

Antiretroviral therapy regimens associated with viral suppression in adolescents on HIV treatment in Kenya

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Abstract

Introduction: According to 2021 UNAIDS report, there were approximately 99,159 adolescents living with human immunodeficiency virus (HIV) in Kenya, with a viral suppression rate of 67%. There are limited studies in Kenya on the types of regimens associated with viral suppression among adolescents. Therefore, this study aimed to determine the antiretroviral therapy (ART) regimens associated with viral load suppression in adolescents on ART.

Material and methods: A retrospective cross-sectional analysis of 38,503 HIV-infected adolescents (age range, 10-19 years) receiving ART for at least 6 months with a documented viral load, was conducted. Data analyzed were Kenyan HIV program data obtained from electronic medical records of HIV-positive patients from January 2018 till December 2022.

Results: The viral suppression rate was 81.2%, distinctly higher than the 2021 UNAIDS estimate of 67% and the national suppression rate of 75% (2022). The highest viral suppression was found in the lamivudine (3TC) + dolutegravir (DTG) + tenofovir disoproxil fumarate (TDF) regimen (86.4%), followed by lamivudine (3TC) + abacavir (ABC) + dolutegravir (DTG) (81.6%) (AOR = 0.57, 95% CI: -0.52 to 1.65). Lamivudine (3TC) + atazanavir/ritonavir (ATV/r) + tenofovir (TDF) exhibited a viral suppression of 70.1% (AOR = 0.4, 95% CI: -0.34 to 0.45), lamivudine (3TC) + ritonavir/atazanavir (ATV/r) + zidovudine (AZT) had viral suppression of 62.7% (AOR = 0.28, 95% CI: -0.24 to 0.32), while lamivudine (3TC) + zidovudine (AZT) + lopinavir/ritonavir (LPV/r) was found with 62.2% rate (AOR = 0.23, 95% CI: -0.21 to 0.26), lamivudine (3TC) + zidovudine (AZT) + dolutegravir (DTG) with 58.7% (AOR = 0.2, 95% CI: -0.17 to 0.22), and lamivudine (3TC) + abacavir (ABC) + lopinavir (LPV/r) with 56.4% (AOR = 0.18, 95% CI: -0.16 to 0.20).

Conclusions: The viral suppression rate for adolescents was 81.2%. It is crucial to expedite treatment optimization for youths with non-optimal regimens to prevent treatment failure and ensure achieving the UNAIDS target of 95%. A comprehensive examination of viral suppression rates for adolescents on protease inhibitors is essential with consideration of shifting to optimal regimens, thereby improving treatment outcomes.

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Introduction

Globally, approximately 1.7 million adolescents aged 10-19 years lived with human immunodeficiency virus (HIV) in 2019 [1]. Adolescents represent a significant population of people living with HIV in the world. In 2020, approximately 410,000 of young people aged between 10 and 24 years were reported as newly infected with HIV, whereas 150,000 were reported as adolescents aged 10-19 years. The study further reported that youths constitute 5% of all people living with HIV [2]. Out of the 1.7 million adolescents infected with HIV, 1.5 million live in sub-Saharan Africa, representing 88% of youths living with HIV [2]. In 2020, UNICEF reported that HIV has been documented as one of the leading causes of death in Africa's youngsters aged between 10-24 years, and further noted that the number of adolescents living with HIV has increased annually by approximately 30%, while the number of their deaths has been increasing exponentially due to HIV-related complications [2].

Antiretroviral therapy (ART) is a significant breakthrough in the management of HIV infection, particularly in achieving viral load (VL) suppression. The type of regimen at initiation has been identified as a crucial factor in achieving VL suppression among people living with HIV, including adolescents [2]. The goal of ART is to inhibit HIV replication, protecting HIV-infected individuals from opportunistic infections and mortality from acquired immunodeficiency syndrome (AIDS), while also preventing spreading of the virus [3]. The choice of antiretroviral regimen should be individualized based on patient's specific clinical and virologic characteristics as well as potential drug interactions and other related considerations.

ART can lead to rapid and sustained reduction in viral load, with many people achieving undetectable levels of the virus within several months of starting a treatment. Undetectable VL means that the amount of virus in the bloodstream is so low that it cannot be detected by standard laboratory tests. Achieving and maintaining an undetectable VL is the goal of ART, as it not only improves the health outcomes of people living with HIV but also reduces the risk of transmitting the virus to others [4]. Virologic suppression refers to a VL of < 200 copies/ml of blood, 6 months of taking ART (according to the Kenya HIV prevention and treatment guidelines, 2022).

