An Assessment of the use of Viral Load monitoring on People Living with HIV/AIDS taking Antiretroviral Therapy by nurses working at rural health centers in Mberengwa District, Zimbabwe.

GABRIEL NYASHA NDAGURWA

A mini-thesis submitted in partial fulfillment of the requirements for the degree of Master in Public Health at the School of Public Health, University of the Western Cape

Supervisor: Prof. Hanani Tabana

11 November 2021

Keywords

National Antiretroviral Therapy guidelines, Viral load monitoring, Enhanced adherence counselling, Antiretroviral therapy, Treatment failure, Unsuppressed viral load, Viral load suppression, Test and Treat, First-line antiretroviral therapy, Second-line antiretroviral therapy.

DECLARATION

I declare that, **An Assessment of the use of Viral Load monitoring on People Living with HIV/AIDS taking Antiretroviral Therapy by nurses working at rural health centres in Mberengwa District, Zimbabwe**. is my own work, that it has not been submitted for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

Full Name: Dr. Gabriel Nyasha Ndagurwa Date: 11 November 2021

Signed: 

ACKNOWLEDGEMENTS

I would like to extend my gratitude and profound appreciation to my supervisor, Prof. Hanani Tabana for her invaluable input and expertise, as well as her sound mentorship throughout the whole process of the study.

I would like to thank my wife, Mels for her love and support throughout the course, my daughters Brielle and Brienne, family and friends for allowing me to sacrifice time that I was supposed to be with them.

ABBREVIATIONS

AIDS - Acquired Immunodeficiency Syndrome

ART - Anti-Retroviral Therapy

HIV - Human Immunodeficiency Virus

EAC – Enhanced Adherence Counselling

MOHCC- Ministry of Health and Child Care

PLWHA- People living with HIV and AIDS

UNAIDS- The Joint United Nations Programme on HIV/AIDS

WHO – World Health Organization

LMICs - Low- and Middle-Income Countries

ZNAC – Zimbabwe National Aids Council

OPERATIONAL DEFINITIONS

Suppressed Viral Load refers to less than 1000 copies of HIV viral particles in one millilitre of blood

Unsuppressed Viral Load refers to more than 1000 copies of HIV viral particles in one millilitre of blood

Table of Contents

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

Background: Human Immunodeficiency Virus (HIV) infection remains a major global public health issue despite all the efforts being made to control and manage infections worldwide. Data reported in Mberengwa district suggests that less than 40% of PLWHA on ART had a viral load test done which translates to 32% viral suppression of all the patients on ART. This falls far short of reaching the national target of 90% viral suppression in patients on ART. The current study assessed the implementation of viral load monitoring guidelines in Mberengwa district.

Methodology: A cross sectional analytical study design was used to describe and analyze use of viral load monitoring on People Living with HIV/AIDS and taking Antiretroviral Therapy. A sample size of 328 participants was included and systematic random sampling was used to select patient files at all the 31 rural health centres in Mberengwa district.

Ethics: Patient reviews were accessed for data collection hence no direct patient contact. In addition, participant identity was protected through use of a study number rather than patient`s name.

Results: The study revealed that only 72% of the participants had at least one viral load test done. The period between ART initiation and first Viral load sample collection had a median value of 297 days. About 6% of the participants who had their first viral load done had samples collected before the standard period of 6 months. Almost a third of the clients eligible for enhanced adherence counselling did not receive any session.

Conclusion: The national guidelines for Viral load monitoring in PLWHA on ART was not being followed in the health centres studied. This has a bearing on the quality of care for PLWHA on ART.

CHAPTER 1: INTRODUCTION

1.0 Introduction

Human Immunodeficiency Virus (HIV) infection remains a major global public health issue despite all the efforts being made to control and manage infections worldwide. Globally in 2019, there were an estimated 38million people living with HIV and AIDS (PLWHA) and 690 000 people who died due to HIV related causes. It is however important to note that globally, HIV incidence and deaths have been declining steadily over the past decade (UNAIDS, 2019). This steady decline is mainly attributable to the increase in coverage of antiretroviral therapy (ART) for PLHIV. In the year 2014, the Joint United Nations programme on HIV/AIDS (UNAIDS) recommended the adoption of 90-90-90 targets in an effort to accelerate the control of HIV/AIDS and end the HIV epidemic by the year 2030.The first '90' target was to ensure 90% of all people living with HIV should know their HIV status. The second 90 aimed to ensure that out of the 90% diagnosed with HIV, 90% of them must be sustained on ART. The third '90' target was to achieve viral suppression to monitor response to ART and early identification of treatment failure (Thinn et al., 2019). Considering that CD4 count and clinical staging had become relatively less sensitive and specific for proper assessment of response to ART, viral load monitoring was recommended as the best alternative (Roberts, Cohn, & Bonner, 2016).

Zimbabwe remains one of the countries with the highest HIV prevalence in sub-Saharan Africa at 12.8%, with 1.4 million people living with HIV in 2019. This is despite managing to reduce the HIV prevalence from 15.4% in 2010 (Global Fund, 2020). The HIV prevalence decrease has been mainly due to reduced number of new HIV infections since the country managed to halve the number of HIV/AIDS deaths in the same period. The relatively high prevalence has been explained to be due to more people surviving HIV due to effective ART treatment rather

than people continuing to contract HIV. The (Ministry of Health and Child Care, Zimbabwe (MoHCC), 2016) recommends a "treat all" approach, which means starting and keeping all PLWHA on ART regardless of their CD4 cell count or WHO clinical stage at diagnosis. The country is making strong progress towards the UNAIDS 90-90-90 targets. As of 2019, 90% of the people living with HIV in the county were aware of their status and 94% of those diagnosed were on treatment. Of the people diagnosed and on treatment, 86% were virally suppressed, meaning that they are likely to be in good health and won't pass HIV on to others. Overall, this equates to 85% of all people living with HIV in Zimbabwe being on treatment and 73% of all HIV positive people being virally suppressed (Avert, 2020). This leaves a huge gap in working towards epidemic control since viral load suppression is pivotal in its attainment.

Viral load monitoring was recommended by the World Health Organisation as the method of choice in monitoring the effectiveness of antiretroviral therapy. It has been noted to be the strongest predictor of transmission of HIV (Thinn et al, 2019; Estill et al, 2012). Viral load testing involves the measurement of the number of HIV viral particles in plasma per unit volume of blood (World Health Organisation, 2019). The samples of blood may be collected as fresh blood or a dry blood spot (DBS) which is sent to the lab for analysis (Pollack et al., 2018). A fresh blood sample is usually used when the point of sample collection and the processing laboratory are close or easily accessible since the sample needs to be processed within 6 hours after collection (Ministry of Health and Child Care, Zimbabwe (MoHCC), 2017). In low-resource settings a DBS sample is used more often since it can be used even days after collection. Hence this bypasses the hurdle of the need for quick transportation to the laboratory.

Supressed viral load is viral load which is not detectable by the machine in the lab and ranges between 20 and 40copies/ml in well-resourced settings (the machines will be more sensitive hence more expensive). However, in low resource settings viral load below 1000copies/ml is

regarded as suppressed (Ellman et al., 2017).

Regular viral load monitoring makes it easier to pick early poor adherence and hence intervene by Enhanced Adherence Counselling (EAC) sessions in order to establish viral load suppression. Furthermore, in the case of treatment failure it allows early detection and switching of treatment regimen. Zimbabwe adopted the Viral Load monitoring algorithm recommended by WHO, PLWHA on ART should have a viral load test done at 6 months after starting treatment. The test is then repeated after completing a year on treatment, from then on annually if the viral load remains suppressed. If a client has high viral load it is recommend that enhanced adherence counselling (EAC) is instituted and repeat the test 3 months after the EAC. If there is evidence of good adherence (greater than 95%) and there are two consecutive unsuppressed viral load clients may be considered for Second-line ART (MoHCC, 2016). Figure 1 shows the algorithm for Viral Load Monitoring which is being used in Zimbabwe.

Despite the importance of monitoring viral load, UNAIDS (2016) indicated challenges in having the services widely available especially in low-middle income countries. Factors like, insufficient Laboratory infrastructure, long results turnaround times and poor results management are the major challenges in the viral load testing particularly in Low- and Middle-Income Countries (LMICs) (Nichols, Girdwood, & Shibemba, 2019). Studies have shown several benefits of viral load monitoring with appropriate actions which include, reduction in morbidity and mortality, reduction in ART resistance and also improvements in treatment outcomes of second line ART. Financial, logistical and human resource constraints have made viral load monitoring very much inaccessible to many people in LMICs. The uptake of routine VL monitoring among the patients ranged from 3% to 95% in seven sub-Saharan countries (Thinn et al., 2019).

