THE IMPACT OF DEMOGRAPHIC FACTORS ON ADVERSE DRUG REACTIONS AND SURVIVAL RATES AMONG HIV PATIENTS IN NAIROBI COUNTY FROM 2015 TO 2021

BY

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W62/34160/2019

A PROJECT REPORT SUBMITTED TO THE DEPARTMENT OF PUBLIC & GLOBAL HEALTH IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF SCIENCE IN MEDICAL STATISTICS OF THE UNIVERSITY OF NAIROBI.

01/11/2023

DECLARATION

I certify that this thesis is my original creation and has not been previously submitted for a degree or any other form of recognition in any other academic institution.

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ACRONYMS AND ABBREVIATIONS

ADR Adverse Drug Reaction
AIDS Acquired Immune Deficiency Syndrome
ALT Alanine amino transferases
ART Antiretroviral therapy
ARV Antiretroviral
AST Aspartate amino transferases
CCC Comprehensive Care Centre
CNS Central Nervous System
HAART Highly Active Antiretroviral Therapy
HCP Health care provider
HIV Human immune deficiency Virus
KAIS Kenya AIDS Indicator Survey
KDHS Kenya Demographic Health Survey
NASCOP National AIDS and STI Control Programme
NACC National AIDS Control Council
NNRTI Non-nucleoside reverse transcriptase Inhibitor
NVP Nevirapine PI Protease inhibitor
PLWHA People Living With HIV/AIDS
STI Sexually transmitted illnesses
UNAIDS United Nations Agency for International Development
USAID United States Agency for International Development
WHO World health organization
AHD Advanced HIV Disease
AHR Adjusted Hazard Ratio
CHR Crude Hazard Ratio
CI Confidence Interval

DEFINITION OF TERMS

Adverse drug reactions: refer to an unintended and harmful response to a drug at doses typically used for prophylaxis, diagnosis, therapy, or physiological function modification.

Side effects: are unwanted effects of drugs at standard dose that are related to the drug's pharmacological properties.

Detection: is the act of discovering something that is not readily apparent or hidden.

Management: involves controlling or skillfully treating an abnormal physiological condition with the goal of making it more manageable.

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ABSTRACT

Background: Among people living with HIV/AIDS (PLWHA) Antiretroviral therapy (ART) plays a pivotal role, substantially elevating the quality of life and life expectancy. However, adverse drug reactions (ADRs) are a significant concern for those on HIV treatment. These reactions often translate to suboptimal adherence, engendering psychological distress and imparting additional financial strains on the healthcare system, especially in cases necessitating hospitalization. Furthermore, they tend to discourage individuals from assuming responsibility for their own health, posing formidable challenges to effective treatment and further prevention of HIV transmission. Hence, effective detection and management of ADRs emerged as critical requisites to ensure optimal treatment outcomes and avert untoward repercussions.

Broad Objective: The broad objective of this study was to comprehensively examine and understand the relationship between demographic factors, adverse drug reactions (ADRs), and survival rates among HIV patients undergoing antiretroviral therapy (ART) in Nairobi County from 2015 to 2021.

Methodology: Employing a cross-sectional design and drawing upon secondary data from healthcare facilities in Nairobi City County offering antiretroviral therapy, the study provided a descriptive summation of the data, offering crucial insights into the distribution of ADRs among PLWHA. Survival analysis techniques, including Kaplan-Meier survival curves, were employed to estimate the prevalence of ADRs over time. The Log-rank test was wielded to scrutinize disparities in survival profiles among different demographic or clinical groups. Additionally, Cox proportional hazards regression models unearthed factors intricately associated with the onset of ADRs among PLWHA. Throughout the study, stringent ethical considerations were upheld. All data was meticulously anonymized and treated with the utmost confidentiality to safeguard the privacy of the individuals encompassed. The study seamlessly aligned with established ethical protocols and frameworks governing data collection and analysis within the ambit of Pharmacovigilance in Kenya.

Significance of the study: The study's findings promised to shed light on crucial facets associated with ADR management, augmenting ART compliance, and ultimately fortifying the public health framework. Its salience lay in its potential to bridge knowledge gaps and elevate the standard of care for PLWHA in Nairobi City County, thereby contributing tangibly to the collective pursuit of a healthier populace.

Summary of Results: The study found significant correlations between demographic factors and ADR occurrences among PLWHA in Nairobi County. Females exhibited higher ADR rates compared to males, and age significantly influenced ADR severity, with the older age group displaying higher risks. Survival analysis indicates that ADR incidence is highest in the initial years of antiretroviral therapy (ART) initiation and diminishes over time.

Conclusion: The influence of demographic factors on survival rate is evident, with age, and education statistically significant. This study underscores the importance of tailored interventions for different demographic groups to enhance ADR management and improve overall treatment outcomes for PLWHA in Nairobi County.

Recommendations: Tailored interventions should be implemented to address ADRs among PLWHA, with specific focus on gender and age-based differences. Continuous pharmacovigilance efforts should be implemented for ongoing ADR monitoring and management. Additionally, healthcare providers should be equipped with the necessary training and resources to effectively identify and address ADRs among PLWHA.

CHAPTER ONE: INTRODUCTION

1.1 Background of the study

As of 2023, HIV/AIDS continues to be a significant global health concern, with sub-Saharan Africa bearing the highest burden of the disease. The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that around 38 million people worldwide were living with HIV/AIDS in 2020, resulting in approximately 690,000 AIDS-related deaths (UNAIDS, 2021). While there has been a 31% reduction in new HIV infections since 2010, progress in reducing AIDS-related fatalities has been slower, with an 8% decrease over the same period (UNAIDS, 2021). Additionally, marginalized groups, including men who have sex with men, sex workers, and individuals who use injected drugs, still face significant barriers in accessing testing, treatment, and preventive services.

Despite these challenges, strides have been made in HIV prevention and treatment. Pre-exposure prophylaxis (PrEP) has proven highly effective in preventing HIV transmission, and the introduction of long-acting injectable PrEP could enhance accessibility to this prevention option (Pinto et al., 2021). The advent of antiretroviral therapy (ART) has transformed HIV from a life-threatening condition to a manageable chronic ailment for many individuals living with the virus (Fellows and Venter, 2021).

However, meeting global targets for HIV/AIDS necessitates sustained investments in prevention, testing, and treatment services, as well as addressing structural factors contributing to HIV vulnerability. UNAIDS has set ambitious goals for 2025, including achieving viral suppression in 95% of individuals on ART, ensuring 95% of those diagnosed with HIV receive ART, and ensuring 95% of people living with HIV are aware of their status (UNAIDS, 2019).

In Kenya, estimates suggest that 1.4 million individuals live with HIV/AIDS, with women disproportionately affected (UNAIDS, 2021). Antiretroviral therapy (ART) remains the most effective intervention for prolonging the survival of people living with HIV/AIDS, and Kenya has made significant progress in increasing access to ART, with 1.2 million people receiving ART by mid-2021 (NASCOP, 2021).

Adverse Drug Reactions (ADRs) refer to harmful or undesirable effects resulting from the use of medications prescribed to treat various medical conditions (WHO,2016). As medical

interventions play a pivotal role in managing HIV infection, the occurrence of ADRs among HIV patients has garnered substantial attention. The prevalence of ADRs among HIV patients in Nairobi County is a critical area of investigation due to the potential impact on patient health, quality of life, treatment adherence, and overall healthcare costs (Mills et al., 2006). Recent research has underscored the significant impact of adverse drug reactions (ADRs) on adherence to Antiretroviral Therapy (ART) and the overall quality of life for individuals with HIV/AIDS. ADRs stand as a primary driver for discontinuing treatment, exerting substantial influence on both mental and physical well-being, as well as on healthcare expenses and productivity (Aina et al., 2021; Belayneh et al., 2021; Sweat et al., 2020; An et al., 2020). Ongoing endeavors to manage and mitigate ADRs among people living with HIV/AIDS are in progress, with interventions such as pharmacist-led counseling and structured ADR monitoring programs demonstrating promising outcomes (Bikara et al., 2021; Sharma et al., 2021). Continuous research and interventions remain crucial in augmenting the effectiveness of HIV/AIDS treatment.

HIV treatment typically involves a combination of antiretroviral therapy (ART) drugs to suppress the virus and enhance immune function (WHO,2017). While ART has significantly improved the prognosis and longevity of HIV patients, it is not without risks. ADRs can range from mild discomfort to severe and life-threatening complications, necessitating careful monitoring and management (van den Berg-Wolf et al.,2008).

The prevalence of ADRs among HIV patients in Nairobi County is further influenced by the evolving landscape of antiretroviral therapy. The introduction of new medications and treatment regimens may carry unique ADR profiles, necessitating ongoing surveillance and assessment. Understanding the prevalence of ADRs can aid healthcare providers in identifying high-risk patient groups and tailoring interventions to minimize the impact of these reactions on treatment outcomes (Sivadasan et al.,2009).

Moreover, the prevalence of ADRs has implications beyond individual patients. It can affect healthcare resource allocation, healthcare costs, and healthcare system sustainability. A comprehensive understanding of ADR prevalence can assist policymakers in making informed decisions about resource allocation and health infrastructure development (Atif et al., 2016).

Adverse Drug Reactions (ADRs) pose a significant challenge in the management of HIV, a complex and chronic medical condition. The advent of highly active antiretroviral therapy (ART)

has transformed HIV from a life-threatening disease to a manageable chronic condition (Deeks et al.,2009). However, the benefits of ART must be weighed against the potential risks of ADRs, which can compromise treatment efficacy and patient well-being (Palella et al.,2016).

The prevalence of ADRs among HIV patients in Nairobi County is influenced by various factors, including the choice of antiretroviral drugs, patient characteristics, co-existing medical conditions, and drug interactions (Degu et al., 2017). Understanding the extent to which ADRs affect this population is essential for healthcare professionals to develop effective strategies to mitigate risks, improve treatment adherence, and optimize the quality of life for patients (Degu et al., 2017).

Understanding the outcomes of ADRs among HIV patients in Nairobi County is essential for assessing the effectiveness of interventions and healthcare practices (WHO,2016). The outcomes of ADRs may include factors such as treatment modifications, hospitalizations, discontinuations of medication, development of drug resistance, or even mortality (Magro et al., 2008). These outcomes have far-reaching implications for both individual patients and the healthcare system as a whole.

The outcomes of ADRs can provide insights into the success of HIV treatment regimens, the need for improved patient monitoring, and the importance of patient education regarding potential side effects (Cipolle et al.,2018). By studying these outcomes, healthcare professionals and policymakers can make informed decisions to optimize patient care and minimize the impact of ADRs on treatment outcomes.

The outcomes of ADRs are closely intertwined with patient-centered care and shared decision-making. When patients experience adverse reactions, they are faced with the challenge of balancing the potential benefits of treatment against the perceived risks and discomfort of ADRs (Zambon et al.,2017). This delicate balance can impact treatment adherence, leading to cascading effects on treatment efficacy and overall health outcomes.

Furthermore, the outcomes of ADRs can impact patient perceptions of treatment effectiveness and safety. Patients who experience positive outcomes after ADR resolution may develop greater trust in their treatment regimen, leading to improved adherence and overall treatment success (Rajpoot et al.,2016). Conversely, unresolved or severe ADRs may erode patient confidence and hamper long-term treatment engagement.

The outcomes of ADRs among HIV patients encompass a wide spectrum of effects, ranging from minor inconveniences to severe health complications. Some ADRs may lead to treatment modifications, necessitating changes in medication regimens to manage side effects. Others may result in hospitalizations, contributing to increased healthcare costs and resource utilization (Thompson et al., 2013).

In more severe cases, ADRs can lead to treatment discontinuation, potentially leading to virologic failure, drug resistance, and compromised immune function (Colgrove et al., 2014). Additionally, certain ADRs, such as hypersensitivity reactions, can have life-threatening implications. Understanding the patterns of ADR outcomes among HIV patients in Nairobi County is critical for clinicians and policymakers to tailor interventions that address the specific needs of the patient population, reduce ADR-related burden, and improve overall treatment outcomes (Santos et al., 2014).

