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EVALUATION OF BIOCHEMICAL MARKERS AMONG HIV PATIENTS ABOVE THE AGE OF 18 ACCESSING ART AT PARIRENYATWA HOSPITAL FAMILY CARE CENTER IN ZIMBABWE: A RETROSPECTIVE CROSS-SECTIONAL STUDY

BY

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Abstract

HIV infection and its treatment with antiretroviral therapy (ART) can have significant effects on various biomarkers, including creatinine levels. Understanding the factors associated with creatinine levels in HIV-positive patients is crucial for optimizing their care and outcomes.This retrospective cross-sectional study included 444 HIV-positive patients receiving ART at PHFCC in Zimbabwe . Data on age, gender, duration of ART, WHO clinical stage, comorbidities, viral load, CD4 count, and ART regimen type were collected. Creatinine levels were measured as a biomarker of kidney function, Chi square test was conducted to test association between creatinine level and various risk factors among patients under ART ,$P< 0.05$ was considered as statisticaly signficants. Age, gender and ART regimen type were found to be significantly associated with creatinine levels. However, no significant associations were observed with the duration of ART, WHO clinical stage, comorbidities, viral load, or CD4 count. Most participants were middle-aged, with females comprising the majority. The majority of participants had been on ART for 1-5 years, with the majority also taking a first-line ART regimen. Only a small percentage of participants had comorbidities. This study highlights the importance of age, gender, and ART regimen type in influencing creatinine levels in HIV-positive patients. Further research with a more generalizable study sample is warranted to fully understand the relationships between these biomarkers. These findings underscore the need for personalized approaches to the management of HIV-positive patients, considering individual characteristics and treatment regimens.

Keywords: HIV, antiretroviral, creatinine

Declaration

I, declare that this is my original work that has never been presented to any other educational institution for any award. Any other Authors' work that is cited here is appropriately credited

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List of abbrevations

AIDS	Acquired Immune Deficiency Syndrome
ALP	Alkaline phosphatase
ALT/AST	Alanine Aminotransferase/Aspartate Aminotransferase
ART	antiretroviral therapy
ARVs	antiretroviral drugs
AZT	Zidovudine (also ZDV)
BMI	Body mass index
cART	Combined antiretroviral therapy
CDC	Centers for Disease Control and Prevention
CKD	Chronic kidney disease
CVD	Cardiovascular disease
eGFR	Estimated Glomerular Filtration Rate
ESKD	End-stage kidney disease
EU	European Union
HAART	highly active antiretroviral therapy
HDL	High-density lipoprotein
HIV	Human Immunodeficiency Virus
HIVAN	HIV-associated nephropathy
LDL	Low-density lipoprotein

LIMS	Laboratory information management system
NNRTI	non-nucleoside reverse transcriptase inhibitors
NVP	Nevirapine
OI	opportunistic infection
PCR	Polymerase Chain Reaction
PEP	post-exposure prophylaxis
PGH	Parirenyatwa Group of Hospitals
PHFCC	Parirenyatwa Hospital Family Care Center in Zimbabwe
PLWH/A	people living with HIV/AIDS
RNA	Ribonucleic acid
RTD	Rapid Test Devices
STI	sexually transmitted infection
TB	Tuberculosis
TLD	Tenofovir, Lamivudine, and Dolutegravir
UN	United Nations
USAID	United States Agency for International Development
VCT	voluntary counselling and testing
VL	viral load
WHO	World Health Organization
ZDV	Zidovudine (also AZT)
ZIMPHIA	Zimbabwe Population-based HIV Impact Assessment

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List of appendices

CHAPTER 1: INTRODUCTION

1.1 Introduction

Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) continues to be a global health challenge. According to the Zimbabwe Population-based HIV Impact Assessment survey of 2020 (ZIMPHIA,2020), HIV prevalence in Zimbabwe was reported at 12.9% among adults, corresponding to 1,230,000 adults living with HIV in the country. Of adults living with HIV, 86.8% were aware of their status and of those aware of their status, 97.0% were on antiretroviral treatment (ART)[1]. As such, this challenge requires ongoing research to enhance precise and effective treatment strategies that are even tailored to our local country context. A thorough understanding of the complex relationship between HIV infection and biochemical markers is crucial for providing personalized and targeted care. This cross-sectional study aims to explore specific biochemical markers in HIV-positive patients receiving care at Parirenyatwa Hospital Family Care Center in Zimbabwe (PHFCC). By comprehensively analyzing the impact of ART regimens, body mass index (BMI), age, HIV stage, clinical history and comorbidities, this research seeks to uncover insights that can revolutionize HIV patient management.

HIV infection affects the immune system including various biochemical markers, indicating potential complications (Adnani et al., 2022). The choice of ART regimens influenced by factors such as patient tolerance and viral resistance patterns, plays a central role in shaping these markers. Additionally patient-specific elements including BMI, age, HIV stage and comorbidities, significantly influence biochemical markers, impacting both disease progression and treatment outcomes. As evidenced in a study conducted by Mgogwe J et al 2012 in Tanzania where ARVs,

particularly those whose action inhibits viral proteases i.e. Protease Inhibitors (PI), are associated with adverse effects after long-term use3. It was documented that all drugs used to treat HIV have side effects, for example, some drugs change lipid levels in the blood thus causing high levels of cholesterol. A previous study conducted in the UK on HIV/AIDS patients revealed that cytopenia is a common complication of infection with HIV type 1

Adverse effects attributable to nevirapine have been reported as eosinophilia, granulopenia, jaundice, increased alanine transaminase (ALAT) and aspartate transaminase (ASAT), serum bilirubin and serum amylase. Anaemia, neutropenia and thrombocytopenia have also been reported as adverse effects of stavudine7. All the information above shows the importance of evaluating the haematological and biochemical parameters in HIV/AIDS patients under ARV therapy to monitor the body's responses to the drugs. These responses may used as a monitoring tool for patients under ARV treatment. Therefore, assessment of haematological and biochemical changes in HIV/AIDS patients under ARV therapy is of paramount importance. The biochemical markers of liver and kidney function tests, lipid profiles and other vital markers in HIV patients will be meticulously examined. Understanding how these markers are influenced by ART choices, patient demographics and clinical histories is essential for tailoring interventions and minimizing complications. Furthermore, recognizing the nuanced interplay between these factors could provide valuable insights into early indicators of potential health issues enabling proactive healthcare measures (Henry et al., 2021). Currently, enough data are lacking concerning this matter in Zimbabwe, hence the need for the present study

1.2 Study Background

HIV is a retrovirus that primarily targets CD4+ T cells, which play a central role in coordinating immune responses. HIV has diverse effects on multiple organs, including the kidney, liver, heart,

skin and lungs (Maggi et al., 2019). Kidney, hypertension, liver, oncological and cardiovascular disorders are some of the most common causes of non-AIDS-related mortality in people living with HIV (Pourcher et.al, 2020). HIV infection induces a myriad of biochemical alterations that reflect the virus's impact on the immune system and various physiologic processes (Henry et al., 2021). Elevated levels of viral replication lead to changes in key biochemical markers, including a decrease in CD4 T-cell counts (Mutuma et al., 2023). HIV-associated biochemical alterations extend beyond the immune system, affecting metabolic and cardiovascular parameters (Bushaku et al., 2022). Individuals with HIV often experience dysregulation in lipid metabolism which might cause dyslipidemia an associated risk factor of cardiovascular disease (Lall et al., 2018). Liver enzyme abnormalities may also occur, reflecting the impact of HIV on hepatic function (Bawah et al., 2021). Antiretroviral Therapy (ART) mitigates some of these biochemical alterations by suppressing viral replication and restoring immune function (Adnani et al., 2022). However, ART itself can introduce metabolic changes, emphasizing the complexity of managing biochemical markers in individuals living with HIV (Shedrac et al., 2020).

