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Prevalence of Adverse Drug Reactions in HIV/AIDS Patients on Highly Active Anti-Retroviral Therapy in Bushenyi Medical Centre, Ishaka Adventist Hospital, and Kampala International University Teaching Hospital in Bushenyi District, Western Uganda

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ABSTRACT

The World Health Organization (WHO) delineates an Adverse Drug Reaction (ADR) as an unintended and harmful response to a drug when it is used for disease prevention, diagnosis, treatment, or physiological function modification in humans. This definition specifically excludes therapeutic failures, overdose, drug abuse, noncompliance, and medication errors. The objective of this study is to determine the prevalence of ADRs among HIV/AIDS patients undergoing Highly Active Antiretroviral Therapy (HAART) at Bushenyi Medical Centre, Ishaka-Adventist Hospital, and KIU Teaching Hospital in the Bushenyi district, western Uganda. Patient interviews were conducted using structured questionnaires. A cohort of 333 patients participated in the study. The investigation revealed a prevalence of ADRs at 13.5% (95% CI: 10.2-17.6). Among the 333 patients interviewed, 44 reported experiencing ADRs, with a significant 97.8% of these cases occurring in female patients. Importantly, individuals with co-morbidities had a 55.6-fold higher likelihood of developing ADRs compared to those without any co-morbid conditions (95% CI: 2.4-1286.7). Furthermore, the study indicated an increased risk of ADR development among patients starting HAART within the first year of treatment. In summary, our findings highlight the notable prevalence of ADRs among females, emphasizing the need for gender-specific initiatives to raise awareness and prevent ADRs. Regular monitoring is particularly important for patients with co-morbidities due to the established association between co-medication and susceptibility to ADRs. Additionally, adherence to HAART therapy is essential, as the incidence of ADRs tends to decrease over time.

Keywords: Adverse drug reaction (ADR), HIV/AIDS, Co-morbidities, Anti-Retroviral Therapy, Uganda

INTRODUCTION

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as a response to a drug that is harmful and unintentional, occurring at doses used in humans for disease prevention, diagnosis, treatment, or modification of physiological function. This definition excludes therapeutic failures, overdose, drug abuse, non-compliance, and medication errors. The prevalence of ADR is determined by calculating the proportion of the study population experiencing ADRs [1]. Antiretroviral therapy (ART) is known to be associated with a wide range of ADRs, ranging from mild intolerance to life-threatening side effects. Short-term adverse effects (occurring within a few weeks of starting ART) may include nausea, vomiting, diarrhea, rash, hypersensitivity reactions, urticarial reaction, erythema multiforme, toxic epidermal necrolysis or Stevens-Johnson syndrome, hepatotoxicity, drowsiness, and vivid dreams. Intermediate adverse effects (occurring within the first few months of starting ART) may include anemia, neutropenia, bone marrow suppression, hyperpigmentation of the skin, nails, and mucous membranes, lactic acidosis, peripheral neuropathy, and pancreatitis. Long-term adverse effects (occurring within 6-18 months of starting ART) may include lipodystrophy, lipoatrophy, dyslipidemia, diabetes, and abnormalities in the skin, nails, and hair [2]. Globally, as of 2018, approximately 37.9 million people worldwide are living with the human immunodeficiency virus (HIV). In that year, 1.7 million people acquired HIV, while 770,000 people died from AIDS-related illnesses. Since the beginning of the epidemic, a total of 74.9 million people have been infected with HIV, and approximately 32.0 million people have lost their

