy (ART). More specifically, it is when the HIV-1 viral load (VL) cannot be brought below 250 copies/ml in the blood (Centers for Disease Control and Prevention (CDC), 2024). Thus, the higher the VL, the greater the likelihood of suffering VNS.

The burden of VNS among People Living with HIV (PLHIV) remains a significant concern globally. As of the year 2020, the rates of VNS in the Asian region and the Pacific ranged from 10-25%. Similarly, the rates of VNS in Eastern Europe and Central Asia were estimated at between 15-25%. In the year 2020, 470,000 PLHIV in sub-Saharan Africa (SSA) experienced VNS. Virological Non-Suppression among PLHIV on ART in East Africa was estimated at approximately 19.4% in a 2024 systematic review spanning 2016–2023 (Namaganda *et al.* 2025). Thus, a significant number of PLHIV in SSA and East Africa experience VNS.

Attempts have been made by researchers to establish factors associated with VNS in SSA, and the majority of such studies have been conducted in Ethiopia (see e.g., Agegnehu, Merid & Yenit, 2020; Bayleyegn, Kifle & Geremew, 2021). The studies recommended that future research should consider other important variables masked as other determinants of health as this is likely to help identify key risk factors associated with VNS among PLHIV.

The situation in Kenya regarding VNS is even more worrying. In the year 2020, it was estimated that 52,000 PLHIV in Kenya experienced VNS. This accounted for approximately 7.5 percent of the global burden, and 3.79% of the population of PLHIV in Kenya (UNAIDS, 2020). On the other hand, Kisumu County, one of the 47 counties in Kenya, recorded VNS of approximately 10.2% among PLHIV in the year 2020, a figure considered to be very high (National Syndemic Disease Control Council, 2020). Whereas only two studies on VNS have so far been done in Kenya in the recent past; one in Busia County in 2021 (Makwaga *et al.*, 2020) and the other in Homa Bay County in 2023 (Masaba *et al.*, 2023), no such studies have been conducted in Kisumu County, yet the prevalence of HIV in Kisumu County is one of the highest in the country. It is imperative that a study on factors related to VNS, as measured by VL whose threshold is 250 copies/ml, is likely to add value to the field of public health. One such factor is hypothesized to be the drug use by type among HIV-1 patients.

WHO (2015) classified HIV-1 drugs into five categories based on their strength. The drugs and their respective classifications are TDF/3TC/DTG (Very Strong), TDF/3TC/LPVr (Strong), TDF/3TC/ATVr (Moderate), AZT/3TC/LPVr (Weak) and AZT/3TC/ATVr (Very Weak). However, studies linking type of ART drug used by HIV-1 patients and VNS were found to be rare in Kenya. This therefore served as a study gap that the current study explored. Therefore, the purpose of this study was to determine the relationship between Drug Use by Type and Virological Non-Suppression among HIV-1 patients on ART in Kisumu Central, Kenya.

Objectives of the Study

The specific objectives of the study were to:

- i) Compare the extent to which five WHO classified ART drugs were used among HIV-1 patients on ART in Kisumu Central, Kenya;
- ii) Establish the pattern of Virological Non-Suppression

- (VNS) among HIV-1 patients on ART in Kisumu Central, Kenya; and
- iii) Determine the relationship between Drug Use by Type and VNS among HIV-1 patients on ART in Kisumu Central, Kenya.

Assumptions of the Study

The assumptions of the study were as follows:

- i. That all the participants were on antiretroviral therapy (ART)
- ii. None of the participants were on a treatment regimen for any other viral infections such as COVID-19, Ebola, Nipher SARs, or MERS-CoV.

Significance of the Study

The findings of this study are likely to benefit various stakeholders as follows.

- i. Administrators and policymakers would be better informed to enable them make correct resource allocation decisions for purposes of developing effective health policies.
- ii. Public health researchers are likely to benefit from the study findings by being more exposed to new knowledge on HIV and AIDS and therefore able to identify gaps in research to inform future studies.
- iii. Healthcare practitioners are likely to benefit from the findings by gaining insights into the effectiveness of different treatment regimens.
- iv. Patients may ultimately benefit by having their quality of care improved.

