UNIVERSITY OF THE WESTERN CAPE

Faculty of Community and Health Sciences

Adherence to Treatment and Retention in Care among Postnatal Women who were initiated on Antiretroviral Therapy during Antenatal and Postnatal Period in Lusaka District, Zambia

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A mini thesis submitted in partial fulfilment of the requirements for the degree of Master of Public Health at University of the Western Cape

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24 October 2021

ABSTRACT

Introduction: Mother-to-child transmission (MTCT) is the cause of most HIV acquisition among children. Prevention of mother-to-child transmission (PMTCT) of HIV programs aim to enable pregnant women to attain viral suppression so that they are unlikely to pass HIV to the foetus in utero or during birth, and to the neonate during breastfeeding. The Option B+ treatment regimen - initiating pregnant and breastfeeding women, diagnosed with HIV, on lifelong triple antiretroviral therapy (ART) regardless of their WHO clinical stage – was introduced in 2013 in Zambia but to date, no evaluation of this program has been done.

Study Aim: The current study described factors associated with adherence and retention in care (RIC) among postnatal women initiated on ART during the antenatal and postnatal period at five PMTCT centres in Lusaka District, Zambia in 2017 and 2018.

Methodology: A quantitative, retrospective cohort analysis of 311 postnatal women who were initiated on option B+ regimen at five PMTCT centres in Lusaka District between 1 January 2017 and 30 April 2018 was done. Adherence to treatment was measured by analysing data on patients' missed clinic appointments and self-reported missed medication doses. Kaplan-Meier survival analysis was used to calculate RIC at 6, 12, 18, and 24 months. Bivariate analysis was conducted to determine the significance of associations between adherence and RIC, and sociodemographic and clinical characteristics, respectively.

Results: Retention in care decreased over time, from 92% at the time of delivery to 81%, 77%, 74% and 70% at 6, 12, 18 and 24 months postnatal, respectively. Higher retention in care was observed amongst married women (p=0.012); who stayed within one kilometer from the health facility (p=0.018); whose spouses were on ART (p=0.027); who knew their HIV status before pregnancy (p=0.005); who were commenced on ART in the first trimester (p=<0.001); and the postnatal period (p=<0.001); who were on other medication, in addition to ART (p=0.001); who did not miss a dose of medication in the week before the last appointment (p=<0.001); and who did not miss any clinic appointment since commencing ART (p=<0.001).

Half of the study participants (50.2%; n=155) reported optimal adherence (did not miss a scheduled clinic appointment since commencing ART). Optimal adherence to ART was significantly associated with women who lived within 1 km from the health facility (p=0.012) and who had a treatment supporter (p=0.030).

Conclusion: Half of the study participants had optimal adherence to their scheduled clinic visits since enrolment into the Option B+ program, and 30% were lost to follow up over the first two years. Staying closer to the health facility where the woman received ART, knowing one's HIV status before pregnancy or earlier in pregnancy, and initiating ART earlier in pregnancy, increased the likelihood of optimal adherence to ART and RIC at 24 months postnatal. Additionally, having a treatment supporter increased the likelihood of optimal adherence.

KEY WORDS: Adherence**,** Antenatal**,** Antiretroviral Therapy**,** Factors**,** HIV**,** Lifelong, Option B+, PMTCT**,** Postnatal and Retention

DECLARATION

I declare that "*Adherence to Treatment and Retention in Care among Postnatal Women who were initiated on Antiretroviral Therapy during Antenatal and Postnatal Period in Lusaka District, Zambia"*, is my work. The study has not been submitted for any degree or examination in any other university and that all the sources I have used or quoted have been acknowledged accordingly and included in complete references.

Full Name: Dr Stephen Mupeta

Date: 24 October 2021

Signature: 

ACKNOWLEDGEMENTS

The successful completion of this study has come as a result of the guidance and support I received from various individuals and institutions from the time of conceptualisation of the study to the development of this report. My first acknowledgement goes to my supervisor, Professor Brian van Wyk, who has provided consistent guidance and support throughout the process.

I would like to thank the team that supported me in data collection (Sharon Nalishebo, Misheck Kagele, Mweene Mukumba, Kafula Mubemba, and Francis Kunda), design of the data collection tool and data management (Thabo Simutanyi, Bruce Sianyeuka, and Emily Keyes), those who supported me in organising the data collection team (Jean Banda and Milupi Matokwani), and to Dr Gershom Chongwe, Dr Margaret Kasaro, and Dr Wilbroad Mutale for useful feedback to my proposal.

I would like to extend my special thanks to the Ministry of Health for allowing me to conduct this study in their health centres, especially the management and staff of the health facilities at which this study was conducted.

My last and special thanks go to my wife, Judith Lembela Mupeta and our three boys, Kaliki Mupeta, Ng'andwe Mupeta, and Mwansa Mupeta for their understanding and support during the busy period of my studies, especially during the periods I had to spend away from home to study.

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ABBREVIATIONS AND ACRONYMS

AIDS:	Acquired Immune Deficiency Syndrome
ABM:	Andersen's Behavioural Model
ART:	Antiretroviral Therapy
ARV:	Antiretroviral
AZT:	Zidovudine
CSO:	Central Statistics Office
HAART:	Highly Active Antiretroviral Therapy
HIV:	Human immunodeficiency virus
IUCD:	Intrauterine Contraceptive Device
LTFU:	Lost to Follow Up
MCH:	Maternal and Child Health
MTCT:	Mother to Child Transmission
NVP:	Nevirapine
PMTCT:	Prevention of Mother to Child Transmission of HIV
RIC:	Retention in Care
UNAIDS:	United Nations Programme on HIV and AIDS
WHO:	World Health Organization

OPERATIONAL DEFINITIONS

Adherence: The extent to which a person's behaviour such as taking medication, following a diet, or making lifestyle changes, corresponds with agreed recommendations.

Retention in care: Refers to patients who are known to be alive and active on ART at the end of a follow up period.

Lost to follow-up: Refers to patients receiving ART who are more than three months late for a scheduled ART refill visit and are not transferred out or dead.

Option B+: Refers to the PMTCT regimen recommended by WHO which requires that HIV positive women are put on lifelong ART upon being found HIV positive regardless of their CD4 count

CHAPTER 1. INTRODUCTION

1.1 BACKGROUND

Over the last three decades, significant advances have been recorded in the prevention and treatment of HIV/AIDS leading to unprecedented gains in the fight against the disease (Fauci and Folkers, 2012). These advances include the use of antiretroviral (ARV) medication to treat and prevent HIV infection, voluntary medical male circumcision, education and counselling about HIV risk and behaviour change, condom use, and needle exchange programs for injection drug users. The abovementioned interventions were complemented by the utilization of a broader array of HIV testing and counselling approaches, including self-testing, provider-initiated counselling and testing, and community-based approaches as key entry points for HIV treatment (UNAIDS, 2017). Harm reduction interventions used in HIV prevention such as encouragement of condom use, clean needles and syringes, treatment of opiate addiction with opiate substitution therapy and other harm reduction interventions have been found to be good practices that have contributed to the reduction in HIV transmission (WHO, 2010). The scale-up of antiretroviral therapy (ART) contributed to a 48% decline in AIDS-related deaths globally, from a peak of 1.9 million in 2005 to 1.0 million in 2016 (UNAIDS, 2017). Higher treatment coverage and better adherence to treatment among women have been the main drivers to the rapid decline in AIDS-related deaths among women and girls - which were 27% lower in 2016 than they were among men and boys (UNAIDS, 2017). With 51% of people living with HIV globally being female, effective interventions targeted at women, including prevention of mother to child transmission (PMTCT) of HIV, can lead to further significant reductions in morbidity and mortality from HIV (UNAIDS, 2017).

Mother-to-child transmission (MTCT) of HIV, which can occur during pregnancy, labour and delivery, and during the breastfeeding period, has been responsible for most of the HIV acquisition among children (Kourtis *et al.*, 2001). Without any intervention, the risk of MTCT of HIV is 15% to 30% in non-breastfeeding HIV infected mothers, whilst breastfeeding by an infected mother increases the risk of MTCT to 20% to –45% (De Cock *et al.*, 2000). The PMTCT interventions aim to attain viral suppression in pregnant women so that they are unlikely to pass on HIV to the foetus in utero or during birth, and the neonate during breastfeeding. The

PMTCT measures are implemented using a four-pronged approach (UNAIDS, 2011). Prong one involves primary prevention of HIV infection among all women of reproductive age. Prong two targets the prevention of unintended pregnancy among HIV positive women. Prong three is aimed at the prevention of MTCT during pregnancy, at delivery and during breastfeeding. The fourth prong is ongoing HIV treatment, care and support for women and children living with HIV and their families. One of the key indicators of the PMTCT approach under prong three is that 90% of HIV positive pregnant women should receive perinatal ART or prophylaxis. These PMTCT measures complement the globally agreed 90-90-90 targets which require countries to have at least 90% of people living with HIV know their status, 90% of those who know their HIV status being started on sustained ART, and 90% of those receiving ART having viral suppression (UNAIDS, 2014). Providing ART to all pregnant and breastfeeding women diagnosed with HIV infection has three benefits, namely, improving the mother's health, preventing MTCT of HIV, and preventing transmission of HIV to a sexual partner (WHO, 2016).

In 2011, the global community committed itself to eliminating MTCT of HIV as a public health priority (WHO, 2014). This initiative, referred to as "*the global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive*", prioritized a set of countries that, in 2009, accounted for 90% of the global number of pregnant women living with HIV who needed targeted services to prevent mother-to-child transmission of HIV (UNAIDS, 2011). Zambia was among the 21 priority countries under the global plan. One of the two goals of the global plan was to reduce the MTCT rate at 18 months of birth to 5% or less among breastfeeding women, and 2% or less among non-breastfeeding women but acknowledged that non-adherence and loss to follow-up, particularly during breastfeeding, continued to leave infants vulnerable to acquiring HIV (UNAIDS, 2011).

To strengthen PMTCT programs and improve outcomes, the World Health Organization (WHO) issues regular updates and recommendations on the use of antiretroviral drugs during pregnancy, childbirth and the postpartum period for PMTCT. The first recommendations for the use of ARV drugs for PMTCT were issued in 2000 (WHO, 2001) and these have undergone several changes over the past 19 years. In 2010, WHO guidelines recommended two options for ARV prophylaxis for PMTCT, namely Option A and Option B (WHO, 2010). In Option A, pregnant

women are recommended to take Zidovudine (AZT) at 14 weeks of gestation and to be continued during pregnancy; and their newly born babies to receive Nevirapine (NVP) throughout the breastfeeding period. In Option B, pregnant women received triple ARV prophylaxis from 14 weeks of pregnancy to the end of the breastfeeding period, while their newly born babies received NVP for the first 4-6 weeks. In both options, lifelong ART was only recommended for women with a CD4 cell count ≤ 350 cells/mm^3 or those in the WHO clinical stage 3 or 4. WHO revised the PMTCT guidelines in 2013 providing two options for PMTCT, namely option B and option B+ (WHO, 2013). Option B+ involves initiating pregnant and breastfeeding women, diagnosed with HIV, on lifelong triple ARV drugs regardless of their WHO clinical stage or CD4 cell count; whilst Option B remains as above (WHO, 2013). WHO considers Option B+ as being of greatest benefit in settings with a high HIV prevalence, high fertility, and long duration of breastfeeding (WHO, 2016).

1.2 INTRODUCTION OF OPTION B+ REGIMEN IN ZAMBIA

Zambia has a generalized HIV/AIDS epidemic, with a national HIV prevalence rate of 11.1% among adults aged 15 to 49 (Central Statistics Office [CSO] and Ministry of Health [MOH], 2018). The prevalence is higher in women compared to men (14.2% vs. 7.5%) in this age group. The country also has a high total fertility rate of 4.7 children per woman, and prolonged breastfeeding is one of the common practices among most communities (CSO and MOH, 2018). Therefore, implementing option B+ PMTCT strategy can be of great benefit to Zambia. In 2013, the Ministry of Health in Zambia adapted option B+ as recommended by WHO (2013) implying that every pregnant woman who tests HIV positive is offered lifelong ART both for PMTCT and for sustained viral suppression. Studies done in Zambia since the adaptation of Option B+ have shown high acceptability and effectiveness of the regimen but with limited data on retention in care. A cross-sectional study of 427 women enrolled in the Option B+ program at five health facilities in Lusaka between November 2016 to March 2017 revealed that 63.2% of the women had a good attitude towards Option B+ and overall, the majority (77.8%) were willing to accept ART for life. The study also found that over half (54%) of the women had inadequate knowledge and about 30% of the women in the study still experience stigma and discrimination (Chanda *et al.*, 2018). However, the study did not reveal how these factors affected adherence and retention in care. A retrospective cohort study of pregnant women in six public health facilities in Lusaka

who were enrolled in option A and B programs in 2012 and option B+ in 2014, showed that option B+ was very effective in preventing infant infections (6% MTCT rate) than Option B (13% MTCT rate) despite not being more superior to option A (Hanunka, 2018). However, Option B+ regimen had very high attrition levels of 37% deaths, 40% transferred out and 23% unknown reasons which were above acceptable limits of 5-10%. Another retrospective cohort study of 1,444 women enrolled in the PMTCT program between 2007 and 2017 revealed that option B+ was more effective in preventing MTCT compared to option A and B regimen (2.9% vs. 6.5%) (Muyunda *et al*., 2020). However, this study did not measure retention in the two groups.

1.3 PROBLEM STATEMENT

The success of ART requires strict adherence to the treatment regimen to maximize the benefits of PMTCT, maintain maternal health, reduce the chances of sexual transmission as well as minimize the risk of drug resistance (Bartlett, 2002). Additionally, successful ART programs require retention in care for all who are enrolled in the treatment program (Thompson *et al.*, 2012). The introduction of option B+ in Zambia requires women who started on ART through the PMTCT program to not only need adhere to treatment throughout the pregnancy and breastfeeding period, but they must be retained in care during and beyond this period. Both adherence and retention in care are important to realizing positive clinical outcomes (Patel *et al*., 2010).

Long-term adherence to ART and retention in care is challenging in itself. The initiation of pregnant women on ART as part of option B+ brings additional challenges with adherence and retention in care because the affected women may not have been symptomatic prior to the diagnosis of HIV and may not experience the efficacy of the treatment and thus may not feel motivated to continue nor to strictly adhere to the treatment (Okawa *et al.*, 2015). Whilst several studies were conducted on adherence to medication for PMTCT prior to the introduction of option B+ in Zambia, and on the effectiveness of the option B+ regimen after its introduction, there is limited information on adherence and retention in care, and the factors that influenced the two outcomes among women initiated on ART in the option B+ program.

1.4 STUDY AIM AND OBJECTIVES

The aim of the current study was to determine the factors associated with adherence to ART and retention in care among postnatal women who were initiated on ART during the antenatal and postnatal period at five PMTCT centres in Lusaka District, Zambia.

The objectives of the study were:

i. To determine levels of adherence to ART among postnatal women initiated on ART during the antenatal and postnatal period using option B plus regimen.
ii. To determine retention in care levels among postnatal women initiated on ART during the antenatal and postnatal period using option B plus regimen.
iii. To determine the sociodemographic and clinical predictors of adherence to ART among postnatal women.
iv. To determine sociodemographic and clinical factors associated with retention in ART among postnatal women.

1.5 OUTLINE OF MINI THESIS

The current chapter elaborated the global and national perspectives on PMTCT and Option B plus including progress made in addressing HIV and the 90-90-90 global HIV targets. The chapter outlined the evolution of the PMTCT treatment regimen up to the recommendation of Option B plus, and the importance of retention in care and adherence to treatment to the elimination of mother to child transmission of HIV. Finally, the chapter elucidated the problem associated with retention in care and adherence to treatment, the lack of studies on retention in care and adherence to Option B plus at target facilities, and the aims and objectives of this study.

