



**EVALUATION OF ADVERSE DRUG REACTIONS TO ANTIRETROVIRAL MEDICATIONS  
AMONG HIV/AIDS PATIENTS IN A TEACHING HOSPITAL IN ILORIN, NIGERIA.**

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**Abstract**

The morbidity and mortality caused by HIV/AIDS have significantly decreased as a result of the introduction of highly active antiretroviral treatment (HAART). The frequent occurrences of HAART adverse drug reactions (ADRs) potentially negate the recent advances made in the treatment of the infection. The aim of this present study is to assess the frequency, severity, and connection between ADRs and the HAART regimens being utilized by HIV/AIDS patients in an Ilorin teaching hospital. Using a validated data capture form created for the study, we retrospectively evaluated and analyzed the clinical records of patients living with HIV/AIDS who received treatment at the Antiretroviral Therapy Clinic in UITH between January 2022 and December 2022. The severity of the ADRs was evaluated using a modified Hartwig and Siegel scale, and causality was evaluated using Naranjo's likelihood scale. The evaluation included 384 patient case files that met the inclusion criteria. The most prevalent adverse medication reactions were seen in young adults between the ages of 31 and 40, and they were more common in females (65.9%) than in males (34.1%). Patients with the most often prescribed first-line combination of Tenofovir, Lamivudine, and Dolutegravir experienced the highest frequency of ADRs. The most frequent ADRs were nausea and vomiting (39.6%), followed by loss of appetite (29.4%), and exhaustion (15.9%). The majority of ADRs (92.7%) were mild in nature, and 80.5% were likely caused by the HAART combination that was being used, according to the assessment of severity. Loss of appetite, nausea, and vomiting were the most frequent ADRs. They were frequently observed in female patients receiving the tenofovir, lamivudine, and dolutegravir first-line combination. The majority of ADRs were low in severity and most likely resulted from the usage of the HAART combination. ADRs should be actively monitored, patients should be taught to promptly report ADRs, and HAART combinations with a history of proven safety and efficacy should be used in order to build on the successes of HAART in the treatment of HIV/AIDS.

**Keywords:** Antiretroviral medications; Adverse drug reactions; HIV; Nigeria.

**INTRODUCTION**

Acquired Immunodeficiency Syndrome (AIDS) is a condition that compromises the human immune system. It is brought on by the Human Immunodeficiency Virus (HIV), which makes an individual more vulnerable to opportunistic infections by impairing their immune system's

ability to fight off infections (1). The area of the world where HIV and AIDS have the most

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detrimental effects is Sub-Saharan Africa (2). Although it was formerly believed that antiretroviral medications for the treatment of HIV/AIDS were prohibitively expensive and out of the financial reach of patients in low-resource countries, by the end of 2020, it was predicted that 27.5 million people living with HIV worldwide were taking antiretroviral medications (2). With an average of 1.5 million new HIV infections and 680,000 deaths from AIDS-related causes in 2020, HIV continues to be a major worldwide health concern (2).

People living with HIV/AIDS (PLWHA) can now have improved immune function thanks to the use of highly active antiretroviral treatment (HAART). A reduction in viral load, a rise in CD4 count, and general clinical improvement are the effects of an effective treatment (3, 4). A lot of hope has been given to PLWHA by HAART; however, the impact of adverse drug reactions (ADRs) is a major worry (4).

An unanticipated and harmful medication response known as an adverse drug reaction can occur at doses that are typically used in people for disease prevention, diagnosis, treatment, or alteration of physiological function (5, 6). All medications, including HAART, have the potential to result in negative side effects. The leading cause of morbidity and mortality in patient care is adverse medication reactions. Hospital admissions associated with ADRs have been rising steadily, placing a heavy strain on the healthcare system and having a major negative impact on the economy (7, 8). One of the major contributors to poor adherence, medication resistance, switch therapy, and treatment failure are ADRs associated with antiretrovirals (9). In order to maintain the benefits of HIV/AIDS treatment using HAART, these ADRs need to be closely monitored and reported as the majority of these reactions in sub-Saharan African countries are either unreported or go unnoticed. There is a lack of data regarding

ADR in relation to HAART used in the management of HIV (10). A crucial part of managing patients with HIV/AIDS is tracking, reporting, and analyzing ADRs and their potential causes. ADRs, their severity, and the cause-relationship with antiretroviral medicines were all evaluated in this study.