Limitations of the Study

One of the limitations of the study is that it entirely depended on secondary data, which may affect the reliability of the data. The second limitation is that there was the risk of suffering selection bias.

II. METHODOLOGY

2.1 Area of Study

The study was conducted in Kisumu County, located in the western part of Kenya at Longitudes 33° 20'E and 35° 20'E and Latitudes (Kisumu County Assembly, 2025). The HIV-1 prevalence rate in the County as of 2021 was 13.9%, significantly higher than the national average of 4.1% (National Syndemic Disease Control Council, 2021).

2.2 Research Design

The study made use of descriptive research design. As observed by Creswell and Creswell (2018), descriptive research is used to describe characteristics of a population or phenomenon being studied. It does not answer questions about how/when/why the characteristics occurred.

2.3 Variables and Measurement

The outcome variable in the study was Viral Load, a proxy for Virological Non-Suppression, measured on a ratio scale. The independent variable was Drug Use by Type, a variable measured on an ordinal scale.

2.4 Target Population

The study focused on individuals receiving ART across three major public health facilities in Kisumu Central:

- i. Lumumba County Hospital: 7,280 patients
- ii. Jaramogi Oginga Odinga Teaching and Referral Hospital: 6,800 patients
- iii. Kisumu County Referral Hospital: 6,569 patients: 6,569 patients

This brought the total study population to 20,649 HIV-1-infected individuals on ART.

2.5 Sample Size

Fisher’s sampling formula was used based on HIV-1 patients on ART (i.e. N=20,649). Fisher’s formula for calculating the sample size is given by:

$$n = N \left\{ \frac{\frac{Z^2 p(1-p)}{e^2}}{\left[N - 1 + \frac{Z^2 p(1-p)}{e^2} \right]} \right\}$$

where

- N is the population size;
- Z is the critical value (95% CI);
- e is the margin of error;
- p is the sample proportion; and
- n is the sample size.

The values of the above symbols are given in Table 1.

TABLE 1: Symbols represented in the sample size and their values

Population Size (N).....	20,649
Critical Value (95%CI) (Z).....	1.96
Margin of Error (e).....	0.05
Sample Proportion (p).....	0.5
Sample Size (n).....	384

The above values gave a sample size of 384 HIV-1 patients. To accommodate non-response, an additional 5% (i.e., 19 participants) was added, resulting in a final sample size of 403 individuals. However, only 322 respondents were accessed.

2.6 Sampling Strategy

Simple random sampling was used, with SPSS software generating randomized identifiers for eligible participants listed in hospital records. Once selected, secondary data for viral load and drug regimen type was obtained from their existing medical records.

2.7 Data Collection Tools

Information for age and gender was obtained using Google Survey Form. Data on drug use by type and viral load was obtained from secondary sources in three government hospitals in Kisumu County which are critical hospitals in HIV care, control and treatment.

2.8 Procedure for Data Collection

Data on viral load and ART regimen were gathered from facility records, most of which are maintained in collaboration with research partners such as Centres for Disease Control (CDC) and Kenya Medical Research Institute (KEMRI). All data were entered into SPSS for coding and analysis.

2.9 Data Analysis Techniques

Descriptive statistics were used to examine the central tendencies and variability of the variables. Graphical methods were used to assess data patterns.

Inferential statistics were used to determine the relationship between drug use by type and Virological Non-Suppression (VNS). More specifically, analysis of variance was used to make statistical inference regarding the difference in VNS across drug use by type.

2.10 Inclusion Criteria

Participants were included in the study based on the following criteria:

- i. Subjects must have tested positive for HIV-1 clade A, D or G.
- ii. Subjects must have been placed on ART regimen following infection by HIV-1 clade A, D or G.