Demographic factors, such as age, gender, socioeconomic status, and access to healthcare services, can significantly influence the survival rates of HIV patients experiencing ADRs (Gupta, 2018). Identifying how these factors impact patient outcomes is crucial for tailoring interventions and support systems to address disparities and promote equitable access to care.

For instance, younger patients may be more susceptible to certain ADRs due to differences in metabolism, while socioeconomic factors could impact access to timely medical attention (Varghese et al., 2020). A comprehensive understanding of how demographic factors interact with ADRs and survival rates can guide the development of targeted interventions to improve patient outcomes and reduce health disparities.

The exploration of demographic influences on survival rates among HIV patients with ADRs holds the potential to uncover disparities in healthcare access and outcomes (Smedley et al., 2003). Factors such as gender, socioeconomic status, and geographic location can significantly impact a patient's ability to access healthcare services, adhere to treatment plans, and manage ADRs effectively.

Furthermore, the influence of demographic factors extends beyond the individual level. Addressing disparities related to ADRs can contribute to achieving broader public health goals, such as reducing healthcare inequalities and improving overall population health (Braveman et al., 2014).

Demographic factors play a pivotal role in shaping the experiences of HIV patients facing ADRs (Sterne et al., 2009). Age-related differences in immune response and drug metabolism can contribute to variations in ADR susceptibility and severity (Kanters et al., 2016). Additionally, socioeconomic status and access to healthcare services may impact a patient's ability to manage ADRs effectively and seek timely medical attention.

The interplay of demographic factors with ADRs can also extend to treatment adherence. Patients from marginalized backgrounds may face challenges in accessing medical care, adhering to complex medication schedules, and managing potential ADRs (Cederfjäll et al., 2015). Addressing these disparities is vital for ensuring equitable healthcare delivery and optimizing survival rates among HIV patients experiencing ADRs.

Nairobi City County (NCC) plays a significant role in the HIV landscape of Kenya. The region is home to approximately 160,000 individuals living with the virus, including 11,104 children. Due to its status as the capital city, Nairobi hosts a dynamic population, characterized by frequent internal migration and the presence of refugees, in addition to external migration. These factors pose an elevated risk for contracting HIV. Despite a consistent decline in HIV prevalence rates over the past decade, from a peak of 14% during the epidemic to the current rate of 8%, the number of new infections in Nairobi remains substantial, with approximately 3,200 new cases reported annually. Of these, 39% are co-infections of HIV and tuberculosis (TB), and nearly 4,000 AIDS-related deaths are recorded.

Nairobi also has a notable population of Key Populations (KPs), which includes sex workers, men who have sex with men, and injecting drug users. These groups exhibit high HIV prevalence rates ranging from 18% to 30%. In Nairobi City County, the prevalence of HIV is higher among women at 8.4%, compared to 5.3% among males. Furthermore, the Kenya Demographic and Health Survey (KDHS) of 2014 revealed that less than 50% of adults consistently use condoms, heightening the risk of infection within the general population.

1.2 Problem statement

Individuals living with HIV/AIDS (PLWHA) now experience extended lifespans and improved quality of life due to the availability of antiretroviral therapy (ART). However, the benefits of ART come with the potential for adverse drug reactions (ADRs) that can jeopardize treatment safety and effectiveness. ADRs may lead to treatment disruptions,

reduced adherence, and diminished quality of life for PLWHA. Additionally, they can contribute to the emergence of drug-resistant viral strains, complicating and increasing the cost of treatment. While ART is provided free of charge through the National AIDS and STI Control Program (NASCOP) across all counties in Kenya, there remains a dearth of information regarding the prevalence and specific patterns of ADRs in PLWHA receiving ART in Nairobi County, the country's capital and largest city.

While previous studies have reported on ADR occurrences in PLWHA receiving ART in other regions of Kenya, it's essential to recognize that the prevalence and characteristics of ADRs in Nairobi County may differ due to various factors. These may include distinctions in patient demographics, prescribed drug regimens, and the presence of comorbid conditions. Various factors have been associated with ADRs, encompassing age, gender, duration of ART, specific ART medications, concurrent health conditions, and potential drug interactions. Identifying these factors linked to ADR incidence in PLWHA on ART can significantly inform the development of strategies aimed at mitigating ADR occurrences and enhancing treatment outcomes.

To make informed clinical decisions and ultimately enhance patient well-being, it is imperative to ascertain the prevalence and specific patterns of ADRs in PLWHA receiving ART in Nairobi County. This study, conducted through a cross-sectional investigation, was designed with the aim of addressing this critical knowledge gap.

One of the primary hurdles in managing HIV/AIDS lies in the occurrence of adverse reactions to medications in individuals undergoing ART. ADRs have the potential to disrupt treatment, reduce adherence, and lead to the emergence of drug-resistant viral strains, intensifying the complexity and cost of treatment. Thus, gaining a comprehensive understanding of the prevalence and patterns of ADRs in HIV/AIDS patients receiving ART is fundamental for guiding clinical decision-making and ultimately improving patient outcomes. This study's objective is to assess the frequency and types of adverse drug reactions (ADRs) experienced by individuals living with HIV/AIDS who are undergoing antiretroviral therapy in Nairobi County.

1.3 Study Justification

The pressing need for a comprehensive investigation into the prevalence of Adverse Drug Reactions (ADRs) among HIV patients in Nairobi County, as well as the potential influence of demographic factors on survival rates, is evident. This study is poised to bridge existing knowledge gaps and make a substantial contribution to the enhancement of patient care, treatment outcomes, and the overall sustainability of the healthcare system.

Understanding the outcomes of ADRs among HIV patients is vital for evaluating the effectiveness of interventions and healthcare protocols (Gupta, 2018). Through the identification of changes in treatment strategies, hospitalizations, discontinuations of medication, and their consequences, healthcare providers can tailor care approaches to meet the unique needs of individual patients. The study's results are anticipated to bring to light the impact of ADRs on treatment adherence (Rajpoot et al., 2016). Demographic factors like age, gender, and socioeconomic status play a significant role in how patients perceive ADRs, subsequently influencing their adherence to treatment plans. These demographic attributes substantially influence patient outcomes (Smedley et al., 2003). This study delved into how factors such as age, gender, socioeconomic status, and access to healthcare contribute to survival rates among HIV patients grappling with ADRs. Identifying these disparities will inform the development of targeted interventions to ensure fair access to healthcare.

Addressing disparities associated with ADRs aligns with broader public health goals (Braveman et al., 2014). By comprehending the intersection of demographic factors with ADRs, policymakers can make informed decisions to alleviate healthcare inequities and uplift the overall health of the population. The study's outcomes will enrich the existing knowledge base by illuminating the prevalence, consequences, and demographic influences of ADRs among HIV patients. This newfound insight will empower healthcare professionals to provide more individualized care and support to patients.

In conclusion, the proposed study holds significance in its potential to uncover valuable insights into the prevalence of ADRs, their outcomes, and the interplay of demographic factors on survival rates among HIV patients in Nairobi County. The study's findings have the capacity to shape healthcare practices, elevate patient care, strengthen treatment adherence, and contribute to broader public health goals. This research marks a crucial stride toward optimizing ADR

management within the context of HIV treatment, ultimately enhancing patient well-being and fostering efficiency within the healthcare system.

1.4 Research Questions

1) What is the prevalence of Adverse Drug Reactions (ADRs) in HIV patients in Nairobi County?
2) What are the outcomes of Adverse Drug Reactions (ADRs) in HIV patients in Nairobi County?
3) Are there different survival rates among people with Adverse Drug Reactions (ADRs) in demographic factors such as gender, age groups and level of education?

1.5 General Objectives

The broad objective of this study was to comprehensively examine and understand the relationship between demographic factors, adverse drug reactions (ADRs), and survival rates among HIV patients undergoing antiretroviral therapy (ART) in Nairobi County from 2015 to 2021.

1.6 Specific Objectives

1) To Determine the Prevalence of Adverse Drug Reactions (ADRs) Among HIV Patients in Nairobi County
2) To ascertain the outcomes of Adverse Drug Reactions (ADRs) Among HIV Patients in Nairobi County
3) To Explore the Influence of Demographic Factors on Survival Rates Among HIV Patients with Adverse Drug Reactions in Nairobi County

1.7 Significance and Anticipated Outcome

The findings of this research had benefits for both individuals living with HIV/AIDS (PLWHA) and healthcare providers (HCPs) in identifying and managing adverse drug reactions (ADRs). ADRs were a major contributor to poor adherence to antiretroviral drugs (ARVs), which could result in treatment failure and the development of multidrug-resistant viruses. Some ADRs had

lifelong disfiguring effects, while others might have been irreversible even after stopping the offending drug. Early detection, prevention, and management of ADRs had the potential to significantly improve and prolong the quality of life of HIV patients.

1.8 Limitation of the study

However, it's worth noting that this research comes with certain limitations. The selection of Nairobi County as the study area was driven by its high population density and a larger number of HIV patients compared to other counties. Additionally, the presence of opportunistic infections associated with AHDS syndrome may pose a challenge for patients in distinguishing ADRs from symptoms of the underlying disease, potentially leading to underreporting. Furthermore, the study relied on patients' recollection of symptoms related to ADRs, which could be susceptible to memory lapses or influenced by the stigma associated with the disease. Moreover, the patient cohort observed in the study was confined to individuals prescribed ARVs recommended by the National AIDS and STI Control Program, potentially not fully representing the spectrum of ARVs available in private hospitals across Kenya.

Various factors concerning both patients and caregivers, including educational attainment, socio-cultural perspectives, and healthcare-seeking behavior, can impact the identification and reporting of ADRs. Individuals with higher levels of education and active religious involvement may exhibit a higher reporting tendency, possibly due to reduced stigma and increased social acceptance. A patient's proficiency in recognizing their medication and understanding their dietary habits could also influence ADR reporting. The specific characteristics of therapy, including the various classes of ARVs and individual drugs, may give rise to distinct ADRs that may manifest under specific circumstances, contingent on other medications the patient is using. The identification and management of ADRs largely hinge on the knowledge and expertise of healthcare providers (HCPs), and it is also incumbent on HCPs to educate patients on how to identify and address ADRs. Additionally, patient attributes such as age, gender, weight, presence of comorbidities, and duration of ARV usage may exert an influence on the occurrence and reporting of ADRs.