The Kenya national HIV prevalence stands at 4.9%, with approximately 1.5 million people estimated to be living with HIV [5]. Adolescents and young people (aged, 10-24 years) constitute 34% of the country's population of 47.5 million [6]. According to global and regional UNAIDS HIV estimates for Kenya, there is a concern that 41% of all new adult HIV infections occur among 10-24 years old youths. Therefore, the focus on adolescents and young people as a key population in the HIV response is of paramount importance. The study aimed to bridge these gaps by determining the ART regimens associated with viral suppression among HIV-positive adolescents in Kenya,

in order to guide regimen selection that can lead to virologic suppression. The results of this study may improve the management of adolescents infected with HIV and their treatment outcomes.

Material and methods

Study population

The population of interest was HIV-positive adolescents in Kenya, who have been on ART for at least six months with VL results documented.

Sample selection

Data analyzed in the study were electronic medical records (EMR) data from HIV program (Kenya National AIDS and STI Control Program, NASCOP) of 38,503 HIV-infected adolescents receiving ART for at least six months with documented VL results, for the period of January 2018 – December 2022. Virologic suppression was defined as no more than 200 HIV RNA copies per mL, as guided by the Kenyan 2022 ART guidelines.

Inclusion criteria

HIV-infected patients aged 10-19 years, who had been initiated on ART and remained active in care, taking ARVs for at least six months, with a documented VL result.

Statement of ethical approval

Ethics approval was sought from the AMREF Ethics and Scientific Review Committee (ESRC), reference number: P1284-2022, after which a research permit was obtained from the National Commission for Science, Technology, and Innovation (NACOSTI) (Ref. No: 394047). Administrative approval was given by the Ministry of Health at the National AIDS and STI Control Program (NASCOP). Patients' identifiers were not collected and remained purely anonymized to maintain information confidentiality of all participants.

Statement of informed consent

A waiver of consent was sought from the Ethics and Scientific Review Committee, because the study utilized retrospective data. This was inevitable, since seeking consent from all the study subjects was not feasible. Research subjects were estimated to be approximately 120,000 medical records of adolescents on care, and therefore the study could not practically be conducted without a waiver of consent. Data collection involved gathering of purely anonymized retrospective data, and the results would not change the care that the study subjects have already received.

Study design

A retrospective cross-sectional analysis of 38,503 HIV-infected adolescents receiving ART for at least six months with a documented valid VL result, was conducted.

Data analysis

Data analysis was done using SPSS version 28 to estimate the proportion of patients with virological suppression and specific ART regimens used. Descriptive analysis was employed to summarize data with continuous variables, such as age and viral load. A total of 38,503 patient records who met the inclusion criteria were analyzed to identify factors associated with viral suppression. To explore associations of viral suppression, bivariate and multivariate logistic regression analyses were conducted using Stata version 15.0 (Stata Corporation, College Station, TX, USA). Univariate analyses were applied to describe socio-demographic and treatment characteristics of the study population. While bivariate analyses were used to determine strengths of association between the independent variables and the outcome variable (viral suppression status). Adjusted odds ratios (AOR) and 95% confidence intervals (CI) were calculated. Statistically significant variables in bivariate analysis were included in multivariate analysis. Multivariate logistic regression was employed to identify factors independently associated with viral suppression. AOR and 95% CI were calculated. Cut-off for statistical significance was set at a *p*-value of less than 0.05.

Results

From the data obtained, 52.9% of the adolescents were between 15-19 years old, while 47.1% were between 10-14 years old. Out of this, in the age group of 15-19 years old, 48.62% were males and 51.3% were females. In the other age set of 10-14 years, males were 49.76% and females were 50.24%.

