Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2067
Original Article

Prevalence and factors associated with suboptimal adherence to dolutegravir-based regimens among people living with HIV in a specialized clinic in Kampala, Uganda. A cross-sectional study.

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ABSTRACT

Background: In Uganda, 54% of people living with HIV(PLHIV) on first-line Antiretroviral Therapy (ART) were taking dolutegravir-based regimens. This study aimed to determine the prevalence and factors associated with suboptimal adherence to dolutegravir-based regimens among PLHIV at a specialized clinic in Uganda.

Methods: A cross-sectional study was conducted at a specialized HIV clinic in Kampala, Uganda, from July to August 2022. Quantitative data were collected using questionnaires and data abstraction tools from 366 consecutively sampled and consented PLHIV. Adherence was measured using a modified Morisky Medication Adherence Scale, which consisted of 9 questions. Qualitative data were collected using in-depth interviews among 13 purposively sampled, consented participants. Quantitative data were analysed using modified Poisson regression in STATA 14 to obtain factors associated with suboptimal adherence at the 5% level of significance. Qualitative data were analyzed using thematic analysis in Open Code version 4.03.

Results: The median age of participants was 44 (IQR: 35 to 52), while 64.8% (237/366) were female. The prevalence of suboptimal adherence to dolutegravir-based regimens was 49% (179/366; 95%Confidence Interval (CI): 44, 54). Alcohol consumption (adjusted Prevalence Ratio (aPR): 1.25; 95%CI: 1.012, 1.543), and unemployment (aPR: 1.27; 95%CI: 1.002, 1.609) were associated with a higher likelihood of suboptimal adherence while the lack of social support (aPR: 0.78; 95%CI: 0.619, 0.993), and talking to the doctor in case of a health problem (aPR: 0.44; 95%CI: 0.307, 1.270) were protective against suboptimal adherence, to dolutegravir-based ART regimens. Barriers to dolutegravir adherence included unemployment, lack of social support, alcohol consumption, and inadequate counseling.

Conclusion: Suboptimal adherence to dolutegravir-based ART was high. Alcohol consumption, unemployment, lack of social support, and inadequate counselling influenced dolutegravir adherence.

Recommendations: Start-up projects to address unemployment should be implemented for PLHIV. Dolutegravir-related virological failure resulting from non-adherence in PLHIV should be investigated.

Keywords: *Dolutegravir adherence, Dolutegravir, People living with HIV, ART suboptimal adherence.*
Submitted: *August 29, 2025* ***Accepted:*** *September 10, 2025* ***Published:*** *September 22, 2025*

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Background

The global burden of Human Immunodeficiency Virus (HIV) infection is estimated at 37.7 million individuals, with Uganda contributing 1.4 million cases (1). In 2016, the World Health Organization (WHO) recommended the transition of all individuals on first-line antiretroviral therapy (ART) or treatment naïve to dolutegravir (DTG)-based ART regimens(2). DTG has been demonstrated to have a high viral load suppression rate, a low incidence of adverse effects, and a low pill burden (3). Furthermore, it has been shown to have better tolerability, a lower discontinuation rate than other regimens (4), and a high genetic barrier to resistance (5).

ART treatment for standardized regimens is composed of combining three or more antiretroviral drugs to optimally suppress the HIV infection and halt the progression of HIV disease. ART regimens usually comprise a backbone of two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) and a third as an anchor antiretroviral medicine (ARV) from a different class. In Uganda, all eligible HIV-infected adults and adolescents weighing ≥ 30kg are initiated on Tenofovir, Lamivudine, and Dolutegravir (TDF+3TC+DTG) as a once-daily fixed-dose combination. If the PLHIV is a known diabetic or has two or more risk factors for hyperglycemia, DTG is replaced with Efavirenz (6).

Following the roll-out of DTG in Uganda in 2018, several adverse events manifested, prompting concerns about their potential effect on adherence to treatment. These include insomnia, itching, blurred vision, vomiting, headache, and weight gain (7). People living with HIV (PLHIV) were not adequately counseled, as this was conducted hastily during a routine facility visit, resulting in a lack of preparation to address these adverse events (7). The majority of the 65 % of people living with HIV in Uganda who are on antiretroviral therapy are taking dolutegravir-based regimens (8).