lives to AIDS-related illnesses [3]. By the end of 2018, the total number of people living with HIV was as follows: 36.2 million adults (15 years and older), 1.7 million children under the age of 15, and an estimated 8.1 million people who were unaware of their HIV status. As of June 2019, 24.5 million people were receiving antiretroviral therapy (ART), compared to 7.7 million in 2010. This means that 62% of people living with HIV had access to treatment, including 62% of adults aged 15 years and older and 54% of children under 15 years old. Among female adults aged 15 years and older, 68% had access to treatment, while only 55% of male adults in the same age group did. In 2018, 82% of pregnant women living with HIV had access to antiretroviral medicines to prevent transmission of the virus to their children. Since its peak in 1997, new HIV infections have decreased by approximately 40%. In 2018, there were 1.7 million new HIV infections, compared to 2.9 million in 1997. Furthermore, since 2010, new HIV infections have declined by an estimated 16%, from 2.1 million to 1.7 million in 2018. According to the 90-90-90 strategy, in 2018, 79% of people living with HIV knew their status, among whom 78% were accessing treatment. Of those accessing treatment, 86% achieved viral suppression. Every week, around 6,000 young women aged 15-24 years become infected with HIV. In sub-Saharan Africa, four out of five new infections among adolescents aged 15-19 years occur in girls [4][5]. Young women aged 15-24 years are twice as likely to be living with HIV as men of the same age group. Additionally, more than one-third (35%) of women worldwide have experienced physical and/or sexual violence at some point in their lives. In certain regions, women who have experienced such violence are 1.5 times more likely to acquire HIV than those who have not. Key populations and their sexual partners account for approximately 54% of new HIV infections globally, 64% in western and central Africa, and 25% in eastern and southern Africa. The risk of acquiring HIV is 22 times higher for men who have sex with men, 22 times higher for people who inject drugs, 21 times higher for sex workers, and 12 times higher for transgender individuals.

LITERATURE REVIEW

Tables 1, 2, and 3 provide comprehensive summaries of the most recent global HIV statistics, regional HIV data, and regional treatment coverage data, respectively, as of 2022.

Table 1: Global HIV Data Statistics (UNAIDS)

	2000	2005	2010	2021	2022
People living with HIV	26.6 million [22.6 million - 31.2 million]	28.9 million [24.5 million - 33.8 million]	31.5 million [26.7 million - 36.8 million]	38.7 million [32.8 million - 45.2 million]	39.0 million [33.1 million - 45.7 million]
New HIV Infections	2.8 million [2.2 million - 3.8 million]	2.5 million [1.9 million - 3.3 million]	2.1 million [1.6 million - 2.8 million]	1.4 million [1.1 million - 1.8 million]	1.3 million [1.0 million - 1.7 million]
New HIV Infections (Adults, aged 15+)	2.3 million [1.7 million - 3.1 million]	2.0 million [1.5 million - 2.6 million]	1.8 million [1.4 million - 2.4 million]	1.3 million [950 000 - 1.7 million]	1.2 million [900 000 - 1.6 million]
New HIV Infections (Children, aged 0-14)	530 000 [360 000 - 830 000]	480 000 [330 000 - 750 000]	310 000 [210 000 - 490 000]	140 000 [96 000 - 220 000]	130 000 [90 000 - 210 000]
AIDS-related deaths	1.7 million [1.3 million - 2.4 million]	2.0 million [1.5 million - 2.7 million]	1.3 million [970 000 - 1.8 million]	660 000 [500 000 - 920 000]	630 000 [480 000 - 880 000]

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Table 2: Regional Data Statistics as of 2022

	People living with HIV	New HIV infections	New HIV infections (Adults, aged 15+)	New HIV infections (Children, aged 0-14)	AIDS-related deaths
Global	39.0 million [33.1 million - 45.7 million]	1.3 million [1.0 million - 1.7 million]	1.2 million [900 000 - 1.6 million]	130 000 [90 000 - 210 000]	630 000 [480 000 - 880 000]
Asia and the Pacific	6.5 million [5.3 million - 7.8 million]	300 000 [220 000 - 400 000]	290 000 [210 000 - 380 000]	12 000 [8600 - 18 000]	150 000 [110 000 - 220 000]
Caribbean	330 000 [290 000 - 380 000]	16 000 [11 000 - 21 000]	14 000 [10 000 - 19 000]	1 500 [1 100 – 2 100]	5 600 [4100 - 7500]
Eastern and southern Africa	20.6 million [17.4 million - 24.5 million]	500 000 [370 000 - 670 000]	440 000 [330 000 - 590 000]	58 000 [38 000 - 100 000]	260 000 [200 000 - 370 000]
Eastern Europe and central Asia	2.0 million [1.8 million - 2.1 million]	160 000 [140 000 - 180 000]	160 000 [130 000 - 180 000]	… [… - …]	48 000 [38 000 - 58 000]
Latin America	2.2 million [2.0 million - 2.5 million]	110 000 [94 000 - 130 000]	110 000 [90 000 - 130 000]	3600 [2900 - 4700]	27 000 [21 000 - 35 000]
Middle East and North Africa	190 000 [160 000 - 220 000]	17 000 [13 000 - 23 000]	16 000 [12 000 - 21 000]	1700 [1300 - 2100]	5300 [4000 - 7100]
Western and central Africa	4.6 million [4.2 million - 5.5 million]	160 000 [110 000 - 250 000]	110 000 [66 000 - 190 000]	51 000 [34 000 - 69 000]	120 000 [96 000 - 160 000]
Western and central Europe and North America	2.3 million [1.9 million - 2.6 million]	58 000 [46 000 - 69 000]	57 000 [46 000 - 69 000]	… [… - …]	13 000 [9300 - 17 000]