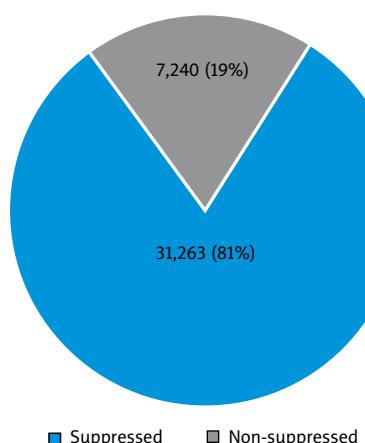


Figure 1. Viral suppression and viral non-suppression rates among adolescents aged 10-19 years on antiretroviral therapy in Kenya

The ART regimen of lamivudine (3TC) + dolutegravir (DTG) + tenofovir disoproxil fumarate (TDF) showed the highest viral suppression rate at 86.4%. Similarly, the lamivudine (3TC) + abacavir (ABC) + dolutegravir (DTG) regimen also showed a high viral suppression rate of 81.6% (AOR: 0.57, 95% CI: -0.52 to 1.65). The lamivudine (3TC) + atazanavir/ritonavir (ATV/r) + tenofovir (TDF) regimen exhibited a viral suppression rate of 70.1% (AOR: 0.4, 95% CI: -0.34 to 0.45), which was relatively lower but still significant. The other ART regimens demonstrated lower viral suppression rates among adolescents in Kenya, with lamivudine (3TC) + atazanavir/ritonavir (ATV/r) + zidovudine (AZT) at 62.7% (AOR: 0.28, 95% CI: -0.24 to 0.32), lamivudine (3TC) + zidovudine (AZT) + lopinavir/ritonavir (LPV/r) at 62.2% (AOR: 0.23, 95% CI: -0.21 to 0.26), Lamivudine (3TC) + zidovudine (AZT) + dolutegravir (DTG) at 58.7% (AOR: 0.2, 95% CI: -0.17 to 0.22), and lamivudine (3TC) + abacavir (ABC) + lopinavir (LPV/r) at 56.4% (AOR: 0.18, 95% CI: -0.16 to 0.20).

Discussion

Viral suppression

Our study involved 38,503 HIV-infected adolescents on ART in Kenya, of whom 31,263 (81.2%) achieved viral suppression. Though below the global UNAIDS target of 95%, it surpasses the current national rate of 75% (Kenya Health Information System, 2022). This 81.2% viral suppression rate among Kenyan adolescents is a positive outcome, indicating successful suppression of the virus with appropriate treatment. This finding highlights the importance of continued efforts to provide effective treatment and care to all adolescents living with HIV, ultimately reducing the virus transmission and enhancing health outcomes.

However, it is essential to acknowledge that a significant proportion of youths in the study (18.8%) did not achieve viral suppression, being at risk of disease progression and potential virus transmission. This highlights the urgency to enhance accessibility and acceptance of ART as well as support adherence for these adolescents.

While the 81.2% viral suppression rate among Kenyan adolescents is promising, there remains room for improvement in ensuring that all HIV-infected adolescents receive optimal ART and adherence support. Continued efforts are required to address the unique needs and challenges faced by this population, ultimately working towards the goal of ending the HIV epidemic. Efforts should focus on providing comprehensive care and support, empowering adolescents to manage their condition effectively, and reduce the risk of onward transmission (Figure 1).

Types of regimens and viral suppression

ART significantly improves treatment outcomes of HIV-infected patients; however, factors, such as adverse drug reactions, poor adherence, and drug resistance, have been shown

to increase the likelihood of clinical and virologic failure [7]. The choice of ART regimen can also influence viral suppression and, as demonstrated by an American study [8], molecules, such as integrase inhibitors and non-nucleoside reverse transcriptase inhibitors, were linked to higher rates of viral suppression when compared with other regimens. The long-term good health of adolescents living with HIV who started ART dependent on achieving and maintaining viral suppression.

The following are the findings of ART regimens used in Kenya for the management of adolescents living with HIV (Tables 1-3).

3TC + DTG + TDF

The current study showed that the 3TC+DTG+TDF regimen was the most common ART option used for HIV management in adolescents in Kenya, found in 63.7% of pa-

Table 1. Types of antiretroviral therapy (ART) regimens and frequencies among adolescents on ART aged 10-19 years in Kenya (N = 38,503)

No.	Type of regimen	n (%)
1	3TC+DTG+TDF	24,517 (63.7)
2	3TC+ABC+DTG	6,742 (17.5)
3	3TC+ATV/r+TDF	1,527 (4.0)
4	3TC+ATV/r+AZT	924 (2.4)
5	3TC+AZT+LPV/r	1,686 (4.4)
6	3TC+AZT+DTG	1,167 (3.0)
7	3TC+ABC+LPV/r	1,018 (2.6)
8	Others	922 (2.4)