## **METHODS**

### **Study setting**

The Antiretroviral Therapy (ART) Clinic at University of Ilorin Teaching Hospital, Ilorin (UITH), is where this study was conducted. The 600-bed UITH hospital is situated in Ilorin, the state capital of Kwara, in Nigeria's North Central geopolitical region. The multiethnic city of Ilorin is home to a large population of farmers, traders, artisans, freelance workers, and government personnel. UITH is a federal tertiary hospital that treats patients from both inside and outside the state and acts as a referral hub. The ART clinic is open from 8 am to 4 pm, Monday through Friday. At the ART clinic, there are about 200 new and old patients (adults and children) treated each day. Approximately 6,000 registered patients with HIV/AIDS, including males, pregnant and non-pregnant women, and children from various regions of Kwara State and Nigeria, are given free antiretroviral medications, each month.

### **Study design**

Using a validated data capture form created for the project, we retrospectively evaluated and analyzed the clinical files of patients with HIV/AIDS, who were receiving treatment and reported side effects at the antiretroviral therapy clinic in UITH between January 2022 and December 2022. The researchers used the main register obtained from the ART clinic's medical record section to find eligible cases. Using a web-based random sampling technique, a unique identification number was given to each case file once it was randomly chosen. Using the validated data collecting form

specifically created for the study, one of the researchers went over the case files and also spoke with the doctor caring for the patients about the documented ADRs. Sociodemographic details, test results (CD4 Count, Packed cell volume), HAART combination, and reported ADRs were all extracted.

Using Naranjo's Probability Scale, the cause-relationship of the ADR to antiretroviral drugs was evaluated (11). The Naranjo's Probability Scale is a questionnaire with three possible answers: yes, no, or don't know. It consists of objective questions. Accordingly, scores were assigned, and the ADRs were divided into three categories: questionable, possible, and probable. The Modified Hartwig and Siegel Scale (12), which divided severity into three categories—mild (bothersome but not requiring a change in therapy), moderate (requiring a change in therapy, additional treatment, and hospitalization), and severe (disabling or life-threatening), was used to assess the severity of the ADR. Two of the researchers (a clinician and a pharmacist) confirmed the data that had been previously gathered. Using Kappa statistics, there was 90% agreement among the three reviewers. A fourth reviewer's (a Consultant Physician or Clinical Pharmacologist) viewpoint was sifted and surpassed in areas where there was conflict.

### **Inclusion Criteria**

Patients must be above the age of 18 years with a proven HIV infection and must have been on HAART for at least one month.

### **Exclusion Criteria**

Children, pregnant women with confirmed HIV infection, and patients with HIV infection on HAART with other non-HIV drugs were excluded from the study. Patients with HIV who also had acute or chronic co-morbid conditions such as diabetes, hypertension, TB,

chronic renal disease, hepatitis B or C, or cancer, were also disqualified.

### **Sample Size determination**

The Fisher's formula (13) and a prevalence from an earlier study (14) were used to calculate the sample size, which resulted in a minimum sample size of 384.

### **Data management and analysis**

Version 22 of IBM SPSS statistics software was used to examine the data. For the variables under study, descriptive statistics and inferential statistics were performed. For categorical data, frequencies and percentages were utilized. On the basis of Naranjo's Probability Scale, the cause-relationship of the ADR was evaluated. The Modified Hartwig and Siegel Scale was used to gauge the ADR's severity. Prior to analysis, patient records were de-identified and anonymized.

### **Ethical consideration**

The University of Ilorin Teaching Hospital's Ethics and Research Committee granted approval for this study, with the approval code ERC PAN/2022/07/2006. During and after the study, strict confidentiality about the patient's information was upheld.