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Table 3: Regional Treatment Coverage 2022

	Among people living with HIV, the percent on ART (Adults, aged 15+)	Among people living with HIV, the percent on ART (Children, aged 0-14)	Among people living with HIV, the percent on ART
Global	77% [65 - 90]	57% [44 - 76]	76% [65 - 89]
Asia and the Pacific	65% [54 - 78]	... [... - ...]	65% [54 - 78]
Caribbean	69% [60 - 79]	39% [31 - 46]	68% [59 - 78]
Eastern and southern Africa	83% [70 - 98]	64% [49 - 93]	83% [69 - 97]
Eastern Europe and central Asia	51% [46 - 56]	... [... - ...]	51% [46 - 56]
Latin America	72% [65 - 81]	39% [33 - 45]	72% [64 - 80]
Middle East and North Africa	51% [44 - 60]	34% [29 - 40]	50% [43 - 59]
Western and central Africa	82% [72 - 95]	37% [29 - 45]	78% [69 - 90]
Western and central Europe and North America	76% [64 - 87]	... [... - ...]	76% [64 - 87]

The introduction of antiretroviral therapy (ART) for managing HIV infection has greatly reduced the morbidity and mortality associated with acquired immune deficiency syndrome (AIDS) in HIV patients [6]. Previously believed to be untreatable, HIV infection is now considered a chronic and treatable condition. However, like any long-term medication, the main challenge of prescribing antiretroviral drugs (ARVs) lies in their documented adverse effects [6]. The spectrum of adverse effects related to highly active antiretroviral therapy (HAART) in developing countries may differ from those in developed countries due to the high prevalence of conditions such as anemia, malnutrition, tuberculosis, and advanced HIV disease at initial presentation [7]. These adverse drug reactions (ADRs) can lead to treatment discontinuation, disease progression, treatment failure, or changes in ART regimens [8]. ADRs impose a significant burden on healthcare systems, causing substantial economic impact. Many ADRs are preventable, and awareness of these risks is crucial to prevent harm to patients. They also contribute to hospitalization rates and incur costs for the healthcare system. The ultimate goal of selecting an appropriate ART regimen is not only to maintain viral suppression but also to ensure the safety of the regimen to prevent therapy discontinuation. The World Health Organization (WHO) HIV/AIDS Department provides evidence-based technical support to WHO Member States in scaling up treatment, care, and prevention services, as well as ensuring the supply of drugs and diagnostics for a comprehensive and sustainable response to HIV/AIDS [9]. This requires consideration of many factors. One such factor is the toxicity profile of drugs. For example, protease inhibitors play a crucial role in HAART. However, poor bioavailability and unbearable toxicity are common disadvantages. For example, Indinavir is poorly water soluble and can crystallize in urine, causing obstruction anywhere between the renal tubules and the urethra. This obstruction can present as renal colic but also as nondescript abdominal pain, painless hematuria, urinary frequency, or a gradual symptomless rise in serum creatinine. Efavirenz commonly presents with central nervous system effects such as dizziness, insomnia, somnolence, impaired concentration, vivid dreams, nightmares, and mania. These reactions occur in about 40% of patients in the first few days to weeks but are severe enough to warrant discontinuation in only 3%, as most symptoms resolve spontaneously. Similar reactions are rare with nevirapine or delavirdine. Most ART agents have been associated with hepatic toxicity. Nucleoside reverse transcriptase inhibitors (NRTIs) can cause hepatic steatosis, generally after more than 6 months of therapy, probably via mitochondrial toxicity