Statistics from the World Health Organisation (WHO) indicate that there were over 39 million people worldwide in 2022 who were known to be human immunodeficiency virus (HIV)-positive. An estimated two-thirds of HIV-positive patients were in Sub-Saharan Africa making it the most affected region in the world (WHO, 2023). ART is the primary treatment for HIV, inhibiting viral replication and slowing disease progression. While not curative, effective ART can significantly prolong the lives of individuals with HIV and reduce the likelihood of transmitting the virus to others (Tesfa et al., 2021). The main ART regimen being used at Parirenyatwa Group of Hospitals (PGH) are Tenofovir, Lamivudine, and Dolutegravir (TLD). The HIV/AIDS pandemic continues to pose significant challenges to global healthcare systems. ART has transformed HIV treatment,

but its impact on various biochemical markers is complex and multifaceted (Adnani et al., 2022). Some biochemical markers such as those that assess liver function like alanine transaminase are elevated due to the use of ART (Tamuno-Boma, 2023). Understanding alterations in liver and kidney function tests, lipid profiles, and other vital markers due to HIV infection and ART regimens is pivotal for optimizing patient care (Henry et al., 2021). Additionally, individual factors such as BMI, age, HIV stage, and comorbidities can significantly modulate these biochemical parameters, influencing disease progression and treatment outcomes (Alfano et al., 2019).

While several studies have explored the impact of HIV on specific markers, few comprehensive cross-sectional analyses integrate diverse patient-specific variables. Studies done by Jackson et al (2018) look at changes in the clinical values of patients while comparing differences between women and men without taking into account specific ART regimes, BMI or comorbidities. Recognizing this gap, our study aims to bridge this knowledge void. Parirenyatwa Hospital, a prominent healthcare facility, provides an ideal setting to conduct this research due to its diverse patient population. By investigating specific biochemical markers and their intricate relationship with ART regimes and patient characteristics, our study aspires to contribute vital insights that can inform tailored treatment approaches, ensuring improved health outcomes and enhancing the overall quality of life for HIV-positive individuals.

1.3 Problem Statement

Despite significant advancements in HIV/AIDS management through ART, understanding the nuanced impact of different ART regimes on biochemical markers in HIV patients remains incomplete (Ikyernum, 2018). This knowledge gap hampers the development of precise, personalized treatment strategies. Furthermore, the interplay of patient-specific variables including BMI, age, HIV stage and comorbidities in shaping these biochemical markers is not

comprehensively studied as most studies focus on one variable such as age (Kabore et al., 2019). This can pose several limitations and may not provide a comprehensive understanding of the factors influencing biochemical markers in PLWH (Bawah et al., 2021). The lack of detailed cross-sectional analyses integrating these factors in the context of ART administration leads to a critical deficiency in tailored patient care.

1.4 Study Justification

This study is crucial for several reasons, firstly in the era of personalized medicine, understanding how different ART regimens affect biochemical markers in HIV patients is vital. Precise knowledge in this area can guide clinicians in tailoring treatment strategies, ensuring not only virus suppression but also optimal organ function and overall health maintenance. Secondly considering patient-specific factors such as BMI, age, HIV stage and comorbidities is pivotal for a holistic approach to HIV/AIDS management. By integrating these variables, our study seeks to unravel patterns that might not be apparent when analyzing each factor in isolation. Studies done by Jackson et al (2018) only focus on liver function markers without integrating HIV stage or BMI while Souza et al (2022) included BMI in their study of biochemical status in PLWH but did not include HIV stage and comorbidities. By meticulously examining the biochemical markers in the context of ART and patient-specific variables, we aim to provide a robust foundation for future treatment guidelines. These guidelines can improve patient outcomes and optimize resource allocation within healthcare systems, ensuring efficient and effective use of resources. Lastly, the study's findings could contribute significantly to HIV research, bridging gaps in our understanding of the disease's impact on various biochemical markers in Zimbabwe setting were enough data are still lacking.

1.5 Research Objectives

1.5.1 Broad Objective

The primary objective of this study was to comprehensively investigate the impact of HIV ART regimens on the alteration of key biochemical markers in HIV-positive patients, considering patient-specific variables such as BMI, age, HIV stage, including comorbidities from June to December 2023

1.5.2 Specific Objectives

i. To investigate kidney function through measurement of creatinine among HIV-positive patients on ART.
ii. To evaluate liver function test enzymes in HIV-positive patients.
iii. To determine the clinical characteristics (such as BMI and comorbidities, e.g. diabetes and cardiovascular diseases) and socio-demographic characteristics (such as age and sex) of HIV patients on ART.
iv. To explore the association beteewen creatinine level and various risk factors among HIV patients under ART

1.6. Research Questions

i. What was the distribution pattern in liver enzyme levels in HIV-positive individuals on ART?

ii. What was the degree of alteration in kidney function through measurement of creatinine, urea and estimated Glomerular Filtration Rate (eGFR) among HIV-positive patients under ART?

iii. What are the clinical characteristics (such as BMI and comorbidities, e.g. diabetes and cardiovascular diseases) and socio-demographic characteristics (such as age and sex) of HIV patients on ART?

1.7. Study Limitations

- Sampling Bias: The study's sample may not fully represent the entire HIV-positive population at Parirenyatwa Hospital, potentially introducing biases in the results. Patients with severe conditions or those who are unable to visit the hospital regularly might be underrepresented.

- Data Accuracy: The accuracy of the biochemical markers heavily relies on the precision of the testing methods. Variations in laboratory equipment or human error could impact the reliability of the results.

- Limited Historical Data: Availability and accuracy of historical data, especially regarding patients' clinical history and comorbidities, could be limited.

- Interpretation of Comorbidities: The study may not capture all possible comorbid conditions comprehensively. Certain conditions, especially those with subtle symptoms, may go undiagnosed or unreported, affecting the analysis of their impact on biochemical markers.

- Temporal Factors: The study's cross-sectional nature means it captures a snapshot of biochemical markers at a specific time. Long-term trends and variations over time may not be fully captured, limiting the understanding of the dynamic changes in these markers.

- External Factors: Factors such as diet, lifestyle, and other non-HIV-related health behaviours, which can influence biochemical markers, may not be fully accounted for in the study, leading to potential confounding variables.

1.8 Study Delimitations

-Geographical Scope: The study is confined to Parirenyatwa Hospital and its immediate surrounding area. Findings may not be universally applicable to regions with different healthcare infrastructures or patient demographics.

-Time Constraints: The study is limited to a specific timeframe, potentially overlooking long-term trends in biochemical markers and ART effectiveness. Future changes in treatment guidelines or healthcare policies beyond the study period may not be taken into account.

-Healthcare Setting: The study focuses on a hospital setting, potentially excluding HIV-positive individuals who primarily receive treatment from smaller clinics or those who rely on alternative medicine, thereby narrowing the scope of the study

Data Sources: The study relies on available medical records and thus incomplete or inaccurate data in medical records could limit the accuracy of the information gathered.

Comorbidity Detail: While the study includes comorbidities as a variable, the depth of information on each specific comorbid condition may be limited. Detailed diagnostic histories or specific treatments for each comorbidity may not be fully explored

1.9 Summary

By examining the relationships between HIV ART regimens and key biochemical markers while accounting for individual patient characteristics, this study intends to enhance the precision of HIV care. The findings will contribute valuable insights, ensuring that ART choices align with patients'

unique profiles, ultimately improving treatment outcomes and quality of life for HIV-positive individuals.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