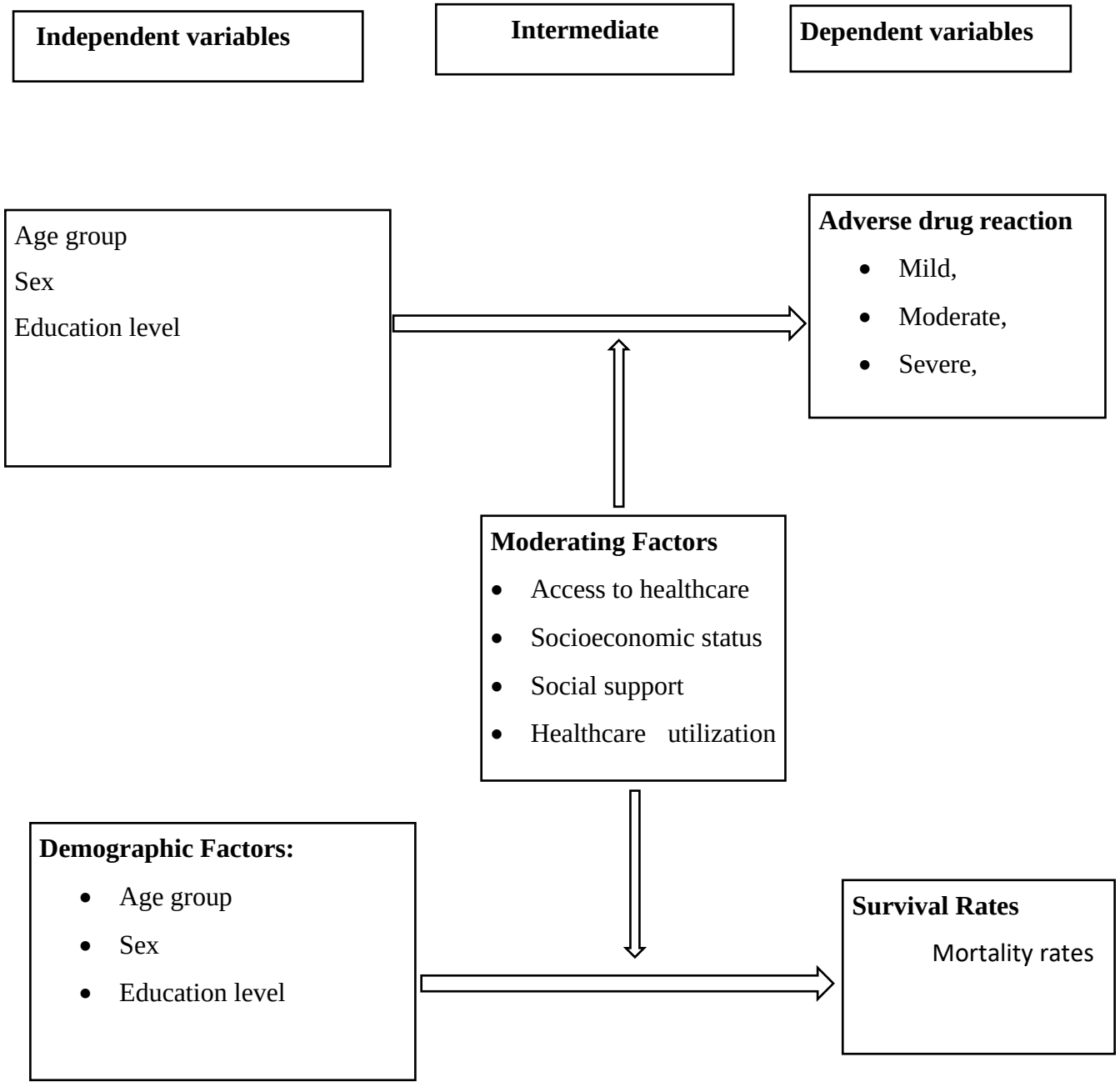

FIGURE 1:Conceptual Framework

1.9 Conceptual Framework

The conceptual framework of this study revolved around three central constructs:

1. **Frequency of ADRs in HIV Patients in Nairobi County:** This component primarily investigated the occurrence rate of Adverse Drug Reactions (ADRs) in individuals living with HIV/AIDS in Nairobi County. Key factors under scrutiny included demographic variables such as age, gender, and education level. Moreover, co-existing medical conditions, specific medication regimens, and the duration of HIV infection were integral to assessing ADR prevalence.
2. **Outcomes of ADRs in HIV/AIDS Patients in Nairobi County:** This segment of the study was dedicated to the exploration of the repercussions stemming from ADRs in HIV patients within Nairobi County. The study delved into outcomes including hospitalization, disability, and mortality as a direct consequence of ADRs. Additionally, the research investigated the impact of ADRs on the overall quality of life for individuals living with HIV/AIDS.
3. **Comparison of Survival Rates among People with ADRs:** This facet placed emphasis on contrasting the survival rates among HIV/AIDS patients who encountered ADRs. Various factors were scrutinized in this context, encompassing geographical region, gender, age groups, and education levels. The primary aim was to determine whether there were significant disparities in survival rates across different groups of individuals experiencing ADRs.

In essence, this study endeavored to furnish valuable insights into the prevalence, consequences, and survival rates related to ADRs within the population of individuals with HIV/AIDS in Nairobi County. The research employed a quantitative research design, with data sourced from medical records and surveys conducted among individuals living with HIV/AIDS in the county. Sample size determination was grounded in a power analysis, taking into account the estimated prevalence of ADRs within the population. The analysis of the collected data encompassed both descriptive statistics and inferential statistics, including the application of chi-square tests and logistic regression models.

The Social-Ecological Model (SEM), which accentuated the interplay between individual, interpersonal, community, and societal factors influencing health outcomes, served as the foundational framework for this study. The individual factors explored included age, gender,

education level, co-morbidities, and medication regimens. Interpersonal factors extended to aspects such as social support, stigma, and discrimination. On a broader scale, the research also scrutinized community and societal factors, encompassing access to healthcare, healthcare policies, and socio-economic status.

This study bore significant importance, as it provided a deeper comprehension of the prevalence, consequences, and survival rates linked to ADRs in HIV patients within Nairobi County. The study's findings were instrumental in shaping healthcare policies and interventions aimed at augmenting the quality of life for individuals living with HIV/AIDS while concurrently mitigating the burden of ADRs. Furthermore, the research contributed to the expanding knowledge base on the Social-Ecological Model and its applicability within the realm of healthcare research.

CHAPTER TWO: LITERATURE REVIEW

Antiretroviral therapy (ART) stands as the established treatment protocol for individuals living with HIV. This treatment regimen has markedly diminished both the morbidity and mortality rates among HIV-positive patients by effectively suppressing the virus and bolstering immune response. However, it's worth noting that ART can sometimes entail adverse drug reactions (ADRs), which encompass undesirable and potentially harmful effects associated with medication. ADRs can, in turn, lead to discontinuation of treatment, suboptimal adherence, treatment ineffectiveness, and an escalation in morbidity and mortality rates. Hence, it is imperative to ascertain the prevalence, severity, and underlying risk factors associated with ADRs in HIV-positive patients undergoing ART. This literature review endeavors to furnish a comprehensive overview of the most up-to-date information regarding adverse drug reactions (ADRs) in HIV-positive patients undergoing ART within Nairobi County.

2.1 Prevalence of ADRs among HIV-positive patients:

The prevalence of adverse drug reactions (ADRs) among HIV-positive patients undergoing antiretroviral therapy (ART) exhibits considerable variability across different populations and settings. A comprehensive review and meta-analysis by Li et al. (2017) revealed an overall ADR prevalence of 31.8% among such patients, with resource-limited settings reporting a higher prevalence (36.2%) compared to high-income settings (24.3%). The most commonly reported types of ADRs encompassed gastrointestinal symptoms, skin rash, hepatotoxicity, and neurological symptoms.

Various studies have highlighted elevated ADR rates within specific subgroups of HIV-positive patients. For instance, research conducted by Oshikoya et al. (2015) in Nigeria identified a higher prevalence of ADRs among older patients and those with comorbidities. Similarly, Hahn et al. (2014) in Kenya found that 65.5% of HIV-positive patients undergoing ART experienced at least one ADR. Likewise, a study by Lakshmi et al. (2019) in India reported that 57.5% of HIV-positive patients experienced at least one ADR. A study conducted by Tetteh et al. (2017) in Ghana reported a prevalence of 37.3%. These disparities in ADR prevalence may be attributed to variations in study design, patient demographics, and methodologies employed for ADR assessment.

The fluctuation in ADR prevalence among HIV-positive patients receiving ART can be ascribed to various factors, including individual patient characteristics, specific ART regimens, and the strategies employed for monitoring. The utilization of multiple ART regimens and potential drug interactions may also heighten the risk of ADRs among this patient population (Afonso et al., 2017). Hence, vigilant patient monitoring and timely identification and management of ADRs play a pivotal role in mitigating their occurrence and severity.

2.2 Type and severity of ADRs:

Adverse drug reactions (ADRs) pose a significant concern for individuals living with HIV and undergoing antiretroviral therapy (ART). These reactions encompass a spectrum of types and severity levels, ranging from mild to severe, with potential life-threatening implications. The most frequently reported ADRs in HIV-positive patients on ART include gastrointestinal, neurological, and dermatological symptoms. Notably, studies by Hahn et al. (2014), Lakshmi et al. (2019), and Tetteh et al. (2017) consistently highlight gastrointestinal symptoms like nausea, vomiting, and diarrhea as prevalent ADRs. Similarly, neurological symptoms such as headaches, dizziness, and peripheral neuropathy are reported in these studies.

In terms of severity, the majority of ADRs encountered by HIV-positive patients on ART tend to be mild to moderate, with only a small fraction considered severe or life-threatening, as demonstrated by findings from Lakshmi et al. (2019) and Tetteh et al. (2017). Gastrointestinal symptoms, including nausea, vomiting, diarrhea, and abdominal pain, hold particular prominence among the reported ADRs. These symptoms not only affect a patient's overall well-being but can also impact adherence to ART, potentially leading to increased morbidity, mortality, and treatment setbacks (Afonso et al., 2017).

Skin rash represents another common ADR in HIV-positive patients on ART. While often mild and self-resolving, some cases necessitate immediate medical attention. In severe instances, conditions like Stevens-Johnson syndrome or toxic epidermal necrolysis can emerge, demanding hospitalization (Veenstra et al., 2017). Additionally, hepatotoxicity, or liver damage, is a well-documented ADR linked to ART utilization in HIV-positive patients. Various antiretroviral drugs have been associated with hepatotoxicity, displaying varying levels of severity.

Neurological symptoms, including headaches, dizziness, and neuropathy, feature prominently as ADRs among HIV-positive patients on ART. These symptoms may arise due to direct

medication toxicity or the immune reconstitution inflammatory syndrome (IRIS) (Kipp et al., 2012). In certain cases, hepatotoxicity can escalate to a severe level, potentially leading to liver failure or even fatality (Naranjo et al., 2018).

Overall, ADRs represent a substantial concern for HIV-positive patients undergoing ART, exhibiting diverse types and degrees of severity. Their impact can range from minor, self-limiting effects to grave, life-threatening consequences. In severe instances, ADRs may necessitate hospitalization, disrupt treatment continuity, or tragically, result in loss of life. Factors influencing ADR severity encompass patient age, concurrent health conditions, specific ART regimens, potential drug interactions, and the presence of drug-resistant HIV (Shibabaw et al., 2020). A comprehensive understanding of the types and severity of ADRs associated with ART is pivotal in enhancing patient outcomes and diminishing the burden of morbidity and mortality.

2.3 Risk factors for ADRs among HIV-positive patients:

Numerous risk factors have been identified for adverse drug reactions (ADRs) in HIV patients undergoing antiretroviral therapy (ART), spanning age, gender, baseline CD4 count, and comorbidities like tuberculosis (TB) and hepatitis B (HBV) co-infections. These risk elements can be broadly categorized into patient-related, treatment-related, and disease-related factors. For instance, Tetteh et al.'s study (2017) in Ghana revealed that female gender, age exceeding 50 years, and TB co-infection emerged as noteworthy risk factors for ADRs in HIV-positive patients on ART. Similarly, Hahn et al.'s research (2014) in Kenya identified patients with a low baseline CD4 count (< 200 cells/mm3) and HBV co-infection as having an elevated risk of ADR development.

Patient-related factors that heighten the risk of ADRs in HIV-positive patients on ART encompass advanced age, female gender, and genetic predisposition. Older patients may face heightened ADR impact, possibly due to factors like diminished renal function, altered drug metabolism, and increased comorbidities. Additionally, the risk of ADRs has been observed to be greater in females, potentially attributed to hormonal disparities (Kasilo et al., 2016). Furthermore, genetic variations in drug-metabolizing enzymes have been associated with an augmented ADR risk (Hossein-Behzad et al., 2020).

Treatment-related factors that amplify ADR risk in HIV-positive patients receiving ART involve the use of multiple medications, resulting in a heightened potential for drug interactions and cumulative toxicity. Non-adherence to ART regimens can also elevate ADR risk, stemming from fluctuating drug levels and reduced treatment efficacy (Cenderello et al., 2015).

