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Investigating the prevalence of abnormal coagulation factors in people living with Human Immunodeficiency Virus on Antiretroviral Therapy: A retrospective cohort.

Sibusiso Sidandala, Nokukhanya Thembane, Ziningi Nobuhle Jaya*
Department of Biomedical Sciences, Faculty of Applied and Health Science, Mangosuthu University of Technology, South Africa, Durban

Abstract

Background
The prevalence of coagulation abnormalities in people living with human immunodeficiency virus (PLHIV) has reduced due to highly active antiretroviral therapy (HAART). However, HAART for HIV may harm the liver, resulting in the disruption of coagulation factor production in the liver. Therefore, it is imperative to understand the extent of coagulation abnormalities within this population to inform healthcare management and intervention strategies. This research aimed to investigate the prevalence of abnormal coagulation factors in PLHIV.

Methodology
This study analysed retrospective laboratory data from HIV-positive individuals on HAART in eThekwini District Municipality, collected between January 2021 and January 2022 at a tertiary hospital laboratory in Durban. The investigation focused on coagulation factor profiles in this patient population. All results were obtained from the National Health Laboratory Services (NHLS) Academic Affairs and Research Management System (AARMS). Excel was used to conduct descriptive statistics, and GraphPad Prism was utilised for comparative analyses (Spearman correlations) to evaluate factor abnormalities.

Results
Fifty-seven percent of the results were from females, and a significant portion of the results were for individuals aged between 35 to 54 years. A total of 70% of the prothrombin time (PT) results and 16.5 of % activated partial thromboplastin time (aPTT) results were abnormally above the normal range. Women were disproportionately affected by this abnormality at 55,5%. There was a poor and significant inverse correlation between CD4 cell count and PT and INR.

Conclusion
The study findings highlighted notable coagulation abnormalities among HIV infected patients on HAART, with a particularly higher prevalence among females and individuals aged between 35 – 54 years.

Recommendation
Regular monitoring of coagulation factors is imperative for early identification of individuals at risk of developing related abnormalities and thus informs the development of effective healthcare interventions.

Keywords: *People-living-with-HIV; Highly active antiretroviral therapy; Coagulation factors*
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Corresponding author: *Ziningi Nobuhle Jaya**
Email: ***jaya.nobuhle@mut.ac.za***
Department of Biomedical Sciences, Faculty of Applied and Health Science, Mangosuthu University of Technology, South Africa, Durban

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Introduction

The prevalence of human immunodeficiency virus (HIV) infection remains a significant global health concern, with an estimated 39 million people living with the virus worldwide and approximately 1.3 million new infections reported annually (UNAIDS, 2023). As of 2023, 29.8 million individuals are on antiretroviral therapy (ART), with varying regimens across different regions (WHO, 2023; Mwavika et al., 2024). South Africa bears the highest burden of HIV globally, with approximately 7.8 million adults (aged 15–49 years) living with the virus (UNAIDS, 2023; Payagala & Pozniak, 2024). By 2022, an estimated 71% of South African PLHIV were receiving ART, reflecting progress achieved in treatment accessibility (SANAC, 2023).

The introduction of highly active antiretroviral therapy (HAART) improved HIV management, enabling viral suppression to undetectable levels and significantly improving patient outcomes (Eissa, 2025). Beyond its virological benefits, HAART has also contributed to a 40–60% reduction in HIV-related haematological abnormalities, including anaemia, thrombocytopenia, and coagulation disorders (Gunda & Kirenga, 2019; Mbah & Okam, 2021; Mandania, 2024). However, despite this, HAART has considerable adverse effects on users, and long-term HAART use has been associated with increased risks of hepatotoxicity and liver disease among PLHIV (Puoti et al., 2017; Pedreiras, 2024). Given the liver's central role in synthesizing coagulation factors, hepatic impairment can lead to coagulation dysregulation, which complicates the clinical management of HIV (Tantia, 2024).