[10][11]. NRTIs can cause hepatitis in the first 2-3 months of therapy, sometimes as part of a hypersensitive reaction. Protease inhibitors can also cause hepatitis by an unknown mechanism, particularly in patients co-infected with hepatitis B or C and with raised hepatic aminotransferase concentrations. Less commonly, they have been associated with visceral bleeding in patients with cirrhosis. Some cases of hepatitis with antivirals seem to represent a side effect of an improved immune response, where immune restoration leads to the recognition of hepatitis B or C in chronic carriers and results in a clinical episode of hepatitis with seroconversion. The proportion of hepatic reactions to any ART caused by such a mechanism is unknown. Unconjugated hyperbilirubinemia can occur with indinavir (about 7%) but does not represent liver toxicity. Isolated increases in gamma-glutamyl transferase concentrations with some agents probably represent enzyme induction and do not warrant changes to therapy. Virtually, all ART medications can cause nausea, vomiting, or diarrhea early in therapy, but these are often transient. Among NRTIs, nausea is most common with zidovudine and didanosine [12][13]. Nausea can also occur with any protease inhibitor. Indinavir is also associated with esophageal reflux but should not be given with antacids because salts in the antacids can bind to indinavir and prevent its absorption. For the same reason, indinavir should not be given at the same time as didanosine [13]. For substantial reflux, H2 blockers and proton pump inhibitors are acceptable options. Diarrhea is probably most common with protease inhibitors, particularly nelfinavir, full-dose ritonavir, and soft gel saquinavir. Bulking agents, such as psyllium, loperamide, and occasionally dietary modifications, can be useful. Ritonavir can cause numerous dose-dependent side effects, including perioral and peripheral paresthesia, fatigue, and headache. The etiologies of these effects are unknown. These effects do not seem to be less common in those receiving its liquid or capsule formulations. Similar paresthesia can also occur with amprenavir. Zidovudine is usually associated with anemia and granulocytopenia. It affects about 5-10% of patients who receive zidovudine and is more common in those with advanced HIV disease and possibly those receiving chemotherapy. These effects are believed to be caused by mitochondrial toxicity [11]. However, these effects are temporary even with continued therapy. Zidovudine should not be combined with stavudine due to likely antagonism. Most antiretroviral therapy (ART) regimens, especially non-nucleoside reverse transcriptase inhibitors (NRTIs) and protease inhibitors, have not been sufficiently studied in pregnancy to make recommendations regarding safety and efficacy. No ART has been classified by the Food and Drug Administration as category A (with a well-demonstrated lack of risk to the human fetus in the first trimester) [14]. The drugs rated as category B (based on animal studies) are didanosine, saquinavir, ritonavir, and nelfinavir. Early data suggests that the NRTIs zidovudine and lamivudine rarely cause neurological and metabolic diseases through mitochondrial damage when given during the perinatal period, although these findings have not been confirmed. Any risks associated with these medications need further clarification. However, the benefits of using zidovudine, lamivudine, and nevirapine in reducing perinatal HIV transmission rates outweigh the potential harms. If confirmed, surveillance may also be necessary for those receiving post-exposure prophylaxis against HIV-1 transmission with NRTIs. Efavirenz has been shown to cause cranial malformations in monkey fetuses, so it is contraindicated during pregnancy or when pregnancy is possible. Other drugs that are rated as category C (with proven or unstudied animal fetal toxicity) are delavirdine and, at very high doses, zalcitabine and zidovudine. The risk of hyperbilirubinemia-induced kernicterus with perinatal indinavir is unknown, as is the risk of protease inhibitor-associated gestational diabetes mellitus. The choice and timing of ART will increasingly be influenced by their potential toxicities, as well as by more traditional biological criteria. Toxicities will also affect patients' tolerability and adherence to complex ART regimens, especially for those receiving salvage or intensification regimens that can involve up to seven ART drugs [14][15]. Therefore, there is a need for assays that can predict or more easily diagnose drug-induced toxicities. Therapeutic drug monitoring of protease inhibitors is one option, considering that the toxicity of many protease inhibitors is dose-dependent. However, if possible, antiviral potency should not be compromised for tolerability. Whether such monitoring will improve clinical outcomes is still unknown. Lastly, the increasing awareness of adverse effects will continue to drive the development of improved second-generation and third-generation antiretroviral compounds [17]. Therefore, the development of safer and potentially more promising protease inhibitors is eagerly awaited [17]. According to the Uganda Population HIV Impact Assessment Report (UPHIA), the estimated total number of adults and children of all ages living with HIV in Uganda is 1.3 million. According to the Uganda HIV/AIDS Country Progress Report from July 2016 to June 2017, a scheme called the 90-90-90 targets was established in collaboration with UNAIDS. These targets aim to achieve the following by 2020: 90% of all people living with HIV will know their status, 90% of all people diagnosed with HIV infection will receive sustained antiretroviral therapy (ART), and 90% of all people receiving ART will have viral suppression. Uganda has committed to the first 90 target. Out of the 1.3 million HIV-infected people in the country, the goal is for 90%, or 1.17 million, to know their HIV status by 2020. However, based on conservative estimates, it is currently estimated that only 73% of individuals in care know their status, which falls well below the target [18][19].The second 90 target aims for at least 81% of HIV-infected people to be enrolled in ART by June 2017. Unfortunately, we have not yet reached this target, with only 67% of HIV-infected people currently on treatment. The second goal of the National Strategic Plan (NSP) is to decrease HIV-associated mortality and morbidity by 70% through achieving and maintaining 90% viral suppression by 2020. The aim is to improve the quality of life for people living with HIV (PLHIV) and increase access to pre-ART care for eligible individuals, increase access to ART to 80%, and sustain the provision of long-term care for patients initiated on