Disease-related factors that escalate ADR risk in HIV-positive patients receiving ART encompass advanced HIV disease, co-infection with hepatitis B or C viruses, and concurrent usage of medications. Advanced HIV disease, characterized by low CD4 cell counts and high viral loads, has been linked to an amplified risk of ADRs due to compromised immune function. Co-infection with hepatitis B or C viruses may raise the likelihood of hepatotoxicity associated with ART use. Simultaneous use of other medications, like antifungal or antibiotic therapy, may also heighten ADR risk due to potential drug interactions (Mukonzo et al., 2013).

Additional factors that could elevate the risk of ADRs in individuals with HIV on ART include a history of prior ADRs, medication errors, and drug-resistant strains of HIV. A prior history of ADRs may indicate a predisposition to developing further ADRs, while medication errors, such as incorrect dosing or administration, could increase the risk of toxicity. The presence of drug-resistant HIV may limit treatment options, potentially necessitating the use of medications with a higher potential for adverse effects (Kasilo et al., 2016).

2.4 Management and prevention of ADRs among HIV-positive patients:

Various strategies have been proposed to manage and prevent adverse drug reactions (ADRs) in HIV-positive individuals undergoing antiretroviral therapy (ART). These include vigilant patient monitoring, timely identification and intervention for ADRs, patient education on ADRs and treatment adherence, and the consideration of alternative ART regimens in cases of severe or life-threatening ADRs. Some studies have even suggested employing pharmacy genetic testing to identify patients with a higher likelihood of experiencing ADRs and to guide the selection of appropriate ART regimens (García-Álvarez et al., 2018; Lubomirov et al., 2014).

The efficacy of these strategies in reducing both the frequency and severity of ADRs has been examined in various studies. For example, a study by Rodríguez-Nóvoa et al. (2016) in Spain demonstrated that pharmacogenetic testing led to a reduction in ADR occurrence and an improvement in treatment adherence among HIV-positive patients on ART. Another study

conducted by García-Álvarez et al. (2018) in Spain found that tailoring ART regimens based on pharmacogenetic testing lowered ADR risk and enhanced treatment effectiveness.

Managing and preventing ADRs among individuals living with HIV and receiving ART is pivotal for enhancing treatment outcomes and decreasing the associated health risks. This can be approached through both pharmacological and non-pharmacological interventions.

Pharmacological interventions involve strategies like substituting problematic drugs, adjusting dosage levels, and providing symptomatic relief. Drug substitution entails replacing the offending medication with an alternative from the same class or a different therapeutic category. Dose reduction may be necessary for medications exhibiting dose-dependent toxicity. Additionally, specific ADRs may necessitate symptomatic treatment, such as addressing issues like rash, nausea, and diarrhea (Rajasuriar et al., 2017).

Non-pharmacological approaches encompass educating patients, monitoring and reporting ADRs, and modifying lifestyle factors. Patient education is paramount in increasing awareness about potential ADRs and promoting adherence to medication regimens. Monitoring and promptly reporting ADRs empower healthcare providers to swiftly identify and manage them. Lifestyle modifications, including reducing alcohol consumption and smoking, can also mitigate the risk of ADRs (Sulaiman et al., 2020).

Preventing ADRs in HIV-positive patients can be achieved through various strategies. These include judiciously selecting medications based on individual patient characteristics, closely monitoring for potential drug interactions, and ensuring adherence to prescribed medication regimens. Careful medication selection should consider factors like age, gender, existing health conditions, and genetic predisposition. Vigilant monitoring for drug interactions is crucial for identifying potential conflicts between ART medications and other drugs, which could elevate the risk of ADRs. Adhering to prescribed medication regimens is essential for maintaining drug levels within the therapeutic range and reducing the risk of ADRs (Rajasuriar et al., 2017).

Additional preventive measures encompass routine monitoring of essential laboratory parameters, screening for coexisting health conditions, and employing drug resistance testing. Regularly assessing factors like kidney and liver function aids in the early identification of potential ADRs. Screening for concurrent conditions such as hepatitis B or C viruses can further reduce the risk of ADRs by enabling healthcare providers to select the most appropriate medications. Lastly, drug resistance testing proves invaluable in identifying HIV strains resistant

to specific medications and guides the selection of effective treatment options (Sulaiman et al., 2020).

In conclusion, effectively managing and preventing ADRs in HIV-positive patients undergoing ART significantly improves treatment outcomes and overall quality of life. This comprehensive approach, combining pharmacological interventions, patient education, lifestyle modifications, and vigilant monitoring, forms a critical component of providing optimal care for individuals living with HIV.

2.5 The long-term impact of ADRs on treatment adherence and outcomes:

The enduring effects of adverse drug reactions (ADRs) on treatment adherence and outcomes in HIV-positive individuals undergoing antiretroviral therapy (ART) are of paramount importance for healthcare providers. ADRs wield substantial influence over the adherence to medication schedules, thereby exerting a consequential impact on treatment outcomes and the overall well-being of patients.

One of the pivotal long-term ramifications of ADRs on treatment adherence revolves around the development of drug resistance. These reactions can precipitate less-than-optimal adherence to medications, heightening the likelihood of virologic failure and the emergence of drug-resistant strains of HIV. Such resistance can necessitate the implementation of more intricate and costly treatment regimens, potentially deleterious to treatment outcomes and the quality of life for patients (Rajasuriar et al., 2017).

Furthermore, ADRs can give rise to the onset of comorbidities, encompassing conditions like renal dysfunction, metabolic irregularities, and cardiovascular disease. These additional health challenges can further convolute treatment efforts and diminish adherence levels. Comorbidities also escalate the potential for hospitalization and mortality among HIV-positive individuals (Sulaiman et al., 2020).

The enduring repercussions of ADRs extend to the realm of treatment outcomes as well. They can lead to interruptions or even discontinuations in treatment, heightening the peril of treatment ineffectiveness and disease advancement. ADRs can also culminate in a diminished quality of life and amplified reliance on healthcare services, culminating in augmented healthcare costs (Rajasuriar et al., 2017).

Moreover, the psychological and emotional toll exacted by ADRs on HIV-positive patients cannot be underestimated. These reactions can instigate feelings of anxiety, depression, and social detachment, perpetuating a cycle that further deteriorates treatment adherence and outcomes (Sulaiman et al., 2020).

Conclusively, the enduring repercussions of ADRs on treatment adherence and outcomes in HIV-positive patients receiving ART constitute a substantial concern for healthcare providers. The emergence of drug resistance, the onset of comorbidities, and their collective impact on adherence and outcomes hold potentially detrimental implications for patient health and the quality of life. It is imperative for healthcare providers to vigilantly monitor ADRs and implement strategies to manage and forestall them, thereby optimizing treatment adherence and overall patient well-being. Additionally, patients should receive comprehensive education regarding potential ADRs and their enduring effects to foster adherence to medication regimens and bolster overall patient health.

2.6 Survival rates among people with ADRs:

Numerous studies have delved into the survival rates of individuals experiencing adverse drug reactions (ADRs). A retrospective cohort analysis carried out in South Africa unearthed that the overall mortality rate within this cohort stood at 27.4%. Interestingly, this rate exhibited an elevated trend among men in comparison to women, with figures standing at 29.6% versus 23.4% respectively (Boulle et al., 2008). Furthermore, this investigation discerned that the mortality rate was notably amplified within older age brackets and among individuals grappling with advanced stages of HIV disease. In a separate study conducted in Nigeria, it was reported that the mortality rate among individuals contending with ADRs amounted to 10.8%. Here again, a similar pattern emerged, with men exhibiting a higher mortality rate compared to women, registering figures of 12.5% versus 9.1% respectively (Ezechi et al., 2013).

2.6.1 Gender and survival rates:

Gender plays a notable role in determining survival rates among individuals facing adverse drug reactions (ADRs). In a study carried out in Zambia, it was observed that women exhibited superior survival rates compared to men, a distinction found to be statistically significant (P=.01)

(Oguntibeju et al., 2012). Similarly, a study conducted in Cameroon underscored those men experienced higher mortality rates in contrast to their female counterparts, with this gender-based variation proving statistically significant (P=.02) (Djibrilla et al., 2016). The study attributed this disparity in mortality rates to discrepancies in healthcare-seeking behaviors observed between men and women.

2.6.2 Age groups and survival rates:

Age significantly influences survival rates among individuals experiencing adverse drug reactions (ADRs). A study conducted in South Africa unveiled that older age groups faced higher mortality rates among those with ADRs (Boulle et al., 2008). The research indicated that individuals aged 50 years and above exhibited a mortality rate of 42.9%, in stark contrast to 23.5% among those aged 20-29 years. Similarly, a study in Nigeria reported elevated mortality rates among individuals aged 40 years and above who experienced ADRs (Ezechi et al., 2013). Numerous studies have also pointed out that the susceptibility to ADRs tends to be higher in older individuals, primarily due to physiological changes associated with aging, such as diminished renal function and altered pharmacokinetics (Hartwig et al., 2010; Rieder et al., 2014). A study in China discovered a markedly higher incidence of ADRs in patients aged 60 years and older compared to those under 60 years (Yang et al., 2013). Moreover, older patients are more likely to have comorbidities and are often prescribed multiple medications, which escalates the risk of drug interactions and subsequently, ADRs (Hohl et al., 2013).

2.6.3 Education levels and survival rates:

Education level plays a substantial role in influencing survival rates among individuals grappling with adverse drug reactions (ADRs). A study in Zimbabwe demonstrated that individuals with higher education levels exhibited superior survival rates in comparison to those with lower education levels (P=.04) (Gwanzura et al., 2007). The research attributed the higher mortality rates among individuals with lower education levels to challenges in adhering to ART and a lack of knowledge regarding ADRs.

Low levels of education have been linked to suboptimal medication adherence, which subsequently heightens the risk of ADRs and diminishes treatment effectiveness (McDonald et

al., 2002; Zullig et al., 2015). A study conducted in Uganda unearthed that individuals with lower education levels were more prone to experiencing ADRs than their counterparts with higher education levels (Kiguba et al., 2016). Additionally, patients with lower education levels may encounter greater difficulty in accessing healthcare information and resources, further exacerbating the risk of ADRs and lowering survival rates.

2.7 Limitations of the literature:

Despite the substantial body of evidence regarding adverse drug reactions (ADRs) among HIV-positive patients undergoing antiretroviral therapy (ART), it is essential to acknowledge several limitations in this area of research. Firstly, the majority of studies have primarily concentrated on the prevalence of ADRs and the associated risk factors, with limited focus on assessing the effectiveness of various strategies and interventions for both managing and preventing ADRs. Secondly, many of these studies have been conducted in resource-limited settings where extensive laboratory testing and specialized care are often lacking, potentially limiting the generalizability of their findings to other settings. Thirdly, a common reliance on patient self-reports of ADRs in these studies raises concerns about the potential for recall bias and underreporting.

ADRs pose a substantial concern for HIV-positive individuals receiving ART in Nairobi County. Effective monitoring and management of ADRs are critical for providing optimal care to this patient population. Notable risk factors for ADRs encompass age, gender, baseline CD4 count, as well as comorbid conditions like tuberculosis (TB) and hepatitis B virus (HBV) co-infections. Various strategies and interventions have been proposed to address the issue of ADRs among HIV-positive ART recipients, including vigilant patient monitoring, timely recognition and management of ADRs, patient education on ADRs and treatment adherence, and the option of transitioning to alternative ART regimens in cases involving severe or life-threatening ADRs. Further research is warranted to comprehensively assess the efficacy of these strategies and interventions and to evaluate the long-term consequences of ADRs on medication compliance, virological suppression, and the overall quality of life among HIV-positive ART patients.

CHAPTER THREE: METHODOLOGY

3.0 Introduction

This chapter recounts the method which were employed to answer the research questions, tools and methods for data collection, sample size and sampling techniques, research design processing and analysis of data, as well as moral considerations.