HIV infection and long-term HAART use contribute to significant disruptions in the coagulation system, manifesting as either hypercoagulability (increased thrombosis risk) or hypocoagulability (bleeding tendencies) (Obeagu & Obeagu, 2024). Chronic inflammation in HIV drives elevated levels of Factor VIII and fibrinogen, promoting a prothrombotic state linked to venous thromboembolism (VTE) and cardiovascular complications (Funderburg, 2014; Baker et al., 2021; Perkins et al., 2023). This hypercoagulability is further exacerbated by immune-mediated tissue factor (TF) upregulation (Jiang et al., 2020) and is detectable via laboratory markers including activated partial thromboplastin time (aPTT) and reduced international normalised ratio (INR) (Tripodi & Mannucci, 2019; Levi & van der Poll, 2017). Conversely, hypocoagulability often arises from HAART-induced hepatotoxicity, which impairs synthesis of vitamin K-dependent factors (II, VII, IX, X), or from HIV-associated thrombocytopenia (Sloand, 2005; Tripodi et al., 2011; Tan et al., 2023). These deficits present as prolonged prothrombin time (PT), PT/INR (extrinsic pathway dysfunction), or elevated aPTT (intrinsic pathway impairment). Additionally, advanced HIV with CD4 counts of <200 cells/μL correlates with elevated D-dimer and fibrinogen, reflecting endothelial dysfunction and heightened coagulation activity (Baker et al., 2021; Bashir et al., 2023).

Given the risks associated with both thrombosis and haemorrhage in PLHIV on HAART, monitoring coagulation factors through Therapeutic Drug Monitoring (TDM) is essential to assess and manage thrombotic or bleeding risks (Zhang et al., 2022). TDM plays a critical role in adjusting ART regimens to reduce adverse drug interactions and ensure optimal drug levels that support both viral suppression and the prevention of coagulation abnormalities (La Via et al., 2025).

Previous studies have shown that ART can enhance the coagulation profiles in HIV-infected patients by improving platelet count and aPTT (Opoku et al., 2024). Monitoring the pharmacokinetics of ART and associated biomarkers, such as PT, aPTT, INR, and CD4 cell counts, can help clinicians tailor interventions to prevent coagulation dysfunction and enhance clinical outcomes for PLHIV (Nel et al., 2023).

Understanding the prevalence and mechanisms of coagulation abnormalities through TDM is especially crucial in regions with high HIV prevalence (Getawa & Adane, 2022). South Africa, with the highest HIV burden globally, presents a unique setting for this investigation. The province of KwaZulu-Natal, with an HIV prevalence of 27.9% among adults aged 15–49 years (significantly higher than the national average), offers an ideal location for studying the relationship between HAART, coagulation factors, and the need for TDM (SANAC, 2022; Kitenge et al., 2025). This study specifically aimed to evaluate coagulation profiles in HIV patients on HAART by assessing PT, aPTT, INR, and CD4 cell counts, to inform the development of targeted TDM-based clinical strategies for improving treatment outcomes and minimizing coagulation-related complications in this population.

Methodology

Study design

This quantitative, cross-sectional study analysed retrospective laboratory data from the National Health

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Laboratory Service (NHLS) in Durban, KwaZulu-Natal, South Africa. The design enabled evaluation of coagulation parameters at a fixed time point using specimens collected between January 2021 and January 2022.

Study population and location

The study included HIV-positive adults (>35 years) on antiretroviral therapy (ART) who underwent coagulation testing at NHLS laboratories serving eThekwini Municipality. The population was unrestricted by gender, race, or ART regimen.

Sampling and sample size

Using the NHLS Academic Affairs Research Management System (AARMS), the study employed a comprehensive sampling of all eligible records meeting these criteria:

- Laboratory-confirmed HIV-positive status
- Current ART use
- Age 35 years and above at testing
- Coagulation profile results, including PT, aPTT, INR, CD4 count (the other coagulation factor tests were not routinely done, and so data were not available).

Statistical analysis

Results received from NHLS AARMS were entered into a Microsoft Excel spreadsheet, and Excel was used to conduct descriptive statistics of the data. GraphPad Prism was employed (Spearman's correlation) to evaluate the correlation between study variables.

Ethical considerations

Ethical approval was granted by the Mangosuthu University of Technology Institutional Research Ethics Committee (REF: RD5/25/2023) on 01 February 2023. Blinded data (with anonymised patient details) was received and securely stored in a manner only accessible to the researcher and supervisor.