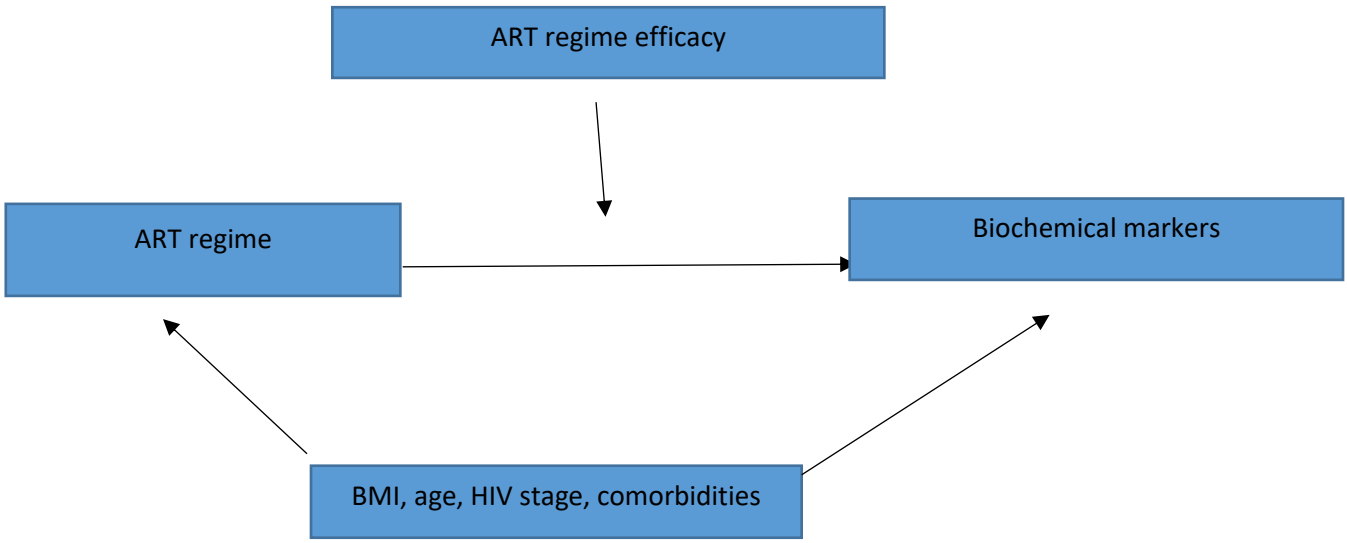
HIV/AIDS, a global pandemic affecting millions, has seen significant advancements in treatment modalities, primarily due to ART. However, understanding the efficacy of ART regimens and their impact on biochemical markers in HIV-positive patients is a complex area of study (Souza et al., 2022). Patient-specific factors, such as BMI, age, HIV stage, and comorbidities, also play a significant role in shaping treatment outcomes (Gabuzda et al., 2020). Therefore, it is crucial to comprehensively explore the interactions between these factors.

The choice of specific nucleoside reverse transcriptase inhibitors (NRTIs) within ART regimens is crucial. Some ARVs have been linked to changes in kidney function markers, highlighting the importance of careful selection to prevent nephrotoxicity (Heron et al., 2020). Body Mass Index (BMI) is a critical determinant that influences the metabolism of ART drugs and consequently, biochemical markers as studied by Batteneni et al (2021) PLWH with higher BMI often experience altered lipid profiles, which may impact cardiovascular health. HIV progression, categorized by CD4 count and viral load, directly affects the immune system and overall health. Patients in advanced stages of the disease show alterations in various biochemical markers, reflecting the severity of their condition. According to Maggi et al (2017), the clusterization of comorbid conditions such as dyslipidaemia and hypertension or chronic renal disease and diabetes prevalent among HIV patients, further complicate the biochemical profile. Studies by Alfano et al., (2019) demonstrate that impaired kidney function increases the risk of other comorbidities especially in PLWH, emphasizing the need for tailored interventions addressing conditions simultaneously.

While existing literature provides valuable insights into the individual impact of ART regimens and patient-specific factors on biochemical markers, there is a notable gap in comprehensively understanding their collective influence (Henry et al., 2021). Few studies have explored the intricate interplay of diverse ART combinations with patient demographics and clinical history simultaneously. This study aims to bridge this gap by conducting a detailed cross-sectional analysis at Parirenyatwa Hospital, a hub for diverse HIV patient profiles. The findings hold the promise of informing personalized treatment guidelines, thereby enhancing the overall quality of care and improving long-term health outcomes for PLWH/A.

2.2 Conceptual framework

This study aimed to explore the intricate relationship between ART regimens, patient-specific factors, and biochemical markers in HIV-positive patients. The conceptual framework provides a visual representation of the various elements and their interconnections, guiding the research and facilitating a comprehensive analysis.



Independent Variables:

ART regimens: This variable encompasses the different classes and combinations of ART drugs prescribed to HIV patients, including protease inhibitors, non-nucleoside reverse transcriptase inhibitors (NNRTIs) and nucleoside reverse transcriptase inhibitors (NRTIs)

Dependent Variables:

Biochemical Markers: This category includes various markers such as liver function tests (ALT, AST, ALP, and bilirubin), kidney markers (U&Es), and lipid profiles (cholesterol, triglycerides, HDL, LDL). These markers reflect the patient's health status and response to HIV infection and ART treatments.

Mediating Variables:

BMI, age, and HIV stage influence drug metabolism, a factor that accounts for the processing of different ART drugs within the patient's body. BMI reflects the patient's body composition, which influences drug metabolism and, in turn, biochemical markers. Age plays a significant role in drug metabolism, affecting liver and kidney function markers. The stage of HIV infection, indicated by CD4 count and viral load, impacts the patient's immune system and overall health, influencing biochemical markers. Comorbidities such as diabetes and hypertension interact with HIV and ART treatments, potentially affecting biochemical markers

Moderating Variables:

ART Regimen Efficacy: The effectiveness of ART regimens can moderate the influence of patient-specific factors and directly impact biochemical markers. Certain regimens may perform better in specific patient profiles, affecting the outcomes.

This conceptual framework illustrates the interconnections between ART regimens, patient-specific factors, biochemical markers, mediating variables, and moderating variables. The study aims to explore these relationships comprehensively to gain a better understanding of how ART choices and patient characteristics collectively influence the biochemical profiles of HIV-positive patients.

2.3 Literature review in relation to Objectives

i. Assess Liver Function: Analyze liver enzymes (ALT, AST, ALP, and bilirubin) in HIV-positive individuals and examine the results with disease progression and the use of ART.

Studies on liver function in HIV-positive individuals reveal a correlation between disease progression and liver enzyme levels. Elevated ALT and AST levels signify potential liver damage, while ALP and bilirubin alterations may indicate cholestasis. Antiretroviral therapy (ART) impact on liver function remains a subject of investigation. Studies by Mutuma et al (2023) and Tesfa et al (2019) suggest a connection between certain ART regimens and liver enzyme abnormalities. Shedrac et al (2020) study did not find any liver damage due to continuous use of ART. But concurred that there is hepatic toxicity which is difficult to measure due to other causes of hepatitis. According to Agbecha & Ikyernum, (2018), HIV in the absence of ART may have a direct impact on liver pathogenesis such that there is a progression to liver disease.

ii. Evaluate Kidney Markers: Investigate kidney function markers (creatinine, urea and electrolytes (U&Es) among HIV-positive patients and examine the impact of HIV and ART on renal health.

The renal health of HIV-positive individuals is a critical concern, given the potential impact of both the virus and ART on kidney function markers. According to Adnani et al (2022), though combined antiretroviral therapy (cART) reduces the risk of progression to end-stage kidney disease (ESKD), drug interactions and metabolic complications may indirectly contribute to kidney injury Kabore et al (2019) did a study which showed that West Africa had the highest risk of CKD but found no association to ART in PLWH. Studies have consistently reported elevated creatinine levels, indicative of renal impairment, in HIV-infected patients (Zhao et al., 2023) HIV-associated nephropathy (HIVAN) contributes to renal dysfunction, marked by glomerulosclerosis and tubulointerstitial disease. Tenofovir, a commonly used antiretroviral, is implicated in nephrotoxicity, necessitating vigilant monitoring (Wearne et al., 2019). Furthermore, studies by Alfanor et al (2019) have demonstrated that specific nucleoside reverse transcriptase inhibitors (NRTIs) within ART regimens could influence kidney function markers, emphasizing the need for regimen-specific assessments

iii. Study Lipid Profile: Examine lipid parameters (cholesterol, triglycerides, HDL, LDL) in HIV-positive patients and evaluate the influence of HIV and ART on lipid metabolism.

Numerous studies have reported alterations in lipid parameters in HIV-infected individuals. Dyslipidemia, characterized by elevated total cholesterol, triglycerides, and altered high-density lipoprotein (HDL) and low-density lipoprotein (LDL) levels, has been associated with HIV infection itself (Kavita et al., 2018). Research by Abriba et al., (2023) indicates that ART can

elevate TG and VLDL and that hypocholesterolaemia could be due to either the virus itself or cytokine effects in different enzymes of lipid metabolism.

iv. Explore Comorbidities: Investigate prevalent comorbidities (diabetes, cardiovascular diseases) in HIV-positive individuals and their correlation with disease duration

Comorbid conditions, such as diabetes and hypertension, can significantly influence lipid profiles. HIV-positive individuals with these comorbidities may experience exacerbated lipid abnormalities (Maggi et al., 2017). The presence of comorbidities can further complicate the management of hepatotoxicity, especially in individuals with chronic viral hepatitis co-infections (Maciel et al., 2018).

v. Examine BMI, Age, and Sex: Analyze BMI variations among HIV patients concerning age, sex, and disease duration, and assess the impact on disease progression and overall health.