2.11 Exclusion Criteria

Participants were excluded from the study based on the following criteria:

- i. All HIV-negative participants
- ii. Participants infected with HIV strain other than HIV-1
- iii. Those who had developed other complications and illnesses during the study

2.12 Ethical Considerations

The World Medical Association's Declaration of Helsinki (2013) proposed seven public health ethics principles: respect for persons, non-maleficence, beneficence, justice, health maximization, proportionality, and efficiency. We adhered to these principles throughout the study after getting approval from Maseno University Scientific and Ethics Review Committee and a research permit from the National Commission for Science, Technology and Innovation (NACOSTI), a government agency in Kenya responsible for regulating and coordinating research, science, technology, and innovation.

III. RESULTS

3.1 Demographic Characteristics

3.1.1 Age Distribution

Statistics for the distribution of participants' ages is provided in Table 2. Their ages ranged from 20 to 81 years, with a mean of 42.38 years and a standard deviation of 12.21. The distribution was moderately skewed to the right, with a median of 39 years and a mode of 36 years, indicating a slight deviation from normality.

TABLE 2: Descriptive statistics for respondents' age

	Minimum	Maximum	Median	Mean (SD)	Kurtosis (SE)	Skewness (SE)
Age (years)	20	81	39	42.38(12.21)	1.172(.271)	.963(.136)

3.1.2 Gender Profile

Fig. 1 indicates that males comprised the majority of respondents, totalling 192 (59.6%), while females were 130 (40.4%).

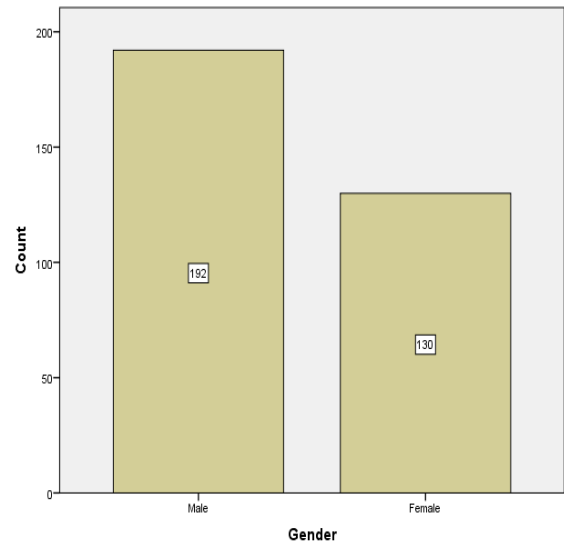


Fig. 1: Gender distribution

3.2 Drug Use by Type

The respondents used five different types of drugs possessing different strengths. The drugs, arranged in ascending order of strength according to WHO (2019) classification were AZT/3TC/ATVr (Very Weak), AZT/3TC/LPVr (Weak), TDF/3TC/ATVr (Moderate), TDF/3TC/LPVr (Strong) and TDF/3TC/DTG (Very Strong).

Fig. 2 shows the distributional characteristics of drugs used by the respondents. The most commonly used drug was TDF/3TC/DTG, classified by WHO as "Very Strong". The drug was used by 181 respondents (56.2%). This was followed by AZT/3TC/ATVr, a drug classified as "Very Weak" and used by 88 respondents (27.3%), then AZT/3TC/LPVr, a "Weak" drug used by 35 respondents (10.9%). Two drugs registered the least usage, one classified as "Moderate" (AZT/3TC/ATVr) and the other classified as "Strong" (TDF/3TC/LPVr), each used by 9 respondents (2.8%).

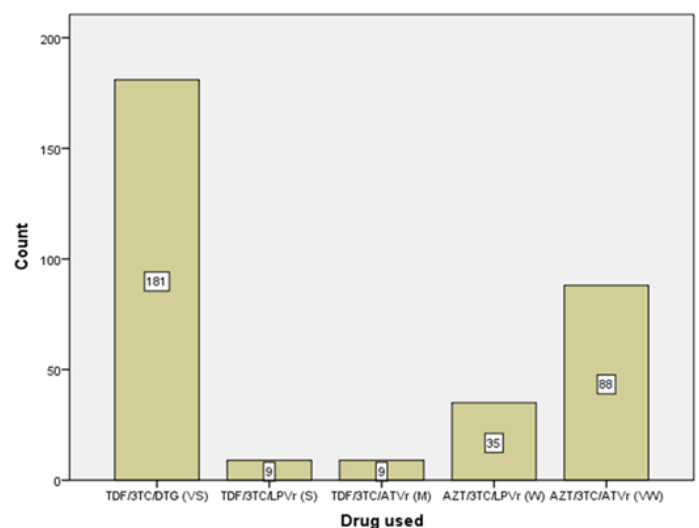


Fig. 2: Distributional characteristics of drugs used by type
 Key: VS=Very Strong
 S=Strong