3.1 Study Area Description

Nairobi, the vibrant capital of Kenya, is a melting pot of cultures and traditions. Its cityscape seamlessly blends modern skyscrapers with lush green spaces, creating a unique urban ambiance. In the 2019 census, Nairobi's population was recorded at 4,397,073 residents, highlighting its role as a hub of opportunity and innovation within Kenya. The administrative setup of Nairobi Province has evolved over the years, transitioning from a province to a county, reflecting the city's growth and the need for localized governance. Comprising 17 constituencies, each delineated to encapsulate distinct characteristics and community dynamics, the county's boundaries may not always align with traditional divisions.

Nairobi is not just a geographical entity; it represents a cultural crossroads, an economic powerhouse, and a beacon of urban vitality within Kenya. With diverse neighborhoods, historic landmarks, thriving markets, and a vibrant arts scene, Nairobi embodies the country's dynamism and future aspirations.

As the dynamic capital, Nairobi County deals with a complex HIV landscape due to its diverse population and urban dynamics. Surveillance data underscores this persistent public health concern, emphasizing the need for tailored prevention and treatment approaches. Significant progress has been made in expanding access to Antiretroviral Therapy (ART), transforming HIV into a manageable chronic condition. The healthcare network, including facilities, clinics, and specialized centers, plays a crucial role in ART service delivery. Despite advancements, challenges like stigma, treatment adherence, and interventions for vulnerable populations persist. Collaborative efforts between healthcare providers, community organizations, and governmental agencies are essential for maintaining care continuity for those with HIV. Nairobi's robust research and innovation foundation positions it to advance evidence-based interventions and

policies in HIV epidemiology. Sustaining progress will rely on continued vigilance and targeted strategies for vulnerable populations. The city's multifaceted nature, combining tradition and modernity, provides an intriguing backdrop for studies exploring complex healthcare phenomena, such as the prevalence of Adverse Drug Reactions (ADRs) among HIV patients and their demographic influences. Research conducted within Nairobi's borders holds the potential to provide critical insights for advancing healthcare policies, interventions, and equitable patient care as the city continues to shape Kenya's trajectory.

3.2 Study Design

The study design chosen for this research is an analytical cross-sectional approach, utilizing secondary data. A quantitative approach was adopted to categorize and analyze data related to HIV patients on Antiretroviral Therapy (ART) within the time span from 2015 to 2021. The cross-sectional design enabled the collection of data from various sources at a single point in time, allowing for the assessment of associations and relationships between variables during this specific period.

3.3 Study Population

The study focused on individuals living in Nairobi County who are HIV positive and are undergoing ART treatment. The data sources were from healthcare workers, stakeholders involved in the management of HIV and Adverse Drug Reactions (ADRs), and patients who have been diagnosed with both HIV and ADRs in Nairobi County. Additionally, community health workers were included as respondents. The study's scope aims to capture a wide range of perspectives and insights to comprehensively address its research objectives.

3.4 Population Characteristics

The research included various demographic categories, ensuring inclusivity and representation across diverse strata. This inclusiveness cut across educational levels, gender (male and female), age groups (youth, children, and adults), and individuals living with disabilities (PLWD). By encompassing a broad spectrum of demographic characteristics, the study provided insights into potential disparities and the influence of these factors on the occurrence and outcomes of ADRs.

3.5 Specific Study Site

The primary focus of this study was the healthcare service providers operating within Nairobi City County, particularly those with knowledge of Adverse Drug Reactions among HIV patients. This includes both National and County-level health service providers, private healthcare entities, as well as community health service providers. The rationale behind this selection was to gather insights from those directly involved in the treatment, management, and observation of ADRs in HIV patients within the county.

3.6 Inclusion Criteria

The study included all HIV-positive patients who were actively undergoing Antiretroviral Therapy (ART) and willingly provided their consent. Their medical information, relevant to the occurrence and outcomes of ADRs, was utilized for the research analysis. This approach ensured that the study included those individuals directly affected by HIV treatment and ADRs, thereby providing a comprehensive view of their experiences.

3.7 Exclusion Criteria

Patients whose data were publicly available, such as those who opted for private clinics or chose not to disclose their medical information, were excluded from the study. This criterion was grounded in the necessity of using data sources that are accessible and shareable, in alignment with the secondary data nature of the research.

3.8 Study Variables

The study incorporated two categories of variables: independent variables and dependent variables. Independent variables were demographics, patient knowledge and awareness of ADR occurrences, healthcare providers' knowledge, and the prevalence of ADRs among HIV patients. Dependent variables focused on the effects of Adverse Drug Reactions (ADRs) and their outcome faced by individuals living with HIV.

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3.9 Data Collection Procedures

Given the reliance on secondary data, the research involved data obtained from the Pharmacovigilance National Data Centre - Pharmacy and Poisons Board, data obtained from healthcare facilities within Nairobi County. This data was initially collected through semi-structured questionnaires administered to patients across various health facilities within a period of 2015 to 2021.

3.10 Data Processing and Analysis

Upon data acquisition, it was compiled in Microsoft Excel and imported into the STATA software for analysis. Thorough data cleaning was ensured consistency, and missing data were managed appropriately. Data management were performed to create a coherent dataset for analysis. The analysis used various techniques including bar graphs, frequency tables, percentages, and summary statistics. Objective three utilized survival analysis techniques, including Kaplan-Meier survival curves and Cox proportional hazards regression.

3.10.1 Cox Regression Model

In the multiple-variable Cox regression analysis, the study assessed the relationship between demographic factors and the outcome of the Adverse Drug Reactions (ADRs) among HIV patients in Nairobi County from 2015 to 2021.

The Cox Regression Model relies on several key assumptions for its validity. Firstly, the Proportional Hazards Assumption asserts that the hazard ratio between any two individuals remains constant over time. Secondly, the Non-censoring Assumption assumes that censoring is non-informative, indicating that the likelihood of an event being censored is independent of the actual survival time. Lastly, the Independence Assumption posits that the occurrence of an event for one individual does not influence the occurrence of an event for another individual. To evaluate the model's appropriateness, the Goodness of Fit is examined. This entails utilizing Cox-Snell Residuals to scrutinize the overall model fit, with deviations from a straight line on the Cox-Snell residuals plot against time suggesting potential lack of fit. Together, these assessments collectively ensure that the Cox regression model is suitably specified and effectively aligns with the observed data, thus providing dependable estimates of hazard ratios and associated inferences.

The model equation was given by:

$$h(t) = h_0(t) \times \exp(\beta_1 * sex + \beta_2 * Age\ category = +\beta_3 * Education\ level)$$

Where:

- $h(t)$ represents the hazard of experiencing an ADR at time t.
- $h0(t)$ is the baseline hazard function, which represents the hazard when all predictors are zero.
- β_1, β_2, β_3 are the regression coefficients associated with the respective predictors.
- exp is the exponential function.

The predictors in the model are:

- Sex: This is a binary variable representing gender (1 for male, 0 for female).
- Age category: This variable includes three categories (<15, 16-49, >49), with reference category <15.
- Education Level: This is a categorical variable representing the education level (Not started, Primary, Secondary, Tertiary), with reference category Not started.

The regression coefficients (β_1, β_2, β_3) quantify the impact of each predictor on the hazard of experiencing an outcome of being censored or event.

3.11 Ethical Consideration

The study is based on secondary data obtained from the Pharmacovigilance National Data Centre - Pharmacy and Poisons Board, within which is mandated to develop, implement, and continuously upgrade an appropriate system for detecting, reporting, and monitoring adverse drug reactions (ADRs) and other relevant problems with medicines in Kenya. Guidelines and the tools to implement Pharmacovigilance in Kenya have been developed and sensitization workshops have been carried out for various cadres of health professionals in Kenya such as Pharmacists, Pharmaceutical technologists, nurses, Clinicians and Clinical officers. As such, the study aligns with established ethical considerations and protocols for data collection and analysis.

CHAPTER 4: RESULTS

4.0 Introduction

This chapter specifically investigates the relationship between demographic factors, adverse drug reactions (ADRs), and survival rates among HIV patients on antiretroviral therapy in Nairobi County from 2015 to 2021. The analysis aligns with three specific objectives: first, to assess the frequency and severity of ADRs; second, to investigate outcomes resulting from ADRs; and third, to explore how demographic factors like gender, age, and education influence survival experiences. This chapter aims to offer a comprehensive understanding of these interplays, providing valuable insights for both academic discourse and practical healthcare interventions in the region.

4.1 Prevalence of Adverse Drug Reactions of HIV patients in Nairobi County from 2015 to 2021

Figure 2 illustrates the frequency and distribution of Adverse Drug Reactions (ADR) among HIV patients in Nairobi County from 2015 to 2021. Among the reported ADRs, the majority were classified as moderate (44.94%), followed by mild (30.11%) and the least records were fatal cases.

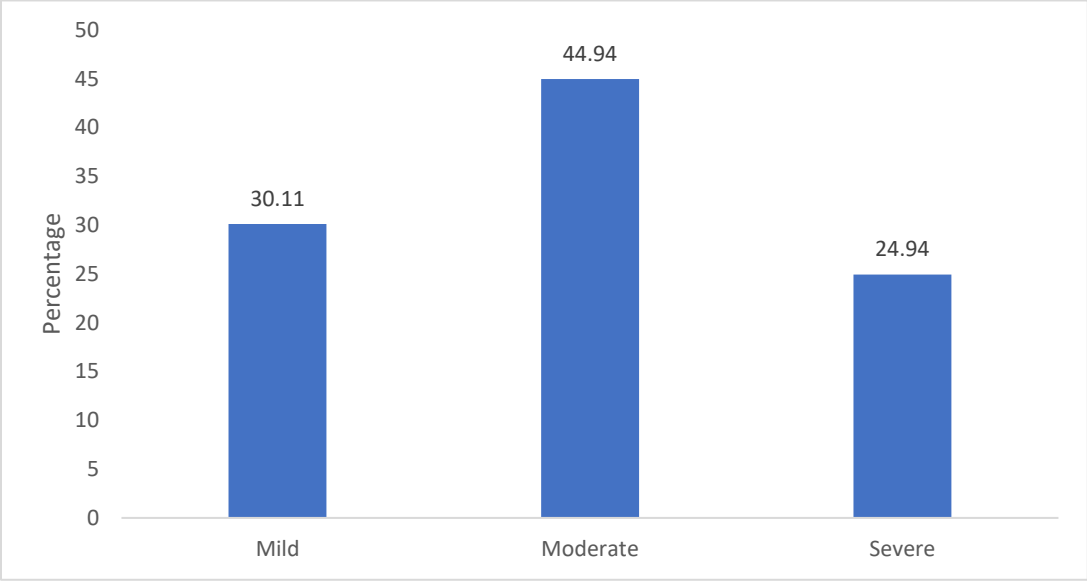

FIGURE 2: Prevalence of Adverse Drug Reactions of HIV patients in Nairobi County from 2015 to 2021

4.2 Socio-demographic Characteristics of HIV patients in Nairobi County from 2015 to 2021

The socio-demographic profile of HIV patients in Nairobi County from 2015 to 2021. It indicates a higher representation of females among HIV patients and the prevalence of HIV in the 15-49 age group. Additionally, it highlights the educational background of the patients, with a majority having attained at least a secondary or tertiary level of education. (table 1)

Table 1: Socio-demographic Characteristics of HIV patients in Nairobi County from 2015 to 2021(N=445)

Variable	Frequency (n)	Percentage (%)
Sex		
Female	282	63.37
Male	163	36.63
Age		
<15	69	15.51
15-49	298	66.97
>49	78	17.53
Education Level		
Not started	28	6.29
Primary	127	28.54
Secondary	159	35.73
Tertiary	131	29.44

***N=445*

4.2.1 Distribution of Socio-demographic Characteristics on Adverse Drug Reactions of HIV patients in Nairobi County from 2015 to 2021

The distribution of socio-demographic characteristics among HIV patients in Nairobi County from 2015 to 2021, concerning adverse drug reactions (ADRs), reveals several patterns. Firstly, regarding gender, a higher proportion of females experienced mild, moderate, and severe ADRs compared to males, the chi-square test showed a statistical significance association between gender and ADRs (p-value = 0.010). Secondly, age significantly impacted ADR severity, as the older age group (>49) had a higher proportion of severe ADRs compared to the other age categories (p-value < 0.001). Lastly, education level did not show a significant association with ADR, though, those who had not started formal education were at a higher rate of mild ADRs, while those with secondary education had a lower rate of mild ADRs compared to other education levels (p-value = 0.060).