BMI, age, HIV stage, and comorbidities significantly affect biochemical markers in HIV-positive individuals. Research by Baillin et al., (2020) indicated that older age was associated with altered liver function markers, emphasizing the influence of age on ART metabolism and efficacy. According to (Raffe et al., 2022) cigarette smoking is linked to multi-comorbidity, especially in women and age increases comorbidities in HIV patients.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This study adopted a cross-sectional design in a retrospective manner to examine biochemical markers in HIV-positive patients accessing ART. Detailed medical records, including ART regimens, clinical history, and comorbidities, will be analyzed alongside biochemical data.

3.2 Research Design

3.2.1 Design: Retrospective Cross-Sectional Study

Rationale: This research employed a cross-sectional stratified design to comprehensively investigate the relationship between ART regimens, patient-specific factors, and biochemical markers without direct patient interaction. By stratifying the data based on specific criteria, this design allows for a structured examination of diverse patient profiles, ART treatments, and associated biochemical markers.

3.2.2. Stratification:

Strata: Patients were stratified based on ART regimens, age groups, BMI categories, HIV stages, and comorbidities.

Purpose: Stratification ensures the representation of various subgroups within the HIV-positive population, allowing for a detailed analysis of each stratum’s biochemical markers without the need for direct patient interaction.

3.3 Study Setting:

Our HIV research study was conducted at Parirenyatwa Hospital, one of Zimbabwe's leading healthcare institutions located in the heart of Harare. This hospital plays a critical role in healthcare

delivery, particularly in the field of HIV/AIDS treatment and research. With its state-of-the-art facilities, experienced medical staff, and robust patient database, Parirenyatwa Hospital provides an ideal setting for our comprehensive investigation into the impact of ART regimens and patient-specific factors on biochemical markers in HIV-positive patients.

Parirenyatwa Hospital stands as a beacon of healthcare in Zimbabwe, equipped with modern medical facilities, laboratories, and clinics. Its advanced infrastructure allows for seamless integration of medical research into routine patient care. Our study leveraged these facilities, enabling efficient data collection and analysis. The hospital's commitment to cutting-edge medical practices creates an environment conducive to pioneering research initiatives. The Opportunistic Infection (OI) clinic within Parirenyatwa Hospital plays a pivotal role in HIV/AIDS management. This specialized clinic offers targeted care, monitoring, and treatment for HIV-positive patients. Regular screenings conducted at the OI clinic provided a rich source of information for our study. The clinic's focus on HIV/AIDS-related complications offered a unique opportunity to delve into the nuances of biochemical markers within this patient population.

Parirenyatwa Hospital boasts a dedicated team of medical professionals, including physicians, nurses, and researchers, who possess expertise in HIV/AIDS care. Their experience ensures accuracy in patient records, precise data extraction, and ethical adherence to research protocols. The collaboration between our research team and these seasoned healthcare providers enhanced the credibility and reliability of our study. The hospital serves a diverse patient demographic, representing various age groups, socioeconomic backgrounds, and urban and rural communities. This diversity enriched our study, allowing for comprehensive analyses across different population segments. Understanding the impact of ART regimens and patient-specific factors on biochemical

markers within this varied population is crucial for the applicability and generalizability of our research findings.

Parirenyatwa Hospital fosters a collaborative research environment by promoting partnerships among researchers, clinicians, and other healthcare professionals. This collaborative spirit facilitates the exchange of knowledge and expertise, which enriched the research process. Regular research seminars, workshops, and conferences provide opportunities for our team to engage with peers, ensuring that our study remains at the forefront of HIV/AIDS research.

The advanced infrastructure, specialized clinics, experienced medical staff, diverse patient demography, and collaborative research environment of Parirenyatwa Hospital created an ideal setting for our HIV research. By conducting our study within this dynamic healthcare institution, we were poised to make significant contributions to the understanding of HIV/AIDS management, benefiting patients not only in Zimbabwe but globally.

3.4 Study Population

The study population consisted of HIV-positive patients registered at Parirenyatwa Hospital, a leading healthcare facility serving a diverse patient demographic. This population selection aligns with the study's objectives to comprehensively explore ART regimens and patient-specific factors related to biochemical markers from June to December 2023.

3.4 Exclusion Criteria:

Incomplete Records: Patients with insufficient medical records lacking essential information regarding ART regimens, biochemical markers, or patient-specific factors from June to December 2023

Pediatric Patients: As the study focuses on adult HIV-positive patients, individuals below the age of 18 years will be excluded.

Patients on Clinical Trials: Participants involved in clinical trials or experimental treatments that may affect standard ART regimens will be excluded to maintain study consistency.

Newly diagnosed patients: newly diagnosed patients and HIV patients under less than 6 months of ART therapy will be excluded as they will not enable us to make comparisons of different ART regimes

3.5 Inclusion Criteria:

HIV-Positive Status: Patients confirmed as HIV-positive through laboratory testing which were under a period of minimum 6 month on ART

Patient Records: Individuals with comprehensive and up-to-date medical records containing information on ART regimens, biochemical markers (such as liver function tests, kidney markers, and lipid profiles), BMI, age, HIV stage, and comorbidities.

ART Regimens: Patients prescribed various ART combinations, including protease inhibitors, non-nucleoside reverse transcriptase inhibitors (NNRTIs) and nucleoside reverse transcriptase inhibitors (NRTIs),

Diversity: Patients from diverse backgrounds, including different age groups, genders, BMI categories, HIV stages, and comorbidities to ensure a representative sample by analyzing and reporting results separately for different strata.

3.6 Sample Size

Sample size will be calculated based on the HIV+ patients attending PHFCC using the following formula:

Since the population is greater than 10,000:

$n = Z^2 p (1-p) / w^2$

Where n=sample size

z=Z-score corresponding to the desired confidence level of 95%; 1, 96

p=population proportion; 50%

w=margin of error, 5%

n=1.96^2x0.5 (1-0.5)/0.05^2

=384.16

=385

Therefore a minimum sample size of 385 was recquired for this research. However, we added a margin of 25% contingency to the sample size, resulting in an actual sample size of 444 participants being enrolled in the study,since the more the sample size the more the clarity in the generalizing findings from this study.

3.3 Data Analysis:

Descriptive Analysis: Descriptive statistics was used to summarize biochemical markers, ART regimens, and patient-specific factors within each stratum.

Data Visualization: Visualization plays a vital role in our analysis. Bar charts, pie charts, and line graphs vividly represent data, making it accessible to a broader audience. Visualizations facilitate the identification of trends and patterns, enhancing our ability to communicate findings effectively.

Comparative Analysis: Inferential statistical methods were employed to compare biochemical markers between different strata, investigating patterns and correlations we will test the association between independent and dependents variables to determine risk factor $P < 0,05$ was considered as statistically significant with 95% confidence interval using Chi-square test.

3.8 Study Pilot

Before embarking on the comprehensive study exploring the impact of ART regimens and patient-specific factors on biochemical markers in HIV-positive patients at Parirenyatwa Hospital, we conducted a pilot study. This preliminary investigation was instrumental in refining our research methodology, identifying potential challenges, and ensuring the efficacy of our data collection processes.

Pilot Objectives:

The pilot study aimed to assess the feasibility of our sampling strategy, refine the data extraction process, and validate the research instruments. By setting clear objectives, we guided our pilot study towards targeted outcomes.

Sampling for the Pilot Study:

For the pilot, we selected a representative subset of patient records from the hospital's database, focusing on diverse age groups, ART regimens, HIV stages, and comorbidities. This subset provided a representation of our larger study population.

Data Collection and Extraction:

Utilizing the standardized data extraction form designed for the main study, pertinent information was collected from the selected patient records. Evaluations were done on the electronic patient record, its relevance to the research objectives, and the completeness of the extracted data.

Sampling Frequency and Timing:

The pilot study spanned for one month, which allowed the assessment of the timeline feasibility. Records were sampled once a week, to ensure capturing a variety of cases over different periods within the pilot duration.

3.4 Ethical Considerations:

Ethical Approval: Ethical clearance was obtained to access and use medical records, ensuring compliance with ethical standards and maintaining patient confidentiality.

Informed Consent: As this study relies solely on anonymized existing data, individual informed consent was not required due to the lack of direct patient interaction.