M=Moderately Strong
W=Weak
VW=Very Weak
S= Strong
VS=Very Strong

3.3 Distribution of Virological Non-Suppression

Participants’ viral loads, a measure of virological non-suppression, are presented in Table 3. The viral loads varied widely, with a mean of 9,384 copies/mL and a median of 2,221. Due to high positive skewness (2.8), depicted in Fig. 3, the median was deemed a more reliable indicator of central tendency than the mean. It is evident from the graph that the distribution of VNS extensively violated the normality assumption.

TABLE 3: VNS of respondents

Missing	0
Mode	1,160
Mean	9,384
Median	2,221
Std. Deviation	17,370
Kurtosis	7.3
Std Error of Kurtosis	.271
Skewness	2.8
Std error of skewness	.14

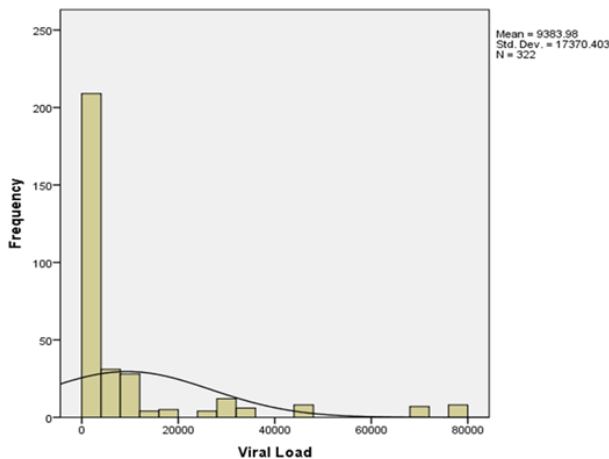


Fig. 3: Histogram for respondents' viral load

3.4 Relationship between Drug Use by Type and VNS

The relationship between drug use by type and VNS (as measured by VL) among HIV-1 patients in Kisumu Central is presented in this section. Analysis involved the use of one-way Analysis of Variance (ANOVA). However, considering that the dependent variable (VNS in this case) extensively violated the normality assumption, the logarithmic transformation was used to normalize the data.

Fig. 4 shows a histogram with a superimposed normal curve for log_eVL. The distribution was reasonably normal, with a mean of 3.48 (SD = 0.615). Therefore, it was this transformed variable that was used as the dependent variable in the ANOVA.

Fig. 5 shows the mean log_e(VL) across the types of drugs used by respondents. The drug type with the highest value of mean log_e(VL) was TDF/3TC/ATVr (Moderate Strength), with a mean of 3.819. This was followed by AZT/3TC/ATVr (Very Weak) with a mean of 3.525, TDF/3TC/DTG (Very Strong) with a mean of 3.501, AZT/3TC/LPVr (Weak) with a

mean of 3.262 and lastly TDF/3TC/LPVr (Strong), with a mean of 3.028. Thus, TDF/3TC/LPVr classified as “Strong” appeared to be the most effective against VNS and not TDF/3TC/DTG (Very Strong) as would be expected. This suggests that there may be a change in the dynamics of drug strength resulting from usage patterns, physiological state, or the presence of other chemicals in the body.