Table 2: Distribution of Socio-demographic Characteristics on Adverse Drug Reactions of HIV patients in Nairobi County from 2015 to 2021(N=445)

Variables	n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	P-value
Sex					
Female	282(63.37)	89(31.56)	136(48.23)	57(20.21)	**0.010**
Male	163(36.63)	45(27.61)	64(39.26)	54(33.13)	
Age Category					
<15	69(15.51)	35(50.72)	20(28.99)	14(20.29)	**<0.001**
15-49	298(66.97)	81(27.18)	157(52.68)	60(20.13)	
>49	78(17.53)	18(23.08)	23(29.49)	37(47.44)	
Education Level					
Not started	28(6.29)	13(46.43)	10(35.71)	5(17.86)	0.060
Primary	127(28.54)	48(37.8)	49(38.58)	30(23.62)	
Secondary	159(35.73)	36(22.64)	78(49.06)	45(28.30)	
Tertiary	131(29.44)	37(28.24)	63(48.09)	31(23.66)	

***N=445*

4.3 Crude Death Rate (per 1,000 person-year) of HIV patients in Nairobi County from 2015 to 2021

During the study period (from 2015 to 2021), there were approximately 56.28 deaths per 1,000 person-years among HIV patients in Nairobi County. This statistic is a crucial indicator of the mortality rate among HIV patients with adverse drug reactions.

4.3.1 Distribution of Adverse Drug Reactions (ADRs) on the Outcome Among HIV Patients in Nairobi County

The distribution of Adverse Drug Reactions (ADRs) among HIV patients in Nairobi County reveals that individuals experiencing mild or moderate ADRs did not progress to adverse outcomes. Severe ADRs were associated with a moderate level of severity linked to adverse consequences whereas 43.24% of the patients under severe ADRs succumbed to the event of interest.

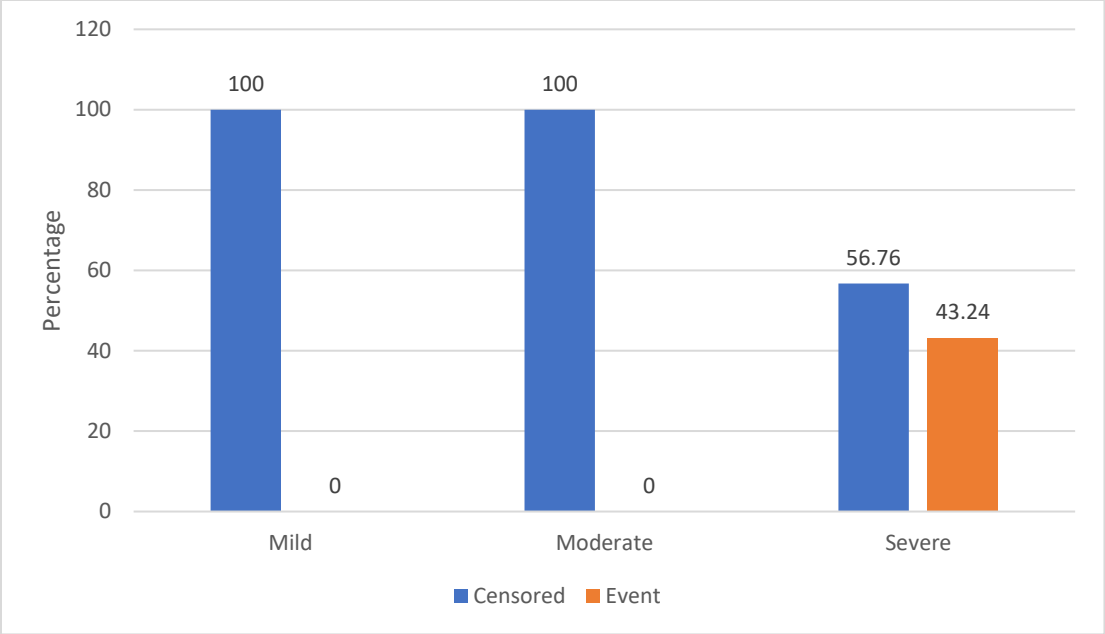

FIGURE 3: Distribution of Adverse Drug Reactions (ADRs) on the Outcome Among HIV Patients in Nairobi County

4.4 Influence of Demographic Factors on Survival Rates Among HIV Patients with Adverse Drug Reactions in Nairobi County from 2015 to 2021

4.4.0 The overall Kaplan-Meier survival estimate curve of HIV patients in Nairobi County from 2015 to 2021

The Overall Kaplan-Meier survival estimate curve indicates that the incidence of Adverse Drug Reactions (ADR) was most pronounced within the initial years of ART initiation, progressively decreasing over the course of treatment for HIV patients in Nairobi County spanning from 2015 to 2021.

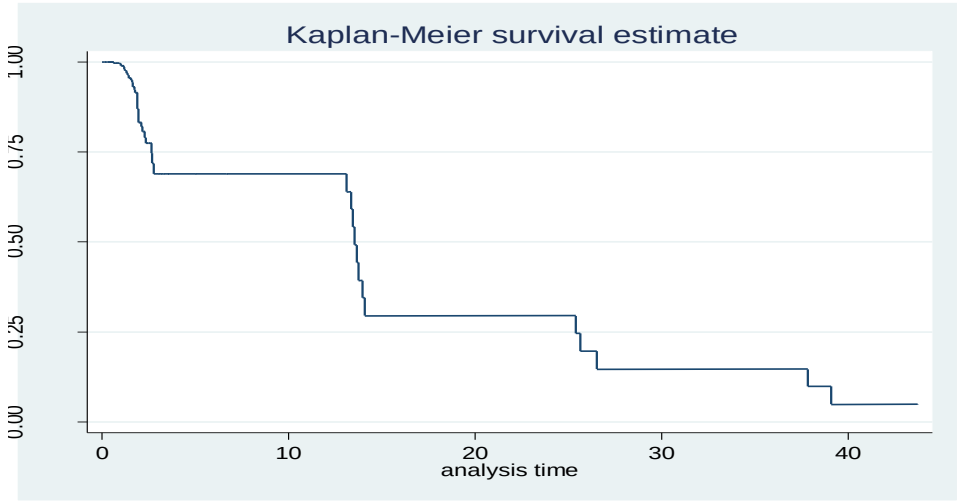

FIGURE 4: The overall Kaplan-Meier survival estimate curve of HIV patients in Nairobi County from 2015 to 2021

4.4.1 Log-rank test for equality of survivor functions between categories of covariates among HIV patients in Nairobi County from 2015 to 2021.

The Log-rank test was employed to evaluate potential disparities in survivor functions among HIV patients in Nairobi County from 2015 to 2021, based on different covariates. The results revealed notable insights. Gender exhibited a marginally significant impact on survival experiences (Chi-squared = 3.14, p = 0.0763), indicating a potential trend towards variation. Age category, on the other hand, emerged as a highly significant factor (Chi-squared = 8.27, p < 0.0160), signifying substantial differences in survival probabilities across different age groups. Education level also played a significant role (Chi-squared = 9.19, p = 0.0269), underscoring its influence on survival outcomes, Overall, these findings evident the crucial impact of gender, age, and education on the survival experiences of HIV patients in Nairobi County during the specified period. (Table 3)

Table 3: Log-rank test for equality of survivor functions between categories of covariates among HIV patients in Nairobi County from 2015 to 2021.

Variables	Chi 2 (X2)	Pr>chi2
Gender	3.14	0.0763
Age Category	8.27	**0.0160**
Education Level	9.19	**0.0269**

4.4.2 Kaplan-Meier survival estimate for sex among HIV patients in Nairobi County from 2015 to 2021

The figure 5, shows that there were differences in survival time between females and males though the difference was not statistically significant (p=0.0763)

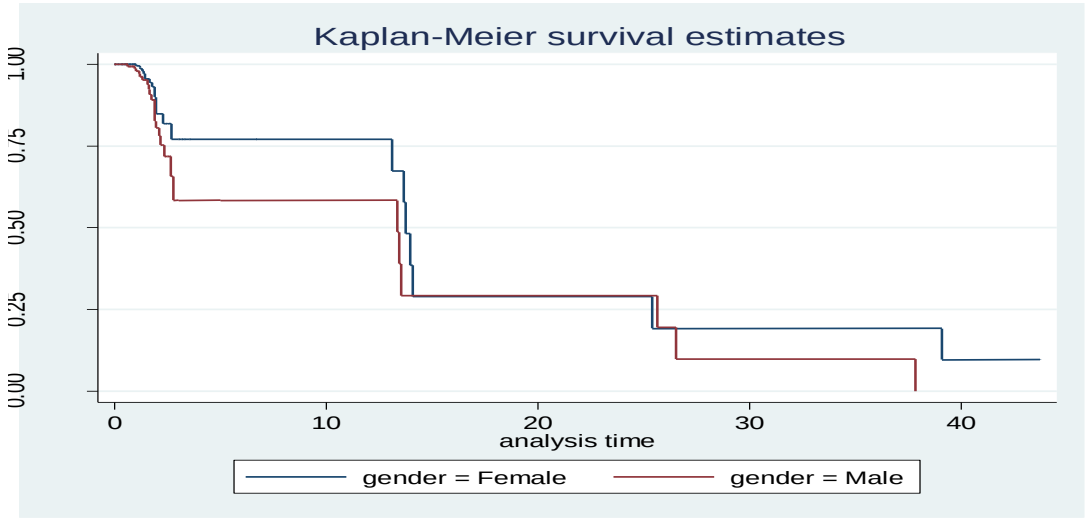

FIGURE 5: Kaplan-Meier survival estimate for sex among HIV patients in Nairobi County from 2015 to 2021

4.3.3 Kaplan-Meier survival estimate for age category among HIV patients in Nairobi County from 2015 to 2021

Figure 6 shows a statistically significant difference in survival probabilities across different age groups with the study participants who are of age category of above 49 years having lower survival time as compared to those who are of age category of less than 15 years (p=0.016).