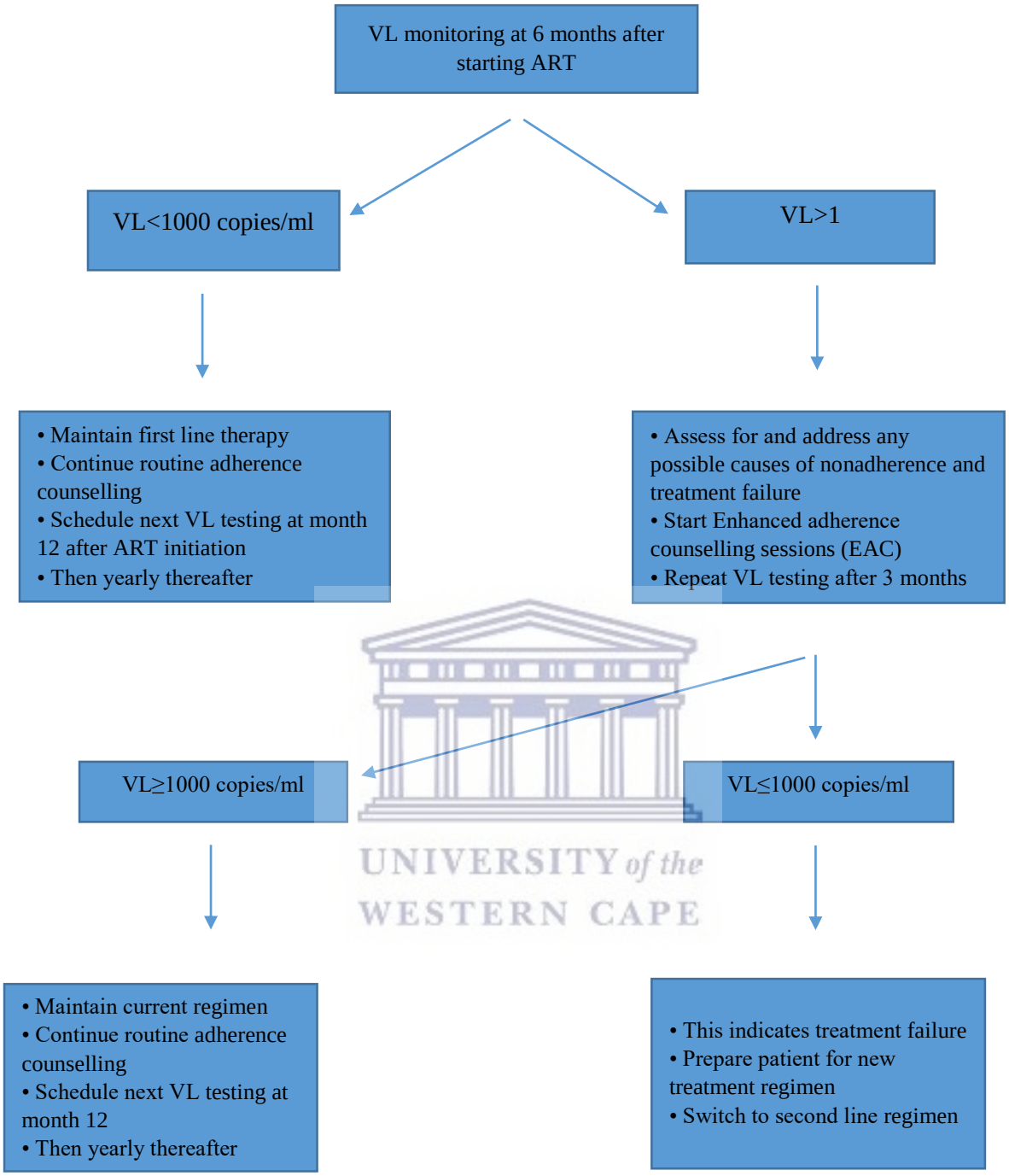


Figure 1. 1: Viral Load testing strategies to detect or confirm treatment failure and switch in adults, adolescents and children. Source: (Guidelines for ART for the Prevention and Treatment of HIV in Zimbabwe 2016, p. 62)

1.1 Problem Statement

The 2019 annual District report by Kapnek Trust shows that Mberengwa district has viral suppression of 80%. However less than 40% of PLWHA on ART had a viral load test done which translates to 32% viral suppression of all the patients on ART. This falls far short of reaching the national target of 90% viral suppression in patients on ART. It also means there is a huge proportion of PLWHA whose risk of HIV transmission is not known. This will derail the achievements realised so far in reducing new HIV infections.

The implementation of routine VL testing has been monitored and presented through district reports. However, there is not much detail to measure VL monitoring against the standard guidelines. Most of the information in the reports is analysis against set targets. There is anecdotal evidence that the uptake of VL testing is poor due to programmatic challenges in adhering to routine VL monitoring protocol. Therefore, there is a need to establish facts with scientific evidence. The information from this study could provide insights on gaps that exist and enable programmers to take appropriate actions that help improve viral load monitoring.

There is therefore a need to establish the extent to which the viral load monitoring guidelines are being adhered to. There is lack of evidence and knowledge thereof on the extent to which patient viral loads are being monitored according to the national guidelines in Mberengwa district.

1.2. Justification of the study

Considering the fact that viral load monitoring has been chosen as the most sensitive test for assessment of response to ART, it is critical to follow up on its implementation if its benefits are to be realised. To the best of our knowledge, this is the first study on viral load monitoring in Mberengwa district. Viral load monitoring has been conducted without a clear assessment

of its implementation at district level. The study will help inform viral load monitoring programming and therefore contribute to the attainment of the 95-95-95 goals. The study will also explore the challenges in the implementation of viral load monitoring in Zimbabwean rural public health facilities.

CHAPTER 2: LITERATURE REVIEW

2.0 Introduction

The purpose of this literature review is to provide the reader with a general overview of the literature relevant to the use of Viral Load monitoring on PLWHA taking Antiretroviral Therapy. The use of Viral Load to monitor patient response to ART and early identification of treatment failure is an area that requires more attention to ensure the benefits of the program are realised. The chapter also highlights the gaps in viral load monitoring programming in the literature.

2.1 HIV/AIDS care progress

Although HIV/AIDS remains a health concern globally, significant strides have been made in fighting the disease. This is because of the use of evidence-based strategies in the fight against HIV. One such strategy by the WHO was the "Test and Treat" where all clients who test HIV positive are commenced on treatment despite some eligibility criteria previously required (MoHCC, 2016). This resulted in global increase in the number of people on ART from 17.2 million in 2015 to 25.4 million in 2019. Sub-Saharan African countries adopted these guidelines and saw increases in number of people on ART. In Zimbabwe numbers increased from 879,271(75%) in 2015 (Zimbabwe National Aids Council, 2018) to 1.4million (85%) in 2019 (UNAIDS, 2020). In addition, a significant reduction in HIV transmission has been achieved. According to the UNAIDS (2019) report a global decline of 40% in new HIV infections has been achieved from a peak of 2.8million people in 1998 to 1.7million people in 2019. This can be sustained if the risk of HIV transmission is low in PLWHA.

Zimbabwe is amongst the countries that realised a significant decrease in the HIV/AIDS disease burden. The country has reduced the HIV prevalence from 15.4% in 2010 to 12.7% in 2018 and managed to halve the number of HIV/AIDS deaths in the same period. The latter achievement was made by only five countries globally (Global Fund, 2020). Zimbabwe was pursuing the global goal on HIV infection management that by the year 2020, 90% of people living with HIV get tested and know their status, of those who know their status 90% should have been started on treatment and of those that are on treatment 90% should have suppressed viral loads (90-90-90 target) (UNAIDS, 2016). By the end of the year 2019 the first 90 was achieved through different strategies that included community-based index testing and self-testing. Of all people living with HIV, 85% are on sustained ART. The third 90 is lagging behind at 73% despite the improved retention in care through implementation of differentiated service delivery (Zimbabwe National AIDS Council (ZNAC), 2020).

Figure 2.1, shows the prevalence rose steeply from 1984 and in 1996 it had reached its peak. After 1996, a decrease in HIV prevalence was observed and this was likely due to a decrease in transmission and new infections as a result of behaviour change, and or deaths. Since the year 2010, the prevalence has plateaued, and this is mainly because more people with HIV have access to ART and are living longer. People infected with HIV and on ART are also less likely to transmit the virus to their contacts when the viral load is suppressed.

HIV Prevalence in Zimbabwe

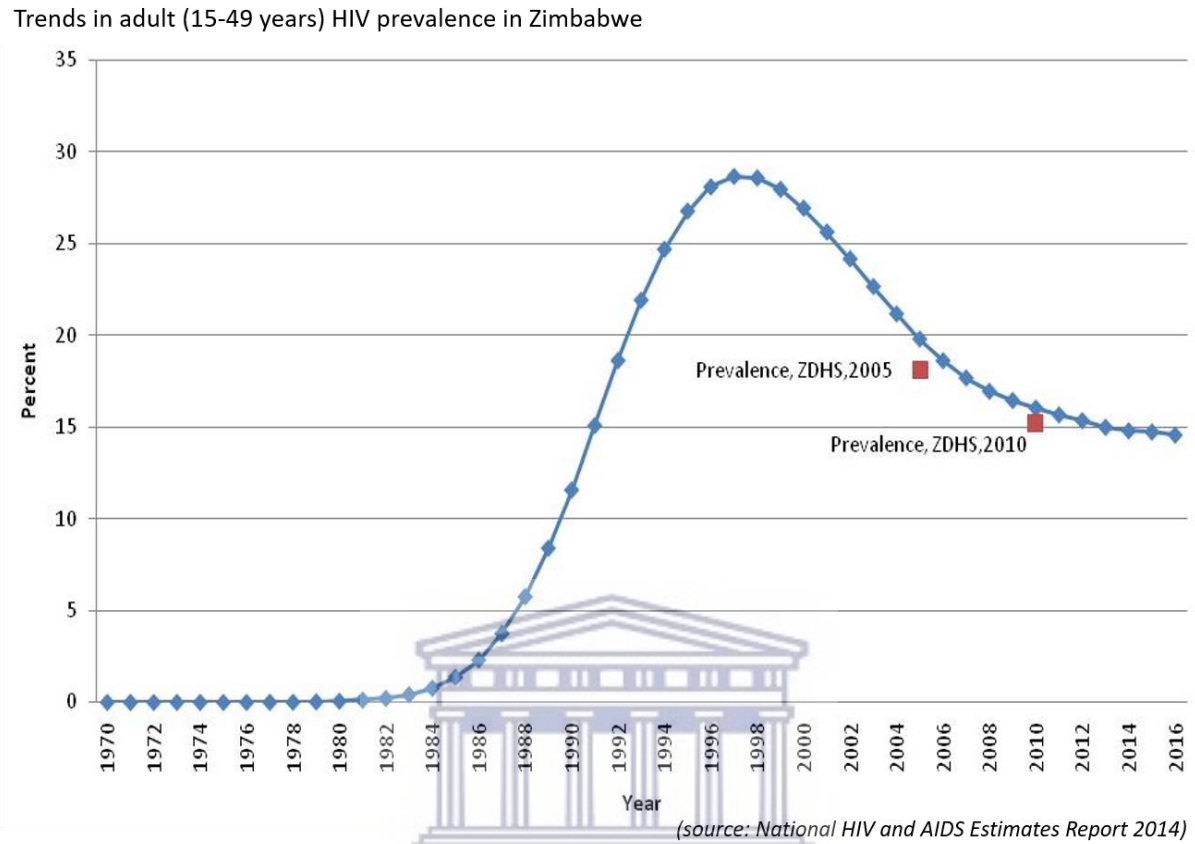


Figure 2. 1: Trends in adult (15-49 years) HIV Prevalence in Zimbabwe.

2.2 Cost-effectiveness of Viral Load monitoring

The use of Viral Load monitoring has economic benefits as well. It is more sensitive than the traditional CD4+ count which was the main b monitoring mechanism. Indeed, a study done by Sigaloff et al., (2011) in 6 African countries showed that close to 50% of patients who were switched to second-line and third-line regimens based on their CD4+ count were in fact not supposed to be switched. Another MSF study done in several countries showed that only 30% of patients who were recommended for switching of medical regimen for treatment failure were actually having treatment failure. This meant that the other 70% were misclassified using other methods of assessing treatment failure (UNAIDS, 2016). Hence appropriate use of viral load will result in significant impact on the cost of healthcare since the cost of second-line and third-

line regimen are way more expensive than the first line medicine. According to Mascolini (2013) the Inter-science Conference on Antimicrobial Agents and Chemotherapy (ICAAC) (2013) approximated that second line medicines have a cost that is about 24% more than the first-line ART medicines. This is more so with third line medicines approximated to cost about 41% more than first line medicines (Mascolini, 2013). Viral load monitoring then becomes critical in Zimbabwe where about two thirds of the HIV expenditure come from international donors (Avert, 2020).

2.3 Viral Load sample collection and interpretation of results

Viral Load monitoring has proved to be a superior predictor of HIV transmission. A strong association has been established between plasma HIV Viral Load and risk of HIV transmission, i.e., the higher the viral load, the higher the risk of transmission (Estill et al, 2012). Viral load testing involves the measurement of the number of HIV viral particles in plasma per unit volume of blood (WHO, 2019). The samples of blood may be collected as fresh blood or a dry blood spot (DBS) which is sent to the lab for analysis (Pollack et al., 2018). A fresh blood sample is usually used when the point of sample collection and the processing laboratory are close or easily accessible since the sample needs to be processed within 6 hours after collection (MoHCC, 2017). In low-resource settings a DBS sample is used more often since it can be used even days after collection. Hence this bypasses the need for quick transportation to the laboratory.

Supressed viral load is viral load which is not detectable by the machine in the lab and ranges between 20 and 40copies/ml in well-resourced settings (the machines will be more sensitive hence more expensive). However, in low resource settings viral load below 1000copies/ml is regarded as suppressed (Ellman et al., 2017).

2.4 Viral load monitoring guidelines

The WHO guidelines recommend that PLWHA should have a viral load test done after six months of being on ART. Patients are expected to have viral load below 1000copies/ml, otherwise they then need to have a repeat at 12months from the date of initiating treatment, then annually if viral load remains suppressed. In a case where the viral load is above 1000copies/ml it is deemed treatment failure and the patient need enhanced adherence counselling and a repeat test done three months later. If it persists above the threshold a diagnosis of treatment failure is made and the patient is switched to second line ART (MoHCC, 2016). Calmy et al. (2007) and Rowley (2014) however argue about the challenges of sustaining implementation of viral load monitoring in low income countries considering the cost of the infrastructure required. In Zimbabwe at the initial implementation of viral load monitoring priority was for patients who were suspected to be failing (Medecins Sans Frontieres (MSF), 2016). Routine monitoring was done with CD4 count. However, upscaling was implemented and Viral Load (VL) is now routine. In a retrospective cohort study in Cameroon, Awungafac et al. (2018) found that an average of 65% of patients had their first viral load done more than 2 years after initiating treatment. This was despite a plausible turn-around time for results of 6days (IQR 6-7days). In addition, they also found that only 54% of patients who met the Viral Load criteria for second line treatment were switched.

2.5 Viral load and adherence counselling

Patients who require adherence counselling may be identified using viral load monitoring hence it can be used as an adherence reinforcing tool (Bonner, Mezochow, Roberts, Ford, & Cohn, 2013). Bangsberg et al (2000) and Sevelius, Saberi, Mas and Johnson (2014) established in their findings the profound association between adherence and the viral load in homeless patients who were taking Protease inhibitors and in transgender women respectively. However,

Birungi et al. (2020) argued that enhanced adherence counselling had no effects in reversing virological treatment failure as demonstrated by a Ugandan study (Mermin et al., 2011). In one of the biggest studies for People Living with HIV, Usitalo et al. (2014) showed that a special group of youth with a history of perinatal infection with HIV, viral load monitoring has been associated closely with adherence.

Although viral load monitoring is being implemented, gaps have been noted on the use of the viral load results for decision making (MSF, 2016; Awungafac et al., 2018; Etoori et al., 2018; Ehrenkranz et al., 2019; Phillips et al., 2016). This in addition equally affects the management of patients as per guidelines. Etoori et al. (2018) in a study involving patients with initial high viral load found that about a third of patients did not receive Enhanced Adherence Counselling, only a third got all three sessions and the rest of the patients had either one or two sessions.

2.6 Use of Viral Load monitoring to switch patients to second line treatment

Viral load monitoring has been shown to be a superior monitoring method for patients on ART (Sigaloff et al., 2011; Shoko & Chikobvu, 2019; Calmy et al., 2007; Rowley, 2014). Sigaloff et al (2011) observed that about 47% of patients who were switched to second-line ART based on clinic-immunological basis were in fact unnecessarily switched. In addition, they noted that viral load monitoring reduced wrong classification of treatment failure four-fold. However other studies (Mermin et al., 2011, Okoboi et al., 2016) argued that there is no significant difference in the outcomes between patients who are being monitored on CD4 count alone and those being monitored by a combination of CD4 and viral load. With the 24% increase in financial burden associated with second line treatment there is need to have only patients who need switching to be switched (Mascolini, 2013).

Viral Load`s superiority in monitoring saw it being adopted as the test of choice for the UNAIDS 90-90-90 target. 90% of people with HIV to know their status, 90% of the positive who know their status to be on ART and 90% of patients on ART to have viral suppression. It is also being used in the criteria for Differentiated Service Delivery (DSD) (MSF, 2016; Jamieson et al., 2016). This is an intervention where patients with undetectable VL are regarded stable and no need to frequently come to the health facility to collect medicines. In that sense they can form Community ART Refill Groups (CARGs) in the community or as a family and their representatives collect medicines on their behalf (ZNAC, 2020).

CHAPTER 3: METHODOLOGY

This chapter gives an outline of research methods that were followed in the study to address the study objectives. It provides information on the participants, that is, the criteria for inclusion in the study, who the participants were and how they were sampled. In this chapter, the researcher describes the research design that was chosen for the purpose of this study and the reasons for this choice. The instrument that was used for data collection is also described and the procedures that were followed to carry out this study are included. The researcher also discusses the methods used to analyse the data. Ethical issues that were followed in the process are also discussed.

3.1 Aim and Objectives

3.1.1. Aim

To assess the implementation of viral load guidelines in Mberengwa district

3.1.2 Specific objectives

1. To assess if patients are being monitored by Viral Load as per national guidelines.
2. To determine the proportion of patients given enhanced adherence counselling after recording a viral load greater than 1000c/ml
3. To assess the use of viral load for switching patients with treatment failure to second line ART.
4. To determine the timeliness of Viral load sample collection and turnaround time of results.

3.2 Study Design

A cross sectional analytical study design was used to describe and analyze use of viral load monitoring on People Living with HIV/AIDS and taking Antiretroviral Therapy. Specifically,

those who were initiated in the years 2017 and 2018 after the adoption of the treat all strategy. The study was based on retrospective review of patients' "green books" (patients' files). A quantitative methodology was used since the study sought to assess the adherence to viral load monitoring guidelines and required proportions to be calculated, analysed and described. The study design was appropriate as it is cost effective compared to other studies and it is quick to do as it has less demanding logistics. It also allows for assessment of a number of exposures at the same time (Süt, 2014). Setia (2016) however explains that the study design does not give information on the timing of outcome relative to exposure. In this study the primary outcomes were viral load monitoring as per guidelines, switching to second line based on viral load, and Enhanced Adherence Counselling. Furthermore, the study described PLWHA's socio-demographic and baseline characteristics, treatment outcomes at various points in time, and determined risk factors for selected outcomes. The use of this study design and the existence of registers of patients initiated on ART were beneficial in that the eligible participants could be identified very efficiently. This also reduced the resources and time required compared to that of prospective study designs.

3.3 Study Settings

Mberengwa District is in the Midlands Province in Zimbabwe. It is one of the 8 districts in Midlands province and is one of the largest in the province. It is the southernmost district in the province bordering with Masvingo and Matabeleland South Provinces. At the time of study, the population was about 200 000 (Zimstat, 2020). It is an all-rural district with no urban part but has several business centres. The district is prone to high temperatures and droughts hence not much agricultural activities are done there. The majority (62%) of households receive social protection support (ZimVac, 2021). It lies within the Great Dyke which is abundant with

mineral like gold, asbestos and other precious metals. Therefore, the most common economic activity is mining. The main form of mining practised is artisanal mining. The district has poor road network thus difficult to access some parts of it especially during the rainy season.

There are 36 health facilities in the district which all offer HIV/AIDS management. Of these 31 are rural health centres, four hospitals and one rural hospital. The ownership of these health facilities is mixed with 21 rural health centres being run by the Local Authority, seven rural health centres run by the government, three Mission hospitals and two hospitals run by the government. Artisanal miners are a high-risk group who live a migratory life hence difficult to follow up for health care. According to the ZimVac (2021) report, 68% of the population have a health facility within five kilometres from their homesteads while 11% are more than 10 kilometres from the nearest health facility. In addition, 77% have access to a community health worker.

The district has an HIV prevalence of 15.2% for the age group 15years and above with an ART coverage of 94.2%. The incidence of HIV is at 0.31%. It is one of the 2 districts in the province that have achieved 95% coverage in the PMTCT programme (Midlands Report, 2020).

3.4 Study Population and Sampling

The population comprised of PLWHA in Mberengwa District who were started on ART that are being managed at rural health centres. The sampling frame was patient notes for patients started on ART from January 2017 to December 2018 at rural health centres.

Inclusion Criteria

PLWHA and started ART in the years 2017 and 2018

Participants have been on ART for at least 1 year. This allowed for better assessment as they were expected to have at least two viral load tests done after a year.

Exclusion Criteria

PLWHA who were on third line ART treatment.

PLWHA who had a history of being followed up at a hospital.

Mothers who attended Antenatal/Postnatal Clinic during the review period.

Sample size

For sample size, a confidence level of 95% and margin of error 5% was used and using Cochran`s formula. Assuming an error risk (z_α) of 1.96, with a precision (Δ) of ± 5% and expecting that 23% (p) of patients are being monitored by viral load (UNAIDS, 2016) our minimum sample calculated was 273 respondents. However, we adjusted and oversampled by 20% to make up for possible incomplete data and inconsistences to a total of 328 participants. Probability sampling was used since it minimises selection bias. Patient files are in cohorts at facilities based on the year they were started hence systematic random sampling was used to select 11 patient files at all the 31 rural health centres. Every 20th file was taken from the 2017 and 2018 cohort folders until 11 files were collected per facility.

3.5 Data Collection

The researcher collected the data from all the 31 facilities with permission from the Midlands Provincial Medical Director (Appendix B). An electronic data extraction form was used for data collection. The data extraction form (Appendix A) was used to collect quantitative data from the patients' paper-based folders. A pilot test for the tool was done to assess feasibility of

the study. Nurses working at hospitals in ART departments participated in the pilot. They also participated in the review of the tool and irrelevant questions were removed and some rephrased. The patients' notes have the detailed history of patients including age, gender, date of enrolment in care, date of ART initiation, the monitoring tests done on them during the tenure of the treatment at these facilities. Some data was not available in the patients` folder and viral load registers were used to collect the rest of the data for completeness.

3.5.1 Baseline Socio-demographic Variables

The variables within this category included the sex of the patient, the age at ART initiation, occupation, marital status, and the year of HIV diagnosis. This is completed by facility nurses and primary counsellors. Occupation gave a glimpse of the socio-economic status of the patient, and also may give reflection on how these variables are related to compliance with viral load monitoring guidelines.

3.5.2 Viral Load and Viral Load Suppression

The measurement of viral load is used in the ART programme as an indicator of response to ART treatment as well as a guide to identify possible issues with adherence. For this study viral load suppression was defined as a viral load less than 1000 copies/ml. The proportion of patients who had viral load testing done as stipulated by guidelines was done. Another quality of care indicator which was assessed was the number of viral load tests done after one year on treatment. Therefore, for this study it translated into determining viral loads done at 6months, 12months and 24 months for those with supressed viral loads. For those who had unsuppressed viral load, they were assessed for the viral load done at 3months after the last viral load.

3.5.3 Enhanced Adherence Counselling

This category is for those who recorded an unsuppressed viral and require EAC. Proportions were calculated on those who received EAC sessions and the numbers of sessions attend. Additionally, the duration of the sessions was assessed to reflect on the quality of the service. Also, on quality of EAC service, qualification of the cadre who took patients for sessions was assessed.

3.6 Data Management and Analysis

Data was collected using an offline Open Data Kit software (ODK). Any errors in the data were checked by the researcher. After data was downloaded from the server it was exported into excel for cleaning. Obvious outliers were removed from the data to avoid distortions in the analysis. Statistical analyses were conducted using the SPSS v16. Descriptive analyses were done to assess the extent of adherence of viral load monitoring guidelines and comparing the distribution of various variables among the patients on ART.

Bivariate analyses were done looking for possible associations between adherence to viral load monitoring guidelines and other variables. In determining these associations, Pearson's chi-square tests were applied at 95% level of significance. In this case, variables which had p-value greater than 0.05 were rendered insignificant. Tables, bar graphs and pie-charts were used for data presentation.

3.7 Validity and Reliability

3.7.1Validity

Validity is the extent to which an instrument measures what its intended to measure (Considine,

Botti & Thomas, 2005). Face validity for the data collection tool was established by having selected nurses working in HIV/AIDS departments at hospitals reviewing them. Pilot testing was done to ensure that data collection tool is useful and able to collect all the required information. The nurses working at hospitals did not participate in the study however they gave their input in the revision of the tool.

3.7.2 Reliability

Drost (2011) defines reliability as the reproducibility of the same result using a tool or instrument under varying circumstances. One person collected the data so as to maintain consistency and hence reliability. Cronbach's alpha was used to check for internal consistency and it was 0.7 which reflects good reliability.

3.8 Ethics considerations

Ethical clearance for the study was sought and granted from the University of Western Cape's Biomedical Research Committees (Reference number, BM20/1/11), Ministry of Health and Child Care and the Medical Research Council of Zimbabwe (Reference number, MRCZ/B/1976). In addition, permission was sought and granted from the Provincial Medical Director to carry out the study.

The study involved a special group of the population that is PLWHA. There was minimal risk expected as patient reviews were accessed for data collection hence no direct patient contact. In addition, participant identity was protected through use of a study number rather than patient`s name or "green" book number.

The findings of the study will be used for the benefit of patients as the study sought to improve

the quality of health service provision for people living with HIV who are on treatment. They will also be used to make recommendations to address gaps identified.

CHAPTER 4: RESULTS

The chapter outlines the results from the study. From a total of 328 patient records collected, a total of 299(91.2%) met the inclusion criteria for the study. The analysis conducted included univariate, bivariate and multivariate analysis. Results of the study are presented in the form of tables, bar graphs and pie charts.

4.1 Demographic variables

Table 4. 1 Demographic variables for study participants

Variable	Frequency	Percentage
Sex		
Male	129	43.1
Female	170	56.9
Occupation		
Artisanal miner	71	23.7
Cross-border trader	17	5.7
Formally employed	22	7.4
Unemployed	137	45.8
Vendor	44	14.7
Other	8	2.7
Marital status		
Single	37	12.4
Married	186	62.2
Divorced	41	13.7
Widowed	22	7.4
Other	13	4.3

More females (56.9%) were sampled than males (43.1%). The majority (62.2%) of the participants were married. About half (45.8%) of the selected clients were unemployed, while 23.7%. of the sample were artisanal miners.

4.2 Monitoring of patients as per national guidelines

Data for periods taken to conduct specific viral load monitoring indicators was analysed using descriptive statistics and the results are as shown in table 4.2 below.

Table 4. 2 Initial and continuation patient management indicators

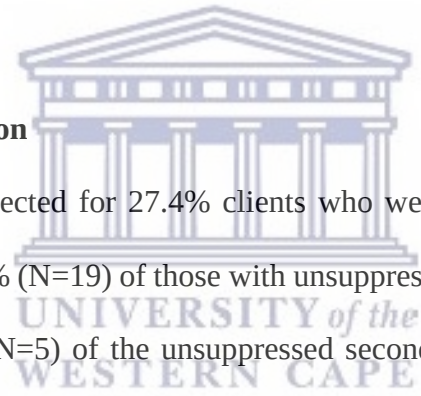
Indicator	Mean duration in days (SD)	Min duration in days	Range in days	Max duration in days	N	Median in days
Initial Patient Management						
Positive HIV test and Initial ART Initiation	11.1 (66.2)	0	730	730	299	0
ART initiation and 1st VL Sample collection	352.5 (169.6)	81	871	952	217	297
1st viral load sample collection and results	88.4 (62.7)	18	346	364	199	70
Unsuppressed clients 1st and 2nd sample collection	282.3 (119.7)	132	399	531	18	257
Suppressed clients 1st and 2nd sample collection	370.7(118.3)	171	417	588	73	354

Indicator	Mean duration in days (SD)	Min duration in days	Range in days	Max duration in days	N	Median in days
2nd viral load sample collection and results	73.7(53.6)	23	314	337	62	60.5
Continuation of Patient monitoring						
Unsuppressed clients 2nd and 3rd sample collection	188 (18.7)	167	45	212	4	186.5
Suppressed 2nd and 3rd sample collection	234	234	0	234	1	234
3rd sample collection and results	49.6 (26.0)	22	67	89	5	43
Unsuppressed 3rd and 4th sample collection	209.5 (21.9)	194	31	225	2	209.5
Suppressed 3rd and 4th sample collection	205.5(12.0)	197	17	214	2	205.5
4th sample collection and results	69.8 (36.4)	39	79	118	4	53

Seventy-two percent (72%) of the patients were initiated on ART on the same day of testing. The median HIV test to ART period was 0 days. However, the range for HIV test to ART period was 730 days. On average, clients were having almost a year before getting their first viral load sample collected. The minimum duration between ART initiation and getting the first viral load sample collected was 81 days, meaning that there were some people who got the first viral load sample collected before the standard period of 6 months. The median

turnaround time for fist viral load test was 70 days. The corresponding tests had median values of 60 days, 43 days and 53 days respectively.

For clients with suppressed viral load, the period between first and second viral load sample collection period had a median of 354 days, while second and third, third and fourth had median period of 234 and 205.5 days respectively. In the management of clients with unsuppressed first viral load, the period between first and second sample collection had a median value of 257 days, while for second and third sample collection, it was 186.5 days and for the third and fourth samples, it was 209.5 days. The turnaround time for results in second, third and fourth viral load sample results were 61 days, 43 days and 53 days respectively.



4.3 Viral load sample collection

No viral load sample was collected for 27.4% clients who were eligible for first viral load sample collection. About 94.7% (N=19) of those with unsuppressed first viral load had second sample collected while 80% (N=5) of the unsuppressed second viral load had third sample collected. All clients who had unsuppressed third viral load test had fourth viral load sample collected (N=3).

Collection of first viral load in less than 6 months

According to HIV management guidelines, the first viral load sample should be collected at 6 months. Below is a pie chart of the period at which the first viral load sample was collected.

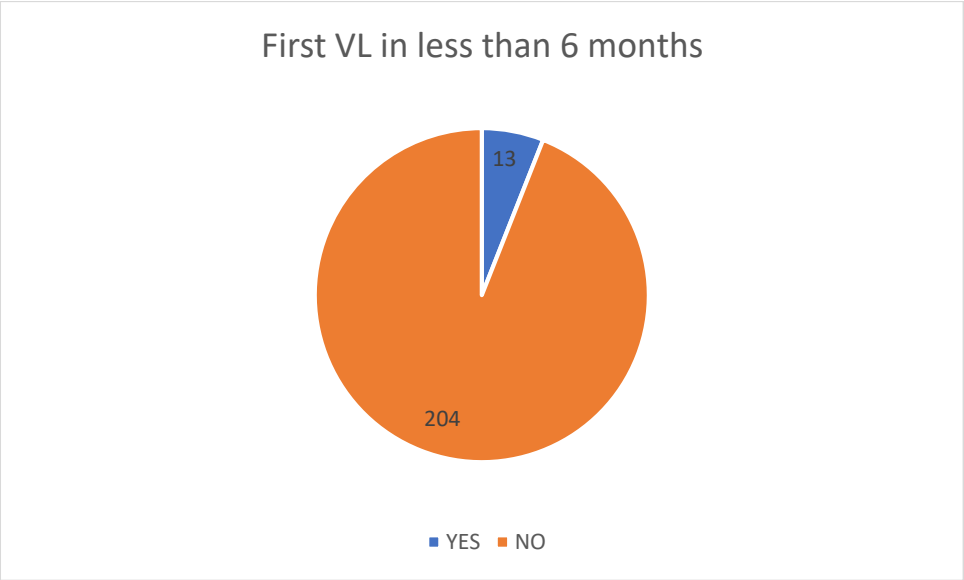


Figure 4. 1**:** First viral load sample collection in less than 6 months

About ninety-four percent (94%) of the participants had their first viral load sample collected after 6 months, while 6 % had their samples collected before 6 months.

4.4 Results of viral load tests

The results of viral load tests are important in determining whether the patient is being virally suppressed or not, which helps detect treatment failure timeously. Figure 4.2 shows the results of the first viral load tests and the subsequent tests for eligible clients.

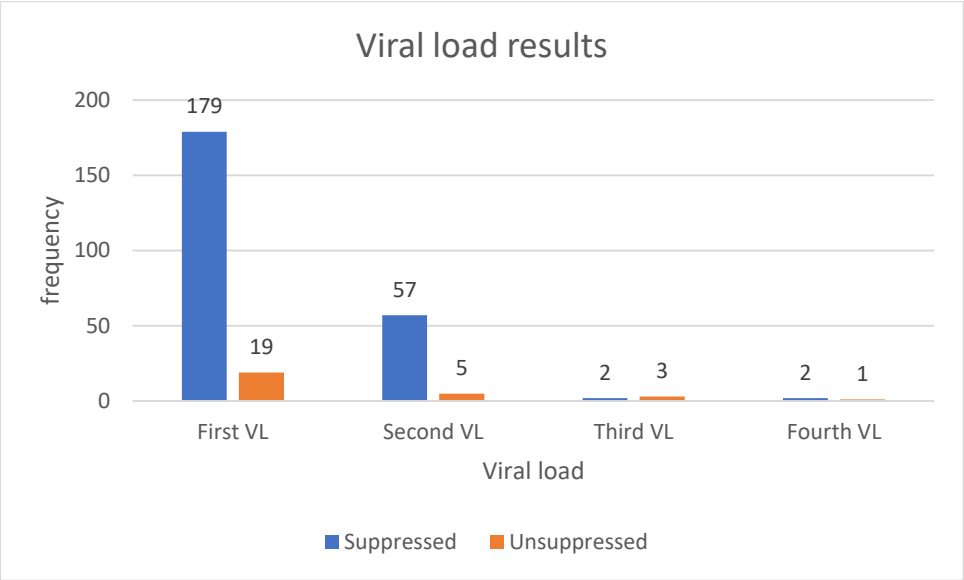


Figure 4. 2**:** Results of the viral load tests

The results in Fig.4.2 indicate that in the first viral load tests done, 90.4% (N=198) had suppressed viral load (VL<1000 copies/ml), 92% (N=62) had suppressed second viral load results, 40% (N=5) had suppressed third viral load results and 75% (N=4) had suppressed fourth viral load results. Fourteen (14) patients who were eligible for the second viral load test were missed. Five (5) patients were eligible for the third viral sample collection and 100% of them had samples collected.

4.5 Enhanced adherence counselling cascade

Enhanced adherence counselling sessions are conducted on clients with unsuppressed viral load. It helps to improve the outcome of subsequent tests as clients are encouraged to adhere to their treatment. Figure 4.3 below shows how the 3 enhanced adherence counselling sessions were done on eligible clients.

Thirty-two percent (6 out of 19) of the eligible patients did not receive any enhanced adherence counselling session. Patients (4) eligible for the second adherence counselling session were

also missed. Out of 9 people eligible for the 3rd enhanced adherence counselling session, 2 were missed.

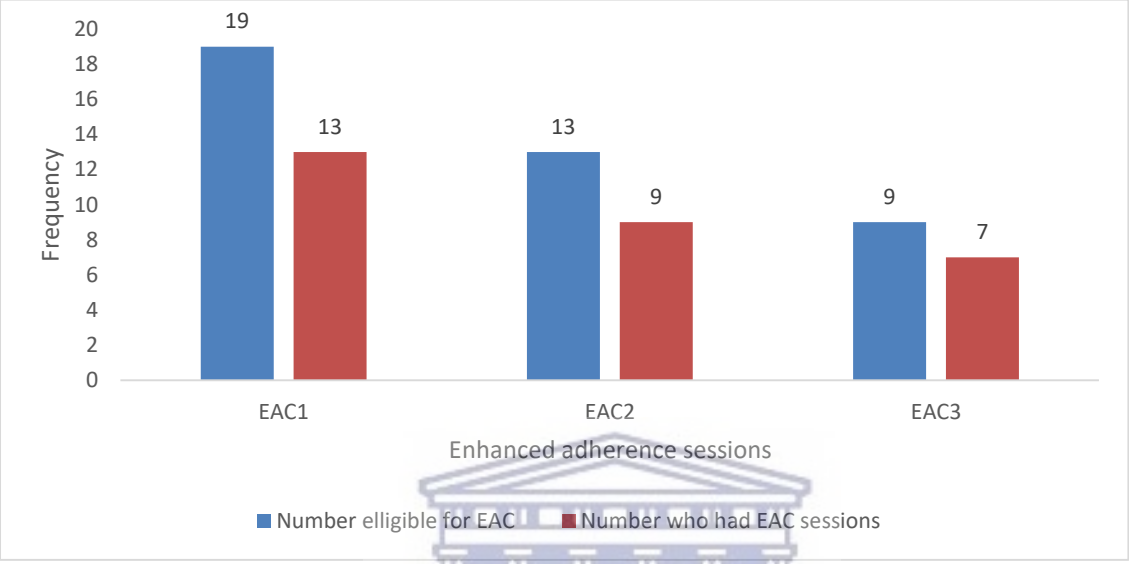


Figure 4. 3: Enhanced adherence counselling cascade

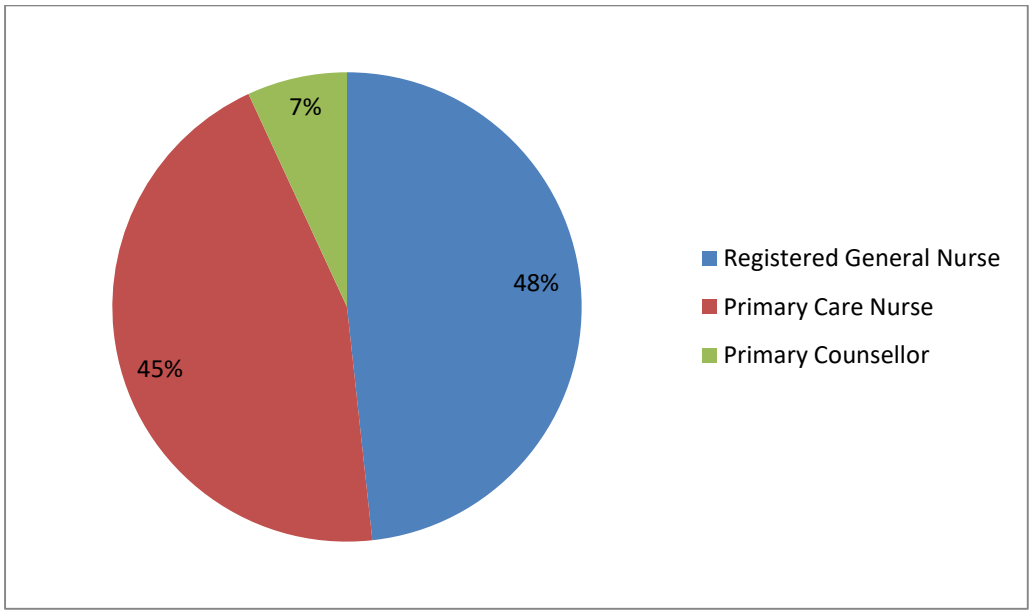


Figure 4. 4**:** Health care workers responsible for enhanced adherence counselling sessions

Only 2 Primary care counsellors were involved in enhanced adherence counselling.

4.6 Period for Enhanced Adherence Counselling sessions

None of the sampled participants had documented period of enhanced adherence sessions. This was a worrying finding as it has an impact on the quality of the enhanced adherence counselling sessions given to eligible clients.

4.7 Bivariate analysis

The association between first viral load test results and patient related variables (sex, occupation and marital status) was assessed using Pearson's chi square tests. The results are shown in Table 4.3.

Table 4. 3 Association between 1st viral load result and demographic variables.

Variable	Chi-square value	P-value
Sex	0.61	0.799
Occupation	1.665	0.893
Marital status	4.392	0.356

The was no significant association between fist viral load result with sex (p=0.799), occupation (0.893) and Marital status (0.356).

4.8 Switching of patients with treatment failure

Clients with treatment failure are expected to be switched to second line ART to improve their outcomes. The pie chart below shows the proportion of clients who were correctly switched on second line ART as per guidelines.

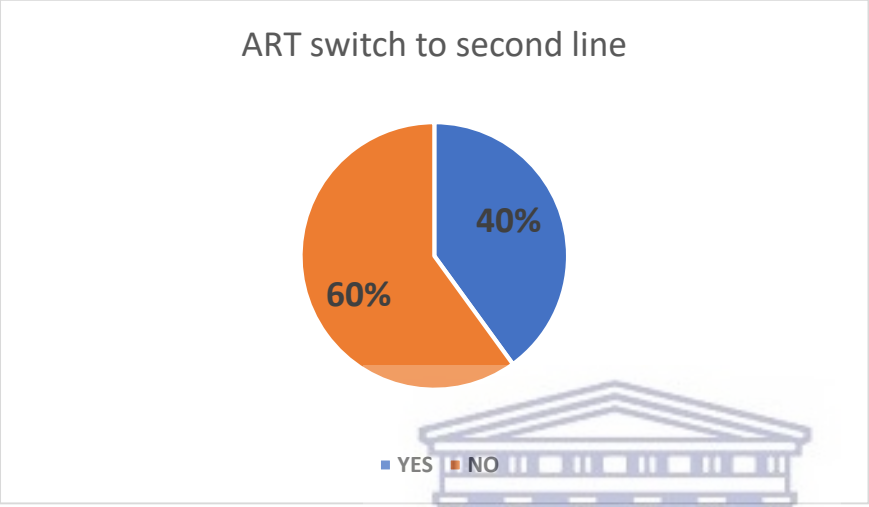


Figure 4. 5**:** Switching of patients with treatment failure

Only 60% of the patients with treatment failure were switched to second line ART based on viral load. The remaining 40% also had viral loads above 1000copies/ml but there are no documented reasons for failure to switch to second line ART.

CHAPTER 5: DISCUSSION

This study was the first in Mberengwa district to assess the use of viral load monitoring on people living with HIV/AIDS who are taking anti-retroviral therapy by nurses working at rural health centres. Routine Viral Load (VL) testing enables early detection of suboptimal anti-retroviral therapy adherence and gives an opportunity for management of patients with treatment failure. Since the year 2016, when VL monitoring policy was launched in Zimbabwe, the adherence to national guidelines in Mberengwa district has not been fully studied.

5.1 ART Initiation and Viral load monitoring timelines

In this study, 72% of the patients were initiated on ART on the same day they received a positive test result, an encouraging finding considering the test and treat approach which was adopted in HIV/AIDS management (MoHCC, 2016).

The coverage for the HIV positive clients who received at least a viral load test is comparable to the national annual coverage for the year 2017 for other African countries such as South Africa and Kenya (Haas et al., 2020). Zimbabwe in 2017 reported a 25.4% first viral load sample collection coverage, according to research conducted in 2017 (Bvochora et al., 2019). The low viral load monitoring coverage is below the United Nations target of 95%.

It was concerning to note that the period between ART initiation and the first Viral Load (median value of 297 days) was way outside the recommended period for the current study. Apollo et al. (2020) found similar results in Zimbabwe where they noted that only 25.4% of patients had a viral load done after a year on treatment. In addition, a Ugandan study reported a median time of 12 months for time to first viral load. Only 1.9% ART naïve mothers had their first Viral Load done timely (Atuhaire et al., 2021). The median period between first and second samples collection was almost a year just as was observed in the ART to first sample

period. Some patients took close to 3 years before the first viral load sample was collected which is concerning as the likely consequence would be a delay in detecting treatment failure, thus leading to undesirable outcomes. In addition to patient factors, to non-adherence to these timelines in low-income countries are high cost, high technical demands and logistics associated with routine VL monitoring (Mungwira et al., 2018)

Another interesting finding from this study was that, about 6% of the participants had their first viral load sample collected before the standard period of 6 months. These results generally suggest that some healthcare workers are not following the stipulated guidelines. This finding may be attributed to the fact that at the time of study some nurses were still new in the system and may not have been exposed to any formal training on viral load monitoring.

5.2 Turnaround time of viral load results

The turnaround time for Viral Load test results was worryingly long and result was similar to findings in other studies conducted in poorly resourced settings in Zimbabwe (Nyakura et al., 2019). According to national HIV/AIDS management guidelines, patients should receive their viral load results within a period of 2 weeks. The observed delays in receiving results for patients under monitoring compromises patient management as it contributes potential treatment failures. In a Tanzanian study conducted in a resource limited setting, long turnaround times for results were also reported (Kroid et al., 2020). These findings suggest that there is need to provide adequate resources for proper implementation of the viral load monitoring guidelines in HIV/AIDS patient management. Delays in giving patients VL test results delay switching of patients who are eligible for second line treatment.

5.3 Viral load suppression and follow up care

About 90.4% of the participants had suppressed (VL<1000copies/ml) viral load for the first viral load test results. This was close to the United Nations target of 95% and there is hope that this can be achieved considering that Mberengwa district has 3 Non-Governmental Organisations (NGOs) who are partnering with the Ministry of health and child care to support HIV/AIDS management. Other researchers in Zimbabwe reported viral load suppression rates which ranged from 89% to 94% (Bvochora et al., 2019; Nyakura et al., 2019; Haas et al., 2020). The greatest concern from the study findings was on the results of the third viral load tests where the viral load suppression rate was only 40%. Switching patients on first line ART to second line ART when they have unsuppressed viral load results has been reported to increase viral load suppression rates in subsequent tests (Mapangisana et al., 2021). However, the findings of this study indicated otherwise, and this may be due to poor adherence to treatment by some clients.

Enhanced adherence counselling sessions are conducted on clients with unsuppressed viral load results (Laxmeshwar et al., 2020). Almost a third of the clients eligible for enhanced adherence counselling did not receive any session. Other studies reported higher enrolment into enhanced adherence counselling sessions (Bvochora et al., 2019). Primary care counsellors are the technocrats in HIV/AIDS counselling as they are specifically trained for that task. The low participation in EAC by primary care counsellors compromises the quality of this important stage in patient management. This result however is mainly due to the high vacancy rate of primary care counsellors with only 9 posts filled at "high volume" sites in a district of 36 health facilities.

The study also revealed that only 60% of the eligible patients were correctly switched to second line ART. Those patients who were not switched to second line ART had no documented reasons for not being put on second line ART. Reasons however, can range from deaths, loss

to follow ups, and movement/relocation of patients (Kroid et al., 2020; Nyakura et al., 2019). Conducting enhanced adherence counselling sessions properly has been proven to promote early switching to second line treatment (Laxmeshwar et al., 2020). Programmatic gaps such as sample transportation and availability of inadequate human resources will need to be addressed to ensure patients are switched early based on viral load monitoring.

5.4 Study Limitations

The period of each enhanced adherence counselling session was not documented in any of the data sources hence it was difficult to assess the quality of enhanced adherence counselling sessions offered to clients. This raises an issue of documentation in HIV/AIDS management. There was poor documentation of some monitoring data in patient registers.

5.5 Generalisability

Generalisability is the extent to which the findings of a study reflect the reality if another different sample is taken (Frey, 2018). Random sampling was used in the study hence findings may be generalized to the study population and other populations with similar contexts.

5.6. Conclusion

In conclusion the national guidelines for Viral load monitoring in PLWHA on ART was not being followed in the health centres studied. The findings of this study identified gaps in following guidelines particularly for enhanced adherence counselling, timeliness viral load monitoring and switching treatment of patients. Resource allocation should prioritize the addressing of the existing gaps to improve HIV management in Mberengwa district.

5.7 Recommendation

The researcher makes the following recommendations for health institutions management, partners and laboratory personnel who play major roles in viral load monitoring.

- Training health facilities on existing viral load monitoring guidelines to address the identified gaps in timeliness, documentation, enhanced adherence counselling and switching of patients.
- Capacitation of district laboratories with adequate equipment to improve turnaround time of results.
- Frequent support and supervision of health institutions providing on-job support to health workers.

5.8 Recommendations for further research

Considering the limitations identified in the findings of the current study, the following are the recommendations for future research.

- Assess the use of viral load monitoring guidelines at a larger scale in Zimbabwe
- Identify client-based factors affecting viral load monitoring programs.

References

Apollo, T., Takarinda, K.C., Phillips, A., Ndhlovu, C., & Cowan, F.M. (2021). Provision of HIV viral load testing services in Zimbabwe: Secondary data analyses using data from health facilities using the electronic Patient Monitoring System. *PLoS ONE,* 16(1). https://doi.org/10.1371/journal.pone.0245720

Atuhaire, P., Matovu, F., Nakalega, R., Kataike, H., Nabwana, M., Lukyamuzi, Z., & Guwattude, D. (2021). Time to first viral load testing among pregnant women living with HIV initiated on option B+ at 5 government clinics in Kampala City, Uganda: A retrospective cohort study. *International Journal of Infectious Diseases,* 104(Suppl 2), 526–531. doi: 10.1016/j.ijid.2021.01.005

Avert (2020). Global HIV and AIDS statistics. Retrieved from https://www.avert.org/global-hiv-and-aids-statistics

Avert. (2020). HIV and AIDS in Zimbabwe. Retrieved from https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/zimbabwe

Awungafac, G., Amin, E.T., Fualefac, A., Takah, N. F., Agyingi, L.A., Nwobegahay, J., & Njukeng, P.A. (2018). Viral load testing and the use of test results for clinical decision making for HIV treatment in Cameroon: An insight into the clinic-laboratory interface. *PLoS ONE*, 13(6), 3–7. https://doi.org/10.1371/journal.pone.0198686

Bangsberg, D.R., Hecht, F.M., Charlebois, E.D., Zolopa, A.R., Holodniy, M., Sheiner L., & Moss, A. (2000). Adherence to protease inhibitors, HIV-1 viral load, and development of drug resistance in an indigent population. *AIDS*, 14(4), 357–366. https://doi.org/10.1097/00002030-200003100-00008

Birungi, Z.C., Okoboi, S., Kapaata, A., Munderi, P., Mukajjanga, C., Nanfuka, M., … Moore, D.M. (2020). Lack of effectiveness of adherence counselling in reversing virological failure among patients on long-term antiretroviral therapy in rural Uganda. *HIV Medicine*, 21(1), 21-29. https://doi.org/10.1111/hiv.12790

Bonner K., Mezochow A., Roberts T., Ford N., & Cohn J. (2013). Viral load monitoring as a tool to reinforce adherence: A systematic review. *Journal of Acquired Immune Deficiency Syndromes*, 64(1), 74–78. https://doi.org/10.1097/QAI.0b013e31829f05ac.

Bvochora, T., Satyanarayana, S., Takarinda, K.C., Bara, H., Chonzi, P., Komtenza, B., … Apollo, T. (2019). Enhanced adherence counselling and viral load suppression in HIV seropositive patients with an initial high viral load in Harare, Zimbabwe: Operational issues. *PLoS ONE*, 14(2), https://doi.org/10.1371/journal.pone.0211326

Calmy, A., Ford, N., Hirschel, B., Reynolds, S.J., Lynen, L., Goemaere, E., & Rodriguez, W. (2007). HIV Viral Load Monitoring in Resource-Limited Regions: Optional or Necessary? *Clinical Infectious Diseases*, 44(1), 128–134. https://doi.org/10.1086/510073

Considine, J., Botti, M., & Thomas, S. (2005). Design, format, validity and reliability of multiple choice questions for use in nursing research and education. *Collegian, 12*(1), 19 - 24.

Drost, E., A. (2011). Validity and reliability in social science research. *Education Research and Perspectives*, *38* (1), 105-124.

Ehrenkranz, P. D., Baptiste, S. L., Bygrave H., Ellman, T., Doi, N., Grimsrud, A., Holmes, C.B. (2019). The missed potential of CD4 and viral load testing to improve clinical outcomes for people living with HIV in lower-resource settings. *PLoS Medicine*, 16(5), 1–8. https://doi.org/10.1371/journal.pmed.1002820

Ellman, T.M., Alemayehu, B., Abrams, E.J., Arpadi, S., Howard, A.A., & El-Sadr, W.M. (2017). Selecting a viral load threshold for routine monitoring in resource-limited settings: optimizing individual health and population impact. *Journal of the International AIDS Society*, 20(Suppl 7), e25007. doi: 10.1002/jia2.25007

Estill, J., Aubriere, C., Egger, M., Johnson, L., Wood, R., Garone, D., … Keiser, O. (2012). Viral load monitoring of antiretroviral therapy, cohort viral load and HIV transmission in Southern Africa: A mathematical modelling analysis. *AIDS*, 26(11), 1403–1413. doi:10.1097/QAD.0b013e3283536988

Etoori, D., Ciglenecki, I., Ndlangamandla, M., Edwards, C.G., Jobanputra, K., Pasipamire, M., Kerschberger, B. (2018). Successes and challenges in optimizing the viral load cascade to improve antiretroviral therapy adherence and rationalize second-line switches in Swaziland. *Journal of the International AIDS Society*, 21(10), 1–8. https://doi.org/10.1002/jia2.25194

Frey, B. (2018). *The SAGE encyclopedia of educational research, measurement, and evaluation* (Vols. 1-4). Thousand Oaks,, CA: SAGE Publications, Inc. doi: 10.4135/9781506326139

Global Fund. (2020, March). *Audit Report GF-OIG-20-008. Global Fund Grants in Zimbabwe* Retrieved from https://www.theglobalfund.org/media/9476/oig_gf-oig-20-008_report_en.pdf?u=637208345520000000

Haas, A.D., Radin, A., Hakim, A.J., Jahn, A., M Philip, N.M., Jonnalagadda, S., Justman, J.E. (2020) Prevalence of non-suppressed viral load and associated factors among HIV-positive adults receiving Antiretroviral therapy in Eswatini, Lesotho, Malawi, Zambia and Zimbabwe (2015 to 2017): Results from population-based nationally representative surveys. *Journal of the international AIDS Society,* 23(11), e25631. doi: 10.1002/jia2.25631

Jamieson, D., & Kellerman, S. E. (2016). The 90 90 90 strategy to end the HIV pandemic by 2030: Can the supply chain handle it? *Journal of the International AIDS Society,* 19(1), 1–4. https://doi.org/10.7448/IAS.19.1.20917

Kroid, A., Burger, T., Urio, A., Mugeniwalwo, R., Mgaya, J., Mlagalila, F., … Maganga L. (2020). High turnaround times and low viral resuppression rates after reinforced adherence counselling following a confirmed virological failure diagnostic algorithm inHIV-infected patients on first-line antiretroviral therapy from Tanzania. *Tropical Medicine and International Health*, 25(5), 579-589. https://doi.org/10.1111/tmi.13373

Laxmeshwar, C., Acharya, S., Das, M., Keskar, P., Pazare, A., Ingole, N., …Isaakidis, P. (2020) Routine viral load monitoring and enhanced adherence counselling at a public ART centre in Mumbai, India. *PLoS ONE*, e0232576. https://doi.org/10.1371/journal.pone.0232576

Mapangisana, T., Machekano, R., Kouamou, V., Maposhere, C., McCarty, K., Mudzana, M., Katzenstein, D. (2021). Viral load care of HIV-1 infected children and adolescents: A longitudinal study in rural Zimbabwe. *PLoS ONE,* 16(1), e0245085. https://doi.org/10.1371/journal.pone.0245085

Mascolini, M. (2013). Second- and Third-Line ART Cost 24% and 41% More Than First Line in US. *53rd Inter-science Conference on Antimicrobial Agents and Chemotherapy,* Denver, Colorado, USA. Retrieved from http://www.natap.org/2013/ICAAC/ICAAC_10.htm

Medecins Sans Frontieres. (2016). Making Viral Load Routine. Successes and Challenges in the Implementation of Routine HIV Viral Load Monitoring. Retrieved from https://www.msf.org/sites/msf.org/files/making_viral_load_routine_part_1_programmatic_strategies.pdf

Mermin, J., Ekwaru, J.P., Were, W., Degerman, R., Bunnell, R., Kaharuza, F., & Moore, D.M. (2011). Utility of routine viral load, CD4 cell count, and clinical monitoring among adults with HIV receiving antiretroviral therapy in Uganda: Randomised trial. *British Medical Journal*, 343(7834), 1134. https://doi.org/10.1136/bmj.d6792

Midlands Province 2020 HIV estimates report. (2021).

Ministry of Health and Child Care, Zimbabwe. (2016). *Guideline for Antiretroviral Therapy for Prevention and Treatment of HIV in Zimbabwe*. Harare, Zimbabwe: MoHCC

Ministry of Health and Child Care, Zimbabwe. (2017). *Operational and Service Delivery Manual for the Prevention, Care and Treatment of HIV in Zimbabwe*. Harare, Zimbabwe: MoHCC.

Mungwira, R.G., Divala, T.H., Nyirenda, O.M., Kanjala, M., Muwalo, F.,Mkandawire, F., … Laurens, M.B. A targeted approach for routine viral load monitoring in Malawian adults on antiretroviral therapy. Tropical medicine and International Health, 23(5), 526-532. doi: 10.1111/tmi.13047

Nichols, B.E., Girdwood, S.J., & Shibemba, A. (2019). Cost and impact of dried blood spot versus plasma separation card for scale-up of viral load testing in resource-limited settings. Clinical Infection Disease, 70(6), 1014-1020. doi: 10.1093/cid/ciz338

Nyakura, J., Shewade, H.D., Ade, S., Mushavi, A., Mukungunugwa, S.H., Chimwaza, A., … Mugurungi, O. (2019). Viral load testing among women on 'option B+' in Mazowe, Zimbabwe: How well are we doing? *PLoSONE*, 14(12), e0225476. https://doi.org/10.1371/journal.pone.0225476

Okoboi, S., Ekwaru, P. J., Campbell. J. D., Egessa, A., King R., Bakanda, C., & Moore, D.M. (2016). No differences in clinical outcomes with the addition of viral load testing to CD4 cell count monitoring among HIV infected participants receiving ART in rural Uganda: Long-term results from the Home-Based AIDS Care Project Global health. *BMC Public Health*, 16(1), 1–8. https://doi.org/10.1186/s12889-016-2781-y

Phillips, A., Vojnov, L., Cohn, J., Roberts, T., Ellman, T., Bonner, K., & Vitoria, M. (2016). Sustainable HIV Treatment in Africa through Viral Load-Informed Differentiated Care. *Nature*, 528(7580), S68–S76. https://doi.org/10.1038/nature16046.Sustainable

Pollack, T.M., Duong, H.T., Truong, P.T., Pham, T.T., Do, C.D., & Colby, D. (2018). Sensitivity and specificity of two dried blood spot methods for HIV-1 viral load monitoring among patients in Hanoi, Vietnam. *PLoS ONE*, 13(1), 1–10. https://doi.org/10.1371/journal.pone.0191411

Roberts, T., Cohn, J., & Bonner, K. (2016) Scale-Up of routine viral load testing in resource-poor settings: current and future implementation challenges. Clinical Infectious Disease, 62(8), 1043–1048. https://doi.org/10.1093/cid/ciw001

Rowley, C.F. (2014). Developments in CD4 and viral load monitoring in resource-limited settings. *Clinical Infectious Diseases*, 58(3), 407–412. https://doi.org/10.1093/cid/cit733

Setia. M.S., (2016). Methodology Series Module 3: Cross-sectional. *Indian Journal of Dermatology*, 61(3): 261–264. doi: 10.4103/0019-5154.182410.

Sevelius, J.M., Saberi, P., & Johnson, M.O. (2014). Correlates of antiretroviral adherence and viral load among transgender women living with HIV. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, 26(8), 976–982. https://doi.org/10.1080/09540121.2014.896451

Shoko, C., & Chikobvu, D. (2019). A superiority of viral load over CD4 cell count when predicting mortality in HIV patients on therapy. BMC Infectious Diseases, 19(1), 1–10. https://doi.org/10.1186/s12879-019-3781-1

Sigaloff, K.C.E., Hamers, R.L., Wallis, C.L., Kityo, C., Siwale, M., Ive, P., … de Wit, T.F. (2011). Unnecessary antiretroviral treatment switches and accumulation of HIV resistance mutations: two arguments for viral load monitoring in Africa. *Journal of Acquired Immune Deficiency Syndrome*, 58(1):23–31. doi: 10.1097/QAI.0b013e318227fc34.

Süt, N. (2014). Study designs in medicine. *Balkan Medical Journal*, 31(4), 273-277. doi:10.5152/balkanmedj.2014.1408

Thinn, K.K., Thekkur, P., Kyaw NTT., Aye, N.S., Zaw, T.M., Soan, P., … Oo, H.N. (2019). Uptake of routine viral load testing among people living with HIV and its implementation

challenges in Yangon region of Myanmar: a mixed-methods study. *BMJ Open*, 9(12), e032678. doi:10.1136/bmjopen-2019-032678

UNAIDS. (2016). *The need for routine viral load testing*. Retrieved from https://www.unaids.org/sites/default/files/media_asset/JC2845_en.pdf

UNAIDS. (2018). *Public health and HIV viral load suppression. Undetectable = Untransmittable*. Retrieved from https://www.unaids.org/sites/default/files/media_asset/undetectable-untransmittable_en.pdf

UNAIDS. (2019). Global HIV and AIDS statistics Fact sheet. Retrieved from https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

UNAIDS. (2020). Country fact sheet, Zimbabwe. Retrieved from https://www.unaids.org/en/regionscountries/countries/zimbabwe

Usitalo, A., Leister E., Tassiopoulos, K., Allison, S., Malee, K., Paul, M.E., … Mellins, C.A. (2014). Relationship between viral load and self-report measures of medication adherence among youth with perinatal HIV infection. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, 26(1), 107–115. https://doi.org/10.1080/09540121.2013.802280

World Health Organization. (2016). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach (2nd edition). Geneva, Switzerland: WHO

World Health Organization. (2016) . Progress report 2016: prevent HIV, test and treat all: WHO support for country impact. World Health Organization. Retrieved from https://apps.who.int/iris/handle/10665/251713

World Health Organization. (2019). *Diagnostic Laboratory frequently asked questions*. Retrieved from https://www.who.int/diagnostics_laboratory/faq/viral_load/en/

Zimbabwe National Aids Council. (2018). Global AIDS Monitoring Zimbabwe country report. Fast-track commitments to end aids by 2030. Retrieved from https://www.unaids.org/sites/default/files/country/documents/ZWE_2018_countryreport.pdf

Zimbabwe National Aids Council. (2020). *Global AIDS Monitoring Zimbabwe country report. Fast-track commitments to end aids by 2030*. Retrieved from https://www.unaids.org/sites/default/files/country/documents/ZWE_2020_countryreport.pdf

Zimstat. (2020). Midlands Province district population projections report.

Zimbabwe Vulnerability Assessment Committee (ZimVAC). (2021). Rural Livelihoods Assessment Report Midlands Province

Appendixes

Appendix A: Biomedical Science Research Ethics Committee approval letter

UNIVERSITY of the WESTERN CAPE

60 YEARS of hope, action & knowledge

20 March 2020

Dr G Ndagurwa
School of Public Health
Faculty of Community and Health Sciences

Ethics Reference Number: BM20/1/11

Project Title: Assessment of the use of viral load monitoring on people living with HIV/AIDS taking antiretroviral therapy by nurses working at rural health centers in Mberengwa District, Zimbabwe.

Approval Period: 19 March 2020 – 19 March 2023

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report by 30 November for the duration of the project.

Permission to conduct the study must be submitted to BMREC for record-keeping.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

Director: Research Development
University of the Western Cape
Private Bag X 17
Bellville 7535
Republic of South Africa
Tel: +27 21 959 4111
Email: research-ethics@uwc.ac.za

NHREC Registration Number: BMREC-130416-050

FROM HOPE TO ACTION THROUGH KNOWLEDGE.

Appendix B: Permission to conduct study from the Provincial Medical Director.

Dr Gabriel Ndagurwa
Number 2187
Eastlea Extension
Zvishavane

+263772895341 3814995@myuwc.ac.za / geendagurwa@gmail.com

19/06/2020

Dear Sir

PERMISSION TO CONDUCT STUDY AT RURAL HEALTH CENTRES IN MBERENGWA DISTRICT, MIDLANDS, ZIMBABWE GRANTED

The above refers.

RESEARCH TITLE: Assessment of the use of Viral Load monitoring on People Living with HIV/AIDS taking Antiretroviral Therapy by nurses working at rural health centers in Mberengwa District, Zimbabwe.

I, Dr Reginald Mhene, the Provincial Medical Director, Midlands Province I have no objection in the request to conduct the above stated study. The permission has been granted. Upon completion of the study, we will request you provide a copy of any research outputs to the Mberengwa District Health Executive and the Ministry of Health and Child Care-Midlands Province.

PROVINCIAL MEDICAL DIRECTOR
P.M.D. MIDLANDS
19 JUN 2020
P.O. BOX 206, GWERU
ZIMBABWE

Thank you

Dr Reginald Mhene (MBChB (UZ), MPH(UZ.)
The Acting Provincial Medical Director - Midlands Province
Ministry of Health and Child Care
P. O. Box 206
Gweru

Appendix C: Data collection tool (data extraction form)

DATA COLLECTION TOOL

TITLE OF THE STUDY: Assessment of the use of Viral Load monitoring on People Living with HIV/AIDS taking Antiretroviral Therapy by nurses working at rural health centers in Mberengwa District, Zimbabwe.

Demographics

Study number					
Age (years)	<20	20-29	30-39	40-49	>50
Sex	Male		Female		
Occupation	Artisanal miner	Cross-boarder trader	Formally employed	Unemployed	Vendor
Marital Status	Single	Married	Divorced	Widowed	Other.

1. **Initial patient management**

Date screened HIV positive		
Date of ART initiation/regimen		
Duration between positive test and initiation on ART		
Date of 1st viral load sample collection		
Duration between ART initiation and VL sample		

Duration between 1st VL sample collection and results.	
Date of 2nd VL sample collection.	
Duration between 1st and 2nd sample collection	
Duration between 1st result and 2nd sample Collection	

1. **Enhanced Adherence Counselling** (fill in only if 1st VL>1000copies/ml)

	Date done	**Qualification of the Counsellor**	**Duration of session**
1st session			
2nd session			
3rd session			

2. **Switching ART**

Results of 2nd VL test/date	**<1000**	**>1000**	
If VL > 1000copies/ml was the patient switched to 2nd line ART.	**Yes**		**No**
If No state the reason documented in the green book			

3. **Continuing patient monitoring**

Date of 3rd VL sample collection		
Date of 3rd VL result		
Date of 4th VL sample collection		
Date of 4th VL result		