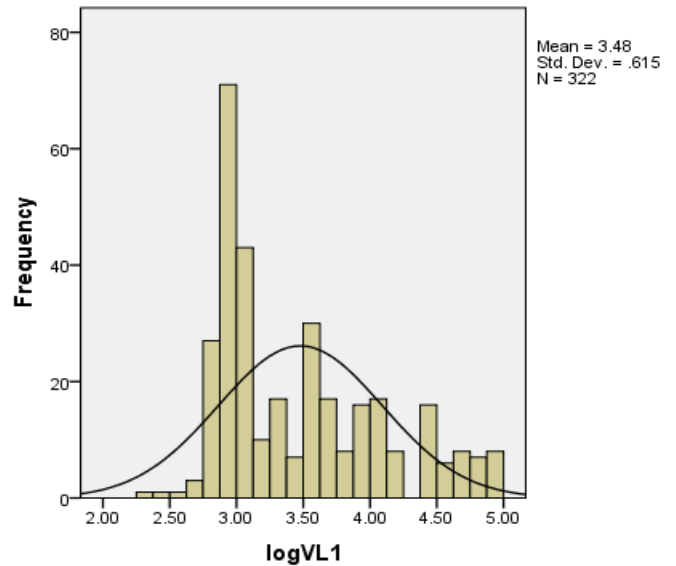


Fig. 4: Histogram for log_e(VL)

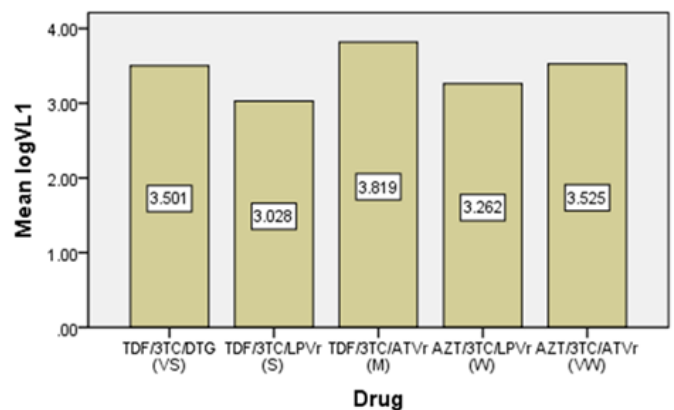


Fig. 5: Mean log_e(VL) across type of drug used

Table 4 is an ANOVA summary for mean differences in ln(VL) across type of drug used. It indicates that overall, there was at least one pair of means whose difference was statistically significant at the .05 level.

TABLE 4: ANOVA summary for mean differences in ln(VL) across drug type

Source	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	4.79	4	1.20	3.26	.012
Within Groups	116.47	317	.37		
Total	121.26	321			

Further, a *post-hoc* test using the Least Squares Difference (LSD) was conducted to determine which pairs of means were significantly different. Table 5 shows the findings of the *post-hoc* test which indicate that significant mean differences in

log_eVL were between “TDF/3TC/DTG (Very Strong)” and “TDF/3TC/LPVr (Strong)”; “TDF/3TC/DTG (Very Strong)” and “AZT/3TC/LPVr (Weak)”; “TDF/3TC/LPVr (Strong)” and “TDF/3TC/ATVr (Moderate)”; “TDF/3TC/LPVr (Strong)” and “AZT/3TC/ATVr (Very Weak)”; “TDF/3TC/ATVr (Moderate)” and “AZT/3TC/LPVr (Weak)”; “AZT/3TC/ATVr (Very Weak)” and “AZT/3TC/LPVr (Weak)”.

TABLE 5: Results for LSD post-hoc tests (Dependent variable=ln(VL))