## **RESULTS**

Three hundred and eighty-four (384) case files in all that satisfied the inclusion requirements were examined and included in the study. The age group between 31 and 40 years (n=125, 32.5%) and the age group between 41 and 50 years (n=97, 25.3%) were the median age range of PLWHA attending the ART clinic and presenting with ADR. The gender distribution revealed that more females (n=253, 65.9%) than males were observed in the ART clinic presenting with ADR. When the marital status of the PLWHA who presented with ADR was analyzed, it was found that 40.4% of the patients were married, 26.8% were single, and approximately 1% of the patients did not have

their marital status mentioned in the case record. Table 1 shows that 25% of the patients had completed post-secondary education, whereas the biggest percentage of patients (43%), had finished secondary school.

The majority (71.6%) of the patients exhibited CD4 counts above 200 cells/mm<sup>3</sup> and Packed cell volumes above 30% (77.1%), according to analysis of the results of the laboratory inquiry (CD4 count and Packed cell volume) (Table 1). The antiretroviral medicine prescription pattern is shown in Table 2. Tenofovir/Lamivudine/Dolutegravir, or TLD, was the most often prescribed combination (n=330, 86.0%), followed by Abacavir/Lamivudine/Dolutegravir, or ALD, (n=27, 7.0%). Less than one tenth of the patients (8.6%) were on a second-line regimen whereas the majority (86.0%) were receiving first-line ARV therapy.

The most common adverse drug reactions (ADRs) associated with the patients' ART treatment were nausea and vomiting (39.6%), followed by loss of appetite (29.4%), and tiredness (15.9%). These ADRs were common in patients taking TLD since it was the first-line antiretroviral drug that was most often prescribed in this facility (Table 3).

Less than one-tenth of the ADRs were of moderate intensity, while the majority were mild (92.7%), according to an analysis of the severity and etiology of the ADRs. Using Naranjo's algorithm to determine causality, it was shown that the patient's antiretroviral regimen was most likely to blame for the majority (80.5%) of the reported ADRs (Table 4).

## DISCUSSION

This study's objective was to assess the relationship of ADRs to antiretroviral medications among PLWHA utilizing UITH healthcare. There are few researches examining

the negative effects of antiretroviral medications in sub-Saharan African nations.

The sociodemographic traits of the evaluated patients revealed that ADRs were frequently experienced by young adults, in contrast to the findings of a different study conducted in India, which found that the majority of ADRs were experienced by elderly patients (15). In addition, females were more likely to experience ADRs than their male counterparts. This result was consistent with reports from Sadiq *et al.* (16) and Chowta *et al.* (17). A third of the patients showed CD4 counts greater than 200 cells/mm<sup>3</sup> and packed cell volumes greater than 30%. The results on PCV were different from what Kumari *et al.* (18) reported in their study. Tenofovir, Lamivudine, and Dolutegravir were the most often administered (86.0%) first-line antiretroviral medication combination in this study. This is in accordance with government recommendations for the treatment of HIV (19). In contrast to certain reports in the literature, where efavirenz-based combinations were utilized as first line therapy, our findings support the use of dolutegravir-based first line combos (20, 21). The higher frequency of adverse events associated with the nevirapine-based combination may have contributed to the adjustments in the regimen. This emphasizes the significance of long-term research to evaluate the impact of ART and potential related ADRs as this could aid healthcare policy makers in making decisions. The preferred form of treatment for those with HIV/AIDS is antiretroviral medication, which must be taken continuously once started. The care of HIV/AIDS patients who experience adverse medication reactions is a critical issue because it affects how well, patients adhere to their treatment plans. ADRs can result in treatment failure, which worsens the disease's morbidity and fatality rates (22). In this study, nausea and vomiting (39.6%) and lack of appetite (29.4%) were the two most frequent ADRs. This finding is consistent with that of