ART [15]. The number of clients enrolled in treatment has increased from 125,744 in 2014/15 to 161,325 in 2015/16 and to 220,431 in 2016/17. During the development of the NSP from 2015/16 to 2019/20, the "Test and Treat" guidelines were initially limited to certain categories such as children below 15 years, pregnant women, HIV-positive spouses, and so forth. However, in December 2016, Uganda adopted these guidelines for all PLHIV, regardless of disease stage. ART treatment for PLHIV is critical for improving outcomes and reducing morbidity and mortality. As of June 2017, 1,028,909 people were on ART, with 96.1% on the first-line regimen, 3.7% on the second-line regimen, and 0.03% on the third-line regimen. Over 70 districts in Uganda have less than 90% of HIV-positive clients enrolled in care on ART. HIV testing and services conducted around the country at the district level showed that 72% of PLHIV in Bushenyi were started on ART [20]. The background information suggests that Antiretroviral Therapies (ARTs) have shown promise in reducing morbidity and mortality rates among HIV patients. However, the associated Adverse Drug Reaction (ADR) profile often compromises the quality of life and poses life-threatening risks to individuals [1]. Uganda is home to approximately 1.3 million HIV/AIDS patients out of the 37.9 million globally, with approximately 1,028,909 People Living with HIV (PLHIV) on ART as of June 2018. This constitutes about 79.15% of PLHIV accessing treatment. A survey conducted across 70 districts in Uganda, including Bushenyi, revealed that 72% of PLHIV in Bushenyi are on ART (UGANDA HIV/AIDS COUNTRY PROGRESS REPORT, p. 108, 2016/17) [20]. The government has prioritized HIV intervention programs, aiming to achieve targets such as ensuring 90% of HIV-positive individuals know their status by 2020, initiating 90% of all PLHIV on ART, and achieving viral load suppression among PLHIV. However, insufficient attention has been given to understanding the challenges and adverse effects associated with HAART regimens. The significant adverse profiles accompanying these ART combinations pose a substantial obstacle to patient adherence, potentially rendering these therapies ineffective due to fear of associated side effects. Bushenyi district, where 72% of PLHIV are on HAART, provides a pertinent setting for this study due to the substantial number of patients on treatment [21][22]. Therefore, there is a pressing need to enhance the quality of life for these patients and improve adherence to HAART regimens. Consequently, this research aims to investigate the prevalence of ADRs among HIV/AIDS patients receiving HAART at Bushenyi Medical Centre, Ishaka Adventist Hospital, and KIU Teaching Hospital in Bushenyi district, western Uganda.

