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Original Research

Prevalence of Adverse Drug Reactions among People Living with HIV in Lagos State University Teaching Hospital, Lagos, Nigeria

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Abstract

Background: Human Immunodeficiency Virus (HIV) remains a major public health concern in Nigeria, which has been rated as having a high HIV burden globally. Antiretroviral therapy (ART) has significantly improved life expectancy and reduced HIV-related morbidity and mortality. However, ART is associated with adverse drug reactions (ADRs), which can lead to treatment failure, regimen changes, and non-adherence, ultimately affecting patient outcomes.
Methodology: This was a retrospective cohort study of newly initiated people living with HIV (PLHIV) accessing care at the Lagos State University Teaching Hospital (LASUTH), Ikeja. All newly initiated HIV patients receiving antiretroviral therapy (ART) at LASUTH between March 2023 and March 2025 were included. Data collected during the study period were abstracted, and individuals who experienced an adverse drug reaction (ADR) were recorded. Data was analysed using the Statistical Package for the Social Sciences (SPSS) version 27.0. Statistical significance was established at $p \leq 0.5$.
Results: Overall, 533 newly initiated into treatment in the study period. Out of the newly initiated (533), a total of 65 reported adverse reactions to the drugs of treatment, which constituted 12.1% prevalence of ADR in the newly initiated. The mean age of all participants was 40.50 ± 11.76 years. All the newly initiated (100%) were on Tenofovir, Lamivudine, and Dolutegravir (TLD) combination. Pruritus is the commonest symptom in both females and males.
Conclusion: The ADR prevalence among the newly enrolled PLHIV is 12% and pruritus is the commonest ADR seen among the newly enrolled.

Keywords: Adverse Drug Reaction; ADR; PLHIV; HIV; Newly Enrolled.

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Introduction

HIV is a significant public health challenge, with Nigeria coming fourth globally in HIV Burden [1]. The country has an estimated 2 million PLHIV [2] and accounts for approximately 38% of fresh HIV infection in West and Central Africa [3]. The Nigeria HIV/AIDS Indicator and Impact Survey estimated an HIV prevalence rate of 1.3% among adults aged 15–49 years [4].

The introduction of ART has significantly improved life expectancy for HIV-infected individuals, making their lifespan comparable to that of the general population [5-7]. Antiretroviral therapy has also proven effective as prophylaxis for individuals at risk of infection [8]. However, while ART provides substantial benefits, it is also associated with ADRs, which can impact treatment adherence and overall patient outcomes [9-12].

People living with HIV (PLHIV) are prescribed highly active antiretroviral therapy (HAART), a blend of three medications taken for life to effectively suppress viral loads and prevent disease progression. It also predisposes patients to various ADRs, particularly as PLHIV age, develop comorbid disease conditions, and require additional medications for the comorbidities [13]. The type and severity of ADRs vary depending on the specific drugs, drug classes, and individual patient characteristics [14]. Studies have reported ADR prevalence rates ranging from 6.4% to 75% in treatment-naïve patients within the first month of therapy to persistent adverse effects in long-term treatment [15-17].

The World Health Organization (WHO) defined ADR as "noxious and unintended reactions to drugs occurring at normal doses used for prophylaxis, diagnosis, therapy, or physiological function modification"[18-19]. These reactions are a leading cause of non-adherence to therapy, treatment discontinuation, hospitalization, and prolonged hospital stays [6,16-17,20]. ADRs also frequently necessitate regimen changes, increasing the cost and complexity of HIV management [7, 15, 21-22].

Nigeria's national first-line ART regimen consists of two nucleoside reverse transcriptase inhibitors (NRTIs) and an integrase strand transfer inhibitor (INSTI), while the second-line regimen includes two NRTIs and a boosted protease inhibitor (PI) [23-24]. These regimens are available as fixed-dose combinations to simplify treatment and improve adherence. However, it's expedient for continuous monitoring of ADRs associated with newer-generation antiretroviral drugs in Nigeria.