The Joint United Nations Program on HIV/AIDS (UNAIDS) recommends that 95% of PLHIV on ART should be virally suppressed (1), an outcome more likely with high optimal ART adherence (6). Globally, suboptimal adherence to DTG-based regimens is estimated to be as high as 31% (9). In Africa, studies have reported suboptimal adherence rates as high as 53% (9, 10). This is associated with unemployment and younger age (13-24 years) (9), as well as a lack of understanding of counseling about patient treatment (11), discussion with a healthcare provider (12), response after disclosure, and medicine refill intervals (10). The level of adherence to ART in Uganda remains suboptimal, with a current adherence rate of 93%(13), compared to the 95% target set for 2025 (14).

Suboptimal adherence to DTG-based regimens results in an increased viral load; higher incidence of morbidity and mortality, and the development of drug resistance, which limits drug options for PLHIV (15). It increases the disease burden and complications, and strains the health budget, hence reducing economic development(16), with a consequent lowering of the gross domestic product. This further poses challenges to the attainment of Universal Health coverage by 2030 (17) and the realization of the National Vision 2040 (18). This study, therefore, aimed to determine the prevalence and factors influencing suboptimal adherence to DTG-based regimens among adult PLHIV in care at a referral HIV/AIDS facility in Kampala, Uganda.

Methods

Study setting

The site was a specialized clinic in Kampala, Uganda, for HIV/AIDS treatment and research. It also served as a referral site for third-line ART in the country. This study site served approximately 3629 PLHIV per month, of whom 2485 were on DTG-based regimens. The facility's viral suppression rate was 97% (facility monthly report), as compared to the national suppression rate of 75.4% (19).

Study design and population

A cross-sectional study was conducted to collect quantitative and qualitative data at a specialized HIV/AIDS treatment and research clinic. Questionnaires were administered to 366 PLHIV, aged 18 years and older in Uganda, who sought care at this clinic, between July and August 2022, and were taking DTG-based regimens. PLHIV who had not taken DTG for more than three months were excluded. It was postulated that three months was sufficient to gain the minimum desirable experience of taking these ARVs. For qualitative data collection, all PLHIV who were not adherent to DTG-based regimens or had a high viral load, and health workers were included.

Sample size and sampling procedure

The Kish-Leslie formula for a single proportion was used to calculate a sample size of 366, with a precision of 5%, a proportion of suboptimal adherence of 31% (9), $Z\alpha/2$- the standard normal value corresponding to a 95% level of confidence (1.96), and 10% missing data. For the associated factors, the formula for two proportions was used to calculate the sample size of 219, with $Z\beta$-the standard normal value corresponding to an 80% power of 0.84. The proportion of subjects who were young (13-24 years) and unemployed, q1 was 0.5. The proportion of subjects who were old 25-44 years) and unemployed, q2 was 0.5. The proportion of subjects who were young and unemployed who developed non-adherence to dolutegravir, P1, was 0.37. The proportion of subjects who were old and unemployed who developed non-adherence to dolutegravir, P2, was 0.2 (9). A sample size of 366 was used for the study. Patients who presented at the outpatient registration point were consecutively sampled and taken to the triage nurse to confirm whether they had been taking DTG-based regimens for at least three months using the computerized system. Participants consented and were administered questionnaires. Data was abstracted using patient numbers. For associated factors, data were collected on age, sex, marital status, education level, comorbidities, alcohol consumption (assessed using a question; Do you drink alcohol? with yes or no responses), income level, employment status, WHO HIV staging, viral load suppression, non-disclosure, and social support. Other

variables included were: facility accessibility, medicine availability, health education, patient-provider relationship, and side effects. Participants were purposively sampled for qualitative data. Health workers were selected if they had been involved in the treatment and management of HIV patients for at least the previous twelve months. These included six non-adhering/high viral load PLHIV, seven health workers, and conducted face-to-face in-depth interviews about barriers to DTG adherence.