Limitations and Delimitations:

Limitations: The study's scope was constrained by the available data and the information recorded in medical records.

Delimitations: The study focused on specific strata without direct patient engagement to provide a broader overview of biochemical markers within these defined categories.

By utilizing a cross-sectional stratified design without direct interaction with patients, the study aimed to gain insights into the relationship between ART regimens, patient-specific factors, and biochemical markers, while respecting patient privacy and without requiring direct patient participation.

CHAPTER 4: RESULTS AND ANALYSIS

4.1 Introduction

This chapter details the findings from the study carried out at Parirenyatwa Hospital in April 2024. These findings will include the sociodemographic, biochemical markers in HIV-positive patients accessing ART, and medical history such as ART regimens, and comorbidities. The chapter will present the associations between the variables that would have been identified through Chi-square test analysis.

4.2 Sociodemographic characteristics of the respondents

Out of four hundred and forty-four respondents, the mean age of the respondents was 39.4 ± 11.8432 years. As(Table4. 1) below shows, the most common age category was the 40+ years age group accounting for 212 (47.7%) of the respondents. A greater majority of the respondents (59.0%) were female (see figure 4.2).

Table 4.1 Demographic characteristics of the respondents (n = 444)

Variable	Frequency (N)	Percent (%)
Age:		
18-24	50	11.3%
25-29	51	11.5%
30-34	69	15.5%
35-39	62	14.0%
40+	212	47.7%

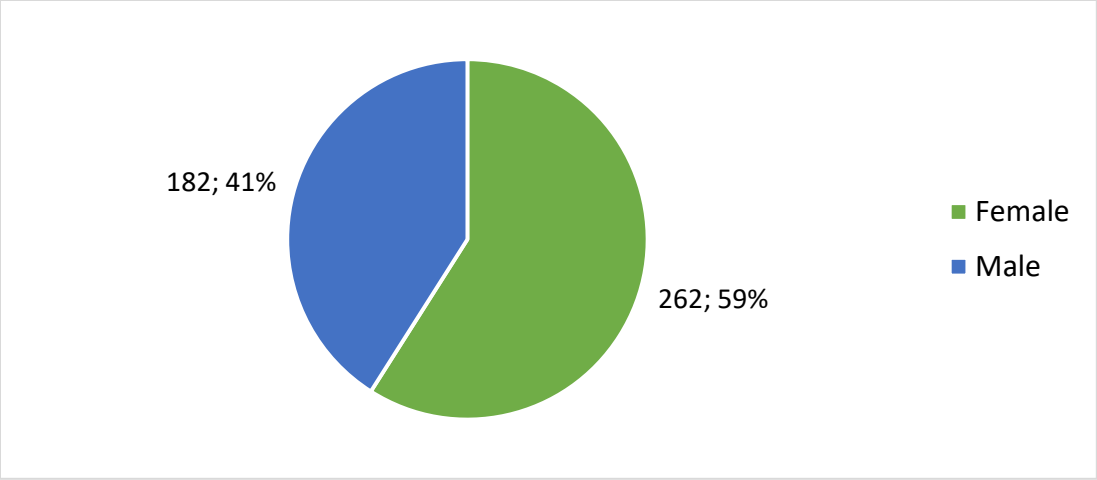


Figure 4.1. Gender among respondents (n=444)

4.3 Clinical characteristics of the respondents

The vast majority of the respondents (80.0%) had been on ART for 1 to 5 years at the time of the study. Only 58 (13.1%) had a normal BMI recorded. The modal group contributing 31.3% of the BMI observations was between 30 to 35, n=139 (see figure 4.2). Four hundred and thirty of the respondents (96.8%) were on first line ART treatment. With respect to WHO clinical staging, 286 (64.4%) were classified as in stage 2. Most of the participants (96.4%) had no known comorbidities recorded. On creatinine levels, majority of the respondents (95.3%) had a creatinine result less than 135 µmol. Only 7.7% of the respondents had a recorded ALT result greater than 57 U/L. Of the 309 respondents that had a viral load collected and result available, most of these respondents (96.4%) had a viral load less than 1,000 copies/mL. Two hundred and forty-eight respondents (55.9%) had a CD4 count of more than 200 cells/µL. However, from figure 4.3, the majority of the results (44%) were actually below 200 cells/µL. (see Table 4.2, figure 4.3).

Table 4.2 Clinical characteristics of the respondents (n = 444)

Variable	Frequency (N)	Percent (%)
Years on ART:		
1-5	355	80.0%
6-10	34	7.7%
11-15	33	7.4%
16-20	21	4.7%
21+	1	0.2%
Body Mass Index (BMI):		
Normal	58	13.1%
Abnormal	386	86.9%
ART regimen type:		
First line	430	96.8%
Second line	14	3.2%
WHO clinical stage:		
1	108	24.3%
2	286	64.4%
3	42	9.5%
4	8	1.8%
Comorbidities:		
At least one	16	3.6%
None	428	96.4%
Creatinine:		
<135	423	95.3%
>135	21	4.7%
GPT:		
<56	410	92.3%
>57	34	7.7%
Viral load*:(n=309)		
<1,000	298	96.4%
>1,000	11	3.6%
CD4 count:		