In Chapter 2, a literature review from various data sources on adherence to lifelong ART and retention in care for pregnant women and postnatal women is outlined. In addition, literature on factors associated with adherence and retention in care among patients on ART in different settings are outlined. Chapter 3 describes the research methodology; subdivided by an overview of the study aim and objectives, study design, description of the study setting, study population and sampling, data collection, data management and analysis, validity and reliability, and ethical considerations. The study results are presented in Chapter 4, and Chapter 5 focuses on discussing

the study findings. Finally, Chapter 6 outlines the conclusions and recommendations from the current study.

CHAPTER 2. LITERATURE REVIEW

2.1 INTRODUCTION

The success of ART requires strict adherence to medication to maximize the benefits of PMTCT, maintain maternal health, reduce the chances of sexual transmission, and minimize the risk of drug resistance (Bartlett, 2002). Additionally, successful ART programs require retention in care for all who are enrolled in the treatment program (Thompson *et al.*, 2012). This chapter will cover the globally accepted definition and measurement of adherence to ART and retention in care, a description of the literature on adherence and retention in sub-Saharan Africa and Zambia, and finally factors associated with adherence to ART and retention in care.

2.2 ADHERENCE TO ART

WHO (2015) defines adherence as the extent to which a person's behaviour such as taking medication, following a diet, or making lifestyle changes, corresponds with agreed recommendations from a health care provider. Optimal adherence to ART is defined as taking more than 95% of prescribed drugs at the correct dosage and intervals (Wakibi *et al.*, 2011). Studies indicate that adherence levels of at least 70% to 80% of ART doses are required to achieve adequate viral suppression using the current combination of antiretroviral drugs (Martin *et al.*, 2008; Kobin and Sheth, 2011).

2.3 MEASUREMENT OF ADHERENCE

Measurement of adherence can be either direct or indirect (McRae-Clark *et al.*, 2015). The most commonly used indirect measures of adherence to medication are self-reported adherence, electronic measurement of adherence, pharmacy refills and claims data, and pill counts. Self-reported measures of adherence include the use of diaries and questionnaires and are simple to administer. However, some patients may not be willing to periodically answer a series of questions or may not regularly enter their medication administration information in a diary. Additionally, self-reported adherence is susceptible to manipulation by patients and recall bias. Diaries may be less influenced by recall bias, and they have been used to improve rates of adherence to medication (Van Berge Henegouwen *et al.,* 1999). Electronic measurement of adherence has been used in HIV care for many years. However, Rotzinger *et al.* (2016) found

that electronic drug monitoring underestimated medication adherence and that it should be combined with patient interviews to ascertain adherence. Clinic attendance logs have been found useful and applicable as an indirect measure of adherence in low resource HIV/AIDS care settings across sub-Saharan Africa (Ross-Degnan *et al.*, 2010). Other indirect methods include pill counts, prescription refills, and patient clinical response but these are equally unreliable as they can either be altered or influenced by other factors (Osterberg, 2005). Pill counts involve counting the number of pills that remain in the patient's medication bottles or vials. Although this method may appear simple, the method has many problems as patients can switch medicines between bottles and may discard pills before visits to appear to be following the regimen (Pullar *et al.,* 1989). For these reasons, pill counts may not be a good measure of adherence. Prescription refilling provides an accurate measure of adherence provided that the refills are measured regularly at several points in time. However, this system requires a good medical system that uses electronic medical records and a closed pharmacy for it to provide objective information on rates of refilling prescriptions. This information can be used to assess whether a patient is adhering to the regimen and to corroborate the patient's responses to direct questions or on questionnaires (Steiner, 1997). Measuring adherence to medication by use of the patient's clinical response has been used in many observational studies that have evaluated the association between medication adherence and outcomes (Osterberg, 2005). In the chronic coronary artery disease setting, non-adherence to cardio-protective medications was associated with a 10% to 40% relative increase in the risk of cardiovascular hospitalizations and a 50% to 80% increase in the risk of mortality (Ho *et al.,* 2008).

Direct measures of adherence include the measurement of levels of medication or metabolites in the blood or urine (Osterberg, 2005). In this method, patients' blood or urine samples are examined at intervals for levels of medication and biological markers, which are directly affected by ingestion of medication. Such methods are expensive and may not be feasible in resource-constrained settings. A cheaper direct method of measuring adherence is directly observed therapy in which the patient takes medication under the direct observation of a health care provider. However, even with this method, patients can hide pills in the mouth and then discard them later and it is impractical for routine use (Osterberg, 2005).

In resource-limited settings, indirect measures of adherence are the most commonly used. In Zambia, both self-reported adherence to treatment through measurement of missed doses, the use of clinic attendance logs, and pharmacy refills are applied (MoH, 2016).

2.4 RETENTION IN CARE

A clear definition of terms is critical when evaluating outcomes of ART programmes. WHO (2011) defines retention in ART care as continuous engagement with the health facility from the time of initiation to ensure lifelong ART. The WHO definition can be interpreted by a formula measuring retention in care as equal to all patients ever started on treatment minus the sum of (patient who dies plus patients who stop treatment plus patients who are lost to follow up) (WHO, 2013). A patient is retained in care if they visit a facility within 90 days of their last scheduled appointment for medicine collection, laboratory testing, and/ or clinical review and is not documented as having died, stopped treatment, transferred out, or as lost to follow up (LTFU).

In the PMTCT program in Zambia, patients are followed up for 24 months postnatal before being transferred to the general ART clinic. A patient is considered to have been retained in care if they continue clinic visits for PMTCT for 24 months postnatal.

2.5 ADHERENCE AND RETENTION IN ART IN SUB-SAHARAN AFRICA

Long-term retention in care and strict adherence to treatment are critical for viral suppression, which will, in turn, reduce MTCT, improve maternal health and prevent transmission to sexual partners (Koss *et al.*, 2017). However, adherence to ART and retention in care has been a challenge in sub-Saharan Africa where 24-month retention in care for ART between 2007-2009 was 70% (Fox and Rosen, 2010). A meta-analysis of adherence to ART or PMTCT during and after pregnancy in low, middle, and high-income countries showed that 74% of pregnant women in these countries were adherent to the treatment and that adherence was higher during pregnancy compared to the postpartum period (Nachega *et al.*, 2012). Studies on adherence to ART for PMTCT have shown varied results within sub-Saharan Africa.

One study in urban Kenya showed adherence levels of 98% of women (Imbaya, 2008) whilst

another study in rural Uganda showed adherence levels of 38% (Barigye *et al.*, 2010). A meta-analysis of 44 studies from 15 sub-Saharan African countries reported significant drop-offs along the cascade of PMTCT care for mother-baby pairs: 70% of HIV-positive pregnant women received antiretroviral prophylaxis; 64% of HIV-exposed infants were tested for HIV using DNA polymerase chain reaction (PCR) at six weeks after birth; and 55% were tested between one year and 18 months of age (Wettstein *et al.*, 2012). A study of Malawi's Option B+ program revealed that pregnant women who initiated ART for their own health were more likely to be retained in care compared to women who were initiated on ART for PMTCT (Tenthani *et al.*, 2014). In this program retention in care at 36 months varied between 65- 87%.

A study in the Zomba district in Malawi found 79% retention in care among women initiated on ART for PMTCT during the antenatal period (Chan *et al.*, 2016). Analysis of data from 546 health facilities offering Option B+ in Malawi showed retention in care of 77% at 12 months, 71% at 24 months, and 70% at 36 months (Haas *et al.*, 2016). Operational research on the impact of Option B+ on the PMTCT program in Lilongwe revealed that whilst there was no significant difference in the proportion of women initiated on ART during the antenatal period before and after commencement of option B+ regimen in Malawi (79% vs. 82%), retention in care at six months was lower following the introduction of Option B+ compared to the period before (79% vs. 89%) (Kim *et al.*, 2015). A study in South Africa reviewed that 58% of HIV-infected pregnant women in care were lost to follow-up (LTFU) by six months after delivery (Clouse *et al.*, 2013). Other studies of Option B+ programs in sub-Saharan Africa have also shown poor retention in care. In Ethiopia retention in care at six months was 88% (Mitiku *et al.*, 2016); and in Zimbabwe 83% (Dzangare *et al.*, 2016). Retention in care at one year in Ghana was 66% (Reece, 2016), whilst a study in Nigeria revealed that 66% of the mothers completed the postnatal follow-up (Rawizza *et al.*, 2015).

A retrospective cohort study that examined appointment-adherence for newly enrolled patients at a regional referral hospital in western Kenya revealed that 44% of the patients defaulted on their scheduled clinic appointments (Muthusi *et al.,* 2016). However, some studies in Africa have shown high rates of adherence to scheduled clinic appointments. A survey conducted in Uganda involving 763 patients on ART in 15 health facilities, who were followed for an average of 33

months, revealed that 97% of the patients had not missed their doses in the last week while 93% had not missed their appointments in the last three months (Shumba *et al.,* 2013). Similarly, in a prospective cohort study involving 392 patients on ART in a district hospital in Uganda who were prospectively monitored over a 28-week period, 92% of the patients attended all appointments for their refills (Kunutsor *et al.,* 2010). The above synopsis shows that adherence and retention in care are problematic in sub-Saharan Africa and that they vary between countries and settings. Hence, there is a need to study factors that influence these two outcomes in any particular setting where option B+ programs are implemented. This will inform the design of targeted interventions to address adherence and retention in care problems, where needed.

2.6 ADHERENCE TO ART AND RETENTION IN CARE IN ZAMBIA

Studies done in Zambia prior to the introduction of option B+ showed that adherence to the prescribed medication for PMTCT was a problem. A longitudinal study conducted between 2011 and 2014 revealed that the ART adherence rate was 82.5 % during pregnancy, 84.2 % at one week postpartum, 81.5 % at six weeks postpartum, and 70.5 % at 24 weeks postpartum (Okawa *et al.*, 2015). Another study of 320 HIV-positive postpartum women in Lusaka district prior to commencement of option B+ program showed that 95% of postpartum women on lifelong triple ART (who were eligible to start ART), were adherent to treatment compared to 83% of women taking the short-course prophylaxis using option A (Hampanda *et al.*, 2017). Whilst no study has been done on adherence and retention in care among postnatal women commenced on lifelong ART during the antenatal and postnatal period in Zambia, other studies done among HIV positive people on ART in the general population report low retention in care. A community follow-up study of 1 343 patients who missed a visit (early defaulters) in Lusaka, found that of 789 patients, 48% had died; and 31% of the patients who were still alive, returned to the clinic (Krebs *et al.*, 2008). According to Zambia's 2014 report to the United Nations General Assembly special session on HIV and AIDS, 76.5%, 59%, and 54% of patients on ART were retained in ART at 12, 24 and 60 months after initiation respectively between 2010 and 2013 (MoH/NAC, 2014). Retention in care at 12, 36 and 60 months in the Mansa district of Luapula Province, was observed to be 91%, 59% and 52% respectively (Malebe *et al.,* 2014). In another study, despite patients starting ART late with a median CD4 cell count of 145 cells/ml, retention in care at 12 months was 75%; with 15% lost to follow-up, and 11% were reported to have died (Scott *et al.*,

2014). Recent studies conducted after commencement of the option B+ program in Zambia show that the use of option B+ regimen is effective in PMTCT and has high acceptability, but some revealed high rates of loss to follow-up. However, none of the studies that was done after the introduction of option B+ measured adherence and retention in care as primary outcomes.

2.7 FACTORS ASSOCIATED WITH ADHERENCE AND RETENTION IN CARE

There are multiple factors affecting adherence to ART in the general population and among women on lifelong ART initiated during pregnancy using option B+ Regimen. One way to classify and understand these factors is by using Andersen's Behavioural Model (ABM) on the use of health services; which provides a theoretical framework for understanding how patient and environmental factors impact health behaviours and outcomes (Andersen, 1995). The factors identified in ABM are *patient factors* (predisposing factors such as stigma, mental illness, substance abuse, and health literacy; enabling factors such as social support, reminder strategies, transportation, housing, insurance; and perceived need based on symptoms and health beliefs), *health care environment factors* (health system factors such as pharmacy services and co-location of services; clinic factors such as appointment scheduling and clinic experience; health care provider factors such as trust, empathy, and individualized care), and *external environment* factors related to other competing life activities. In addition, the factors can be classified either as facilitating patient and environmental factors and patient and environmental factors that act as barriers. (Boyles, 2011; Lifson, 2013; Bezabhe, 2014).

2.7.1 FACILITATORS OF ADHERENCE TO TREATMENT AND RETENTION IN CARE

The factors facilitating adherence to ART can be categorized as facilitating patient factors and facilitating environmental factors.

Facilitating Patient Factors

Facilitating patient factors include older age, self-efficacy and health literacy. Younger women were found to be less likely accept combination prophylaxis for PMTCT AND to be retained in care than older women, in a study from Tanzania (Kirsten *et al*., 2011). A multicenter retrospective cohort study in Zambia, Uganda and Tanzania found that older patients 30 years and above were more likely to be retained in care compared to younger patients less than 30 years old (Koole *et*

al., 2014). A study in Malawi on the influence of self-efficacy on the relationship between depression and HIV-related stigma with art found that self-efficacy mediated and moderated the relationship between stigma and ART adherence (Umar *et al*., 2019). A study on a multimedia-based antiretroviral therapy adherence intervention for counsellors and patients in South Africa called "Masivukeni" showed that good health literacy leads to better patient adherence to ART (Remien *et al*. 2013).

Facilitating Environmental Factors

Facilitating environmental factors include medication-related factors such as a simple drug regimen, simple dosing and use of mechanical devices and technologies (Wasti *et al.*, 2012). Others include health system factors such as adequate number of human resource availability, adequate financial and other material resources, and a good relationship with health care providers (Chirambo *et al*., 2019). Socio-economic factors include short distances to the health facility and reduced transport fees, beneficial socio-cultural practices, and availability of social support (Peltzer *et al*., 2013). A meta-analysis of randomized controlled trials comparing once-daily versus twice-daily ART regimens showed that lower pill burdens and once-daily regimens were independently associated with improved adherence to ART (Nachega *et al*., 2014).

A study on resourcing and relational health system factors that influence retention in care for people living with HIV in Zambia demonstrated a good health system with adequate, well trained, health workers who have good attitudes and health facilities that are well resourced with supplies, facilitates retention in ART care (Mwamba *et al*., 2018).

Other studies have demonstrated that improved retention in PMTCT care has been associated with male partner involvement, couples HIV counselling and testing programs, and disclosure of HIV status disclosure (Conkling *et al.*, 2010; Tam, Amzel and Phelps, 2015; Ambia and Mandala, 2016).

2.7.2 BARRIERS TO ADHERENCE AND RETENTION IN CARE

The barriers to adherence and retention in care can be distinguished as patient barriers and environmental barriers.

Patient Barriers

Patient-related barriers include factors such as being of young age, mental health such as depression, forgetfulness, substance abuse, poor self-efficacy, low health literacy, patient health beliefs, and perceived wellness. Young age has been associated with poor retention in ART care. Maternal age younger than 20 years has been associated with poor adherence and retention in care (Stringer, 2010). A systematic review and meta-analysis of studies in Africa on retention ART care among postpartum women reviewed participants who were younger (under 25 years) were at higher risk for LTFU (Knettel *et al*., 2018). Physical impairment and cognitive limitations, lack of knowledge about the disease and the reasons medication is needed, lack of motivation, low self-efficacy, and substance abuse have been reported as barriers to adherence and retention in care (Kalogianni, 2018). Patient's health beliefs influence adherence and retention in care. A qualitative study using the ecological framework to conceptualize factors affecting retention in care of patients on antiretroviral treatment in Kabwe District, Zambia, revealed that patients and healthcare workers agreed that some church pastors in their communities who conducted healing prayers sessions persuade patients to discontinue ART because they are healed (Mukumbang *et al*., 2017). A meta-analysis of studies on predictors and correlates of adherence to ART showed that psychological factors are among the strongest correlates of non-adherence, stronger than other factors such as pill burden (Langebeek *et al*., 2014).