Outcome measurement

Optimal adherence in the current study was defined as when a participant takes ≥95% of ART in a given period (20); that is, missing no doses, or only one dose in the once-daily regimen, or not more than three doses in a twice-daily regimen of the DTG-based regimen in the last 30 days. Suboptimal adherence is therefore observed if a participant takes < 95% of ART; that is, missing more than one dose of the once-daily regimen or more than three doses of the twice-daily regimen of the DTG-based regimen in the last 30 days as measured by self-report using a scale modified from the Morisky Medication Adherence Scale (21). The Morisky Medication Adherence Scale has eight (8) questions relating to medication adherence. The first seven items have a dichotomous response of yes or no answers (22). Open-ended questions were added to the data collection tool, namely, In the past month, have there been any days when you did not take your HIV medication? How many days did you fail to take your medication? Have you ever cut back or stopped taking your HIV medication without telling your doctor because you felt worse when you took it? When you travel or leave home, do you sometimes forget to bring along your medication? Did you take your HIV medication yesterday? When you feel like you have improved, do you sometimes stop taking your HIV medication? Do you ever feel hassled about sticking to your HIV treatment plan? How often do you have difficulty remembering to take your HIV medication? When was the last time you failed to take your medication? The number of days a participant missed medicine from question two was used to calculate adherence.

Data management and analysis

Continuous variables were summarized as medians and interquartile ranges, and categorical variables as frequencies and percentages with a 95% confidence interval for suboptimal adherence. Bivariate analysis was performed for all variables using modified Poisson regression with robust standard errors. A cut-off of 0.2 was used to get variables for multivariable analysis. Prior knowledge from the published literature was used to identify other variables from the data that were associated with suboptimal adherence but had a p-value greater than 0.2. Variables included in the multivariable analysis were age, alcohol consumption, employment status, social support, culture, health worker preferred, disclosure status, drug availability, dolutegravir side effects, and WHO clinical staging. Multivariable modified Poisson regression was used at a 5% significance level, and interaction was assessed using the likelihood ratio test. Confounding was assessed using a change in prevalence ratio >10% to determine whether any variables confounded others in the final model. Factors independently associated with suboptimal adherence to DTG-based regimens were identified. Qualitative data were thematically analyzed using the Open Code software to identify barriers to DTG adherence.

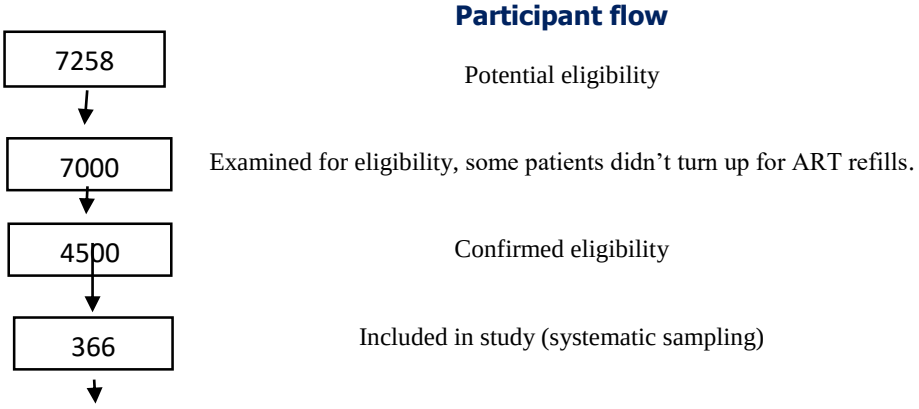
Ethical consideration

Ethical approval was obtained from the Makerere University School of Medicine Research and Ethics Committee, approved on 11th July 2022, with approval number: Mak-SOMREC-2022-359. Informed consent was obtained from the participants. The uneducated participants had educated relatives who traveled with them to collect medicine refills. The relatives would read the informed consent form to the participants and ensure they understood everything. The uneducated participants would then provide a fingerprint to confirm their agreement to participate in the study. The relatives would also sign the informed consent forms as witnesses. All the methods in this study were executed per the relevant guidelines and regulations, namely, the Declaration of Helsinki and the Uganda National Guidelines for Research involving Humans as Research Participants.

RESULTS

Baseline characteristics

Participant flow



366	Analyzed

Table 1: Characteristics of 366 PLHIV, taking dolutegravir-based ART regimens in a specialized clinic in Uganda