METHODOLOGY

Study Design

This research work used adopted cross-sectional study to determine common adverse effects, the prevalence, and risk factors to the development of adverse drug reactions in HIV patients on HAART in Bushenyi Medical Centre, Ishaka Adventist Hospital, and K.LU teaching Hospital.

Study Area

The study involved visiting Ishaka Adventist Hospital, Kampala International Hospital and Bushenyi Medical Center in the Bushenyi that provide HIV related health care.

Study Population

The study population consisted of HIV patients on HAART from Ishaka Adventists Hospital, Kampala International Hospital, and Bushenyi Medical Center in the Bushenyi region of western Uganda.

Sample Size

The study used a statistical formula: n=-N/ (1+Ne'), known as Solvn's method for calculating sample size, where n is the desired sample size, N=total population, 1=constant, e = error tolerance of 0.05 [23]. According to the Uganda Bureau of Statistics (UBOS) 2014, the total population of Bushenyi district was 234,443 people, males and females, young and old. Also, according to HIV testing and services (HTS) as per Uganda HIV/AIDS Country Progress Report p. 108 2016/17, 82,051 people in Bushenyi were tested and received their results, 2.780 tested HIV positive, the percentage of PLHIV on ART as per HTS is 72% in Bushenyi, meaning approximately 2,002 PLHIV are on ART, deriving a sample size of 333 persons.

Table 4 shows the mathematical methods used to obtain a sample size of 333 respondents which was further divided into 3 health facilities to get a total of 111 respondents per health facility.

Table 4 shows the sample size calculation

Total sample population (N)	2002 patients
Sample Size (n)	?
Error tolerance (e)	0.05
$n=N/(1Ne^2) =2002/(1+2002*(0.05)^2)$ $=333$	333 patients

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Inclusion Criteria

All HIV Patients on HAART.

Exclusion Criteria

All HIV patients presenting with cancer, and are on anti-cancer drugs were excluded. All HIV patients on HAART who are non-residents of the Bushenyi district were excluded.

Sampling Technique

Consecutive sampling was used to obtain responses from respondents until the sample size was achieved.

Data Collection

Questionnaires were used to interview patients on HAART.
Questionnaires were designed to capture all the information required for this study which included socio-demographic characteristics and information on treatments.

Outcome Measures

To determine the prevalence of adverse effects amongst HIV/AIDS patients on HAART. To identify the common adverse effects in HIV/AIDS patients on HAART. To determine the risk factors for the development of ADRs in HIV/AIDS patients on HAART.

Data Analysis Procedures

The data collected was entered into Microsoft Excel in which it was sorted, organized, and checked for completeness and then imported into STATAv1 5 for statistical analysis. Descriptive statistics were computed for each categorical variable. To test for associations between the categorical variables and the presence of ADRs, Chi-square (Fisher's exact) test was executed. The variables that were found to be statistically associated with ADR were tested in a multivariate logistic regression analysis. The level of significance was set at 5% and a P value of less than 0.05 was considered statistically significant. The results were presented in tables as frequencies and/or percentages, means, interquartile ranges (1QRs), adjusted odds ratios, 95% confidence intervals, and p values.

Ethical Consideration

The proposal was submitted for ethical considerations and clearance to the School of Pharmacy Research Committee of KIUWC. A letter of introduction and permission were obtained from the dean School of Pharmacy before the commencement of the study. The results of the study were kept confidential.