Environment Barriers

Literature identifies various categories of factors that hinder adherence to ART and RIC. Kalogianni (2018) argues that adherence is a multidimensional phenomenon that is determined by the interaction of five sets of factors that are barriers to adherence and retention in care. Four of these factors are environmental barriers, namely:

i. *therapy-related factors* such as the complexity of the medication regimen which includes the number of medications and number of daily doses required, duration of therapy, therapies that interfere with a person's lifestyle and side effects;
ii. *health system factors* such as medication stock-outs, relationship with health care providers, staff shortages, long waiting times, poor services delivery;

iii. *socio-economic factors* such as poverty, lack of family support, food insecurity, stigma and discrimination and transportation challenges; and
iv. *socio-cultural factors* such as alternative treatment, male dominance and gender-based violence, and religious beliefs (Kalogianni, 2018).

Other researchers have found an array of other clinical and sociodemographic factors that negatively influence adherence to ART for PMTCT. Some of the sociodemographic factors include, not having high school-level education (Albrecht *et al.*, 2006), illiteracy, and no history of prior foetal or infant death (Stringer *et al.*, 2003). A qualitative study using the ecological framework to conceptualize factors affecting retention in care of patients on antiretroviral treatment in the Kabwe District, Zambia, revealed that long distance to health facilities was a barrier to attending scheduled clinic appointments for ART (Mukumbang *et al*., 2017).

Another qualitative analysis of the barriers to antiretroviral therapy in Swaziland found distance to health facilities as a barrier (Ahmed *et al.,* 2017). Other studies from various countries have revealed distance to a treatment center as a barrier to adherence. These studies include South Africa (Eyassu *et al.,* 2016); Nepal (Wasti *et al.,* 2012); Kenya (Wakibi *et al.,* 2011); and Nigeria (Chineke *et al.,* 2015). The clinical factors that negatively influence adherence to ART for PMTCT medication include multi-gravidity, one or fewer antenatal clinic visits, vaginal delivery compared to caesarean section, and single-dose Nevirapine regimen compared to Highly Active Antiretroviral Therapy (HAART) regimen (Stringer, 2010). The first diagnosis of HIV infection during pregnancy (Laine *et al.*, 2000), and longer intervals between HIV testing and delivery were also found to negatively impact adherence (Stringer *et al.*, 2005). Other studies have identified factors associated with LTFU of patients on ART to include, being younger than 25 years, ART initiation during pregnancy, and pregnancy itself (Barker, Mphatswe and Rollins, 2011; Boyles *et al.*, 2011; Tenthani *et al.*, 2014; Tweya *et al.*, 2014).

2.8 SUMMARY

Viral suppression is key to achieving epidemic control of HIV including the elimination of mother to child transmission. To achieve viral suppression, retention in care and adherence to treatment is vital to ensuring the efficacy of ART. Achievement of the 90-90-90 initiative will

not be possible without ensuring adherence to treatment and retention in care of women enrolled in the option B+ program. Therefore, understanding the factors that influence adherence to treatment and retention in care is critical to the success of the PMTCT program, as this will help in designing appropriate interventions to address the gaps.

CHAPTER 3. METHODOLOGY

3.1 STUDY DESIGN

A quantitative, retrospective cohort analysis of 311 postnatal women who were initiated on option B+ regimen at five PMTCT centres in Lusaka District between 1 January 2017 and 30 April 2018, was done. The retrospective study design allowed for the collection of data elements on exposure and outcome variables that had already occurred. The primary outcomes were retention in care and adherence to treatment whilst exposure variables were the selected sociodemographic and clinical characteristics influencing the outcomes. The retrospective cohort study design was appropriate because it was inexpensive and could be conducted in a relatively short time as the researcher collected data on exposure and outcome variables that had already occurred. The retrospective cohort study design establishes the temporal relationship between different exposures and the outcome, ensuring that the measurement of the exposure is not biased by the outcome (Ho, Peterson and Masoudi, 2008). In this study the exposure

3.2 STUDY SETTING

The study was conducted in Lusaka District, in Lusaka Province, Zambia. The district is located in the south-central part of the country, covers an area of about 360 square kilometers and is home to a projected population of 2.5 million people which is 78% of the population of Lusaka province (CSO, 2011). The district has a total number of 60 government health facilities of which 38 provide PMTCT services (MOH, 2019).

The study was conducted at five PMTCT centres, namely Chawama Level One hospital, Kanyama Level One Hospital, Matero Level One Hospital, George Health Center, and Chaisa Health Center. The study sites were purposively selected because they attended to the highest number of women on the PMTCT program in the district, based on 2018 PMTCT data, and had been implementing Option B+ regimen for at least two years (MoH, 2019). The PMTCT program in Zambia was initiated in 1999, and at the time of this study, Lusaka District had 38 PMTCT centres (MoH, 2019). The five study sites are among the 28 health facilities in the district that use the SmartCare electronic health record system. The SmartCare record system is a robust online data management system consisting of various modules including the PMTCT

module. The system aims to improve the timeliness of data processing on maternal and child health, HIV/AIDS, tuberculosis and malaria interventions, and ultimately enhance the utilization of the data by health care system officials in the respective jurisdictions (Muyunda, 2011). This database is used to collate sociodemographic and clinical data of patients on ART at the selected health centres. The use of the SmartCare online data management platform made the five sites ideal for this study as data collection was easier.

3.3 STUDY POPULATION AND SAMPLING

The study population constituted postnatal women living with HIV who were initiated into lifelong ART during pregnancy and the immediate postnatal period using option B+ regimen between 1 January 2017 and 30 April 2018 and received services from the five selected PMTCT centres in Lusaka District. The study focused on data from 1 January 2017 to 30 April 2018 because the clients had to be followed up for at least 24 months for the researcher to analyse the exposures and outcomes of interest at 6, 12, 18 and 24 months postnatal. In addition, option B+ guidelines were only fully rolled out to all PMTCT sites in Zambia by the end of 2015, and Option B+ module was integrated into the SmartCare system in 2017. Information obtained from Lusaka District Health office showed that the five high volume PMTCT centres collectively initiated 1 313 women on lifelong ART for the first-time during pregnancy between 1 January 2017 and 30 April 2018 as shown in the table below and this was used as the study population.

Sample size calculation

The sample size was calculated using Yamane's formula (Yamane, 1967) as shown below:

$n= N \div [1+N(e)^2]$, where n is the minimum sample size, N is the study population and e is the level of precision (for this study precision will be +/-5%). $n= 1,313 \div [1+1,313\ (0.05)^2] =$ **307.**

Sampling strategy

The cluster random sampling method was used to select files to be included in the study. The selected files were clustered according to the facility and the sample of files per facility was determined by the proportion of the patients that each facility had recorded in the study period out of the total. Within each cluster (health centre), systematic random sampling was done using

a calculated sampling interval. The table below shows sample estimation per facility and sampling intervals.

Table 3.1 Sample estimation per health facility (study site)

Facility	**Number of PMTCT clients seen during the study period**	**Proportion of clients out of study population**	**Sample size per facility**
Chawama Health Centre	234	0.178	55
Kanyama Health Centre	349	0.266	82
Chaisa Health Centre	242	0.184	56
George Health Centre	217	0.165	51
Matero Reference Centre	271	0.206	63
Total	**1 313**	**1**	**307**

3.4 DEVELOPMENT AND PRETESTING OF THE DATA COLLECTION TOOL

Data on patient sociodemographic variables, disease characteristics, treatment regimens and other clinical information were extracted from SmartCare using a data extraction tool (Appendix I). The data collection tool was specifically designed for this study by the researcher, in consultation with PMTCT program officers and the district health information officer and was based on data elements from the Ministry of Health data management tools. The data extraction tool was programmed on tablets using Survey Solutions, a free software developed in the data group of the World Bank. The tool was pretested prior to the commencement of data collection to improve the validity of the research. The tool was pretested on five PMTCT patient records to ensure that the selected variables could be collected from the SmartCare data management system. The study team concluded that all the variables were found on SmartCare, but some data elements had to be redefined. For example, whilst the researcher initially intended to measure the missed dose of medication during the month prior to the visit, SmartCare only captured the

missed dose during the seven days prior to the visit. In addition, whilst SmartCare had a provision to collect data on the HIV exposed infants, this data was not routinely entered in the PMTCT modules and data collectors had to access the physical records for the infant - which was a difficult task. Following the pretest, the data collection tool was refined.

3.5 DATA COLLECTION

The researcher recruited data collectors who were data entry clerks at the study site. The data collectors were trained by the principal investigator, a volunteer from the central statistics office of Zambia who has experience in data management, and staff specialized in PMTCT and data management from the Ministry of Health. This team also helped in the supervision of data collection.

Data collection took place from 18 March to 9 May 2020. The data collectors extracted data, of all PMTCT clients from SmartCare, and reviewed the records based on the inclusion criteria, calculated sample size and following the sampling methodology. Clinical records of pregnant women who were initiated on ART during pregnancy between 1 January 2017 and 30 April 2018 were extracted for the sociodemographic and clinical characteristics under investigation, and outcomes of interest using a data extraction sheet (Appendix 1).

Patients enrolled in PMTCT care program in Zambia are followed up for 24 months before they are transferred to the general ART clinics. Therefore, under this study, data on patient sociodemographic variables and clinical characteristics were abstracted with the endpoint being LTFU or retention in care by the end of the 24-month follow-up period.

The data collectors entered the selected variables into the data extraction tool which was pre-programmed on tablets and uploaded to an online central portal for quality monitoring. Only the researcher and supervisors had passwords to access the consolidated online data. Data was blinded from the researcher, the data cleaning and data analysis team, and all those contributing to report writing and review. The client files were only accessed by the data collectors and health centre staff who helped with shortlisting client files that met the inclusion criteria.

3.6 DATA MANAGEMENT AND ANALYSIS

Data was transferred to Survey Solutions software and analysed using Stata statistical software (Stata Corp., Texas, USA). During the data collection period, data was periodically exported to Excel for the researcher to review for completeness, duplicate entries, and invalid entries such as women who started ART before pregnancy. Any wrong data entry such as unreasonable age of 5 years or body weight of 5 kilograms, was rejected, and the data collector had to make necessary corrections and resubmitted. In cases of invalid entries such as women who started ART before pregnancy, the record was deleted, and the data collector had to choose a replacement. Once data entry was complete, the researcher reviewed the complete set again to ensure it was clean before analysis.

Univariate analysis was done to describe the sociodemographic and clinical characteristics of the sampled women. Continuous variables were reported using the means and standard deviations, while categorical variables were summarized using frequencies and percentages. Kaplan-Meier survival analysis was done to estimate the proportion of women retained in care at 6, 12, 18 and 24 months postnatal. Bivariate analysis was conducted to determine the significance of associations between adherence and retention in care, and sociodemographic and clinical variables. Chi-square tests were conducted with cut off for statistical significance set at *p*-value <0.05. Where statistical significance was detected, odds ratios (OR) with 95% confidence interval (95% CI) were calculated to illustrate the strength of associations between independent and dependent variables. To measure associations between socio-demographic and clinical characteristics, and adherence to treatment, the researcher chose to use the variable on missing clinic appointment and not missing clinic appointment to take a dose of ART because data on missing an appointment was objectively recorded in the patients' files whilst missing a dose relied on patient recall which could be subjective. The researcher dichotomized adherence into optimal adherence for the study participant who did not miss any clinic appointment, and poor adherence for study participants who missed at least one clinic appointment.

3.7 VALIDITY AND RELIABILITY

The concepts of reliability and validity are used to assess the quality of a study. Validity refers to the extent to which the results of a study measure what is intended to be measured which implies

that the conclusions made from the study are true (WHO, IDRC, 2003). In this study, the researcher enhanced the validity of the results by strictly adhering to the study protocol, particularly by employing systematic random sampling as per the sampling strategy above, and strictly adhering to eligibility criteria to prevent selection bias. Data was blinded from the researcher, the data cleaning and data analysis team, and all those contributing to report writing and review. The client files were only accessed by the data collectors and health centre staff who helped with shortlisting client files that met the inclusion criteria, and a different data analysis team.

Reliability refers to the extent to which the results produced from a study can be replicated if the study was repeated by other researchers in the same circumstances, implying that the findings are repeatable (WHO, IDRC, 2003). Reliability of the results was ensured by using a predesigned data extraction tool that was pretested prior to the commencement of data extraction. Data collectors underwent training on the data collection process, data recording, and research ethics. After completion of data entry, the data was reviewed by an independent person for completeness, accuracy, and consistency, to enhance reliability.

3.8 ETHICS CONSIDERATIONS

The researcher received ethics clearance from the University of Western Cape Biomedical Research Ethics committee in South Africa (Ref. BM19/7/22, Appendix II), and the Eres Converge research ethics committee in Zambia (Ref. 2019-Oct-010, Appendix III). There was no direct contact with patients under this study, and they were not contacted to give consent for use of their medical records for study purposes. Permission was obtained from the Ministry of Health (Appendix IV) and the Zambia National Research Authority (Appendix V), for the researcher to use the patients' medical records from the targeted PMTCT centres.

The study had minimal risks to the study subjects as no actual patients were interviewed and the medical records were not identified with a physical patient. Patient records were treated with the utmost confidentiality by removing any personal identifying information from the data extraction form and computer files. Each client file was assigned a unique identification number which was recorded on the data extraction tool and the client file. Only unique identification numbers were

used on the data extraction form, and no names or any other information that could be traced to the actual client was recorded.

All data records, once entered in data extraction software, were only accessed by the data analysis team. The client files were only accessed by the data collectors and health centre staff helping with the extraction of files and shortlisting client files that met the inclusion criteria. The soft copies of the metadata were kept in a password protected folder and will be kept for a minimum period of three years.

This chapter described the methodology used in this study in terms of study design, study setting, study population, and sampling method. The chapter also described the process taken in designing the data collection tools, how the data collection was done, the data management, and data analysis process. Lastly, the chapter describes the measures taken to ensure validity and reliability of the study findings and the steps taken to ensure adherence to study ethics. The next chapter will describe the result from this study and the associated data analysis.

CHAPTER 4. RESULTS

4.1 INTRODUCTION

This chapter describes the results from the study - how the study sample was realized; the baseline socio-demographic and clinical characteristics of the study participants; retention in care at 6, 12, 18 and 24 months, and adherence. Further, the section describes the determinants of retention in care and adherence to ART.

4.2 REALISATION OF SAMPLE

Data of 311 postnatal women who were initiated on option B+ regimen at five PMTCT centres in Lusaka district between 1 January 2017 and 30 April 2018, were extracted from the SmartCare data management system. To identify patients to be included in the study, a cluster random sampling method was used based on the inclusion criteria. The selected files were clustered by the facility and the number of files selected per facility was determined by the proportion of the patients that each facility had recorded in the study period out of the total. Within each cluster (health centre), systematic random sampling was done using a calculated sampling interval. Once the files were randomly selected, variables of interest were extracted and entered into survey solutions software which is a Computer-Assisted Personal Interview (CAPI) technology developed by the World Bank (World Bank, 2018). The total sample realized was 311. Four PMTCT centers (Chawama, Chaisa, Matero Reference, and George) extracted data for one extra client each as shown in Table 4.1 below. Data from 56 patient files were extracted at Chawama health center, 82 at Kanyama, 57 at Chaisa, 52 at George, and 64 in Matero Reference.

Table 4.1 Realized sample by Health Facility

Facility	Planned Sample	Realized Sample n(%)
Chawama Health Centre	55	56(101.8)
Kanyama Health Centre	82	82(100.0)
Chaisa Health Centre	56	57(101.8)
George Health Centre	51	52(102.0)
Matero Reference Centre	63	64(101.6)
Total	**307**	**311(101.3)**

4.3 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

The median age of the study participants was 28 years with an inter-quartile range of 8 years. The majority of participants were between the ages of 20 and 34 years [257 (82.6%)] with the youngest 16 years and the oldest 48 years. Twenty participants (6.4%) were younger than 20 years (teenagers) whilst only two participants (0.6%) were 45 years or older.