**Table 1: Socio-demographic and Laboratory Characteristics of PLWHA in UITH**

| <b>Variable</b>                         | <b>Frequency (n=384)</b> | <b>Percentage (%)</b> |
|-----------------------------------------|--------------------------|-----------------------|
| <b>Age group (years)</b>                |                          |                       |
| 18 – 30                                 | 82                       | 21.4                  |
| 31 – 40                                 | 125                      | 32.5                  |
| 41 – 50                                 | 97                       | 25.3                  |
| 51 – 60                                 | 48                       | 12.5                  |
| ≥ 61                                    | 32                       | 8.3                   |
| <b>Gender distribution</b>              |                          |                       |
| Male                                    | 131                      | 34.1                  |
| Female                                  | 253                      | 65.9                  |
| <b>Marital status</b>                   |                          |                       |
| Single                                  | 103                      | 26.8                  |
| Married                                 | 155                      | 40.4                  |
| Divorced                                | 41                       | 10.7                  |
| Widow                                   | 59                       | 15.4                  |
| Widower                                 | 22                       | 5.7                   |
| Undocumented                            | 4                        | 1.0                   |
| <b>Educational Status</b>               |                          |                       |
| None                                    | 52                       | 14.0                  |
| Primary                                 | 80                       | 17.3                  |
| Secondary                               | 155                      | 43.0                  |
| Post-secondary                          | 97                       | 25.7                  |
| <b>CD4 Count (cells/mm<sup>3</sup>)</b> |                          |                       |
| <200                                    | 109                      | 28.4                  |
| >200                                    | 275                      | 71.6                  |
| <b>Packed cell volume (%)</b>           |                          |                       |
| <30                                     | 88                       | 22.9                  |
| >30                                     | 296                      | 77.1                  |

**Table 2: Antiretroviral drug combinations in use in PLWHA attending UITH**

| Antiretroviral drug Combinations                          | Gender |        | Total | Percentage (%) |
|-----------------------------------------------------------|--------|--------|-------|----------------|
|                                                           | Male   | Female |       |                |
| <b>Zidovudine/Lamivudine/Dolutegravir</b>                 | 9      | 10     | 19    | 5.0            |
| <b>Abacavir/Lamivudine/Dolutegravir</b>                   | 4      | 23     | 27    | 7.0            |
| <b>Tenofovir/Lamivudine/Dolutegravir</b>                  | 115    | 215    | 330   | 86.0           |
| <b>Tenofovir-<br/>alafenamide/Lamivudine/Dolutegravir</b> | 2      | 2      | 4     | 1.0            |
| <b>Zidovudine/Lamivudine/Nevirapine</b>                   | 1      | 3      | 4     | 1.0            |
| <b>Total</b>                                              | 131    | 253    | 384   | 100            |

**Table 3: Suspected adverse drug reactions and relationship with ART combination**

| ADR                         | ZLD | ALD | TLD | TALD | ZLN | Total | Percentage (%) |
|-----------------------------|-----|-----|-----|------|-----|-------|----------------|
| <b>Nausea/Vomiting</b>      | 5   | 7   | 137 | 2    | 1   | 152   | 39.6           |
| <b>Rashes/Itching</b>       | 9   | -   | 11  | -    | 2   | 22    | 5.7            |
| <b>Abdominal discomfort</b> | 4   | 6   | 34  | 5    | -   | 49    | 12.8           |
| <b>Anaemia</b>              | 2   | 4   | 10  | -    | 6   | 22    | 5.7            |
| <b>Loss of appetite</b>     | 2   | 2   | 105 | 4    | -   | 113   | 29.4           |
| <b>Diarrhoea</b>            | 1   | 1   | 7   | -    | -   | 9     | 2.3            |
| <b>Dizziness</b>            | 1   | 2   | 2   | -    | 2   | 7     | 1.8            |
| <b>Headache</b>             | 3   | 4   | -   | -    | -   | 7     | 1.8            |
| <b>Insomnia</b>             | -   | -   | 21  | 2    | -   | 23    | 5.9            |
| <b>Fatigue</b>              | 2   | 1   | 55  | 3    | -   | 61    | 15.9           |
| <b>Sedation</b>             | -   | -   | 4   | -    | -   | 4     | 1.0            |
| <b>Lipodystrophy</b>        | -   | 1   | -   | -    | -   | 1     | 0.3            |
| <b>Paraesthesia</b>         | -   | 1   | -   | -    | -   | 1     | 0.3            |
| <b>Hyperpigmentation</b>    | -   | -   | 6   | -    | 2   | 8     | 2.1            |
| <b>Restlessness</b>         | -   | -   | -   | 1    | -   | 1     | 0.3            |
| <b>Fever</b>                | -   | 1   | 7   | -    | -   | 8     | 2.1            |
| <b>Jaundice</b>             | -   | 1   | -   | -    | -   | 1     | 0.3            |
| <b>Lactic acidosis</b>      | -   | -   | 1   | -    | -   | 1     | 0.3            |