Research results/Findings

Gender distribution analysis

The gender distribution in this dataset reveals distinct patterns. Of the total number of individuals, 8,436 are male, which makes up 42.14% of the overall population. Meanwhile, 11,237 individuals are female, comprising 56.13% of the total. This shows a clear majority of females in the dataset, outnumbering males by a notable margin. Additionally, 347 individuals, or 1.73%, are listed as having an unknown gender. While this represents a relatively small portion of the population, it highlights the presence of individuals whose gender was either not recorded or was not disclosed. Figure 1 offers a summary of the age (in years) composition within the dataset, providing a foundation for further analysis and insights.

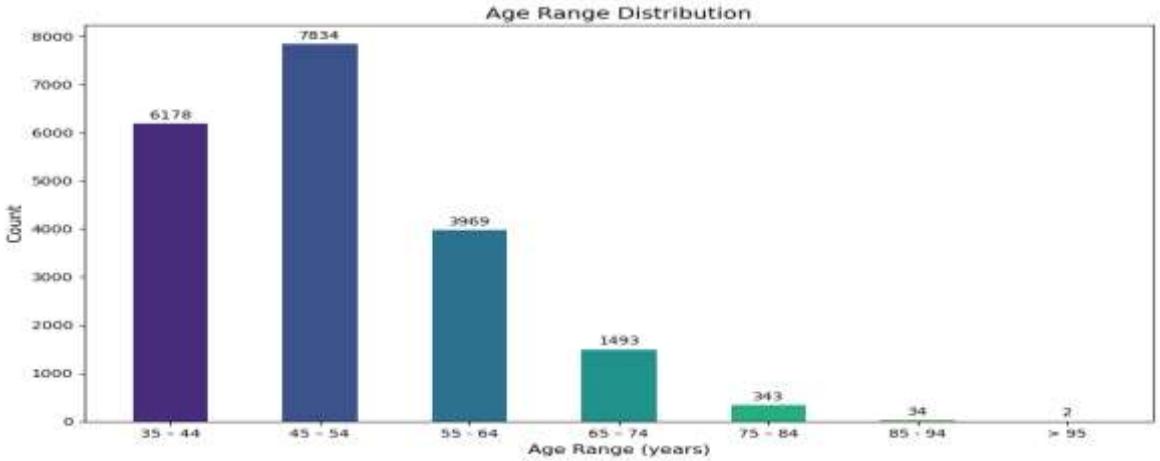

Figure 1: Age distribution of the study participants

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Statistical analysis of medical parameters

Table 1 presents the descriptive statistics for CD4, aPTT, PT, and INR test results conducted on HIV-infected patients in the eThekwini District, KwaZulu-Natal, South Africa, from January 2021 to January 2022. A total of 19,853 CD4 tests were performed, while 2,106 aPTT tests and 19,833 PT tests were conducted.

Table 1: Descriptive statistics of CD4, aptt, PT, and INR test results

Statistic	CD4	aPTT	PT	INR
Minimum	1	16.3	0.9	0.08
Maximum	3,815	119.5	147.1	15.62
Range	3,814	103.2	146.2	15.54
Mean	459.7	33.2	15.85	1.397
Standard Deviation	337.9	12.35	10.13	0.968
Standard Error of Mean	2.388	0.2691	0.0719	0.0068
Number of values	19,853	2,106	19,833	19,761

Prevalence of coagulation abnormalities

Prevalence of Abnormal Coagulation Results in HIV-Infected Patients of eThekwini District, KwaZulu-Natal, South Africa, from January 2021 to January 2022. Figure 2 illustrates the proportion of abnormal coagulation test results (including aPTT and PT) in the study population during the specified time frame.