Married women constituted the majority of the study participants [263 (89.1%)]. Most of the women had given birth at least once previously [271 88.5%)]; 196 (64%) had a history of giving birth two or more times, whilst 35 (11.4%) did not have a history of giving birth (para zero). Most of the study participants [278 (99.3%)] delivered a live baby and only 2 out of 280 women had a stillbirth and infant death each.

More than half of the participants [173 (64.1%)] had attained at least secondary education, with 15 (5.6%) having gone up to tertiary level. A small proportion [11 (4.1%)] indicated that they had not attended any formal schooling.

Of the 156 (50.2%) participants who had employment status recorded, 88 (56.4%) were unemployed, and 59 (37.8%) and 9 (5.8%) were in formal employment or self-employed, respectively.

The majority of the study participants [259 (83.3%)] lived within five kilometers of the health facility from which they received care for ART, and only 8 (2.6%) lived more than 10 kilometers away.

Most participants [276 (96.5%)] had disclosed their HIV status to someone; with the spouse being the person disclosed to by most [230 (80.4%)], followed by relatives at 52.2%, whilst a friend was the least disclosed to at [10 (3.5%)]. The majority of the study participants [266 (94%)] reported that they had a treatment supporter.

Data on the HIV status of the spouses was not available for 121 (38.9%) study participants. Of the 190 participants (61.1%) with records on the HIV status of their spouses, the majority [120 (63.2%)] indicated that they did not know the spouses' HIV status. Only 54 out of 70 (77%) women who knew the HIV status of their spouse, reported that their spouse was HIV positive; of whom 38 were on ART.

Table 4.2 Socio-demographic characteristics of the pregnant women initiated on Option B+ in Lusaka (N= 311)

Socio-demographic Variable	Category	Frequency n(%)
Age (in years)	15 - 19	20(6.4)
	20 - 24	76(24.4)
	25 - 29	92(29.6)
	30 - 34	89(28.6)
	35 - 39	27(8.7)
	40 - 44	5(1.6)
	>=45	2(0.6)
Marital status (N=295)	Married	263(89.1)
	Cohabiting	0(0.0)
	Never been married	18(6.1)
	Divorced	7(2.4)
	Widowed	7(2.4)
Parity (N=306)	0	35(11.4)
	1	75(24.5)
	2 - 4	180(58.8)
	>4	16(5.2)
Gravidity (N=306)	1	57(18.6)
	2	85(27.8)
	3 - 5	151(49.3)
	>5	13((4.2)
Outcome of the childbirth (N=280)	Live Birth	278(99.3)
	Still Birth	1(0.4)
	Neonatal Death	0(0.0)
	Infant death	1(0.4)
Any previous pregnancy/child loss (N=232)	Miscarriage	16(6.9)
	Elective pregnancy termination	0(0.0)
	Child death below 5 years	9(3.9)
	Child death above 5 years	3(1.3)
	None	204(87.9)
Highest education level attained (N=270)	No formal school	11(4.1)
	Primary Education	86(31.8)
	Secondary Education	158(58.5)
	Tertiary Education	15(5.6)

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Table 4.3 Socio-demographic characteristics of the pregnant women initiated on Option B+ in Lusaka (N= 311)/cont.

Employment status (N=156)	Unemployed	88(56.4)
	Self-employed	59(37.8)
	Formal Employment	9(5.8)
Distance (in kilometers) to health centre (N=311)	<1	92(29.6)
	1 to <5	167(53.7)
	5 to 10	44(14.1)
	>10	8(2.6)
Disclosure of HIV status (N = 286)	Yes	276(96.5)
HIV status of spouse (N=190)	Positive	54(28.4)
	Negative	16(8.4)
	Unknown	120(63.2)
Spouse on ART (N=54)	Yes	38(70.4)
	No/Not known	16(29.6)
Have a treatment supporter (N=283)	Yes	266(94.0)

4.4 CLINICAL CHARACTERISTICS OF STUDY PARTICIPANTS

WHO classification was recorded for 276 (88.7%) of the study participants. The majority of participants [269 (97.4%)] were classified as WHO stage I at the initiation of ART, with 6 (2.2%) and 1 (0.4%) as stage II and III, respectively.

The majority of the clients found out about their HIV-positive status during pregnancy [303 (97.4%)]; with 126 (40.5%) in the first trimester, 150 (48.2%) in the second and 27 (8.7%) in the 3rd trimester. Six clients (1.9%) found out their HIV-positive status before pregnancy and 2 (0.6%) found out during the postnatal period.

Just over half of the participating women [168 (54%)] commenced ART in the second trimester; followed by [108 (34.7%)] in the first trimester, and 31 (10%) and 4 (1.3%) in the third trimester and postnatal period, respectively. Almost all study participants [301 (96.8%)] were on Atripla (Tenofovir, Emtricitabine and Efavirenz). The majority [290 (97.0%)] of them had not changed ART regimens since commencing treatment. Most participants [263 (84.6%)] were on treatment for more than 12 months, and 28 (9%) were less than six months on treatment. Records on side effects from ART were not available for the majority of the clients [176 (56.6%)]. Out of the 135 clients with side effects recorded only 6 (4.4%) were reported to have experienced any side effects.

One-third of study participants [107 (34.6%)] reported being on other medication besides ART. Almost all participants who reported being on other medication [105 (98.1%)] had been on Septrin prophylaxis. One in ten clients [32 (10.3%)] had been on tuberculosis (TB) treatment since commencing ART and 4 (1.3%) had been admitted at least once for any reason.

Information on contraceptive use, following the last delivery, was not available for 58.7% (n=183) of clients. Out of the 128 clients who had this information in their records, 87 (68%) did not report contraceptive use. Out of the 41 participants who were on a method of contraceptive 16 (39.0%) were on injectable contraceptives, 15 (36.6%) on combined oral contraceptives, 5 (12.2%) on implants whilst 1 (2.4%) was on permanent method (bilateral tubal ligation). None of the clients was on an intrauterine contraceptive device (IUCD) and 4 (9.8%) were using condoms

for contraceptive reasons.

Only 36% (n=112) of the clients had at least one CD4 count recorded. Sixty-nine (22.2%) had only one test result recorded and 43 (13.8%) had 2 to 5 tests done. Based on the available records, the CD4 count was increasing in 29 (39.2%) of the participants and generally constant in 34 (45.9%) whilst 5 (6.8%) showed a reducing CD4 count.

Just over half of the study participants [174 (56%)] had at least one viral load count done. Sixty-nine (22.2%) had only one test result and 105 (33.8%) had 2 to 4 test results. Out of the clients with viral loads recorded, 65 (48.5%) showed generally constant trend, 50 (37.3%) was reducing whilst in 14 (10.5%) it was increasing.

Data on body weight was available for 285 (91.6%) of study participants. The bodyweight of almost one-third of the participants [79 (27.7%)] was either increasing [40 (14%)] or remained generally constant [39 (13.7%)], whilst almost half of the participants [141 (49.5%)] had their weight fluctuating, and 65 (22.8%) had their weight decreasing.

About two out of five clients 128 (42.8%) reported having missed a dose of medication within seven days prior to a visit.

Almost half of the study participants [154 (49.8%)] had missed at least one clinic appointment since commencing ART, whilst 155 (50.2%) had not. Out of the 154 clients who missed clinic appointments since commencing ART, 115 (74.7%) had missed more than once, with almost half [75 (48.7%)] having missed at least three times. The majority of the women [134 (87%)] who had missed a clinic appointment, did so more than three months prior to their last visit, 17 (11%) had missed their scheduled appointment between one and three months prior to their visit, and 3 (1.9%) had missed within the same month of their visit.

Table 4.4 Clinical characteristics of the pregnant women initiated on Option B+ in Lusaka (N= 311)

Clinical characteristics	Category	Frequency n(%)
WHO clinical stage at initiation	Stage I	269(97.4)
(N=276)	Stage II	6(2.2)
	Stage III	1(0.4)
	Stage IV	0(0.0)
Awareness of HIV status (N=311)	Before Pregnancy	6(1.9)
	In 1st trimester	126(40.5)
	In 2nd trimester	150(48.2)
	In 3rd trimester	27(8.7)
	Postnatal	2(0.6)
Timing of ART initiation (N=311)	Before Pregnancy	0(0.0)
	In 1st trimester	108(34.7)
	In 2nd trimester	168(54.0)
	In 3rd trimester	31(10.0)
	Postnatal	4(1.3)
ART Regimen (N=311)	AZT + 3TC + NVP	0(0.0)
	AZT + 3TC + EFV	1(0.3)
	AZT + 3TC + LPV-r	1(0.3)
	TDF + XTC + EFV400	301(96.8)
	TDF + XTC + DTG	4(1.3)
	TDF + 3TC + DTG	1(0.3)
	TAF + XTC + EFV400	1(0.3)
	ABC + 3TC + LPV-r	1(0.3)
	Any Other Regimen	1(0.3)
Change of Regimen (N=299)	Yes	9(3.0)
Duration on ART (months) (N=311)	<= 6	28(9.0)
	7 - 12	20(6.4)
	13 - 24	263(84.6)
Trend in body weight (N=285)	Increasing	40(14.0)
	Decreasing	65(22.8)
	Fluctuating up and down	141(49.5)
	Generally constant	39(13.7)
Treatment for TB (N=311)	Yes	32(10.3)
Being on other medication (N=309)	Yes	107(34.6)

Table 4.5 Clinical characteristics of the pregnant women initiated on Option B+ in Lusaka (N= 311)/cont.

	3	5(1.6)	1.6
	4	3(1.0)	1.0
	5	1(0.3)	0.3
Number of Viral Load tests Done	0	137(44.1)	44.1
(N=311)	1	69(22.2)	22.2
	2	70(22.5)	22.5
	3	30(9.6)	9.6
	4	5(1.6)	1.6
Trend in Viral Load counts (N=134)	Increasing	14(10.5)	10.5
	Decreasing	50(37.3)	37.3
	Fluctuating up and down	5(3.7)	3.7
	Generally constant	65(48.5)	48.5
Missed taking medication in 7 days prior to last visit (N=299)	Yes	128(42.8)	42.8
Missed a clinic follow-up appointment since commencing treatment (N=309)	Yes	154(49.8)	49.8

4.5 ADHERENCE TO TREATMENT

To measure associations between socio-demographic and clinical characteristics, and adherence to treatment, the researcher chose to use the variable on missing clinic appointment and not missing to take a dose of ART because data on missing an appointment was objectively recorded in the patient files whilst missing dose relied on patient recall which could be subjective. The researcher dichotomized adherence into optimal adherence for the study participant who did not miss any clinic appointments, and poor adherence for study participants who missed at least one clinic appointment since ART initiation. Based on this, 50.2% of the study participants had optimal adherence to ART.

4.5.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS AND ADHERENCE TO TREATMENT

Table 4.4 shows that distance to the health facility was significantly associated with adherence to ART (p=0.015). As shown in Table 4.6, compared with women who lived less than one kilometer from the health facility, those who lived between one and five kilometers away (44.2% vs 63%; OR=0.46 [95% CI 0.26 - 0.81]), or more than ten kilometers away from the health facility (25% vs 63%; OR 0.20 [95% CI 0.11 - 0.36]) had a lower probability of optimal adherence. However, the difference in the odds of optimal adherence to treatment between women who lived less than one kilometer from the health facility and women who lived between five kilometers and ten kilometers from the health facility did not reach statistical significance (50% vs 63%; OR=0.59 [95% CI 0.33 - 1.03]).

Having treatment support was significantly associated with adherence to ART (p=0.044). Compared to women who did not have a treatment supporter, those who had a treatment supporter had a higher probability of optimal adherence to treatment (50.9% vs 25%; OR=0.32 [95% CI 0.18 - 0.58]). However, even among the women who had treatment supporter adherence was a problem as almost half were non-adherent (49.1%; p=0.044).

There were no statistically significant associations between adherence to ART and age (p=0.153), marital status (p=0.899), parity (p=0.106), education status (p=0.539), employment status (p=0.513), Disclosure of HIV status (p=0.767), and the spouse's HIV status (p=0.845).

Table 4.6 Adherence to treatment by socio-demographic characteristics of pregnant women initiated on Option B+ in Lusaka (N= 311)

		Total	Optimal adherence n (%)	Poor adherence n (%)	*p*-value
Age (years)	15 – 24	95	47(49.5)	48(50.5)	0.153
	25 – 34	180	96(53.3)	84(46.7)	
	35+	34	12(35.3)	22(64.7)	
Marital Status	Never been married	17	7(41.2)	10(58.8)	0.899
	Married	263	131(49.8)	132(50.2)	
	Divorced	6	3(50.0)	3(50.0)	
	Widowed	7	3(42.9)	4(57.1)	
Parity	0	35	12(34.3)	23(65.7)	0.106
	1	74	36(48.6)	38(51.4)	
	2 to 4	179	100(55.9)	79(44.1)	
	>4	16	7(43.8)	9(56.2)	
Education level	No formal education	10	4(40.0)	6(60.0)	0.539
	Primary	85	37(43.5)	48(56.5)	
	Secondary	158	83(52.5)	75(47.5)	
	Tertiary	15	7(46.7)	8(53.3)	
Employment status	Not Employed	86	34(39.5)	52(60.5)	0.513
	Formal Employment	9	5(55.6)	4(44.4)	
	Self Employed	59	21(35.6)	38(64.4)	
Distance to Facility (km)	< 1	92	58(63.0)	34(37.0)	0.015*
	1 to <5	165	73(44.2)	92(55.8)	
	5 to 10	44	22(50.0)	22(50.0)	
	>10	8	2(25.0)	6(75.0)	
Disclosure of HIV Status	Yes	275	136(49.5)	139(50.5)	0.767
	No	9	4(44.4)	5(55.6)	
	Positive	54	28(51.9)	26(48.1)	
Spouse's HIV status	Negative	16	7(43.8)	9(56.2)	0.845
	Unknown	118	58(49.2)	60(50.8)	
Having a Treatment supporter	Yes	265	135(50.9)	130(49.1)	0.044*
	No	16	4(25.0)	12(75.0)	

4.5.2 CLINICAL CHARACTERISTICS AND ADHERENCE TO TREATMENT

Table 4.5 shows that there were statistically significant associations between adherence to ART and the stage of pregnancy (trimester) when HIV status was known (p=<0.001).

Table 4.6 shows that those who knew their status in the first trimester (66.4% vs 83.3%; OR=0.40 [95% CI 0.20-0.77]), in the second trimester (36.9% vs 83.3%; OR=0.12 [95% CI 0.06 - 0.23], or in the third trimester (40.7% vs 83.3%; OR=0.14 [95% CI 0.07 - 0.27]), and during the postnatal period (50% vs 83.3%; OR=0.20 [95% CI 0.11 - 0.39]) had a lower probability of optimal adherence compared to women who knew their HIV status before pregnancy.

There were statistically significant associations between adherence to ART and the trimester of pregnancy when ART was initiated (p=<0.001). As shown in Table 4.6, compared to women who were initiated on ART in the first trimester, those who were initiated in second trimester ((38.6% vs 72.2%; OR=0.24 [95% CI 0.14 - 0.43]), the ones initiated in third trimester (35.5% vs 72.2%; OR=0.21 [95% CI 0.12 - 0.39]), and those initiated in the postnatal period (50% vs 72.2%; OR=0.39 [95% CI 0.22 - 0.70]) had a lower probability of optimal adherence.

Duration on ART was significantly associated with adherence to ART (p=<0.001). Compared to women who were on ART for at least 24 months, those who were on ART for 13 to 18 months (28.6% vs 58.6%; OR=0.28 [95% CI 0.16 - 0.51]), on ART for 7 to 12 months (5% vs 58.6%; OR=0.04 [95% CI 0.01 - 0.10]), and on ART for six month or less (0% vs 58.6%; OR=0.01 [95% CI 0.003-0.06]) had a lower probability of optimal adherence. However, women who were on ART for 19 to 24 months (64.5% vs 58.6%; OR=1.35 [95% CI 0.76 - 2.40]) had a higher probability of optimal adherence compared to women to were on ART for at least 24 months.