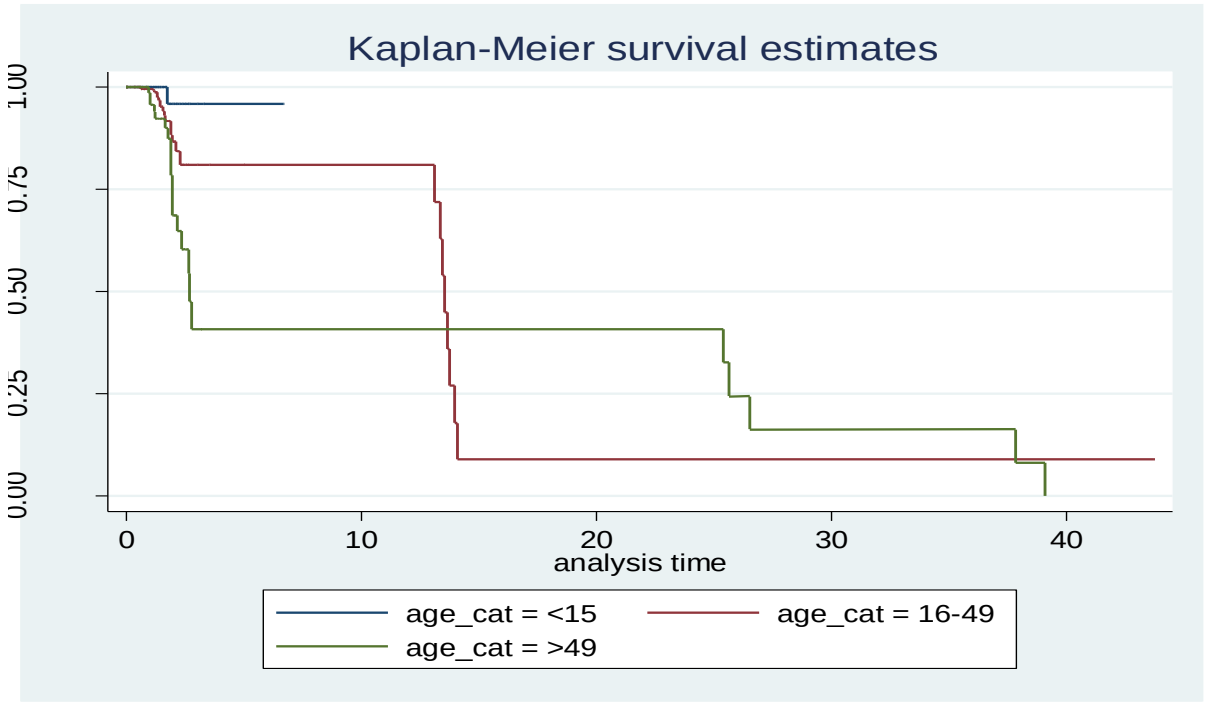

FIGURE 6: Kaplan-Meier survival estimate for age category among HIV patients in Nairobi County from 2015 to 2021

4.4.4 Kaplan-Meier survival estimate for education level among HIV patients in Nairobi County from 2015 to 2021

Figure 7 shows a statistically significant difference in survival probabilities across different education levels (p=**0.0269**).

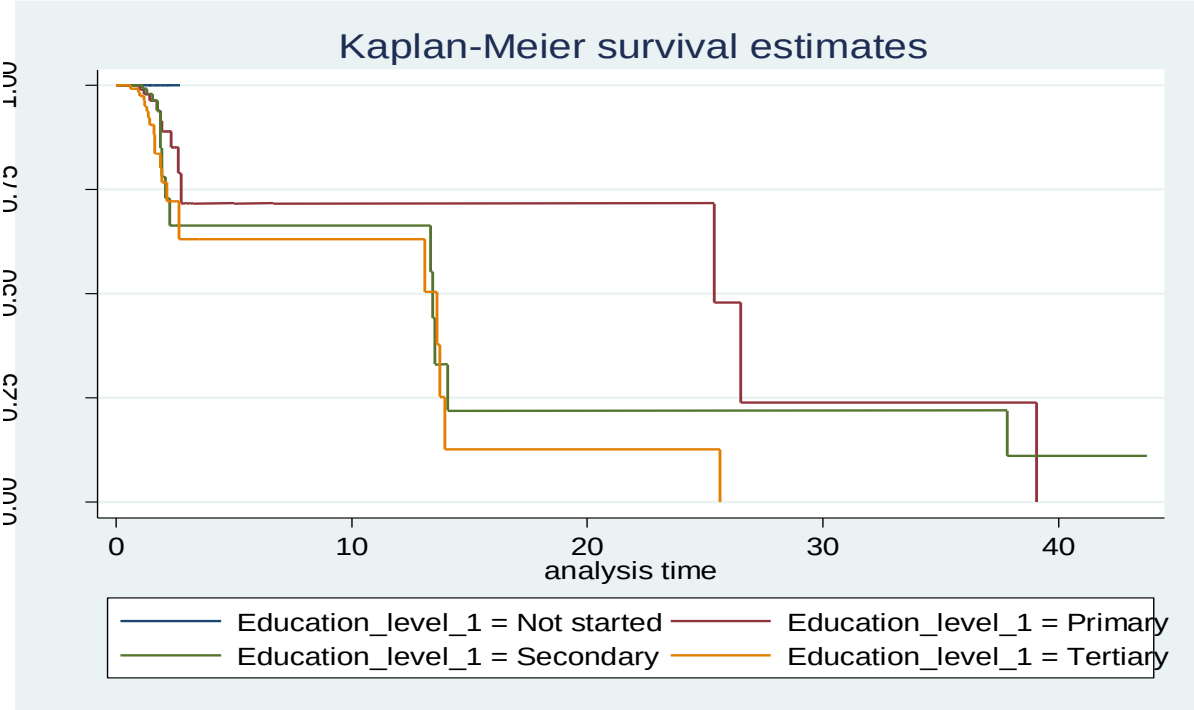

FIGURE 7: Kaplan-Meier survival estimate for education level among HIV patients in Nairobi County from 2015 to 2021

4.4.5 Bi-variable Cox regression for predictors of ADRs Outcome among HIV patients in Nairobi County from 2015 to 2021

In the bi-variable Cox regression analysis assessing predictors of Adverse Drug Reactions (ADRs) outcome among HIV patients in Nairobi County from 2015 to 2021, several key findings emerged. Specifically, male patients demonstrated a non-significant trend towards experiencing the event as compared to females (HR = 1.67, 95% CI: 0.94-2.97, p = 0.080). Age played a significant role, with patients aged 16-49 showing a non-significant increased ADR outcome risk compared to those under 15 (HR = 6.26, 95% CI:0.84-46.46, p = 0.073), while patients over 49 exhibited a significant high risk of experiencing the event as compared to those under 15 (HR = 10.17, 95% CI: 1.35-76.59, p = 0.024). Education level also had influence, with those who had attained primary education showing significantly reduced ADR outcome risks as compared to

tertiary education level (p = 0.019), whereas the trend was non-significant for patients with secondary and the ones who had not started the formal education with (p = 0.124) and (p=1) respectively.

Table 4: Bi-variable Cox regression for predictors of ADRs outcome among HIV patients in Nairobi County from 2015 to 2021 (N=445)

Variables	n (%)	Event n(%)	Censored n(%)	CHR (95% CI)	P-value
Gender					
Female	282(63.37)	23(8.16)	259(91.84)	1	
Male	163(36,63)	25(15.34)	138(84.66)	1.67(0.94-2.97)	0.080
Age category					
<15	69(15.51)	1(1.45)	68(98.55)	1	
16-49	298(66.97)	24(8.05)	274(91.95)	6.26(0.84-46.46)	0.073
>49	78(17.53)	23(29.49)	55(70.51)	10.17(1.35-76.59)	**0.024**
Education Level					
Not started	28(6.29)	0(0)	28(100)	0(0)	1
Primary	127(28.54)	12(9.45)	115(90.55)	0.42(0.20-0.87)	**0.019**
Secondary	159(35.73)	16(10.06)	143(89.94)	0.59(0.30-1.16)	0.124
Tertiary	131(29.44)	20(15.27)	111(84.73)	1	

***N=445*

4.4.6 Multiple-variable Cox regression for predictors of ADRs Outcome among HIV patients in Nairobi County from 2015 to 2021

The multiple-variable Cox regression analysis examined predictors of Adverse Drug Reactions (ADRs) outcome among HIV patients in Nairobi County from 2015 to 2021. The results indicate that education level play significant roles in ADR outcome occurrences. While there was a moderate increase in the risk of ADRs for males compared to females (AHR: 1.58, 95% CI: 0.84-2.97, p=0.158), this difference was not statistically significant. Patients aged 15-49 and above 49 years showed a relatively higher risk of experiencing ADRs outcome, although not statistically significant (AHR:2.42, 95% CI: 0.29-19.87, p=0.411) and (AHR:3.96, 95% CI: 0.50-31.51, p=0.194) respectively, as compared to the reference category of <15 years. In terms of education, patients with primary education demonstrated a significantly lower risk of ADRs outcome (AHR: 0.40, 95% CI: 0.19-0.88, p=0.022) compared to those who had tertiary education. However, education levels of secondary and those who had not started going to school (underage) were not found to be statistically significant predictors of ADRs outcome.

Table 5: Multiple-variable Cox regression for predictors of ADRs Outcome among HIV patients in Nairobi County from 2015 to 2021 (N=445)

Variables	n (%)	Event n (%)	Censored n (%)	AHR (95% CI)	P-value
Gender					
Female	282(63.37)	23(8.16)	259(91.84)	1	
Male	163(36,63)	25(15.34)	138(84.66)	1.58(0.84-2.97)	0.158
Age category					
<15	69(15.51)	1(1.45)	68(98.55)	1	
16-49	298(66.97)	24(8.05)	274(91.95)	2.42(0.29-19.87)	0.411
>49	78(17.53)	23(29.49)	55(70.51)	3.96(0.50-31.51)	0.194
Education Level					
Not started	28(6.29)	0(0)	28(100)	0(0)	1
Primary	127(28.54)	12(9.45)	115(90.55)	0.40(0.19-0.88)	**0.022**
Secondary	159(35.73)	16(10.06)	143(89.94)	0.55(0.28-1.09)	0.086
Tertiary	131(29.44)	20(15.27)	111(84.73)	1	

***N=445*

4.4.6.1 Cox Regression Model

In the multiple-variable Cox regression analysis, the study assessed the relationship between demographic factors and the outcome of the Adverse Drug Reactions (ADRs) among HIV patients in Nairobi County from 2015 to 2021.

Table 6: Multiple-variable Cox regression for predictors of ADRs

Outcome	AHR	95% CI	P-Value
Gender	1.50	0.80-2.78	0.199
Age	1.85	1.05-3.25	**0.034**
Education level	1.68	1.17-2.41	**0.005**

Based on the results of the Cox regression analysis,

The model equation level

$$h(t) = h_0(t) \times \exp(\beta_1 * Gender + \beta_2 * Age\ category = +\beta_3 * Education\ level)$$

Where:

- β_1=0.4055 (for gender)
- β_2=0.616 (for age category)
- β_3=0.52 (for education level)

The updated model equation, incorporating the estimated coefficients, is:

$$h(t) = h_0(t) * \exp(0.4055 * Gend + 0.616 * Age\ category = +0.52 * Education\ level)$$

The specific values of the coefficients have been obtained from the Cox regression analysis.

4.4.6.2 Goodness of fit (Cox-Snell Residuals)

Table 4: Test of proportional-hazards assumption

	chi2	dif	P-Value
Global Test	0.52	3	0.9134

The output displays the results of a test assessing whether the proportional hazards assumption holds in a survival analysis model. This assumption implies that the hazard ratio between any two individuals remains constant over time. The global test, which evaluates the overall consistency of hazard ratios over time, yielded a chi-squared test statistic of 0.52 with 3 degrees of freedom. The associated p-value of 0.9134 indicates that we do not have enough evidence to reject the null hypothesis, suggesting that, based on the available data, the proportional hazards assumption holds. This implies that the hazard ratios for the variables in the model do not significantly change over time.

CHAPTER 5: DISCUSSION

5.0 Introduction

In this study, it examined the socio-demographic characteristics of HIV patients in Nairobi County from 2015 to 2021 and their association with adverse drug reactions (ADRs) and survival outcomes. The findings shed light on critical aspects of HIV patient demographics, ADR prevalence, and survival dynamics in this region. The study also found age to be the most significant factor associated with ADR. This chapter have discussed these results in details in comparison to existing studies and relevant literature.

5.0.1 Socio-demographic Characteristics of HIV Patients

The study revealed a gender distribution among HIV patients in Nairobi County, with 63.37% being female and 36.63% male. This gender distribution aligns with the global trend of a higher HIV prevalence among females, attributed to various social and biological factors (UNAIDS, 2020). The predominance of females in the study underscores the importance of gender-specific HIV interventions, including prevention, testing, and treatment access (Djomand et al., 2016).