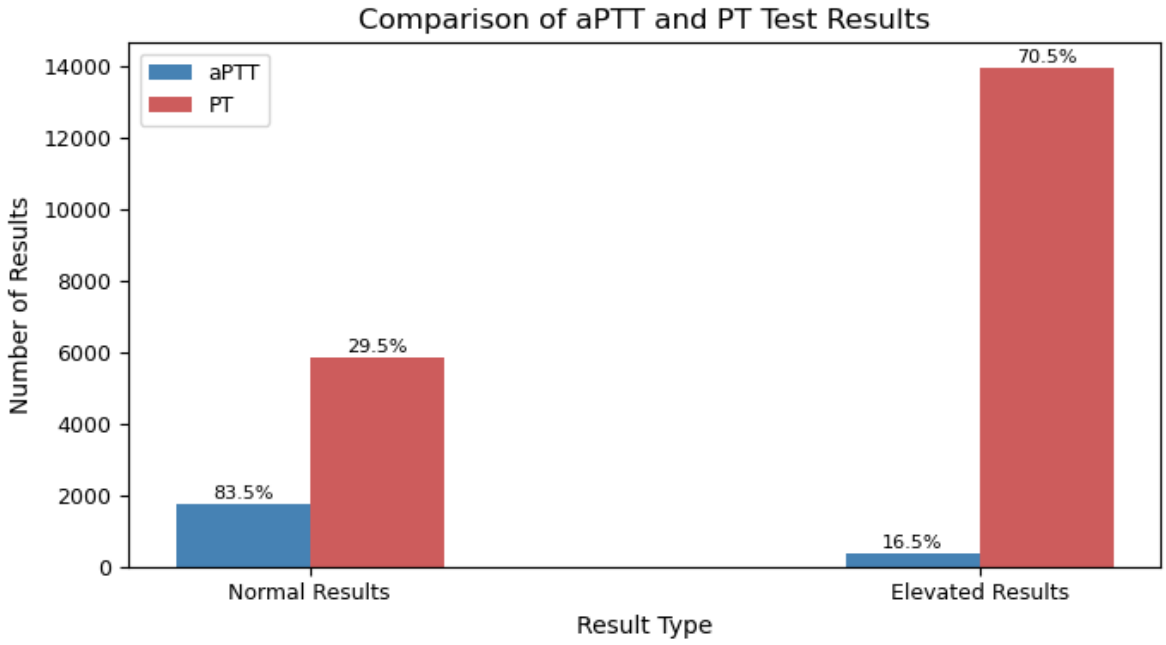

Figure 2: Comparison of aPTT and PT test results

Figure 3 illustrates a summary of the proportion of abnormally elevated aPTT and PTT among females and males. Overall, there was a higher proportion of elevated PT results compared to elevated aPTT across both genders.

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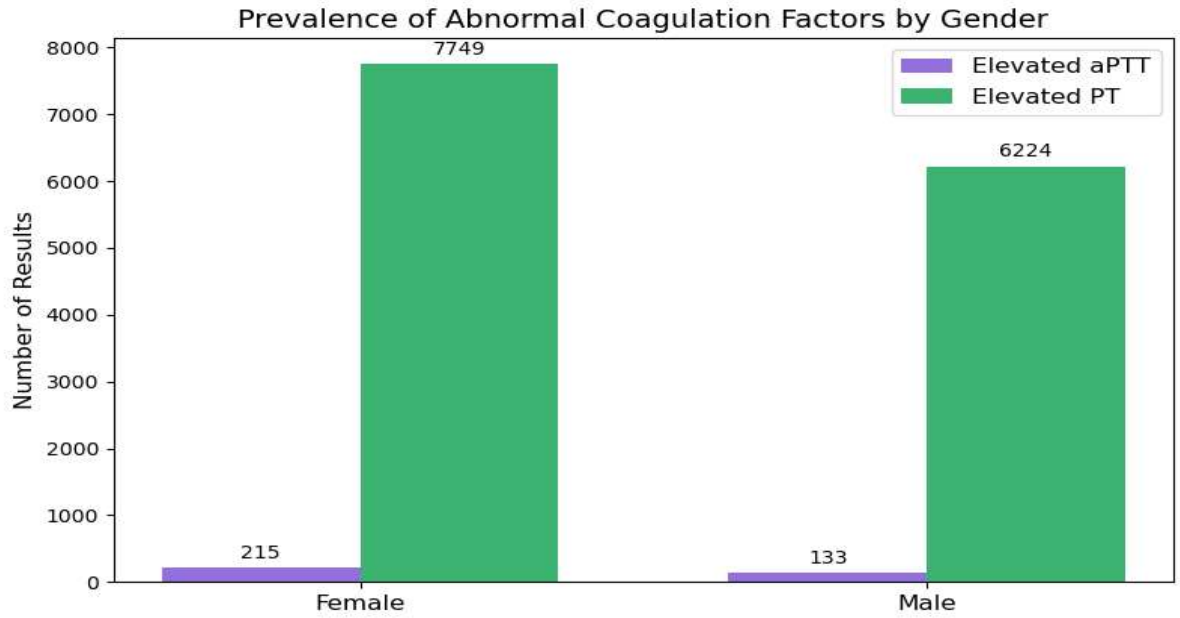