<200	196	44.1%
>200	248	55.9%

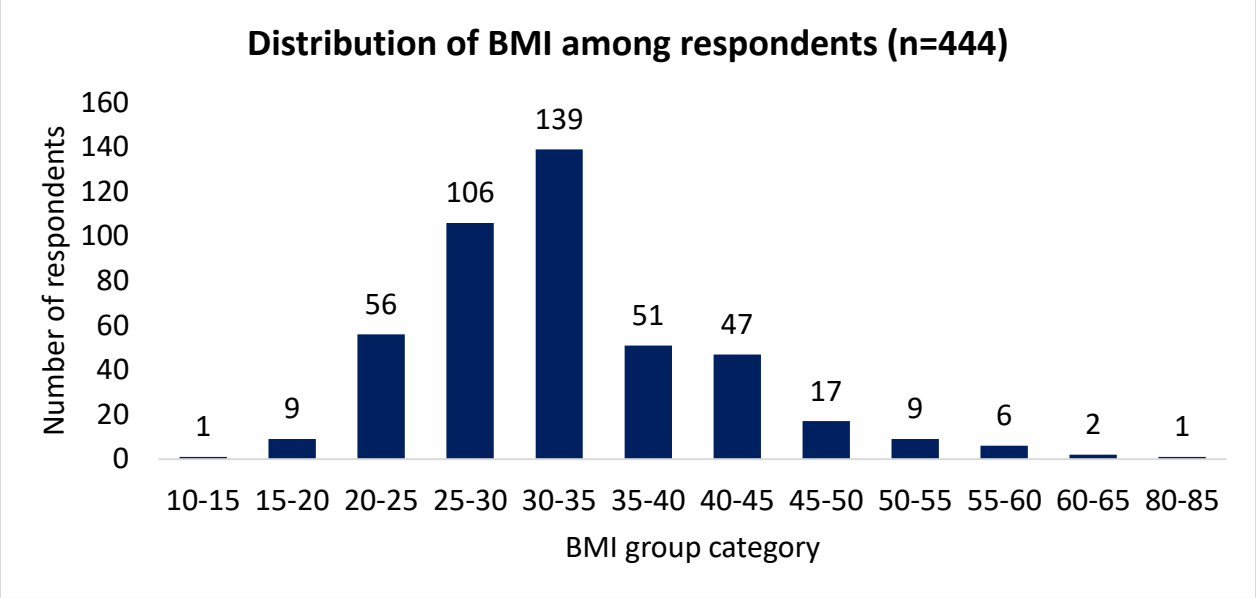


Figure 4.2. Distribution of BMI among respondents

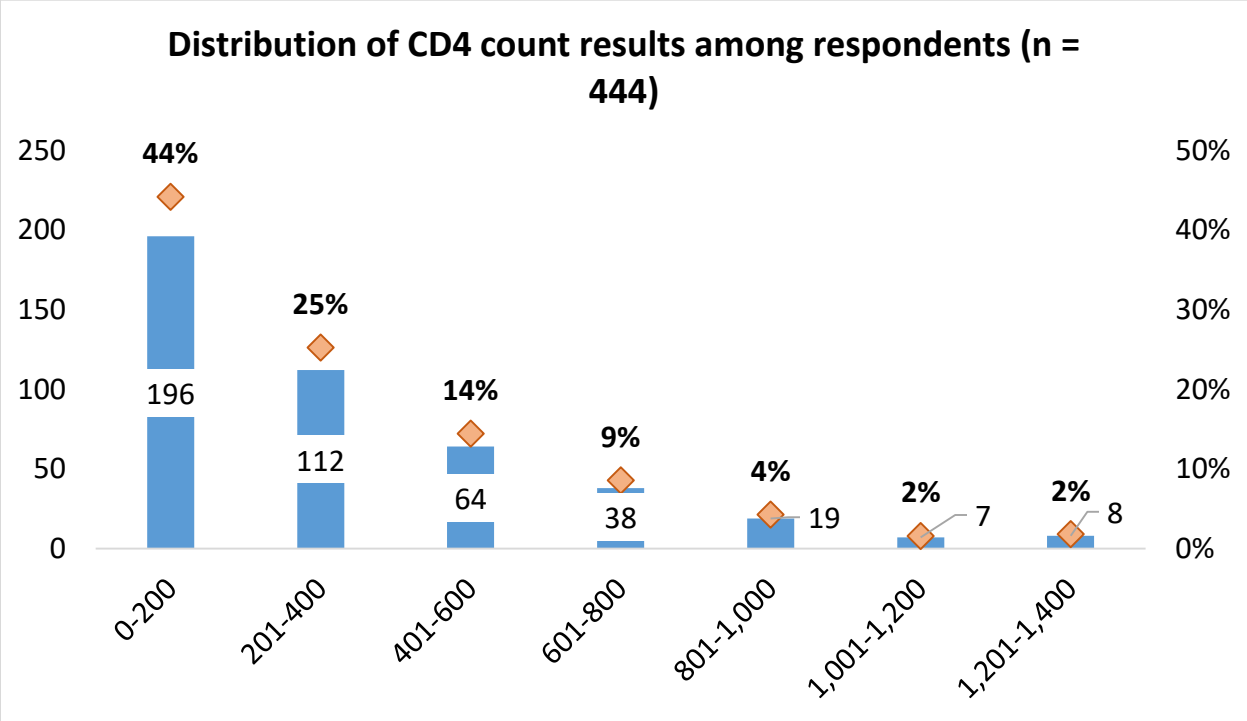


Figure 4.3. Distribution of CD4 count results among respondents

4.3 Sociodemographic risk associated with creatinine level during ART therapy

Chi square test showed that Respondents' age was significantly associated with the creatinine level (p-value = 0.0363). Similarly, gender was also significantly associated with the creatinine (p-value = 0.0144) (see Table 4.3 below).

Table 4.3 Chi square test : risk associated with creatinine level during ART therapy

Category	**Creatinine level**		**Total**	**p-value**
	<135	>135		
Age:				0.0363
18-24	50 (11.8%)	0 (0.0%)	50	
25-29	51 (12.1%)	0 (0.0%)	51	
30-34	65 (15.4%)	4 (9.0%)	69	
35-39	61 (14.4%)	1 (4.8%)	62	
40+	196 (46.3%)	16 (76.2%)	212	
Gender:				0.0144
Female	255 (60.3%)	7 (33.3%)	262	
Male	168 (39.7%)	14 (66.7%)	182	

4.4 Association between various risk factors and creatinine level during ART

Among respondents' clinical characteristics, only the ART regimen type that respondents were taking had significant association with creatinine levels (p = 0.0028). Other variables under study such as years on ART, WHO clinical stage, viral load, and CD4 count had no significant association with the creatinine level among the respondents (see Table 4.4).

Table 4.4 Chi square test for association between risk factors and creatinine level

Category	Creatinine level		Total	p-value
	<135	>135		
Years on ART:				
1-5	340 (80.4%)	15 (71.4%)	355	0.2716
6-10	30 (7.1%)	4 (19.0%)	34	
11-15	31 (7.3%)	2 (9.5%)	33	
16-20	21 (5.0%)	0 (0.0%)	21	
21+	1 (0.2%)	0 (0.0%)	1	
BMI:				
Normal	57 (13.5%)	1 (4.8%)	58	0.2480
Abnormal	366 (86.5%)	20 (95.2%)	386	
WHO clinical stage:				
1	107 (25.3%)	1 (4.8%)	108	0.0904
2	270 (63.8%)	16 (76.2%)	286	
3	38 (9.0%)	4 (19.0%)	42	
4	8 (1.9%)	0 (0.0%)	8	
Comorbidities:				
At least one	14 (3.3%)	2 (9.5%)	16	0.1363
None	409 (96.7%)	19 (90.5%)	428	
ART regimen type:				
First line	412 (97.4%)	18 (85.7%)	430	0.0028**
Second line	11 (2.6%)	3 (14.3%)	14	
ALT:				
<56	391 (92.4%)	19 (90.5%)	410	0.7421
>57	32 (7.6%)	2 (9.5%)	34	
Viral load*:				
<1,000	286 (96.3%)	12 (100%)	298	0.4979
>1,000	0 (3.7%)	0 (0.0%)	11	
CD4 count:				
<200	183 (43.3%)	13 (61.9%)	196	0.0935
>200	240 (56.7%)	8 (31.8%)	248	

***Total number with viral load results = 309,**P<0.05**

4.5 Conclusion

Most of the participants were middle-aged, with females being the majority. A majority of the respondents (80.0%) have been on ART for 1-5 years with 96.8% of the participants also taking first line ART regimen. Only 3.6% of the respondents had at least one comorbidity that they were being treated for. Age, gender, and ART regimen type were significantly associated with the creatinine level among the respondents. However, no significant association was demonstrated on variables such as years respondents have been taking ART, the WHO clinical stage, comorbidities, viral load, and CD4 count.

CHAPTER 5: DISCUSSION AND CONCLUSION

5.1 Introduction

Knowledge of factors influencing biomarker levels in HIV-positive patients is one of the critical conditions that ensures management is best tailored to ensure optimum care is provided(Gabudza et al, 2020). This current study demonstrates that age, gender, and ART regimen type were significantly associated with creatinine levels. This chapter will give context to these findings by making relevant comparisons with outcomes from previous studies from other countries in terms of social and clinical characteristics and their association with creatinine levels among HIV-positive patients. Finally, strengths and limitations are presented followed by a short conclusion of the chapter.

5.2 Factors associated with creatinine biomarker levels

Creatinine though affeceted by age, gender, liver disease and diet is an important marker of renal function(Adnani et al, 2022). Age, gender, and ART regimen type were found to be significantly associated with creatinine levels in this study. These findings are consistent with previous research by Alfanor et al (2019) that has identified these factors as important determinants of kidney function in HIV-positive individuals. The association of age with creatinine levels could be attributed to the natural decline in kidney function with age (Wearne et al., 2019) .Studies done by Jin et al (2015) showed an association between creatinine ,old age, gender and low CD4+ count. On the other hand studies done by Yilma et al (2019) found an association in urine creatinine levels for both HIV and non HIV adults with age and gender due to the impact of body mass on creatinine production rate. Unfortunately their study did not look rule other other

diseases in the non HIV adults that could have influenced the association to creatinine levels. Additional studies are however recommended that examine actual impact of the individual regimens on kidney function including other parameters such as urea and electrolytes. These findings could also be a potential area of further research by other authors to determine associations between age, gender and creatinine levels.

The impact of ART regimen type on creatinine levels is well-documented, with certain antiretroviral drugs known to be nephrotoxic(Adnani et al, 2022).This study demonstrated significant association between the type of ART regimen respondents were taking and the creatinine levels. This could be a result of the individual drug classes in the regimen types and their effect on kidney function(Wearne et al , 2019). Inferring from findings from other studies such as one by Zhao et al (2023) that reported elevated creatinine levels indicative of renal impairment in HIV-infected patients, this study also shows an association between ART and creatinine levels.

Comorbidities have been shown to influence various characteristics in HIV-positive patients, such as their lipid profiles (Maggi et al., 2017; Maciel et al., 2018). This study however attempted to evaluate the influence of comorbidities on kidney function, unlike these previous studies that looked at lipid profiles. Studies done by Chireshe et al (2019) expected that comorbidities such as hypertension and diabetes will have some influence on kidney function, but this study could not demonstrate any association between comorbidities and creatinine levels. Possibly more studies that employ wider patient variability or incorporating multi-center study areas might provide better insights on influence of comorbidities on kidney function.