Variable	Median (IQR)	Frequencies (n=366)	Percentage (%)
Age (years)	44(35-52)		
18-24		30	8.2
25-49		210	57.4
≥50		126	34.4
Sex			
Females		237	64.8
Males		129	35.2
Monthly income*	150,000 (30,000-300,000)		
<Poverty line		236	64.5
≥Poverty line		130	35.5
Distance from facility (km)	20 (10-34)		
< 5km		20	5.5
≥ 5km		346	94.5
Education (highest level)			
Certificate (from a tertiary institution)		32	8.7
Diploma		34	9.3
Degree		30	8.2
Others (below tertiary level)		250	68.3
Uneducated		20	5.6
Employment status			
Employed		293	80.1
Unemployed		73	19.9
Marital status			
Married		152	41.5
Single (never married)		147	40.2
Divorced		35	9.6
Widowed		32	8.7
Alcohol consumption			
Yes		123	33.6
No		243	66.4
Duration at facility			
Less than one year		16	4.4
More than one year		350	95.6
WHO HIV Staging (highest)**			
Early stage		319	87.2
Advanced stage		47	12.8
Viral load suppression			
Yes		331	90.4
No		35	9.6
Comorbidities			
Yes		82	22.4
No		284	77.6
Preferred health worker			
Doctor		219	59.8
Counselor		143	39.1
Pharmacist		4	1.1

IQR-Interquartile range

**The poverty line is equivalent to 1.77 United States Dollars per person per day (23)*
***Early stage includes stages 1 and 2, Advanced stage includes stages 3 and 4*

The median age for participants was 44 years (IQR: 35-52). Approximately 64.8% (237/366) of the participants were female, 80.1% (293/366) were employed, and 33.6% (123/366) consumed alcohol. The majority of participants, 87.2% (319/366), had early-stage HIV at the start of treatment, and 9.6% (35/366) were not virally suppressed (HIV RNA less than 50 copies/ml) **(Table 1).**

Prevalence of suboptimal adherence to dolutegravir-based regimens

Table 2: Adherence to dolutegravir-based ART regimens for 366 PLHIV in a specialized clinic in Uganda.

Adherence type	Prevalence (n)	95% Confidence interval	
		Lower limit	Upper limit
Self-reported adherence			
Optimal	51(187)	46	56
Suboptimal	**49(179)**	44	54
Suboptimal grading			
Average (85-94.9%)			
Poor (<85%)	35(129)	30	40
	14(50)	10	17

Out of the 366 participants enrolled in the study, 49% (n=179; 95%CI: 44, 54) reported suboptimal adherence to DTG-based regimens. About 14% (50/366; 95%CI: 10, 17) of the participants had poor adherence to DTG-based regimens (**Table 2**).

Factors associated with suboptimal adherence to dolutegravir-based regimens in Uganda

Table 3: Factors associated with suboptimal adherence to dolutegravir-based ART regimens in 366 PLHIV in Uganda

Variable	Sub-optimal adherence		Crude Prevalence ratio, cPR (95% CI)	Adjusted Prevalence ratio, aPR (95% CI)
	Yes, n (%)	No, n (%)		
Alcohol consumption				
Yes	68 (55.3)	55 (44.7)	1.210 (0.981, 1.493)	**1.250 (1.01, 1.54)**
No	111 (45.7)	132 (54.3)	1	
Employment status				
Yes	138 (47.1)	155 (52.9)	1	
No	41 (56.2)	32 (43.8)	1.193 (0.942, 1.510)	**1.270 (1.01, 1.61)**
Social support				
Yes	121 (51.9)	112 (48.1)	1	
No	58 (43.6)	75 (56.4)	0.839 (0.667, 1.056)	**0.785 (0.62, 0.99)**
Preferred health worker				
Counselor	84 (58.7)	59 (41.3)	1	
Doctor	92 (42.0)	127 (58.0)	**0.560 (0.581, 0.880)**	**0.442 (0.22, 0.90)**
Pharmacist	3 (75.0)	1 (25.0)	0.750 (0.713, 2.287)	0.625 (0.31, 1.27)

CI-Confidence interval

All the variables were adjusted for each other to obtain factors associated with suboptimal adherence.
Alcohol consumption (aPR: 1.25; 95%CI: 1.012, 1.543) and unemployment (aPR: 1.27; 95%CI: 1.002, 1.609) were positive predictors of suboptimal adherence. Lack of social support (aPR: 0.78; 95%CI: 0.619, 0.993) and talking to the doctor in case of a health problem (aPR: 0.44; 95%CI: 0.307, 1.270) were negative predictors of suboptimal adherence (**Table 3**).
Barriers to DTG adherence

In-depth interviews revealed that unemployment and jobs that make patients so busy that they forget to take their medicines affect DTG adherence. The jobs do not give PLHIV time to pick up medicine refills, and hence, they miss drugs on some days. Others work so far, and therefore cannot pick drugs easily. *".....now for me, I am a builder. They require me to report at 7 am at the site, and sometimes we leave at 8 pm. I cannot take medicine before eating in the morning. Breakfast is at 10 am, and by that time, I have forgotten about medicine. At night, I am so tired that when I reach home, I just sleep."* **Male participant, 25 years old.**