Figure 3: Prevalence of abnormal coagulation factors by gender

Correlation between CD4 count and coagulation parameters (aPTT, PT, and INR)

Table 3 presents a summary of the correlations between the CD4 count and the coagulation parameters aPTT, PT, and INR, along with the count of observations, 95% confidence intervals, and the significance of the results. The analysis shows that the aPTT results did not significantly correlate with the CD4 count ($r = -0.0528$, $p = 0.0154$). A poor but significant inverse correlation was observed between the CD4 count and PT results ($r = -0.0413$, $p < 0.001$). Similarly, the INR results showed a poor but significant inverse correlation with the CD4 count ($r = -0.0451$, $p < 0.001$).

Table 3: Correlation between CD4 count and coagulation parameters

Variables	Correlation	Count	Lower (95%)	Upper (95%)	Significant Probability
CD4 with aPTT	-0.0528	2,106	-0.0953	-0.0101	0.0154*
CD4 with PT	-0.0413	19,833	-0.0552	-0.0274	< 0.0001*
CD4 with INR	-0.0451	19,761	-0.059	-0.0312	< 0.0001*

Discussion

This study evaluated coagulation abnormalities in HIV-positive patients on HAART in eThekwini District, KwaZulu-Natal, South Africa, utilizing retrospective laboratory data. The findings reveal significant differences in coagulation profiles, demographics, and correlations with immunosuppression, which vary from other similar African studies illuminating regional variations in HIV-related haematological complications.

The cohort was predominantly female (56.13%), aligning with South Africa's HIV epidemiology, where women bear a disproportionate burden of infection (SANAC, 2022). The age distribution peaked in the 45–54-year group (39.46%), consistent with studies from KwaZulu-Natal highlighting accelerated aging and metabolic complications in middle-aged HIV patients on long-term HAART (Mkhize et al., 2021). This pattern reflects the cumulative impact of chronic HIV inflammation and long-term HAART exposure on endothelial function

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(Meintjes et al. 2020). However, a study in Mozambique reported increased coagulation dysfunction in younger patients (30-39 years) (Augusto et al. 2022), likely caused by delayed ART initiation, leading to advanced disease progression at an early age. These findings highlight how timely access to ART and diagnosis can potentially impact the demographic profile of HIV-related complications.

The study found markedly elevated PT (70.5% of patients) with relatively normal aPTT (83.5%), suggesting predominant extrinsic pathway dysfunction in the study cohort. This aligns with findings in a Nigerian study by Okoroiwu et al. (2022), which reported 58% PT prolongation in HIV patients attributed to liver impairment and marked immunosuppression. However, it contrasts with a study conducted in Malawi in which aPTT abnormalities were more common (Banda et al., 2020). This difference is possibly due to differing comorbidities that affect the liver in the different regions. The prevalence of elevated PT (70.5%) exceeds reports of 42.3% in Ethiopia (Seyoum et al. 2018). This may be due to South Africa's distinct HAART regimens and possibly higher metabolic disease burdens.

Women had significantly higher rates of elevated PT (55.5%) and aPTT (61.8%) compared to men, a pattern consistent with findings from Ghana. The Ghanaian study reported HIV-positive women had 1.8-fold higher odds of prolonged PT, primarily attributed to prevalent iron-deficiency anaemia (Owiredu et al. 2021). Similarly, research by Banda et al. (2020) in Malawi demonstrated oestrogen-mediated increases in fibrinogen among women on HAART, which supports biological mechanisms for these disparities. Contrasting data emerged from Uganda, where Kiragga et al. (2020) found no significant gender differences in coagulation parameters. These findings suggest the need for programmatic gender-specific monitoring interventions, which include anaemia for PLHIV.