Gender disparity in HIV prevalence and treatment outcomes is also significant. Women aged 15–49 have a higher HIV prevalence (1.9%) compared to men in the same age group (1.1%) [4]. Over half of PLHIV globally are women and girls, which is due to biological and socio-economic vulnerabilities [17,25-26]. Studies suggest that women are at higher risk of experiencing ADRs compared to men [25,27].

The World Health Organization,[28] the United States Food and Drug Administration,[29] (USFDA), and the European Medicines Agency,[30] (EMA) have acknowledged the need to assess both the advantageous and detrimental impacts of medications, to ensure the provision of suitable, secure, and efficacious therapeutic drug interventions.

The grading of the Adverse Drug Reactions (ADRs) could be evaluated employing the modified Hartwig and Siegel scale [31], which classifies the ADRs into categories of mild, moderate, and severe reactions. Although modern ART regimens are very reliable in viral suppression, ADRs remain a significant barrier to adherence, retention in care, and overall treatment success. Clinicians must prioritize ADR prevention and management to optimize long-term treatment outcomes. This study aimed to determine the prevalence of ADRs in newly initiated PLHIV receiving care at LASUTH, Ikeja, Lagos.

Materials and Methods

Study Site: This study was conducted at LASUTH, Ikeja, a leading healthcare facility in Nigeria, acting as a key referral centre for hospitals within Lagos State and nearby states. LASUTH provides comprehensive HIV/AIDS care to over 6,000 patients through support from the Center for Integrated Health Program (CIHP) Nigeria, a PEPFAR-funded program.

Operating every weekday, the clinic offers a range of tailored treatments, including counselling, screening, consultation, pharmaceutical services, laboratory investigations, and medical and surgical interventions. It serves a diverse patient population, ensuring accessible and inclusive care for individuals from various ethnic and socioeconomic backgrounds.

Study Design: This was a retrospective cohort study of newly initiated PLHIV accessing care at the study site.

Study Population and Sample: The study included all newly enrolled PLHIV on ART at LASUTH.

Study Duration: March 2023 to March 2025

Sampling Technique: A total sampling technique of all newly enrolled PLHIV on ART at LASUTH was employed.

Eligibility Criteria: All newly initiated PLHIV on ART and those who were newly started on ART who presented at the ART clinic in LASUTH within the period of study were included in the study.

Inclusion Criteria: All newly initiated PLHIV on ART and all individuals who received antiretroviral as post exposure prophylaxis during the study period

Exclusion Criteria: Patients with comorbidities such as liver or renal impairment and pregnant women.

Confidentiality: This study utilized hospital registration numbers instead of participant names to ensure confidentiality during data collection. Electronic data were securely password-protected, while hard copy data were maintained in a secure location, safeguarding the privacy and confidentiality of participants' information, such as the sociodemographic data, brand name of the drugs, adverse reactions, and name of manufacturer of the medications.

Ethics committee approval: Ethics committee approval was obtained before commencement from the Health Research and Ethics Committee of LASUTH, Ikeja, with reference number LREC/06/10/2827.

Statistical analysis

This study employed the Statistical Package for Social Sciences (SPSS) version 27.0 for data analysis. The association between demographic characteristics and adverse drug reactions was investigated. The continuous variables were given as means ± standard deviation (SD) when normally distributed. Statistical significance was established at $p \leq 0.5$.

Results

The study retrieved data between March 2023 and March 2025. A total of 533 were newly initiated on treatment. Out of 533 clients, there were65 reported adverse reactions to the drugs of treatment, which constituted 12.1%adverse drug reaction prevalence in the newly initiated. The mean age of all the newly initiated on therapy participants was 40.50 ± 11.76 years.

There were 43 females and 22 males who had ADRs. The mean ages of the female and male patients were 41.18±11.02 years and 39.05 ± 13.38 years, respectively. P-value was 0.9 – Table 1. All the patients were on Tenofovir, Lamivudine, and Dolutegravir (TLD) combination. Two of the sixty-five participants (One male patient and one female patient) had a life-threatening episode. The female had Stevens-Johnson syndrome and was referred to the dermatology clinic; the male was hospitalised based on immune reconstitution syndrome. None of them had a history of allergies.