There was a statistically significant association between having been on TB treatment since ART initiation and adherence to ART (p=<0.001). Compared to women who were not on TB treatment since ART initiation, those who had been on TB treatment (9.4% vs 54.9%; OR=0.08 [95% CI 0.04 - 0.18]) had a lower probability of adherence to ART.

Another measure of adherence used examined in this study was missing dose on medication in the one week preceding the last clinic visit. Missing a dose of medication had a statistically significant association with adherence to scheduled clinic visits (p=<0.001). The probability of optimal adherence to the scheduled clinic visits was higher among women who did not miss a dose of ART in the seven days prior to their last visit compared to those who reported missing a dose (88.9% vs 1.6%; OR=0.003 [95% CI 0.00 -0.01].)

There were no statistically significant associations between adherence to treatment and WHO stage (p=0.418), ART regimen (p=0.537), being on medication other than ART and TB treatment (p=0.315), and hospital admission since ART initiation (p=0.110).

Table 4.7 Adherence to treatment by clinical characteristics of the pregnant women initiated on Option B+ in Lusaka (N= 311)

		Total	Optimal adherence n (%)	Poor adherence n (%)	*p*-value
WHO Clinical Stage	Stage 1	267	136(50.9)	131(49.1)	0.418
	Stage 2	6	2(33.3)	4(66.7)	
	Stage 3	1	0(0.00	1(100.0)	
When they knew their HIV status	Before Pregnancy	6	5(83.3)	1(16.7)	<0.001*
	1st Trimester	125	83(66.4)	42(33.6)	
	2nd Trimester	149	55(36.9)	94(63.1)	
	3rd Trimester	27	11(40.7)	16(59.3)	
	Postnatal	2	1(50.0)	1(50.0)	
Timing of ART initiation	1st Trimester	108	78(72.2)	30(27.8)	<0.001*
	2nd Trimester	166	64(38.6)	102(61.4)	
	3rd Trimester	31	11(35.5)	20(64.5)	
	Postnatal	4	2(50.0)	2(50.00	
ART Regimen	AZT + 3TC + EFV	1	1(100.0)	0(0.00	0.537
	AZT + 3TC + LPV-r	1	0(0.0)	1(100.00	
	TDF + XTC + EFV40	299	151(50.5)	148(49.5)	
	TDF + XTC + DTG	4	2(50.0)	2(50.0)	
	TDF + 3TC + DTG	1	0(0.0)	1(100.0)	
	TAF + XTC + EFV40	1	0(0.0)	1(100.0)	
	ABC + 3TC + LPV-r	1	1(100.0)	0(0.0)	
	Any Other Regimen	1	0(0.0)	1(100.0)	
Duration on ART (Months)	</= 6	28	0(0.0)	28(100.0)	<0.001*
	7 to 12	20	1(5.0)	19(95.0)	
	13 to 18	7	2(28.6)	5(71.4)	
	19 to 24	62	40(64.5)	22(35.5)	
	More than 24 months	192	112(58.3)	80(41.7)	
TB treatment whilst on ART	Yes	32	3(9.4)	29(90.6)	<0.001*
	No	277	152(54.9)	125(45.1)	
Being on other medication	Yes	107	51(47.7)	56(52.3)	0.315
	No	200	102(51.0)	98(49.0)	
Hospital admission since ART	Yes	4	0(0.0)	4(100.0)	0.110
	No	168	66(39.3)	102(60.7)	
Missed taking Medication	No	171	152(88.9)	19(11.1)	<0.001
	Yes	127	2(1.6)	125(98.4)	

Table 4.8 Determinants of adherence to treatment among pregnant women initiated on Option B+ in Lusaka (N= 311)

		Total	Optimal adherence n(%)	Poor adherence n(%)	OR (95% CI)
Distance to facility (km)	< 1	92	58(63.0)	34(37.0)	1.00
	1 to <5	165	73(44.2)	92(55.8)	0.46 (0.26 - 0.81)
	5 to 10	44	22(50.0)	22(50.0)	0.59 (0.33 - 1.03)
	>10	8	2(25.0)	6(75.0)	0.20 (0.11 - 0.36)
Having a treatment supporter	No	16	4(25.0)	12(75.0)	1.00
	Yes	265	135(50.9)	130(49.1)	0.32(0.18 - 0.58)
Awareness of HIV status	Before Pregnancy	6	5(83.3)	1(16.7)	1.00
	1st Trimester	125	83(66.4)	42(33.6)	0.40(0.20 - 0.77)
	2nd Trimester	149	55(36.9)	94(63.1)	0.12(0.06 - 0.23)
	3rd Trimester	27	11(40.7)	16(59.3)	0.14(0.07 - 0.27)
	Postnatal	2	1(50.0)	1(50.0)	0.20(0.11 - 0.39)
Timing of ART initiation	1st Trimester	108	78(72.2)	30(27.8)	1.00
	2nd Trimester	166	64(38.6)	102(61.4)	0.24(0.14 - 0.43)
	3rd Trimester	31	11(35.5)	20(64.5)	0.21(0.12 - 0.39)
	Postnatal	4	2(50.0)	2(50.00	0.39(0.22 - 0.70)
Duration on ART (mmonths)	>24	192	112.5(58.6)	79.5(41.4)	1.00
	19 to 24	62	40.5(64.5)	21.5(35.5)	1.35(0.76 - 2.40)
	13 to 18	7	2.5(28.6)	4.5(71.4)	0.28(0.16 - 0.51)
	7 to 12	20	1.5(5.0)	18.5(95.0)	0.04(0.01 - 0.10)
	</= 6	28	0.5(1.8)	27.5(98.2)	0.01(0.003-0.06)
TB treatment whilst on ART	No	277	152(54.9)	125(45.1)	1.00
	Yes	32	3(9.4)	29(90.6)	0.08(0.04 - 0.18)
Missed taking Medication	No	171	152(88.9)	19(11.1)	1.00
	Yes	127	2(1.6)	125(98.4)	0.003(0.00 -0.01)

OR = odds ratio; CI = confidence interval

4.6 RETENTION IN CARE

Retention in care (RIC) decreased steadily from the time of enrolment in ART up to 24 months postnatal as shown in the Kaplan Meier survival curve (Figure 4.7). A total of 93 women (30%) were lost to follow-up from pregnancy to 24 months postnatal. The rate of retention in care decreased over time, from 92% at the time of delivery, to 81% at six months postnatal, 77% at 12 months, 74% at 18 months and 70% at 24 months postnatal.

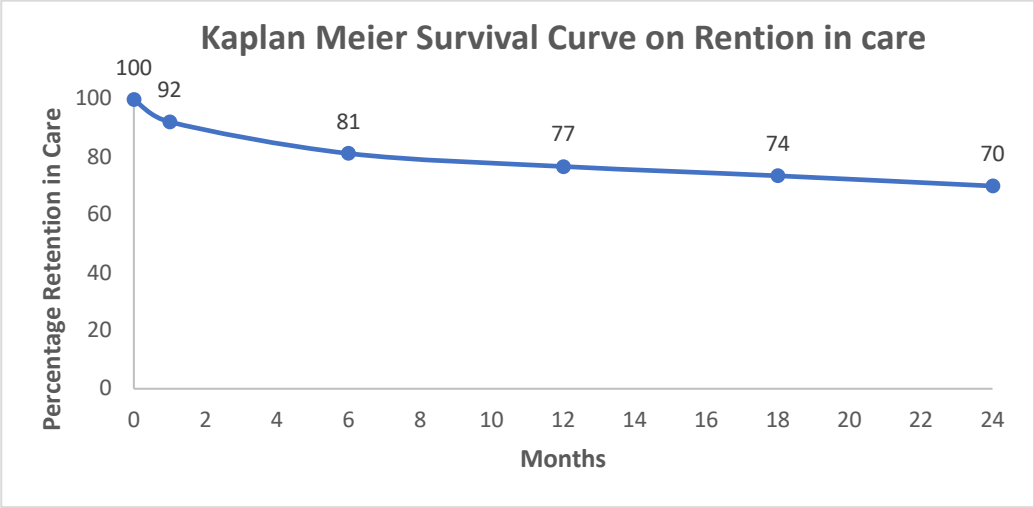

Figure 4.1 Retention in Care over 24 months post-delivery of 311 PMTCT clients enrolled in the study

4.6.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS AND RETENTION IN CARE

Table 4.7 shows that marital status was significantly associated with RIC at 24 months postnatal. Table 4.9 shows that compared to married women, those who have never been married (50% vs 70.3%; OR=0.42 [95% CI 0.24 - 0.77]), or women who were divorced (28.6% vs 70.3%; OR=0.18 [95% CI 0.10 - 0.32]) had a lower probability of RIC at 24 months. However, the difference in the probability of RIC at 24 months between married women and those who were widowed, was not statistically significant (57.1% vs 70.3%; OR=0.57 [95% CI 0.32 - 1.02]).

There were statistically significant associations between distance to the health facility where the woman received ART and RIC at 24 months (p=0.014). Compared to women who lived less than one kilometer from the health facility, those who lived between one kilometer and five kilometers from the health facility (65.9% vs 79.4%; OR=0.53 [95% CI 0.27 - 0.97]), the ones

who lived between five kilometers and ten kilometers from the health facility (54.6% vs 79.4%; OR=0.32 [95% CI 0.17 - 0.61]); and those who lived more than ten kilometers from the health facility (50.0% vs 79.4%; OR=0.27 [95% CI 0.14 - 0.49]) had a lower probability of RIC at 24 months.

As shown in Table 4.7, there was no statistically significant association between RIC at 24 months postnatal and Age (p=0.135), parity (p=0.463), outcome of the latest childbirth (p=0.169), previous pregnancy or child loss (p=0.463), education level (p=0.067), disclosure of HIV status (p=0.881), and having a treatment partner (p=0.431).

Table 4.9 Retention in Care at 24 months by socio-demographic characteristics of the pregnant women initiated on Option B+ In Lusaka (N= 311)

		Total	Retention in Care n (%)	*p*-value
Age (years)	15 – 24	96	62 (64.6)	
	25 – 34	181	130 (71.8)	0.135
	35+	34	19 (55.8)	
Marital status	Never been married	18	9 (50.0)	
	Married	263	185 (70.3)	0.034*
	Divorced	7	2 (28.6)	
	Widowed	7	4 (57.1)	
Parity	0	35	22 (62.9)	
	1	75	47 (62.7)	0.463
	2 to 4	180	128 (71.1)	
	>4	16	12 (75.0)	
Outcome of latest childbirth	Live Birth	278	213 (76.6)	
	Still birth	1	1 (100.0)	0.169
	Infant Death	1	0 (0.0)	
Previous pregnancy or child loss	None	204	150 (73.5)	
	Miscarriage	16	12 (75.0)	
	Under 5 deaths	9	7 (77.8)	0.463
	Child death > 5 Years	3	1 (33.3)	
Education level	No formal education	11	5 (45.5)	
	Primary	86	56 (65.1)	0.067
	Secondary	158	106 (67.1)	
	Tertiary	15	14 (93.3)	
Distance to facility (km)	< 1	92	73 (79.4)	
	1 to <5	167	110 (65.9)	0.014*
	5 to 10	44	24 (54.6)	
	>10	8	4 (50.0)	
Disclosure of HIV status	Yes	276	187 (67.6)	0.881
	No	10	7 (70.0)	
Having a treatment supporter	Yes	266	181 (68.1)	0.431
	No	17	10 (58.8)	

4.6.2 CLINICAL CHARACTERISTICS AND RETENTION IN CARE

Table 4.8 shows that stage of the pregnancy (trimester) when HIV status was known, was significantly associated with RIC at 24 months postnatal (p=0.008). As shown in Table 4.9, compared to women who knew their HIV status before pregnancy, those who knew their status in the first trimester (76.2% vs 100%; OR=0.02 [95% CI 0.00 to 0.26]), the ones who knew in the 2nd trimester (58.7% vs 100%; OR=0.001 [95% CI 0.00 - 0.11]), and the ones who knew their status in the third trimester (70.4% vs 100%; OR=0.01[95% CI 0.00 - 0.19]) had a lower probability of RIC at 24 months postnatal. There was no statistically significant difference in the odds of RIC at 24 months postnatal between women who knew their HIV status before

pregnancy and those who knew their status during the postnatal period (OR=1 [95% CI 0.020 - 50.89]).

There were statistically significant associations between the trimester of pregnancy when ART was initiated and RIC at 24 months postnatal (p=<0.001). Compared to women who were initiated on ART in the first trimester of pregnancy, those who were initiated in the second trimester (58.9% vs 82.4%; OR=0.32 [95% CI 0.17 - 0.60]) and the ones initiated in the third trimester (61% vs 82.4%; (OR=0.34 [95% CI 0.18 - 0.66]) had a lower probability of RIC at 24 months postnatal. However, women who were initiated on ART in the postnatal period had a higher probability of RIC at 24 months than women who were initiated in the first trimester and those (100% vs 82.4%; OR=45 [95% CI 2.68 - 759.30]).

There were statistically significant associations between duration on ART and RIC at 24 months postnatal (p=<0.001). Compared to women who were on ART for more than 24 months, those who were on treatment for less than 12 months (0.01% vs 80.7%; OR=0.13 [95% CI 0.07 - 0.25]) and the ones on ART for 13 to 18 months (35.7% vs 80.7%; OR=0.13 [95% CI 0.07]) had a lower probability of RIC at 24 months postnatal. However, women who were on ART for 19 to 24 months had a higher probability of RIC at 24 months compared to women who were on ART for more than 24 months (86.3% vs 80.7%; OR=1.44 [95% CI 0.68 to 3.06]).

There were statistically significant associations between RIC at 24 months postnatal and being on other medication in addition to ART and TB treatment (p=0.007). Compared to the women who were not on other medication, those who took other medication had a lower probability of RIC at 24 months postnatal (61.9% vs 78.5%; OR=0.45 [95% CI 0.24 - 0.85]).

Missing a dose of ART within seven days prior to the last visit was significantly associated with RIC at 24 months postnatal (p=<0.001). Compared to women who did not miss a dose of ART within seven days prior to the last visit, those who missed a dose had a lower probability of RIC at 24 months postnatal (95% vs 35%; OR=0.03 [95% CI 0.01 0.08]).

There were statistically significant associations between missing clinic appointments since ART initiation and RIC at 24 months postnatal. Compared to women who did not miss a clinic visit, those who missed a visit had a lower probability of RIC at 24 months postnatal (97.4% vs 38.3%; OR=0.02 [95% CI 0.01-0.06]).

Table 4.8 shows that there were no statistically significant associations between RIC and WHO clinical stage (p=0.157), ART regimen (p=0.346), change in ART regimen (p=0.242), having been on TB treatment (p=0.908), experience of side effects from ART (p=0.269), and hospital admission (p=0.154).