PLHIV lack the transport to pick up medicines. They also lack money to buy food to eat before swallowing medicines, and hence end up missing to swallow drugs; *" .....if someone can fail to get 500 shillings to buy mukene (silverfish), how can that person get transport to come and pick medicine here?"* **Female participant, 22 years old.**

PLHIV reported that having no one to remind them to take medication, or pick up their refills from the health facility when they don't have time, affects their adherence; *"When you are having issues with the family, you reach a point when you are not happy about the situation. In my family, I am the only one who takes medicine; the rest of my siblings are HIV-free. I have to remind myself to take medicine and pick up my refills. If I fail, then no one in the family cares."* **Male participant, 28 years old.**

Key informants revealed that some alcoholics believe that alcohol can kill the virus, and hence there is no need to swallow the medicine; *"...they always tell you, but me, I always take my bottle of waragi. That one will kill the virus. I have to rest a bit from taking drugs. You see, this waragi will kill the virus. It will go to sleep. Until I wake up in the morning, and I swallow."* **Female healthcare provider, working for 20 years at the facility.**

The great relatability of the health workers, good care at the facility, and proper counseling enhance adherence. An informant narrated, *".....that great relatability at this facility is what motivates us to come and pick up medicine on appointments and hence not miss swallowing. If you people were not treating us well, we wouldn't come back."* **Male participant, 25 years old.**

Limited and inadequate counseling, before being switched to DTG, especially if PLHIV are not told about the probable side effects, might lead to failure to take the medicine. An in-depth informant explained, *"When they were switching my medicine to this one tablet, they told me, let us try this one and see. They did not tell me about side effects."* **Female participant, 19 years old.**

DISCUSSION

Prevalence of suboptimal adherence to Dolutegravir-based ART regimens

Approximately 49 out of 100 adult PLHIV were suboptimally adherent to their DTG-based regimens. This is high considering that Uganda aims to increase ART adherence to 95% by 2025 (17). Non-adherent PLHIV are given shorter appointments, and the clinic distributes ART to adherent PLHIV in the surrounding communities of Kampala and Wakiso districts every Friday. A greater number of non-adherent PLHIV attend the facility, hence this level of suboptimal adherence.

The high suboptimal adherence to dolutegravir is possibly because of the high poverty level in Uganda. Although only 19.9% of the participants were unemployed, and 10% had no monthly income, this income was low, with 64.5% living below the poverty line (<1.77 United States Dollars/person/day) (23). Therefore, most participants lack access to food and transportation to collect refills, resulting in low adherence to DTG. These results are higher than those found in the NAMSAL trial (31%) (9), possibly because it used self-reports combined with pill counts. However, the results are consistent with a cross-sectional study (10) and a prospective cohort in Tanzania (24).

Factors associated with suboptimal adherence to dolutegravir-based regimens

The prevalence of suboptimal adherence was 25% higher among participants who drank alcohol than among those who did not drink alcohol. Alcohol consumption is usually associated with HIV-related stigma. In-depth interviews revealed that stigma leads to anxiety, depression, discrimination at work or home, and suicidal tendencies. This forces PLHIV to drink a lot of alcohol to overcome peer pressure, resulting in suboptimal adherence. Drinking too much alcohol can lead to alcohol overdose, resulting in vomiting and mental confusion, hence suboptimal adherence (25). The findings are consistent with a study in Uganda, which reported that alcohol consumption was significantly associated with suboptimal ART adherence (26).

Participants who did not have social support were 21.5% less likely to have suboptimal adherence than those who did. This may be because PLHIV without social support tend to take charge of their lives. They improvise all sorts of ways to remind themselves to take their medication every day. In-depth interviews revealed that these PLHIV set alarm clocks and have calibrated medicine storage tins for each day of the week. They know that if they relapse, no one will take care of them, so they avoid non-adherence as much as possible. A lack of social support can motivate adherence. However, in-depth interviews also revealed that having someone to remind participants to take their medication and to attend their medication appointments, as well as having someone to help them collect their medication from the facility, improves adherence. A systematic review also reported that social determinants influence the type of support available for PLHIV of all ages, which affects ART adherence (27). A study in Uganda also reported that strong social networks help to overcome many barriers to ART adherence (28).