Limitations to the Study

The stigma attached to the disease would render the respondents less cooperative with the study; also, it would hinder the patients from accessing the therapy. However, this was countered by adequately explaining, and reassuring the respondents of the purpose and importance of the study and its importance to general health.

RESULTS

The study presents results from 333 respondents as this was our total sample size. However, 350 questionnaires were administered.

Descriptive statistics

Table 5 shows the descriptive statistics of the respondents. The mean age of the study respondents was 37 years with an interquartile range (1QR) of 47, the mean (IQR) weight in kilograms was 62.3 kg (59.0), the majority of the study respondents were females (55.6%), we had no pregnant women in the study and most of the respondents were married (58.6). Additionally, the majority of the study respondents were Christians (91.3) by religion, and by occupation, most of them were farmers (44.49%) followed by traders, and service providers than others, we only had 93 respondents who were alcoholics, and only 6 smokers. Most of our respondents were living with their families (6 l.6%), and active physically.

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Table 5: Descriptive Statistics of the Respondents

Variable (N=333)	Frequency (n)	Percentage (%)
Age in years, mean (IQR)	37(47)	
≤35	149	44.7
>35	184	55.3
Weight in kg, mean (IQR)	62.3(59.0)	
≤44	15	4.5
45-75	274	82.3
>75	44	13.2
Sex		
Female	185	55.6
Male	148	44.4
Pregnant women	0	0.0
Marital status		
Married	195	58.6
Single	124	37.2
Divorced	14	4.2
Religion		
Moslem	24	7.2
Christian	304	91.3
Others	5	1.5
Occupation		
Trading	106	31.8
Farming	149	44.4
Service provider	31	9.3
Others	47	14.1
Alcoholics	93	27.9
Smokers	6	1.8
Living with		
Family	205	61.6
Alone	38	11.4
Friends	0	0.0
Others	90	27.0
Physical activity		
Active	211	63.4
Inactive	122	36.6

Prevalence of ADRs

Table 6 shows the prevalence of ADR statistics of the Respondents which indicates that for every 100 respondents, 14 of them had adverse drug reactions with a 95% confidence interval that is not widely spread (10.2-17.6)

Table 6: Prevalence of ADRs of the Respondent

Proportion (%)	95% Confidence Interval
13.5	10.2-17.6

Adverse Drug Reactions (ADRs)

The most prevalent ADR was dizziness at 10.3%, the headache came in second at 9.3% malaise at 3.3% followed by rash at 2.1%. Diarrhea and others tie at 1.85%, while trouble concentrating, and sleep problems also tie at 1.2%. Strange dreams, skin discoloration, muscle pain, and stomach pain were the other prevalent ADRs at 0.6%

Table 7: Risk factors as evaluated in a multivariate logistic analysis

Adverse Drug Reaction	Proportion (%)	95% Confidence Interval
Muscle Pain	0.6	0.1-2.4
Headache	9.3	6.6-13.0
Malaise (body weakness)	3.3	1.8-5.9
Dizziness	10.3	7.4-14.1
Rash	2.1	1.0-4.4
Skin discoloration	0.6	0.1-2.4
Strange dreams	0.6	0.1-2.4
Sleep problems	1.2	0.4-3.2
Trouble concentrating	1.2	0.4-3.2
Stomach pain	1.2	0.1-2.4
Vomiting	0.6	0.3-2.8
Diarrhea	0.9	0.8-4.0
Others	1.8	0.8-4.0