3TC – lamivudine, DTG – dolutegravir, TDF – tenofovir disoproxil fumarate, ABC – abacavir, ATV/r – atazanavir/ritonavir, AZT – zidovudine, LPV/r – lopinavir/ritonavir

Table 2. Types of regimens and viral suppression

Variable/Regimen	Viral suppression		χ^2 value	p-value
	Suppressed, n (%)	Unsuppressed, n (%)		
Type of regimen				
3TC+DTG+TDF	21,191 (86.4)	3,326 (13.6)	2,093.413	0.000
3TC+ABC+DTG	5,499 (81.6)	1,243 (18.4)		
3TC+ATV/r+TDF	1,070 (70.1)	457 (29.9)		
3TC+ATV/r+AZT	579 (62.7)	345 (37.3)		
3TC+AZT+LPV/r	1,048 (62.2)	638 (37.8)		
3TC+AZT+DTG	685 (58.7)	482 (41.3)		
3TC+ABC+LPV/r	574 (56.4)	444 (43.6)		
Others	617 (66.9)	305 (33.1)		

3TC – lamivudine, DTG – dolutegravir, TDF – tenofovir disoproxil fumarate, ABC – abacavir, ATV/r – atazanavir/ritonavir, AZT – zidovudine, LPV/r – lopinavir/ritonavir

Table 3. Antiretroviral therapy regimens associated with viral suppression

Variables	UAR (95% CI)				AOR (95% CI)			
	OR	p-value	LCL	UCL	OR	p-value	LCL	UCL
Age (years)								
15-19	1				1			
10-14	1.169	0.00	1.11	1.231	1.27	0.00	1.181	1.357
ART regimen								
3TC+DTG+TDF	1				1			
3TC+ABC+DTG	0.694	0.00	0.646	0.746	0.57	0.00	0.523	0.615
3TC+ABC+LPV/r	0.203	0.00	0.178	0.231	0.18	0.00	0.156	0.204
3TC+ATV/r+TDF	0.367	0.00	0.327	0.412	0.40	0.00	0.359	0.454
3TC+ATV/r+AZT	0.263	0.00	0.229	0.302	0.28	0.00	0.239	0.316
3TC+AZT+DTG	0.223	0.00	0.197	0.252	0.20	0.00	0.172	0.221
3TC+AZT+LPV/r	0.258	0.00	0.232	0.286	0.23	0.00	0.206	0.256
Others	0.318	0.00	0.275	0.366	0.31	0.00	0.271	0.362

OR – odds ratio, LCL – lower control limit, UCL – upper control limit, 3TC – lamivudine, DTG – dolutegravir, TDF – tenofovir disoproxil fumarate, ABC – abacavir, LPV/r – lopinavir/ritonavir, ATV/r – atazanavir/ritonavir, AZT – zidovudine, LPV/r – lopinavir/ritonavir

tients, with an impressive 86.4% viral suppression rate. While falling short of the global UNAIDS target, it surpasses the current national rate. As the recommended first-line ART regimen as per Kenyan guidelines, achieving an 86.4% suppression rate signifies its promising effectiveness in managing HIV among young people. Previous studies also support its efficacy in attaining and maintaining viral suppression among individuals living with HIV. A study by Taiwo *et al.* [9] reported that a two-drug regimen of DTG+3TC was effective in maintaining viral suppression in HIV-infected patients through 48 weeks. The study found that at 48 weeks, viral suppression (defined as HIV-1 RNA < 50 copies/ml) was maintained in 95% of participants.

It is worth considering that achieving an 86.4% suppression rate may not be sufficient for some patients to reach the desired undetectable VL level, which is the primary goal of HIV treatment. Despite this, the combination therapy of 3TC+TDF+DTG shows promise for HIV treatment. However, close monitoring and strict adherence to the regimen are crucial factors in ensuring its success.

3TC + ABC + DTG

The study revealed that HIV-infected adolescents using 3TC+ABC+DTG achieved a suppression rate of 81.6%, and the results were statistically significant ($p < 0.001$). Although the viral suppression rate fell below the global UNAIDS target of 95%, it was notably higher than the national rate of 75% reported by the Kenya Health Information System (KHIS, 2022).

These findings agree with a study by Cahn *et al.* [11], who found that the 3TC+ABC+DTG combination was non-inferior to the standard regimen in terms of achieving viral suppression at 48 weeks, with 89% of participants in the 3TC+ABC+DTG group achieving viral suppression compared with 93% of individuals in the standard regimen group.