The prevalence of suboptimal adherence was 55.8% lower among participants who preferred to talk to the doctor about any health problem than among those who preferred to talk to the counselor. The doctor is the most preferred contact in this study (59.84%). Patients only interact with the counselor if they are non-adherent or if they feel there is a need. In-depth interviews showed that some patients prefer certain doctors because they are the only ones who

understand them and can allay their fears about side effects, and any other challenges of DTG treatment, thus improving adherence. Another study in Brazil reported that patients who did not receive or understand counseling about ART from health professionals had lower adherence to DTG (11). The prevalence of suboptimal adherence was 27% higher among unemployed participants than among those in employment. Interestingly, we learned from in-depth interviews that unemployment might be related to other factors such as depression, alcohol consumption due to redundancy, and lack of food, which may affect adherence. Depression is a major problem among the unemployed (29). Depression is associated with poor medication adherence in several chronic diseases (30). Work commitments may prevent someone from collecting refills or taking their medication, hence deterring DTG adherence. The ADVANCE trial reported that unemployment combined with younger age was associated with suboptimal adherence to DTG (9), and a meta-analysis reported that employed people are more likely to adhere to ART than their unemployed counterparts (31).

Generalizability of findings

The specialized clinic acts as a referral for all HIV clinics in the country; hence, the results are generalizable nationally.

Conclusion

The prevalence of suboptimal adherence to DTG-based regimens among PLHIV was high. Alcohol consumption and unemployment were positive predictors, while lack of social support and preferred healthcare provider (doctor) were negative predictors of suboptimal adherence. Barriers to dolutegravir adherence included: unemployment, lack of social support, alcohol consumption, and inadequate counseling.

Limitations

The main limitation of the study was that the population sampled might have overestimated the true burden of suboptimal adherence, given that the site served as a referral point for third-line ART in the country. However, this was reduced by systematic sampling so that each PLHIV had an equal chance of participating in the study.

The alcohol assessment did not use a validated tool to adequately measure alcohol consumption. However, the study had a qualitative aspect, which strengthened the evidence about the barriers to DTG adherence.

Recommendations

Interventions such as start-up projects to address social vulnerability, including unemployment, should be implemented for PLHIV. Dolutegravir-related virological failure due to non-adherence in PLHIV should be investigated.

Consent for publication

Not applicable

Availability of data and materials

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

Competing interests

The authors declare that they have no competing interests.

Funding

Mulago National Referral Hospital provided NE with salary support. The Joint Clinical Research Center provided HM with salary support. Makerere University provided FEK, RK, and JNK with salary support. The authors received financial support during the writing of this manuscript from a UK Medical Research Council grant (MR/VO3510X/1) on drug safety research capacity building held by the Department of Pharmacology and Therapeutics, Makerere University.

Authors' contributions

NE, HM, and JNK designed and conceptualized the study. NE did the data cleaning, data management, and preliminary analysis of the data. NE, HM, FEK, ANK, RK, and JNK contributed to the data analysis and report writing. All authors contributed to the interpretation of findings. NE wrote the first draft of the paper. HM, FEK, ANK, RK, and JNK reviewed, revised, and contributed to writing the paper. All authors read and approved the final manuscript. NE, HM, FEK, ANK, RK, and JNK read and met the ICMJE criteria for authorship.

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All authors declared no conflict of interest

Acknowledgements

The authors extend their sincere thanks to the management of the study site, the research participants, and Makerere University for supporting the implementation of the study.

List of abbreviations

AIDS- Acquired Immunodeficiency Syndrome
aPR- Adjusted prevalence ratio
ART- Antiretroviral Therapy
CI- Confidence interval
DTG- Dolutegravir
HIV- Human Immunodeficiency Virus
MOH-Ministry of Health
PLHIV-People Living with HIV
RNA- Ribonucleic acid
SOMREC-School of Medicine Research and Ethics Committee**.**
UNAIDS-Joint United Nations Program on HIV/AIDS
WHO- World Health Organization

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PUBLISHER DETAILS

Student's Journal of Health Research (SJHR)
(ISSN 2709-9997) Online
(ISSN 3006-1059) Print
Category: Non-Governmental & Non-profit Organization
Email: studentsjournal2020@gmail.com
WhatsApp: +256 775 434 261
Location: Scholar's Summit Nakigalala, P. O. Box 701432, Entebbe Uganda, East Africa