Table 4.10 Retention in care at 24 months by clinical characteristics of the pregnant women initiated on Option B+ in Lusaka (N= 311)

		Total	Retention in Care n (%)	*p*-value
WHO clinical stage	Stage 1	269	183(68.0)	0.157
	Stage 2	6	2(33.3)	
	Stage 3	1	1(100.0)	
Awareness of HIV status	Before Pregnancy	6	6(100.0)	0.008*
	1st Trimester	126	96(76.2)	
	2nd Trimester	150	88(58.7)	
	3rd Trimester	27	19(70.4)	
	Postnatal	2	2(100.0)	
Timing of ART initiation	1st Trimester	108	89(82.4)	<0.001*
	2nd Trimester	168	99(58.9)	
	3rd Trimester	31	19(61.3)	
	Postnatal	4	4(100.0)	
ART regimen	AZT + 3TC + EFV	1	1(100.0)	0.346
	AZT + 3TC + LPV-r	1	0(0.0)	
	TDF + XTC + EFV40	301	205(68.1)	
	TDF + XTC + DTG	4	3(75.0)	
	TDF + 3TC + DTG	1	1(100.0)	
	TAF + XTC + EFV40	1	0(0.0)	
	ABC + 3TC + LPV-r	1	1(100.0)	
	Any Other Regimen	1	0(0.0)	
Change of ART regimen before	Yes	9	8(88.9)	0.242
	No	290	206(71.0)	
Duration on ART (Months)	</= 12	48	0(0.0)	<0.001*
	13 to 18	7	2(28.6)	
	19 to 24	62	53(85.5)	
	More than 24 months	194	156(80.4)	
TB treatment whilst on ART	Yes	32	22(68.8)	0.908
	No	279	189(67.7)	
Experience of side effects	Yes	6	6(100.0)	0.269
	No	129	107(83.0)	
Being on other medication	Yes	107	84(78.5)	0.007*
	No	202	125(61.9)	
Hospital admission since ART initiation	Yes	4	4(100.0)	0.154
	No	168	111(66.1)	
Missed taking Medication	Yes	128	45(35.2)	<0.001*
	No	171	163(95.3)	
Missed clinic appointment	Yes	154	59(38.3)	<0.001*
	No	155	151(97.4)	

Table 4.11 Sociodemographic and clinical characteristics determinants of retention in care at 24 months among pregnant women initiated on Option B+ in Lusaka (N= 311)

		Total	Retention in Care	
			n (%)	OR (95% CI)
Marital Status	Married	263	185 (70.3)	1.00
	Never married	18	9 (50.0)	0.42 (0.24 - 0.77)
	Divorced	7	2 (28.6)	0.18 (0.10 to 0.32)
	Widowed	7	4 (57.1)	0.57 (0.32 to 1.02)
Distance to Facility (Km)	< 1	92	73 (79.4)	1.00
	1 to <5	167	110 (65.9)	0.53 (0.27 - 0.97)
	5 to 10	44	24 (54.6)	0.32 (0.17 - 0.61)
	>10	8	4 (50.0)	0.27 (0.14 - 0.49)
Awareness of HIV status	Before Pregnancy	6	6(100.0)	1.00
	1st Trimester	126	96(76.2)	0.02 (0.00 to 0.26)
	2nd Trimester	150	88(58.7)	0.001 (0.00 - 0.11)
	3rd Trimester	27	19(70.4)	0.01 (0.00 - 0.19)
	Postnatal	2	2(100.0)	1.00 (0.02 - 50.89)
Timing of ART initiation	1st Trimester	108	89(82.4)	1.00
	2nd Trimester	168	99(58.9)	0.32 (0.17 - 0.60)
	3rd Trimester	31	19(61.3)	0.34 (0.1793 - 0.66)
	Postnatal	4	4(100.0)	45.0 (2.68 - 759.30)
Duration on ART (months)	>24 months	194	156.5(80.7)	1.00
	19 to 24	62	53.5(86.3)	1.44(0.68 to 3.06)
	13 to 18	7	2.5(35.7)	0.13 (0.07 - 0.25)
	</= 12	48	0.5(0.01)	0.002 (0.0003 - 0.02)
Being on other medication	No	202	125(61.9)	1.00
	Yes	107	84(78.5)	0.45 (0.24-0.85)
Missed taking Medication	No	171	163(95.3)	1.00
	Yes	128	45(35.2)	0.03 (0.01 0.08)
Missed clinic appointment	No	155	151(97.4)	1.00
	Yes	154	59(38.3)	0.02 (0.01-0.06)

OR = odds ratio; CI = confidence interval

CHAPTER 5. DISCUSSION

5.1 INTRODUCTION

This section discusses the results of this study and compares them with findings from other related studies. The discussion will highlight factors that can inform the implementation of interventions aimed at improving adherence and RIC care in PMTCT programs.

5.2 ADHERENCE TO ART

In the current study, 50.2% of the women who were initiated on ART during the antenatal and postnatal period in Lusaka District, Zambia, had optimal adherence to ART [defined as not missing any scheduled clinic appointments since ART initiation]. Further, 57.2% of the women did not miss a dose of ART medication in the seven days prior to their last visit. Studies done, on adherence to ART, in similar settings revealed varying results compared to the results from the current study. A retrospective cohort study that examined adherence to scheduled appointments for newly enrolled patients at a regional referral hospital in western Kenya revealed that 44% of the patients defaulted on their scheduled clinic appointments, which implied that 56% had adhered to their appointments (Muthusi *et al.,* 2016). A survey in Uganda found that 97% of the patients had not missed their doses in the last week, and 93% had not missed their appointments in the last three months (Shumba *et al*., 2013). Similarly, a prospective cohort study in a district hospital in Uganda revealed that 92% of the patients attended all appointments for their refills (Kunutsor *et al.,* 2010). The lower rates of adherence found in this study could be attributed to the reporting period. Whilst the studies, referenced here, reported higher rates of adherence to scheduled appointments had shorter reporting periods (three months and seven months, respectively), in this study the median reporting period was 26 months.

5.3 SOCIODEMOGRAPHIC AND CLINICAL FACTORS ASSOCIATED WITH ADHERENCE TO ART

The sociodemographic and clinical characteristics associated with adherence to ART under this study are comparable to those found under similar studies in the region. The factors that had statistically significant associations with adherence to ART included distance to the health facility, having a treatment support, stage of pregnancy (in trimester) when HIV status was

known, the trimester of pregnancy when ART was initiated, duration on ART, having been on TB treatment since ART initiation, and missing a dose of medication.

5.3.1 DISTANCE TO HEALTH FACILITY

The study shows that women who lived less than one kilometer from the health facility had higher rates of optimal adherence to ART compared to those who lived further from the health facilities. Generally, the further the women lived from the health facility, the less likely they were to have optimal adherence to scheduled clinic appointments. Other studies done within Africa that have revealed that distance to a treatment center is a barrier to accessing ART services include, a qualitative study to conceptualize factors affecting retention in care of patients on ART in Kabwe District, Zambia, using the ecological framework in which participants indicated that distance to the health facility was a barrier to accessing ART (Mukumbang *et al*., 2017), a qualitative analysis of the barriers to ART in Swaziland which found distance to health facilities as a barrier (Ahmed *et al.,* 2017), a qualitative study on barriers to and facilitators of ART adherence in Nepal revealed that most interviewees stated that they became non-adherent because of difficulties in reaching the treatment centers due to long travel distance (Wasti *et al*., 2012), an assessment of level of adherence to ART among HIV/AIDS patients at the Imo State University Teaching Hospital in Orlu, Nigeria found distance to health facility as one of the major reasons for non-adherence to therapy. However, a study on adherence to ART among HIV/AIDS patients at the Kwa-Thema clinic in Gauteng Province, South Africa, revealed no association between distance from the facility and ART adherence (Eyassu *et al*., 2016), and a study on factors associated with non-adherence to highly active antiretroviral therapy in Nairobi, Kenya, found that respondents who accessed therapy in clinics within a walking distance from their homes were about two and a half times more likely not to adhere than patients who refilled in faraway clinics (Wakibi *et al*., 2011). The reason why distance to health facilities was found to be a barrier to adherence to ART could be related to the cost of transport or the long walking hours to reach facilities.

5.3.2 HAVING A TREATMENT SUPPORTER

The study revealed that women who had a treatment supporter had double the probability of optimal adherence to treatment compared to those who did not have a treatment supporter

(50.9% vs 25%). However, even among the women who had a treatment supporter, adherence was a problem as almost half were non-adherent (49.1%). The association between having a treatment supporter and adherence to ART had been postulated in many studies done in similar settings. A systematic review and meta-analysis of the effectiveness of treatment supporter interventions in ART adherence in sub-Saharan Africa reported that treatment supporters are effective in promoting ART adherence (Nyoni *et al.,* 2020). A review of antiretroviral therapy adherence and retention in care in middle-income and low-income countries demonstrated that adherence in resource-limited settings is equal or superior to that in resource-rich settings, possibly due to focused efforts on support groups (Nachega *et al*., 2010). A randomised controlled trial in Rakai district in Uganda, which followed up on pre-ART patients for one year, reported less attrition from the care cascade, slower HIV-related disease progression and better quality of daily life in the arm with treatment supporters compared to the one without supporters (Nakigozi *et al.,* 2015). Similarly, a study on the effect of treatment partners on adherence to HAART in central Mozambique revealed higher rates of adherence to treatment among patients that had treatment supporters (Stubbs *et al.,* 2009).

5.3.3 AWARENESS OF HIV STATUS

Women who knew their HIV status before pregnancy had a higher probability of optimal adherence compared to those who knew their status during pregnancy and the postnatal period. This finding is consistent with other studies done in similar settings. A systematic review of studies on medication adherence in pregnant women living with HIV and receiving antiretroviral therapy in sub-Saharan Africa revealed that knowing one's HIV status before pregnancy was an enabler for adherence to ART (Omonaiye *et al*., 2018). This systematic review showed that women who knew their HIV status before pregnancy had good adherence to ART whilst women who found out their HIV infection status during pregnancy were linked with non-adherence to ART (Omonaiye *et al.,* 2018). Given that some of the women enrolled in option B+ regimen may not have been symptomatic when they were tested for HIV and commenced on ART during pregnancy, they may not be as motivated to adherence compared to the ones who knew their status before pregnancy.

5.3.4 TIMING OF ART INITIATION

Women who were initiated on ART in the first trimester had a higher probability of optimal adherence compared to those who were initiated on ART later in pregnancy or during the postnatal period. Whilst rates of optimal adherence reduced from 72.2% among women who were initiated on ART in the first trimester to 38.6% and 35.5% among those initiated in the second and third trimester, respectively, there was a slight increase in adherence among those initiated during the postnatal period (50%). Other studies have shown similar findings. A study of longitudinal adherence to maternal antiretroviral therapy and infant Nevirapine prophylaxis from 6 weeks to 18 months postpartum in South Africa, revealed that mothers who initiated ART after delivery were at higher risk for non-adherence than those who initiated ART before delivery (Larsen *et al*., 2019). A cohort study on adherence to ART during and after pregnancy in Malawi's "Option B+" program showed that the proportion of adequately adhering women who started ART during pregnancy dropped from 71.1% during the first 3 months of ART to 64.9% during months 4– 6 (Haas *et al.,* 2016).

5.3.5 DURATION ON ART

The study revealed that women who were on ART for at least 24 months had a higher probability of optimal adherence compared to those who were on ART 13 to 18 months, 7 to 12 months, and those on ART for six months or less. However, women who were on ART for 19 to 24 months had a higher probability of optimal adherence compared to women to were on ART for at least 24 months. Generally, the longer the women remained on ART, the higher the probability of adherence. The reduction in the probability of adherence for women who were on ART for at least 24 months compared to those on ART for 19 to 24 months could be because the PMTCT program follows up on women for 24 months and, thereafter, they are transferred out to mainstream ART within the same health facility or another health facility. Similar findings were noted in a retrospective study of long-term adherence to antiretroviral therapy in a South African adult patient cohort which revealed that the mean adherence peaked (99.3%) at 18–24 months after ART initiation and remained above 98% from 32 months onward, though this study was in the general adult population (Moosa *et al*., 2019). A study on predictors of adherence to antiretroviral therapy in rural Zambia found that adherence to ART was higher for those on ART for a longer time (Carlucci *et al.,* 2008).

5.3.6 History of TB treatment since ART initiation

The current study found that women who were not on TB treatment since ART initiation had a higher probability of optimal adherence compared to those who had been on TB treatment. Among the studies that were reviewed on adherence to option B+ regimen, none of them studied the effect of concurrent treatment for TB on the rate of adherence. However, a study on adherence to concurrent TB treatment and ART among co-infected persons in South Africa revealed that of the 1 252 persons receiving concurrent treatment, only 138 (11.0%) were not adherent (Mazinyo *et al*., 2016). In a retrospective study on long-term adherence to ART in a South African adult patient cohort, concurrent ART and TB treatment, or switching to a second line ART regimen with higher pill burden, did not impair ART adherence (Moosa *et al*., 2019).

5.3.7 Missing taking medication

In the current study, women who did not miss a dose of ART in the seven days prior to their last visit had a higher probability of optimal adherence compared to those who reported missing a dose. This finding is consistent with that of a study on missed doses and missed appointments and adherence to ART among adult patients in Uganda which revealed that there was a significant association between missing doses and missing appointments, with patients who missed doses having higher probability of missing clinic appointments (Shumba *et al*., 2013).

5.4 Retention in Care

In this study, retention in care decreased over time, from 92% at the time of delivery, to 81% at 6 months postnatal, 77% at 12 months, 74% at 18 months and 70% at 24 months postnatal. These findings are consistent with findings from other studies in similar settings. A meta-analysis of studies on retention in HIV care during pregnancy and the postpartum period in the Option B+ programs in Africa revealed pooled retention estimates of 89.9%, 79.4%, 74.5%, and 69.3% at 3, 6, 12, and 24 months after ART initiation, respectively (Knettel *et al*., 2018). An analysis of health facilities offering Option B+ in Malawi showed retention in care of 82% at 6 months, 77% at 12 months, 71% at 24 months, and 70% at 36 months (Haas *et al*., 2016). A study in South Africa reviewed that 58% of HIV-infected pregnant women in care were LTFU by 6 months after delivery (Clouse *et al*., 2013). In a retrospective cohort study of factors associated with loss to follow-up among women in Option B+ PMTCT program in northeast Ethiopia, retention in

care at 6 months was 88%, 84% at 12 months, and 77% at 24 months (Mitiku *et al*., 2016); and in Zimbabwe 83% at 6 months (Dzangare *et al*., 2016). Retention in care at 12 months in Ghana was 66% (Reece, 2015). In an outcome evaluation of the early implementation of Option B+ in Cameroon entitled, "A Prospective Cohort Observational Survey in the Northwest and Southwest Regions", RIC was 90% and 79% at 6 and 12 months respectively (Muffih, P. *et al*., 2018).

Studies of RIC in the general ART program in Zambia revealed comparable findings to women in the option B+ program. According to Zambia's 2014 report to the United Nations General Assembly special session on HIV and AIDS, 76.5%, 59%, and 54% of patients on ART were retained in care at 12, 24, and 60 months after initiation, respectively, between 2010 and 2013 (MoH/NAC, 2014). In a study in Mansa District of Zambia, retention in care at 12 months was 91%, 59% at 36 months, and 52% at 60 months (Malebe *et al.,* 2014). In another retrospective cohort study on retention in care, resource utilization, and costs for adults receiving antiretroviral therapy in Zambia, retention in care at 12 months was 75% (Scott *et al.*, 2014).

Women initiated on ART under the option B+ regimen have been found to have lower rates of RIC compared to women initiated prior to pregnancy (Haas *et al.,* 2016). A retrospective cohort study of on retention in care during the first three years of antiretroviral therapy for women in Malawi's option B+ program, revealed that patients in Option B+ had a higher risk of having no follow-up and, for the first two years of ART, higher risk of loss to follow-up than did patients who started ART because they had CD4 counts less than 350 cells per μL or WHO clinical stage 3 or 4 disease (Haas et al., 2016). Table 5.1 below summarises RIC from the various studies described above for ease of comparison.

Table 5.1: Comparison of rates of RIC in various studies

Study	Location	Retention in Care			
		3 months	6 months	12 months	24 months
This Study	Zambia	92% (at birth)	81%	77%	70%
(Knettel et al.,2018).	Meta-analysis	89.9%	79.4%	74.5%,	69.3%
Haas et al., 2016	Malawi	-	82%	77%	71%
Clouse et al., 2013	South Africa	-	42%	-	-
Mitiku et al., 2016	Ethiopia		88%	84%	77%
Dzangare et al., 2016	Zimbabwe	-	83%	-	-
Reece, 2015	Ghana	-	-	66%	-
Muffih, P. et al.,2018	Cameroon	-	90%	79%	
MoH/NAC, 2014	Zambia	-	-	76.5%	59%
Malebe et al., 2014	Zambia	-	-	91%	-
Scott et al., 2014	Zambia	-	-	75%	-

5.5 SOCIODEMOGRAPHIC FACTORS AND CLINICAL CHARACTERISTICS ASSOCIATED WITH RETENTION IN CARE

The study revealed that marital status, distance to facility in kilometers, timing of knowing HIV status, timing of commencing ART, duration on ART (in months), being on other medication, missing to take medication, and missing clinic appointment had statistically significant associations with Retention in Care at 24 months postnatal.