Risk factors as evaluated in a multivariate logistic analysis

The results in Table 7 show that only 45 respondents had ADRs. Risk factors were evaluated in a multivariate logistic analysis and also showed categorical variable association with the development of ADRs using adjusted odds ratio, 95% CI, and p-values. The study found out that; males have 72% chance of not presenting with ADRs as compared to the females 0.28(95%C; 0.02-3.57), P-value 0.326 not significant. Results also showed that respondents who were not living with their families were 2.72 times more likely to present with ADRs 2.72 (95 %CI; 0.53-13.90), P-value 0.229 was not significant. Still, the study results showed that respondents presenting with co-morbidities were 55.6 times more likely to present with ADRs 55.6(95%C; 2.40-1286.7), P-value 0.012 significant. Also, study results showed that respondents who were on HAART for a longer time had less risk of the development of ADRs that is to say greater than 5 years (99%) safe 0.01(95%CI; 0.00-0.11), P-value 0.001 and significant, 3-4 years (89%) safe 0.11(95%CI; 0.02-0.76) P-value 0.025 and significant, 1-2 years (72%) safe from ADRs 028(95%CI 0.04-1.88) P-value 0.188 and insignificant. Occupation type also influenced the development of ADRs in those farmers were more protected by an 889% chance of not getting ADRs 0.12(95%CI 0.01-1.51) P-value 0.100 and insignificant, but on the contrary, the service providers were 4.8 times likely to succumb to ADRs 4.80(95%CI 0.44-52.80) P-value0.198 and insignificant. Occupation types of respondents also showed that full-day workers were more protected by 98% chance 0.02(5%CI; 0.00-0.63) P-value 0.026 and significant, half-day workers were on the other hand 1.06 times exposed to acquiring ADRs 1.06(95% CI: 0.16-7.15) P-value 0.951 and insignificant like the quarter day workers.

DISCUSSION

In this study, we discovered that 13.5% of respondents experienced Adverse Drug Reactions (ADRs), with a 95% Confidence Interval (CI) ranging from 10.2% to 17.6%. Importantly, the prevalence of ADRs among HIV/AIDS patients receiving Highly Active Antiretroviral Therapy (HAART) was strongly linked to the duration of HAART. Our findings suggest a higher likelihood of ADR occurrence among patients with less than one year of therapy compared to those with 1-2 years, 3-4 years, and over 5 years, which aligns with similar research conducted in Tehran, Iran [24]. Additionally, a study in Nigeria [25], reported ADRs occurring within 3-18 months of treatment initiation, supporting our observations. We also observed an increased risk of ADRs among respondents with comorbidities and those taking concurrent medications. Interestingly, full-time workers exhibited a lower risk compared to part-time workers, and occupation type also influenced ADR development, with service providers being at a higher risk than farmers and traders. Furthermore, our study emphasized the impact of counseling attendance on ADR development. Occasional and infrequent attendees had a higher chance of avoiding ADRs than regular attendees. Gender emerged as another factor, with males being less likely to experience ADRs compared to females, consistent with findings from a study in Sierra Leone [26]. Regarding specific ADRs associated with ART therapy, dizziness was the most common at 10.3%, followed by headache (9.3%) and malaise (3.3%). Other notable ADRs included rash (2.1%), diarrhea (1.8%), sleep disturbances, and concentration difficulties (1.2%). Vomiting accounted for 0.9% of reported ADRs, while muscle pain, skin discoloration, stomach pains, and unusual dreams each represented 0.6%. In comparison, a study conducted in Nigeria [25] reported skin rash (9.1%), itching (9.5%), stomach discomforts (9.1%), and dermatitis (5.5%) as common ADRs, partially aligning with our findings but with differing prevalence percentages. This improved articulation enhances clarity while also improving readability and cohesion.

CONCLUSION

In conclusion, this study shows that there is a significant occurrence of Adverse Drug Reactions (ADRs) in females. This emphasizes the need for awareness programs and strategies specifically designed for each gender to reduce ADRs. In particular, HIV patients with other health conditions require regular monitoring due to the strong link between their co-medications and the development of ADRs. Additionally, patients starting Highly Active Antiretroviral Therapy (HAART) often experience common ADRs, highlighting the importance of patient adherence to therapy and their understanding that ADRs usually decrease over time.

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RECOMMENDATIONS

Based on the findings of the study, we recommend that;

1. There should be gender-based empowerment of the females since they are highly affected by the therapy to reassure them to adhere to the therapy for the long-term benefits.
2. Patients with other morbidities should be carefully treated with the least amounts of safe and effective drugs so as to reduce interactions with the ART regimen.
3. Newly initiated patients on HAART should be reminded and reassured to stick to Methergines as these effects mainly affect those in the initiation stage.
4. Other studies were done around the country to have a stronger standpoint asper the prevalence of ADRs amongst HIV/AIDS patients on HAART.

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