Regarding age, the study observed that 66.97% of HIV patients were aged 15-49, a group crucial for HIV prevention and family planning efforts. This age distribution corresponds to the peak reproductive age group, emphasizing the need for integrated sexual and reproductive health services (UNFPA, 2019). Notably, 17.53% were aged 49 or older, reflecting the aging population of HIV patients. This finding aligns with a global trend of increasing HIV prevalence among older individuals (Pellowski et al., 2013). To address the unique healthcare needs of older HIV patients, tailored geriatric HIV care should be considered (Oni et al., 2018).

Education level revealed diverse backgrounds among HIV patients, with 29.44% having tertiary education. This educational diversity highlights the importance of education-aware HIV interventions (Peters et al., 2019). Notably, 28.54% had completed primary education, indicating the need for accessible and informative HIV education programs targeting this group (Avert, 2021).

5.1 Prevalence of Adverse Drug Reactions (ADRs)

The study examined the prevalence of ADRs among HIV patients. The majority of reported ADRs were classified as moderate, followed by mild, the severity was the least but a noticeable proportion. This spectrum of ADR severity levels highlights the multifaceted challenges in managing ADRs in HIV treatment. While moderate ADRs are more common, severe ADRs emphasize the need for stringent monitoring and early intervention. These findings align with studies that underscore the importance of monitoring and managing ADRs to enhance overall well-being and treatment outcomes (Broussard et al., 2010; Walmsley et al., 2018).

5.2 Survival Outcomes

The study examined the survival outcomes of HIV patients over time. The Kaplan-Meier survival estimate curve showed that the incidence of ADRs was most pronounced within the first two years of ART initiation, progressively decreasing over time. This finding emphasizes the critical role of early monitoring and intervention to mitigate ADRs and improve long-term survival. Similar observations have been reported in other studies, highlighting the importance of early ADR detection and management (Ford et al., 2015; Robbins et al., 2009).

5.3 Association between Socio-demographic Factors and ADRs

The distribution of socio-demographic characteristics in relation to ADRs revealed significant patterns. Gender appeared to influence ADR severity, with females experiencing higher rates of mild, moderate, and severe ADRs compared to males. However, the fatality rates were similar between the two genders. This aligns with studies suggesting gender-related differences in ADR susceptibility (Mosepele et al., 2013). Further research is warranted to explore gender-specific factors contributing to ADRs.

Age significantly impacted ADR severity, with the younger age group (<15) exhibiting higher rates of severe and fatal ADRs. This is consistent with findings suggesting that children may be more susceptible to certain ADRs (Hirt et al., 2018). Tailored pediatric HIV care and vigilant ADR monitoring are crucial for this age group.

Education level showed significance, with those who had not started formal education exhibiting a higher rate of mild ADRs, while those with tertiary education had a lower rate of mild ADRs

compared to other education levels. This underscores the importance of health literacy and education in ADR recognition and reporting (Bhattacharjee et al., 2018). Religion did not appear to significantly influence ADR severity, indicating that ADRs may not be associated with specific religious practices.

The log-rank test revealed the significance of various covariates on survival experiences. Gender exhibited a marginally significant impact, suggesting a potential trend towards variation in survival probabilities. Age category emerged as highly significant, indicating substantial differences in survival probabilities across different age groups. This finding underscores the importance of age-specific interventions and care models (Smit et al., 2015).

Education level also played a significant role in survival outcomes, highlighting the influence of education on healthcare-seeking behavior and treatment adherence (Patten et al., 2018). Religious affiliation was not statistical significance, suggesting distinct survival patterns associated with different religious beliefs. This finding underscores the complex interplay between cultural factors and HIV care outcomes (Afolabi et al., 2019).

These findings align with existing literature on HIV demographics and ADR prevalence. However, it's essential to acknowledge variations across different regions and populations. Studies in diverse settings have reported similar trends in gender distribution, age demographics, and the impact of socio-demographic factors on ADRs and survival outcomes (Gupta et al., 2020; Spiegelman et al., 2013). These consistent patterns highlight the global relevance of tailored HIV interventions based on socio-demographic characteristics.

Furthermore, the results corroborate the importance of early ADR detection and intervention to improve long-term outcomes. Studies emphasizing the significance of timely ADR management in enhancing treatment adherence and overall well-being support our findings (de Boer et al., 2018; Long et al., 2018).

Nevertheless, it's crucial to recognize the unique contextual factors that may influence HIV demographics and outcomes in Nairobi County. Socio-cultural nuances, healthcare infrastructure, and access to resources may contribute to specific patterns observed in this population. Therefore, while these findings are consistent with broader trends, a nuanced understanding of the local context is essential for effective HIV care and intervention strategies in Nairobi County.

In conclusion, this study provides valuable insights into the socio-demographic profile, ADR prevalence, and survival dynamics of HIV patients in Nairobi County from 2015 to 2021. The findings underscore the importance of tailored interventions based on gender, age, education level, and religious affiliation. These insights contribute to the broader discourse on optimizing HIV care and treatment outcomes, highlighting the need for context-specific approaches in the management of HIV in Nairobi County.

CHAPTER 6: CONCLUSION AND RECOMMENDATION

6.1 Conclusion:

The findings of this study provide valuable socio-demographic insights into HIV patients in Nairobi County from 2015 to 2021. Notably, the majority of patients were female, underscoring the need for gender-specific interventions. Additionally, a significant proportion fell within the 15-49 age group, emphasizing the importance of targeted efforts in HIV prevention and family planning. The diverse educational backgrounds of patients further highlight the need for tailored approaches to education and awareness campaigns. In terms of adverse drug reactions (ADRs), the study reveals that moderate reactions were the most prevalent, emphasizing the necessity for vigilant monitoring and timely intervention. Survival analysis indicates that ADR incidence is highest in the initial years of antiretroviral therapy (ART) initiation and diminishes over time. This underscores the critical importance of continuous ADR monitoring throughout the course of treatment. The influence of socio-demographic factors on ADRs is evident, with gender, age, and education level playing significant roles. Age emerges as a significant determinant of ADR risk.

6.2 Recommendations:

1. Tailored Interventions: Develop targeted HIV interventions based on gender, age, and education level to address the specific needs and challenges faced by different demographic groups in Nairobi County.
2. ADR Monitoring: Strengthen ADR monitoring programs to detect and manage ADRs early, especially during the initial years of ART initiation.
3. Education and Awareness: Implement education and awareness campaigns to promote safe ART use, particularly among patients with lower education levels.
4. Age-Related Care: Provide specialized care and support for older HIV patients, considering their increased vulnerability to ADRs.
5. Continuous Research: Encourage ongoing research to understand evolving patterns of HIV demographics and outcomes in Nairobi County, ensuring that interventions remain effective and relevant.

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APPENDIX I: Data Extraction Tool

(FOM001/MIP/PMS/SOP/001)

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
P.O. Box 27663-00506 NAIROBI
Tel: (020)-3562107 Ext 114, 0720 608811, 0733 884411 Fax: (020) 2713431/2713409
Email: pv@pharmacyboardkenya.org

IN CONFIDENCE

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

REPORT TITLE: .....

The report is on:
☐ Suspected adverse drug reaction ☐ Therapeutic ineffectiveness

Report Type:
☐ Initial Report ☐ Follow Up Report

Product category (Tick appropriate box)
☐ Medicinal product ☐ Blood and blood products. ☐ Herbal product. ☐ Cosmeceuticals. ☐ Others.....

Institution details

Name of Institution	Contact/Tel No.	Facility Code:	County:

1. Patient Information
Patient name/initials: ..... IP/OP. No: .....
D.O.B/Age: ..... Patient address: ..... WARD/CLINIC: .....
(NAME/NUMBER)
Gender: ☐ Male ☐ Female

Any known allergy ☐No ☐Yes (specify).....
Pregnancy status
☐ Not Applicable ☐ Not pregnant
☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester
Weight: ..... kg Height: ..... cm

2. Suspected Adverse Reaction
Date of onset of reaction: .....
Brief description of reaction: .....

3. Medical History. (Other relevant history including pre-existing medical conditions e.g. allergies, smoking, alcohol use, hepatic/ renal dysfunction etc)
.....
.....

4. List all medicines being currently used by the patient including OTC, and herbal products (* Tick the suspected medicine)**

Tick (✓) Suspected drug	INN/ Generic Name	Brand Name	Batch/ Lot No.	Manufacturer	Dose	Route	Frequency	Treatment Period		Indication
								Start date	Stop Date	

5. Past medication history (List all medicines used in the last 3 months including OTC, herbals, if pregnant indicate medicines used in the 1st trimester)

INN/Generic Name	Brand Name	Batch/Lot No.	Manufacturer	Dose	Route	Frequency	Treatment Period		Indication
							Start date	Stop date	

6. Dechallenge/Rechallenge
Did the reaction resolve after the drug was stopped or when the dose was reduced?
☐ Yes. ☐No ☐Unknown. ☐N/A
Did the reaction reappear after the drug was reintroduced?
☐ Yes. ☐ No. ☐Unknown ☐ N/A

7. Any lab investigations and results.....
.....

8. Grading of the reaction /event
I. Severity of reaction : ☐ Mild ☐ Moderate ☐ Severe ☐ Fatal ☐ Unknown
II. Is the reaction serious? ☐Yes ☐No
III. Criteria/reason for seriousness : ☐ Hospitalization/Prolonged Hospitalization ☐ Disability. ☐ Congenital anomality ☐ Life threatening ☐ Death
IV. Action taken: ☐ Drug withdrawn. ☐ Dose reduced. ☐ Dose increased. ☐ Dose not changed ☐ Not applicable. ☐ Unknown
V. Outcome: ☐ Recovered. ☐ Recovered with sequelae. ☐ Recovering ☐ Not recovered ☐ Death. ☐ Unknown

9. Any other comment .....
.....

10. Reporter Details

Name of Initial reporter:	Cadre/designation:	Mobile no: Email:	Date of report:
Name of Person Submitting to PPB if different from reporter:	Cadre/designation:	Mobile no: Email:	Date of Submission:

You need not be certain... just be suspicious!

Your support towards the National Pharmacovigilance system is appreciated
Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.
Patient's identity is held in strict confidence and program staff is not is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address

FOR OFFICIAL (PPB) USE ONLY
ADR Report No: ..../...../..... Date Received ..../...../.....
Vigiflow Entry Number..... Date Committed ..../...../.....

APPENDIX II: Data Extraction Site

TURNITIN REPORT

THE IMPACT OF DEMOGRAPHIC FACTORS ON ADVERSE DRUG REACTIONS AND SURVIVAL RATES AMONG HIV PATIENTS IN NAIROBI COUNTY FROM 2015 TO 2021

ORIGINALITY REPORT

13%	7%	5%	8%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to Flagler College Student Paper	6%
2	journals.plos.org Internet Source	2%
3	www.science.gov Internet Source	1%
4	aura.abdn.ac.uk Internet Source	<1%

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Ref: KNH-ERC/A/472

12th September, 2023

KENYATTA NATIONAL HOSPITAL APPROVED 12 SEP 2023 QUALITY HEALTH CARE KNH/UoN-ERC P.O. Box 20723 - 00202 NAIROBI

Gideon Kiplimo Keter
Reg. No. W62/34160/2019
Dept. of Public & Global Health
Faculty of Health Sciences
University of Nairobi

Dear Gideon

ETHICAL APPROVAL-RESEARCH PROPOSAL: EXPLORING THE IMPACT OF DEMOGRAPHIC FACTORS ON ADVERSE DRUG REACTIONS AND SURVIVAL RATES AMONG HIV PATIENTS IN NAIROBI COUNTY FROM 2015 TO 2021 (P502/05/2023)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P502/05/2023.** The approval period is 12th September 2023 –11th September 2024.

This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

PROF. BEATRICE K.M. AMUGUNE
SECRETARY, KNH- UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept., KNH
The Chair, Dept. of Public & Global Health, UoN
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