5.5.1 MARITAL STATUS

Married women had a higher probability of RIC compared to those who have never been married or women who were divorced. The difference in the probability of RIC at 24 months between married women and those who were widowed, was not statistically significant. Other studies in the general ART programs that have shown statistically significant associations between marital status and retention in ART include, a cross-sectional study on retention in care and adherence to HIV and AIDS treatment in Anambra State Nigeria, which revealed that participants who were married were more likely to be retained in care compared to those who were not married

(Umeokonkwo *et al*., 2019), and study on RIC among HIV-infected patients entering care with CD4 Levels >350 cells/μL under routine program conditions in Uganda revealed that marital status was significantly associated with RIC with women who were divorced having higher risk of disengagement from care compared to women who were married or widowed (Namusobya *et al.,* 2013).

5.5.2 DISTANCE TO FACILITY

Women who lived less than one kilometer from the health facility, where they received ART, had a higher probability of RIC at 24 months postnatal compared to those who lived between one kilometer and five kilometers from the health facility, the ones who lived between five kilometers and ten kilometers from the health facility, and those who lived more than ten kilometers from the health facility. The study demonstrated that the further away the patient lived from the health facility, the less likely they were to be retained in care.

The importance of distance to health facility in option B+ has been demonstrated in other studies in similar settings. These studies include a retrospective cohort study in Neno district in Malawi, which revealed that patients living more than eight kilometers from a health facility had a greater hazard of being LTFU compared to patients living less than eight kilometers from a facility and that ART decentralization was associated with increased RIC (Bilinski *et al.,* 2017), and a qualitative study on health facility challenges to the provision of Option B+ in western Kenya which revealed that several patients mentioned that they have difficulty reaching the clinic in time due to distance (Helova *et al*., 2017).

5.5.3 AWARENESS OF HIV STATUS

This study shows that women who knew their HIV status before pregnancy had a higher probability of RIC compared to those who knew their status in the first trimester, second, and third trimesters. This might be because mothers who only recently knew their HIV status through the PMTCT program may not have had symptoms related to HIV and were only tested as part of the antenatal care routine, thus not perceiving themselves to be at risk for disease and be less likely to stay engaged in care. Other studies that have demonstrated that knowing one's HIV status prior to pregnancy increased the chances of RIC include, a retrospective cohort study on

RIC and health outcomes in PMTCT) in Addis Ababa, Ethiopia which revealed that mothers who were diagnosed with HIV at enrolment in PMTCT had a 65% higher risk of LTFU compared to mothers who were already known to be HIV-positive before enrolling in PMTCT (Alamdo, 2021), and a study in Kericho County, Kenya which showed that knowledge of mothers' pre-pregnancy HIV status reduced the odds of LTFU (Kigen *et al.,* 2018). In this regard, women diagnosed with HIV during pregnancy may need additional support to increase the probability of retention in the PMTCT cascade.

5.5.4 TIMING OF ART INITIATION

The study revealed that women who were initiated on ART in the first trimester of pregnancy having higher probability of RIC than those who were initiated in the second trimester and the ones initiated in the third trimester. However, women who were initiated on ART in the postnatal period had a higher probability of RIC at 24 months than women who were initiated in the first, second or third trimester.

These findings are consistent with other studies in similar settings, such as the study on RIC among HIV-infected pregnant women in Haiti found that diagnosis of HIV during pregnancy and later ART initiation during the third trimester was associated with LTFU, (Dionne-Odom *et al.,* 2016), and the study on challenges and successes in the implementation of option B+ in southern Swaziland, which revealed that attrition was highest among HIV positive women who initiated ART during the last trimester of their pregnancy (Etoori *et al*., 2018). This supports the need for pre-pregnancy HIV diagnosis and early ART initiation.

5.5.5 DURATION OF TREATMENT

In this study women who were on ART for more than 24 months had a higher probability of RIC at 24 months postnatal than those who were on treatment for less than 18 months. Actually, in this study, none of the women who were on ART for less than 12 months was retained in care. These findings show that the longer the women were on ART, the more likely they were to be retained in care. However, women who were on ART for 19 to 24 months had a higher probability of RIC at 24 months compared to women who were on ART for more than 24 months. This could be because, after 24 months postnatal, the women are transitioned from

PMTCT program to the regular ART. Findings from this study are consistent with those from a prospective cohort study done in Dar es Salaam, Tanzania which revealed that being on ART for the duration of 12 months or more prior to pregnancy was protective against being LTFU (Siril *et al.,* 2017).

5.5.6 BEING ON OTHER MEDICATION

Women who were on other medication had a lower probability of RIC at 24 months postnatal compared to those who were not on any other medication. Almost all the patients that reported being on other medication, were on Septrin prophylaxis (98%) with or without Isoniazid prophylaxis. The number of medications a patient is taking has been associated with poor adherence to treatment and retention in care (Kalogianni, 2018). However, findings from the current study, contradict those from a study done in Kenya which showed that ART ineligible clients enrolled in the period following free cotrimoxazole (Septrin) provision had a higher 12-month retention (84%) than those who enrolled prior to free cotrimoxazole program (Kohler *et al.,* 2011).

5.5.7 MISSED TAKING MEDICATION

The study revealed that women who did not miss a dose of ART within seven days prior to the last visit had a higher probability of RIC at 24 months postnatal compared to those who missed a dose. This could be because women who do not miss a dosage of ART are committed to the treatment protocols including scheduled visits. A retrospective review of patients LTFU from the ART program at Mulanje Mission Hospital, Malawi, found that patients most likely to get LTFU in MMH who had been on antiretroviral therapy for a short duration and had missed over four doses in the last 12 months (Webb and Hartland, 2018).

5.5.8 MISSED CLINIC APPOINTMENT

This study shows that women who did not miss a clinic visit had a higher probability of RIC at 24 months postnatal compared to those who missed an appointment. This finding is comparable to the study on re-engagement in HIV care following a missed visit in rural Uganda which found that people living with HIV who missed scheduled visits had reduced odds of RIC (Nabaggala *et al.,* 2018). Another study entitled “Beyond Core Indicators of Retention in HIV Care”, revealed

that missed clinic visits were more common among patients classified as not retained in care at 24 months (Mugavero *et al.,* 2014).

5.6 LIMITATIONS OF THE STUDY

The limitations under this study were mainly related to limited documentation of the medical records for some variables. Having used a retrospective cohort study design meant that the researcher depended on the accuracy of the routine data available in the patient records. The SmartCare record system has been evolving over time and not all facilities have the same level of expertise in data entry. This may have led to incomplete and inaccurate data on some variables. The researcher was unable to verify or take corrective actions on missed data such as lack of records on CD4 and viral load test records, HIV status of spouse or whether the spouse was on ART. These variables had limited data available and may have affected the outcomes. Therefore, the researcher could not analyse these variables further.

Another limitation is that retention in care in this study was based on the availability of records from the facility at which a woman attended antenatal and postnatal care. It is possible that those lost to follow-up may have transferred to other health facilities without documentation and they may have been misclassified as having been LTFU. This may affect the conditions and recommendations.

To measure adherence, the researcher dichotomized the study participants into optimal adherence for those who did not miss any clinic appointment and poor adherence for the participants who missed at least one clinic appointment since commencing ART. This may have led to low rates of adherence (50.2%) given that the period of follow-up was up to two years, and one is likely to miss a visit in such a long period.

CHAPTER 6. CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

This study is one of the few studies done to assess the outcomes of the option B+ program since its inception in Zambia. The findings have provided useful data on the rates of, and factors associated with adherence and retention in care in the option B+ program in Zambia. Given that the data extraction was limited to the five health facilities, further studies involving more PMTCT centres may help to improve the generalisability of the findings.

As per the aim of the study, the researcher was able to determine the levels of optimal adherence and RIC among postnatal women initiated on the option B+ regimen at the five PMTCT centers. About half of the study participants had optimal adherence to their scheduled visits since enrolment into the MTCT program. Whilst this was found to be lower than some studies done in similar settings, the long follow-up period of two years could have led to this finding. The rates of RIC at 24 months postnatal in this study were comparable to other countries. The rate of retention in care decreased over the two years' follow-up period.

This study has shown that staying closer to the health facility, having a treatment supporter, knowing one's HIV status before pregnancy or earlier in pregnancy, initiating ART earlier in pregnancy, and being on ART for more than 12 months increased the likelihood of optimal adherence to ART. However, history of TB treatment whilst on ART decreased the likelihood of optimal adherence to ART.

Additionally, the study revealed that being married, staying closer to the health facility where the woman received ART, knowing HIV status before pregnancy or earlier in pregnancy, initiating ART earlier in pregnancy, and being on ART for longer than 12 months, increased the likelihood of RIC at 24 months postnatal. However, being on additional medication other than ART and TB medication reduced the likelihood of RIC at 24 months postnatal.

6.2 RECOMMENDATIONS

Based on the findings from this study, the following recommendations arranged using the ecological approach are suggested:

Public Policy level

- The study found that the nearer the health facility where the women received their ART, the higher the rates of adherence and retention in care. This finding implies that there is a need to decentralise ART services for option B+, as close to the communities as possible. Given that the health system in Zambia requires the establishment of a health facility within five kilometers of the community, the implication of this finding is that each health centre should be able to offer ART services to ensure adherence and retention in care for the women in the option B+ program.
- The SmartCare electronic data management system has the potential to improve data management across the health sector and improve patient follow-up mechanisms. Therefore, the government should take a deliberate policy to scale up the system to all health facilities.

Institutional and Community Level

- In this study, high levels of missing data on some variables made it difficult to conduct analysis especially logistic regression. There is a need to address poor data capture in the records of the PMTCT clients. This may require interventions such as (i) orientation of data entry staff to the entire PMTCT module in SmartCare, (ii) district health information officers to conduct random online monitoring of the completeness of data entry using sampled health facilities to ensure timely interventions, and (ii) regular data audits such as quarterly audits and taking actions on issues related to data completeness and quality.
- There is a need for enhancement of the patient follow mechanisms to determine the status of the women that are LTFU, and this information should be recorded in the SmartCare system to inform future programming. Such information can include whether the patient has continued ART at another site, or the patient had a miscarriage and continued ART from the mainstream ART clinic, or if the patient had died.

- The measure of adherence chosen in this study (missing a clinic visit), should be analysed at more frequent intervals, such as every three months, to enable early recognition of non-adherence and taking timely preventive action.
- In view of higher rates of adherence among women who lived close to health facilities, there is need to intensify community sensitisation to encourage the public to utilise services at health facilities close to their homes.

Interpersonal level

- Given that RIC declined over time after enrolment into the PMTCT program, there is a need to intensify patient follow-up to ensure that the women remained in care. This can be done through the use of mobile phone reminders to individuals, or home visits by specifically trained community health workers.
- One of the key findings from the study is that 42.8% of the women had missed taking a dose of medication within the week preceding their last clinic visit. This is an important finding because missing a dose within the week might lead to clients missing several doses during the month and predispose themselves to ineffective viral suppression which subsequently may also lead to drug resistance. Therefore, there is a need to enhance adherence counselling in the option B+ program and initiate other measures of adherence such as pill counts or regular viral load tests to monitor response.
- Given that one of the key finding of this study is that women who had treatment supporters had higher rates of adherence to treatment, there is a need to introduce or scale-up treatment support programs in the option B+ program.

Individual level

- Since the study revealed that women who knew their HIV status before pregnancy and those who started ART early in pregnancy (in the first trimester) had higher rates of adherence and RIC, there is a need to enhance programs aimed at promoting HIV testing and early ART initiation in the general population (as outlined in PMTCT prong 1). In addition, programs that support early antenatal booking should be promoted so that pregnant women are tested and commenced on ART early in their pregnancy.

- Given that women enrolled in the option B+ program may not have experienced HIV related symptoms before the diagnosis, there is a need to enhance patient education on the implications of the positive HIV test on their health and well-being, and the importance of preventing transmission of the virus to their child and their sexual partners. This may contribute to increased levels of adherence to ART and overall self-efficacy.

The public health implications of poor adherence and retention in care among women commenced on ART through the option B+ program may include increased incidence of opportunistic infections, increased HIV transmission to the child and sexual partners, high possibilities of developing drug resistance, and reduced ART survival rates. Therefore, there is a. need to address the identified sociodemographic and clinical factors hindering progress, to improve the rates of retention in care among women initiated on ART during pregnancy.

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APPENDICES

Appendix I Data Extraction Tool

Serial Number: …….

Date of data extraction: ----------

Name Health facility: ----------

INSTRUCTIONS FOR THE INTERVIEWER

1 Do not record the name of the patient on the data extraction sheet.

2 Fill in the most appropriate information into the appropriate space

3 Insert the data collection sheet serial number on the space provided

4 Upon completion of each patient file, review the data extraction sheet before saving.

5 Once certain of the entries and no further revision required, send the questionnaire to the central online portal.

SECTION ONE: SOCIO-DEMOGRAPHIC CHARACTERISTICS

Q1.1: Age of patient in years (as at date of ART Initiation)? _____

Q1.2: Marital Status?

(a) Married
(b) Cohabiting
(c) Never been married
(d) Divorced
(e) Widowed
(a) No data

Q1.3: What is the highest education level attained?

(b) Never been to formal school
(c) Primary School Education
(d) Secondary School Education
(e) Tertiary Education
(f) No data

Q1.4: What is the patient's employment status?

(a) Unemployed
(b) Self-employed (Business, Farmer etc.)
(c) Formal Employment
(g) No data

Q1.5: Name of residential area of the patient? _____

Q1.6: Approximate Distance in kilometers from place of residence to the health centre?

(a) Less than 1km
(b) 1km to 5km

(c) 5km to 10km

(d) More than 10km

Q1.7: Had the patient disclosed the HIV status to someone else? [If No or no data then skip Q1.8]

(a) Yes

(b) No

(c) No Data

Q1.8: If yes to Q1.7, mention the persons disclosed to (indicate all that applies):

(a) Spouse/Partner,

(b) Parents

(c) Children

(d) Other relative

(e) Friend

(f) No Data

(g) Others (Specify) _____

Q1.9: Does the patient have treatment supporter? [If No or no data, then skip Q1.10]

(a) Yes

(b) No

(c) No Data

Q1.10: If yes to Q1.9, who is her treatment supporters (indicate all that applies):

(a) Spouse/Partner,

(b) Parents

(c) Children

(d) Other relative

(e) Friend

(f) Treatment support group

(g) No Data

(h) Others (Specify) _____

Q1.11: What is the HIV status of the patient's partner/husband: [If negative, unknown, or no data, skip Q1.12]

(a) Positive

(b) Negative

(c) Unknown

(d) No data

Q 1.12 If partner is HIV positive, are they on ART?.

(a) Yes

(b) No

(c) No Data

Q1.13: Does the patient smoke cigarettes?

(d) Yes

(e) No

(f) No Data

Q1.14: Does the patient take alcohol?

(a) Yes

(b) No

(c) No Data

Q1.15: Does the patient take any other recreational drugs?

(a) Yes

(b) No

(c) No Data

SECTION TWO: CLINICAL CHARACTERISTICS

Q 2.1 When did she give birth (date of delivery)? _____

Q 2.2 How many children does the patient have now (parity)? _____

Q 2.3 What number was the last pregnancy (Gravidity)? _____

Q 2.4 Gestational age in weeks at delivery (at child birth)? _____

Q 2.5: What was the outcome of the childbirth?