The combination of 3TC+ABC+DTG is one of the recommended first-line ART regimen for treating HIV in Kenya, and considered an optimal regimen for adolescents who weigh less than 30 kg. Generally, the viral suppression of 81.6% exhibited high efficacy in achieving viral suppression among adolescents living with HIV in Kenya compared with other ART regimens. This regimen may be considered by healthcare providers when choosing an optimal ART regime.

3TC + ATV/r + TDF

The 3TC+ATV/r+TDF regimen achieved a suppression rate of 70.1%, which is below the global UNAIDS target of 95% and the national rate of 75% (KHIS, 2022). Nevertheless, our study observed relatively good treatment outcomes with this regimen. In Kenya, it is considered a second-line ART option for adolescents living with HIV-1 infection, who have experienced treatment failure

or intolerance to first-line therapy, according to the Kenya HIV prevention and treatment guidelines (2022).

A retrospective study by Dong *et al.* [12] observed that 68% of patients presenting with a VL of 400 copies/ml achieved suppression using 3TC+ATV/r+TDF treatment. The study concluded that this regimen was well-tolerated, safe, and maintained viral suppression. Another study by Lennox *et al.* [13] demonstrated that after 96 weeks of treatment, 85% of participants on the 3TC+ATV/r+TDF regimen achieved viral suppression.

Generally, the combination of 3TC+ATV/r+TDF appears to be an effective ART regimen for achieving and maintaining viral suppression in individuals living with HIV. However, it is important to note that individual response to ART tends to vary, hence the need to closely monitor adherence to medication as well as VL in order to optimize treatment outcomes.

3TC + ATV/r + AZT

The effectiveness of the 3TC+ATV/r+AZT regimen was examined, and the results revealed a viral suppression rate of 62.7%. This rate is notably lower than both the global UNAIDS target of 95% and the existing national suppression rate of 75% (KHIS, 2022). It is essential to emphasize that, currently, this specific regimen is not recommended as a standard ART option for adolescents living with HIV-1 infection in Kenya. However, despite this recommendation, our study found a significant number of youths in Kenya still receiving this regimen.

These findings shed light on the need to re-evaluate the usage and efficacy of the 3TC+ATV/r+AZT regimen in the context of HIV management in adolescents in Kenya. Further research and considerations are warranted to understand the reasons for its continued use, and its impact on viral suppression and overall treatment outcomes in this specific population. The ACTION study [14], however, demonstrated that after 48 weeks of ART, 32% of patients treated with 3TC+ATV/r+AZT regimen maintained viral suppression below 50 copies/ml.

While a viral suppression rate of 62.7% is not as high as some other ARTs, it is still a significant improvement over no treatment or less effective therapies. Nevertheless, it is important to note that individual response to ART tends to vary and should be closely monitored. There may be a need to consider a switch to other optimal regimens as recommended by the national ART guidelines.

3TC + AZT + LPV/r

Based on the study, only 4.4% of adolescents on 3TC+AZT+LPV/r achieved a viral suppression rate of 62.2%. This rate is notably lower than both the national suppression rate of 75% (KHIS, 2022) and the global UNAIDS target of 95%.

The findings contradict a Kenyan study by Ndemwa *et al.* [15], who found that lopinavir/ritonavir-based regimens were

effective in suppressing HIV viral load and improving CD4+ counts in HIV-infected patients in Kenya. Specifically, the study found that 89.8% of patients achieved viral suppression (defined as HIV VL < 400 copies/ml) after six months of treatment, and 95.1% of patients achieved viral suppression after 12 months of treatment. The study concluded that lopinavir/ritonavir-based regimens should continue to be used as a treatment option for HIV-infected patients in Kenya, as they are effective and safe in suppressing HIV VL and improving immune function.

The CASTLE study [16] concluded that the 3TC+AZT+LPV/r combination was non-inferior to the standard regimen in terms of achieving viral suppression at 48 weeks, with 84% of patients achieving viral suppression. Protease inhibitors (PI)-based regimens were demonstrated to be effective in suppressing VL for HIV treatments. Nevertheless, it is important to note that the effectiveness of any ART regimen can vary depending on individual patient characteristics. This calls for close monitoring and further research to attain and maintain viral suppression.