To the best of our knowledge, few studies have explored in detail the association between WHO clinical stage and creatinine levels(Yilma et al, 2019). This study aimed to contribute to this gap with study results indicating that there is no association between WHO clinical stage and creatinine levels. But this warrants more studies to determine true correlation.

This study also went on further to assess influence of number of years on ART on creatinine levels. However, there was no significant association demonstrated. This warrants further studies to explore the relationship between duration of ART on kidney function. According to the findings, only the type of antiretroviral therapy (ART) regimen showed a significant association with creatinine levels among the clinical characteristics examined. This aligns with studies by Zhao et al (2023)suggesting that specific antiretroviral drugs can affect kidney function.

While Mutuma et al., (2023) indicated that older age was associated with altered liver function markers, our study found ALT had no associations. Based on the variables examined, there was no significant correlation observed between ALT levels and the factors investigated.Our study only looked at one variable in the liver function panel while studies done by Mutuma had more variables. Another study done by Shedrac et al (2020) had more variables including liver proteins like albumin and total protein,yet their study found no association between liver biomarkers and continuous use of ART.This study did not fully encompass other factors that affect liver function in HIV-positive patients and therefore additional research is required to investigate the connection between ALT levels and other factors like drugs, alcohol intake and diet which were not taken into account.

It is worth noting that there were no significant associations found with other variables such as the duration of ART, WHO clinical stage, viral load, and CD4 count. These results indicate that factors beyond these clinical characteristics may be influencing creatinine levels in HIV-positive patients. Genetic factors, lifestyle choices, or unaccounted medications could potentially play a role(De Francesco et al, 2018).

These findings emphasize the intricate nature of factors that impact kidney function in individuals with HIV. They highlight the importance of considering individual patient characteristics and treatment regimens when assessing and managing kidney function in this population. Further research is necessary to uncover the underlying mechanisms and identify additional factors that may affect creatinine levels in HIV-positive patients.

While initial intentions were to examine lipid parameters (cholesterol, triglycerides, HDL, LDL) in HIV-positive patients and evaluate the influence of HIV and ART on lipid metabolism, this was not possible as the study location did not perform lipid profile tests to their patients.

5.3 Limitations of present study

Because the study was carried out in an urban hospital setting, one of the limitations is that there may be sampling error with the study setting possibly missing adequate representation from HIV patients in other geographies such as those in rural areas. In addition, patients with severe conditions or those who are unable to visit the hospital regularly might be underrepresented. For these reasons, findings may not be generalizable to the broader public based on this study alone. Furthermore, due to the cross-sectional nature of the study, cause-effect relationships could not be determined.

Some biochemical tests were not offered at Parirenyatwa Hospital, such as lipid prolife. This impacted having full picture of biochemical markers and their status in HIV-positive patients.

5.4 Strengths of present study

This study is important because it contributed to adding assessment of several clinical characteristics and their influence on biomarkers, particularly creatinine level. To the best of our knowledge, few studies had approached such from that perspective.

5.5 Conclusion

Age, gender, and ART regimen type were significantly associated with the creatinine level among the respondents. However, no significant association was demonstrated with variables such as years respondents have been taking ART, the WHO clinical stage, comorbidities, viral load, and CD4 count. More research is however warranted to fully establish the true relationships between the various biomarkers in HIV-positive patients from a more generalisable study sample of patients.

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Appendix 1. Budget

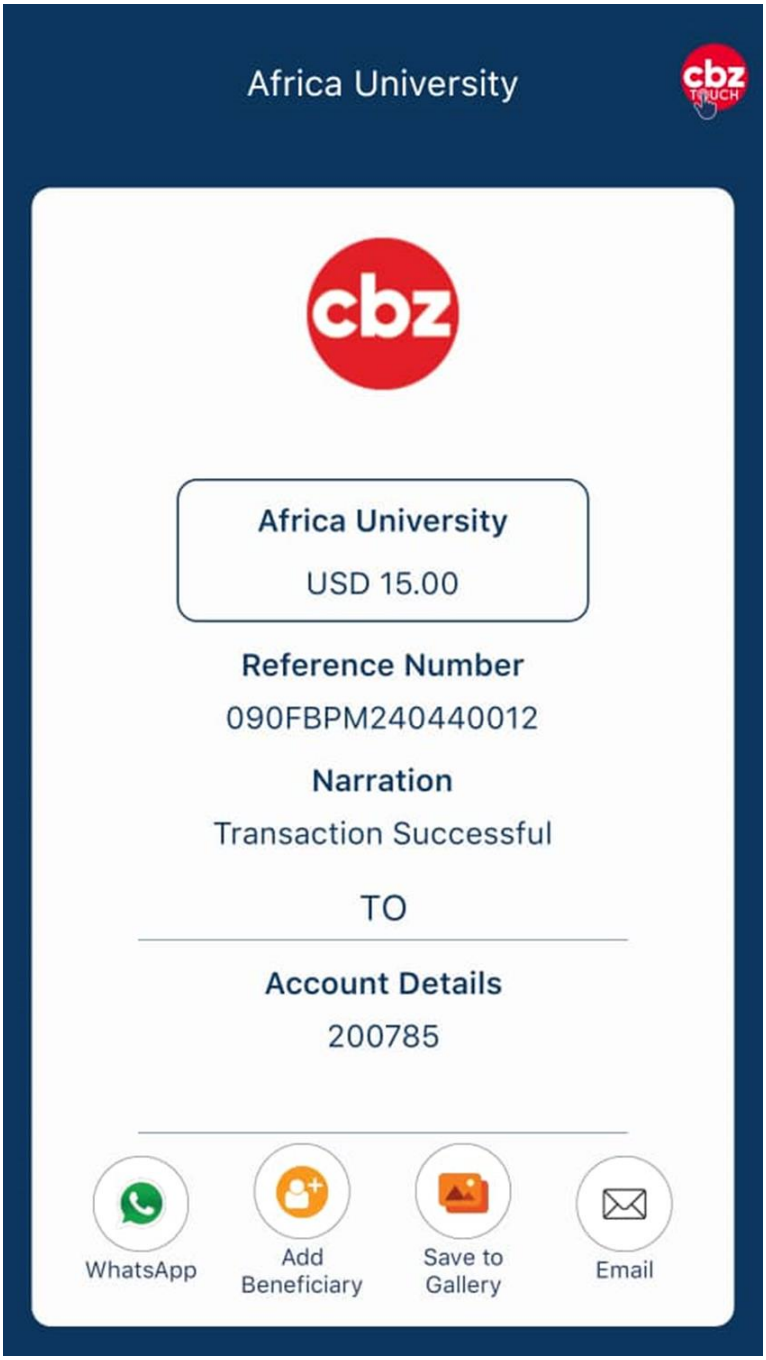
Item	**Unit Cost (US $)**	**Quantity**	**Total cost (US$)**
Printing	0.1	50	5
Photocopying	0.02	200	4
Transport	60	2	120
AUREC	15	1	15
Airtime	1	25	25
Pens	0.2	5	1
Total			**170**

Appendix 2. Timeframe

Activity	**Responsible**	01/2024	02/2024	02/2024	03/2024	04/2024
Writing project proposal	Researcher					
Write permission letter seeking permission to conduct research at Parirenyatwa hospital						
Send permission letter to Parirenyatwa hospital	Researcher					
Permission granted	Clinical Director Parirenyatwa hospital					
Ethics approval	AUREC					
Submission of proposal	Researcher					
Data collection, analysis and interpretation	Researcher					
Results and recommendations	Researcher					

Submission of final research project report	Researcher					

Appendix 3. AUREC proof of payment



Appendix 4. Data collection form

Patient	Gender	Age	Race	Date of diagnosis	ART regimen	HIV stage	Height	Weight	BMI	CD4 count	Viral load	Liver enzymes	Kidney markers	Lipid profile markers	Comorbidities
1															
2															
3															
4															
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Appendix 5. AUREC Application form

AFRICA UNIVERSITY
(A United Methodist-Related Institution)

For office use only
Protocol no. .....
Type of review: Full Committee ☐
Expedited ☐
Exempted ☐
Fees paid/receipt number: .....
Office stamp

AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC)

APPLICATION FOR INITIAL REVIEW

NB: This form must be completed by all persons/teams applying for ethical review by AUREC. Upon completion by the investigator(s) /researcher(s) it should be submitted electronically to AUREC, Africa University, Fairfield Road, Old Mutare, P.O. Box 1320, Mutare. Application fees (to cover the costs of reviewing prposal) should be paid to the Africa University Business Office, and proof of payment should accompany each application. Please complete all sections of this application form. If there is insufficient space on the form you may use additional pages.