(a) Live Birth

(b) Still Birth

(c) Neonatal Death (Baby died within 28 days postnatal)

(d) Infant death (Baby died after 28 days but within 1 year)

(e) No Data

Q 2.6 Any previous pregnancy/child loss?_____

(a) Miscarriage

(b) Elective pregnancy termination

(c) Child death below 5 years

(d) Child death above 5 years

(e) None

(f) No data

Q 2.7 When did they know their HIV status?

(a) Before Pregnancy

(b) 3 months or less into pregnancy (1st trimester)

(c) 4 to 6 months into pregnancy (2nd trimester)

(d) to 9 months into pregnancy (3rd trimester)

(e) After delivery (Postnatal)

(f) No Data

Q 2.8: In which month of the pregnancy did they start taking ART?

(a) Before Pregnancy
(b) 3 months or less into pregnancy (1st trimester)
(c) 4 to 6 months into pregnancy (2nd trimester)
(d) to 9 months into pregnancy (3rd trimester)
(e) After delivery (Postnatal)
(f) No Data

Q 2.9: When did they start taking ART (Date)? _____

Q 2.10: Duration on ART based on record (in months) at 24 months postnatal or at last visit prior to loss to follow-up or transfer to another facility or death? _____

Q 2.11 WHO clinical stage of HIV at start of ART?

(a) Stage I
(b) Stage II
(c) Stage III
(d) Stage IV
(e) No Information

Q 2.12 ART Regimen the patient was on at time of data extraction or at lost to follow-up or death? Please record the regimen

(a) AZT + 3TC + NVP
(b) AZT + 3TC + EFV
(c) AZT + 3TC + LPV-r
(d) TDF + XTC + EFV400
(e) TDF + XTC + DTG
(f) TDF + 3TC + DTG
(g) TAF + XTC + EFV400
(h) TAF + XTC + DTG
(i) TAF + 3TC + DTG
(j) ABC + 3TC + DTG
(k) ABC + 3TC + LPV-r
(l) ABC + 3TC + EFV
(m) ABC + 3TC + AZT
(n) Any Other Regimen

Q 2.13 Any change of ART Regimen since commencement of ART? [If No or No data, skip Q2.14]

(a) Yes
(b) No
(c) No data

Q2.14 If yes to Q2.12a, indicate the initial regimen the patient was on,

(a) AZT + 3TC + NVP
(b) AZT + 3TC + EFV
(c) AZT + 3TC + LPV-r
(d) TDF + XTC + EFV400
(e) TDF + XTC + DTG
(f) TDF + 3TC + DTG
(g) TAF + XTC + EFV400
(h) TAF + XTC + DTG
(i) TAF + 3TC + DTG
(j) ABC + 3TC + DTG
(k) ABC + 3TC + LPV-r
(l) ABC + 3TC + EFV
(m) ABC + 3TC + AZT
(n) Any Other Regimen

Q 2.15a Body-weight (in Kilograms) at start of ART? _____

Q2.15b Body-weight (in Kilograms) mid ART? _____

Q 2.16a Latest body weight, in Kilograms (taken in last 3 months, or within 3 months prior to date of being lost to follow-up or prior to their death)? _____

Q 2.17 Trend in body weight:

(a) Increasing
(b) Decreasing
(c) Fluctuating
(d) Generally constant
(e) No data

Q 2.18: Has the patient been on treatment for Tuberculosis since commencing ART?

(a) Yes
(b) No

Q 2.19: Has the patient had other comorbidity (other illnesses) since commencing ART, apart from TB? [If No, the skip Q2.20]

(a) Yes
(b) No

Q 2.20: If Yes to Q2.19, Name of comorbidity? _____

Q2.21: Has the patient experienced any side effects from the ART drugs? (check record) [If No or No data to Q2.21 then skip Q2.22]

(a) Yes
(b) No

(c) No data

Q2.22: If yes to Q2.21, What side effects were recorded? _____

Q 2.23: Other long-term medication they are currently taking? _____

Q 2.24: Has the patient been admitted to hospital for any reason since commencing ART? [If No or No data, then skip Q2.25]

(a) Yes

(b) No

(c) No data

Q2.25: If yes to Q2.24, what was the main season for the last admission? _____

Q2.26: Number of CD 4 Counts done since initiation of ART till 24 months Postnatal, or prior to the date of being lost to follow-up or death _____

Q2.27: (a) CD 4 Count at Start of ART _____ (b) 2nd CD4 count (c) 3rd CD4 Count

Q2.28: Last CD4 Counts Done within 3 months prior to reaching 24 months Postnatal, or at date of being lost to follow-up or death? _____

Q 2.29: Trends in CD4 Counts:

(a) Increasing

(b) Decreasing

(c) Fluctuating

(d) Generally constant

Q2.30: Number of Viral Load tests Done since initiation of ART up 24 months postnatal, or at date of being lost to follow-up or death? _____

Q 2.31: (a) Viral Load at Start of ART _____ (b) 2nd Viral Load (c) 3rd Viral Load

Q2.32: Last Viral Load test within 3 months prior to reaching 24 months postnatal, or at date of being lost to follow-up or death? _____

Q 2.33: Trend in Viral Load Counts:

(a) Going up

(b) Going Down

(c) Fluctuating

(d) Generally constant

(e) No data

Q2.34: Baby's HIV Status at 6 weeks postnatal?

(a) Negative

(b) Positive

(c) Don't know (Not Tested)

(d) No records

Q2.35: Babies HIV Status at 24 months postnatal?

(a) Negative

(b) Positive

(c) Don't know (Not Tested)

(d) No records

SECTION THREE: ADHERENCE TO TREATMENT AND RETENTION CARE

Q3.1: Has patient ever missed to take medication in the past seven days prior to last visit? [If No or No data, then skip Q3.2 and Q3.3]

(a) Yes

(b) No

(c) No Data

Q 3.2: If Yes to Q.3.1, how many times have they missed to take medication since starting the treatment?

(a) Once

(b) Twice

(c) Thrice

(d) More than thrice

Q3.3: If yes to Q3.1: What was the reason for missing the dose? Select all that apply.

(a) Forgot

(b) Ran out of pills

(c) Fear of side effects

(d) Fear of stigma;

(e) Was traveling and did not carry medication

(f) Any other (Specify) _____

(g) No Data

Q3.4: Has the patient ever missed a clinic follow-up appointment since commencing treatment? (If they came within 5 days after the appointment date, then they are not considered as having missed the appointment) [If No or No Data, then skip Q3.5 and Q3.6]

(a) Yes

(b) No

(c) No Data

Q 3.5: If Yes to Q3.4., how many times have they missed appointments since they started the treatment?

(a) Once

(b) Twice

(c) Thrice

(d) More than thrice

Q3.6: If Yes to Q3.4, when was the last time they missed the appointments?

(a) Within this week;

(b) More than a week ago but within this month

(c) More than one month but within 3 months

(d) Moth than three months

Q 3.7: Is the client on any family planning method?

(a) None

(b) Oral Contraceptive pills

(c) Injectables

(d) Implant

(e) IUD

(f) Bilateral tubal legation

(g) No information

Q 3.8: Has the patient been retained in care or LTFU?

(a) Retained in care

(b) LTFU During pregnancy

(c) LTFU within 6 months postnatal

(d) LTFU Between 7 and 12 months postnatal

(e) LTFU Between 13 and 18 months postnatal

(f) LTFU between 19 and 24 months postnatal

END OF DATA EXTRACTION

Please ensure the following is done before ending the data extraction

- Go through the data entries quickly to check if all questions have been filled in
- If complete save the work and send to online portal.

Appendix II BREC Ethics approval

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DIRECTOR: RESEARCH
RESEARCH AND INNOVATION DIVISION

Private Bag X17, Bellville 7535
South Africa
T: +27 21 959 4111/2948
F: +27 21 959 3170
E: research-ethics@uwc.ac.za
www.uwc.ac.za

10 October 2019

Mr S Mupeta
School of Public Health
Faculty of Community and Health Sciences

Ethics Reference Number: BM19/7/22

Project Title: Adherence and retention in care among postnatal women who were initiated on anti-retroviral therapy during their antenatal period in Lusaka District, Zambia.

Approval Period: 09 October 2019 – 09 October 2020

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

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

Please remember to submit a progress report in good time for annual renewal.

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

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

BMREC REGISTRATION NUMBER -130416-050

Appendix III ERES Converge Ethics approval

Plot No. 1, Cnr Joseph Mwilwa & Great East Road
Rhodes Park, Lusaka - Zambia
Tel: +260 955 155 633
+260 955 155 634
Cell: +260 977 493220
Email: eresconvergeltd@gmail.com

I.R.B. No. 00005948
F.W.A. No. 00011697

6th November, 2019

Ref. No. 2019-Oct-010

The Principal Investigator
Dr. Stephen Mutepa
United Nations Population Fund.
United Nations House, Alick Nkhata Road
P.O. Box 31966,
LUSAKA.

Dear Dr. Mutepa,

RE: ADHERENCE AND RETENTION IN CARE AMONG POSTNATAL WOMEN WHO WERE INITIATED ON ANTI-RETROVIRAL THERAPY DURING ANTENATAL PERIOD IN LUSAKA DISTRICT, ZAMBIA.

Reference is made to your protocol dated 23rd October, 2019. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	**Ordinary**	Approval No. **2019-Oct-010**
Approval and Expiry Date	Approval Date: 6th November, 2019	Expiry Date: 5th November, 2020
Protocol Version and Date	Version - Nil.	5th November, 2020
Information Sheet, Consent Forms and Dates	• English.	5th November, 2020
Consent form ID and Date	Version - Nil	5th November, 2020
Recruitment Materials	Nil	5th November, 2020
Other Study Documents	Questionnaire.	5th November, 2020
Number of participants approved for study	307	5th November, 2020

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- A reprint of this letter shall be done at a fee.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB

Dr. Jason Mwanza
Dip. Clin. Med. Sc., BA., M.Soc., PhD
CHAIRPERSON

Appendix IV Letter of permission from Ministry of Health, Zambia

All Correspondence should be addressed to the Permanent Secretary
Telephone: +260 211 253040/5
Fax: +260 211 253344

REPUBLIC OF ZAMBIA
MINISTRY OF HEALTH

In reply please quote:

No.....

NDEKE HOUSE
P. O. BOX 30205
LUSAKA

23rd October, 2019

Dr. Stephen Mupeta,
United Nations Population Fund,
P.O Box 31966,
UN House, Alick Nkhata Road, Long Acres,
LUSAKA

RE: PERMISSION TO CONDUCT RESEARCH AT FIVE HEALTH CENTRES IN LUSAKA DISTRICT

Reference is made to your letter dated 20th October 2019, with the above subject matter, in which you requested for permission to conduct research at five health centers in Lusaka District as part of your Master of Public Health Degree that you are pursuing with the University of the Western Cape (UWC) in South Africa.

Following review of the proposed study protocol, I am pleased to inform you that the Ministry of Health has authorized you to conduct the research at the proposed health centers in Lusaka district. Should there be need to change the facilities, you are advised to inform the Lusaka District Health Office to obtain their concurrence. You are, further, advised to ensure that you obtain ethics clearance from a local ethics committee and follow all the guidance provided.

I am confident that the results from this study will be useful to strengthening the PMTCT program in Zambia. The Ministry of Health, therefore, expects that once the study report has been produced, you shall share with my office the key findings and recommendations.

By copy of this letter, I have asked the Lusaka Provincial health Office (PHO) and the Lusaka District Health Office (DHO) to provide the necessary support for you to conduct the proposed study.

I wish you success in your research and completion of your studies.

Dr. Andrew Silumesii
Director Public Health
For/Permanent Secretary – TS
MINITSRY OF HEALTH

CC: Lusaka Provincial Health Office
Lusaka District Health Office

Appendix V Letter of permission from National Health Research Authority, Zambia

NATIONAL HEALTH RESEARCH AUTHORITY
Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA
Tell: +260211 250309 | Email: zphrasec@gmail.com | www.nhra.org.zm

Ref No:..... **Date: 26th November, 2019**

The Principal Investigator
Dr. Stephen Mupeta
United Nations Population Fund
United Nations House, Alick Nkhata Road
PO Box 31966
LUSAKA.

Dear Dr. Mupeta,

Re: Request for Authority to Conduct Research

The National Health Research Authority is in receipt of your request for authority to conduct research titled **"Adherence and retention in care among postnatal women who were initiated on antiretroviral therapy during antenatal period in Lusaka District, Zambia."** I wish to inform you that following submission of your request to the Authority, our review of the same and in view of the ethical clearance, this study has been **approved** on condition that:

1. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;
2. Progress updates are provided to NHRA quarterly from the date of commencement of the study;
3. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, University leadership, and all key respondents.

Yours sincerely,

Dr. Godfrey Biemba
Director/CEO
National Health Research Authority

All correspondences should be addressed to the Director/CEO National Health Research Authority

Appendix VI Letter of permission from Lusaka Provincial Health Office

All correspondence should be addressed to the Provincial Health Director
Telephone: +260 211 256813
Fax: +260 211 256814
Telephone: +260 211 256815
Cell: +260 956 399643
+260 963 908260

REPUBLIC OF ZAMBIA
MINISTRY OF HEALTH

In Reply please quote:

File No.....

PMOLSK/101/8/1

Lusaka Provincial Health Office
P.O. Box 32573
LUSAKA

18th November, 2019

Dr. Stephen Mupeta
United Nations Population Fund
P.O.Box 31966
UN House, Alick Nkhata Road, Long Acres
LUSAKA

Dear Dr. Stephen Mupeta,

RE: PERMISSION TO CONDUCT RESEARCH AT FIVE HEALTH CENTRES IN LUSKA DISTRICT

Lusaka Provincial Health Office is in receipt of your minute requesting for permission to conduct research on, " ***Adherence and retention in care among postnatal women who were initiated on anti-retroviral therapy during antenatal period*** " at five health centers in Lusaka District as part of your Masters of Public Health Degree that you are persuing with the University of the Western Cape (UWC) in South Africa.

My office is glad to inform you that it has no objection to your request, provided that;

1. The relevant District Health Director where the study is being conducted are fully appraised;
2. Progress updates are provided to Lusaka Provincial Health Office and the District Health Office biannually from the date of commencement of the study;
3. The final study report is cleared by NHRA before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, University Leadership and all key respondents.

Kindly ensure minimum interruption in health service delivery during the period you will be undertaking your research.

By copy of this letter, Lusaka District Health Office is advised to allow you undertake the above mentioned study in the selected facility and provide you with the relevant support.

Dr. Consity Mwale
Provincial Health Director
Lusaka Province

cc. District Health Director – Lusaka District

Appendix VII Editor's Certificate

Sury Bisetty Academic Editing Services –
CIPC No. 2021/360666/0

To whom it may concern,

I confirm that I have edited the thesis entitled: Adherence to Treatment and Retention in Care among Postnatal Women who were initiated on Antiretroviral Therapy during Antenatal and Postnatal Period in Lusaka District, Zambia: A mini thesis submitted in partial fulfilment of the requirements for the degree of Master of Public Health at University of the Western Cape by Stephen Mupeta, Student Number: 3706330

Sury Bisetty
09 August 2021

Professional Language and Technical Editor
(BA. UHDE)

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South African Council of Educators (222277)
South African Monitoring and Evaluation Association (761237008553)

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Complete writing, editing master class.
ELSEVIER – Editor's guide to reviewing articles

CONTACT DETAILS

Email: surybisetty11@gmail.com

Cell no: 0844932878
Tel.: 031 7622 766

Disclaimer: I provided only language and technical editing as per discussion with the client. The content of thesis was not amended in any way. The edited work described here may not be identical to that submitted. The author, at his/her sole discretion, has the prerogative to accept, delete, or change amendments/suggestions made by the editor before submission. Furthermore, I returned the document to the author with tracked changes; it is the responsibility of the author to implement the suggestions accurately.