(I) Drug	(J) Drug	Mean Difference (I-J)	Std. Error	Sig.
	TDF/3TC/LPVr (S)	1.09020*	.47665	.023
	TDF/3TC/ATVr (M)	-.73046	.47665	.126
TDF/3TC/DTG (VS)	AZT/3TC/LPVr (W)	.55126*	.25772	.033
	AZT/3TC/ATVr (VW)	-.05407	.18138	.766
	TDF/3TC/DTG (VS)	1.09020*	.47665	.023
	TDF/3TC/ATVr (M)	-1.82066*	.65793	.006
TDF/3TC/LPVr (S)	AZT/3TC/LPVr (W)	-.53895	.52163	.302
	AZT/3TC/ATVr (VW)	-1.14427*	.48844	.020
	TDF/3TC/DTG (VS)	.73046	.47665	.126
	TDF/3TC/LPVr (S)	1.82066*	.65793	.006
TDF/3TC/ATVr (M)	AZT/3TC/LPVr (W)	1.28172*	.52163	.015
	AZT/3TC/ATVr (VW)	.67639	.48844	.167
	TDF/3TC/DTG (VS)	-.55126*	.25772	.033
	TDF/3TC/LPVr (S)	.53895	.52163	.302
AZT/3TC/LPVr (W)	TDF/3TC/ATVr (M)	1.28172*	.52163	.015
	AZT/3TC/ATVr (VW)	-.60533*	.27891	.031
	TDF/3TC/DTG (VS)	.05407	.18138	.766
AZT/3TC/ATVr (VW)	TDF/3TC/LPVr (S)	1.14427*	.48844	.020
	TDF/3TC/ATVr (M)	-.67639	.48844	.167
	AZT/3TC/LPVr (W)	.60533*	.27891	.031

*. The mean difference is significant at the 0.05 level.

IV. DISCUSSION

The study participants were all adults aged 20 years or older. Central tendency metrics (Median = 39; Mean = 42.38) highlight a dominance of middle-aged adults, consistent with ART cohorts in Kenya. Comparable age-related findings were reported by Marukutira *et al.* (2023) in Nairobi. The mode of 36 years further emphasizes a clustering within the mid-thirties age group.

A slight positive skew was observed in the age distribution, indicating the presence of a few older participants, with the oldest being 81 years. Such variation mirrors actual HIV demographics in Kenya, where older individuals are increasingly represented in long-term ART programs. Their inclusion provides critical insights, especially since treatment response and comorbidity profiles may differ significantly between age groups.

The number of males in the study was 192. This constitutes 59.6% of the study sample. Thus, males were the majority in the study sample.

TDF/3TC/DTG, classified by WHO (2019) as the most effective, emerged as the most frequently used regimen, reported by 56.2% of the participants. On the other hand, AZT/3TC/ATVr, considered the least effective among the regimens by WHO, was used by 27.3% of the participants. Other regimens included AZT/3TC/LPVr (10.9%), and

AZT/3TC/ATVr as well as TDF/3TC/LPVr registering a paltry 2.8% each.

The distribution of virological non-suppression (VNS), measured by viral load, was markedly right-skewed, indicating that the majority of participants had low VNS. Despite this skew, most had VLs exceeding 250 copies/mL, suggesting incomplete suppression. Such distribution patterns are common in sub-Saharan populations. Similar trends have been noted in large-scale surveys like the Population-based HIV Impact Assessments (PHIAs), which observed heavy clustering of VL values at the lower end of the spectrum but with long-tailed extensions toward higher values.

4.5 Conclusion

Based on the study findings, it is concluded that the most commonly used drug in Kisumu Central Sub-county was TDF/3TC/DTG, classified by WHO as “Very Strong”. In addition, the type of drug used by PLWHIV in the sub-county was significantly related to virological non-suppression. Further analysis indicated that the drug classified by WHO as “Strong” was the most effective against VNS compared to the one classified as “Very Strong”, and the other drugs as well. This potential decline in the efficacy of a “Very Strong” drug suggests the possibility of drug failure.

4.6 Recommendations

The following are recommendations of the study based on the findings:

- i. Considering that those on ART were found to be middle-aged adults, a typical age distribution for long-term ART in Kenya, this age group should be targeted more by health professionals for ART. In addition, the fact that more males were found to be on ART than females suggests that males may need more behavior change interventions than females.
- ii. The distribution of VL had a strong positive skew, implying that the vast majority of the data points were clustered towards the lower end of the viral load spectrum. However, almost all the respondents had VL far above the 250 copies/ml threshold, and were therefore suffering VNS. It is recommended that administration of ART be continued by public health officials.
- ii. The most commonly used ART in Kisumu Central Sub-county was TDF/3TC/DTG, classified by WHO as “Very Strong”. However, this drug was found to be less effective than TDF/3TC/LPVr classified as “Strong”. This potential decline in the efficacy of a “Very Strong” drug suggests potential drug failure and therefore calls for further research and evaluation.

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