**N.B:** Some patients reported more than one ADR.

**ZLD:** Zidovudine/Lamivudine/Dolutegravir

**ALD:** Abacavir/Lamivudine/Dolutegravir

**TLD:** Tenofovir/Lamivudine/Dolutegravir

**TALD:** Tenofovir-alafenamide/Lamivudine/Dolutegravir

**ZLN:** Zidovudine/Lamivudine/Nevirapine

**Table 4: Assessment of Severity and Causality of the Adverse drug reactions**

| Severity                               | Number of patients | Percentage (%) |
|----------------------------------------|--------------------|----------------|
| Mild                                   | 356                | 92.7           |
| Moderate                               | 27                 | 7.0            |
| Severe                                 | 1                  | 0.3            |
| Total                                  | 384                | 100            |
| <b>Causality (Naranjo's algorithm)</b> |                    |                |
| Probable                               | 309                | 80.5           |
| Possible                               | 66                 | 17.2           |
| Doubtful                               | 9                  | 2.3            |
| Total                                  | 384                | 100            |

Chowta *et al.* (17) in 2018, but differed from reports by Sadiq *et al.* (16) in 2016, Oumar *et al.* (23) in 2019, and Usman *et al.* (24) in 2014, which identified dizziness as the most frequent adverse drug reaction in their respective studies. It is significant to highlight that these researchers' patients were on zidovudine-based combination therapy, which either has nevirapine or efavirenz as a component. Tenofovir, Lamivudine, and Dolutegravir combination was the most frequently prescribed antiretroviral medication in our study. Fatigue (15.9%), abdominal discomfort (12.8%), and sleeplessness (5.9%) were the other ADRs often reported. Abacavir, lamivudine, and dolutegravir was the combination of second line antiretroviral medication that approximately 7% of the patients were receiving. Additionally, it was discovered that the second line combination was linked to ADRs like nausea, vomiting, and abdominal pain. The fact that the TLD combination was the most frequently prescribed could be the reason for the link

between the development of ADRs and the combination.

According to the severity level of the observed ADRs, the majority of these side effects were minor and did not call for hospitalization, medical attention, or stopping the suspected HAART drugs. Oreagba *et al.* (25) and Usman *et al.* (24) reported a comparable result in their studies. The bulk of the ADRs were most likely (80.5%) caused by the HAART combination, according to the causality evaluation, which is consistent with prior reports in literature (26, 27). If the suspected ART medicine is to be stopped or exchanged with a different combination, it is critical to assess the causation and severity of ADRs (28, 29). This will help the healthcare professional to educate the patient about the likelihood of developing ADRs during therapy, importance of reporting it promptly, and management options.

## CONCLUSION

According to our findings, HIV/AIDS patients had ADRs rather frequently. When using the

first-line combination of Tenofovir, Lamivudine, and Dolutegravir, female patients experienced nausea, vomiting, and loss of appetite more frequently. The HAART combination is likely to be responsible for the majority of ADRs, which were minor in severity. To build on the successes of HAART in the treatment of HIV/AIDS, ADRs should be actively monitored, patients should be taught to promptly report ADRs, and HAART combinations with established safety and efficacy should be used.

### Conflicts of interest

There is no conflict of interest

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