3TC + AZT + DTG

In the present study, HIV-infected adolescents on the 3TC+AZT+DTG regimen exhibited a remarkable suppression rate of 58.7%. This rate is notably lower than both the current national rate of 75% (KHIS, 2022) and the global UNAIDS target of 95%. However, it is essential to note that the 3TC+AZT+DTG regimen remains recommended by the World Health Organization (WHO) as the preferred first-line ART option for adults and adolescents living with HIV, despite the lower suppression rate observed in the current study. However, the findings differ with the GEMINI-1 and GEMINI-2 studies [10], which compared the 3TC+AZT+DTG combination with two other regimens. The study demonstrated that this regimen was effective in reaching viral suppression at 48 weeks, with 89-93% of participants in this group achieving viral suppression.

This first-line ART regimen in Kenya has been shown by other studies to be highly effective in achieving viral suppression; however, a suppression rate of 58.7% is relatively low compared with the current standard of care. Effectiveness of ART among adolescents can be influenced by several factors, such as adherence to treatment and drug resistance. Therefore, it is important to further interrogate individual patient characteristics, which could have influenced these results as well as rationale of this regimen selection.

3TC + ABC + LPV/r

Surprisingly, the study established that the HIV-positive adolescents who were started on a combination of 3TC+ABC+LPV/r, achieved a viral suppression of 56.4%. This suppression rate is markedly lower than the global UNAIDS target of 95% as well as the current national suppression rate of 75% (KHIS, 2022). In Kenya, this PI-based combination

is used as a first-line regimen for adolescents who weigh less than 30 kg, and has been shown to be effective in achieving viral suppression and improving long-term health outcomes in people living with HIV.

Our findings are in line with a study by Kityo *et al.* [17], demonstrating that children who were treated with ABC and LPV/r regimens took a longer time to achieve viral suppression and a shorter time to viral rebound (> 1,000 copies/ml). The children on ABC had an almost 2-fold increased risk of not achieving viral suppression by 12 months. These findings, however, are contrary to the LOLIPOP study [18], showing that the first 31 children who had completed the 4-in-1 regimen, i.e., lopinavir/ritonavir, abacavir, and lamivudine, confirmed safety, acceptability, and effectiveness in achieving and maintaining undetectable viral load. Majority of the children (76%) who had been on LPV/r-based ART for at least 6 months, had achieved viral suppression.

From our findings, the combination of 3TC+ABC+LPV/r displayed some limitations achieving viral suppression in adolescents living with HIV compared with other regimens, hence the need for healthcare providers to individualize ART regimens factoring patient-specific aspects, such as adherence to medication, when making treatment decision. In addition, there is need to conduct further research to determine the long-term effectiveness as well as cross-examine other factors affecting this combination's efficacy.

Other regimens

The findings from our study highlight an important concern regarding the viral suppression rates of other non-standard ART regimens used by HIV-infected adolescents. Among the 38,503 adolescents included in the study, 617 were using these non-standard regimens, and the overall viral suppression rate for this group was only 67%. This rate falls significantly below the global UNAIDS target of 95%. The data suggest that these non-standard regimens may not be as effective in achieving viral suppression compared with the recommended ART options. This poses a potential risk for treatment failure and disease progression among adolescents on such regimens. Therefore, it becomes imperative to closely monitor and evaluate the effectiveness of these non-standard regimens, and consider alternative approaches to optimize viral suppression rates among this vulnerable population. Efforts should be directed towards ensuring that all adolescents living with HIV have access to standardized and effective ART regimens.

Conclusions

The viral suppression rate among adolescents on ART was 81.2%, lower than the UNAIDS 95-95-95 global target but higher than the 2021 UNAIDS estimate of 67% as well as 2022 KHIS suppression rate of 75%. There was a better suppression in adolescents who were on DTG-based regimens compared with those using protease inhibitors either

as first- or second-line regimens. There is a need to interrogate the viral suppression rate, especially for adolescents on protease inhibitors-based combinations, and consider switching to optimal regimens in order to accomplish better treatment outcomes.

Disclosures

1. Institutional review board statement: The study was approved by the Ethics Committee of the AMREF Ethics and Scientific Review Committee (ESRC), reference number: P1284-2022, after which a research permit was obtained from the National Commission for Science, Technology, and Innovation (NACOSTI) (Ref. No: 394047). Administrative approval was given by the Ministry of Health at the National AIDS and STI Control Program (NASCOP).
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