The study found a significant but weak inverse correlation between CD4 count and coagulation parameters (PT/INR $r = -0.041$ to -0.045), suggesting that advanced immunosuppression is associated with worsening coagulation. These findings align with a study in Botswana, which reported that CD4 counts <200 cells/μL increased INR elevation risk 3.2-fold (Mosepele et al. 2020). Similarly, a study in Kenya also observed 1.5-second PT prolongation in patients with CD4 <100 versus >500 cells/μL (Maina et al. 2019). These consistent findings imply that HIV-related liver dysfunction and impaired clotting factor synthesis progress with declining immunity. In contrast, a Tanzanian study did not find a CD4-coagulation association (Muhando et al. 2021). The overall study findings highlight regional differences in disease burdens requiring context-specific guidelines for managing HIV-related coagulation abnormalities, including monitoring of anaemia in females.

Limitations of the study

This study was limited by its reliance on only three coagulation parameters (PT, aPTT, and INR), which, while clinically useful, provide an incomplete assessment of haemostatic function in HIV patients. Without these additional tests, we cannot definitively determine whether the observed PT and aPTT prolongations resulted from impaired hepatic synthesis of clotting factors (e.g., due to HAART hepatotoxicity or viral hepatitis), consumptive coagulopathy, or specific factor deficiencies. Furthermore, the lack of D-dimer measurements precludes assessment of subclinical hypercoagulability, which has been documented in other African HIV cohorts.

Conclusion

This study confirms HAART's association with coagulopathies, exacerbated by aging and potentially influenced by gender. While our findings align broadly with sub-Saharan African studies on HIV-related coagulation dysfunction, regional variations in comorbidities, HAART protocols, and healthcare access influence these effects. This highlights the need for context-specific guidelines—e.g., prioritizing PT screening in high HIV/ tuberculosis (TB) burden settings. Future research should explore HAART-specific effects and comorbidity interactions across various regions. Additionally, future studies should incorporate comprehensive coagulation panels to better characterize the underlying mechanisms and clinical significance of these abnormalities in HAART-treated populations.

Recommendations

These findings highlight critical needs for context-specific coagulation screening and monitoring in high-TB and HIV prevalent settings. Integrated comorbidity screening is essential, particularly for hepatitis and diabetes, given their demonstrated synergistic effects on coagulation in HIV patients. Additionally, the study's gender disparities necessitate targeted interventions, including iron supplementation for anaemia and consideration of hormonal influences on coagulation in women.

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Conflict of interest

The authors declare there is no conflict of interest.

Author biography

Sibusiso Sidandala is a Bachelor of Health Science in Medical Laboratory Science student, specializing in Clinical Pathology from Mangosuthu University of Technology. He is committed to delivering high-quality work with integrity and efficiency and is dedicated to making a positive impact in his community.

Nokukhanya Thembane is a Medical Laboratory Scientist/Technologist, Senior Lecturer, and Researcher at Mangosuthu University of Technology and the University of KwaZulu-Natal. She specializes in Clinical Pathology, with a focus on therapeutic drug monitoring and drug discovery. Her work involves teaching and supervising students and conducting research to contribute to advancements in patient care in disenfranchised communities and medical laboratory science.
ORCID: https://orcid.org/0000-0001-9146-3809

Ziningi Nobuhle Jaya is a qualified Medical Technology lecturer, lecturing and supervising student research in the Department of Biomedical Science at Mangosuthu University of Technology. Her research focuses on investigating diverse healthcare interventions for infectious diseases, mainly to respond to the diverse healthcare needs of people in surrounding communities.
ORCID: https://orcid.org/0000-0003-1053-5458

Author contributions

SS collected the data. ZNJ and NT were involved in conceptualising and supervising the work. SS cleaned and analysed the data and wrote the draft manuscript. ZNJ and NT supervised all stages of the research, reviewed the draft manuscript, and provided general supervision and mentorship.

Abbreviations

ART: Antiretroviral Therapy
AARMS: Academic Affairs and Research Management System
aPTT: activated Partial Thromboplastin Time
HAART: Highly Active Antiretroviral Therapy
HIV: Human Immunodeficiency Virus
INR: International Normalized Ratio
NHLS: National Health Laboratory Service
PT: Prothrombin Time
PLHIV: People Living with Human Immunodeficiency Virus
TF: Tissue Factor
TDM: Therapeutic Drug Monitoring
TB: Tuberculosis
VTE: Venous Thromboembolism

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Data availability

Data will not be available to avoid a breach of patient confidentiality.

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