Check list

This checklist is meant to aid researchers in preparing a complete application package and to help expedite review by the AUREC. Please tick all boxes as appropriate (Indicate **N/A** where inapplicable).

CONTACT PERSON'S NAME : Kudzai olgah Mabhodho
CONTACT ADDRESS: 4441 Sandton, Zvimba
EMAIL ADDRESS : muzamhindok@africau.edu
CONTACT NO: 0776985951

UNDERGRADUATES

		Applicant	AUREC
1	Application form duly completed	✓	
2	Electronic version of research proposal to aurec@africau.edu	✓	
3	Consent forms in English and local language of study population	N/A	
4	Advertisement or letter or card used for recruiting participants and any supplementary information *(if applicable)*.	N/A	
5	Data collection tools being administered during the study in English and local language of study population *(if applicable)* included in the proposal	N/A	
6	Budget and timeframe included in the proposal.	✓	
7	Approval letter from your academic supervisor/college or institution	✓	
8	Approval letter from authorities where study will be conducted		
9	Application fee paid at AU Business Office and receipt (or copy) attached to application form.	✓	

POST GRADUATES AND OTHER RESEARCHERS

		Applicant	AUREC
1	Application form duly completed		
2	Electronic version of full research proposal (chapter 1 – 3 completed) to aurec@africau.edu		
3	Proposal summary (see guidelines below)		
4	Consent form in English and local language of study population		
5	Advertisement or letter or card used for recruiting participants and any supplementary information *(if applicable)*.		
6	Data collection tools being administered during the study in English and local language of study population (if applicable)		
7	Budget and timeframe		
8	Approval letter from academic supervisor/college or institution *(if you are a student)*		
9	Approval letter from authorities where study will be conducted		
10	Application fee paid at AU Business Office and receipt attached to application form.		
12	CV's for D Phil and Phd candidates.		

Signature: Investigator/Researcher	Name	Date
	K. Mabhodho	19/02/2024

1. General information
   1.1. Study title: Evaluation of biochemical markers among HIV patients

above the age of 18 acessing ART at Parirenyatwa Hospital Care Center in Zimbabwe Family

1.2. Name of Principal Investigator(PI)/ Researcher: Kudzai olgah Mabhodho

1.3. Nationality of Investigator/Researcher: Zimbabwean

1.4. Proposed date of start of study: _(dd/mm/yyyy) 01/01/2024

1.5. Expected duration of study: 4 months

1.6. Study site(s) in Zimbabwe: Parirenyatwa Hospital Care Center, Harare

1.7. Sites outside Zimbabwe: _____

1.8. Study budget: _____ Source of Funding: Self

1.9. Is the researcher a student? Yes/No

1.10. If Yes, indicate the following:

1.10.1. Name and address of institution: Africa University ,1 Fairview Rd, Old Mutare

1.10.2. College: Health agriculture and natural sciences

1.10.3. Level of study Undergraduate/Master's/PhD Undergraduate

1.10.4. Name of Supervisor: Dr Sallissou Maibouge

1.11. If No to question 1.10, then indicate the following:

1.11.1. Name and address of institution: _____

1.11.2. Academic Title of PI: _____

1.11.3. Existing Qualifications: _____

1.11.4. Co Investigators:

Names:	Qualifications	Institution

2. Statement by the investigator

I Kudzai olgah Mabhodho certify that the information in this application document and the accompanying documents is true and complete in all respects. I confirm that the application has NOT been rejected by any other ethics review committee.

Signature _____ Date: 19/02/2024

Appendix 6. Supervisor's approval letter

AFRICA UNIVERSITY
A United Methodist-Related Institution

Investing in Africa's Future

COLLEGE OF HEALTH, AGRICULTURE AND NATURAL SCIENCES

P.O. BOX 1320, MUTARE, ZIMBABWE – Cell: (+263) 780079459 E
MAIL: salissoum@africau.edu.

5, February, 2024

To whom it may concern

Dear Sir

Re: Permission to submit To AUREC for Kudzai Olgah Mabhodho Reg No: 200785

Program: Bachelor of Medical laboratory sciences

This letter serves to confirm that I have supervised the above mentioned student and she has satisfied all the requirements of the college and she is ready in conducting research on *Evaluation of biochemical markers among HIV patients above the age of 18 accessing ART at Parirenyatwa Hospital Family Care Center in Zimbabwe: A retrospective cross sectional study*

Your facilitation in assisting him is greatly appreciated

Thank you

Research Supervisor:
Dr Maibouge T.M.Salissou PhD
Endowed Chair of Pathology CHANS Africa University

Appendix 7. Parirenyatwa Hospital approval letter

All communications should be addressed to
THE GROUP CHIEF EXECUTIVE
Telephone: 701520-701554/7
Fax: 704627
Website: www.parirenyatwa.org

PARIRENYATWA GROUP OF HOSPITALS
P.O Box CY 198
Causeway
Zimbabwe

14 February 2024

RE: REQUEST FOR PERMISSION TO CONDUCT RESEARCH STUDY AT PARIRENYATWA GROUP OF HOSPITALS: KUDZAI MABHODHO

The above matter refers.

The Parirenyatwa Group of Hospitals hereby grants you permission to conduct research on:-

Evaluation of biomedical markers among HIV patients above the age of 18 accessing ART at Parirenyatwa Group of Hospitals.

The permission is granted subject to the following conditions: -

1. The researcher will provide all sundries necessary for sample collections. ☑
2. The researcher sponsors all payments for the tests involved. ☑
3. The hospital incurs no cost in the course of the research. ☑
4. All relevant departments are notified in advance and the Head of section/ward signs acknowledgement of such notification. ☑
5. The conduct of the research does not interfer or interrupt the daily service provision by the hospital. ☑
6. Formal written feedback on research outcomes must be given to the Director of Clinical Services. ☑
7. Permission for publication of research must be obtained from the Director of Clinical Services. ☑

DR M. MHLANGA
ACTING CLINICAL DIRECTOR

Appendix 8. AUREC Approval letter

Investing in Africa's future

AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC)

P.O. Box 1320 Mutare, Zimbabwe, Off Nyanga Road, Old Mutare-Tel (+263-20) 60075/60026/61611 Fax: (+263 20) 61785 Website: www.africau.edu

Ref: AU3158/24

1 March, 2024

Kudzai Olgah Mabhodho
C/O Africa University
Box 1320
MUTARE

RE: **EVALUATION OF BIOCHEMICAL MARKERS AMONG HIV PATIENTS ABOVE THE AGE OF 18 ACCESSING ART AT PARIRENYATWA HOSPITAL FAMILY CARE CENTER IN ZIMBABWE: A RETROSPECTIVE CROSS-SECTIONAL STUDY**

Thank you for the above-titled proposal that you submitted to the Africa University Research Ethics Committee for review. Please be advised that AUREC has reviewed and approved
your application to conduct the above research.

The approval is based on the following.

a) Research proposal

- **APPROVAL NUMBER** AUREC3158/24
  This number should be used on all correspondences, consent forms, and appropriate documents.
- **AUREC MEETING DATE** NA
- **APPROVAL DATE** March 1, 2024
- **EXPIRATION DATE** March 1, 2025
- **TYPE OF MEETING**: Expedited
  After the expiration date, this research may only continue upon renewal. A progress report on a standard AUREC form should be submitted a month before the expiration date for renewal purposes.
- **SERIOUS ADVERSE EVENTS** All serious problems concerning subject safety must be reported to AUREC within 3 working days on the standard AUREC form.
- **MODIFICATIONS** Prior AUREC approval is required before implementing any changes in the proposal (including changes in the consent documents)
- **TERMINATION OF STUDY** Upon termination of the study a report has to be submitted to AUREC.

AFRICA UNIVERSITY
RESEARCH ETHICS COMMITTEE (AUREC)
APPROVED
P.O. BOX 1320, MUTARE, ZIMBABWE

Yours Faithfully

MARY CHINZOU
ASSISTANT RESEARCH OFFICER: FOR CHAIRPERSON
AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE