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CHARACTERISATION OF TREATMENT INTERRUPTIONS AT MPILO HIV CENTRE OF EXCELLENCE, BULAWAYO PROVINCE, ZIMBABWE, 2020-2021

BY

NTOMBIYAKOGASA SITHOLE

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Abstract

Non-adherence to Antiretroviral Therapy treatment is a growing concern in ART programs and is causing significant adverse outcomes amongst People Living with HIV (PLHIV). Whilst significant strides have been made in terms of HIV epidemic control with the introduction, roll-out and scaling up of ART in the public sector and more recently emphasis on retention in care, non-adherence, including missed doses, missed appointments and treatment interruption are posing a significant threat to the success of ART programs. Treatment interruptions amongst the cohort of PLHIV in care at Mpilo Centre of Excellence (CoE) has not been investigated, and as such, not much is known about the characteristics and factors associated with treatment interruption within this group. This study sought to understand the demographic and clinical characteristics of treatment interrupters, the timing, frequency and duration of treatment interruption spells as well as determine the themes associated with treatment interruption amongst the cohort of Recipients of Care (ROC) at Mpilo CoE. A case study research design using mixed methods research approach was conducted on ROC at Mpilo CoE using data from electronic medical records and interviews with research participants using a modified Adherence Barriers Questionnaire. Adults aged between 20 and 49 are most liable to treatment interruption with this age group making up 64.0% of treatment interrupters. 40% of patients interrupting treatment at Mpilo Centre of Excellence initiated ART after 2015, with 22.1% initiating between 2011 and 2015 and 28.4% initiating between 2006 and 2010. There is a correlation between frequency of treatment interruption and duration of treatment interruption with a p-value of 0.010 and correlation coefficient of -0.152. The two most significant of the responses to reasons for treatment interruption were psychological reasons (27.5%) and geographical reasons (17.4%). Sociological reasons and financial/economic/political reasons accounted for 14.7% and 11.9% of respectively. Chi-square test was conducted the 9 themes and 24 subthemes linked to treatment interruption using Likelihood Ratio's. Two sub-themes under Technological themes are significantly associated with treatment interruption; poorly documented treatment records with moderate association (Cramer's V = 0.228) and usefulness of SMS reminders with a relatively strong association (V = 0.454). High number of clinic visits has moderate association with treatment interruption (V = 0.264) and is the only sub-theme under Technical and Service Provision linked theme with a significant association with treatment interruption. The results of the study will assist Mpilo COE managers and other policy makers to restructure patient care so as to offer a holistic approach to HIV management thereby improving client retention .In conclusion treatment interruption characteristics vary across different demographic groups, which indicates that for these different demographic groups, factors and themes associated have varying influence, and as such, interventions and strategies to counter treatment interruption should be tailor made for each sub group in order to be effective.

Keywords Treatment interrupters, Antiretroviral therapy, People living with HIV,CD4 count

Declaration Page

I declare that this dissertation is my original work except where sources have been cited and acknowledged. The work has never been submitted, nor will it ever be submitted to another university for the award of a degree.

Ntombiyakogasa Sithole

Student's Full Name | Student's Signature (23/11/21)

Dr E. Mugomeri

Main Supervisor's Full Name | Main supervisor's Signature

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Dedication

This study is dedicated to the almighty God who has taken this far and to my beloved husband, Mr. Thabani Ncube whose prayers, unconditional love and encouragement, contributed to my success.

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List of Acronyms and Abbreviations

AHD	Advanced HIV Disease
AIDS	Acquired Immune Disease Syndrome
ART	Antiretroviral Therapy
ATI	Analytic Treatment Interruption
AUREC	Africa University Research Ethics Committee
CD4	Cluster of Differentiation 4
CDCP	Centers for Disease Control and Prevention
EAC	Enhanced Adherence Counselling
EPMS	Electronic Patient Monitoring System
EPOC	Enterprise Point of Care
HIV	Human Immune Virus
HIV-DR	HIV drug resistance
NAC	National Aids Council
OIC	Opportunistic Infection Centre.
OIC	Opportunistic Infection Clinic
PC	Pill Count
PLHIV	People living with HIV
PTC	Post-Treatment Control

PWUD	People Who Use Drugs
SADC	Southern Africa Development Committee
SPSS	Statistical Package for Social Sciences
STI	Sexual Transmitted Infection
TB	Tuberculosis
USA	United States of America
VL	Viral Load
WHO	World Health Organisation
ZIMSTAT	Zimbabwe National Statistics Agency
ZMOHCC	Zimbabwe Ministry of Health and Child Care

Definition of Key Terms

Good adherence was defined as adherence necessary to achieve full and durable viral suppression, thus taking (= or > 95%) of the pills. Non adherence was defined as taking < 95% of the pills (Muyingo et al., 2008).

Teklu and Yirdaw (2017) and Federal Ministry of Health (2010).

Treatment Retention was defined as active antiretroviral treatment therapy at the treatment- initiating health facility.

Treatment interruption was defined as having terminated HAART treatment for more than 3 months. This could be due to being lost from care at treatment initiating health facility, decision to stop treatment, or death.

Loss to follow up was defined as failure to present medication refill at the treatment-initiating health facility, with inability to be traced back by phone or home visit for more than 3 months, without a documented reason for failing to present (e.g. no confirmed death nor decision to stop treatment in agreement with health care worker).

Death was defined as a known client death from any cause, confirmed by health care worker or post-loss tracking.

Transfer Out/In: when a patient is referred/received from the facility where they started ART to another health facility.

Health Care Worker Managed Stop was defined as discontinuation of HAART in agreement with health care worker at treatment-initiating health facility.

Restart Treatment was defined as resuming treatment at the treatment-initiating health facility after treatment interruption.

Favorable treatment outcome was defined as being active in treatment up to 60 months post-HAART initiation, at a treatment- initiating health facility.

Unfavorable treatment outcome was defined as being classified as lost, dead, or stopped from treatment following agreement with treating health care worker, at the last contact visit prior to 60 months post-HAART initiation at treatment-initiating health facility.

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CHAPTER 1 INTRODUCTION

1.1 Introduction

Zimbabwe is one of the countries badly affected by the HIV/AIDS epidemic, with an HIV prevalence of 12.9% amongst the 15–49-year age group (ZIMPHIA, 2020). Though the establishment of the introduction of antiretroviral therapy (ART) in 1995, greatly decreased HIV–associated mortality and morbidity in industrialized countries, it is difficult for PLHIV to take their medications as per expectation of medical personnel. (Lima, Hogg, Levy, Harrigan, Anema & Montane, 2007). Thus, despite the increase of PLHIV receiving ART, there is a growing concern in most ART programs of patient retention in care, which is critical for the programs' success (Gross et al, 2006). This has prompted, researchers to research on interruptions of antiretroviral therapy (ART) due to the fact that non-adherence to treatment is still an issue, and causing adverse HIV outcomes (AIDS Info Net, 2014).

Mpilo HIV Centre of excellence provides HIV health services to approximately more than 10 000 people living with HIV and numerous cases of treatment interruptions and missed appointments have been occurring. Data from the patient electronic patient monitoring system at the institution showed that for the period starting April 2021 to June 2021, the clinic was managing 68 HIV patients returning to ART treatment care after a gap in care and in the month of October 2021 more than 500 patients missed their appointments for various reasons (EPOC Mpilo OIC).

With respect to the approach chosen to solve the research problem, the researcher will use a case study, mixed research which constitutes both quantitative and qualitative research approaches. The case study will involve analyzing research units within their natural environment: by using a quantitative approach to collect official

HIV documents and or databases at Mpilo Hospital mainly to characterize the HIV treatment interruption spells so that statistical data and relationships of variables can be found; and also by using a quantitative approach to conduct face to face or online interviews with research participants to get in-depth understanding of the reasons leading to HIV treatment interruption and return to care made by patients who are receiving care.

The researcher will also include a control group consisting of HIV patients who are continuously retained in care to determine the challenges that may face and the actions they take which have successfully led to them not to interrupt their HIV care treatment. This study seeks to bring out an understanding of real world evidence of issues affecting people living with HIV and also bring about strategic interventions aimed at improving HIV treatment adherence thereby attaining Global Health Outcomes. It will focus on characterizing HIV treatment interruptions at Mpilo Centre of Excellence, Bulawayo Province, Zimbabwe 2020-2021.This chapter presents the background, problem statement, research objective, delimitations and assumptions of this research in detail with respect to characterizing HIV treatment interruptions.

1.2 Background of the Study

Zimbabwe still battles with the HIV epidemic, the prevalence was 12.9% in adults, incidence 0.38% and 20000 people died of AIDS related deaths in 2019 (ZIMPHIA ,2020. Nevertheless, the introduction of antiretroviral therapy (ART) in 1995, greatly decreased HIV–associated mortality and morbidity in industrialized countries (Lima et al., 2007). Continuing HIV treatment is a long-term indefinite commitment of which there is supported evidence of a strong relationship between

treatment adherence, effective viral suppression, and improved survival (POZ, 2018; Gross et al., 2006).

However, it is difficult for PLHIV to take their medications as per expectation of medical personnel (POZ, 2018). Thus, despite the increase of PLHIV receiving ART, there is a growing concern in most ART programs of patient retention in care, which is critical for the programs' success (Rosen, Fox, and Gill, 2007). Muyingo, et al., (2008); AIDS Info Net (2014) and POZ (2018) noted that HIV patients interrupt ART treatment for various reasons like: dealing with side effects; treatment fatigue or depression from using the treatment, new illnesses; loss of access to health care services, forgetting medication at home; and extended travel.

Non-adherence to treatment has been associated with the drug regimen changes, personal factors, stigma, side effects, and travel away from home (Byakika-Tusiime, Oyugi, Tumwikirize, Katabira, Mugyenyi &Bangsberg, 2005). Also, according to AIDS Info Net (2014); POZ (2018) treatment interruptions may results in increase in the viral load ,drop in the CD4 counts drop ,clinical deterioration and resistance to treatment making it difficult to manage PLHIV over time Hence, it is recommended that patients living with HIV must not attempt to stop and restart their HIV meds on their own, but should discuss and be guided by their health care provider based on constant monitoring of viral load and CD4 count (AIDS Info Net, 2014; and POZ, 2018).

Mannheimer et al. (2002); and Chesney (2006) highlighted that measurement of adherence to treatment is difficult but at the same time vital to reducing treatment interruption. The only proxy gold standard used is electronic based monitoring of pill bottle opening is used though expensive and intrusive. However, self-report and pill

count (PC) seem to overestimate adherence, though highly associated with viral load suppression (Mannheimer, et al., 2002).

The need for the continuous use of antiretroviral drugs throughout the life course poses a challenge to people living with HIV and their caregivers. This amongst other issues, has prompted, researchers to continuously research on interruptions of antiretroviral therapy (ART) due to the fact that non-adherence to treatment is still an ongoing issue, and causing adverse HIV Treatment outcomes (AIDS Info Net, 2014). This research is worthy undertaking because it will bring out an understanding of real world evidence on the treatment interruptions issues affecting PLHIV and also bring about strategic interventions aimed at reducing HIV treatment interruptions, thereby attaining Global Health Outcomes. HIV programs stakeholders at Mpilo Centre of Excellence may be informed with qualitative and quantitative evidence designed to offer highly accurate knowledge for decision making and policy formulation.

1.3 Problem Statement

HIV programs have been struggling with patients who default treatment, and this has a negative effect on the UNAIDS 95, 95, 95 global targets. The Mpilo HIV Centre of excellence manages approximately 10 000 people living with HIV .It has not been spared and continues to struggle with treatment interrupters. For the period April to June 2021 alone, the clinic had 68 HIV patients returning to care after a gap in care. During the year 2021, in the period July to September a total of 1381 clients missed their appointment dates which could be an early warning sign for treatment interruption. This has a negative bearing on HIV related mortality, morbidity and in the long run can reduce the hard earned reduction in HIV prevalence and incidence. The proposed study has programmatic implications as it will help to characterize

treatment interruptions at the COE and develop strategies to improve patient retention.

1.4 Research Objectives

1.4.1 Broad objective

The broad objective of this study is: To characterize treatment interruptions at Mpilo HIV Centre of excellence, Bulawayo Province, Zimbabwe 2020-2021.

1.4.2 Specific objectives

This research will be guided by the following research specific objectives:

i. To analyse treatment interruption frequencies, durations and associated factors using the electronic patient monitoring system in HIV patients returning to care at Mpilo HIV Centre of Excellence,2020-2021 .
ii. To determine factors leading to treatment interruption at Mpilo HIV Centre of Excellence, 2020-2021.
iii. To determine themes linked to treatment interruptions at Mpilo Centre of Excellence, Bulawayo, 2020-2021

1.5 Research Questions

This research will be guided by the following research questions:

i. What are the common characteristics of treatment interruption spells in HIV patients returning to HIV care at Mpilo Centre of Excellence, Bulawayo, 2020-2021?
ii. What are the themes linked to treatment interruptions at Mpilo Centre of Excellence, Bulawayo, 2020-2021?

1.6 Research Hypothesis

The researcher will use the following hypothesis to test the effects of HIV Treatment Interruptions on HIV treatment outcomes:

Ho: HIV Treatment Interruptions do not negatively, strongly and significantly affect HIV treatment outcomes.

H1: HIV Treatment Interruptions negatively, strongly and significantly affect HIV treatment outcomes.

1.7 Justification

This research will generate characteristics of treatment interrupters and reasons of HIV treatment interruptions. It will provide evidence on the factors leading to treatment interruptions, there by assist HIV Treatment Program Policymakers to identify gaps and resources needed to avoid and or minimize HIV treatment interruptions. Also, this study is important as it aims at providing community based strategic interventions that will properly and adequately manage HIV Treatment Programs and improve HIV Treatment Outcomes. Thus, in the long run, this will improve the consistent uptake of public health programs for people living with HIV.

1.8 Significance of the Study

The researcher notes that the significance of this research is centred upon establishing valuable information pertaining to HIV treatment interruptions and how this may be eliminated in order for the country as a whole to achieve their HIV outcome that are linked with HIV treatment issues. Thus, the researcher looked into the following significances of the research with may accrue to various stakeholders:

i. **The Researcher:** This research is significant to the researcher as it is a requirement for the partial fulfilment of the requirements for the Degree Of Master Of Public Health In The College Of Health, Agriculture And Natural Sciences at Africa University. This research will afford the researcher to acquire research skills, analytical skills and a critical thinking skills required to effectively and efficiently manage HIV program at Clinic or Hospital level and also provide scientific or academic proof needed to inform educated decision making.

ii. **People Living with HIV:** This study may be useful in bringing out real world factors that affecting people living with HIV and also reducing or avoiding HIV treatment interruption, thereby improving the health of people living with HIV.

iii. **Employees and Management of HIV Programs:** By conducting this research it is hoped that employees and Management of HIV Programs are empowered with knowledge help identify, predict and stop HIV treatment interruptions by people living with HIV, before it affects their HIV Program outcomes. This research is also significant because it is intended to provide communities based strategic interventions to improve uptake of HIV Treatment, as HIV Programs are run on community basis.

iv. **HIV Treatment Programs Investors and Donors:** This research is significant as it is hoped that it will inform HIV Treatment Programs Investors and Donors on the areas that require funding, man power and other resources so that the risk of HIV Treatment Interruptions may be eliminated. Also it is hoped that the findings of this research will result in new and

effective community based methods of distributing and monitoring HIV Treatment.

v. **The Government and HIV Policy Makers:** It is hoped that this research will offer important empirical evidence that may be used to inform the Zimbabwean government and HIV Treatment Programs Policy Makers on the best policies, methods and procedure that may be used to effectively distribute, monitor and encourage people living with HIV not to Interrupt their HIV Treatment.

1.9 Delimitation of the Study

Research delimitations by definition focus on the pre-selected scenarios made by a researcher in order to create a boundary which restricts the researcher from addressing non-relevant issues with respect to research topic and the situational problem at hand, there by conducting a workable and manageable research. Hence, with respect to delimitations of this research the researcher will consider:

i. The scope of the research will be delimited to HIV treatment interruptions.

ii. The geographical boundary of the research will be delimited to a Large Tertiary HIV Clinic in Bulawayo.

iii. The timeframe of the research will be delimited from 2020 to 2021.

iv. The population or research participants will be delimited to health employee who work Large Tertiary HIV Clinic in Bulawayo and people living with HIV.

v. The methodology of the research will be delimited to a mixed research approach that caters for both quantitative and qualitative data or research approaches.

1.10 Limitation of the Study

The researcher noted the following limitations of the research

i. The Researcher noted that some potential participants with valuable information may be unwilling to participate due to the fact that no financial rewards are offered for the information that they will offer with regards to Characterizing treatment interruptions at Mpilo Centre of Excellence, Bulawayo hence, the researcher will motivate the research participants by indicating how the results of the study will impact treatment and HIV treatment Outcomes at Mpilo Centre of Excellence, Bulawayo.

ii. The Researcher foresees that this research may be limited by respondents who may provide biased answers which project a wrong image of the program so as to avoid victimisation by custodians of HIV treatment programs. To mitigate this limitation, the Researcher will give assurance the anonymity, privacy and confidentiality of the research participants so that no research instrument can be traced to any participant. This limitation may also be mitigated by designing easy to follow and understanding research instrument that are aimed to bring out the truth about Characterising Treatment Interruptions at Mpilo Centre of Excellence, Bulawayo, Zimbabwe.

iii. The researcher also noted that time and financial constraints pose as limitations to the researcher to effectively explore the topic on advertising on consumer behaviour, due to the academic and work pressure currently and simultaneously undertaken by the researcher. Thus, to mitigate these limitations the researcher will try by all means to stick to the time schedule

as planned also the researcher will use cost effective strategies that will lessen financial pressure of conducting academic research.

iv. The researcher also noted that due to the limited or non-previous researches done on The Characterization of Treatment Interruptions at Mpilo Centre of Excellence, Bulawayo, Zimbabwe, the researcher may find it difficult to produce relevant and dedicated local literature review.

CHAPTER 2 REVIEW OF RELATED LITERATURE

2.1 Introduction

The Literature Review of this research showcases an assessment of previous academic work, like peer reviewed journals, academic textbooks and research papers with regards to characterizing and generating themes linked to treatment interruption spells experienced and perceived by PLHIV who are on ART. Also, this chapter seeks to review the research gap exposed by the reviewed literature thereby informing the methodological direction and research instruments design which are in line with treatment interruptions.

2.2 Theoretical Framework

The researcher used the therapeutic citizenship to lay out the theoretical framework of this research. The therapeutic citizenship theory offers valuable framework for characterizing treatment interruption at the Mpilo Centre of Excellence in Bulawayo. This theory was established through the works of Nguyen and colleagues (Nguyen, 2005) in West Africa, which documents the socio-cultural and historical context of ART access and adherence in Africa. Nguyen, Ako, Niamba, Sylla, and Tiendrebeogo (2007) define therapeutic citizenship in terms of the identities and associated practices that ART patients need to adopt in order to gain access to the very limited supply of HIV services available to them.

Nguyen (2005) defines therapeutic citizenship as “a bio-political citizenship, a system of claims and ethical projects that arise out of the conjugation of techniques used to govern populations and manage individual bodies”, which may not always fit well with the local identities of those who at the receiving ends of biomedical treatment regimes. Nguyen argues for an understanding of HIV service provision that

views even local settings as the culmination of a hybrid of discourses and practices of bio medics, policy makers and service providers world-wide (Skovdal, Campbell, Madanhire, Mupambireyi, Nyamukapa, and Gregson, 2011).

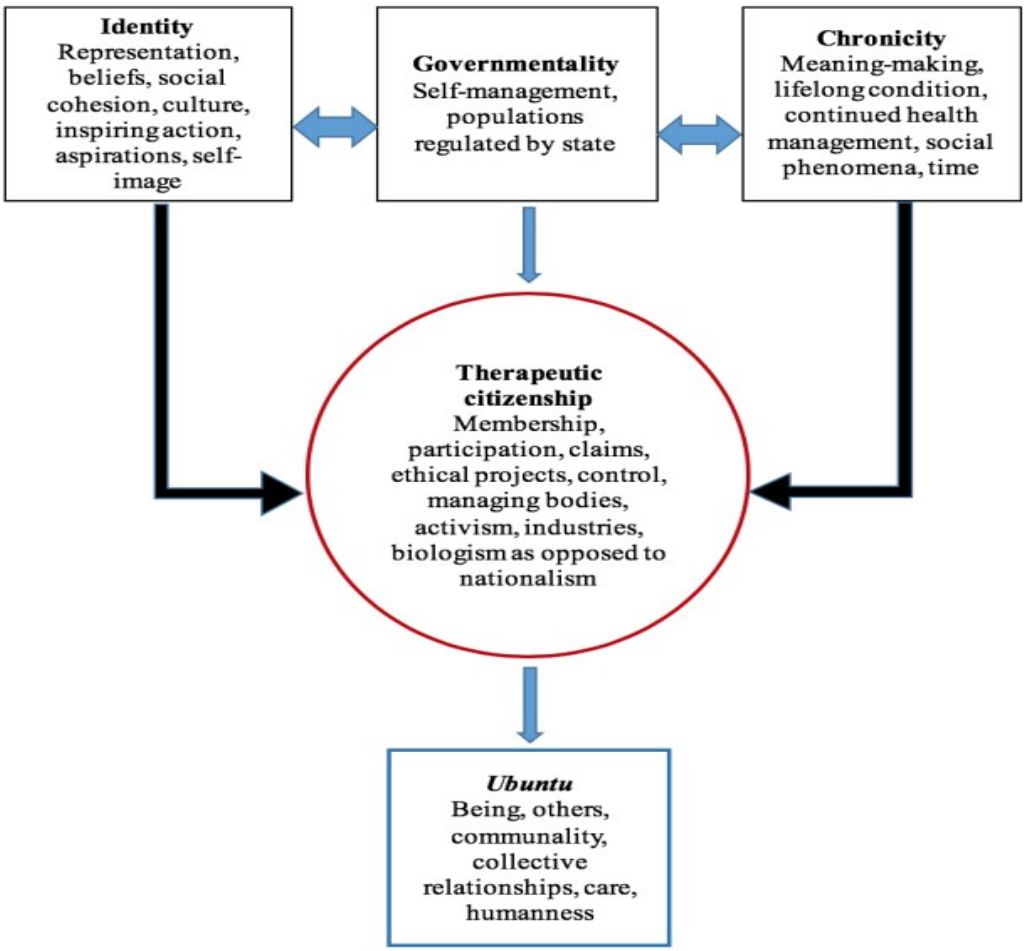

Figure 1: Theoretical framework

2.3 Relevance of the Theoretical Framework to the study

Despite pessimistic predictions that levels of adherence to anti-retroviral therapy (ART) by HIV-infected Africans would be low, PLHIV in many African countries achieved higher levels of treatment adherence than in North America. This has raised questions with regards to how such high levels of adherence been reached in contexts

of poverty, social disruption, under-resourced services and poor infrastructure faced by PLHIV especially in Zimbabwe (Campbell et al., 2012).

Hence, the therapeutic citizenship theoretical framework will assist the researcher to move beyond a narrow focus on locally restricted cultural contexts of treatment, widening our lens to take account of global assemblages of organizations, norms and practices which constitute the global public health framework within which ART treatment interruption is conceptualized, accounted for and specifically linked with HIV services in the local and global settings.

The biomedical clinic, in theory, offers an integrated care package involving a suite of monitoring technologies operated by a full complement of specially trained healthcare employee consultants and specialists. However, the responses of participants in numerous studies have illustrated that this ideal set up of biomedical clinic is more aspirational than reality (Apollo, Takarinda, Mugurungi, Chakanyuka, Simbini & Harris, 2010). Thus, the therapeutic citizenship theoretical framework adopted by this research will assist the researcher bring about the reality faced by PLHIV and how it is influencing treatment Interruptions.

2.4 Characteristics of HIV care treatment interruption spells

In order for health care givers to fully understand treatment interruption, first the interruption spells need to be characterized. Thus, this section of the research the researcher will look at the duration, frequency and associated factors of the treatment interruption spells.

2.4.1 Demographic characteristics of treatment interrupters

Age has been shown to be an important contributing factor to treatment interruption .A study showed that patients under the age of 40 were more likely to

interrupt treatment compared to older patients .This study showed that young adults and adolescents were more likely to suffer from treatment failure due to social and psychological barriers (Dorcelus, Bernard, Georgery &Vanessa, 2021). Another study also showed that adherence improved with age, however the study showed that after the age of 75years adherence declined due to other underlying comorbidities thereby increasing the risk of treatment interruption (Mehta, Moore &Graham, 1997).

Mehta ,Moore and Graham also noted that males were likely to interrupt treatment compared to females .This is supported by a multisite study conducted in Western Africa which showed that males had a 14% higher rate of treatment interruption compared to females (Ochieng-Ooko, Ochieng, Sidle, Holdsworth &Wools-Kalaustian,2010) .Poor socioeconomic status coupled with low income and low level of education has been shown to be contributing factors to treatment interruption (Mehta, Moore & Graham ,1997). This study is supported by another study which showed a very strong link between employment, higher level of education and income with good retention on treatment (Dorcelus, Bernard, Georgery &Vanessa, 2021). Unemployed or low-income levels also contribute to treatment interruption (Ndubuka, Van der Wal & Ehlers, 2016).

2.4.2 Timing, Duration and frequency of Treatment Interruption.

According to Mutasa-Apollo et al. (2014), Zimbabwean data between 2007 and 2009 revealed that patient retention on ART initiations decreased with longer duration on ART, from 91% at 6 months to 64% at 36 months, and that this reduction in retention was mainly associated with accessing health care from higher level health care facilities compared to primary care facilities. This pattern of ‘in and out’ of the clinic

can be observed in the adherence rate whereby 15% of new ART patients stopped taking their drugs within 12 months (GoZ 2012). Whereas, Jewell, Smith, and Hallett (2020) noted that 40% of those on ART are forced to temporarily discontinue ART.

PLHIV with interrupting treatment were more likely to have previous interruptions in ART (aOR 8.3, 95% CI 5.6 to 12.3). Teklu1 and Yirdaw, (2017) showcased that 39% (8,759/22,647) of clients interrupted treatment for more than 1 month at least at one point during follow-up. Of these, only 35% ever restarted treatment. Among those who did restart, median time to restarting treatment was 7 months (IQR: 2.2 months–1.7 years). Of those who restarted treatment, 24% (735) discontinued treatment for second time over follow-up. Half, or 50% of the cases who discontinued a second time, had done so within five months of follow-up. Teklu1 and Yirdaw (2017) further showcased that at the end of follow-up, retention was 57% for re-starters within 6 months, and 76% among comparable individuals who had not discontinued by 6 months.

2.4.3 Clinical characteristics of treatment interrupters

Generally low and high CD4 counts have been associated with treatment interruption for various reasons .A cohort analysis study conducted in West Africa showed that retention in care was lower for patients with baseline CD4 count < 50 compared to patients with a CD4 count more than 200 (Zannou et al ,2008).However this study is in contrast with a study conducted in Kenya which showed more than 3 fold risk of non-retention among patients with a CD4 count of more than 200 (Ochieng-Ooko,Ochieng,Sidle,Holdsworth &Wools-Kalaustian,2010) .

Zhang et al in 2010 however noted that patients with lower CD4counts were unlikely to miss their scheduled visits. The contradicting nature of the results of the different

studies could mean that patients with higher CD4 counts could be relocating to other areas whilst the patients could be assumed to have died while they are assumed to have interrupted treatment.

2.4.4 Effects of ARVs Treatment Regimen on treatment interruption.

The National Aids Council (NAC, 2017) report revealed that about 35% of the estimated one million people on ARVs are on second line treatment. While having people living with HIV on second line treatment is proving to be expensive for Zimbabwe, quite a sizeable number are failing this line as well and are being moved to a third line regimen (Sithole et al., 2018). In a study by McNeil et al. (2015) noted that most of the participants in their research experienced the emergence of viral drug resistance as a result of both long treatment duration (i.e., ≥15 years) as well as structured and unplanned treatment interruptions.

This study is supported by a meta-analysis which was conducted on studies between 2005 and 2014. The results of the analysis showed that there was significantly higher retention and adherence in once daily fixed doses compared to more complex regimens (Clay, Nag, Graham, Narayanan, 2015).Complex regimens to treat other comorbidities also act as barriers to adherence to ART hence the need to simplify regimens for these patients (Gimeno-Gracia, Crusells-Canales, JavierArmesto – Gomez, Rabanaque-Hernandez,2015) .Non adherence can be predicted if a patient is experiencing side effects and is on multiple drugs which are co –administered with ARVs (Cantudo-Cuenca, Jimenez-Galan, Almeida-Gonzalez, Morillo-Verdugo, 2014).

2.5 Themes linked to treatment interruptions

As ART reduces or halts disease progression rather than eliminates HIV, thus requiring the body to coexist with the virus a long-term chronic condition on a long-term basis (Nixon *et al*. 2011). In order for ART to be effective numerous screening and monitoring tests which include viral load, TB, kidney and liver tests need to be conducted so as to provide a range of empirical body function data (MoHCC, 2010). Nevertheless, ART carries some physical, emotional and economic cost for the recipients, thus causing some PLHIV to frequently interrupt treatment (Nixon, Hanass-Hancock, Whiteside & Barnett, 2011 thus this section will highlight themes linked with treatment interruptions

2.5.1 Technological Themes

According to Takarinda, Harries, and Mutasa-Apollo (2016) proper documentation of HIV management using VL testing services and VL testing algorithms for predicting treatment interruption are very important, with respect to reducing treatment interruption amongst PLHIV especially under differentiated care approaches. Thus, when talking about treatment interruption, healthcare facility readiness to provide ART services is always important, as, necessary program elements like basic laboratory testing, reagents and equipment upkeep should be available to facilitate ART based program, thereby avoid treatment interruption (Noguera et al., 2003).

The usage of old methods of monitoring and recording patient's information through paper-based means have made difficult to keep track of patients who miss appointments, this has been further worsened by the increased number of people on ART after the implementation of the treat all policy. However, the introduction of an

electronic patient monitoring system (ePMS) for electronic capture of individual patient data has made patient tracking easier (National AIDS Programme, Zimbabwe, 2016).

Takarinda, Harries, and Mutasa-Apollo (2016) further explained that ePMS tracks patients who delay or miss scheduled review visits in real-time, making it better than conventional paper-based registers, thus further investigations are required to run on the impact of ePMS on the ART treatment interruptions. Also, Noguera et al. (2003) pointed out that strikes by laboratory technicians, and failure to maintain frequently breaking down machines, power outages (though power backups generators are present) has been an issue contributed to service interruption to conduct conducive health test which contributes to treatment interruption.

2.5.2 Technical and Service Provision Themes

The Zimbabwe Ministry of Health and Child Care (2013) pointed that in Zimbabwe challenges concerning follow-up and retention in care of PLHIV is unavoidable mainly due to the increased size of ART patient-to-clinician cohorts' ratios ranging from 551:1 to 2665:1. This ratio was further increased in HIV centers adoption of the HIV 'treat all' approach which saw an increased in number of patients on ART .However this approach was adopted when ART was being decentralized to all public health facilities nationwide ,increasing ART services from 150 (9.6%) in 2007 to 1459 (94%) facilities in 2015(Takarinda, Harries, and Mutasa-Apollo 2016).

Decentralization of ART services helped the health sector move from a more centralized service provision of ART programs housed at big facilities like hospitals run by doctors, to a more decentralized system housed at clinics or other small health facilities run/initiated by nurses, thereby reducing treatment interruption as people

living with HIV reside near ART service providers in their communities be it urban or rural, especially where medical doctors are scarce (Takarinda, Harries, and Mutasa-Apollo 2016).

Jewell, Smith, and Hallett (2020) pointed out that extreme pressure on the health system and/or strict interventions and stressed supply chains domestically and internationally combine to interrupt the supply of key medicines, resulting in a fraction of PLHIV on ART being temporarily forced off ART. Takarinda, Harries, and Mutasa-Apollo (2016) further outlined that as the number of PLHIV who are on Treatment increase due to the treat all policy, appropriate or convenient number visits for clinic attendance and medication pickups need to be revised. This is mainly for the purpose of decongesting clinics, lessening travel costs and pressure, whilst maintaining acceptable retention in care especially amongst asymptomatic or adolescents' population who often interrupt treatment.

According to Mutasa-Apollo et al. (2014), a big increase in the number of patients in care at a facility causes difficulties in the active follow-up of patients who miss scheduled review visits, and an increasing numbers of patients lost to follow-up. This is due to limited resources available for ART services, thereby worsening the characteristics and durations on treatment interruption. After noticing these technical challenges WHO (2020) and PEPFAR (2020) recommended that negative impacts of service disruption could be minimised by using long-term beneficial policy changes like the adaptations of multi-month ART prescriptions and or dispensation of medication outside of health facilities based on patient circumstances.

2.5.3 Biological, Virology and Treatment Regimens Themes

Steele and Grauer (2003) noted that HIV care and treatment were complex and drug regimens had to be carefully adhered to, hence requiring consistent and meticulous monitoring. Hence, patients are subjected to consume long-term, techno-scientific model and potentially toxic synthetic drugs which control the HIV virus in accordance with a strict and specific combinations adherence regime (Skovdal, Campbell, Madanhire, Mupambireyi, Nyamukapa & Gregson 2011). But, Vella et al., (2012) noted that now ART regimens have become more potent, less complex and better tolerated, however, poor adherence and treatment interruption still occurs, especially in PLHIV with high CD4 counts and are asymptomatic.

Harrigan et al. (2005) and Jordan et al. (2008) explained that ART induced side effects have been discovered to cause treatment interruptions and imperfect levels of adherence, which are then associated with the development of drug-resistant HIV. This is costlier to treat as they use second and third-line ARV drugs which are highly costly. Wilhelm-Solomon (2016) explained that regimen changes are possible and can be managed successfully, particularly to viral resistance cases to specific regimen, but regimen changes have been known to cause serious side effect for PLHIV who are on treatment, thus rigorous monitoring is required.

Takarinda, Harries, and Mutasa-Apollo (2016) observed that unconfirmed Zimbabwean reports indicated that some patients are experiencing side effects from the current ART regimens, hence there is need to conduct researches to inform appropriate intervention by assesses the drug-induced adverse events on PLHIV affects ART adherence and treatment interruption. Wilhelm-Solomon (2016) noted that missed treatment or poor adherence and management of treatment can lead to the

development of drug resistant strains of HIV thereby contributing to treatment failure. However, (Muyingo et al., 2008), observed that there was a less likelihood of treatment interruptions, drug resistances and adherence failure particularly to PLHIV with a support group, where on 2nd line treatment, additionally who correctly and consistently used of a condom as a protective measure

2.5.4 Psychological Themes

Despite the beneficial impact of optimal adherence to treatment on disease outcomes, ART interruptions remain common among some key populations, particularly people who use drugs (PWUD) as they are at high risk of experiencing ART interruptions, thus understanding psychological factors that influence PWUD is key in successfully attaining ART program Outcomes (Milloy, Montaner and Wood, 2012; Hughes, et al., 2014). However, McNeil et al., (2015) found that ART treatment unpleasantly made some patients constantly feel nauseous, sleepy, having diarrhea, sick, and having a difficult time sleeping. Thus, most patients resorted to heroin and other dangerous drugs to make themselves feel better than the drugs that keep me alive.

Samji, et al., (2015) pointed out that treatment fatigue also known as the potential of decreased desire or willingness to adhere to ART treatment, is another psychological aspect which is faced by PLHIV and it often leads to treatment interruptions, hence, it has to be dealt with constantly to achieve positive and high treatment outcomes. Also, Clinicians need to provide enhanced adherence counselling (EAC) especially to PLHIV with high VL, thereby counteracting any possible suboptimal adherence. Nevertheless, for those who then fail to achieve VL suppression, clinicians can switch to second-line or third-line treatment as necessary (Takarinda, Harries, and Mutasa-Apollo, 2016).

In a study by McNeil et al. (2015), some participants underlined that regimen changes induced stress related to their diagnoses and also stress related to negative experiences with early ART treatments. Thus, some participants admitted that they were tired of ART, leading to them interrupting treatment particularly after change to more complex regiment, so that they avoid remembering and re-experiencing the initial hardships which they encountered when they started with ART. In another psychological theme of treatment interruption, O'brien & Broom (2014) pointed out that some feared experiencing side effect and the emergence of other dangerous diseases after consuming ARV pills each and every day, so they interrupted treatment in order to avoid this fear.

McNeil et al. (2015), also stated that participants expressed that experiences of depression resulting from thinking about the way life's supposed to be, feeling alone and having no family to talk to particularly during holidays or birthdays, reduced motivation to adhere to ART regimens and led to the intensification of drug use patterns, which fuelled ART interruptions.

2.5.5 Sociological Themes

According to McNeil et al. (2015), social isolation stemming from structural vulnerability undermined participants' motivation to adhere to ART regimens. Most participants reported few opportunities or limited sources of social support, with many reporting that the stigma associated with drug use, everyday violence, exploitive relationships, and their subsequent feelings of shame had led to estrangement from family and friends. These findings were similar to Jobanputra et al., (2014) who highlighted that past studies have showcased difficulties with drug

adherence among adolescents, include alcohol and substance use, lack of caregiver support, fear of disclosure, fear of stigma and discrimination.

Treatment supports like directly-observed/maximally-assisted therapy, case management were implemented to increase access and adherence to ART, this enabled many participants to maintain optimal ART adherence despite their structural vulnerability. Nevertheless, McNeil et al., (2015) noted that some participants admitted that they tried to keep communicating with their regular nurses who provided them ART care, but it didn't work out, as there were so many starts and stops in the continuity of HIV care due to structural vulnerability which led to limited responsiveness of treatment supports to their changing circumstances

The cumulative impact of social isolation and loss fuelled depression and functioned to undermine motivation to adhere to ART was explained by participants who get scared, have no direction, feel lost, feel left behind by loved ones who have passed on particularly due to HIV- or drug-related complications (McNeil et al., 2015).According to Milloy, et al., 2012 and McNeil et al. (2015), the concept of structural vulnerability specialises in looking at how structural inequities (like the differences in incarceration rates under drug criminalization, food insecurity, housing instability, homelessness) and also socio-cultural processes like racism and sexism are linked with how the marginalized populations are at risk of treatment interruptions.

Milloy, et al., 2012, confirmed that in Vancouver, Canada factors associated with structural vulnerability are most likely to contribute to ART treatment interruption by PLHIV who use drugs. McNeil et al. (2015) also added that disruptions in everyday patterns and breakdowns in the continuity of HIV care occurring as a consequence of

the intersection of extreme poverty often led to ART interruptions. However, Participants emphasized that they foolishly neglected their individual responsibility for adhering to ART, due to significant barriers brought about by structural vulnerability.

2.5.6 Religious and Spiritual Themes

The Zimbabwe National Statistics Agency & ICF International 2012 proclaimed that in Zimbabwe there are a variety of religious and spiritual philosophies mainly categorized as: traditional religious beliefs and practices; mission churches (Catholic and Protestant); African Christian White garment churches also known as Apostolic or Vapostori; Pentecostal ministries; Islam, Hindu; other religious minority groups; and non-believers. These religious and spiritual Organisations offer communication with the spirit world, healing through faith, prayer and exorcism (Maxwell, 2000).

O'Brien & Broom (2014) highlighted that in Zimbabwe, traditional medicine and faith healers also offer different forms of therapeutic HIV treatment which are mostly shaped by contemporary lived experiences of HIV through the lens of both clinical and cultural encounters with illness. This is because traditional medicine and spiritual beliefs continue to significantly influence the way in which HIV is understood, and the forms of help and care people seek (O'Brien & Broom, 2014). Thus, bringing about rarely investigated questions of alternative healing practices' impact on Treatment Interruption; or highlighting the perceptions and experiences biomedicine in relation to traditional medicine and spiritual healing; and also life experience of patients who combine traditional medicine and spiritual healing in relation to biomedicine HIV therapies.

According to O'Brien & Broom (2014) people mix both spiritual healing therapies and biomedicine therapies when it comes to curing HIV/AIDS, however they observed that people sometimes skip consuming ARVs and start using immune boosters like Moringa alone after going to a witch doctor or traditional healers. Also they observed that the participants in their research generally had an allegiance with alternative therapies, particularly spiritual healing which informed judgment on their continued treatment interruption, therefore some who refused to restart treatment died. O'Brien & Broom (2014) discovered that the promise of a cure and the stigma of being known to take ART (especially for men) added to the overall appeal of traditional medicine and spiritual healing and the decision to continue treatment interruption.

2.5.7 Financial, Economic and Political Themes

Structural factors can shape biomedical treatment interruptions as one-third of the participants in a research stated that they could not afford a balanced diet and, and also they found it challenging cover the costs associated with treatment (O'Brien & Broom, 2014). In Zimbabwe Interruptions in laboratory services were reported as some sites did not have reagents in stock due to foreign currency shortages and or delays in payments to suppliers, hence causing treatment interruptions (Noguera et al., 2003). These financial and economic challenges can be further explained by Zimbabwe's massive ART roll-out backed with the lowest level of per capita HIV funding in sub-Saharan Africa as hyperinflation, political contestation, economic crisis and healthcare shortages ravaged the country (Apollo *et al*., 2010; O'Brien & Broom, 2010; UNAIDS, 2012).

PlusNews (2012) further elaborated that the erratic supply and availability of ARVs or drug stock-out, is negatively affecting Zimbabwe ART Programs, thereby causing increase in nurses' frustrations, interruption treatments which are imminent threats on drug resistance. To avoid stock-outs patients have been reported to have been sharing drugs. Nevertheless, unpleasant news of drugs expiring while some people are dying from lack of access to treatment have exposed poor ART Program management.

The Global Fund to Fight AIDS, Tuberculosis and Malaria, offered a US$84 million grant to Zimbabwe so that they may secure at least six-month ARV buffer stock to prevent treatment interruptions for the 480,000 patients currently receiving the medication. Also, this funding will cover the cost of ARVs for an additional 10,000 new patients, thereby helping Zimbabwe reach 85 percent ARVs coverage goal of the year 2012 (The Global Fund, 2012). Important to note is that in, 2015 only 5% of patients in ART care had undergone VL monitoring, due to the fact that testing facilities were stationed at higher level health facilities, thus the authorities planned to make VL testing available for more than 90% of eligible patients by 2017, through the use of efficient and timely referral of dry-blood spot specimens from lower level ART sites. Nevertheless, in order to meet these numbers investment in equipment, clinical training and patient awareness is needed to scale-up of VL (Zimbabwe Ministry of Health and Child Care, 2015).

2.5.8 Geographical Themes

Wilhelm-Solomon (2016) highlighted that geographical themes have been presented when discussing Treatment Interruption by patient on ART. Patients cited that it was difficult for them to continue their treatment when they visited or relocated to another area especially another country, worse of asylum seekers, thus lead to

treatment interruption. Wilhelm-Solomon (2016) further postulated that though antiretroviral treatment has been freely available in South Africa and asylum seekers and refugees are eligible for treatment. However, some Zimbabwean in South Africa patients have been forced to change their treatment regimen and have risked and experienced side effects, with some forced to interrupt treatment. The changes are being experienced due to the incompatibility of treatment regimens across the SADC region and also there are no regionally harmonized or implemented and adopted treatment guidelines or referral systems for cross-border migrants who need antiretroviral.

Wilhelm-Solomon (2016) therefore concluded that Cross-border migrants they may risk missing treatment while registering in a new system in a foreign country mainly due to the fact that Cross-border migrants often do not know how to negotiate foreign systems, and sometimes have to deal with xenophobia in clinics.

2.5.9 COVID-19 Pandemic Themes

One of the themes that has lately dominated the treatment interruption of PLHIV all over the world who are receiving ART is the COVID-19 Pandemic. Chen, et al. (2020) noted that governments placed a series of prevention and control measures aimed at COVID-19 like: citywide lockdowns, non-essential shops were closed, public transportation suspended and residents confined to their homes, and travel restrictions. Though highly necessary these COVID-19 regulations and guidelines impacted daily life of people including access to primary healthcare and prescription medications especially HIV health care programs leading to increased treatment interruptions.

ART services are almost exclusively provided through the government-designated clinics and hospitals in most countries which posed a serious problem for PLWHIV who could not travel to these facilities (Xu, Liu, Hu, and Wang, 2020). And the ART treatment interruption risk increased especially for PLHIV had previous interruptions in ART, travelled away from where they typically receive HIV care or lived in an area that implemented strict COVID-19 prevention and control measures (Sun, et al., 2020).

Thus, in order to avoid treatment interruption Zhang, et al. (2005) and UNAIDS (2020) recommended that PLHIV could obtain at least one-month supply of ART at a time and if possible allow PLHIV to get medication from the nearest health care facility. Nevertheless, despite efforts by the government agencies and professional societies to mitigate the impact of COVID-19, more than one third PLHIV in countries like China and even Zimbabwe likely experienced or are at risk of some disruption in primary HIV care, including ART interruption (ATI) during the COVID-19 Pandemic (Guo, et al., 2020). However, Sun, et al. (2020) explained that PLHIV where worried that actively seeking ART refills from new sources would disclose their HIV status. Hence, many PLHIV resorted to seeking ART from their peers or community-based organisations, which was often unsuccessfully and led to treatment interruption.

Jewell, Smith, and Hallett (2020) noted that concerns are high for the interruption of HIV services due to the COVID-19 Pandemic in the sub-Saharan Africa, this is mainly due to the challenges of widespread uncertainty in maintaining HIV services and the expected increase in HIV deaths. Thus they recommended that maintaining ART treatment during any health system disruptions is an overriding priority for all

HIV programs. Thus, Sun, et al., (2020) suggested that an urgent need for interventions to maintain access to ART during public health emergencies is required at all costs. If not, treatment interruption and HIV deaths could increase substantially during the COVID-19 pandemic under reasonable worst-case assumptions about interruptions to HIV services. It is a priority in high-burden countries to ensure continuity of ART during the pandemic (Jewell, Smith, and Hallett, 2020).

2.6 Chapter summary

McNeil et al. (2015) observed that social-structural forces underlying experiences of 'treatment fatigue' functioned as primary drivers of ART interruptions among PLHIV who use drugs. Prior adverse experiences with early ART regimens influenced sub-optimal treatment outcomes among those with long-term treatment histories (≥15 years), including viral drug resistance, subsequent to being transitioned to complex ART regimens. Social isolation stemming from structural vulnerability also undermined the motivation of PLHIV who use drugs—particularly indigenous persons—to adhere to ART regimens.

Moreover, breakdowns in the continuity of HIV care stemming from increases in structural vulnerability due to events such as evictions and incarceration fostered ART interruptions despite the availability of treatment supports in the local setting. This information will also be useful in shaping the upcoming Chapter 3 – Research Methodology.

CHAPTER 3 RESEARCH METHODOLOGY

3.1 Introduction

The researcher used this chapter to give important information that will shape the research methodology with respect to characterization of the HIV treatment interruption spell. When carrying out a Research methodology, the researcher intricately created an understandable pathway that scientifically deciphers the research problem at hand and also assist in the effective and competent gathering of research data from the research respondents (Singh, 2006).

3.2 The Research Design

Study Design: The researcher used a case study as a research-methods and also used a mixed-research which constitutes both quantitative and qualitative research approaches. The case study involved collecting data from an electronic patient monitoring system used at Mpilo Centre of Excellence mainly to characterize the HIV treatment interruption spells and also conducting interview with research participants using a modified Adherence Barriers Questionnaire to get in-depth understanding of the reasons leading to HIV treatment interruption. Yin (2003) highlighted that one advantage of a case study is that it uses a limited number of units of analysis within their natural conditions.

In order to achieve study's sub-objective which aims to characterize HIV treatment interruption spells, the researcher used a Quantitative Approach to collect and used in house data at Mpilo Centre of Excellence to find statistical data and relationships of variables. In order to achieve the study's second sub-objective that is to derive typologies of themes linked to reasons for treatment interruptions, the researcher used Qualitative Research Approach, via a case study to conduct Face to face and

online Interviews with HIV heal care employees and HIV treatment defaulter to get in-depth understanding of the reasons leading to HIV treatment interruption and also understand the reasons that lead defaulters back to HIV care treatment. The researcher also included a control group consisting of HIV patients who are continuously retained in care to determine the challenges that may face and the actions they take which have successfully led to them not to interrupt their HIV care treatment.

3.3 Population and Sampling

Igwenagu (2016), described sampling as a process that helps the researcher drawing or selection from a segment taken form a distinct population or population frame with the aim of approximating the characteristics of an entire population in a manner that indisputably answer the research questions and preset objectives through the use of data.

3.3.1 Study Site

The study site was carried out at the Mpilo Centre of Excellence, Bulawayo Zimbabwe. This site was chosen because the researcher is an employee at the institution and thus the researcher is familiar with the Institutions protocols. Mpilo Central Hospital Opportunistic Clinic is one of the biggest health facilities in the Zimbabwe rolling out the ART program. This site offers ART to over 10000 patients who are registered in this site and an almost similar number of referrals from nearby facilities and provinces. Mpilo Central hospital was one of the pilot sites to offer ARVs and to date its now offering first line, second line and third line antiretroviral therapy.

3.3.2 Study Population

According to Alvi (2016), a target population is an electorate of individuals who are eligible for a research criterion which seeks to investigate and extract a conclusion with regards to the research objectives and questions. The study population will be made up of a study Group consisting of HIV patients returning to care after a gap in care, and also a control Group consisting of HIV patients who have been continuously retained in care without interruptions. Thus, the study population is made up of: 68 participants representing Study Group; 68 participants representing Control Group; hence the total study population frame list of 136 participants that will be provided by the Mpilo Centre of Excellence. The electronic patient monitoring system at Mpilo will also be used to run a query and collect data to characterize durations, frequencies and associated factors of treatment interruptions.

3.3.3 Sample Size

For the sampling methods and the minimum sample size to be appropriate, the researcher will use the Dobson formula which states that: $n= z_a^2$ X p (1-p)/ $delta^2$, where Z_a=1.96, p=0.21 (Muringazuva et al., 2017), delta is 0.10, confidence interval 95%, non response of 10%. The sample size of 70 for the respondents was calculated and found using Dobson's formula.The minimum sample size of the study will be made up of 136 participants including: The Study group with 68 participants; Control Group with 68 participants.

3.3.4 Sampling Approach

The researcher used stratified sampling method so that each group of respondents identified in the study population can have an equal voice in the research. Nguyen (2019) showcased that proportionate stratified random sampling is used to guarantee an equal or balanced representation of the research's participants which is founded

and or weighted based on the subgroups (strata) size in a population. Thereby presenting balanced knowledge, perceptions and experiences that covers all the cited participants of the research. According Etikan and Bala (2017) the main advantage of proportionate stratified random sampling is that it gives a flexible emphasis on the ability of some strata overshadowing others, thereby, through controlling the allocation of sample sizes and also stratified sampling gives more reliable and detailed information about the sample.

3.3.5 Inclusion/Exclusion Criteria

For PLHIV, this will research will include only treatment disruptors in the study group who returned into care between 2020 and 2021 and non-treatment treatment interrupters as control group participants. Treatment interrupters who returned to care out of this time period will be excluded in the study.

3.4 Data Collection Instruments

According to Trigueros, Juan and Sandoval (2017) a research instrument is a tool used to collect, measure, and analyse data related to your research interests. Research instruments are designed to avoid instrument failure and or researchers misinterpreting the phenomena under scrutiny, hence properly valid and well-defined instruments are needed (Chikweche, 2009). Therefore, this section will look at how data collection instruments are used to collect data.

3.4.1 Data Sources and Rationale for Their Inclusion

Both primary data source that is original data collected from the field; and secondary data sources that is data generated by other people was used in this research. Data to characterise treatment interruptions was collected from a patient monitoring system at Mpilo HIV COE. Also the researcher collected primary data using open ended

interviews thereby providing in-depth understanding of reasons for treatment interruptions.

3.4.2 Questionnaires for themes on interruption of treatment

Mcleod (2018) noted that a questionnaire is a research instrument which contains a numerous question in a predetermined order that are designed to collect direct responses from the research participants and they can be conducted face to face, by telephone or sending through E-mail. Close-ended questionnaire that is aimed at collecting quantitative primary data at a large scale of various knowledge, experiences and opinions from the study's participants with respect to insights highlighting the Treatment Interruption at Mpilo Centre of Excellence. Also open-ended questions were used to obtain qualitative data from the research's respondents. The responses from the open ended questions were used to generate themes with respect to Treatment Interruption at Mpilo Centre of Excellence.

3.4.3 Data List for Characterizing Treatment Interruption Spells

The researcher also used a data list which will guide the research on the type of data required to complete the research satisfactory. This list will contain for example the information like age, gender, residential area, date of ART initiation, and date of interruption, date of returning to care, treatment regimen and clinical stage of the client. This information was extracted from the electronic patient monitoring system and will be used to characterize the Treatment Interruption Spells faced by patients at the Mpilo Centre of Excellence.

3.5 Pilot Study

To pre-test the data collection tools, questionnaires were administered at a small scale at Mpilo HIV COE so as to test the validity of the questionnaires and clarify questions.

3.6 Data Collection Procedure and Techniques

Primary and secondary documents from the period 2020 to 2021 detailing ART Treatment Interruption's: program patients' hospital records, processes used, and the Health Treatment were collected from Mpilo Centre of Excellence, Bulawayo. These primary data was used to provide factual evidence required to characterise treatment interruption. Also, Interviews and Questionnaires were used to collect knowledge and perceptions of the respondents of the research and their responses were used to assess and or link theme with treatment interruption. A checklist was also used to make fundamental assessments with respect to treatment interruption.

3.7 Analysis and Organization of Data

Data analysis plan is defined as a strategy that researchers use to prepare, combine, make sense of and scrutinize the collected data (Simpson, 2015). Hence, the data analysis plan will assist the researcher dismember and understand the information provided by the research participants so that the data gathered can be appreciated and used for improving HIV treatment outcomes.

3.7.1 Statistical Analysis

The researcher used statistical analysis to describe and analyze the quantitative data collected and seek relationships between the variables that affect treatment outcomes of HIV patients and projects. Descriptive statistical analysis was applied to summarize experiences of PLHIV and have interrupted treatment as well as socio-

demographic information and potential correlates of interrupted treatment. The researcher used SPSS version 22.0 to code and analyse the data collected from this research's participants. Hence, SPSS will help the researcher to encode quantitative information so that it can be further systematically analyzed and presented. The types of statistical analysis used to analyse the collected research data by the researcher include: frequencies and percentages; Sample mean; Standard deviation; Pearson correlation index; and Chi Squared Tests.

3.7.2. Thematic Analysis and grounded Theory

Also, the researcher used thematic analysis to analyze qualitative information and identify themes that explain themes linked to why HIV patients interrupts HIV care treatment and also why they return to care at Mpilo Centre of Excellence. According to Tuckett (2005) that thematic analysis is a breakdown technique that is used by researchers to identify, scrutinise, and report themes that are common, popular amongst the qualitative information collected from the respondents of the research. Therefore, thematic analysis will assist by showcasing common themes as per research respondents' knowledge, experience and perspective.

Hays & Singh (2012) explained that, "when using thematic analysis, the researcher may: Group similar and overlapping statements; identify non-repetitive, non-overlapping statements; categorise refined data with similar meaning and depth; Choose and retain the best verbatim experiences of the respondents; identify and constructs multiple composite textural-structural descriptions of potential meanings and essence within the textural description make structural description; generate themes which based on common elements and universal description of experiences; and lastly the Presentation of the discovered themes."

3.8 Ethical Consideration

In order to implement ethical considerations, the researcher obtained permission to carry out the research from the Chief Executive Officer of Mpilo Central Hospital, Mpilo central hospital opportunistic infections clinic management, the Africa University Faculty of Health Sciences and the Medical Research Council of Zimbabwe. Ethical clearance was sought from AUREC. This will assure that the research and it's all its dictates are permissible by law and do not go against the guidelines and standards set by these research bodies.

Also, written and informed consent was obtained from the study participants so that proof of voluntary participation is available for inspection, no payment for participating in the research was awarded to the respondents. Also the participants were informed that they have a right to withdraw from the research for any undisclosed reason. The researcher asked the participants to enforce anonymity by not including their names when presenting or writing their responses to the researcher. Confidentiality of responses was assured by securing safely the data from the respondents, with the electronic files being protected by a password only accessed by authorised personnel.

3.9 Budget

The researcher created an appropriate and reasonable budget that details the resources, quantities and monetary values required to make the research financially feasible and a success.

3.10. Timelines

The researcher proposed timelines which are represented in annex 3 for implementing program evaluation research with respect to characterizing treatment interruptions at Mpilo COE

3.9 Chapter Summary

This research methodology chapter was used to highlight clearly how this research was undertaken. Hence, this chapter was used to show how the research objectives and questions were addressed by considering and infusing them in the designing of the research's data collecting methods and instruments which apply to the characterising of and linking theme pertaining to Treatment Interruption. The data received from the respondents and also the primary and secondary documents was analysed using both SPSS 22.0 and thematic analysis, thereby allowing the researcher to extract important information that will inform the characterising and theme linking of Treatment Interruption. The forthcoming chapter will provide a comprehensive analysis, presentation and interpretation of the research results and findings obtained by the researcher with respect to the Treatment Interruption.

CHAPTER 4 DATA PRESENTATION, ANALYSIS AND INTERPRETATION

4.1 Introduction

In this chapter, the researcher will present the findings of data collected from the electronic patient monitoring system as well as data collected from interviews with research participants. The data from the electronic patient monitoring system addressed the first objective of characterizing treatment interruption of patients returning to care between January 2020 and September 2021 whilst data collected through interviews addressed the second objective which is to analyse themes linked to treatment interruptions.

4.2 Demographic Characteristics of Study Population

A total of 306 patients were identified to have returned to care during the period 1 January 2020 and 31 September 2021 according to the electronic patient monitoring system. However, of these, 5.6% (17 patients) were excluded from the study because they had i) interrupted treatment for less than 90 days as per the definition of treatment interruption (6 patients) and ii) did not have baseline CD4 Test results (11 patients). Thus, the final study population was 289.

The age range of the 289 patients identified as having returned to care was 4 to 75 years. The median age was 37.0 with a lower quartile of 23.0 years and upper quartile of 48.0 years. 63.3% (183 patients) of those returning to care were female whilst 36.7% (106 patients) were male. Nearly half the patients were in the two age bands 20-29 years (24.2%) and 40-49 years (22.5%). Responses under highest level of education ranged from unknown to university level with a cumulative 6.9% having attained college graduate or university level. 48.1% of patients have high

school level whilst 34.3% have primary school level. 14.5% and 11.8% of patients returning to care are employed and self-employed respectively with females dominating in the two employment categories, while more than half (53.6%) having an unemployed employment status.

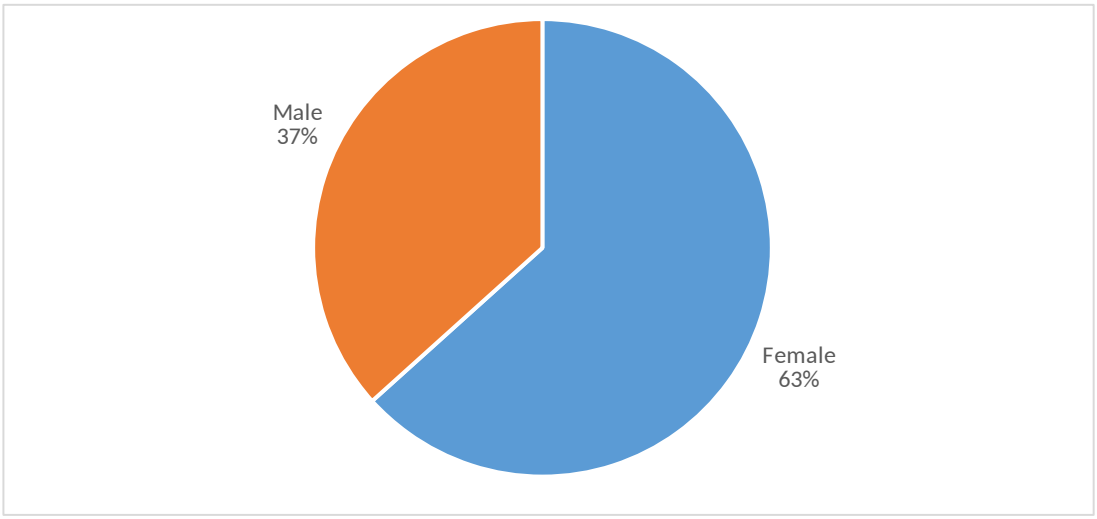

Figure 2: Sex

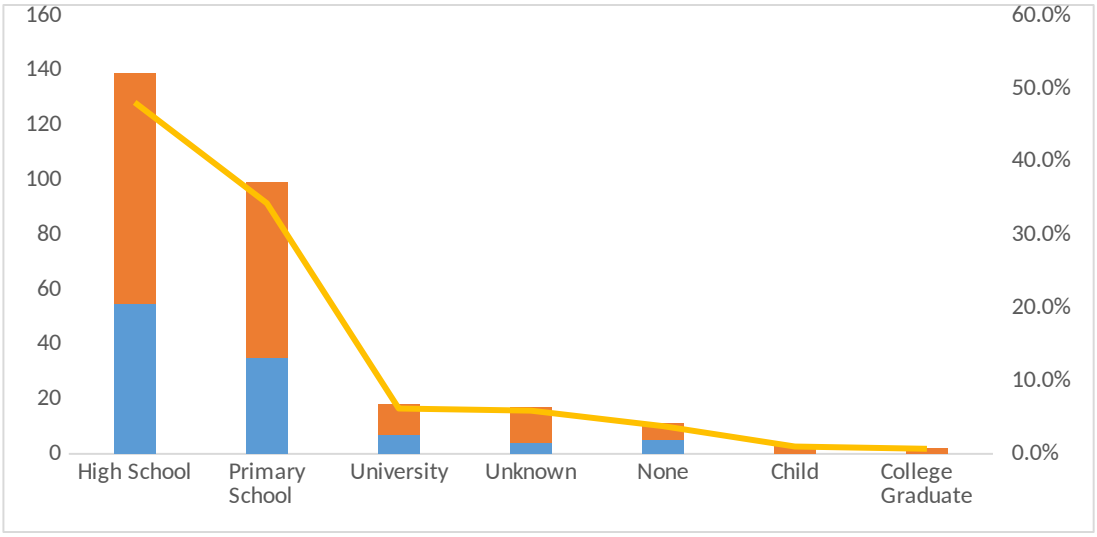

Figure 3: Level of Education

Table 1: Age Analysis

	Age (Years)

Mean	36.21
Median	37
Std. Deviation	15.47
Range	71
25th Percentile	23
75th Percentile	48

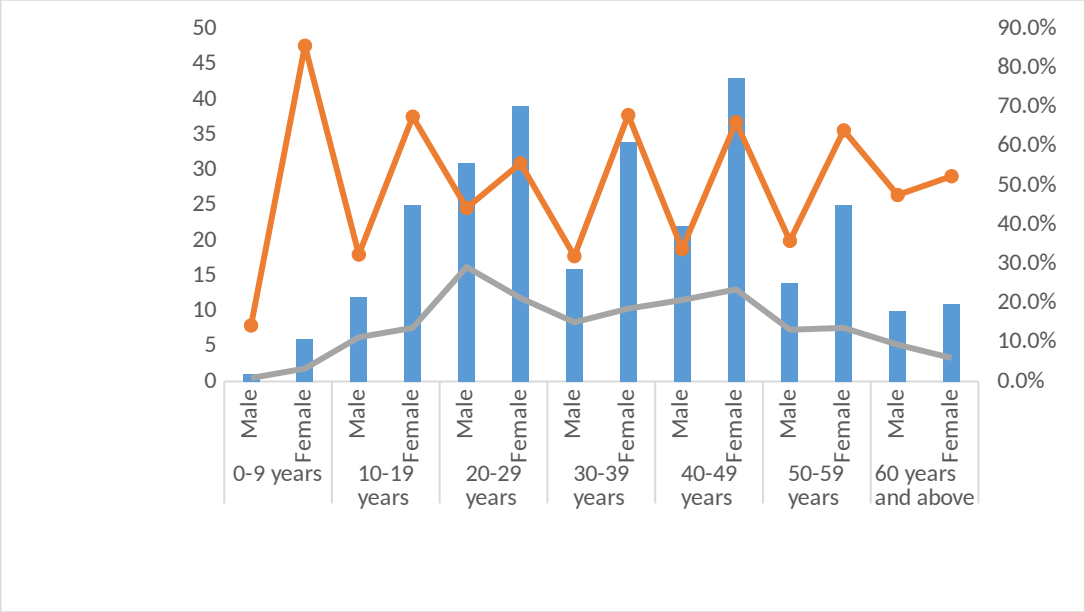

Figure 4: Age Band by Sex

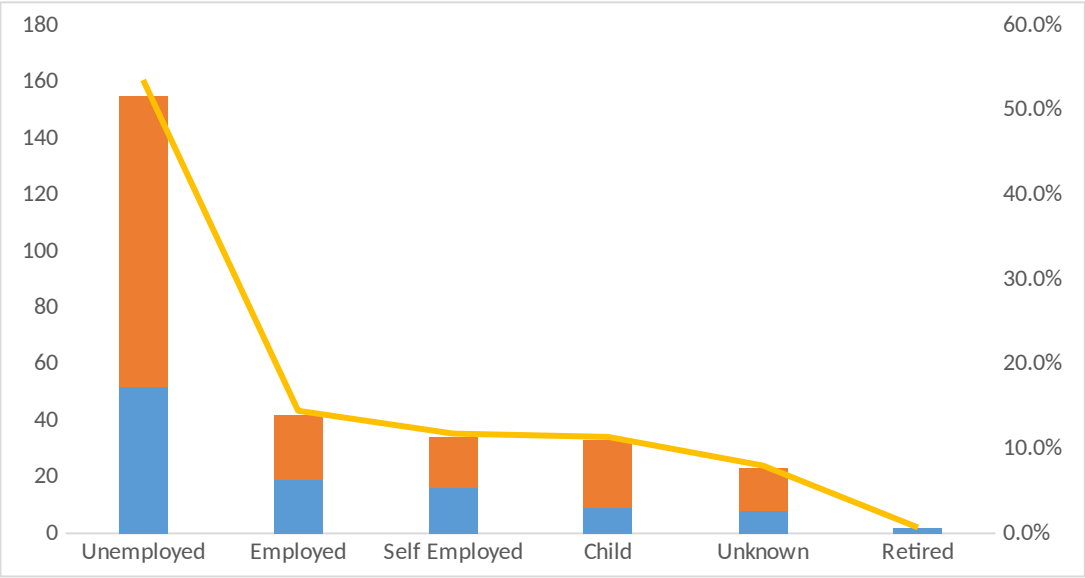

Figure 5: Employment Status

4.3 Clinical Characteristics of Study Population

The median CD4 Count for patients returning to care is 397 cells/mm3 with a lower quartile of 225.5 cells/mm3. In terms of Advanced HIV Disease, 21.1% of the study population had a CD4 Count of less than 200 cells/mm3. Of the patients with CD4 Count of less than 200 cells/mm3, 54.1% are female and 29.5% are in the 20-29 years age band. Median days defaulted is 294.0 days with an inter-quartile range of between 203.0 and 452.5 days. 79.9% (231 patients) of patients returning to care had defaulted on a first line regimen, with those defaulting on second line and third line making up 19.7% and 0.3% of patients returning to care respectively. 75.8% of patients defaulted on a 1 tablet once daily dose, whilst those who defaulted on 2 tablets once daily and 2 tablets twice daily dose are 13.8% and 10.0% respectively. The proportion of patients interrupting just once is significantly higher (61.9%) whilst those interrupting twice is 29.4%.

Table 2: CD4 Cell Count Characteristics

	CD4 Cell Count (Cells/mm3)
Mean	478.5
Median	397
Std. Deviation	355.1
Minimum	5
Maximum	2502
25th Percentile	225.5
75th Percentile	658.5

Table 3: CD4 cell count and Sex analysis

	Sex		Total
	Male	**Female**	
CD4 Count <200	28	33	61
% within CD4 Count <200	45.9%	54.1%	1
% within Sex	26.4%	18.0%	21.1%
CD4 Count >=200	78	150	228
% within CD4 >=200	34.2%	65.8%	1
% within Sex	73.6%	82.0%	78.9%

Table 4: Regimen and Dose

	N = 289	
	Frequency	**Percent (%)**
Regimen		
1st Line	231	79.9%
2nd Line	57	19.7%
3rd Line	1	0.3%
Dose		
1 tablet once daily	219	75.8%
2 tablets once daily	40	13.8%
2 tablets twice daily	29	10.0%
3 tablets twice daily	1	0.3%

There is significant correlation between number of days defaulted and number of times defaulted with a p-value of 0.01 and Pearson's coefficient of -0.152 at 0.01 level of significance which is to say as the number of days defaulted increase the number of times defaulted decreases. There is significant correlation between age and days defaulted at 0.01 level of significance (p-value <0.001, ρ = -0.216) and significant correlation at 0.01 level of significance between age and CD4 Count (p-value <0.001, ρ = -0.275).

Table 5: Correlation of characteristics

	P-value	Pearson's R (ρ)
Age and Days Defaulted	0.000**	-0.216
Age and Baseline CD4 Count	0.000**	-0.275
Age and Number of Times Defaulted	0.829	-0.013
Age and Regimen	0.485	-0.041
Days Defaulted and Number of Times Defaulted	0.010**	-0.152
Days Defaulted and Baseline CD4	0.078	0.104
Days Defaulted and Regimen	0.122	-0.091
Number of Times Defaulted Baseline CD4	0.445	0.045
Number of Times Defaulted and Regimen	0.361	0.054
Baseline CD4 and Regimen	0.167	-0.082

** Correlation is significant at the 0.01 level (2-tailed test).

4.4 Background of Research Participants and Sample Characteristics

4.4.1 Sampling and Sample Response Rate

The expected sample size for this study was 100 participants for the Research Study Group (interrupters) and 100 participants for the Research Control Group (non-interrupters). A total of 95 participants were interviewed from the group of interrupters giving a 95% response rate. For the study group, convenience sampling was conducted where by the researcher recruited participants when they came for clinical visits or participants were reached through telephone using the contact details documented in the system. The response rate can be attributed to lack of phone numbers, invalid numbers, wrong phone numbers and phone numbers not being reachable.

For the control group, 100 participants were interviewed giving a 100% response rate. Participants in the control group were sampled randomly from the total 10311 clients in care as at the end of November 2021. Randomization was done using Excel

Rand () function and participants were interviewed either when they attended clinic appointment or reached through telephone.

4.4.2 Demographic Characteristics

The median age for interrupters is 37.0 years (Standard Deviation +/- 14.45 years) compared to a median age of 40.5 years (Standard Deviation +/- 15.68 years) for non-interrupters. There is a 4.0 years difference for both the 25th and 75th percentiles between the two groups. The age at HIV diagnosis for interrupters and non-interrupters is 26.00 years and 31.00 years respectively. Using non-parametric test for significance to compare the median ages and median age at HIV diagnosis of interrupters and non-interrupters, there is significant difference in both median Age of respondents and median Age at HIV diagnosis between interrupters and non-interrupters at 0.01 level of significance using Mann-Whitney U with p = 0.049 for respondent age and p = 0.034 for age at HIV diagnosis.

Table 6: Respondent age and age at HIV diagnosis

	Interrupters (n = 95)	**Non-interrupters (n = 100)**	**Mann-Whitney U P - value**
Respondent Age			
Mean	37.2	41.8	
Median	37	40.5	0.049
Std. Deviation	14.4	15.7	
Minimum	16	18	
Maximum	71	74	
25th Percentile	23	27	
75th Percentile	50	54	
Age at HIV Diagnosis			
Mean	27.6	32.2	
Median	26	31	0.034
Std. Deviation	13.7	14.5	
Minimum	3	2	
Maximum	63	62	
25th Percentile	17	23	

75th Percentile	38	43

Table 7: Age disaggregation

	Interrupters n = 95		Non-interrupters n = 100	
	Frequency	Percentage	Frequency	Percentage
15-19 years	11	11.6%	6	6.0%
20-29 years	24	25.3%	24	24.0%
30-39 years	20	21.1%	18	18.0%
40-49 years	16	16.8%	20	20.0%
50-59 years	18	18.9%	15	15.0%
>=60 years	6	6.3%	17	17.0%

The proportion of interrupters having level of education above Primary School is 72.6% compared to 84% for non-interrupters. 42.1% of interrupters have Unemployed employment status which is 9.1% higher than non-interrupters. A higher proportion of non-interrupters (57%) is either self or formally employed whereas only 50.5% are in these categories for interrupters. For both interrupters and non-interrupters, the majority are married/cohabiting (38.9% and 44.0% respectively). The most significant reason for treatment interruption identified in the interrupters group was Psychological (27.5%) followed by Geographical reasons (17.4%). Under current self-assessed risk of treatment interruption, for non-interrupters, 5 respondents (5%) had experienced treatment interruption at some point in time (beyond time period considered by study) whilst 80% reported as having No risk of ART treatment interruption.

Table 8: Sample socio-demographic characteristics

	Interrupters		**Non-interrupters**	
	Frequency	**Percent**	**Frequency**	**Percent**
Highest Level of				

None	8	8.4%	5	5%
Primary	18	18.9%	11	11%
Secondary	53	55.8%	66	66%
Tertiary	16	16.8%	18	18%
Occupation				
Unemployed	40	42.1%	33	33%
Formally employed	28	29.5%	26	26%
Self employed	20	21.1%	31	31%
Student	7	7.4%	10	10%
Marital Status				
Single	34	35.8%	27	27%
Married/Cohabiting	37	38.9%	44	44%
Divorced/Separated	14	14.7%	13	13%
Widowed	10	10.5%	16	16%
Orphan hood Status				
Maternal Orphan	1	1.1%		
Paternal Orphan	2	2.1%		
Double Orphan	2	2.1%		
N/A	90	94.7%	100	100%

4.4.3 Duration and timing of treatment interruptions

For respondents in the study group, 37.9% interrupted for 13 to 24 months, 25.3 % interrupted for 0 to 12 months, 20.0% for more than 36 months and 16.8% for 25 to 36 months. For the 5 respondents in the control group who experienced treatment interruption, 3 of the respondents interrupted for 0-24 months whilst the other two could not recall the exact time period and duration of treatment interruption. 41.1% of interrupters initiated on ART between 2016 and 2021 whilst 58.9% initiated before 2016. For non-interrupters, 61.0% initiated on ART between 2016 and 2021 whilst 39.0% initiated before 2016.

The majority of interrupters indicated that the main factors that led them to return to care was becoming ill followed by 24.2% citing family and relative support leading

them to return to care. Change in location was accounted for 20.0% of respondents returning to care whilst counselling and change in caregiver/family support were factors for 13.7% and 10.5% of interrupters respectively. In terms of current health status, 67.4% of interrupters said they felt very healthy or healthy compared to 85.0% who said the same from non-interrupters. 9.5% of interrupters reported feeling sick compared to 3.0% from non-interrupters.

Table 9: Duration of interruption

	Interrupters n = 95		Non-interrupters n = 100	
	Frequency	Percentage	Frequency	Percentage
0-12 Months	24	25.3%	1	1.0%
13-24 Months	36	37.9%	2	2.0%
25-36 Months	16	16.8%		
>36 Months	19	20.0%		
Unknown			2	2.0%
N/A			95	95.0%

Table 10: ART initiation

	Interrupters		Non-interrupters	
	Frequency	Percentage	Frequency	Percentage
2000-2005	8	8.4%	13	13.0%
2006-2010	27	28.4%	26	26.0%
2011-2015	21	22.1%	22	22.0%
2016-2020	38	40.0%	34	34.0%
2021	1	1.1%	5	5.0%

Table 11: Factors leading to return to care

	Interrupters n = 95 Frequency	Percentage
Family or relative support	23	24.2%
Became sick	30	31.6%
Changed location	19	20.0%
Counselling	13	13.7%
Changed caregiver/family support system	10	10.5%

	Interrupter n = 95		Non-Interrupter n = 100	
	Frequency	Percent	Frequency	Percent
Healthy	52	54.7%	49	49.0%
Very healthy	12	12.6%	36	36.0%
Neutral	22	23.2%	12	12.0%
sick	9	9.5%	3	3.0%

4.5 Themes Associated with Treatment Interruption

The two most significant of the responses to reasons for treatment interruption were psychological reasons (27.5%) and geographical reasons (17.4%). Sociological reasons and financial/economic/political reasons accounted for 14.7% and 11.9% of respectively. 5 out of the 100 non-interrupters provided a response to reasons for treatment interruption as these had experienced treatment interruption either before or after the period considered for this study. For responses from non-interrupters, the majority response was geographic reasons (80%) with the only other response being psychological (20%).

Table 12: Reasons for treatment interruption

	Interrupters		Non-interrupters	
	Frequency	Percent of Responses	Frequency	Percent of Responses
Technological	2	1.8%		
Technical and Service Provision	6	5.5%		
Biological, Virology and Treatment	9	8.3%		
Psychological	30	27.5%	1	20.0%
Sociological	16	14.7%		
Financial, Economic/Political	13	11.9%		
Geographical	19	17.4%	4	80.0%
COVID-19 Pandemic	7	6.4%		
Religious and Spiritual	7	6.4%		

4.5.1 Association of themes linked with treatment interruption using Chi-square test

Chi-square test was conducted the 9 themes and 24 subthemes linked to treatment interruption using Likelihood Ratio's. Two sub-themes under Technological themes are significantly associated with treatment interruption; poorly documented treatment records with moderate association (Cramer's V = 0.228) and usefulness of SMS reminders with a relatively strong association (V = 0.454). High number of clinic visits has moderate association with treatment interruption (V = 0.264) and is the only sub-theme under Technical and Service Provision linked theme with a significant association with treatment interruption. Side effects of ARV's Treatment has a moderate association (V = 0.350) under Biological, Virology and treatment linked themes. Psychological and religious and Spiritual linked all showed no significant association with treatment interruption.

All sub-themes under Sociological linked Themes have significant association with treatment interruption with sub-themes linked to peer pressure and social loneliness

having moderate association (V = 0.271, V = 0.205 respectively) whilst hearing societal views has a weak association (V = 0.0249). Difficulty in raising transport money showed no significant association with treatment interruption whilst sub-themes on ARV stock outs and lifestyle and dietary requirements have a moderate association with treatment interruption (V = 0.179, V = 0.209). Geographic sub-themes associated with interruptions include continuity with ART when visiting or relocating (V = 0.339) and preference of pick-up centres closer to place of residence (V = 0.25), both with moderate association whilst for COVID-19 linked sub-themes Difficulty in taking ART medication during the pandemic is moderately associated with treatment interruption and COVID-19 prevention and control measures had no significant association with treatment interruption (P = 0.062). Table 14 below provides a detailed report of the results of Chi-square tests.

Table 13: Association of themes linked to treatment interruption

Themes	Likelihood Ratio	P-value	Cramer's V
Technological			
Poorly documented treatment records	10.327	0.016	0.228
Unavailability/breakdown of equipment, laboratory testing and reagents	2.583	0.461	
Usefulness of SMS reminders	43.472	<0.001	0.454
Technical and Service Provision			
Time to understand and ask questions during service provision	7.174	0.127	
High number of clinic visits	15.4	0.004	0.264
ART caregivers rarely doing home follow-ups	6.426	0.169	
Biological, Virology and Treatment			
Level of side effects experienced during treatment	5.979	0.113	

Side effects of ARV's Treatments	28.996	<0.001	0.35
Psychological			
Provision of Adherence counselling	3.458	0.177	
Other patient's views on treatment interruption	1.553	0.46	
Sociological			
Peer Pressure very influential in treatment interruption	17.79	0.001	0.271
Social loneliness cause by structural vulnerability can lead to treatment interruption	10.605	0.031	0.205
Hearing Societal views about PLHIV can lead to treatment interruption	14.845	0.002	0.249
Religious and Spiritual			
Religious and spiritual beliefs about ART treatment	1.686	0.64	
Advice from religious or spiritual leader	0.994	0.608	
Rating of religious and spiritual support received for ART treatment adherence	6.961	0.138	
Financial, Economic and Political			
Shortages of ARVs or drug stock-outs resulting in sharing medicines	8.155	0.043	0.179
Diet and lifestyle expenses to sustainably remain on treatment	9.01	0.029	0.209
Difficulty in raising transport money for health visits/pick-up medications	7.576	0.056	
Geographical			
Continuity of ART treatment when visiting or having relocated	25.955	<0.001	0.339
Difficulty in travelling to health centre from place of residence	6.821	0.078	
Preference of pick-up centre closer to place of residence	12.588	0.002	0.25
COVID-19			
Difficulty in taking ART medication during Covid-19 Pandemic	12.186	0.016	0.238

Impact of Covid-19 prevention and control measures on taking treatment	5.561	0.062

4.6 Chapter Summary

Treatment interruption is most prevalent amongst PLHIV between the ages of 20 and 49 and the majority of respondents (53.6%) are unemployed. For respondents in the study group, 37.9% interrupted for 13 to 24 months, 25.3 % interrupted for 0 to 12 months, 20.0% for more than 36 months and 16.8% for 25 to 36 months. The majority of interrupters indicated that the main factors that led them to return to care was becoming ill followed by 24.2% citing family and relative support leading them to return to care.

The two most significant of the responses to reasons for treatment interruption were psychological reasons (27.5%) and geographical reasons (17.4%). Sociological reasons and financial/economic/political reasons accounted for 14.7% and 11.9% of respectively. Chi-square test was conducted the 9 themes and 24 subthemes linked to treatment interruption using Likelihood Ratio's. Two sub-themes under Technological themes are significantly associated with treatment interruption; poorly documented treatment records with moderate association (Cramer's V = 0.228) and usefulness of SMS reminders with a relatively strong association (V = 0.454). High number of clinic visits has moderate association with treatment interruption (V = 0.264) and is the only sub-theme under Technical and Service Provision linked theme with a significant association with treatment interruption. Side effects of ARV's Treatment has a moderate association (V = 0.350) under Biological, Virology and treatment linked themes.

CHAPTER 5 SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

In this chapter, the researcher will discuss whether the study findings fulfilled the study objectives and provide conclusions to the hypothesis put forward. The study process and findings will also be summarized and recommendations to relevant policy makers, stakeholders and partner organisations will be presented. Finally, the researcher will give suggestions for areas for further study that have been indicated through this study.

5.2 Discussion

5.2.1 Characteristics of Treatment Interruption

From the study, it is evident that the adults aged between 20 and 49 are most liable to treatment interruption with this age group making up 64.0% of treatment interrupters and this can be linked to the fact that this is also the age group that makes up the bulk of patients in care at Mpilo Centre of Excellence. This finding resonates with literature earlier presented that treatment interruption is prevalent amongst patients under 40 years (Dorcelus, Bernard, Georgery and Vanessa, 2021), but is atypical in that it does not identify adolescents as being prone to treatment interruption. The 20 to 40 years age group is also considered the most significant in terms of both sexual reproduction for females and economic productivity for both sexes. As such, there is need to invest in addressing adherence issues in this age group in order to achieve positive treatment outcomes and ultimately reduce the impact of HIV related morbidity and mortality on this key demographic group.

Although adolescents are reported as a less dominant age group in this study, results from correlation analysis conducted by the researcher in the study indicate that there

is significant negative correlation between age and number of days defaulted, meaning that younger patients default treatment for longer time periods as compared to their older counterparts. This is also typical in a study by Mehta, Moore &Graham (1997), whose results showed that adherence improved with age but this relationship is contradicted in beyond 75 years of age due to other underlying co-morbidities. A study by Awachana Jiamsakul et al (2016) carried out in 13 Asian countries found that longer treatment interruption spells have more severe adverse HIV treatment outcomes as compared to shorter treatment interruption spells. Their study further emphasized that durations of interruptions of more than 30 days was a key factor associated with larger increases in subsequent risk of treatment failure.

The majority of patients interrupting treatment at Mpilo Centre of Excellence initiated ART after 2015 (40.0%) with 22.1% initiating between 2011 and 2015 and 28.4% initiating between 2006 and 2010. In Zimbabwe, the Test and Treat program was officially rolled out in 2016. ART was officially rolled out in the public sector in 2004 (Rufu et al, 2018). This finding may suggest that the test and treat may have had an adverse impact on ART adherence. Similarly, in a retrospective cohort analysis using routinely collected data from multiple ART clinics, Ismael Ahmed and Meaza Demissie et al (2021) observed lower optimal adherence among individuals who started ART on the same-day of HIV diagnosis compared to those who started ART > 7 days after their HIV diagnosis in a study conducted. Their study's main findings highlight the importance of identifying adherence barriers, providing support, and ensuring treatment readiness before initiating individuals on same-day ART.

Another interesting finding from the study related to treatment frequency and duration is the correlation between frequency of treatment interruption and duration of treatment interruption with a p-value of 0.010 and correlation coefficient of -0.152. This finding is a reflection of findings by Teklu1 and Yirdaw, (2017) who reported that of clients followed up who restarted treatment, 24% discontinued treatment for second time over follow-up and of these, half interrupted again within 5 months of being followed up. It is perhaps prudent after realising such a result to try and understand the drivers of returning to care and from this study it was highlighted that becoming sick/ill (31.6%) was a key factor leading to returning to care. A study by Cunningham et al (2015) revealed that among clients who had repeated gaps in care, a third had a mental health problem, nearly half had issues with drug and other substance abuse and nearly half again had a medical core-morbidity. Such finding is indicative that a when it comes to repeated treatment interruption there are a lot of cross cutting factors that are at play.

In terms of clinical characteristics, this study's findings revealed that 78.9% of patients who interrupted treatment between January 2020 and September 2021 had a baseline CD4 cell count of more than 200 cells/mm^3. This result concurs with Ochieng-Ooko et al (2010) whose study in Kenya showed a more than 3-fold risk of non-retention among patients with a CD4 count of more than 200 cells/mm^3. Mpilo Centre of Excellence being part of a referral facility typically enrols into care patients who are clinically unstable, with most being admissions in the main medical wards with Advanced HIV Disease (AHD). According to Armour et al (2022), such a finding could mean that patients who are symptomatic or who perceive a heightened risk of morbidity or mortality are more likely to be adherent to ART in order to

improve their health status and get better with the opposite being true for clients who are asymptomatic and clinically stable.

5.2.2 Themes associated with Treatment Interruption

Consistent with findings from other authors on Technical and Service Provision themes, the results of the study show that high number of visits for clinic attendance and medication pick-ups discourages patients from properly adhering to treatment. This may mostly be attributed to the pressure on health care facilities in terms of limited resources that lead to compromised services delivery including increased waiting times. Mutasa-Apollo et al (2014) highlights that increased number of patients in care at facilities results in difficulties in active follow up of patients who have missed review appointments; and such is the case with Mpilo Centre of Excellence which has about 10500 patients enrolled in care.

From the study, the theme that was found to have the strongest association with treatment interruption with a Cramer's V value of 0.454 was the Technological theme on usefulness of medication taking SMS reminders in avoiding treatment interruption. With the advent of the information and technology revolution globally, engaging with patients is no longer limited to physical contact through clinic visits or home visits. The use of platforms including phone-based chat applications and SMS. SMS reminders to patients' personal phones by clinical services are increasingly being used to promote patient engagement, including adherence to antiretroviral treatment (ART) for HIV.

In a study conducted in Australia, 98 participants all on living long term with HIV and 43.5% having interrupted treatment in the past were recruited to receive randomised SMS reminder for ART adherence over a period of 6 weeks. The

outcomes of the study revealed that, after being engaged through SMS reminders over a period of 6 weeks, based on the standard SMAQ measure, 82% had consistently adhered to ART in the previous week. Furthermore, the study underscores the essential role of empowerment through enhancing disease self-management, increasing social support and reducing stigma, particularly for long-term HIV survivors (Limin Mao et al, 2018). The use of platforms such as SMS and Whatsapp could significantly improve patient engagement at Mpilo COE, however they require financing, which is difficult for public institutions to secure, as well as advanced information and technology infrastructures and systems.

According to findings form this study, side effects from ARVs Treatments also exhibited a strong association with treatment interruption under Biological, Virology and Treatment themes. The more complex combination regimens that are currently recommended for the control of HIV are potentially toxic synthetic drugs and potentially expose patients to side effects such as renal failure. ART induced side effects have been discovered to cause treatment interruptions and imperfect levels of adherence, which are then associated with the development of drug-resistant HIV (Harrigan et al, 2005 and Jordan et al, 2008). Drug resistance is one of the major threats to the success across many HIV ART programmes, and Mpilo COE is no exception. Approximately 1800 patients, which is 17% of the patients in care is currently receiving Second Line ART.

Furthermore, Mpilo COE is one of the few tertiary facilities offering Third Line ART with 88 patients enrolled on this regimen as at December 2021. A key concern is the number of patients having repeat high viral loads and not being switched due to poor adherence the majority of these being in the adolescent and young adult age

group and patients failing on Second Line ART. The facility reported switching just 43% of clients with repeat high viral loads in the last quarter of 2021.

An unanticipated finding was the lack of association between Psychological themes and treatment interruption. This finding contradicts much of the literature that points to strong association between psychological themes and treatment association. Scholars such as Samji, et al., (2015) pointed out that treatment fatigue as another psychological aspect which is faced by PLHIV and it often leads to treatment interruptions. McNeil et al. (2015) in their study found similar results that showed that experiences of depression resulting from thinking about the way life's supposed to be, feeling alone and having no family to talk to particularly during holidays or birthdays, reduced motivation to adhere to ART regimens.

The reason for this divergent result could be that psychological themes are the same for interrupters and non-interrupters, but how the two groups cope and adapt to psychological themes may be where there is a significant difference. Support groups play a key role in psychological themes and it may be of interest to find out how these are linked treatment adherence. In comparison, all the subthemes under sociological themes were found to have moderate association with treatment interruption, and this finding is similar to findings by other researchers.

5.3 Conclusions

From the results of this study, it can be concluded that ART treatment interruption plays a major role in both the clinical outcomes of patients in care as well as the outcomes of ART treatment programmes. It has been shown through this study that treatment interruption characteristics vary across different demographic groups, which indicates that for these different demographic groups, factors and themes

associated have varying influence, and as such, interventions and strategies to counter treatment interruption should be tailor made for each sub group in order to be effective.

This study has also highlighted clearly that treatment coverage only is not enough and optimal treatment adherence is now more key in order to achieve viral suppression and ultimately epidemic control. Without treatment adherence, HIV ART programs such as the one at Mpilo COE, stand not only to lose ground in terms of viral suppression, but would also be exposed to the threat of extensive drug resistance amongst their patients in care.

5.4 Recommendations

The researcher recommends the establishment of more social support structures for clients on ART through peer-to-peer support. Support groups are an essential element to in addressing sociological themes and are a key treatment support actor outside the family structure. Such groups can also be used to conduct other interventions such as income generating activities that will assist patients' money for transport as well as to sustain the recommended lifestyle and diet to sustainably remain on treatment.

The second recommendation is to implement multi month dispensing and strengthening of Differentiated Service Delivery models such as Community ART Refill Groups (CARGs) and Family ART Refill Groups (FARGs) for stable patients. This is a crucial element in reducing risks associated with financial and technical and service provision themes. By supplying refills for up to 6 months, patients reduce the number of clinic visits and this also relieves pressure on the limited resources, especially human resources.

Decentralisation of ART services to smaller facilities will assist tertiary facilities to give enough quality time to the complicated cases at the same time making ART collection convenient for uncomplicated cases. Decentralisation will also ease pressure on limited resources and allow for better follow-up of patients who are missing reviews.

HIV ART programs should invest in the use of SMS reminders on adherence to continually engage patients and address technical service provision themes. Besides treatment adherence SMSs can be used to extend health education outside the facility and thus assist in improving on patient self-management.

5.5 Suggestions for further studies

The researcher recommends that follow up studies be conducted on the treatment interrupters at Mpilo COE after implementing the study recommendations .There is also need to conduct a similar study on clients currently in the diaspora so as to identify the challenges they are facing so to remain in care.

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APPENDICES

Appendix 1: Informed consent for the questionnaire

My name is Ntombiyakogasa Sithole, a final year MPH student at Africa University. I am conducting a research on characterizing treatment interruptions at Mpilo Central hospital opportunistic infections clinic. Purpose of the study is to assess the study is to characterize and analyse treatment interruptions at the facility .This will help in developing strategies aimed at improving the quality of care at facility thereby improve patient retention You were selected for the study as you are among the client collecting their ARVs at the facility ,as either returning to care after interrupting treatment as a client who has never interrupted treatment .Should you decide to participate you will take about twenty minutes to answer questions asked by the interviewer. The researcher will address the sensitive questions in a respectable manner and maintain the information obtained confidential. The participant is also free to divulge the information voluntarily. It is essential to note that there are no material benefits attached to the study. All the information obtained would be kept confidential, no names or any other identification will appear on questionnaires. However, coding of questionnaires will be done using serial numbers. Privacy will also be maintained. Participation in this study is on voluntary basis. Should the participant feel unable to participate, the action will not affect their relationship with the participant organization or any authority. If they chose to participate they are free to withdraw their consent and discontinue participation without penalty. Please feel free to ask any questions pertaining to the study. You may take as much time as necessary to make a decision. If you have decided to participate in this study kindly sign the form in the spaces provided below as an indication that you have read the information and have agreed to participate.

Name of Research Participant

Please print Date …….

Signature of Research Participant

If you have any queries, questions or concerns beyond those addressed by the researcher or anything to with the research, like your rights as a research participant.

If you feel you have been treated unfairly, and would like to talk to someone other than the researcher feel free to contact my supervisor Dr Mugomeri or the Africa University Research Ethics Committee on telephone. (020) 60075 or 60026 extension 1156 or email aurec@africa.edu.

Name of researcher: Ntombiyakogasa Sithole ----------

Appendix 2

Questionnaire: Themes linked to treatment interruption spells

SECTION A: General Questions Questionnaire No: ____ Date of interview: _____

1. How old are you?	----------
2. What is your highest level of education *Ufunde wafika kuliphi ibanga?*	a) None b) Primary c) Secondary d) Tertiary
3. What is your occupation *Usebenza msebenzi bani?*	a) Unemployed b) Formally employed c) Self-employed d) Student
4. (if below 18 years) Opharnhood status *Isimo sakho sobuntandane sinjani*	a) Non-orphan b) Maternal Orphan c) Paternal orphan d) Double orphan
5. (If above 15 years) What is your marital status *Utshadile yini*	a) Single b) Married / cohabitating c) Divorced / Separated d) Widowed

-

HIV –infection related questions
Imibuzo ephathelene lokuba legcikwane leHIV emzimbeni

6. How old where you when you were diagnosed of HIV	……
7. When did you start taking ARVs	Date started ART----------
8. When did you interrupt ART treatment?	*Date the patient last seen before interrupting treatment* ----------
9. What were your reasons for interrupting treatment? (Tick all that apply)	Technological Technical and Service Provision Biological, virology and treatment Psychological Sociological

Financial, economic /political
Geographical
Covid 19 Pandemic

For all the ticked themes move to the relevant theme section.

1. Describe your current self-assessed risk of ARV Treatment Interruptions:

[ ] Having experienced ARV Treatment Interruption;

[ ] Nearly experienced ATI but obtained ART prior to interruption;

[ ] Risk of ARV Treatment Interruption is imminent;

[ ] No risk of ARV Treatment Interruption.

2. Can you explain the main factors that has led you to return back to care?

_____

_____

_____

_____

_____

_____

3. How are you feeling in terms of your Health?

[ ] Very healthy; [ ] Healthy; [ ] Neutral; [ ] Sick; [ ] Very Sick.

SECTION B: Technological Themes

4. Poorly documented treatment records have causes you to be at treatment interruption risk?

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

5. Unavailability or breakdown of equipment, laboratory testing, and reagents have put you at treatment interruption risk.

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

6. How helpful are medication taking SMS reminders to in avoiding treatment interruption?

[ ] Very Unhelpful; [ ] Unhelpful; [ ] Moderate; [ ] Helpful; [ ] Very Helpful.

7. What strategy do you use to manage risks associated with Technological Themes: _____?

_____

_____

_____

SECTION C: Technical and Service Provision Themes

8. During ART service provision, not enough time is given to understand or ask questions.

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

9. The high number of visits for clinic attendance and medication pickups discourages you from properly adhering to Treatment.

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

10. ART care givers rarely do follow up to see how we are coping with the treatment at home.

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

11. What strategy do you use to manage risks associated with Technical and Service Provision Themes: _____?

_____

_____

_____

SECTION D: Biological, Virology and Treatment Themes

12. Can you describe the level of side effects that you have experienced during treatment?

[ ] No side effects; [ ] Low Side Effects; [ ] Moderate Side Effects; [ ] High Side Effects;

13. Side effects of ARVs Treatments put you at risk of interrupting treatment?

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

14. Which of the following is the leading cause of treatment interruptions?

[ ] Imperfect adherence to treatment; [ ] Changing Drug Regiments; [ ] Drug Resistance; [ ] Art induced Side effects; [ ] Poor Monitoring of the Body's Health Indicators

15. What strategy do you use to manage risks associated with Biological, Virology and Treatment Themes: _____?

_____

_____

SECTION E: Psychological Themes

16. Which of the following Psychological factors have put you at risk of interrupting treatment?

[ ] Stress related to diagnoses and or negative experiences of previous experiences;

[ ] Decreased desire or willingness to adhere to ART treatment

[ ] Reduced motivation to adhere to ART regimens;

[ ] Depression resulting from thinking about the way life's supposed to be;

[ ] Feeling alone and having no family to talk to particularly during special occasions,

17. Has the provision of adherence counselling helped you avoid treatment interruption?

[ ] Yes; [ ] Maybe; [ ] No.

18. Have other patients ever said that they interrupting treatment in order to avoid remembering and re-experiencing treatment hardships?

[ ] Yes; [ ] Maybe; [ ] No.

19. What strategy do you use to manage risks associated with Psychological Themes?

_____
_____
_____
_____
_____
_____

SECTION F: Sociological Themes

20. Do you agree that peer pressure is very influential in treatment interruption?

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

21. Do you agree that social loneliness caused by structural vulnerability like lack of food, no family and friends to help when you are down may lead a patient to interrupt treatment?

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

22. Hearing Societal views about People Living with HIV can lead to treatment interruption.

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

23. What strategy do you use to manage risks associated with Sociological Themes: _____?

_____
_____
_____
_____
_____
_____

SECTION G: Religious and Spiritual Themes

24. Which is true about your religious and spiritual consultation beliefs about ART Treatment?

[ ] There is need to make religious and spiritual consultations when taking ART treatment.

[ ] Care is needed when making religious and spiritual consultations about ART Treatment

[ ] There is no need to make religious and spiritual consultations when taking ART treatment.

[ ] Religious and spiritual consultations dangerously misinform ART Treatment.

25. Has any religious and spiritual leader ever advised you to stop your treatment?

[ ] Yes Directly; [ ] Yes but Indirectly; [ ] No.

26. Rate the religious and spiritual support you have received for adhering to ART treatment.

[ ] Very Low; [ ] Low; [ ] Moderate; [ ] High; [ ] Very High.

27. What strategy do you use to manage risks associated with Religious and Spiritual Themes?

_____
_____

_____
_____

_____
_____

SECTION H: Financial, Economic and Political Themes

28. Shortages of ARVs or drug stock-out has led you to share medications with other patients?

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

29. How expensive is the diet and life style required for you to sustainably remain on treatment?

[ ] Not expensive; [ ] Moderate; [ ] Expensive; [ ] Very Expensive

30. Do you find it difficult to raise transport money for health visits and or pick up medications?

[ ] Never; [ ] Sometimes; [ ] Most of the Time; [ ] All of the Times.

31. What strategy do you use to manage risks associated with Financial, Economic and Political Themes?

_____

_____

_____

_____

_____

SECTION I: Geographical Themes

32. Is it difficult for you to continue ART treatment when you visit or relocate to another area?

[ ] Never; [ ] Sometimes; [ ] Most of the Time; [ ] All of the Times.

33. How difficult is travelling to the health care center from your place of residence?

[ ] Very Difficult; [ ] Difficult; [ ] Moderate; [ ] Easy; [ ] Very Easy.

34. Would you prefer medication pick up centers that are close to your place of residence?

[ ] Yes; [ ] Maybe; [ ] No.

35. What strategy do you use to manage risks associated with Geographical Themes?

_____

_____

_____

_____

_____

_____
_____

SECTION J: COVID-19 Pandemic Themes

36. Taking ART medication has been difficult during the COVID-19 Pandemic, do you agree?

[ ] Highly Disagree; [ ] Disagree; [ ] Neutral; [ ] Agree; [ ] Highly Agree.

37. Which COVID-19 prevention and control measures have highly impacted your ability to take your treatment?

[ ] Citywide lockdowns & Curfew; [ ] Travel restrictions; **[ ]** Social distancing;

[ ] Access to various COVID-19 information; [ ] Public Gathering Ban limits socializing

[ ] Other measures Specify: _____.

38. Can you tell us how misinformation about COVID-19 Pandemic has affected you in taking your ART Treatment?

_____
_____
_____
_____
_____

39. What strategy do you use to manage risks associated with COVID-19 Pandemic Themes?

_____
_____
_____
_____
_____
_____

THANK YOU FOR YOUR PARTICIPATION!!

Appendix 3: Budget

ITEM	QUANTITY	UNIT COST (US$)	TOTAL COST (US$)
Bond Paper (Rim)	2	5	10.00
Toner (Black)	1	20	20.00
Pens and Pencils (pair)	5	0.30	1.50
Broad Band Internet (8gig)	1	15	15.00
Teas for meetings	6	5	30.00
Fuel for Transport	15	1.40	21
Total			97.50

Appendix 4: Timelines

Activity (2021)	October				**November**				**December**				**January**			
Week	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Research Proposal																
Protocol Completion																
Submission to AUREC																
Data collection and analysis																
Findings Presentations																
Report writing and Submission																