Table 1: Age distribution of study participants who had ADRs

Gender	**Male**	**Female**	**P value**
Number	22	43	0.9
Age (years) Minimum	16	17	
Age (years) Maximum	70	70	
Mean Age (Years)	39.05 ± 13.38	41.18±11.02	

Pruritus was the commonest symptom (64.61%) in both females and males. Other symptoms experienced include rashes (1.54%), dizziness (15.38%), headache (13.85%), IRIS (1.54%), and nausea (3.08%) - Table 2.

There was no statistically significant relationship between the adverse drug reactions reported and the gender of the participants,
p=0.97.

Table 2: ADRs experienced by study participants

ADR	**Number**	**Percentage**
Pruritus	42	64.61
Dizziness	10	15.38
Headache	9	13.85
Nausea	2	3.08
IRIS	1	1.54
Rashes	1	1.54

Discussion

The present study found a 12.1% prevalence of ADRs among the 533 treatment-naive PLHIV who were newly initiated on ART at LASUTH between March 2023 and March 2025. This rate falls within the range of ADR prevalence previously described in Nigeria,7.9% to 13.7%[22, 32-33], but fell short of some sub-Saharan Africa studies that documented a broad range of 30% to 60% in treatment-naive cohorts [17,34]. Differences in case definitions, data-capture methods, and the ART regimens in use likely account for much of this variability[14,17,35].

All the participants were initiated on the first-line fixed-dose combination of tenofovir, lamivudine and dolutegravir (TLD). Previous reports suggest that dolutegravir–based regimens generally have favourable tolerability profiles [9] with overall serious ADR rates below 10% in many cohorts. The finding of 12.1% in this report may reflect the real-world complexity of a diverse Lagos population and the inclusion of non-serious cutaneous and gastrointestinal reactions commonly seen in the first few weeks of therapy commencement.

Pruritus emerged as the most frequent ADR, reported by over two-thirds of affected patients, followed by dizziness, headache, nausea, and rashes. This contrasts with some studies where gastrointestinal events predominate [16,28,36] but aligns with observations that integrase inhibitors can trigger neurologic and cutaneous symptoms early in treatment[12]. The predominance of pruritus may also reflect genetic or environmental factors specific to our cohort.

Women in many settings have reported ADRs more frequently than men, possibly due to pharmacokinetic differences, hormonal influences, and reporting behaviour. Notably, none of the women in our study required hospitalisation for ADRs; two life-threatening events occurred, such as the Stevens-Johnson syndrome and immune reconstitution syndrome. These severe outcomes, while rare, underscore the need for vigilant monitoring when initiating therapy in both men and women.

ADRs represent a major barrier to adherence, retention in care, and overall treatment success. Even non-serious reactions such as pruritus, nausea and headache can undermine quality of life and willingness to continue therapy [7,22]. Our data support the continued rollout of TLD regimens in Nigeria, given their generally low rate of serious ADRs, but also highlight the importance of pre-treatment counselling about common, manageable side effects.

The study's strength is its large, real-world patient population drawn from a major urban treatment center. By including all newly initiated PLHIV over two years, we captured a comprehensive snapshot of ADRs in daily clinical practice. However, the retrospective design relies on routinely documented reports, which may under-capture mild or transient ADRs [12,35,37]. We also excluded patients with significant comorbidities (e.g., renal or hepatic impairment) and pregnant women, limiting generalizability to those groups. Finally, without active follow-up, late-onset ADRs beyond three months may have been missed. Pruritus is a common symptom of HIV, most especially in Advanced HIV Disease, but it also occurs occasionally with ART, which is a limitation of this study

To build on these findings, prospective pharmacovigilance studies—ideally with structured patient diaries and direct follow-up—should be undertaken to quantify the true incidence and time course of ADRs on dolutegravir-based regimens. Inclusion of pharmacogenomic testing could elucidate individual susceptibility to cutaneous and neurologic reactions. Moreover, extending surveillance to special populations (pregnant women, people with comorbidities) will ensure that national guidelines remain evidence-based and responsive to emerging safety signals.

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Conflict of Interest: None declared

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